Study on the Calculation of the Benefits of Chemicals Legislation on Human Health and the Environment

Development of a System of Indicators

Final Report

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List of Abbreviations

AF	Attributable Fraction
AfA	Application for Authorisation
AN	Attributable Number
APE	Alylphenyl ethyoxylates
ATP	Adaptations to Technical Progress
BAT	Best Available Techniques
BBP	Benzyl butyl phthalate
BPR	Regulation (EC) No 528/2012 on the making available on the market and use of biocidal products
BSEF	Bromine Science and Environmental Forum
BV	Bequest Value
CBVI	Comparative Biological Value Index
CLP	Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures
CAD	Chemical Agents Directive 98/24/EC
CLH	Harmonised Classification and Labelling
CLI	Classification and Labelling Inventory
CMD	Carcinogens and Mutagens Directive 2004/37/EC
CMR	Carcinogens, mutagens and substances with reproductive toxicity
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
CSTEE	Scientific Committee on Toxicity, Ecotoxicity and the Environment
CV	Contingent Valuation
DALY	Disability-Adjusted Life Year
DBP	Di-n-butyl phthalate
DDE	Dichloro diphenyl dichloroethylene
DEHP	Bis(2-ethylhexyl)phthalate
DG	Directorate-General
DIDP	Diisodecyl phthalate
DINP	Diisononyl phthalate
DNEL	Derived No-Effect Level
DNOP	Di-n-octyl phthalate
DSD	Dangerous Substances Directive 67/548/EEC
DUV	Direct Use Value
EBD	Environmental Burden of Disease
EC	European Commission
ECHA	European Chemicals Agency
EEA	European Environment Agency
EEE	Electrical and Electronic Equipment
EFTA	European Free Trade Association
EHES	European Health Examination Survey
EPS	Expanded polystyrene
ESR	Council Regulation (EEC) No 793/93 known as the Existing Substances Regulation
ELV	End of Life Vehicle Directive
EU	European Union
EU-OSHA	European Agency for Health and Safety at Work
FCM	Food Contact Material
GerES	German Environmental Survey
GP	General Practitioner

HBCD	Hexabromocyclododecane
HCB	Hexachlorobenzene
HCH	Hexachlorocyclohexane
HSE	Health and Safety Executive
IARC	International Agency for Research on Cancer
ICES	International Council for the Exploration of the Sea
IED	Industrial Emissions Directive
IIDB	Industrial Injury and Disablement Benefit
IOELV	Indicative Occupational Exposure Level Value
IUCN	Internaitonal Union for the Conservation of Nature
IUD	Indirect Use Value
LFS	Labour Force Survey in Great Britain
NGO	Non-governmental organisation
NP	Nonylphenol
NPE	Nonylphenol ethoxylates
NUV	Non-Use Value
OEL	Occupational Exposure Level
OSH	Occupational Safety and Health legislation
OV	Option Value
PACT	Public Activities Coordination Tool
PAF	Population Attributable Fraction
PAH	Polyaromatic hydrocarbon
PARCOM	Paris Commission
PBB	Polybrominated biphenyls
PBDE	Polybrominated diphenyl ethers
PBT	Persistent, Bioaccumulative and Toxic substance
PCB	**P**olychlorinated biphenyl
PCP	Pentachlrorophenol
PFAS	Perfluoroalkyl sulphonate
PFC	Perfluorocarbon
PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctanesulfonic acid
PNEC	Predicted No-Effect Concentration
POP	Persistent organic pollutant
PPPR	Regulation (EC) No 1107/2009 on the placing of plant protection products on the market
PVC	Polyvinyl chloride
QALY	Quality-Adjusted Life Year
RAC	Risk Assessment Committee
RAR	Risk assessment report
RBMP	River Basin Management Plan
RDB	Red Data Books
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals
REFIT	Regulatory Fitness Programme
REP	Risk exposure period
RMM	Risk Management Measure
RMOA	Risk management option analysis
RoHS 2	Restriction of Hazardous Substances Directive 2011/65/EU
RRS	Risk reduction strategy
SME	Small-Medium Enterprise
SWI	Self-reported Work-related Illness survey in Great Britain

TDI	Tolerable daily intake
TEV	Total Economic Value
THOR	The Health and Occupation Research Network
ToR	Terms of Reference
UNECE	United Nations Economic Commission for Europe
US EPA	Environmental Protection Agency of the United States of America
UV	Use Value
UVCB	Unknown or Variable composition, Complex reaction product or Biological origin
VOC	Volatile Organic Compound
VOLY	Value of a Life Year
vPvB	Very Persistent and very Bioaccumulative substance
VSL	Value of Statistical Life
WEEE	Waste Electrical and Electronic Equipment Directive 2002/96/EC
WHO	World Health Organisation
WTP	Willingness to Pay
XPS	Extruded polystyrene
XV	Existence Value

Executive Summary

This study has been commissioned by the European Commission DG Environment in the framework of the Regulatory Fitness Programme (REFIT) for the chemicals policy area. Together with the findings of other studies, its results will inform the general report on the operation of the REACH Regulation and, more in general, of the chemical legislative framework, expected in 2017.

The objective of the study was to develop a system of indicators which can establish and measure the links between chemical substances and their impacts on human health and the environment, and measure the role that chemicals legislation has had in reducing such impacts. The ultimate aim is to indicate the benefits of EU chemicals legislation over the period 2004-2013.

The focus is on the REACH and CLP Regulations, the recognised cornerstones of the chemicals acquis. However, the benefits on human health and the environment are delivered through synergies with other legislation, such as the occupational health and safety legislation (e.g. the Chemical Agents Directive, the Carcinogens and Mutagens Directive), the product safety legislation (e.g. Cosmetic Product Regulation, Plant Protection Products Regulation, the Biocidal Products Regulation), the emissions control legislation (e.g. Industrial Emissions Directive, Water Framework Directive) and the Waste legislation (e.g. Waste Electrical and Electronic Equipment Directive, End of Life Vehicles Directive).

The project team reviewed over 70 studies published in the last 15 years in order to identify indicators previously suggested, sources of information, methodologies, and monetary values for use in the valuation of benefits to human health and the environment. At the same time, more than fifteen European and national databases were screened for information on production, trade, use and emissions of chemicals, data from human biomonitoring activities, data on concentrations of pollutants in the environment and for human health and disease burden statistics.

In accordance with the Better Regulation guidelines, indicators have been defined at three different levels of objectives (operational, specific and general). Although the focus of the study is on REACH and CLP, the sensitivity of indicators to changes in the level of legislative action decreases passing from output indicators to result indicators to impact indicators, due to the inter-linkages highlighted above and the inability to separate out the impacts of REACH and CLP vis a vis the other legislation. Consequently impact indicators will reflect the legislative framework more broadly and are subject to more confounding factors than output or result indicators.

Output indicators relate to the deliverables that the legislation is expected to produce and aim to measure the specific actions of the legislative mechanisms (operational objectives). Since the aim of the study is to monitor the benefits of the chemicals legislation on human health and the environment, it has been chosen to focus on those legislative mechanisms of the REACH and CLP Regulations that are likely to result in a change in exposure (captured by result indicators) and, ultimately, in a reduction of negative effects on human health and the environment (captured by impact indicators). These mechanisms are harmonised classification and labelling, self-classification, authorisation and restriction.

The proposed output indicators are:

1. *Substances with harmonised classification and labelling implemented after the entry into force of the REACH and CLP Regulations per hazard class;*

2. *Change in self-classifications (per hazard class) since the entry into force of the REACH and CLP Regulations;*
3. *Restriction decisions implemented after the entry into force of the REACH and CLP Regulations per hazard class, PBT/vPvB profile and endocrine activity of the substances and groups of substances covered by the decisions;*
4. *Substances of Very High Concerns included in Annex XIV per hazard class, with a PBT/vPvB profile, or with clear evidence of endocrine activity.*

The increase in the number of substances with harmonised classification and labelling (CLH) denotes an improvement in knowledge of properties and safe uses of chemicals. Output indicator 1 counts and lists the substances with harmonised classification and labelling per hazard class. Since harmonised classification and labelling is a mechanism that has not been newly introduced by the CLP Regulation, the indicator quantifies the harmonised classifications and labelling that have been implemented after the entry into force of the REACH and CLP Regulations.

The REACH registration requirement leads to new and better physicochemical and (eco)toxicological information for the classification of substances. Output indicator 2 measures the change in self-classifications (per hazard class) since the entry into force of the REACH and CLP Regulations.

The progressive restriction of substances and groups of Substances of Very High Concern contributes to lowering human and environmental exposure to hazardous substances. Output indicator 3 quantifies the number of restrictions dossiers and lists the substances, groups of substances and scope of the restrictions per hazard class. As for harmonised classification and labelling, the restriction mechanism has not been newly introduced by the REACH Regulation: the indicator quantifies the restriction decisions that have been implemented after the entry into force of the REACH and CLP Regulations.

The authorisation mechanism was introduced by the REACH Regulation and aims to assure that the risks from Substances of Very High Concern are properly controlled and that these substances are progressively replaced by suitable alternatives. Output indicator 4 counts and lists the substances that have been included in the authorisation list per hazard class.

Hazard classes have been linked to disease groups, as defined by the World Health Organisation, and to substances for which data on exposure are available, in order to measure the extent to which the main legislative mechanisms are contributing to a decrease in the human health impacts linked to exposures to chemical substances.

The Table below summarises the quantitative data for the four output indicators and provides indications on how the legislative mechanisms have addressed substances and groups of substances across all the different hazard classes, despite harmonised classification and labelling, restriction and authorisation focusing particularly on CMR substances. The data for output indicator 2 highlight how the REACH Regulation is improving the knowledge in the hazard profiles of the chemical substances on the market and, ultimately, how it is helping to ensure the protection of human health and the environment.

Data summary for the output indicators				
Hazard class – PBT/vPvB – Endocrine activity	***No. of substances with CLH (June 2008 – April 2016)***	***Change in self-classifications (January 2005 – February 2016)***	***No. of restriction decisions (April 2010 – April 2016)***	***No. of substances in Annex XIV (June 2008 – April 2016)***
Acute toxicity	*80*	*+32%*	*9*	*12*

Data summary for the output indicators				
Hazard class – PBT/vPvB – Endocrine activity	**No. of substances with CLH (June 2008 – April 2016)**	**Change in self-classifications (January 2005 – February 2016)**	**No. of restriction decisions (April 2010 – April 2016)**	**No. of substances in Annex XIV (June 2008 – April 2016)**
Skin corrosion / skin irritation	*30*	*+51%*	*5*	*12*
Skin Sensitisation	*37*	*+132%*	*2*	*12*
Serious eye damage / eye irritation	*30*	*+164%*	*4*	*6*
Respiratory Sensitisation	*1*	*+538%*	*1*	*6*
Mutagenicity	*13*	*+3,329%*	*2*	*12*
Carcinogenicity	*41*	*+264%*	*5*	*25*
Reproductive toxicity	*47*	*+229%*	*8*	*19*
Specific Target Organ Toxicity	*72*	*+4,127%*	*9*	*7*
Aspiration hazard	*9*	*+251%*	*2*	*0*
Hazardous to the aquatic environment	*90*	*+99%*	*10*	*25*
Hazardous for the ozone layer	*0*	*+80%*	*0*	*0*
PBT/vPvB profile	*-*	*-*	*0*	*4*
Endocrine activity	*-*	*-*	*4*	*3*

Result indicators measure the immediate effects of the legislation on the direct recipients (specific objectives) and have therefore been defined in terms of changes in exposure to chemical substances. The most reliable indicator of actual human exposure is a biological measure of body burden. Unfortunately, only two hundred chemical substances can currently be assessed through human biomonitoring data and these are usually well-known substances for which legislative measures have been adopted for a long period of time. In addition, the historic trend data that would allow an assessment of the effect of legislation are generally lacking and comparability of data from different laboratories and years is problematic.

Assessment of changes in the concentration of chemicals in environmental media presents similar issues. Surrogate measures, such as changes in the production of hazardous chemicals are influenced by large confounding factors (e.g. macroeconomic situation) while data on concentrations of specific chemicals in consumer products refer to limited subsets of both chemicals and products and the datasets are not systematically updated. Although potential levels of exposure can be calculated for many chemicals on the basis of data on industrial emissions and ambient concentrations from environmental monitoring, a number of factors may intervene between these listed factors and actual exposure, including changes in human behaviour.

According to the level of approximation with which they can be linked to the action of the chemicals legislation, five result indicators have been proposed:

1. *Change in the concentration level of selected chemicals in human body tissues*
2. *Change in the concentration level of selected chemicals in animal and plant tissues*
3. *Change in the concentration level of selected chemicals in air, water and soil samples*
4. *Change in emissions of selected chemicals in air, water and soil*
5. *Change in production volume of selected chemicals.*

Different biomonitoring programmes have been carried out in the last decades in Europe, on specific substances and populations exposed and with varying geographical scope. Various databases also exist, with public and restricted access. The European Commission is aware of the need to develop an EU-wide human biomonitoring initiative and has set aside €50 million to fund this action. The information generated by this initiative will be of vital importance for the policy-making process in a wide variety of sectors, one of the most important being the EU chemicals legislation.

The European Commission Joint Research Centre is working on the development of an information platform for chemical monitoring data (https://ipchem.jrc.ec.europa.eu) gathering together the available experiences in Europe to enhance access to data on chemicals.

The German Environmental Specimen Bank (ESB) is the most visible and publicly accessible database in Europe that allows inference of the effect of past and present EU chemicals legislation in lowering human exposure to chemicals. Some data on concentrations in environmental specimens are also reported by the European Environment Agency. These databases have been used to populate the first four result indicators. It should be noted that data on the concentration level of certain chemicals in human, animal and plant tissues in samples located in Germany are not representative of the situation in all other Member States. However, these data have been reproduced in this report to illustrate their importance for the assessment of the effectiveness of the legislation in lowering exposure to chemicals. Historic trends of the biomonitoring data have been reported for the available substances and geographical regions and, where possible, have been linked to legislative measures which have likely contributed to lowering exposure. The Table below summarises the estimated average changes in the concentration of certain chemicals on the basis of the German ESB data.

Summary of the average changes (in percentage) of the concentration of specific chemicals in Germany in different samples (human, animal and plant tissues, soil samples)			
Substances	***Sample***	***Average Δ %***	***Period***
Cadmium	*Whole blood (Students) – µg/l ww*	*+33%*	*2000-2009*
	Saliva (Students) – ng/l ww	*-58%*	*1995-2004*
	Scalp hair (Humans) – ng/g ww	*-75%*	*1995-2004*
	Pubic hair (Students) – ng/g ww	*-83%*	*1995-2004*
	Organic layer/root network – AN extract µg/g dw	*-75%*	*2002-2010*
	Organic layer/root network – AR extract µg/g dw	*-11%*	*2002-2010*
Mercury	*Whole blood (Students) – µg/l ww*	*-57%*	*2001-2010*
	24h-sampling urine (Students) - µg/l ww	*-92%*	*1995-2013*
	Topsoil – AR extract - µg/g dw	*-30%*	*2002-2010*
Lead	*Whole blood (Students) – µg/l ww*	*-58%*	*1995-2013*
	Whole blood (Students - Münster) – µg/l ww	*-85%*	*1981-2013*
	Pubic hair (Students) – µg/g ww	*-62%*	*1995-2004*
	Scalp hair (Students) - µg/l ww	*-57%*	*1995-2004*
	Subsoil – AN extract - µg/g dw	*+3%*	*2002-2010*
Hexachlorobenzene	*Blood plasma (Students) - µg/l ww*	*-79%*	*1995-2010*
	Suspended particulate matter – ng/g dw	*-66%*	*2005-2012*
Pentachlorophenol	*24h-sampling urine (Students) - µg/l ww*	*-92%*	*1995-2010*
	Blood plasma (Students) - µg/l ww	*-87%*	*1995-2010*
PCB138	*Blood plasma (Students) - µg/l ww*	*-81%*	*1995-2010*
PCB153	*Blood plasma (Students) - µg/l ww*	*-66%*	*1995-2010*
PCB180	*Blood plasma (Students) - µg/l ww*	*-68%*	*1995-2010*
Phthalates			
DEHP	*24h-sampling urine (Students) - µg/l ww*	*-67%*	*1988-2008*
DiNP	*24h-sampling urine (Students) - µg/l ww*	*+67%*	*1988-2008*
BBP	*24h-sampling urine (Students) - µg/l ww*	*-52%*	*1988-2008*
DnBP	*24h-sampling urine (Students) - µg/l ww*	*-90%*	*1988-2008*
DiBP	*24h-sampling urine (Students) - µg/l ww*	*-15%*	*1988-2008*

Summary of the average changes (in percentage) of the concentration of specific chemicals in Germany in different samples (human, animal and plant tissues, soil samples)			
Substances	**Sample**	**Average Δ %**	**Period**
Bisphenol A	*24h-sampling urine (Students) - µg/l ww*	*-36%*	*1995-2009*
PFOA	*Blood plasma (Students) - µg/l ww*	*-13%*	*1982-2010*
PFOS	*Blood plasma (Students) - µg/l ww*	*-71%*	*1982-2010*
Hexabromocyclododecane	*Herring Gull Eggs – ng/g lipid*	*+8%*	*1988-2008*
Nonylphenol	*Fish musculature (Bream) – ng/g ww* *Soft body (Blue mussel) – ng/g ww*	*-65%* *-47%*	*1995-2001* *1992-2001*
Nonylphenol ethoxylates	*Fish musculature (Bream) – ng/g ww*	*-70%*	*1995-2001*
Methylmercury	*Soft body (Zebra mussel) – ng/g dw* *Soft body (Blue mussel) – ng/g ww*	*-33%* *-20%*	*1995-2013* *1992-2013*
Tributyltin	*Fish musculature (Bream) – ng/g ww* *Soft body (Blue mussel) – ng/g ww*	*-73%* *-50%*	*1995-2003* *1992-2005*
Source: Own elaboration on German ESB data			

Almost all the data in the German ESB refer to substances with regulation spanning across one or more decades. Nevertheless, they provide indications of how the regulatory pressure and other factors such as technological progress, voluntary initiatives, increased consumers' awareness, and research and development of suitable alternatives, have contributed to lowering exposure to hazardous chemicals. The data also help in identifying potential issues with the persistence and bioaccumulation of certain substances in different samples (e.g. cadmium in whole blood, lead in subsoil). Human biomonitoring data can also be used to verify the substitution of certain hazardous chemicals with less (or not) hazardous substances (e.g. substitution of DEHP, DBP and BBP with DiNP).

With regard to result indicator 5, EU-wide data are not easily collected. Moreover, human biomonitoring data have revealed that estimates of human exposure based on production and consumption data may supply misleading information. In the framework of the Sustainable Development Indicators, Eurostat developed two indicators based on the industrial production statistics of chemicals toxic to human health and the environment. However, the suitability of result indicator 5 for the assessment of the chemicals legislation in lowering chemicals' exposure is limited and should be used for specific chemicals only and even then in combination with other data on exposure.

Impact indicators measure the ultimate consequences of the legislation beyond its direct interaction with recipients. Within the context of this study, this has been interpreted as moving from changes in exposures to changes in effects, either in terms of chemicals related diseases or chemicals related impacts on environmental ecosystems and biota.

The following impact indicators have therefore been defined:

1. *Change in incidence, prevalence and mortality following a change in chemicals' exposure due to chemicals legislation requirements per disease group*
2. *Change in environmental impacts (defined on ecosystem services or number of species) following a decrease in exposure due to chemicals legislation requirements.*

Only the impact indicator on human health has been carried forward for the monetisation of benefits and for two occupational health endpoints only. Statistics on the incidence of occupational diseases caused by some specific chemicals from the German DGUV database have also been reproduced, to illustrate the potential importance of a single and coherent European health statistics database for

assessing the effectiveness of the chemicals legislation in lowering the burden of diseases attributable to chemicals exposure. The EU Occupational Safety and Health Strategic Framework 2014-2020 has recognised the need for the systematic collection and harmonisation of occupational health and safety statistics throughout the EU and work is ongoing in this regard. This should ensure the availability of better information to quantify the fraction of human health impacts that can be attributed to chemical exposures.

Health and environmental outcomes are the results of the synergies of multiple factors. Consequently, information for the quantification of the attributable fraction of chemicals exposure to causation of illness is necessary. Human health statistics relative to the European Union are available from different sources (i.e. WHO, OECD and Eurostat). However, changes in the health statistics at national population level, as recorded by these organisations, depend on a large number of factors such that the effects of the chemicals legislation cannot be singled out. Occupational health and safety statistics are more likely to register changes in health outcomes due to the reduction of exposure to chemicals thanks to the implementation of risk management measures required by the legislation. Unfortunately, this information is available for occupational skin diseases and occupational asthma only, as these are short latency diseases for which health practitioners can attribute a causative (chemical) factor. For long latency diseases (e.g. chronic obstructive pulmonary diseases, cancers), attribution is more complex and requires a number of assumptions which seriously limit the value of any indicator trying to measure the marginal contribution of chemicals legislation in lowering the burden of disease. Chemical- and workplace-specific examples clearly exist, but these are case studies rather than broader indicators of effects. Two national OSH databases (the UK HSE and the German DGUV) have been identified as reporting systematically the causative (chemical) factors for certain occupational diseases, namely occupational dermatitis and occupational asthma. DGUV also reports suspected and recognised cases of occupational diseases caused by some specific chemical compounds. DGUV presents statistics on malignant neoplasms caused by specific chemicals too, but statistics on incidence, prevalence and mortality reflect past exposure. For example, the time from exposure to asbestos to the diagnosis of mesothelioma is on average greater than 40 years and incidence is expected to peak in developing countries before 2030. Trends on the incidence, prevalence and mortality of cancer and other long-latency diseases will reflect the action (or inaction) of legislation prior to the implementation of the REACH and CLP Regulations.

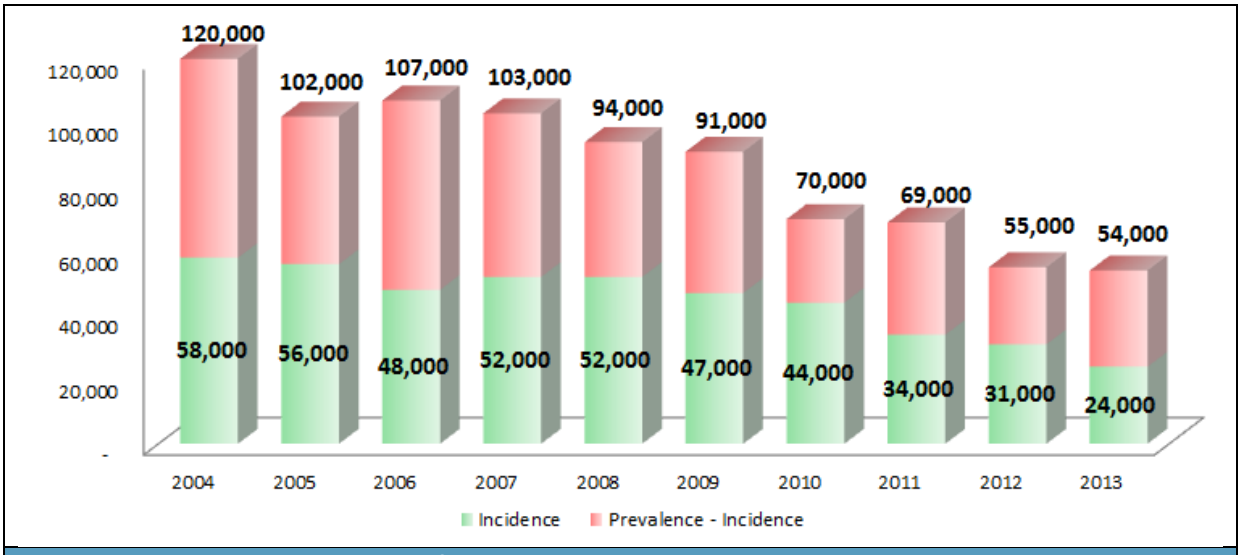
DGUV statistics show that while occupational diseases linked to exposure to metals and metalloids, asphyxiating gases and solvents, pesticides and other chemical agents have decreased to none or fewer than 5 cases per year, the incidence and mortality of diseases linked to exposure to asbestos are on the rise and still have to reach the peak. Although some occupational diseases attributed to chemicals other than asbestos have substantially decreased over the last 20 years, the number of cases is still significant, highlighting the need for further action. These are: diseases caused by chromium or its compounds, with 17 cases in 2014, but overall decrease in the period 1995-2014 of around 47%; diseases caused by carbon monoxide, with 12 cases in 2014, but an overall decrease in the period 1995-2014 of around 70%; diseases caused by halogenated hydrocarbons, with 16 cases in 2014, but overall decrease in the period 1995-2014 of around 84%; diseases caused by isocyanates, with 27 cases in 2014, but an overall decrease in the period 1995-2014 of around 54%; polyneuropathy or encephalopathy caused by organic solvents or their mixtures, with 9 cases in 2014, but an overall decrease in the period 2000-2014 of around 47%.

A notable exception to the general decrease in occupational diseases attributed to chemicals other than asbestos is the occurrence of mucosal changes, cancer or other neoplasms of the urinary tract caused by aromatic amines, with 180 cases in 2014 and an increase in the period 1995-2014 of around 173%. It should be noted that aromatic amines are a constituent of coal tar products which were used in the hot processing of road tar and the sealing of flat roofs until the 1960s and 1970s. It

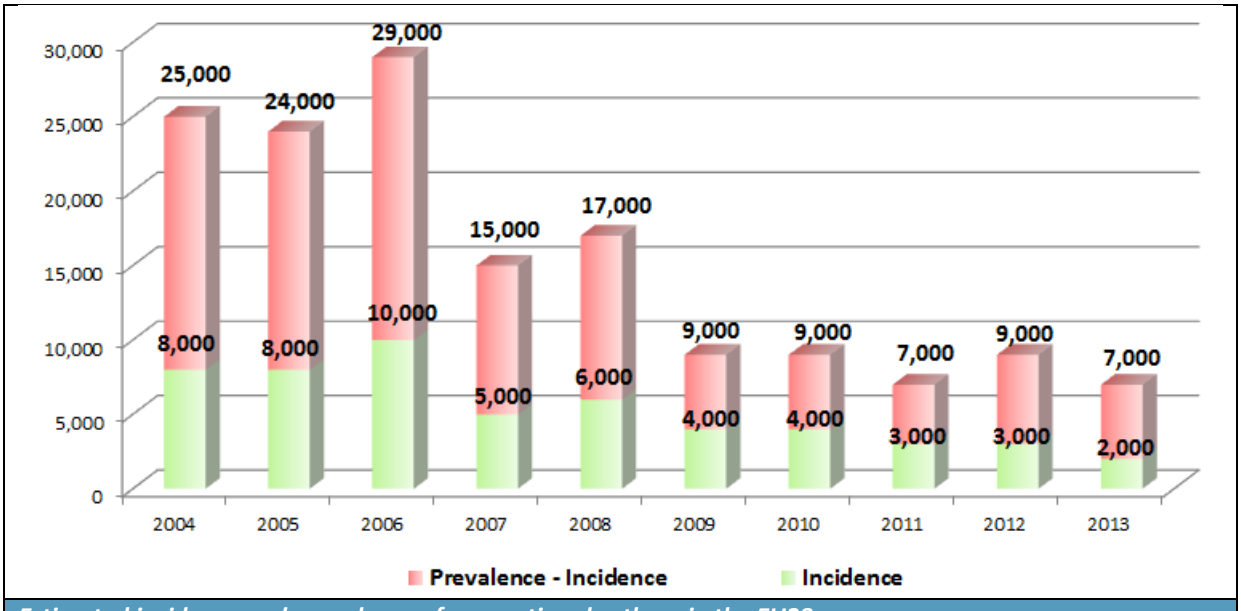
is possible that the peak incidence of bladder neoplasms caused by exposure to aromatic amines has still to be reached.

Impact indicator 1 has been populated with data on occupational skin diseases and occupational asthma from Great Britain and Germany. These have been extrapolated to the European level and translated into monetary terms for illustrative purposes. Data referring to skin and respiratory sensitisation for the defined output indicators have been pulled out, in order to provide information on the measures that have been recently implemented to tackle substances linked to these diseases and to contribute to lowering exposure to them.

The Figures below present the estimated incidence and prevalence of occupational skin diseases and occupational asthma in the EU28.



Estimated incidence and prevalence of occupational skin disorders in the EU28



Estimated incidence and prevalence of occupational asthma in the EU28

The progressive reduction in the occurrence of occupational skin diseases and occupational asthma attributed to the exposure to chemical substances has resulted in total cost savings of, respectively, around €1.59-1.87 billion and €249.9 million for the period 2004-2013. As these values have been derived on the basis of the statistics of two Member States only and using medical treatment cost figures from the UK National Health System, their validity in representing the effective situation in the EU28 is limited. However, they provide an indication of the order of magnitude of the accrued benefits.

The latter are the likely result of multiple factors, such as an increased awareness on health and safety in workplaces, the pro-active adoption of better risk management measures, the restriction/withdrawal of some skin and respiratory sensitisers, the reduction of the workforce in sectors where workers are particularly exposed to skin or respiratory sensitisers and technological progress in the production processes. Nevertheless, the chemicals legislation is a determinant and confounding factor of many of these aspects and has played a major role in reducing the number of cases of occupational skin diseases and occupational asthma.

Although consideration was given to various means of linking changes in chemical exposures to environmental benefits, it was not possible to identify robust and reliable environmental impact indicators in relation to ecosystem services or species level effects. Indeed, a workshop attended by experts in the field of chemicals management concluded that the indicators that could be developed for the environment were limited due to a lack of monitoring data, changes in monitoring practices, and the absences of economic valuations. It is therefore believed that the environmental result indicators provide the most appropriate set for illustrating the benefits – in a non-monetised manner – of chemicals legislation.

It is important to note that the objective of this study has been to develop indicators to monitor the benefits of the chemicals legislation. Monetary estimates can be provided, but their suitability as indicators is very limited, as they rely on assumptions that are likely to be (and should be) changed over time.

1 Introduction

1.1 Study Objectives

The main objective of the study is:

> "T*o assess the beneficial impact of EU legislation and policies specific to the EU chemical sector related to both the environment and human health, through the definition of a set of indicators.*

In order to meet the main objective, four specific objectives have been defined:

i. "*Propose candidates for a set of indicators. A precondition for the indicators is to a) establish and measure the causal link between chemical substances and their effects on the environment and/or human health and/or b) establish and measure the causal link between chemicals legislation and the reduced effects on the environment and/or human health;*

ii. *Among the proposed indicators, the contractor will identify a selection of key indicators;*

iii. *For the key indicators, the contractor will provide data (preference should be given to the period 2004-2013, but historical data and where possible projections on future developments must also be considered);*

iv. *Propose a way to update and improve the set of key indicators*".

The study has been commissioned by the Directorate-General (DG) for Environment in the framework of the Regulatory Fitness Programme (REFIT) for the chemicals area that is being carried out by the European Commission following its commitment to ensuring that its policies "*meet the goals at minimum cost and deliver maximum benefits to citizens, businesses and workers while avoiding all unnecessary regulatory burdens*"[1]. Several parallel studies have been commissioned or have been planned[2] by both DG Environment and DG Growth on the costs and benefits of the chemicals legislation:

- Cumulative costs assessment of the chemicals legislation;
- Study on the impacts of REACH[3] on innovation, competitiveness and small-medium enterprises (SMEs);
- Study on the impacts of REACH on international competitiveness of the EU industry;
- The follow-up study to the cumulative cost assessment strengthened to international comparison of costs for the chemical industry in other jurisdictions;
- Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP[4] Regulation and related legislation;

[1] EC (2015): Better Regulation Guidelines, Commission Staff Working Document. Available at: http://ec.europa.eu/smart-regulation/guidelines/toc_guide_en.htm

[2] As for December 2015.

[3] Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals

[4] Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures

- The Fitness Check on occupational health and safety legislation;
- Cumulative health and environmental benefits of the chemicals legislation;
- The REACH Baseline study – 10 years update;
- The public consultation about the approach to the REACH report 2017 which is expected to collect views on any potentially missing elements;
- The study on the socio-economic benefits of chemical legislation;
- The study on the evaluation process of ECHA;
- Eurobarometer survey on the perception of chemicals' safety;
- The study on the costs and benefits of the REACH authorisation process;
- REACH contribution to meeting the World Summit Sustainability Development 2020 goals.

The results of the present study, along with the outputs of the projects listed above, will inform:

- The general report on the operation of the REACH Regulation expected in 2017[5];
- The development of the EU's Non-Toxic Environment Strategy as mandated by the 7th Environmental Action Plan (7EAP);
- The development of the next EU Environmental Action Plan;
- The Fitness Check on the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries.

1.2 Scope

The REACH and CLP Regulations are the recognised cornerstones of the chemicals acquis and it was agreed during the kick-off meeting that the study would focus on these Regulations. However, benefits are often delivered through synergies with other legislation, such as the occupational health and safety legislation (e.g. the Chemical Agents Directive, the Carcinogens and Mutagens Directive), the product safety legislation (e.g. Cosmetic Product Regulation, Plant Protection Products Regulation, the Biocidal Products Regulation), the emissions control legislation (e.g. Industrial Emissions Directive, Water Framework Directive) and the Waste legislation (e.g. Waste Electrical and Electronic Equipment Directive, End of Life Vehicles Directive).

Thus, although the focus of the study is on REACH and CLP, due to the inter-linkages highlighted above and an inability to separate out the impacts of REACH and CLP vis a vis the other legislation, it was subsequently agreed that the indicators would have to reflect the legislative framework more broadly.

In developing the system of indicators, the project team followed the Better Regulation guidelines on monitoring[6], defining indicators at three different levels:

- Output indicators: relate to the deliverables that the legislation is expected to produce and aim to measure the specific actions of the legislative mechanisms;
- Result indicators: measure the immediate effects of the legislation on the direct addressees or recipients;

[5] According to Article 117(4) of the REACH Regulation.

[6] EC. Better Regulation Guidelines. Commission Staff Working Document. Strasbourg, 2015, p. 46. Available at: http://ec.europa.eu/smart-regulation/guidelines/docs/swd_br_guidelines_en.pdf

- Impact indicators: measure the ultimate consequences of the legislation beyond its direct interaction with the recipients.

Data to feed the system of indicators have been searched and provided focusing on the period 2004-2013, but historical data and possible projections on future developments have also been considered. It has to be noted that information for the period 2004-2013 is likely to capture the effects of past legislation only (both the REACH and CLP Regulations allow for a gradual entry into force of their provisions, with REACH commencing in 2007 and CLP in 2009).

To define output indicators for the over 150 pieces of legislation currently regulating, *inter alia*, product safety and efficacy, environmental protection, workers' protection and food safety[7] would have not been possible in the context of this study, also considering that the project team should have had to look into the requirements of past legislation. Output indicators have therefore been defined focusing on the main mechanisms of the REACH and CLP Regulations delivering benefits in terms of human health and the environment, i.e. classification, authorisation and restriction[8]. An additional output indicator has been defined to allow catching the synergies with other past and current legislative measures.

Result and impact indicators, that are likely to measure the short, medium and long term effects of a broader list of present and past chemicals legislative acts as well as the effects of other confounding factors (e.g. the economic situation), have been defined in general terms. The data trends feeding the result indicators refer to specific substances, for which the project team has established the linkages with the current and past chemicals legislation. The statistics feeding the impact indicators allow the monetisation of the benefits of the chemicals legislation for short latency diseases only, namely for occupational skin diseases and occupational asthma. However, the systematic collection of data on the incidence and prevalence of diseases linked to chemicals' exposure, along with the improvement and increase of toxicological and epidemiological studies, should allow future expansion of the assessment of the benefits of the chemicals legislation on long latency diseases with strong associations with exposure to specific chemicals.

1.3 Structure of the Report

The methodology has been articulated in five main tasks, with task 1 been further divided in 6 subtasks:

- Task 1: State of the science:
  - Subtask 1.1 Profile of the indicators characteristics;
  - Subtask 1.2 Screening of existing literature;
  - Subtask 1.3 Sorting of information;
  - Subtask 1.4 Candidate list of indicators;
  - Subtask 1.5 Participation in a brainstorming workshop;
  - Subtask 1.6 Analysis of the extracted information;

[7] Milieu (2012): Technical assistance related to the scope of REACH and other relevant EU legislation to assess overlaps, Report prepared for DG Environment. Available at: http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/scope-final-report_en.pdf

[8] Authorisation has been introduced by the REACH Regulation, while classification of chemical substances was required by the Dangerous Substance Directive 67/548/EEC and restriction were implemented under the Council Regulation (EEC) No 793/93 known as the Existing Substances Regulation (ESR).

- Task 2: Selection and development of indicators;
- Task 3: Assessment of the benefits;
- Task 4: Workshop;
- Task 5: Conclusions and recommendations.

We organised the structure of the report accordingly. Each Section provides details on the methodology followed for each task and subtask and the results of the work carried out.

Section 2 presents the state of the science, detailing the indicators characteristics according to the Better Regulation guidelines and the results of the literature review and of the screening of databases. It also presents a first selection of indicators based on the literature review and the results of the brainstorming workshop, a half day event aimed at gaining the Commission services' views on the criteria for the selection of indicators and on the types of indicators to be prioritised.

Section 3 presents the system of key indicators developed and selected by the project team, providing the relevant data and highlighting the information gaps.

Section 4 provides the monetisation of the benefits of the chemicals legislation through the use of the system of indicators developed.

Section 5 presents the outcomes of the one-day workshop held in Brussels in November 2015, where socio-economic and risk assessment experts in the fields of public health, environmental protection and occupational health and safety were called to provide their views on the interim results of the project and discuss the problems in assessing the benefits of the chemicals legislation and the methodologies and information available to solve them.

Finally, Section 6 provides some recommendations on how to update and improve the system of indicators proposed and some overall conclusions on the study, drawing on the results of the work carried out, on the difficulties encountered and on the advice and comments provided by the Commission services and external experts during the workshops.

2 State of the Science

2.1 Introduction

The aim of Task 1 has been to identify, review, analyse and summarise all of the relevant and available information that can be used as the basis for the identification and development of indicators. The work included the specification of a series of criteria for screening and prioritising indicators in terms of their quality and relevance. The project team used the RACER and the SMART[9] criteria.

The study team then identified and analysed over 70 relevant studies published in the last 15 years and screened different national and international databases providing statistics on chemicals, chemicals' exposure and human health. Some of these information sources provide indicators, suggest indicators, present data that could feed the indicators or aid in developing new ones. Other studies set out methodologies or values for use in estimating the benefits of chemicals legislation, or estimates of the benefits associated with particular pieces of legislation or more specific legal requirements. An overview of each of the studies and data sources is presented in Annexes 1 and 2 to this report, while a summary of the findings is provided in Section 2.3 and 2.4.

The screening and prioritisation criteria together with a summary of the identified indicators and the assessment of how indicators perform against each criterion were presented to a brainstorming workshop open to the Commission services only. The aim of this workshop was to establish the Commission's views on the relative importance of the different criteria and on how well the identified indicators performed against these, in order to trigger discussion on the indicators and provide useful indications to the project team.

2.2 Profile of the Indicators Characteristics

Indicators provide evidence that certain results have or have not been achieved. More precisely, an indicator can be defined as a quantitative or qualitative factor or variable against which one can measure changes associated with particular policies. The European Commission's Better Regulation Guidelines (2015)[10] state that for monitoring and evaluation purposes, indicators should refer to the objectives of an "initiative", i.e. a piece of legislation; and, they should allow one to measure to what extent the objectives have been achieved. In this respect, they may reflect the achievement of the general objectives of the legislation in terms of its impacts overall (i.e. a high level of protection of human health or the environment) or of the outcomes or results of the legislation (i.e. increased risk management and reduction in chemical exposures) or of the outputs associated with specific objectives and the associated results against these (i.e. the establishment of a classification and labelling inventory or the restriction of certain SVHCs). Table 2-1 provides further examples of how these different types of indicators can be linked to the REACH Regulation.

[9] RACER stands for: Relevant, Accepted, Credible, Easy to monitor, Robust. SMART stands for: Specific, Measurable, Achievable, Realistic, Time-dependent. The SMART criteria are used in the definition of the policy objectives, but can be used as criteria for the definition of indicators. See for example the European Commission Impact Assessment guidelines, available at: http://ec.europa.eu/smart-regulation/impact/commission_guidelines/docs/iag_2009_annex_en.pdf

[10] http://ec.europa.eu/smart-regulation/better_regulation/key_docs_en.htm

A set of criteria was developed to facilitate an assessment of the quality of the different indicators for the purposes of the study. The project team merged the SMART and RACER criteria together to avoid overlaps and then added additional criteria to reflect the importance of geographic factors and the nature of the data. This resulted in the criteria set out in Table 2-1. The additional criteria included: the geographic level at which the indicator could be applied, whether a source had indicators relevant to multiple impacts, the legislative specificity of the indicators, and the nature of the data (qualitative versus quantitative etc.).

Table 2-1: Type of indicators

Level of objectives	Type of indicators	Definition	What do they achieve?	Examples
Operational objectives	Output indicators	*Relate to the deliverables that the programme is expected to produce*	To measure the specific actions of the legislative mechanisms	e.g. No. of substances registered (and for which information has been provided)
Specific objectives	Result indicators	*Represent the immediate effects of the programme on the direct addressees or recipients*	To measure the immediate effects of legislation	e.g. No. of companies that had to improve risk management measures as a result of new information; or Level of selected chemicals in human body tissues in the EU workers population
General objective	Impact indicators	*Represent the consequences of the programme beyond its direct interaction with the recipients. These include:* - *The direct addressees of the programme* - *People or organisations not directly addressed by the programme, as well as* - *Unintended impacts.*	To measure the ultimate effects of legislation: change in the effects on human health and the environment	e.g. Change in health or environmental outcomes due to the implementation of REACH

Source: Commission Staff Working Document – Better Regulation Guidelines, p.46

Table 2-2: Criteria for the assessment of the indicators

Specific	Is it clear exactly what is being measured? Are there any other confounding factors?
Measurable	Is it qualitative or quantitative? Is it sensitive to changes in policies and programmes? Can it be translated into monetary values?
Achievable and Easy	Are data publicly available at reasonable cost and effort? How reliable, complete and coherent (i.e. same units) are the data?
Relevant	Does the indicator establish and measure either: - The causal link between chemical substances and their effects on the environment and/or human health; or - The causal link between chemicals legislation and the reduced effects on the environment and/or human health?
Timed (timely)	Are data available for this indicator for today? Are data available for the baseline year? Are data regularly updated?
Accepted, Credible and Robust	Is the indicator widely accepted, unambiguous and easy to interpret for non-experts?
Geographical level	*e.g. (Global/European/National/Regional)*
Multisectoral elements	*e.g. (Climate change/biodiversity/air pollution/waste/etc.)*

2.3 Screening of Existing Literature

2.3.1 Introduction

The project team reviewed reports and articles aiming at developing indicators and at quantifying and monetising the benefits of regulating chemicals. A long list of studies, published over the past 15 years, has been compiled and each has been reviewed in order to identify any indicator used or proposed in the past, the methodologies followed for the quantification/monetisation of the benefits and any relevant information sources (the list of papers reviewed is presented in Table A1-1 of Annex I).

The following subsections present a brief summary of the methodologies and of the main results, organised by:

- Impact assessments of the chemicals legislation;
- Studies focusing on the health impacts;
- Studies focusing on the environmental impacts; and
- Other relevant studies for the development of a system of indicators or for the assessment of the benefits of the chemicals legislation.

An in-depth review of the most relevant reports is presented in Annex I.

2.3.2 Impact assessments of chemicals legislation

RPA (2003) assesses the impacts of REACH regulation on occupational health. The study reviews the health and safety legislation already in place that would interact with REACH and provide an enhanced level of protection to workers against occupational diseases that may arise from exposure to chemicals. It then reviews the literature on the economic costs of ill-health and combines different approaches to provide an economic valuation (direct and indirect resource costs, human costs) of the potential benefits from REACH, taking into account: the costs of medical treatment; the value of lost output; and the human costs, where these reflect an individual WTP to avoid a particular health effect. Based on a WTP to avoid the risk of fatality in the range of €0.65 million to €1 million, the estimated benefits for occupational health over a 30 year period, based on a 3% discount rate, are estimated to be between €18 billion and €54 billion.

The Commission's Extended Impact Assessment (2003) focusses on the quantification of the costs of REACH for the Chemicals Industry, providing a qualitative description of the potential health and environmental benefits and some illustrative quantitative figures. It identifies four benefit drivers[11]:

- The generation of information about the properties of the chemicals and the potential risks that they may pose for health and the environment, and to develop strategies to manage these risks;
- The availability and accessibility to this information to downstream users, the authorities and the general public;
- The replacement of substances of very high concern by new substances less dangerous for health and the environment; and
- Faster action by authorities when risk reduction measures are needed.

[11] EC (2003): *Extended Impact Assessment,* Commission staff working paper, SEC (2003) 1171/3, 29/10/2003.

Given the lack of information, the Impact Assessment adopts a conservative figure of 1% as representing the proportion of all diseases (measured in Disability Adjusted Life Years - DALYs) due to agro-industrial chemicals and chemical pollution from diffuse sources; this is based on the estimated range of 0.6% to 2.5% by Murray and Lopez (1996)[12]. The proportion of diseases that will be identified and tackled by REACH is assumed to be 10%[13]. It is then further assumed that 10 DALYs are equivalent to 1 life saved[14] with the value of a statistical life assumed to be €1 million. It is also assumed that REACH would start to deliver benefits after 10 years of implementation and that these would continue for another 20 years. The magnitude of the estimated benefits from this assessment is similar to that derived by RPA (2003) at €50 billion.

WWF (2003) uses three different modelling approaches to assess the benefits of the REACH regulation:

- The first two use DALYs to estimate the burden of disease and premature mortality but use different methods to value DALY –
  - the first calculates health expenditure per DALY, based on UK and EU data, and then applies this ratio to the number of DALYs avoided through REACH to give an estimate of total healthcare expenditure savings
  - the second model applies WTP estimates to the proportion of DALYs saved by the REACH regulation
- The third model estimates the medical costs and forgone productivity associated with specific diseases or health end-states, using US data from a study estimating the social healthcare costs plus productivity effects of toxic substances in the USA for 1997. This data is then applied within the UK and EU contexts, assuming the same level of incidence among the respective populations and making adjustments for EU incomes. The two DALY approaches suggest significantly different estimates of per DALY values: the first suggests €5,624 per DALY and the second recommends €90,000.

Pearce and Koundouri (2004), building on their 2003 study for WWF, consider the potential health benefits that could arise from the REACH Regulation using DALYs from WHO/World Bank datasets. This study assumes that regulation will lead to a 10% reduction in exposure levels. As for the WWF study, the authors consider two approaches to valuing the DALYs avoided: one based on medical expenditure and the other involving WTP values.

A study by ECORYS (2004) for the Dutch government examines 36 studies which attempt to estimate the impacts (including benefits) of the REACH regulation. One of the methodologies which comes out of this review is the estimation of the extent of illness avoided through the implementation of chemicals legislation and how this can be valued using the DALY methodology or the WTP methodology.

Pickvance et al (2005) combine a range of techniques to calculate the direct and indirect health benefits of REACH, calculating the burden of occupational disease from information obtained on incidence rates, estimating the proportion of cases attributable to exposure to substances affected by the Regulation, and using this estimate to calculate preventable diseases for the EU-25 workforce.

[12] Murray and Lopez (1996): *The global burden of disease,* World Health Organisation, 1996.
[13] RPA (2003): *Assessment of the impact of the new Chemical Policy on Occupational Health*, 2003.
[14] WHO (2002): *World Health Report,* 2002.

They then analysed the costs associated with skin and respiratory diseases in terms of the associated health service costs, productivity costs and the value of the lost health-related quality of life to the individual using QALYs (quality-adjusted life years), the value of which is assumed to be between €28,000 and €43,000.

Ökopol (2007) analyse various studies relating to the calculation of the costs and benefits of REACH. They consider three types of benefits, one of which is health and includes less public spending on public health. The study also considers the costs and benefits of REACH on the environment and three key methodologies are identified: case studies analysing costs of remediation; assessment of costs incurred in preventing substance-related environmental damage; and assessment of WTP for certain environmental goods.

The Eurostat REACH baseline study (2009) sets out a system of indicators to monitor the impact of REACH on human health and the environment over time, based on a series of specifically-developed surrogate markers and other indicators related to the quality of the information available for risk assessment purposes. The system is composed of administrative indicators, risk and quality indicators and supplementary indicators[15]. The system is based on the premise that neither the calculation of risk nor the understanding of changes in data quality and provision are manageable for all substances falling within the scope of REACH (approximately 30,000 substances). Thus the system focuses on the detailed statistical analysis of 237 substances from the high, medium and low production volume chemicals (approx. 10 000 existing substances in volumes >10 tonnes/year as reported to the European Commission) which act as representatives of the wider chemicals market across Europe. For each of these 237 substances, a 'Risk Score' between 1 and 1,000 is calculated based on estimates of exposure and toxicity. The intention of these Risk Scores is to assess how they change and to compare these changes to changes in other metrics relating to workers and consumer over time. A score which ranges from 1 (very good quality of data) to 100 (very poor quality of data) characterises data quality. This quality assessment is a key element of the Risk and Quality indicator system. The baseline study approach was developed to indirectly inform on the degree of REACH's success in ensuring a high level of protection through information provision throughout the supply chain. The Risk and Quality indicator system constitutes the core element of the assessment but provides a mechanism for the future prediction of impacts using surrogates of real-world risk rather than directly measuring 'real' changes in burdens.

The REACH baseline study – 5 years update (2012) found clear indications that registration under REACH leads to a significant improvement of the knowledge on substance properties. For the first time, for many substances, existing data have been used to derive toxicity estimates such as DNELs (Derived No Effect Levels), DMELs (Derived Minimal Effect Levels) and PNECs (Predicted No Effect Concentrations), and to perform exposure estimations and risk characterisations. The results of the 5 Years Update show increase in the quality of the data available for the assessment of the registered substances. In addition, for a relevant part of the substances analysed the nominal risks show a clear decrease. The fraction of reference substances with risk characterisation ratios at or below 1 increased. This can be seen as an indication for a better control of risks due to the chemical safety assessments required by REACH.

COM (2009) assesses the impact of proposed revisions to the Directive 98/8/EC, which seeks to harmonise the placing of biocidal products on the market whilst guaranteeing a high level of protection for humans, animals and the environment. The report considers the potential costs and benefits that may arise from various options under five policy areas. The estimated total costs to the industry of all preferred options would amount to between €193.6 million and €706 million, over

[15] See Annexe A1.25 for information about these indicators

10 years. The report also estimates that the total costs savings (from sharing of test data involving vertebrate animals at the substance evaluation and authorisation stage) could be between €2.7 billion and €5.7 billion. The report provides a list of indicators which are used, alongside policy objectives and data sources, in the monitoring and evaluation process.

A scoping study by RPA (2009) provides an overview of how the impact of REACH and CLP in the UK might be evaluated in a manner that is suitable to meet the short-term need for appropriate information with which to complete the UK's first quinquennial report to the EC. The study also establishes an outline for the specification of a monitoring programme over the longer-term. In this way, the specific objectives of the scoping study were to:

- Ascertain the feasibility of obtaining information on how the principal objectives of REACH and CLP are being delivered, and how baselines for each of these may be established for evaluation purposes;
- Identify possible options for data-gathering methodologies; and
- Propose possible options for longer-term monitoring, evaluation and reporting of REACH and CLP impacts.

In order to achieve this, a staged approach was applied involving the identification of objectives/sub-objectives (for which indicators might be sought); identification of indicators and data sets; and repeated iterations of these two activities until a 'master list' of possible indicators matched to objectives/sub-objectives was identified. Using a transparent scoring process, indicators were then screened and scored according to a range of different criteria to allow the identification of suitable candidates for indicators relevant to different options (in terms of effort required to satisfy data requirements and level of detail/coverage of indicators)[16].

DEFRA (2011) estimate the costs and benefits of chemicals regulation for business in the UK, derived over a 10 year period with baseline year 2011. The estimates are taken from a variety of sources such as regulatory impact and compliance cost assessments, Defra's internal value for money analyses and a paper on administrative burdens conducted by PriceWaterhouseCoopers. The study estimates that the benefits arising from REACH regulation and mercury regulation are around £17 million per annum (around €22.1 million[17]). The paper goes on to state that the benefit-cost ratio of chemicals regulation is 38:1.

RPA et al (2012) estimate the benefits to human health and the environment due to the implementation of REACH (up until 2012). It includes the development of a framework for assessing these benefits. The framework suggested involves the identification of: drivers of benefits (such as legal provisions triggering direct or indirect effects); the pathways through which the drivers deliver these benefits; indicators of benefits; and enhancers (the provisions that help to realise the benefits)[18]. This study has been drawn on in Sections 3 and 4.

Oltmanns et al (2014), in their study on the impact of REACH on the classification for human health hazards, compare information from REACH registration dossiers with harmonised classifications of 142 substances produced at very high tonnages and for which assessments were already carried out in the past. They found that 12 substances lacking a harmonised classification were classified in the registration dossiers submitted by the manufacturers/importers. Thirty-seven substances had

[16] See Annexe A1.27 for more details on the scoring criteria applied to selection of indicators.
[17] Exchange rate GBP – EUR: 1.3.
[18] See Annexe A1.35 for a full list of the indicators identified.

stricter classifications and twenty-nine of these were classified for an additional end-point. These finding led the authors to conclude that REACH is improving the hazard characterisation even for those substance for which a good data base is available. The study, despite not suggesting any particular indicators, does validate some of the proxies which could be used as indicators of human health and environmental benefits, such as "number of companies that have had to improve risk management measures as a result of REACH".

2.3.3 Studies focusing on health impacts

WHO (2000) provides an overview of the methodologies used for calculating environmental burden of disease (EBD). The paper is based on a consultation with 39 environmental health experts and discusses the various concepts, frameworks and challenges associated with deriving EBD. It also provides examples of previous EBD estimations and considers levels of evidence and uncertainty surrounding the subject matter. The paper offers several recommendations for future EBD assessments with a focus on risk factor categorisation, scenario analysis and determining causation. Nevertheless, the key value of the paper is within the accompanying annexes, which provide different methodologies and indicators that could be applied within the context of this study. The paper focuses on four thematic areas for which work groups were assigned[19]: water and sanitation; air quality; global environment; and chemicals. The findings compiled by the chemicals work group (Annex 5.2) identify four groups of chemical risk factors to be considered in EBD assessments, these include: metals, pesticides, other organochlorines and related compounds, and solvents and volatile organic compounds (VOCs). The work group also suggests that the most reliable indicator of actual human exposure is a biological measure of body burden. More specifically, the work group mentions two studies that could provide indicators of chemical exposure:

- An analysis of breast milk samples from 19 countries for dioxin and PCBs;
- Long-term study of arsenic exposures and health effects in a district in Slovakia.

While these studies could provide useful insights into the levels of exposure at the European level (especially for dioxin and PCBs), it is likely that the data is not relevant to the current time period - although a recent literature search indicates that more recent data may be available (e.g. the WHO's Global Environment Monitoring System)[20]. Furthermore, direct references to the studies are not made available within the text.

COWI (2004) calculates both the direct costs of ill health from exposure to chemicals and the social costs. The direct costs are calculated using data available from the literature and expert judgments, with a patient's own lost earnings included in the calculation. Estimates are based on the prevalence of the disease in the general population, as the aim of the study is to value the costs associated with the burden of disease. Prevalence rates are estimated and then multiplied by individual disease 'state' costs of treatment, etc. to generate the direct costs. Social welfare costs are estimated based on a benefits transfer approach using available WTP values.

Ostertag et al (2004) estimate that, in Germany, dangerous substances contribute some 7% to the unfitness to work in Germany and generate approximately €3 billion in direct costs (i.e. treatment of illnesses) and €2.7 billion in indirect costs (i.e. disability from exposure to substances) per year.

[19] Each work group was asked to consider risk factors, the strength of evidence, and relevant alternative scenarios for each of their thematic areas.

[20] Available at: http://www.who.int/foodsafety/areas_work/chemical-risks/gems-food/en/

Eftec (2004) reviews the literature relating to measuring mortality and morbidity using Value of Statistical Life (VSL) or Value of Life Year (VOLY) calculations. The paper suggests that in the UK, the VSL values derived from stated preference studies range between £1 million and £1.2 million.

WORKHEALTH (2004) provides a shortlist of indicators for monitoring work-related health in Europe[21] along with more detailed, 'operational' indicators and data sources relating to these indicators. For example, "Accidents at work" is a main indicator which can be assessed using operational indicators like 'incidence rate of serious accidents at work in comparison to 1998'. Data for this is available from Eurostat.

WHO (2004) provides guidance on assessing the current burden of disease from past and current occupational exposures to carcinogens, outcomes of which include lung cancer, leukaemia and malignant mesothelioma. The paper shows how workforce and exposure data can be used alongside relative risk factors from the literature to estimate the impact (in terms of DALYs) of occupational exposures to carcinogens.

US EPA (2004) is a background paper on the VSL methodology used by the United States Environmental Protection Agency (US EPA). Since 1999, the US EPA has used a central VSL estimate of $6.2 million (in 2002 dollars) for the majority of its economic analyses. The paper conducts a review of three EPA funded studies in conjunction with three meta-analyses that derive VSL estimates. The paper concluded that this central VOSL estimate used by the EPA may now need to be revised, in light of the growth of the literature available relating to VSL methodology.

RIVM (2008) uses a case study analysis to assess the total health gain of measures on chemicals in consumer products. The case studies focus on a number of substances products and control measures[22]. For each case study, exposure is estimated before and after the implementation of a specific measure. The study also provides estimates of the incidence of cancers linked with each substance before and after measures are implemented. WTP-type values or VSL values for these incidence rates could be applied to calculate the monetary value of the impact of chemicals legislation on human health.

Remoundou and Koundouri (2009) critically review the literature on the contribution of the environmental factors on the global burden of disease and deaths. They describe the different economic valuation techniques and present some of the applications of these techniques that have been carried out to estimate the social benefits associated with increased quality of the environmental media. The appendix to the study provides a useful summary of valuation studies and benefits of environmental legislation estimated using the different techniques.

The results of the benOSH (Benefits of Occupational Safety and Health) project are presented in the 2010 EU-OSHA report. The project aims to evaluate the costs of accidents at work and work-related ill health. It also demonstrates the incremental benefit to enterprises in developing an effective prevention policy in Occupational Safety and Health. The report suggests ways in which the monetary value of accidents at work and work-related ill health can be calculated, such as obtaining the sum of costs of activities, fines and payments following a work-related fatality.

An OECD (2010) report analyses the differences in the approaches followed by different countries in establishing a VSL. While in the US the most common approach is to rely on Revealed Preference methods in terms of wage risk, in Europe the Stated Preference methods are more common, eliciting

[21] See table A1-8 of Annexe 1 for this list of indicators.
[22] See Table A1-11 of Annexe 1 for more detail

people's WTP for changes in mortality risks. The authors provide useful recommendations on how to adjust VSL base values for differences in population, risk characteristics and other differences. These recommendations may be of value in the monetisation stage of the present study.

The report by COWI et al (2011) quantifies the costs deriving from the non-full implementation of the EU environmental acquis. For this reason, the report considers wider legislation and does not focus exclusively on chemicals. The identification of the implementation gaps was carried out through the assessment of the overall policy objectives and targets and their comparison with the actual scenario. However, the authors do not quantify the environmental and health costs, instead referring to previous studies (such as the Extended Impact Assessment by the Commission and the DHI (2005) report.

Prüss-Ustün et al. (2011) apply the standard methodology of the Global Burden of Disease study developed by WHO to chemicals' exposure. The authors undertake a systematic review of the previous studies looking into the burden attributable to exposure to chemicals and conclude that the unknown aspects were still prevailing on what was already known. The article first describes how human exposure to chemicals occurs, identifying the chemical groups of most concern, the processes that provoke the exposure, the life-cycle stages of the chemicals when the exposure might occur and the legislative areas in which policies to reduce the exposure are implemented. In order to compare the available estimates to the total burden of disease from chemicals, the authors review the literature and list the main health outcomes associated with exposure to toxic chemicals. The authors find that the global burden of disease attributable to environmental exposure and management of selected chemicals amounts to 4.9 million deaths (86 million DALYs) per year. This accounts for approximately 8.3% of the total deaths and 5.7% of the total burden of disease in DALYs worldwide.

Rushton et al (2012) estimate the burden of occupational cancer in Great Britain and develop a methodology for predicting the future burden of occupational cancer. The authors follow the attributable fraction method to estimate the cases of cancer which could be attributed to occupational exposure. To predict the future burden of occupational cancer, three possible approaches were suggested: estimating attributable fractions; estimating the "lifetime risk" of a cohort of newly exposed workers; and estimating the attributable numbers. The authors estimated that the proportion of cancer deaths in 2004 attributable to occupation was 8.0% for men and 1.5% for women. The estimated number of deaths attributable to occupational cancer was 6,259 for mean and 1,058 for women. The authors take data from HSE regarding the main causes of occupational cancer in Great Britain; exposure to asbestos was responsible for nearly 4,000 deaths in 2005.

UNEP (2013) assess the economic impacts of chemicals on human health and the environment. The study also shows how these information sources could be used to extrapolate costs to the national, regional and global levels. The authors conduct a literature review of previous studies that have attempted to measure and quantify the impact of chemicals on the environment and human health. The authors identify a study by WHO which found that a subset of chemicals accounted for 964,000 deaths (1.6% of total deaths) and nearly 21 million DALYs (1.4% of total DALYs) globally in 2004. However the study did not attempt to monetise these impacts. The authors take costs suggested in a study by UNEP FI and PRI (2010) for environmental costs; this study found that VOCs (volatile organic compounds) and mercury emissions account for $236.3 billion and $22 billion, respectively, of environmental costs due to human activity. The baseline costs associated with pesticide poisonings in sub-Saharan Africa were around $4.4 billion in 2005.

A report by Trasande et al (2014) estimates the disease burden and costs of endocrine disrupting chemicals (EDCs) in relation to obesity and diabetes, reproductive disorders and neurobehavioural

deficits. The authors estimate the probability that different EDCs contribute to the different outcomes based on toxicological and epidemiological evidence. The authors apply values for the cost per case for different health endpoints, taken from other literature. For example, the authors cite Legler et al (2014) who estimate the cost per case of direct adult obesity from exposure to phthalates as €21,500. However, it is not made clear how these values have been estimated.

The Health and Environmental Alliance commissioned a report (published in 2014) which estimates the cost of health impacts relating to exposure to EDCs. The authors focus on conditions such as: reproductive and fertility problems; abnormalities of the penis and testicles in baby boys; cancer of the breast, prostate or testes; children's behavioural disorders; and obesity and diabetes. They then associated treatment costs available for the above conditions and multiplied these for the number of cases attributable to exposure to EDCs in the EU, using an attributable fraction of 2-5%. Total costs are extrapolated to the European level by multiplying the treatment costs for a member state by a scaling factor (defined on population size). The authors identify that this methodology oversimplifies the reality, not taking into account differences in treatment costs and in incidence rates between countries.

ECHA (2014) commissioned a stated-preference study, the objective of which was "*to estimate the willingness to pay to avoid selected adverse human health outcomes due to exposure to chemicals in the European Union and to derive representative EU-wide benefit estimates reference values*". These values are intended for use by ECHA and other bodies when performing and evaluating SEAs in the context of REACH. Health endpoints for which recommended WTP values are derived include: skin sensitisation; acute and chronic kidney disease; cancer; etc. Values range from €222 for a case of acute mild dermatitis to a VSL (Value of a Statistical Life) for cancer of €5 million.

2.3.4 Studies focusing on environmental impacts

In their paper, Nunes et al (2001), provide an overview of economic and ecological indicators of biodiversity as well as the underlying valuation approaches. In terms of indicators the paper presents two approaches to measuring biodiversity: biotic-richness and ecosystem health/integrity. In assigning a value to biodiversity, the biotic-richness approach considers the magnitude of biological products and services flows provided by nature. Under this approach the measurement of biological diversity is typically undertaken with the use of genetic, species, and ecosystem richness or variety indices. The authors provide a broad overview of the economic valuation literature with regards to biodiversity. One valuation method reviewed by the paper is total economic value (TEV). The TEV of an environmental resource is defined by two components – its use value (UV) and non-use value (NUV). Use values can be further subdivided into direct (DUV), indirect (IUV) and option values (OV) while non-use values can also be further defined by bequest value (BV) and an existence value (XV)[23].

DHI (2005) presents a study, identifying three approaches for assessing the potential benefits of REACH on the environment and humans exposed via the environment. The aim of applying all three approaches is to circumvent the lack of suitable data. The first approach makes use of WTP estimates for avoiding the impacts of chemicals. The second approach is the damage function approach, which was applied using a risk ranking-type system based on the EURAM method. The third approach used the avoided costs approach to estimate the benefits from chemicals regulation.

Norden (2004) estimates the environmental costs to society across the EU-25 of late action on PCBs. Using Swedish data (and then extrapolating to the EU level), Norden estimates the total social cost

[23] See table 1-3 in Annexe 1 for more detail of TEV, its value components and valuation methods.

associated with a "PCB misstep", using data relating to: the amount of money that society has paid to research and monitor PCB; costs associated with handling PCB contaminated waste; cost of replacing PCB contaminated parts in buildings; cost of an eagle conservation project to counteract the effects of PCB.

A study conducted by Lancaster University (2006) quantifies the links between the substances identified as having an effect on the environment and their reported environmental and human health impacts. They study gathers quantitative data relating to the adverse impacts of four selected substances (TBT, methiocarb, DDT and PCBs) and applies monetary evaluation to these impacts, with an emphasis on the use of WTP values and avoided costs. For the assessment of the economic costs associated with a change in human health due to chemical exposure, the study utilised a number of concepts such as: the direct medical costs associated with cancer cases; VSL values; and QALYs monetised using WTP estimates. For the economic assessment of environmental services/goods, the study utilised the concept of Total Economic Value (TEV). The TEV of a species is calculated by summing its direct use, indirect use, option and non-use values. The study concludes that the more a chemical persists and travels in the environment, the larger the benefits are from regulating it. Furthermore, there are large costs associated with ecosystem functioning. Finally, the results of the study indicate that human health impacts are more significant than environmental impacts, though the authors attribute this to data limitations and thus the inability to quantify them.

UNEP (2013) take costs suggested in a study by UNEP FI and PRI (2010) for environmental costs; this study found that VOCs (volatile organic compounds) and mercury emissions account for $236.3 billion and $22 billion, respectively, of environmental costs due to human activity. The baseline costs associated with pesticide poisonings in sub-Saharan Africa were around $4.4 billion in 2005.

2.3.5 Other relevant studies

The Nordic Council of Ministers (2004) calculates the direct costs to businesses of the REACH regulation, taking into account several factors including the number of substances that will be registered under REACH. The authors then calculate the costs per substance for testing and registration in each volume tier and multiply this by the total number of chemical substances expected to be affected. They also consider the potential price impacts of the REACH regulation using a single market model: they estimate a price increase of 0.03%, a decrease in output of 0.06% and a decline in consumer and producer surplus for the whole European chemical industry of €45,000 per year.

Ostertag et al (2004), in addition to assessing the health impacts of REACH, also look at the extent to which REACH improves the existing foundation for assessment and communication of substance-oriented risks in the supply chain and how it contributes to improved knowledge management with regard to assessing old substances. From a review of the literature, the authors find that the cost of PCB remediation in public buildings is equivalent to €25 per resident. Additionally, the paper presents data on the costs of removing pesticides from drinking water at the European level, which varies between €65 per annum to €162 per annum.

ECHA has issued guidance on SEAs in 2008 and 2011, on Restriction and Authorisation, respectively. Both guidance documents propose a stepwise approach whereby the assessment focuses on those health and environmental impacts that are considered to be significant. The guidance documents suggest that human health can be measured using the following impacts as indicators: morbidity (acute effects and chronic effects); mortality (e.g. premature death due to cancer); and morbidity or mortality due to different explosive characteristics of the substance. The following indicators have been suggested for measuring environmental impacts: ecological impairment; habitat destruction;

water quality impairment; air quality impairment; soil quality impairment; and others such as climate change and water consumption.

RPA et al (2011) develop logic frameworks for the assessment of human health and environmental impacts, using the ECHA Guidance on SEA for restrictions as the starting point. The aim of the frameworks is to provide further suggestions and refinements as to how health and environmental impacts in particular could be assessed within the overall SEA process for restriction and authorisation, as envisaged by ECHA. The frameworks do not seek to develop a new approach. The study suggests the use of different tools for benchmarking human health impacts as well as proxy indicators for impacts. Such tools and indicators include: changes in exposure level/frequency; changes in concentration of a chemical of consumer products; and changes in emissions. Fuller quantification may be possible but should be accompanied by information and the level and sources of uncertainty. The approaches to valuation are those included in the earlier guidelines, namely the use of QALYs or DALYs, the use of VSL estimates and the use of cost-of-illness or resource cost estimates.

The Commission's Impact Assessment (IA) Guidelines, revised in 2009, give general guidance to the Commission services for assessing the potential impacts of different policy options. Public health and safety is included under the Guidelines, including a number of questions aimed at assessing whether there are changes in health risks in the workplace and with respect to the general public via the environment. It also includes public health risks associated with waste disposal and some stages of the life-cycle, like energy use. In terms of the valuation of health impacts, the Guidelines suggest quantification whenever possible by using the Healthy Life Years indicator[24], or measuring both quality and quantity of life using QALYs (quality adjusted life years) or DALYs (disability adjusted life years). Monetary valuation is also recommended although the guidance acknowledges the problems in doing so. Approaches suggested in Annex 9 to the Guidelines include market based approaches, such as the Cost of Illness (COI) or human capital approach, revealed preferences based approaches, such as Willingness to Pay (WTP) or Willingness to Accept (WTA), and related units based on these, such as Value of Statistical Life (VSL) and Value of Statistical Life Year (VOLY)[25]. Annex 9 suggests a range of values for different units of measurement, as: €50,000 to €80,000 per QALY; €1 to 2 million per VSL; and €50,000 to €100,000 per VOLY.

UNEP (2013b) provides a detailed analysis of the global chemicals industry and reviews the available literature to assess its human and environmental impacts. The study presents a range of indicators on the chemicals industry and its impacts on human health and the environment. It also builds on data from the Prüss-Ustün et al. (2011) study on the global burden of disease due to chemicals.

A study conducted by the European Environment Agency (2013) builds on the first report published in 2001, looking at a selection of occupational, public health and environmental problems which have occurred in the past few years. It determines whether the authorities' actions were sufficient in anticipating and dealing with hazards and problems. The study focuses on the dynamics between science, risk communication, risk management and policy-making. The authors use case studies to support their arguments; most of these studies focus on the effects of chemical substances on human health and environment, substantiating the evidence with indicators that have been suggested in the other reports reviewed, e.g. BPA or lead concentration in human tissues, emissions of mercury or lead and concentration of pesticides in pollen or nectar.

[24] The Healthy Life Years (HLY) indicator is in the core set of the European Structural Indicators as its importance was recognised in the Lisbon Strategy.

[25] For more discussion on the individual units, please refer to: http://ec.europa.eu/governance/impact/commission_guidelines/docs/iag_2009_annex_en.pdf

2.4 Databases and Other Information Sources

2.4.1 Introduction

Several national and pan-European databases are available that provide data and information on a range of factors such as: levels and emissions of environmental pollutants; identification of harmful chemicals, their uses and their levels of production; and bio-monitoring data relating to these substances. We provide an overview of these databases below, identifying and analysing the potential indicators which can be developed based on the data sources available. We also consider the frequency with which the databases are updated, the temporal extent of the database (i.e. the number of years for which data is available), the spatial extent of the database (i.e. whether the data has been georeferenced at a local, regional or national level) and the extent to which the data and methodologies presented in these sources are relevant and useful to monitoring the benefits of chemicals legislation. The potential indicators identified in these sources are also listed.

The various sources of available information can be broadly separated into four categories:

- Information on the production, trade and use of chemicals;
- Emissions of chemical substances;
- Human biomonitoring data and concentrations of pollutants in the environment; and
- Human health statistics.

The list of the databases and other sources that have been considered is presented in Table A2-1 in Annex II.

2.4.2 Information on the production, trade and use of chemicals

In terms of chemicals' exposure, the best indicator is the concentration of harmful chemicals in human body or environmental samples. In the absence of this information, data on the emission of certain chemicals can be used as a proxy. A third-best is information on the production, trade and use of chemicals. The farther from the concentration of chemicals in human or environmental samples, the more assumptions are needed to correlate the information with chemicals' exposure: a reduction in the production of harmful chemicals and substitution with less harmful chemicals can work as indicator of the progress and impact of chemicals legislation, but important confounding factors need to be controlled for (such as the macroeconomic situation).

The primary source of European production data is Eurostat. Eurostat data are collated and presented in a way which enables comparisons between countries and regions, including Member States and non-Member States in Europe. Eurostat has developed indicators relating to chemicals production[26] based on information from Prodcom[27] regarding the production of industrial chemicals, particularly substances classed as being toxic to human health or harmful to the environment. Statistics on toxic chemicals as well as environmentally harmful chemicals start in 1996 but data for the EU28 aggregate are only available from reference year 2004 onwards and are updated annually.

Substances are aggregated into ten classes, as listed in Table 2-3; these classes follow the official classification as set out in EU legislation based on scientific expert judgement. This separation of classes allows more accurate tracking of the changes in chemicals production, thus providing a

[26] http://ec.europa.eu/eurostat/statistics-explained/index.php/Chemicals_production_statistics
[27] http://ec.europa.eu/eurostat/web/prodcom/data/database

clearer indication of the impact of chemicals legislation and whether the legislation is achieving its intended targets. The data presented in the chemicals production database cannot be disaggregated into individual substances. The PRODCOM database contains the total production of the covered industry in volumes manufactured, as well as in monetary values within the statistical coverage (threshold due to size of manufacturers, etc.). Certain important products (at 8-digits level) are created in physical units and these products are 'highlighted' in the statistics. Only if the PRODCOM positions used are detailed enough, e.g. if the product covers a single process or a well-defined product is possible to identify a 'chemical' to which attributes concerning physical, chemical or toxic properties could be added. Only for these detailed, well-defined products can the database serve as a source for a set of chemicals. The statistics focus on major chemicals with a high production value and volume.

Table 2-3: Classes of environmental harmful chemicals and toxic chemicals

Classes of environmental harmful chemicals[1]	Classes of toxic chemicals[2]
Severe chronic effects Significant chronic effects Moderate chronic effects Chronic effects Significant acute effects	Carcinogenic, mutagenic and reprotoxic (CMR) chemicals Chronic toxic chemicals Very toxic chemicals Toxic chemicals Harmful chemicals

Note:
[1] Based on their effects on the aquatic environment. These are categorised with the most harmful at the top and reducing harmfulness down the list.
[2] These are categorised in terms of danger to human health with the most dangerous at the top of the list.

The Eurostat website makes it clear that these indicators are concerned only with the quantities of the chemicals produced, rather than the actual risks associated with their use. It is reiterated that production and consumption are not synonymous with exposure to chemicals, given that some chemicals are handled in closed systems or used as intermediate goods in a controlled supply chain.

The Swedish Chemicals Agency (Keml) has developed a Commodity Guide[28] which identifies which substances and materials are used in the production of commodities on the Swedish Market. Keml has also developed a database of flow cards[29] which provide statistics relating to specific chemicals. The former is based on the Miljøprojekt 281/1995 conducted by the Danish Environmental Protection Agency, for which a comprehensive survey was undertaken asking manufacturers about the composition of their products. The intention is to update the Commodity Guide when there is reason to believe that the composition of a commodity has changed considerably.

Within the Commodity Guide, it is possible to search across different types of commodities to identify the materials they usually consist of and the substances that may be included in these materials. Searches can also be made for single materials and substances to identify what commodities and groups of commodities these are used in. Examples of different chemical substances that can be part of materials that are plastics, rubbers and textile fibres have been retrieved from KemI reports and from handbooks. Information on the quantities of the commodities produced, imported and exported is retrieved from Statistics Sweden data and is available for the years 1996, 2001 and 2007. At present, there are approximately 900 substances included in the database; for around 258 substances, 1,068 flow cards have been developed. The database allows searches to be made using the name of the substance or the CAS number. Potential indicators that

[28] http://webapps.kemi.se/varuguiden/Default.aspx
[29] http://webapps.kemi.se/flodesanalyser/

could be developed using these data include: change in the content of substances within certain materials over time; and change in the amount of each material used in different commodities over time. Thus, potential indicators could be developed using the data to reflect the change in the quantity of particular raw materials used in downstream applications over time.

In addition to detailing the use of specific chemicals, the KemI Commodity Guide and flow cards also provide statistics on the production, consumption and imports of certain substances and raw materials. These could be compared to the Eurostat data, Prodcom data and the changes in the quantities of raw materials used in different downstream applications to provide linkages between regulatory actions and health and/or environmental benefits.

2.4.3 Emissions of chemical substances

As for information on the production, trade and use of chemicals, data on chemicals' emissions could be used as a proxy for the results of the chemicals legislation in the EU, but important confounding factors need to be controlled for.

A key resource for information relating to emissions is the European Pollutant Release and Transfer Register (E-PRTR)[30]. This register provides annual data reported by 28,000 industrial facilities, covering 65 economic activities within the 9 industrial sectors listed in Table 2-4. The register contains data for 91 pollutants which fall under the 7 groups also listed in Table 2-4. Table A2-4 in the annex provides the full list of pollutants for which data are available on the Register.

Table 2-4: Categories under which data is listed in E-PRTR

Industrial Sectors	Groups of Pollutants
Energy	Greenhouse gases
Production and processing of metals	Other gases
Mineral industry	Heavy metals
Chemical industry	Pesticides
Waste and waste water management	Chlorinated organic substances
Paper and wood production and processing	Other organic substances
Intensive livestock production and aquaculture	Inorganic substances
Animal and vegetable products from the food and beverage sector	
Other activities	

A facility is obliged to report data under the E-PRTR if it meets any of the following criteria: it falls under any of the 65 E-PRTR economic activities which are listed in Annex I of the E-PRTR regulation and it exceeds at least one of the E-PRTR capacity thresholds[31]; if it transfers waste to an off-site facility and the specific thresholds listed in Article 5 of the Regulation are exceeded[32]; if the pollutants released by the facility exceed the specified thresholds for each media (air, water, land) in Annex II of the E-PRTR Regulation[33]. Data reported by the facilities include:

- Releases to air, water and land of any of the 91 E-PRTR pollutants;
- Off-site transfers of any of the 91 E-PRTR pollutants in waste water destined for waste-water treatment outside the facility; and

[30] http://prtr.ec.europa.eu/Home.aspx
[31] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:033:0001:0017:EN:PDF#page=8
[32] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:033:0001:0017:EN:PDF#page=4
[33] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:033:0001:0017:EN:PDF#page=12

- Off-site transfers of waste for recovery or disposal.

Data regarding emissions released and waste transferred are available for 2007, 2008 and 2009. From 2011 onwards, data is updated annually.

Another European data source for statistics on emissions is the Norwegian Climate and Pollution Agency[34], which provides monitoring surveys on environmental pollutants such as PCBs, heavy metals, PBDEs, siloxanes, PFCs, chlorinated paraffins, and stable isotopes of nitrogen and carbon. The web-portal developed by the Agency provides information on the 30 priority substances, as classified by the Norwegian government. A list of these substances is given in Table A2-5 in the annex. Statistics are available regarding changes in emissions in these substances over the period 1995-2013. However, as data are only available for Norway (a non-Member State), the information provided may not be relevant to monitoring the impacts of chemicals legislation in the EU, though it certainly provides useful auxiliary evidence.

2.4.4 Human biomonitoring data and concentrations of pollutants in the environment

Measuring human exposure to harmful chemicals is an integral component of assessing the impacts of chemicals legislation and how effectively it has achieved its objectives. Data on changes in human exposure to chemicals and changes in the concentrations of specific chemicals in humans can be linked to dose-response or risk-ratio data to quantify changes in the number of disease cases that may be attributable to chemical exposures.

The Consortium to Perform Human monitoring on a European Scale (COPHES)[35] and the feasibility study DEMOCOPHES (DEMOnstration of a study to COordinate and Perform Human bio-monitoring on a European Scale) provides data from national surveys that took place between September 2010 and November 2012. In the surveys, biomarkers for chemicals of concern were measured in the hair and urine of almost 400 mothers and children. The COPHES and the feasibility study DEMOCOPHES have been able to demonstrate that a more coordinated and harmonised approach to Human Bio-Monitoring (HBM) in Europe is possible and can become an important tool to monitor the exposure of Europeans to chemical substances and to address the potential health effects that may derive from this exposure. The results are reported in a final report and a technical report and published in the scientific literature[36].

Exposures are monitored by measuring the concentration of the selected chemicals in urine and hair (subtargets), to provide snapshots for the years 2010 to 2012 (temporal level). So far, the HBM survey has been conducted at the national level or lower scale in 17 European countries (spatial level). The potential indicators for assessing the benefits of chemical legislation based on the data available in this study are:

- Changes in levels of mercury in human hair; and
- Changes in levels of cadmium, Bisphenol A and metabolites of phthalates in urine.

As indicated above, the data from the study represent a snapshot for the years 2010 to 2012, so would need to be combined with data for earlier years for the purposes of this study, for example to establish a pre-regulatory action and a post-regulatory action set of figures.

[34] www.klif.no
[35] www.eu-hbm.info/cophes
[36] www.eu-hbm.info/euresult

The TNO-report "*R 2004/493 Man-made chemicals in human blood*"[37] is a study sponsored by Greenpeace and completed in 2004. The objective of this study was to determine the presence of a number of chemicals in blood samples of 100 volunteers in the Netherlands. The study reports the results of man-made chemicals in blood samples as a snapshot in 2004. The following substances were monitored in the samples: Bromated flame retardants (polybromated diphenyl ethers, hexabromocyclodecane, tetrabromobisphenol-A); phthalates; musk compounds (nitro musks, polycyclic musks); organotin compounds; alkylphenols; alkylphenol ethoxylates; and bisphenol-A. These data can be used as a background levels for the analysis time period and it may be able to combine them with some of the other data discussed above to establish potential indicators.

The German Environment Specimen Bank provides data on concentrations of different chemicals in human and environmental samples. The data bank is managed by the German Umweltbundesamt[38] (UBA) and is based on results from analyses of exposures. Analyses have been undertaken annually since 1981, including measurements of heavy metal contents and organics in environmental species and compartments. Table 2-5 lists the information available from the data bank.

Table 2-5: Information held in the German Environmental Specimen Bank

Ecosystem Types	Specimen Types	Pollutants
Agrarian ecosystems Ecosystems close to conurbations Forestry ecosystems Marine ecosystems Nearly natural terrestrial ecosystems Riverine ecosystems	Limnetic samples Marine samples Terrestrial Samples Human Samples	Metals Non-metals Organometallic compounds Chlorohydrocarbons Polycylic Aromatic Hydrocarbons Phthalates Bisphenol-A Biocides Perfluorinated compounds Polycyclic musks Alkylphenol compounds Hexabromocyclodecane

Given the data available, the following potential indicators could be developed to assist in informing the benefits of chemical legislation:

- Changes in level of selected chemicals in aquatic organisms;
- Changes in level of selected chemicals in terrestrial organisms.

The International Council for the Exploration of the Sea (ICES) is a global organisation that develops science and advice to support the sustainable use of the oceans. The strategic partnership aims to understand the marine ecosystems in the Atlantic Ocean and in the Arctic, the Mediterranean Sea, the Black Sea, and the North Pacific Ocean. The ICES network includes over 350 marine institutes in 20 member countries. The ICES data portal[39] includes monitoring data over several years and for a large number of parameters (with a function allowing data to be searched and exported). The extensive datasets allow a range of potential environmental indicators to be developed. These include:

- Changes in biological communities;

[37] http://www.greenpeace.org/eu-unit/Global/eu-unit/reports-briefings/2009/3/man-made-chemicals-in-human-bl.pdf

[38] www.umweltprobenbank.de/en/documents/investigations/analytes

[39] ecosystemdata.ices.dk/inventory/index.aspx

- Changes in concentration levels of chemicals in marine organisms and sub-compartments; and
- Changes in biological effects.

Data are available for the Atlantic Ocean and in the Arctic, the Mediterranean Sea, the Black Sea, and the North Pacific Ocean. Relevant data sets include biological communities (1979 to 2013); contaminants and biological effects (1977 to 2014); and eggs and larvae (1862 to 2013). Matrices covered include water, sediment, organisms such as mussels and fish, and organs of the organism (sub targets), while the analytes are dioxins, chlorinated hydrocarbons, PAHs, pesticides and heavy metals. The parameter groups include biological effects such as endocrine effects and toxicity.

2.4.5 Human health statistics

There are different sources for European health statistics:

- The WHO Regional Office for Europe;
- The OECD Health Statistics;
- The Eurostat statistics on health.

The WHO Regional Office for Europe[40] lists several databases focusing on different subjects, from mortality to tobacco control to human and technical resources for health. The European Health for All database (HFA-DB) is the most relevant for the purpose of this study and integrates three other databases, namely: the mortality indicator database - mortality indicators by 67 causes of death, age and sex (HFA-MDB); the European detailed mortality database (DMDB); the European hospital morbidity database (HMDB).

The HFA-DB provides statistics and indicators for the 53 countries in the WHO Europe region from 1970 to 2015 on:

- Demographic and socio-economic conditions;
- Mortality;
- Morbidity, disability and hospital discharges;
- Life styles;
- Environment;
- Health care resources;
- Health care utilisation and expenditure;
- Maternal and child health.

The information is available for all the 28 Member States and covers a wide time range, allowing for the monitoring of the changes in mortality and morbidity of diseases that may be linked to chemicals' exposure. However, the database does not provide information on what part of the mortality and morbidity rate can be linked to such exposure.

The OECD Health database[41] provides statistics on the health status of the population and data on the health systems of the OECD members. For the health status, the information is organised by:

- Mortality;

[40] http://www.euro.who.int/en/data-and-evidence/databases
[41] http://www.oecd.org/els/health-systems/health-data.htm

- Life expectancy;
- Causes of mortality;
- Maternal and infant mortality;
- Potential years of life lost;
- Morbidity;
- Perceived health status;
- Infant health;
- Dental health;
- Communicable diseases;
- Cancer;
- Injuries;
- Absence from work due to illness.

The database provides high level data for some of the EU Member States and covers the years 2000-2014. The information is very detailed but, as for the WHO database, does not provide any information that could be used to estimate the attributable fraction of morbidity and mortality to chemicals' exposure.

Another source of health statistics comparable among European countries is Eurostat. The Eurostat database[42] provides statistics on:

- Health status;
- Health determinants;
- Health care;
- Disability;
- Causes of death;
- Health and safety at work.

As for the WHO and the OECD databases, Eurostat provides high level data on all the 28 Member States. The information is available for shorter time ranges (depending on the level of disaggregation) and some of it on a snapshot basis (for example, data on work-related health problems are available for 1999 only).

There are currently several initiatives to develop a harmonised EU health information system, among them:

- The European Health Examination Survey[43], an initiative aiming at collecting evidence about health and health risks of the population to fulfil the demand of the European Commission and the Member States for high quality information for the better planning and evaluation of health policies; and
- The BRIDGE Health project[44] aiming at preparing "*the transition towards a sustainable and integrated EU health information system for both public health and research purposes*" and that will look at, among other things, promoting the use of environmental health

[42] http://ec.europa.eu/eurostat/data/database
[43] http://www.ehes.info/index.htm
[44] http://www.bridge-health.eu/

surveillance to improve the information on environmental chemical determinants of ill-health.

At national level, the United Kingdom and Germany collect occupational health and safety statistics that allow for the estimate of the chemicals' attributable fraction.

The UK Health and Safety Statistics[45] provide a detailed picture of the occupational injuries and diseases from current working conditions in the United Kingdom and estimates of the costs of these in terms of productivity loss, medical treatment costs and non-financial human costs (pain, grief and suffering). The Health and Safety Executive (HSE) maintains the database that is fed by five main sources:

- RIDDOR – Reporting of Injuries, Diseases and Dangerous Occurrences Regulations - fatal and defined non-fatal injuries to workers and member of the public are reported by employers;
- LFS – Labour Force Survey (also known as "Self-reported Work-related Illness - (SWI)") – Work-related ill health and workplace injuries self-reported by workers;
- THOR – Voluntary reporting of occupational diseases by specialist doctors;
- THOR-GP – Voluntary reporting of occupational diseases by General Practitioners; and
- IIDB – Industrial Injuries Disablement Benefit Scheme.

The information from the THOR and THOR GP allows for the estimate of the attributable fraction to chemicals' exposure, as specialist doctors and general practitioners report cases by causative factor. These two databases tend to underestimate the occurrence of occupational diseases, as they do not capture all those cases not resulting in sick leaves. Moreover, not all the workers report ill health. Therefore, incidence and prevalence are based on the results of the Labour Force Survey. These are presented as incidence and prevalence rate (number of cases per 100,000 workers). The IIDB database tends to substantially underestimate the occurrence of occupational diseases, as only the most severe access the compensation scheme. However, it is a useful source for checking whether the trends detected by the other databases are reconfirmed by its data.

For over 100 years Germany has had a system of statutory accident insurance under which, rather than having to claim compensation for an occupational accident or disease directly an employer, a claim is made to statutory occupational accident insurance institutions who investigate claims, make judgements and award compensation and pensions from the insurance funds as appropriate. An outcome of this system is a detailed and consistent set of statistics stretching over a large timescale. The system is operated by DGUV (Deutsche Gesetzliche Unfallversicherung)[46] and the statistics cover a number of occupational diseases including:

- Diseases caused by chemical agents
- Diseases of the respiratory tract, lungs, pleura and peritoneum; and
- Skin diseases.

For each occupational disease annual statistics are reported in terms of:

- Listings on suspicion of an occupational disease;
- Recognised occupational diseases (i.e. those identified and verified from the list of suspected);

[45] http://www.hse.gov.uk/statistics/
[46] http://www.dguv.de/en/index.jsp

- New occupational disease pensions (i.e. those of sufficient severity to require pension); and
- Deaths due to occupational disease.

2.4.6 Comparison of the databases

The following table summarises the sources discussed and links these to indicators which could be developed to measure the benefits of the chemicals legislation.

Table 2-6: Summary Table of Different Sources and Databases						
Report/Data Source	**Category/ Categories**	**Country/ Region**	**No of Substances/ Pollutants**	**Potential Indicators**	**Data from**	**Frequency of Update**
Consortium to Perform Human Monitoring on a European Scale (COPHES)	Bio-monitoring	17 European countries	4 (mercury; cadmium; bisphenol A; metabolites of phthalates)	- Changes in levels of mercury in human hair - Changes in levels of cadmium, bisphenol A and metabolites of phthalates in urine	2010	One off study; likely to be repeated
Eurostat	Production Volumes	EU-27/ EU-28	Substances aggregated and categorised into 5 classes related to toxicity/harmful effects	- Production of chemicals	2004	Annual
European Health Examination Survey (EHES)	Bio-monitoring	12 European countries		- Changes in health outcomes related to effects of exposure to chemicals	2010	One off study; likely to be repeated
E-PRTR	Emissions	EU-27 (Croatia not included) Iceland Liechtenstein Norway Serbia Switzerland	91 pollutants listed under 7 groups	- Change in pollutant emissions over time by industrial activity/ economic sector - Change in pollutant emissions over time by country/region - Change in pollutant emissions over time by environmental medium (i.e. air, water and soil) - Change in pollutant emissions over time at the facility level (where reporting occurs over multiple years)	2007	Annual
FOREGS/ EuroGeoSurveys	Concentrations in Environment	26 European countries	70+ substances	- Baseline against which to compare concentrations of substances in environment	1998	Not updated
International Council for the Exploration of the Sea (ICES)	Concentrations in Environment	Atlantic Ocean Arctic Ocean Mediterranean Sea Black Sea North Pacific Ocean	700+ contaminants	- Changes in biological communities - Changes in concentration levels of chemicals in marine organisms and sub-compartments - Changes in biological effects	1978	Annual
Danish Natural	Concentrations in	Denmark	N/A	- Changes in concentration levels of chemicals	N/A	N/A

Table 2-6: Summary Table of Different Sources and Databases						
Report/Data Source	**Category/ Categories**	**Country/ Region**	**No of Substances/ Pollutants**	**Potential Indicators**	**Data from**	**Frequency of Update**
Environmental Portal	Environment			in surface water, groundwater and in the terrestrial environment		
German Environmental Specimen Bank (ESB)	Concentrations in Environment Bio-monitoring	Germany	70+ substances	- Changes in level of selected chemicals in humans - Changes in level of selected chemicals in aquatic organisms - Changes in level of selected chemicals in terrestrial organisms	1981	Annual
German Environmental Survey (GerES)	Concentrations in Environment Bio-monitoring	Germany	70+	- Changes in internal human exposure to metals and xenobiotics - Changes in concentrations of xenobiotics in indoor air and dust - Environmental impacts on the population as a whole	1985	Study is conducted every few years, covering a three-year period
Norwegian Climate and Pollution Agency	Emissions Concentrations in Environment	Norway	20 pollutants	-Change in emissions -Changes in levels of selected chemicals in water and sediment samples -Changes in levels of selected chemicals in aquatic species -Number of sites with severe contaminated sites	1994	Annual
Swedish Chemicals Agency (KemI)	Production Volumes	Sweden	900+	- Nature of chemicals - Use of chemicals	1996 2001 2007	N/A

2.5 Summary of Identified Indicators

Table 2-7presents the list of indicators that have been identified from the review of past studies (see also the more in-depth discussion of the various sources in Annexes 1 and 2), and links them to database and information sources, when possible, distinguishing between output, result and impact indicators.

Table 2-7: Indicators identified by previous studies		
Indicator	**Suggested in**	**Data from**
Output indicators		
Number of substances restricted on their own, in mixtures or in articles per hazard class	DHI (2005); Eurostat (2009); RPA et al (2012)	ECHA list of Restrictions (Annex XVII of REACH) http://echa.europa.eu/addressing-chemicals-of-concern/restrictions/list-of-restrictions
Number of substances registered	Eurostat (2009)	ECHA registered substances database http://echa.europa.eu/information-on-chemicals/registered-substances
Number of substances evaluated	Eurostat (2009)	ECHA CoRAP list http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table
Number of substances authorised	Eurostat (2009)	ECHA Authorisation list (Annex XIV of REACH) http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list
Number of active substances for biocidal products evaluated	EC (2009)	ECHA Biocidal Active Substances list http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances
Speed of biocidal product authorisation	EC (2009)	-
Number of biocidal products on the market	EC (2009)	ECHA Biocidal Active Substances list http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances
Number of low risk biocidal products	EC (2009)	ECHA Biocidal Active Substances list http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances
Number of data sharing failures	EC (2009)	-
Number of newly identified PBTs or vPvBs	RPA et al (2012)	ECHA registered substances database http://echa.europa.eu/information-on-chemicals/registered-substances
Number of substances reclassified (Improvement of knowledge on properties and safe uses of chemicals)	Eurostat (2009); RPA (2009); RPA et al (2012); Oltmanns et al (2014): The impact of REACH on classification for human health hazards	ECHA Classification and Labelling Inventory http://echa.europa.eu/information-on-chemicals/cl-inventory-database Oltmanns et al (2014)
Changes in DNELs and PNECs	RPA et al (2012)	ECHA registered substances database http://echa.europa.eu/information-on-chemicals/registered-substances
Number of substances with harmonised classification (Improvement of knowledge on properties and safe uses	Eurostat (2009)	ECHA Classification and Labelling Inventory http://echa.europa.eu/information-on-chemicals/cl-inventory-database

Table 2-7: Indicators identified by previous studies		
Indicator	**Suggested in**	**Data from**
of chemicals)		
Changes in quality of safety data sheets	Eurostat (2009); RPA (2009)	CSES & RPA (2015)
Availability of hazard data	Eurostat (2009)	ECHA registered substances database http://echa.europa.eu/information-on-chemicals/registered-substances
Availability of use and exposure data	Eurostat (2009)	ECHA registered substances database http://echa.europa.eu/information-on-chemicals/registered-substances
Number of substances withdrawn from the market because of concerns about human health, restrictions or other reasons under REACH or CLP	RPA (2009); RPA et al (2012)	ECHA Authorisation list (Annex XIV of REACH) http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list ECHA list of Restrictions (Annex XVII of REACH) http://echa.europa.eu/addressing-chemicals-of-concern/restrictions/list-of-restrictions
Result indicators		
Percentage of enterprises complying with OSH regulations	WORKHEALTH (2004)	
Changes in concentration of SVHCs in consumer products	RPA et al (2011)	KemI's Commodity Guide http://www.kemi.se/en/Content/Statistics/The-Commodity-Guide/ Danish EPA database on chemicals in consumer products http://eng.mst.dk/topics/chemicals/consumers--consumer-products/database-of-chemicals-in-consumer-products/
Expenditures on occupational health and safety measures	WORKHEALTH (2004); RPA (2009); RPA et al (2012)	Somme data obtainable from the Eurostat prodcom database (ex.: expenditure on protective gloves) http://ec.europa.eu/eurostat/web/prodcom/data/database
Number of companies that had to change their RMM as result of REACH	EC (2003); RPA (2003); DHI (2005); Eurostat (2009); RPA (2009); RPA et al (2012)	CSES & RPA (2015)
Increased transparency and consumer awareness	Eurostat (2009)	Eurobarometer? http://ec.europa.eu/public_opinion/index_en.htm
Promotion of alternative methods for assessment of hazard of chemicals	Eurostat (2009)	-
Introduction of alternative substances to replace chemicals of concern under REACH	EC (2009)	Substitution portal http://www.subsport.eu/
Toxic chemicals in households	Eurostat (2009); RPA (2009)	KemI's Commodity guide http://www.kemi.se/en/Content/Statistics/The-Commodity-Guide/ Danish EPA database on chemicals in consumer products http://eng.mst.dk/topics/chemicals/consumers-

Table 2-7: Indicators identified by previous studies		
Indicator	**Suggested in**	**Data from**
		-consumer-products/database-of-chemicals-in-consumer-products/
Production of toxic chemicals and Production of environmentally harmful chemicals	Eurostat (2009); RPA (2009)	Eurostat database http://ec.europa.eu/eurostat/data/database
Cross-border transport of toxic chemicals	Eurostat (2009)	Eurostat trade statistics database http://ec.europa.eu/eurostat/data/database
Changes in use patterns in specific countries	Eurostat (2009)	KemI's product register https://www.kemi.se/en/Start/The-Products-Register/ KemI's Commodity guide http://www.kemi.se/en/Content/Statistics/The-Commodity-Guide/ Danish EPA database on chemicals in consumer products http://eng.mst.dk/topics/chemicals/consumers--consumer-products/database-of-chemicals-in-consumer-products/
Change in number of SVHCs in articles on the market	RPA (2009)	KemI's product register https://www.kemi.se/en/Start/The-Products-Register/ KemI's Commodity guide http://www.kemi.se/en/Content/Statistics/The-Commodity-Guide/ Danish EPA database on chemicals in consumer products http://eng.mst.dk/topics/chemicals/consumers--consumer-products/database-of-chemicals-in-consumer-products/
Change in emissions of specific chemicals	Prüss-Ustün et al (2011); RPA et al (2011)	E-PRTR http://prtr.ec.europa.eu/PollutantReleases.aspx The Norwegian Climate and Pollution Agency http://www.environment.no/ Danish database on Air Quality http://envs.au.dk/en/knowledge/air/monitoring/
Impact indicators		
Human (Breast milk, hair, blood, urine) samples for specific chemicals	WHO (2000); Rice et al (2003); UNEP (2013b)	COPHES http://www.eu-hbm.info/cophes Environment Specimen Bank (Germany) http://www.umweltprobenbank.de/en German Environmental Survey, GerES http://www.umweltbundesamt.de/en/topics/health/assessing-environmentally-related-health-risks/german-environmental-survey-geres TNO-report R 2004/493
Phenetic diversity	Nunes et al (2001); University of Lancaster (2006); RPA (2009)	The International Council for the Exploration of the Sea http://www.ices.dk/Pages/default.aspx
α, β and γ diversity	Nunes et al (2001); University of Lancaster (2006); RPA (2009)	The International Council for the Exploration of the Sea http://www.ices.dk/Pages/default.aspx

Table 2-7: Indicators identified by previous studies		
Indicator	**Suggested in**	**Data from**
Change in the number of (occupational) skin diseases due to chemicals' exposure	RPA (2003); COWI (2004); WORKHEALTH (2004); Pickvance et al (2005); Eurostat (2009); RPA (2009);	The UK Health and Safety http://www.hse.gov.uk/skin/statistics.htm
Change in the number of (occupational) respiratory diseases due to chemicals' exposure	RPA (2003); COWI (2004); WORKHEALTH (2004); Pickvance et al (2005); RPA (2009); Prüss-Ustün et al (2011)	The UK Health and Safety http://www.hse.gov.uk/statistics/causdis/respiratory-diseases.htm
Change in the number of (occupational) eyes disorders due to chemicals' exposure	RPA (2003); WORKHEALTH (2004); Pickvance et al (2005); RPA (2009)	
Change in the number of (occupational) central nervous system disorders due to chemicals' exposure	RPA (2003); COWI (2004); WORKHEALTH (2004); Pickvance et al (2005); RPA (2009)	
Change in the number of (occupational) cancers (various end-points) due to chemicals' exposure	RPA (2003); COWI (2004); WORKHEALTH (2004); WHO (2004); Pickvance et al (2005); RPA (2009); Prüss-Ustün et al (2011); Rushton et al (2012); HEAL (2014)	The UK Health and Safety http://www.hse.gov.uk/statistics/causdis/cancer/index.htm
Cost savings in remediation of specific chemicals	Ostertag et al (2004); Norden (2004); Okopol (2007); RPA (2009)	
Cost savings in chemicals monitoring programmes	Ostertag et al (2004); Norden (2004); RPA (2009)	
Sickness absence related to illness due to chemicals' exposure	WORKHEALTH (2004); EU OSHA (2010)	
Disability (defined as percentage of workers with chronic health problems due to chemicals' exposure)	WORKHEALTH (2004); EU OSHA (2010)	
Change in morbidity or diseases occurrence (prevalence and/or incidence)	WORKHEALTH (2004); RIVM (2008); EU OSHA (2010); Prüss-Ustün et al (2011)	http://www.who.int/healthinfo/global_burden_disease/en/
Cost savings in health assistance	University of Lancaster (2006)	
Loss of QALYs	Pickvance et al (2005)	
Number of DALYs	EC (2003); WWF (2003); Pearce and Koundouri (2004); Prüss-Ustün et al (2011)	
Change in the number of chemical incidents involving exposure of workers	RPA (2009)	Eurostat database – Causes of death http://ec.europa.eu/eurostat/web/health/causes-death/data/database
Number of poisoning incidents	EC (2009); Prüss-Ustün et al (2011); UNEP (2013); UNEP (2013b)	Eurostat Health and Safety at Work http://ec.europa.eu/eurostat/web/health/health-safety-work/data/database
Change in the number of the	RPA (2009); EU OSHA	

Table 2-7: Indicators identified by previous studies		
Indicator	**Suggested in**	**Data from**
workers affected by chemical incidents	(2010)	
Change in rates of serious worker injury or death attributable to chemicals	RPA (2009)	
Change in numbers claiming compensation because of industrial injuries attributable to chemicals	RPA (2009); EU OSHA (2010)	
Change in the numbers of the public affected by chemical incidents	RPA (2009)	
Change in the level of congenital abnormalities in the public that can't be attributed to causes other than chemicals	RPA (2009)	
Change in the number of chemical incidents involving exposure of the public	RPA (2009)	
Change in levels of selected chemicals in ambient air samples	RPA (2009)	The Norwegian Climate and Pollution Agency http://www.environment.no/ German Environmental Survey, GerES http://www.umweltbundesamt.de/en/topics/health/assessing-environmentally-related-health-risks/german-environmental-survey-geres
Change in levels of selected chemicals in water and sediment samples	RPA (2009)	The Norwegian Climate and Pollution Agency http://www.environment.no/ The Danish Natural Environment Portal http://www.miljoeportal.dk/English/Sider/default.aspx German Environmental Survey, GerES http://www.umweltbundesamt.de/en/topics/health/assessing-environmentally-related-health-risks/german-environmental-survey-geres The UK Environment Agency – River basin Management plans - rivers http://maps.environment-agency.gov.uk/wiyby/wiybyController?x=357683&y=355134&scale=1&layerGroups=default&ep=map&textonly=off&lang=_e&topic=wfd_rivers
Change in levels of selected chemicals in soil samples	RPA (2009)	The Norwegian Climate and Pollution Agency http://www.environment.no/
Change in levels of selected chemicals in waste sludge samples	RPA (2009)	
Change in levels of selected chemicals in tissue samples of terrestrial species	RPA (2009)	Environment Specimen Bank (Germany) http://www.umweltprobenbank.de/en
Change in levels of selected chemicals in tissue samples of aquatic species	RPA (2009)	Environment Specimen Bank (Germany) http://www.umweltprobenbank.de/en
Change in soil biodiversity	RPA (2009)	
Change in the number of	Legler et al (2014); HEAL	

Table 2-7: Indicators identified by previous studies		
Indicator	**Suggested in**	**Data from**
cases of childhood/adulthood obesity due to exposure to EDCs	(2014)	
Change in the number of cases of diabetes due to exposure to EDCs	Legler et al (2014); HEAL (2014)	
Direct/indirect costs of childhood/adulthood obesity due to exposure to EDCs	Legler et al (2014); HEAL (2014)	
Male reproductive disorders due to exposure to EDCs	Hauser et al (2014); HEAL (2014)	
Neurobehavioral deficits and diseases due to exposure to EDCs	Bellanger et al (2014); HEAL (2014)	
Social costs of intellectual disability due to exposure to EDCs	Bellanger et al (2014)	
Treatment cost savings on infertility cases due to exposure to EDCs	Hauser et al (2014); HEAL (2014)	

2.6 Brainstorming Workshop

The brainstorming workshop was a half day event held in Brussels in April 2015, aimed at gaining the Commission services' views on what the most important criteria are for the selection of indicators and, following on from this, what these imply in terms of the types of indicators that should be prioritised over others. Background materials were sent out to attendees of the workshop which provided a summary of the aims of the workshop, the criteria to be used in assessing the indicators (presented in Table 2-2) and the preliminary assessment of a selection of indicators identified from the literature review. The list of indicators discussed and a more detailed description of the brainstorming workshop are provided in Annex 3.

Discussions at the workshop confirmed the importance of ensuring that there is an understanding of how the indicators are related to the different provisions within chemicals legislation and that the benefits likely arise from:

- Increase in information on the hazardousness of chemical substances;
- Substitution of chemicals and/or process in order to limit risks to man/environment;
- Improved risk management, which leads to reduced exposures or emissions; or
- Other controls which lead to decreases in exposures of human populations and/or the environment to hazardous chemicals.

This will involve linking the main provisions within the different legislative acts to the modes of action through which these requirements lead to human health and environmental benefits. The identification of the modes of action is important for the assessment of the benefits (Task 3), as it should help in attributing changes in the burden of disease and/or environmental damage to chemicals legislation.

The other main conclusions of the workshop were as follows.

1) The study team needs to discuss with ECHA what data may be available for use as output indicators, e.g. what the value of additional information in the supply chain really is for the downstream users, in terms of improved risk management and possible reduced costs as a result of better chemicals management.

2) Based on the views expressed by the four groups, specificity, measurability and relevance (with an average weight of 17.5) would appear to be the three most important criteria for the selection of the indicators, followed by achievability and ease of gathering the necessary data (with an average weight of 15) and the time dimension of the data (criterion closely linked to the data availability). Acceptability, credibility and robustness characteristics of the indicators were considered to be dependent on the performance of the indicators against the other criteria.

3) Indicatively, 300 was used as cut-off value in terms of the resulting total weighted scores for the selection of the indicators that have been considered by the Commission services during the brainstorming workshop as the most useful for the purpose of the study. However, it is important to note that the weighting and scoring exercise was used by the project team as a means for triggering the discussion over the indicators rather as a tool for their selection and prioritisation. Although some of the indicators as defined and presented during the workshop did not score highly, the groups discussed how to improve them, better define their specificity or suggest the necessary data that, if available or achievable, would make them very relevant for the scope of the study.

4) The project should include a broader range of indicators, which are relevant not only for REACH and CLP but for other chemicals legislative acts as well.

5) It will be difficult for the study team to ascribe some changes in impact solely to REACH and CLP or even to chemicals legislation, due to the level of confounding. In this respect, the team has to be careful to ensure that confounding, due for example to changes in the macroeconomic situation, is acknowledged in the development of any of the indicators.

6) The study team should also consider the definition of indicators that would operate at a case study level, focusing on selected substances and on the benefits of their regulation.

7) Members of the steering group commented that the contractor should be very cautious with the selection of indicators, for which the causal link is not clear. If the study does not try and make linkages between exposures/emissions and effects, then it is not possible to provide quantitative estimates of impacts, and to then value these in monetary (or other terms). Such an approach is in contrast with part of the aims of this study, which is to provide quantitative monetary estimates of the benefits of chemicals legislation. It therefore suggests that it may be important for this study to recommend exposure/emission indicators regardless of whether they can or cannot be valued in monetary terms; the project team could then define sub-indicators referring to specific chemicals for which there is enough evidence to support linkages between exposures/emissions and effects.

3 Key Indicators

3.1 Introduction

The review of the relevant literature highlighted that none of the previous studies have tried to develop a system of indicators able to monitor the legislative activities and their final results in terms of human health and environmental impacts, to be fed with real data. Therefore, in selecting the indicators to be taken forward, additional consideration was given to the availability of data necessary for the quantification of the indicators in both physical and monetary terms. In some cases, this included, for example, whether attributable fractions were available to link chemical emissions or exposures to the number of cases of an occupational disease. In other cases, it was the degree to which one could link trend data to the timing of legislative action.

The process of developing, linking and testing each of the indicators to establish measurable links between the legislative provisions and the benefits is complex but essentially draws on combining two basic approaches. These are:

- **Top down approach:** working from specific legislative provisions, identifying suitable indicator datasets that measure the effect of the legislation and identifying information (from other indicators or values) that provides a means of calculating what the impact has been (or can be expected to be in future) in terms of human health and environmental damages avoided; and

- **Bottom up approach:** working from monitoring and other indicator datasets that measure chemical related impacts (such as rates of diseases, emissions, concentrations in the environment, etc.) and identifying information (from other indicators or values) that provides a means of calculating the extent to which any observed changes in chemicals or their effects can be attributed to legislative provisions.

The inter-linkages between these are illustrated in the simplified diagram below showing how, using the indicators and datasets as a starting point, the project team worked towards identifying the indicators that provide a measurable and quantifiable link between the legislative provisions and resulting benefits (preferably measured in monetary terms).

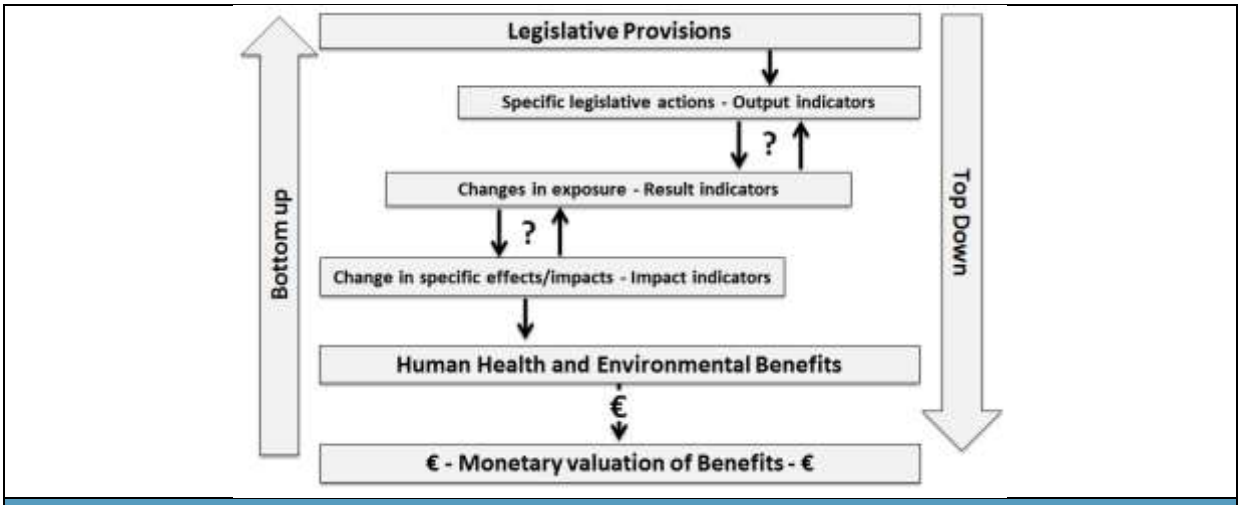


Figure 3-1: Top-down and bottom-up approaches

The diagram also highlights why it may be the case that these links cannot be made, e.g. it is not possible to clearly link a dataset to specific legal provisions, or there are no datasets to support the calculation of benefits against a legal provision.

3.2 Top down Approach: Linking Legislation to Changes in Exposure and Effects

Although REACH and CLP are the recognised cornerstones of the chemicals *acquis*, their effects and, therefore, their benefits are often realised through synergies with other legislative acts, such as:

- On the human health side, the Occupational Health and Safety legislation (e.g. the Chemical Agents Directive, the Carcinogens and Mutagens Directive) and the different acts dedicated to controlling and minimising risks to consumers exposed to chemical substances (e.g. the Cosmetic Products Regulation, the Restriction of Hazardous Substances in electrical and electronic equipment (RoHS), the Plant Protection Products and the Biocidal Products Regulations);

- On the environmental side, pollutant emissions control legislation such as the Industrial Emissions and the Water Framework Directives.

In addition, international treaties have been ratified by the European Union in order to strengthen the protection of human health and the environment from dangerous substances. These are:

- The Stockholm Convention on Persistent Organic Pollutants;
- The Basel Convention on the control of trans-boundary movements of hazardous wastes and their disposal;
- The Rotterdam Convention on the international trade in hazardous chemicals;
- The Minamata Convention on mercury;
- The Montreal Protocol on Substances that Deplete the Ozone Layer.

To measure any change in the exposure to chemicals and, ultimately, in the impacts on human health and the environment caused by the chemicals legislation, the legal requirements of REACH and CLP and the pathways through which these may generate human health and environmental benefits need to be established. An overview of the requirements of these two Regulations that act as pathways to generating benefits is provided below. Moreover, an overview on other legislative acts that have an important effect on decreasing the human and environmental exposure to chemicals is also provided. The European environmental legislation that contributes in decreasing chemicals' exposure is formed by over 150 European legislative acts[47]. The overview does not aim to be exhaustive but rather to acknowledge the contribution of other important pieces of legislation in reducing the chemicals' exposure (result indicators) and human health and environmental impacts (impact indicators), contribution which cannot be singled out.

[47] Milieu (2012): Technical assistance related to the scope of REACH and other relevant EU legislation to assess overlaps, report prepared for DG Environment. Available at: http://ec.europa.eu/environment/chemicals/reach/pdf/studies_review2012/report_study8.pdf

3.2.1 The REACH Regulation

The Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) entered into force on 1 June 2007, with one of its overarching objectives being "*to ensure a high level of protection of human health and environment*".

Under REACH, this is to be achieved by filling the knowledge gap on the intrinsic properties of chemical substances and placing obligations on industry to:

- Register all substances manufactured or imported in the EU in quantities greater than one tonne per year per company, either on their own, in mixtures or in articles; and
- Exchange information throughout the supply chain.

On the basis of the information supplied by industry, public authorities can:

- Identify the Substances of Very High Concern (SVHCs), the use of which should be phased out or continued only if a time limited authorisation is granted; and
- Restrict the marketing and use of substances considered to pose unacceptable risks at the EU-wide level.

One of the reasons for the adoption of REACH was the fact that information on the inherent properties needed to manage chemicals safely was not available for a significant percentage of the substances that have historically been placed on the European market. As the production, use and disposal of chemicals and products containing hazardous chemicals has been linked to a wide range of environmental and health impacts, this lack of data was a key concern. At the time, impact assessments were able to draw on some examples of the adverse consequences of a limited number of recognised hazardous substances but, due to the lack of data, a comprehensive quantitative assessment of the overall impact of chemicals on the environment and human health was (and is still) not possible.

The REACH Regulation reversed the burden of proof from regulators to industry, making them responsible for the safety of their chemicals, requiring them to identify risks, establish and document conditions of safe use and to ensure that users are able to take appropriate measures throughout the life-cycle of substances. Through its Registration obligations, the Regulation should generate information on substance properties, allowing the identification, improvement, and implementation of risk management measures. Similarly, obligations associated with supply chain communication requirements should help improve information on the uses of chemicals and on available risk management measures.

In addition to the registration requirements, in the event of a substance identified as meeting the criteria for classification as carcinogenic, mutagenic or toxic to reproduction 1A or 1B, as persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) or for which the scientific evidence of probable serious effects on human health or the environment give rise to an equivalent level of concern, the substance is likely to be subject to other provisions of the Regulation, such as Evaluation, Authorisation and Restriction. These provisions are aimed at assuring that risks from substances with properties of very high concern are properly controlled.

When a substance is identified as meeting the classification criteria listed in Article 57 of the REACH Regulation and therefore is considered to be of very high concern (SVHC), this classification triggers actions on the part of manufacturers, importers and downstream users to comply with other pieces

of community legislation covering areas such as workers' health and safety, products' safety, waste and emissions' control.

A series of figures setting out the pathways through which REACH delivers benefits were developed as part of a 2012 study aimed at identifying the benefits of REACH arising from its first five years of implementation (RPA et al, 2012). These are set out in Annex 4.

3.2.2 The CLP Regulation

The CLP Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures came into force on 20 January 2009 in all EU Member States. The CLP Regulation repeals Directives 67/548/EEC (DSD) and 1999/45/EC (DPD) on the classification, packaging and labelling of dangerous substances and preparations, and adopts the United Nations' Globally Harmonised System on the classification and labelling of chemicals (GHS).

The stated purpose of the CLP Regulation, as laid down in Article 1:

> *"The purpose of this Regulation is to ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures and articles…."*

This is to be achieved through a series of different activities, all of which are relevant to understanding how human health and environmental benefits may be linked to this Regulation. These activities include:

a) Harmonising the criteria for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures;

b) Providing an obligation for: (i) manufacturers, importers and downstream users to classify substances and mixtures placed on the market; (ii) suppliers to label and package substances and mixtures placed on the market; (iii) manufacturers, producers of articles and importers to classify those substances not placed on the market that are subject to registration or notification under Regulation (EC) No 1907/2006;

c) Providing an obligation for manufacturers and importers of substances to notify the Agency of such classifications and label elements, if these have not been submitted to the Agency as part of a registration under Regulation (EC) No 1907/2006;

d) Establishing a list of substances with their harmonised classifications and labelling elements at Community level in Part 3 of Annex VI; and

e) Establishing a classification and labelling inventory of substances, which is made up of all notifications, submissions and harmonised classifications and labelling elements referred to in points (c) and (d).

The adoption of the CLP in itself was not considered likely to lead to significant human health or environmental benefits, given the already existing framework provided by the DSD and DPD. Some benefits were expected, but not quantified, in relation to the potential for more strict classification of a sub-set of chemicals but also due to clear and more consistent communication of chemical hazards. It is important to recognise though that the CLP itself does not require the risk management of chemical exposures (other than through some packaging requirements).

In addition, in terms of assessing the benefits of chemicals legislation, it is important to recognise that CLP classifications (and DSD and DPD before this) are based on available data, which in many instances would have been limited pre-REACH. Article 5 (1) of the CLP Regulation provides a list of other data sources and, for some substances, this may include pre-existing data, and/or data generated under independent studies, or under other EU legislation (e.g. Biocides, Plant Protection Products, Cosmetics, Food Contact Materials legislation). However, for certain chemical substances manufactured or imported into the EU, REACH may represent the main tool for generating data. With the exception of data on physicochemical properties, there is no requirement under CLP for the generation of additional information solely for the purposes of classification. However, companies may choose to generate new data while fully respecting Articles 7 and 8 of CLP.

3.2.3 Other Legislation

International agreements

Stockholm Convention on Persistent Organic Pollutants

The Stockholm Convention on Persistent Organic Pollutants is a global treaty aiming at reducing and eliminating the release of certain persistent and toxic chemicals which pose a serious threat to human health and the environment and which cannot be regulated at national level due to their long range transport.

The Convention was adopted in 2001 and entered into force in 2004 and requires its parties to eliminate the production, use and trade, with specific exemptions, of the intentionally produced POPs listed in Annex A, to restrict the production, use and trade of the intentionally produced POPs in Annex B and to take measures (such as the adoption of best available techniques and best environmental practices) to reduce the unintentional releases of chemicals listed in Annex C. **Error! Reference source not found.** lists the chemicals currently regulated by the Convention, according to the Annex in which they are listed and their nature.

Table 3-1: Persistent Organic Pollutants regulated by the Stockholm Convention

	Pesticide	Industrial chemical	Unintentional production
Annex A (Elimination)	Aldrin; Chlordane; Chlordecone; Dieldrin; Endrin; Heptachlor; Hexachlorobenzene (HCB)*; Alpha hexachlorocyclohexane; Beta hexachlorocyclohexane; Lindane; Mirex; Pentachlorobenzene*; Technical endosulfan and its related isomers;	Hexabromobiphenyl; Hexabromocyclododecane (HBCD); Hexabromodiphenyl ether and heptabromodiphenyl ether; Polychlorinated biphenyls (PCB); Tetrabromodiphenyl ether and pentabromodiphenyl ether.	
Annex B (Restriction)	DDT	Perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride	
Annex C (Unintentional production)			Hexachlorobenzene (HCB); Pentachlorobenzene; Polychlorinated biphenyls (PCB); Polychlorinated dibenzo-p-dioxins (PCDD); Polychlorinated

			dibenzofurans (PCDF)
*Notes:*Both pesticide and industrial chemical*			

The Basel Convention on the control of trans-boundary movements of hazardous wastes and their disposal

The Basel Convention, adopted in 1989, focuses on the reduction of hazardous waste generation and the promotion of environmentally sound management of hazardous waste. Moreover, it imposes restrictions on the transboundary movements of hazardous waste and subordinates any exceptions to the principle of being no less environmentally sound than the Basel Convention itself. The transboundary movements of hazardous waste are heavily regulated and the Convention establishes the concept of "prior informed consent", requiring that any export of hazardous waste by a State is agreed in writing by the authorities of the State receiving the waste, after reception of detailed information on the intended movement.

The Rotterdam Convention on the international trade in hazardous chemicals

The Rotterdam Convention focuses instead on the international trade of hazardous chemicals and promoted the sharing of information and responsibilities for the environmentally sound management of pesticides and industrial chemicals that have been banned or severely restricted. It was adopted in 1998, entered into force in 2004 and made legally binding the Prior Informed Consent procedure used voluntarily prior to the Convention. Table 3-2 lists the 46 chemicals covered by the Convention.

Table 3-2: Chemicals covered by the Rotterdam Convention

Pesticide	Industrial chemical
2,4,5-T and its salts and esters; Alachlor; Aldicarb; Aldrin; Azinphos-methyl; Binapacryl; Captafol; Chlordane; Chlordimeform; Chlorobenzilate; DDT; dieldrin; Dinitro-ortho-cresol (DNOC) and its salts (such as ammonium salt, potassium salt and sodium salt); Dinoseb and its salts and esters; EDB (1,2-dibromoethane); endosulfan; Ethylene dichloride; Ethylene oxide; Fluoroacetamide; HCH (mixed isomers); Heptachlor; Hexachlorobenzene; Lindane (gamma-HCH); Mercury compounds, including inorganic mercury compounds, alkyl mercury compounds and alkyloxyalkyl and aryl mercury compounds; Methamidophos; Monocrotophos; Parathion; Pentachlorophenol and its salts and esters; Toxaphene (Camphechlor); Tributyl tin compounds; Dustable powder formulations containing a combination of benomyl at or above 7%, carbofuran at or above 10% and thiram at or above 15%; Methyl-parathion (Emulsifiable concentrates (EC) at or above 19.5% active ingredient and dusts at or above 1.5% active ingredient); Phosphamidon (Soluble liquid formulations of the substance that exceed 1000 g active ingredient/l)	Actinolite asbestos; Anthophyllite; Amosite asbestos; Crocidolite; Tremolite; Commercial octabromodiphenyl ether (including Hexabromodiphenyl ether and Heptabromodiphenyl ether); Commercial pentabromodiphenyl ether (including tetrabromodiphenyl ether and pentabromodiphenyl ether); Perfluorooctane sulfonic acid, perfluorooctane sulfonates, perfluorooctane sulfonamides and perfluorooctane sulfonyls; Polybrominated Biphenyls (PBBs); Polychlorinated Biphenyls (PCBs); Polychlorinated Terphenyls (PCTs); Tetraethyl lead; Tetramethyl lead; Tris(2,3 dibromopropyl)phosphate

The Minamata Convention on mercury

The Minamata Convention was agreed upon in 2013 and focuses on the regulation of one single toxic chemical: mercury. This metal is ubiquitous, naturally occurring and with a broad range of applications. The Convention, through the ban on new mercury mines, the phase-out of existing ones, control measures on air emissions and the regulation of its use in the small-scale gold mining, tries to minimise the anthropogenic releases to air, soil and water.

The Montreal Protocol on Substances that Deplete the Ozone Layer

The Montreal Protocol aims to protect the fragile ozone layer surrounding the Earth by reducing the production and consumption of ozone depleting substances. It entered into force in 1989 and covers five groups of chemicals and four individual chemicals. These are:

- Chlorofluorocarbons (CFC);
- Halons;
- Other fully halogenated CFCs;
- Carbon tetrachloride;
- 1, 1, 1-trichloroethane (methyl chloroform);
- HCFCs;
- HBCFs;
- Bromochloromethane;
- Methyl bromide.

Occupational Health and Safety Legislation

With regard to occupational health and safety (OSH) legislation, key regulations and associated requirements include:

- Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (CAD) – which requires the determination of the presence of any hazardous chemical agents in the workplace and the assessment of any risk to the safety and health of workers;

- Carcinogens and Mutagens Directive 2004/37/EC (CMD) – which requires that, as a priority, workers' exposure must be prevented through substitution. If not possible, the employer shall use a closed technological system. Where a closed system is not technically possible, the employer shall reduce exposure to a minimum through a number of risk management measures specified in the Directive;

- Pregnant and Breastfeeding Workers Directive 92/85/EEC – which requires employers to assess the nature, degree and duration of exposure, assess any risks to the worker safety or health and any possible effects on the pregnancy or breastfeeding of workers and then decide what measures should be taken;

- Directive 94/33/EC on Young Workers – under which employers are obliged to assess the hazards to young people, generate new site-specific data on the nature, degree and duration of exposure to chemical agents and adopt the measures necessary to protect the safety and health of young people; and

- The Indicative Occupational Exposure Limit Values Directives 2000/39/EC, 2006/15/EC and 2009/161/EU – aiming to establish indicative occupational exposure limit values for some chemicals as part of the implementation of the CAD. These Directives require Member States to establish national exposure limit values for the chemicals listed in their respective Annexes. While Member States do not have to adopt the actual values as set by the Directives, they do have to take into account and make reference to these Community values when establishing their own. Moreover, Member States may establish different Occupational Exposure Limits for substances not listed by the IOELVDs.

The CAD, CMD, Pregnant Workers and Young Workers Directives all require the employer to undertake a risk assessment. The first step of the risk assessment involves the identification of hazards. Employers will draw on Safety Data Sheets (SDS) developed to comply with REACH and provided by suppliers for all substances independently of their production volumes, and taking into account classifications according to the CLP. Employers will then combine this hazard data with exposure data generated for specific workstations to assess the risk to individual workers. The SDS should enable the employer to assess the risks to the health and safety of workers. For substances that are placed on the market at below 10 tonnes per year, the SDS will include exposure characterisation and handling instructions, but not exposure scenarios or a risk assessment.

The aim of this legislation is to provide a high level of protection to workers from exposures to chemical hazards. However, pre-REACH, its effectiveness has been affected in practice by the limited amount of information that was available on the properties of most of the existing chemicals being used in the workplace.

Product Specific legislation

In addition to worker health and safety requirements, classification as C, M or R 1A/1B under CLP has implications in terms of safety of products. Annex XVII of REACH (entries 28 to 30) prohibits the placing on the market and the use of CMRs 1A/1B as substances or as constituents of other substances or mixtures for supply to the general public when the individual concentration in the substance or the mixture is equal to or greater to the generic/specific concentration limit of the CLP Regulation. However, currently consumer articles are not in the scope of the entries 28 to 30, but some specific legislation applies to some of these articles.

Directive 2001/95/EC on General Product Safety

The General Product Safety Directive (GPSD) is complementary to specific product safety legislation by sector. It applies in its entirety to consumer products falling outside the scope of sector Directives. In addition, it applies partially to consumer products covered by sector legislation (for example toys or cosmetics). In general specific sector provisions have priority over general provisions although the GPSD for certain aspects may be more detailed than the sector directives.

Under Article 3 of the GPSD producers are obliged to place only safe products on the market where:

- 'Product' means any product — including in the context of providing a service — which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them;

- 'Producer' means the manufacturer of the product, the manufacturer's representative, when the manufacturer is not established in the Community or the importer of the product or other professionals in the supply chain, insofar as their activities may affect the safety properties of a product; and

- 'Safe product' means any product which, under normal or reasonably foreseeable conditions of use does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons including the categories of consumers at risk when using the product, in particular children and the elderly.

In cases where products may pose a serious risk, the GPSD establishes that Member States are to assess and take appropriate action. Here, under certain conditions, the Commission may adopt a formal temporary Decision requiring the Member States to ban the marketing of a product, to recall it from consumers or to withdraw it from the market. A Decision of this kind is temporary but it may be renewed and result in permanent legislation. Emergency measures have been taken in the past for dimethylfumarate (DMF) and phthalates.

Biocides and Plant Protection Products

Regulation (EC) No 1107/2009 on the placing on the market of plant protection products (PPPR) lays down rules for the authorisation, placing on the market, use and control of such products within the EU. To be authorised, active substances need to fulfil certain criteria on efficacy, composition, characteristics, residues and (eco)toxicological properties. In principle, plant protection products that are:

- Classified as 1A or 1B mutagenic, carcinogenic or toxic for reproduction (CMR); or
- Considered to have endocrine disrupting properties; or
- Considered to be persistent organic pollutants or persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB);

shall not be approved. Some exceptions may be applied to active substances with the above properties only if the plant protection products are used in conditions excluding contact with humans and where residues on food and feed do not exceed the default value set.

Authorisation of active substances is the responsibility of Member States, as it is recognised that different agricultural, plant health and environmental conditions influence efficacy and characteristics of the products. An authorisation is valid for 10 years, although Member States may review it at any time if the active substance no longer complies with one of the criteria for which the authorisation was granted.

Regulation (EC) No 528/2012 concerning the making available on the market and use of biocidal products (BPR) lays down rules on the approval, placing on the market, use and control of such products and treated articles within the EU. As with the PPPR, the BPR restricts the approval of active substances that are classified as CMR 1A or 1B, considered to have endocrine-disrupting properties or are PBT/vPvB. Exceptions to this rule may apply only when the risk under realistic worst case scenarios is negligible (exclusion of contact with humans and release to the environment) or there is evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment or the approval of the active substance is essential to avoid a disproportionate negative impact on society when compared to the risk to human health, animal health or the environment. The decision on the approval of an active substance according to these exceptions should consider the availability of suitable substitutes and, if finally approved, the use of the biocidal products should be subject to appropriate risk mitigation measures.

Cosmetic Products and Food Contact Materials Regulations

Regulation (EU) 1223/2009 on cosmetic products entered into force in 2013 and strengthened the previous European framework ensuring the safety of these products. It introduced a centralised notification of all cosmetic products placed on the market and established clear rules for the designation and identification of the responsible persons. Moreover, it lists authorised and non-authorised cosmetic ingredients by function in the product and introduces new rules for the use of nanomaterials in cosmetics.

Regulation (EC) 1935/2004 on food contact materials (FCMs) provides a harmonised European legal framework, establishing clear principles of safety of these materials. These are:

- FCMs shall not release their constituents into food at levels harmful to human health;
- FCMs shall not change food composition, taste or odour in an unacceptable way.

The Regulation set procedures for carrying out safety assessments, rules on labelling and special rules on active and intelligent materials.

RoHS, ELV, WEEE and Batteries Directives

Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment, otherwise known as the Restriction of Hazardous Substances Directive (RoHS 1), was adopted by the European Union in February 2003 and came into effect on 1 July 2006.

The RoHS 1 Directive restricts the use of six hazardous substances in the manufacture of electric and electronic equipment (with exemptions), linking it closely with the Waste Electrical and Electronic Equipment Directive 2002/96/EC (WEEE). WEEE sets collection, recycling and recovery targets for electrical and electronic goods, forming part of the legislative initiative to reduce the amount of toxic e-waste.

RoHS restricts the use of the following:

1. Lead (Pb)
2. Mercury (Hg)
3. Cadmium (Cd)
4. Hexavalent chromium (Cr^{6+})
5. Polybrominated biphenyls (PBB)
6. Polybrominated diphenyl ether (PBDE)

The maximum permitted concentration of these substances (excluding cadmium which is 0.01% or 100ppm) in non-exempt products is 0.1% or 1000ppm by weight. These concentrations apply to the homogenous material in a product, meaning that the restriction applies to any single substance that can, in theory, be mechanically separated from the finished product, not to the weight of the finished product.

RoHS 1 was repealed and superseded by RoHS 2 (Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment), which entered into force on 21 July 2011 and had to be transposed into Member States law by 2 January 2013. RoHS 2 seeks to align and harmonise the restriction of hazardous substances with other EU legislation such as REACH, in order to reduce administrative burden and increase cost effectiveness. The restriction now applies to all EEE, cables and spare parts (with exemptions). Exemptions include weapons, space equipment, large-scale stationary industrial tools and fixed installations.

Batteries are not included in RoHS 1 or 2, but are subject to the Battery Directive 2006/66/EC. This Directive prohibits the placing on the market of certain batteries and accumulators that have a mercury or cadmium content above the designated threshold. As with the WEEE and RoHS Directives, it promotes a high level of collection and recycling of e-waste in order to reduce the amount of hazardous substances entering the environment. The threshold for mercury and cadmium is 0.0005% w/w and 0.002% w/w respectively (medical, emergency and portable power-tool devices are exempt). Member States must take whatever measures necessary to "promote and maximise separate waste collections" for batteries an accumulators in order to prevent them being disposed of with unsorted municipal waste[48]. Collection rates of 45% must be met by 26 September 2016. The Batteries Directive also requires Member States to ensure that waste batteries and accumulators are treated and recycled using best available techniques, including the removal of all fluids and acids as a minimum requirement[49]. Provisions include the labelling of batteries with symbols in regard to metal content and recycling collection information.

As with the WEEE, RoHS and Batteries Directives, the End-of-Life Vehicles Directive 2000/53/EC lays down measures which aim to prevent waste through reuse, recycling and recovery. Reuse of components and the recovery of components which cannot be reused should be encouraged by Member States, with recycling being the preferred option of recovery when environmentally viable. In order to reduce the environmental impact of hazardous substances, materials and components of new vehicles may not contain lead, mercury, cadmium or hexavalent chromium (with exemptions under Annex II). Hazardous substances are those that fulfil the criteria of the hazard classes or categories set out in Annex 1 of the CLP Regulation 1272/2008. ELVs should be stored and treated in accordance with Article 4 of Directive 75/442/EEC and in compliance with the minimum technical requirements for treatment outlined in Annex I. In order to trace the recycling and recovery of ELVs, a destruction certificate is issued by the authorised treatment facility.

Pollutant emissions legislation

Industrial Emissions Directive

Directive 2010/75/EU aims at reducing pollutant emissions from industrial installations in particular through better application of Best Available Techniques (BAT). It covers the whole environmental performance of the industrial plants, regulating "*emissions to air, water and land, generation of waste, use of raw materials, energy efficiency, noise, prevention of accidents and restoration of the site upon closure*"[50].

Annex II to the Directive lists the groups of pollutants covered by environmental media. These are:

- Air
    - Sulphur dioxide and other sulphur compounds
    - Oxides of nitrogen and other nitrogen compounds
    - Carbon monoxide
    - Volatile organic compounds
    - Metals and their compounds
    - Dust including fine particulate matter

[48] http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=URISERV:l21202&from=EN&isLegissum=true

[49] http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=URISERV:l21202&from=EN&isLegissum=true

[50] http://ec.europa.eu/environment/industry/stationary/ied/legislation.htm

- Asbestos (suspended particulates, fibres)
- Chlorine and its compounds
- Fluorine and its compounds
- Arsenic and its compounds
- Cyanides
- Substances and mixtures which have been proved to possess carcinogenic or mutagenic properties or properties which may affect reproduction via the air
- Polychlorinated dibenzodioxins and polychlorinated dibenzofurans

- Water

  - Organohalogen compounds and substances which may form such compounds in the aquatic environment
  - Organophosphorus compounds
  - Organotin compounds
  - Substances and mixtures which have been proved to possess carcinogenic or mutagenic properties or properties which may affect reproduction in or via the aquatic environment
  - Persistent hydrocarbons and persistent and bioaccumulable organic toxic substances
  - Cyanides
  - Metals and their compounds
  - Arsenic and its compounds
  - Biocides and plant protection products
  - Materials in suspension
  - Substances which contribute to eutrophication (in particular, nitrates and phosphates)
  - Substances which have an unfavourable influence on the oxygen balance (and can be measured using parameters such as BOD, COD, etc.)
  - Substances listed in Annex X to Directive 2000/60/EC.

The European Pollutant Release and Transfer Register (E-PRTR)[51] contains data on the main pollutant releases and off-site transfers of waste water and waste from around 28,000 industrial facilities in the EU and EFTA countries. It should be noted that the E-PRTR covers more activities than the IED.

Waste legislation

Water Framework Directive

The Water Framework Directive 2000/60/EC (WFD) seeks to reduce the pollution of European waters from priority substances, with a focus on pollutants that are released into the environment in high volumes. The main provision of the WFD with regard to hazardous substances is Article 16. Together with the Directive 2008/105/EC on Environmental Quality Standards in the Field of Water Policy (the EQS Directive), Article 16 of the WFD provides for the establishment of a list of priority substances which present a significant risk to or via the aquatic environment, and which are identified on the basis of risk assessment. Within the list of priority substances, priority hazardous substances, i.e. substances that are toxic, persistent and liable to bio-accumulate or which give rise to an equivalent level of concern, are to be identified. The classification of substances as priority substances and priority hazardous substances triggers specific risk management measures.

[51] http://prtr.ec.europa.eu/#/home

The WFD demands data specifically on the aquatic toxicity of substances, and draws on both CLP and REACH, and takes into account information from REACH risk assessments (during registration or substance evaluation) or using the REACH risk assessment approach. The first list of priority substances is given in Table 3-3 below (together with those that have subsequently been added – see reference below to Directive 2013/39/EU); those that were also classed as priority hazardous substances (PHS) due to their persistence, bioaccumulation and/ or toxicity, or equivalent levels of concern, are also identified.

Moreover, when a substance is subject to the substance evaluation process set up by REACH, Member States may conclude, amongst other things, that measures for the protection of the environment are necessary and should be considered under the Water Framework Directive 2000/60/EC.[52]

Directive on Environmental Quality Standards (Directive 2008/105/EC)

The first list of priority substances was replaced by Annex II of the Directive 2008/105/EC on Environmental Quality Standards (EQS). The EQS Directive set environmental quality standards for substances in surface waters as a threshold which, in order to achieve good chemical and ecological status and prevent deterioration, must not be exceeded. A water body has reached good chemical status when it complies with the EQS for all priority substances and the eight other pollutants listed in Annex I of the EQS Directive for water and biota. Table 3-4 lists the other eight substances for which EQS are set in this Directive.

The EQS Directive also established a requirement for Member States to establish an inventory of emissions, discharges and losses of the substances.

The WFD and EQS Directive have been amended by Directive 2013/39/EU as regards priority substances in the field of water policy. Twelve new Priority Substances have been introduced, six of which are Priority Hazardous Substances (with these included in the list given in Table 3-2). DEHP and trifluralin were also reclassified as Priority Hazardous Substances. According to Article 1(2), emissions to water of PHS must be phased out within 20 years. Directive 2013/39/EU also updates the EQS for seven of the original PS in line with the latest scientific and technical knowledge concerning their properties. This Directive has introduced a provision requiring the Commission to assess whether the measures set under REACH, the Plant Protection Products Regulation, the Biocides Regulation and the Industrial Emissions Directive are in line with the objectives of the WFD and EQS Directive for Priority Substances. If these measures are insufficient then the Commission or Member States must take additional measures under those legislative acts in order to ensure compliance.

Table 3-3: Priority substances according to Annex I of Directive 2013/39/EU

CAS number	EC number	Substance	Priority hazardous substance
15972-60-8	240-110-8	Alachlor	
120-12-7	204-371-1	Anthracene	*
1912-24-9	217-617-8	Atrazine	
71-43-2	200-753-7	Benzene	

[52] ECHA (2011): Questions and answers regarding CoRAP (Community Rolling Action Plan) and Substance Evaluation, published by the European Chemicals Agency, Helsinki. Available at: http://echa.europa.eu/documents/10162/13626/qa_corap_en.pdf

Table 3-3: Priority substances according to Annex I of Directive 2013/39/EU			
CAS number	**EC number**	**Substance**	**Priority hazardous substance**
N/A	N/A	Brominated diphenylethers (Tetra, penta, hexa and heptabromo dipheyl ethers)	*
7440-43-9	231-152-8	Cadmium and its compounds	*
85535-84-8	287-476-5	Chloroalkanes, C10-13 iv	*
470-90-6	207-432-0	Chlorfenvinphos	
2921-88-2	220-864-4	Chlorpyrifos (Chlorpyrifos-ethyl)	
107-06-2	203-458-1	1,2-Dichloroethane	
75-09-2	200-838-9	Dichloromethane	
117-81-7	204-211-0	Di(2-ethylhexyl)phthalate (DEHP)	*
330-54-1	206-354-4	Diuron	
115-29-7	204-079-4	Endosulfan	*
206-44-0	205-912-4	Fluoranthenevi	
118-74-1	204-273-9	Hexachlorobenzene	*
87-68-3	201-765-5	Hexachlorobutadiene	*
608-73-1	210-158-9	Hexachlorocyclohexane	*
34123-59-6	251-835-4	Isoproturon	
7439-92-1	231-100-4	Lead and its compounds	
7439-97-6	231-106-7	Mercury and its compounds	*
91-20-3	202-049-5	Naphthalene	
7440-02-0	231-111-4	Nickel and its compounds	
25154-52-3 104-40-5	246-672-0 203-199-4	Nonylphenols (4-nonylphenol)	* *
1806-26-4 140-66-9	217-302-5 N/A	Octylphenols (4-(1,1',3,3'-tetramethylbutyl)-phenol)	
608-93-5	210-172-5	Pentachlorobenzene	*
87-86-5	201-778-6	Pentachlorophenol	
N/A 50-32-8	N/A 200-028-5	Polyaromatic hydrocarbons (Benzo(a)pyrene)	* *
122-34-9	204-535-2	Simazine	
N/A (36643-28-4)	N/A	Tributyltin compounds (Tributyltin-cation)	*
12002-48-1	234-413-4	Trichlorobenzenes	
67-66-3	200-663-8	Trichloromethane (chloroform)	
1582-09-8	216-428-8	Trifluralin	*
115-32-2	204-082-0	Dicofol	*
1763-23-1	217-179-8	Perfluoroctane sulfonic acid and its derivatives	*
124495-18-7	N/A	Qinoxyfen	*
N/A	N/A	Dioxins and dioxin like compounds	*
74070-46-5	277-704-1	Aclonifen	
42576-02-3	255-894-7	Bifenox	
28159-98-0	248-872-3	Cybutryne	
52315-07-8	257-842-9	Cypermethrin	
62-73-7	200-547-7	Dichlorvos	
N/A	N/A	Hexabromocyclododecanes (HBCDD)	*
76-44-8/ 1024-57-3	200-962-3/ 213-831-0	Heptachlor and heptachlor epoxide	*
886-50-0	212-950-5	Terbutryn	
Source: European Commission. Annex I of Directive 2013/39/EU. Available: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:226:0001:0017:EN:PDF			

Table 3-4: Substances which are not in the priority substance list but for which Environmental Quality Standards exist under Directive 2008/105/EC	
CAS number	**Substance**
56-23-5	Carbon-tetrachloride
50-29-3	DDT total[(1)] para-para-DDT
309-00-2 60-57-1 72-20-8 465-73-6	Cyclodiene pesticides Aldrin Dieldrin Endrin Isodrin
127-18-4	Tetrachloro-ethylene
79-01-6	Trichloro-ethylene

Source: *European Commission. Annex II of Directive 2008/105/EC. Available: http://ec.europa.eu/environment/water/water-framework/priority_substances.htm*

[(1)] DDT total comprises the sum of the isomers 1,1,1-trichloro-2,2 bis (p-chlorophenyl) ethane (CAS number 50-29-3; EU number 200-024-3); 1,1,1-trichloro-2 (o-chlorophenyl)-2-(p-chlorophenyl) ethane (CAS number 789-02-6; EU Number 212-332-5); 1,1-dichloro-2,2 bis (p-chlorophenyl) ethylene (CAS number 72-55-9; EU Number 200-784-6); and 1,1-dichloro-2,2 bis (p-chlorophenyl) ethane (CAS number 72-54-8; EU Number 200-783-0).

The Groundwater Directive

Directive 2006/11/EC on the protection of groundwater against pollution and degradation sets groundwater quality standards and introduces measures to prevent or limit inputs of pollutants into groundwater

Waste Framework Directive

Directive 2008/98/EC (the Waste Framework Directive) establishes a legal framework for the treatment of waste within the Community, defining a hierarchy that should be followed for the prevention and management of waste: prevention, preparing for reuse, recycling, other recovery (e.g. energy recovery) and disposal. It also provides a common terminology for the classification of waste and, most importantly for this study, of hazardous waste, and requires that adequate risk management measures are applied during waste treatment activities.

3.3 Bottom up Approach: Linking Chemical Properties and Effects on Health and the Environment to Legislation

The production, use and disposal of chemicals and of products containing hazardous chemicals has been linked to a wide range of environmental and health impacts. These include impacts ranging from acute effects due to occupational or consumer exposures, to longer term chronic effects for workers, consumers and the general public. Effects include diseases such as cancer, infertility, developmental effects, asthma, skin sensitisation, amongst a range of other diseases. Some of these diseases may be short-term in nature, recurring (e.g. as a result of sensitisation), continuous, or essentially translate into a death brought forward (e.g. cancer).

Environmental impacts at the species level include lethal effects (in the aquatic, sediment and soil environments, as well as for insects, birds and mammals), impacts on growth rates, on reproductive functions (including endocrine disruption) and developmental effects. These species level effects may then in themselves lead to ecosystem level effects due to the loss of a particular species or due

to reductions in species diversity, as well as a result of impacts up the food chain and hence on higher predators. The latter are a particular concern for persistent and bioaccumulative chemicals.

One of the reasons for the adoption of REACH was the fact that information on the inherent properties needed to manage chemicals safely was not available for a significant percentage of the substances that have historically been placed on the European market. Pre-REACH there was a growing evidence of the adverse consequences associated with recognised hazardous substances but, due to the lack of data, a comprehensive quantitative assessment of the overall impact of chemicals on the environment and human health was not possible. Indeed, much of the necessary information is only becoming available now, with the ongoing registration and evaluation of the chemicals currently placed on the market (a process involving the development of consolidated risk assessments supplemented - where necessary – by additional testing) in line with the requirements of REACH. As indicated by the discussion on the linkages between the different pieces of legislation within the chemicals legislative framework, this previous lack of information will have also impacted on the ability of other legislation to deliver a high level of protection of human health and the environment and, hence, its intended benefits.

For the purposes of this study, we have adopted the CLP classification criteria as the basis for linking specific chemicals to human health and environmental effects. These the different hazard classes considered:

- Acute toxicity;
- Skin Corrosion / skin irritation;
- Skin Sensitisation;
- Serious eye damage / eye irritation;
- Respiratory Sensitisation;
- Mutagenicity;
- Carcinogenicity;
- Reproductive toxicity;
- Specific Target Organ Toxicity;
- Aspiration hazard;
- Hazardous to the aquatic environment;
- Hazardous for the ozone layer.

It should be noted that not all the hazard categories of the hazard classes have been considered, as the focus has been on identifying the most relevant and significant with respect to human health and the environment.[53] Moreover, it should be recognised that substances suspected of being endocrine disruptors do not have a specific hazard class or statement code under the CLP Regulation. Also PBT and vPvB substances do not have a specific hazard class or statement under the CLP Regulation, but the parameters to be recognised as such are established by the REACH Regulation. In addition, substances associated with reproductive toxicity, germ cell mutagenicity and specific organ toxicity may also have an impact on particular wildlife species and on ecosystem

[53] Only the first three categories have been considered. "*Some hazard classes have only one category (e.g., corrosive to metals), others may have two categories (e.g., carcinogenicity (cancer)) or three categories (e.g., oxidizing liquids). There are a few hazard classes with five or more categories (e.g., organic peroxides). The category tells you about how hazardous the product is (that is, the severity of hazard).*"
Source: http://www.ccohs.ca/oshanswers/chemicals/whmis_ghs/hazard_classes.html

diversity. More details on the hazard classes, hazard categories and environmental parameters considered are presented in Annex 7.

3.4 The System of Key Indicators

3.4.1 Introduction

A system of indicators needs to be able to link and measure the action of the chemicals legislation to the changes that occur at multiple levels, e.g.:

- Volume of chemicals used, type of use (but also technology, economic factors (e.g. demand), macro factors, etc.);
- Population at risk – e.g. Number of workers, population exposed to diffuse sources;
- Use conditions – Risk Management Measures, technology, working practices (e.g. shift durations);
- Exposures – Baseline, increment, durations;
- Health responses – Changes in cancer risk, changes in disease incidence, etc.;
- Physical impacts – Morbidity, mortality risk, capabilities (ability to work etc.), health service treatments; impacts on environmental quality, yields, reproduction rates, etc.
- Economic impacts – Value of illness, risk, lost productivity/lost output, treatment costs, etc.

Section 2 set out those indicators identified through the literature review, the brainstorming workshop and follow-up analysis as being potential indicators to be further developed and act as the basis for 'key indicators' for the purposes of this study. As noted in Section 1 of this report, the 'key Indicators' that are the main output of this study must be capable of providing:

- An estimate of the human health and environmental benefits accrued over the time period of interest (where the Commission has expressed as a priority an interest in 2004 onwards), and preferably in monetary terms; and

- Using projections where necessary and possible, the likely human health and environmental benefits of the ultimate destination – that of achieving the goals of the EU chemicals legislation initiatives (again, preferably in monetary terms).

It is therefore a fundamental requirement of the key indicators that they must be capable of quantifying the benefits (robustly) and, preferably, quantifying them in monetary terms. When appropriately connected to one another, these should provide a contiguous and quantifiable link between, on one hand, legislative provisions and, on the other, human health and environmental damages avoided. Where monetary valuation is not possible, further monitoring and data collection may be recommended to the Commission services.

As previously mentioned, in accordance with the Better Regulation guidelines three categories of indicators (output, result and impact indicators) have been proposed for the evaluation and monitoring of the human health and environmental benefits.

The sensitiveness of indicators to changes in the level of legislative action decreases passing from output indicators to result indicators to impact indicators, as the last will have a higher level of confounding factors. Inversely, impact indicators are the most easily translated into monetary values, where result indicators require some more assumptions and output indicators requiring the strongest assumptions. The following subsections present the proposed output, result and impact indicators.

3.4.2 Output indicators

Output indicators are aimed at measuring performance in relation to specific actions of the legislative mechanisms that are likely to result in a change in exposure (captured by result indicators) and, ultimately, in a reduction of negative effects on human health and the environment (captured by impact indicators). In order to identify relevant output indicators, the project team looked at the operational objectives of REACH and CLP and how these interact with other legislation. In the simplest terms, EU legislative provisions on chemicals, as a whole, are aimed at:

- Identification of substances with hazardous properties; and
- Ensuring that appropriate risk management measures are introduced to reduce exposure of humans and environmental receptors to hazardous substances (either in general or for specific [named] substances (even through substitution)).

The combined effect of this 'identify and manage' approach is (intended to be) a reduction in human health and environmental damages from exposure to chemicals, or, more precisely, from exposures at levels sufficient to cause damages.

Over the period of interest for the study (2004 to 2013), the introduction of REACH and CLP is expected to have created human health and environmental benefits through the following outputs:

- An increase in the numbers of substances that are classified for different hazardous endpoints and are, therefore, subject to parallel OSH and environmental regulation – this includes changes in the number of substances that hold harmonised classifications at the EU level;
- An increase in the numbers of substances for which there is sufficient information to generate a PNEC/DNELs, which can be used for other legislative purposes;
- An increase in the numbers of substances for which a quantitative assessment of risk has been undertaken;
- Through CSAs/CSRs and extended safety data sheets, improvements in the identification and communication of required RMMs for uses of a substance;
- Through voluntary withdrawal of substances from use, registrants no longer supporting certain uses, and withdrawal/substitution due to REACH Restrictions or Authorisation; and
- Through the above, a decrease in the number of substances used in circumstances where human health and/or environmental risks cannot be adequately controlled.

Owing to a lack of pre-REACH data on uses and risk management measures in place, it is not possible to develop indicators for all of these. Moreover, indicators such as "number of registered substances", although relevant and easy to be measured, have not been proposed as key indicators, as the project team chose to focus on those mechanisms for which indicators can be linked to changes in exposure and impacts. Substances that have certain hazardous properties that can be of concern for human health and/or the environment, once they have been identified, "*are processed using relevant regulatory steps to make sure that the risks associated with their use are properly addressed*"[54]. These are: harmonised classification, Restriction and Authorisation. The indicator on harmonised classifications covers also the action of the BPR and PPPR (all active substances used in biocidal and plant protection products receive a harmonised classification)[55]. During the Experts Workshop (detailed in Section 5), it was suggested that the project team should also look into self-classifications, as this will have changed more over time and may be more informative. An indicator

[54] http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern
[55] http://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling

on self-classifications was discarded as there were difficulties in finding data on self-classifications before the entering into force of REACH and CLP. However, the project team has retrieved an old database with pre-CLP self-classifications and an indicator on these has subsequently been included.

All the indicators have been defined in general terms and all of them have been defined so that changes in human health and environmental impacts are more easily linked to legislative initiatives. Table 3-5 sets out the proposed output indicators. These have been classified according to the screening criteria and the "classification cards" are presented in Annex 3.8.

Table 3-5: Proposed output indicators
1. Substances with a harmonised classification and labelling implemented after the entry into force of the REACH and CLP Regulations per hazard class
2. Change in self-classifications (per hazard class) since the entry into force of the REACH and CLP Regulations
3. Restriction dossiers implemented after the entry into force of the REACH and CLP Regulations per hazard class, PBT/vPvB profile and endocrine activity of the substances and groups of substances covered by the dossiers
4. Substances of Very High Concerns included in Annex XIV per hazard class, PBT/vPvB profile or with clear evidence of endocrine activity

Output indicator 1 - Substances with a harmonised classification and labelling implemented after the entry into force of the REACH and CLP Regulations per hazard class

The increase in the number of substances with harmonised classification and labelling (CLH) denotes an improvement of knowledge on properties and safe uses of chemicals.[56] Harmonised classifications may be proposed by Member States, manufacturers, importers and downstream users to ensure an adequate risk management throughout the European Community. They primarily concern the most hazardous substances, in particular those that are carcinogenic, mutagenic, toxic for reproduction or respiratory sensitisers. The indicator, in particular how many CLH proposals are submitted and implemented every year, is also influenced by the availability of resources of the different organisations that can propose harmonised classification and labelling and by the number of new active substances proposed to be used in plant protection and biocidal products.

Harmonised classification and labelling is not a mechanism newly introduced by the CLP Regulation: Annex I of Council Directive 67/548/EEC on the approximation of law, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (so called Dangerous Substances Directive – DSD) listed harmonised classification and labelling for substances and groups of substances which were (and still are) legally binding within the EU. Annex I of DSD was regularly updated through Adaptations to Technical Progress (ATP), so to revise classifications and add new classifications to the list. With the entry into force of the CLP Regulation, Annex I of DSD has been integrated into Annex VI of CLP.

The number of substances with harmonised classification and labelling per hazard class can be easily identified by searching through the Classification and Labelling Inventory (available at: http://echa.europa.eu/information-on-chemicals/cl-inventory-database) maintained by the European Chemicals Agency. The CLI allows searching for substances with harmonised classification and labelling only, per hazard class (Figure 3-2).

[56] The indicator, in particular the strength of the change in CLH proposals, is also influenced by the availability of resources of the different organisations that can propose harmonised classification and labelling and by the number of new active substances proposed to be used in plant protection and biocidal products.

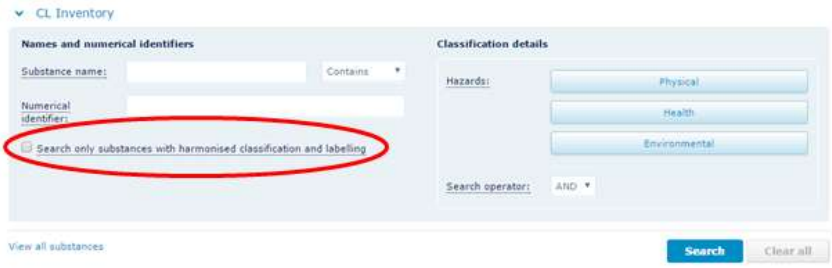


Figure 3-2: Search dashboard[57] of the CLI

The output indicator has been defined as "Substances with a harmonised classification and labelling implemented after the entry into force of the REACH and CLP Regulations per hazard class" since it aims to provide a first measure of the performance of these two Regulations in generating new data triggering new CLH that, ultimately, ensure the better protection of human health and the environment. Therefore, in order to populate the indicator, instead of the CLI, the list of submitted CLH proposals (available at: http://echa.europa.eu/web/guest/registry-of-submitted-harmonised-classification-and-labelling-intentions) needs to be considered. The list includes CLH proposals made after the entry into force of the CLP Regulation. Moreover, the CLH proposals need to be distinguished between those covering active substances regulated by the Biocidal Products and Plant Protection Products Regulations and those covering other substances regulated by the REACH Regulation.

To populate the indicator the following steps need to be followed:

1. Download the list of harmonised classification and labelling (http://echa.europa.eu/information-on-chemicals/cl-inventory-database);
2. Download the list of CLH proposals (http://echa.europa.eu/web/guest/registry-of-submitted-harmonised-classification-and-labelling-intentions);
3. Compare the two lists: using the "Vlookup" formula of Microsoft Excel®, keep only the substances that are present in both lists, copying columns "name", "EC number", "CAS number", "Regulatory Programme" and "Proposed future entry in Annex VI of CLP Regulation"; this allows the identification of those CLH that have been effectively implemented[58];
4. Delete those rows in which neither the name nor the EC number nor the CAS number have been found ("Name", "EC number" and "CAS number" cells displaying "#N/A");
5. Delete those rows referring to the removal of a certain classification and labelling for certain substances[59];
6. Using the "Countif" formula of Microsoft Excel®, search the "Proposed future entry in Annex VI of CLP Regulation" for the hazard classes considered and note the results per hazard class[60];
7. Using the "Lookup & Reference" formulas of Microsoft Excel®, identify the name, EC number and CAS number of the substances per hazard class[61];

[57] It should be noted that the CLI search dashboard has been recently changed (January 2016). As a consequence, it is now possible to search for hazard class and categories only and not for hazard statements as in the previous version.

[58] Example of formula used: =VLOOKUP(E2 *[CAS number of substance with submitted CLH proposal]*,C2:C7380 *[table array of CAS numbers of substances with CLH]*,1,FALSE).

[59] In column "Proposed future entry in Annex VI of CLP Regulation".

[60] Example of formula used: =COUNTIF(E:E *[column with the proposed future entries in Annex VI of CLP Regulation]*,"*"&AX2 *[cell with value "Carc"]* &"*").

8. Sort the substances by "Regulatory Programme"[62].

The indicator could be updated every year or every five years, in coincidence with the REACH review periods.

Currently (April 2016), the CLI has 122,726 entries, of which 4,522 have harmonised classification and labelling. Between June 2008 and April 2016, 296 CLH proposals have been submitted, of which 163 have passed the scrutiny of the Risk Assessment Committee (RAC), of the REACH Regulatory Committee and of the Commission and have been effectively implemented. Some proposals regard changes to substances already with harmonised classification and labelling; these have not been considered.

Table 3-6 presents the number of substances (per hazard class and regulatory programme) with harmonised classification and labelling implemented after the entry into force of the REACH and CLP Regulations. Name, EC and CAS numbers of the substances are presented in Tables A8-1 to A8-09 in Annex 8. Most of the substances are classified for several hazard classes and the CLH are usually proposed for particular hazard classes. Nevertheless, their harmonised classification and labelling is likely to trigger better risk management measures that would lower the exposure to those substances, irrespective of the hazard class addressed by the CLH.

Table 3-6: Substances with a harmonised classification and labelling implemented after the entry into force of the REACH and CLP Regulations by hazard class (June 2008 – April 2016)

Hazard class	No. of substances with CLH				
	REACH	BPR	PPPR	BPR, PPPR	Total
Acute toxicity	28	22	22	8	80
Skin Corrosion / skin irritation	9	4	5	0	30
Skin Sensitisation	9	4	8	1	37
Serious eye damage / eye irritation	17	6	6	1	30
Respiratory Sensitisation	0	0	0	0	1
Mutagenicity	10	1	1	1	13
Carcinogenicity	24	3	12	2	41
Reproductive toxicity	27	2	14	4	47
Specific Target Organ Toxicity	35	17	15	5	72
Aspiration hazard	9	0	0	0	9
Hazardous to the aquatic environment	18	20	40	12	90
Hazardous for the ozone layer	0	0	0	0	0
Number of substances with CLH implemented after the entry into force of the REACH and CLP Regulations per hazard class	78	27	45	13	163

Output indicator 2 - Change in self-classifications and new self-classifications (per hazard class) since the entry into force of the REACH and CLP Regulations

The list of substances with self-classifications for human health and environmental hazard (around 98,000 substances)[63] has been retrieved from the Classification and Labelling Inventory on January

[61] Example of formula used: =IF(ISNUMBER(SEARCH(F1 *[cell with value "acute tox"]*, E2 *[cell with the proposed future entry in Annex VI of CLP Regulation]*)), A2 *[cell with the name of the substance]*,"No").

[62] "Custom sort" function in "Sort & Filter".

[63] Excluding physical hazard.

1st 2016 and compared with a list of substances with self-classifications retrieved from a 2005 extract[64] of the IUCLID system, part of the European chemical Substances Information System (ESIS) maintained by the European Chemical Bureau[65]. The comparison resulted in the identification of 7,709 substances which appeared to be listed on both the IUCLID and CLI lists. The Risk-phrases from the IUCLID list have been translated into Hazard-phrases according to Annex VII of the CLP Regulation.

The number of substances having self-classifications for one or more H-phrases has been counted and the distribution of H-phrases has been noted for all the 7,709 substances included in both lists (Table 3-7). Since substances may have more than one H-phrase (due to several hazard properties), the numbers presented in the table do not add up to 7,709. For each substance, all the notified H-phrases have been included[66].

The REACH requirement of generating physicochemical and (eco)toxicological information for the registration of the substances has led to an increase in the number of substances classified with one or more H-phrases: the comparison found that, since 2005, the number of self-classifications has increased for all hazard groups (Table 3-7), with the only exceptions being the environmental H-phrases H412 and H413 (Aquatic Chronic 3 and Aquatic Chronic 4). This may indicate that more long-term studies have been carried out and have led to higher classifications for aquatic chronic toxicity.

It should be noted that a large number of substances with self-classifications notified to the CLI were not included in the IUCLID system. Many of these substances are not registered either, highlighting how the CLP Regulation has played a role as important as the REACH Regulation in ensuring the protection of human health and the environment.

The indicator could be updated at the end of the 2018 registration deadline and, subsequently, in coincidence with the REACH review periods (every five years).

Table 3-7: Change in self-classifications – substances in IUCLID (2005) and CLI (2016)

Self-classifications		IUCLID	Registered substances database		CLI	Change in percentage (IUCLID - CLI)
			Registered	Not registered		
No. of substances		**7,709**	**3,989**	**3,720**	**7,709**	**-**
Acute toxicity	H300	94	135	106	241	156%
	H301	599	676	388	1,064	78%
	H302	2,448	1,906	1,453	3,359	37%
	H310	70	168	93	261	273%
	H311	446	564	245	809	81%
	H312	977	867	558	1,425	46%
	H330	183	430	208	638	249%
	H331	506	630	206	836	65%
	H332	1,154	1198	614	1,812	57%
∑ Acute toxicity		**3,327**	**2,562**	**1,842**	**4,404**	**32%**
Corrosive/irritating	H314	1,154	1,016	587	1,603	39%
	H315	2,274	2,209	1,640	3,849	69%
	H318	678	1,466	977	2,443	260%
	H319	2,361	2,250	1,686	3,936	67%
	H335	1,175	2,044	1,289	3,333	184%

64 Before the entering into force of the REACH Regulation.
65 The ECB completed its mandate in 2008 and has been replaced by ECHA.
66 Excluding physical hazard phrases.

Table 3-7: Change in self-classifications – substances in IUCLID (2005) and CLI (2016)						
Self-classifications		IUCLID	Registered substances database		CLI	Change in percentage (IUCLID - CLI)
			Registered	Not registered		
	H373	366	1,304	912	2,216	505%
∑ Corrosive/irritating		**4282**	**3,574**	**2,904**	**6,478**	**51%**
Specific target organ toxicity	H336	18	555	295	850	4622%
	H370	23	378	184	562	2343%
	H371	0	298	178	476	-
∑ Specific target organ toxicity		**41**	**1,119**	**1,733**	**1,733**	**Over 4,000%**
Chronic toxicity	H372	110	805	486	1,291	1,074%
∑ Chronic toxicity		**110**	**805**	**486**	**1,291**	**1,074%**
Aspiration hazard	H304	167	443	143	586	351%
∑ Aspiration hazard		**167**	**443**	**143**	**586**	**251%**
Sensitizing	H317	903	1,264	831	2,095	132%
	H334	208	622	704	1,326	538%
∑ Sensitizing		**948**	**1,520**	**1,290**	**2,810**	**196%**
Carcinogenicity	H350	458	1,017	792	1,809	295%
	H350i	26	61	56	117	350%
	H351	335	657	562	1,219	264%
∑ Carcinogenicity		**720**	**1,500**	**1,263**	**2,763**	**284%**
Mutagenicity	H340	52	459	277	736	1315%
	H341	0	658	523	1,181	-
∑ Mutagenicity		**52**	**1,027**	**756**	**1,783**	**Over 3,000%**
Reproductive toxicity	H360D	104	88	60	148	42%
	H360F	34	55	26	81	138%
	H361	92	977	771	1,748	1,800%
	H362	15	158	178	336	2,140%
∑ Reproductive toxicity		**168**	**293**	**259**	**552**	**229%**
Environmental hazard	H400	578	983	711	1,694	193%
	H410	410	954	637	1,591	288%
	H411	658	1,112	615	1,727	162%
	H412	626	240	39	279	-55%
	H413	1,577	86	19	105	-93%
	H420	15	20	7	27	80%
∑ Environmental hazard		**1,750**	**1,909**	**1,263**	**3,172**	**81%**

Output indicator 3 – Restriction decisions implemented after the entry into force of the REACH and CLP Regulations per hazard class, PBT/vPvB profile and endocrine activity of the substances and groups of substances covered by the decisions

The progressive restriction of substances and groups of substances of very high concern contributes in lowering the human and environmental exposure to these substances and groups of substances. Restrictions can be proposed by Member States or by ECHA on request of the European Commission, when risks need to be addressed at EU level. Furthermore, restrictions on articles containing substances that are in the Authorisation list can be proposed by ECHA. Restrictions can apply to the manufacture, placing on the market, use or import of any substance (or group of substances) on its own, in a mixture or in an article.[67]

[67] http://echa.europa.eu/regulations/reach/restriction

As for harmonised classification and labelling, the restriction process has not been newly introduced by the REACH Regulation: Annex I of Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations listed restrictions on substances and groups of substances which were (and still are) legally binding within the EU.

The substances and groups of substances restricted can be found on the ECHA website (http://echa.europa.eu/addressing-chemicals-of-concern/restrictions/substances-restricted-under-reach) and include restrictions adopted under both the REACH Regulation and Directive 76/769/EEC. Currently, the database contains 61 entries, each one covering a substance or a group of substances (grouped on the basis of their toxic profiles) and detailing the scope of the restriction. In order to determine the number of restrictions implemented after the entry into force of the REACH Regulation, the list of submitted restriction proposals (http://echa.europa.eu/web/guest/registry-of-submitted-restriction-proposal-intentions) needs to be compared with the actual list of restrictions. The substances or groups of substances that are covered by the resulting restrictions need to be searched in the CLI and compared to the list of substances with clear endocrine activity and the list of PBT/vPvB substances. The latter can be obtained from the ECHA registered substances database[68] (Figure 3-3).

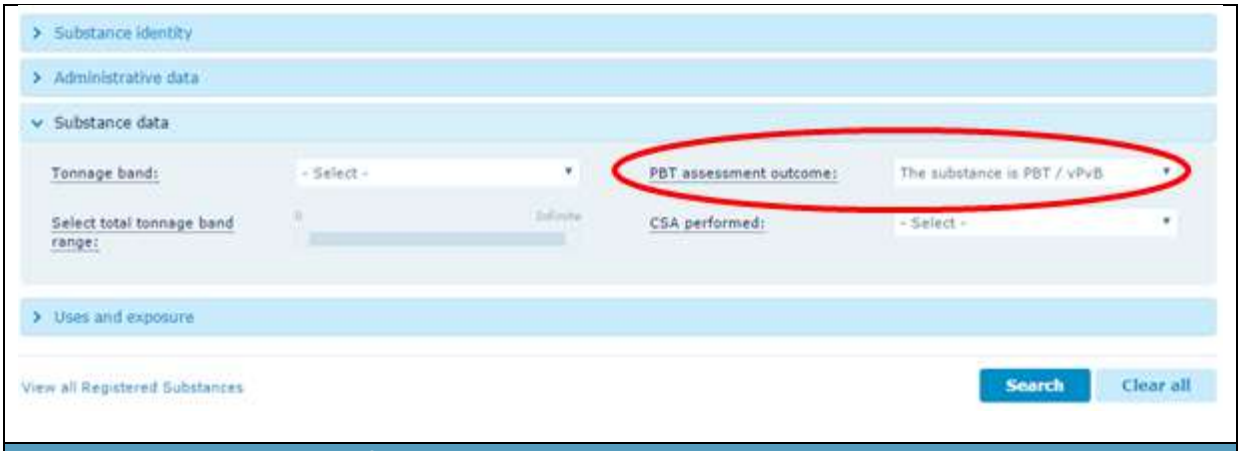


Figure 3-3: Search dashboard of the registered substances database

Since the entry into force of REACH, 31 restriction proposals have been submitted, of which 11 have been implemented and included in Annex XVII.

In summary, to quantify the indicator, the following steps need to be followed:

1. Download the restriction list (Annex XVII - http://echa.europa.eu/addressing-chemicals-of-concern/restrictions/substances-restricted-under-reach);
2. Download the list of submitted restriction proposals (http://echa.europa.eu/web/guest/registry-of-submitted-restriction-proposal-intentions);
3. Compare the two lists: using the "Vlookup" formula of Microsoft Excel®, keep only the substances that are present in both lists, copying columns "name", "EC number", "CAS number". The application of the vlookup formula to name, EC number and CAS number ensures a more thorough screening of the substances, where some entries may have

[68] http://echa.europa.eu/information-on-chemicals/registered-substances

spelling errors or some substances or group of substances may not have assigned EC or CAS numbers[69];

4. Check for the scope of the restriction dossiers: some of the substances may have been targeted by multiple restrictions (e.g. cadmium and its compounds, lead and its compounds). This allows the identification of those restrictions that have been effectively implemented;
5. Search the resulting substances in the Classification and Labelling Inventory (http://echa.europa.eu/information-on-chemicals/cl-inventory-database) and note the results per hazard class;
6. Download the list of PBT/vPvB substances (http://echa.europa.eu/information-on-chemicals/registered-substances)[70] and compare it with the list of submitted restriction proposals (Using the "Vlookup" formula of Microsoft Excel®);
7. Download the list of substances with clear evidence of endocrine activity (http://ec.europa.eu/environment/archives/docum/pdf/bkh_annex_15.pdf), transpose it from PDF to XLS and compare it with the list of submitted restriction proposals (Using the "Vlookup" formula of Microsoft Excel®);
8. Using the "Countif" formula of Microsoft Excel®, search the hazard classifications of the restricted substances (by dossier) for the hazard classes considered and note the results per hazard class[71];
9. Using the "Lookup & Reference" formulas of Microsoft Excel®, identify the name, EC number and CAS number of the substances per hazard class, PBT/vPvB profile and with clear evidence of endocrine activity[72].

The indicator could be updated every year or every five years, in coincidence with the REACH review periods.

The indicator allows quantifying the number of restrictions implemented since the entry into force of the REACH Regulation per certain type of hazards (e.g. since 2010, 4 restrictions have been implemented addressing substances or group of substances with clear evidence of endocrine activity). The results are presented in Table 3-8. Name, EC and CAS numbers of the substances restricted and scope of the restrictions are presented in Tables A8-10 – A8-21 in Annex 8.

Table 3-8: Restriction decisions implemented after the entry into force of the REACH and CLP Regulations per hazard class, PBT/vPvB profile and endocrine activity of the substances and groups of substances covered by the decisions (April 2016)

Hazard class – PBT/vPvB – Endocrine activity	No. of restriction decisions
Acute toxicity	9
Skin Corrosion / skin irritation	5
Skin Sensitisation	2
Serious eye damage / eye irritation	4
Respiratory Sensitisation	1
Mutagenicity	2
Carcinogenicity	5
Reproductive toxicity	8

[69] Example of formula used: =VLOOKUP(E2 *[CAS number of substance with submitted restriction proposal]*,C2:C7380 *[table array of CAS numbers of restricted substances]*,1,FALSE).

[70] In the search dashboard, under "Substance data", for PBT assessment outcome select "The substance is PBT / vPvB.

[71] Example of formula used: =COUNTIF(E:E *[column with the hazard classifications of the restricted substances]*,"*"&AX2 *[cell with value "Carc"]* &"*").

[72] Example of formula used: =IF(ISNUMBER(SEARCH(F1 *[cell with value "acute tox"]*, E2 *[cell with hazard classifications of the restricted substance(s)]*)), A2 *[cell with the name of the substance]*,"No").

Table 3-8: Restriction decisions implemented after the entry into force of the REACH and CLP Regulations per hazard class, PBT/vPvB profile and endocrine activity of the substances and groups of substances covered by the decisions (April 2016)	
Hazard class – PBT/vPvB – Endocrine activity	**No. of restriction decisions**
Specific Target Organ Toxicity	9
Aspiration hazard	2
Hazardous to the aquatic environment	10
Hazardous for the ozone layer	0
PBT/vPvB profile	0
Endocrine activity	4

Output indicator 4 – Substances of Very High Concerns included in Annex XIV per hazard class, PBT/vPvB profile or with clear evidence of endocrine activity

The authorisation procedure has been introduced by the REACH Regulation and, according to ECHA, "*aims to assure that the risks from Substances of Very High Concern are properly controlled and that these substances are progressively replaced by suitable alternatives while ensuring the good functioning of the EU internal market.*"[73]

The indicator aims to quantify the number of substances with different hazard profiles that have been included in the authorisation list.

In order to quantify the indicator, the following steps need to be followed:

1. Download the authorisation list (http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list);
2. Search the resulting substances in the Classification and Labelling Inventory (http://echa.europa.eu/information-on-chemicals/cl-inventory-database);
3. Note the results per hazard class;
4. Download the list of PBT/vPvB substances (http://echa.europa.eu/information-on-chemicals/registered-substances)[74] and compare it with the list of submitted CLH proposals (Using the "Vlookup" formula of Microsoft Excel®);
5. Download the list of substances with clear evidence of endocrine activity (http://ec.europa.eu/environment/archives/docum/pdf/bkh_annex_15.pdf), transpose it from PDF to XLS and compare it with the list of submitted CLH proposals (Using the "Vlookup" formula of Microsoft Excel®).

Table 3-9 presents the results for output indicator 4. Name, EC and CAS numbers of the substances included in Annex XIV of the REACH Regulation are presented in Tables A8-22 to A8-33 in Annex 8.

Table 3-9: Number of SVHCs included in Annex XIV per hazard class, PBT/vPvB profile or with clear evidence of endocrine activity (April 2016)	
Hazard class – PBT/vPvB – Endocrine activity	**No. of substances in Annex XIV**
Acute toxicity	12
Skin Corrosion / skin irritation	12
Skin Sensitisation	12

[73] http://echa.europa.eu/regulations/reach/authorisation

[74] In the search dashboard, under "Substance data", for PBT assessment outcome select "The substance is PBT / vPvB.

Table 3-9: Number of SVHCs included in Annex XIV per hazard class, PBT/vPvB profile or with clear evidence of endocrine activity (April 2016)	
Hazard class – PBT/vPvB – Endocrine activity	**No. of substances in Annex XIV**
Serious eye damage / eye irritation	6
Respiratory Sensitisation	6
Mutagenicity	12
Carcinogenicity	25
Reproductive toxicity	19
Specific Target Organ Toxicity	7
Aspiration hazard	0
Hazardous to the aquatic environment	25
Hazardous for the ozone layer	0
PBT/vPvB profile	4
Endocrine activity	3
Total No. of SVHCs in Annex XIV	**31**

The indicator "SVHCs not registered per hazard class, PBT/vPvB profile or with clear evidence of endocrine activity" was also considered, as manufacturers and importers of SVHCs may have decided to drop them from their product portfolio also in consideration of the regulatory pressure and the associated costs to register and pursue an authorisation. However, it has not been proposed as key indicator because the data are not unambiguous. ECHA has tried to determine how many CMR substances were not registered during the 2010 registration deadline[75]. They identified 1,116 CMR substances by EC and/or CAS numbers listed in Annex VI (harmonised classifications) of the CLP Regulation and searched them in the registered substances database, finding that 406 (around 40%) were registered. This would imply that around 60% of the substances with a CMR classification were not registered and therefore not put on the EU market. However, ECHA lists a number of valid reasons why the substances could not be found in the registered substances database. Many of the pre-CLP harmonised classifications were agreed upon over several decades. Many of those substances may simply be obsolete. Other substances are rare and unlikely to have ever been placed on the market. Another important factor to be taken into account is that many of the CMR substances listed were oil derivatives, that are UVCB substances[76]. During the preparatory phase to REACH, industry tried to evaluate and verify the substance identity of many of them, leading to a reduction in the number and names of substances placed on the market.

The indicator could be updated every year or every five years, in coincidence with the REACH review periods.

Conclusions

Table 3-10 summarises the quantitative data for the four output indicators defined. It helps in highlighting how the legislative mechanisms have addressed substances across all the different hazard classes, despite these mechanisms (harmonised classification and labelling, restriction and authorisation) focus particularly on CMR substances. The data for output indicator 2 on changes in self-classifications highlight how the new (eco)toxicological information generated by the REACH Regulation is improving the knowledge in the hazard profiles of the chemical substances on the market and, ultimately, how it is helping in ensuring the protection of the human health and the environment.

[75] ECHA (2012): CMR substances from Annex VI of the CLP Regulation, European Chemicals Agency, Helsinki. Available at: http://echa.europa.eu/documents/10162/13562/cmr_report_en.pdf

[76] UVCB stands for: Unknown or Variable composition, Complex reaction product or Biological origin.

Output indicators have been used together with impact indicators to establish and measure the link between the action of the chemicals legislation and the reduction in occupational skin and respiratory diseases due to the reduction in exposure to skin and respiratory sensitisers (see Section 4).

Table 3-10: Data summary for the output indicators (April 2016)				
Hazard class – PBT/vPvB – Endocrine activity	**No. of substances with CLH (June 2008 – April 2016)**	**Change in self-classifications (January 2005 – February 2016)**	**No. of restriction decisions (April 2010 – April 2016)**	**No. of substances in Annex XIV (June 2008 – April 2016)**
Acute toxicity	80	+32%	9	12
Skin corrosion / skin irritation	30	+51%	5	12
Skin Sensitisation	37	+132%	2	12
Serious eye damage / eye irritation	30	+164%	4	6
Respiratory Sensitisation	1	+538%	1	6
Mutagenicity	13	+3,329%	2	12
Carcinogenicity	41	+264%	5	25
Reproductive toxicity	47	+229%	8	19
Specific Target Organ Toxicity	72	+4,127%	9	7
Aspiration hazard	9	+251%	2	0
Hazardous to the aquatic environment	90	+99%	10	25
Hazardous for the ozone layer	0	+80%	0	0
PBT/vPvB profile	-	-	0	4
Endocrine activity	-	-	4	3

3.4.3 Result Indicators

Result indicators represent the immediate effects of the programme on the direct addressees or recipients. With regard to chemicals legislation, they can therefore be interpreted in terms of changes in chemical exposures:

- In the first instance, the best measure would be changes of exposure to chemicals, as measured by changes in concentrations of chemicals in human and/or animal tissues;
- A related measure would be changes of concentrations of chemicals in environmental media;
- A less reliable indicator would be data on changes in the production of hazardous chemicals or of concentrations of specific chemicals in consumer products.

As argued by the WHO (2000) with respect to the assessment of the environmental burden of disease, "*an exposure-based approach to assessment of chemical risk factors requires the availability of reliable exposure data. In general, the most reliable indicator of actual human exposure is a biological measure of body burden. Likely exposure can also be calculated for many chemicals on the basis of data on industrial emissions and ambient concentrations from environmental monitoring,*

although a number of factors may intervene between these listed factors and actual exposure, including human behaviours"[77].

With respect to changes in concentrations of chemicals in human (general population) or animal tissues, the main issue is the availability of biomonitoring data that reflect a time series and their comparability. Biomonitoring surveys are resource-intensive and expensive[78], therefore their availability is limited. They are often one-off studies focusing on a limited number of substances of concern which, upon detection, highlight the importance of the legislative intervention to reduce exposure. Data are therefore available for a limited number of chemicals (only around 200 chemical substances can currently be assessed by HBM)[79] and comparability of data from different laboratories and years is problematic. There are also issues in the interpretation of such data, due to the limited availability of epidemiological data and differences and changes in dietary habits across the EU, which can have a higher influence on exposures than changes in the concentration of specific chemicals in human tissues driven by legislative action.

The assessment of the changes in concentrations of chemicals in environmental media presents similar issues. With regard to other surrogates, changes in the production of hazardous chemicals are influenced by large confounding factors (e.g. macroeconomic situation) while data on concentrations of specific chemicals in consumer products refer to limited subsets of both chemicals and products and the datasets are not systematically updated. Data from the German Environmental Specimen Bank have revealed that estimations of human exposure based on production and consumption data may supply misleading information.[80]

The only easily accessible database in Europe that allows inferring the effect of the past and present EU chemicals legislation is the German Environmental Specimen Bank (ESB), which is a permanent monitoring instrument and an archive for human specimens, allowing for retrospective monitoring. Moreover, the German UBA employs environmental surveys (GerES), which are nationwide population representative studies on internal and external human exposure to specific chemicals. These initiatives have been active since the early 1980s.

The need for a European joint programme for the monitoring and scientific assessment of human exposure to chemicals and the potential health impacts in Europe has been highlighted by the COPHES and DEMOCOPHES projects and there is currently a Horizon 2020 call for developing a European Human Biomonitoring initiative[81]. The European Commission has set aside €50 million to fund this action that has the ultimate aim to support the "*policy-making process in a wide variety of sectors, one of the most important being the EU chemicals legislation under REACH*".

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[77] WHO (2000): Methodology for assessment of environmental burden of disease, World Health Organisation, Geneva, p. 53.

[78] The COPHES project, an overall cost of between €3.7 million to €13.7 million per year has been estimated as the minimum and maximum scenario, respectively, for implementing an HBM programme for the 27 EU Member States.

[79] "German experiences with human biomonitoring, its impacts on policy and future perspectives", presentation by Marike Kolossa (Umwelt Bundes Amt) during the conference "From HBM to policy" held in Brussels on Ocotber 2010. Available at: http://www.lne.be/en/environment-and-health/human-biomonitoring-conference/kolossa-gehring

[80] Kolossa-Gehring M., Becker K, Conrad A, Schröter-Kermani C, Schulz C, Seiwert M., Environmental surveys, specimen bank and health related environmental monitoring in Germany. Int J Hyg Environ Health. 2012 Feb;215(2):120-6. doi: 10.1016/j.ijheh.2011.10.013. Epub 2011 Dec 14. Available at: http://www.ncbi.nlm.nih.gov/pubmed/22172995

[81] https://ec.europa.eu/research/participants/portal4/desktop/en/opportunities/h2020/topics/3050-sc1-pm-05-2016.html

During the Experts Workshop (see Section 4), it was discussed the opportunity of launching EU-wide surveys to collect the missing data for the best functioning of a system of indicators, information such as the types of risk management measures implemented by the actors in the supply chains following changes in the SDS accompanying the chemical substances. It should be noted that some of this information has been recently collected during the survey of European companies for the monitoring of the impacts of REACH on innovation, competitiveness and SMEs[82]. According to this report, "*around 53% of the respondents reported to have improved risk management procedures because of REACH, with another 39% reporting to have improved the management of environmental emissions and waste*". Among the companies that reported to have had to improve their RMMs, most had to change personal protection equipment and had to adopt new safety instructions, with some having to invest in emission reduction technologies or had to change products/articles compositions. The improvement of RMMs leads to lower levels of exposure to chemicals and, ultimately, results in a reduction of impacts on the human health and the environment.

According to the level of approximation, Table 3-11 presents the proposed result indicators. These indicators have been classified according to the screening criteria and the "classification cards" are presented in Annex 3.8.

Table 3-11: Proposed results indicators (linked to changes in exposures)
1. Change in the concentration level of selected chemicals in human body tissues
2. Change in the concentration level of selected chemicals in animal and plant tissues
3. Change in the concentration level of selected chemicals in air, water and soil samples
4. Change in emissions of selected chemicals in air, water and soil
5. Change in production volume of selected chemicals

Table 3-12 lists the substances (per hazard class) for which exposure data are available and have been used to populate the result indicators.

Table 3-12: Substances with exposure data presented in this Section per hazard class	
Hazard class – PBT/vPvB – Endocrine activity	**Substances**
Acute toxicity	Cadmium, mercury and methylmercury, lead, pentachlorophenol, PFOS and PFOA, nonylphenol and nonylphenol ethoxylates, tributyltin, triphenyltin
Skin Corrosion / skin irritation	Pentachlorophenol
Skin Sensitisation	Bisphenol A
Serious eye damage / eye irritation	Pentachlorophenol, bisphenol A, PFOS and PFOA, nonylphenol and nonylphenol ethoxylates, tributyltin
Respiratory Sensitisation	Pentachlorophenol
Mutagenicity	Cadmium
Carcinogenicity	Cadmium, lead, hexachlorobenzene, pentachlorophenol, PFOS and PFOA
Reproductive toxicity	Cadmium, mercury and methylmercury, phthalates, bisphenol A, PFOS and PFOA, HBCD, nonylphenol and nonylphenol ethoxylates
Specific Target Organ Toxicity	Cadmium, mercury and methylmercury, lead, hexachlorobenzene, PCBs, bisphenol A, PFOS and PFOA, tributyltin
Aspiration hazard	-

[82] CSES et al (2015): Monitoring of the impacts of REACH on innovation, competitiveness and SMEs, Report prepared for DG Growth, pages 70-71.

Table 3-12: Substances with exposure data presented in this Section per hazard class	
Hazard class – PBT/vPvB – Endocrine activity	**Substances**
Hazardous to the aquatic environment	Cadmium, mercury, lead, hexachlorobenzene, pentachlorophenol, PCBs, phthalates, PFOS and PFOA, HBCD, nonylphenol and nonylphenol ethoxylates, tributyltin, triphenyltin
Hazardous for the ozone layer	-
PBT/vPvB profile	PFOS and PFOA, tributyltin, DIBP
Endocrine activity	Phthalates, nonylphenol, bisphenol A, PCBs

Result indicator 1 – Change in the concentration level of selected chemicals in human body tissues

In relation to indicators of change since 2004, there are no human biomonitoring data valid across all of Europe that would provide a complete and continuous picture over time. Some time-limited HBM data are available for mercury, cotinine, cadmium, phthalates and bisphenol A (COPHES/DEMOCOPHES initiatives). These show significant variations across the Member States, highlighting differences in exposure and, consequently, differences in the role that chemicals legislation may play at the national level.

For result indicator 1, the project team therefore chose to use the information from the German ESB[83]. Substances for which some retrospective monitoring has been done include: dioxins, furans, dioxin-like PCBs, phthalates, BPA, PFC, flame retardants. Real time monitoring is carried out on heavy metals, persistent organochlorines (DDE, PCB, HCH, HCB), organophosphates, PAHs, PCP and other chlorophenols. It should be noted that German biomonitoring data cannot be extrapolated at the EU level, as they are not representative of the situation in the other 27 Member States. However, the data trends show interesting correlation between legislation and reduction in concentrations of chemicals in human and animal samples.

Cadmium

Cadmium and its compounds have been found to have the following hazard properties:

- Acute toxicity;
- Carcinogenicity;
- Mutagenicity;
- Toxic to reproduction;
- Specific target organ toxicity; and
- Acute and chronic toxicity to the aquatic environment.

They are used in a large number of applications (such as manufacture of batteries and production of stabilisers, pigments, alloys and plated products)[84] but, due to their toxic properties, they have been increasingly targeted by the legislation. According to JRC (2007), "*Cadmium (and its compounds) is a multi-regulated substance: in the EEC several directives have been adopted spread over the whole spectrum of risk reduction legislative instruments actually in use in the EU i.e. limitations in the marketing and use, environmental quality standards (emission and immission standards, protection*

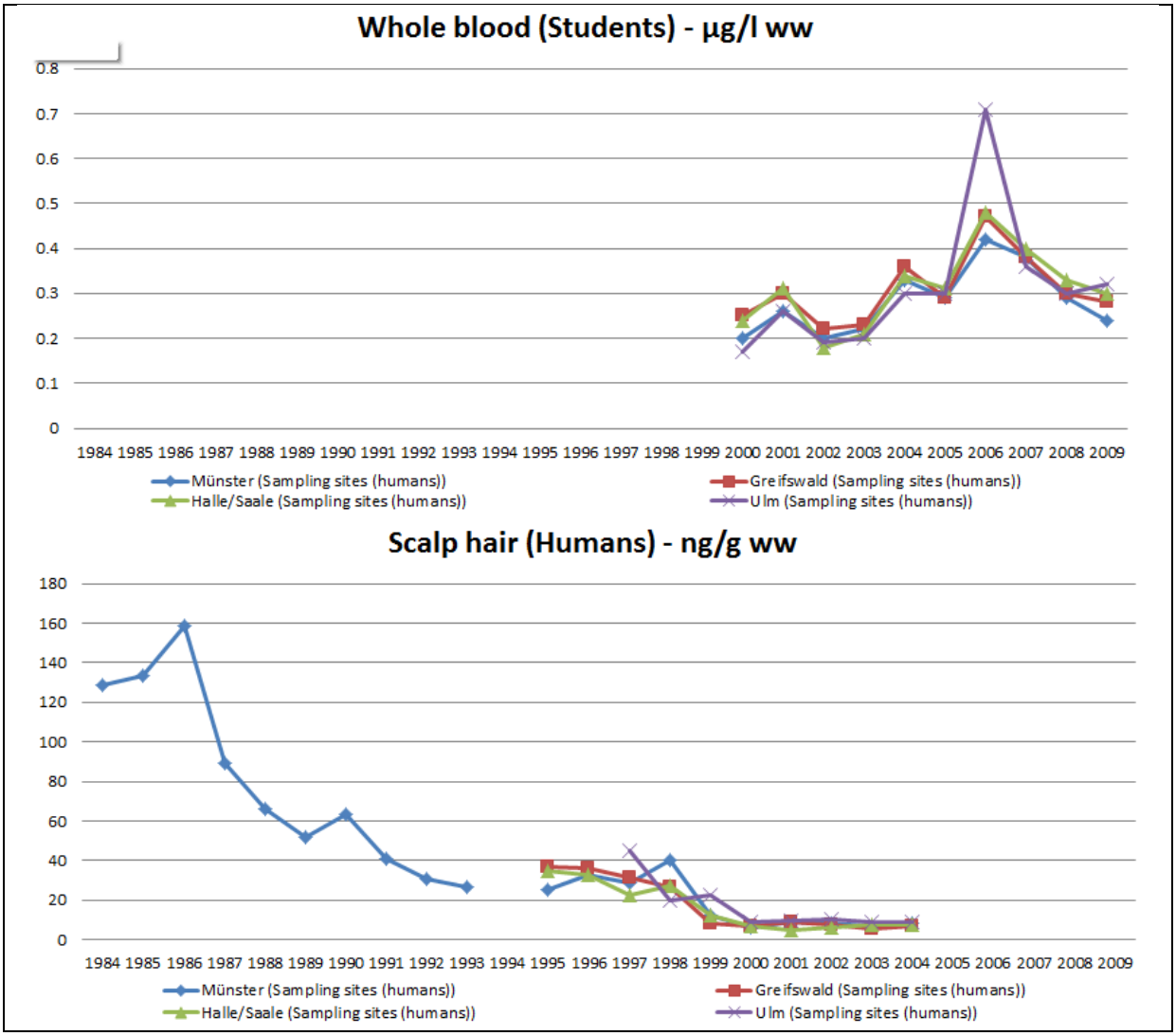
[83] https://www.umweltprobenbank.de/en/documents

[84] JRC (2007): European Union Risk Assessment Report on Cadmium oxide and cadmium metal, Part I – Environment. Available at: http://echa.europa.eu/documents/10162/4ea8883d-bd43-45fb-86a3-14fa6fa9e6f3

of natural resources (groundwater, drinking water)), workplace (OEL's, etc.) and consumer." The applications that have been progressively restricted at EU level are:

- Use in plastic material;
- Use in paints;
- Use for plating metallic articles or components of the articles in some specific sectors;
- Use in brazing fillers;
- Use in jewellery.[85]

Figure 3-4 presents the HBM data from the German Environmental Specimen Bank. The whole blood samples show an increase in the blood concentration of cadmium of around 30% between 2000 and 2009, in contrast with a reduction of around 60% between 1995 and 2004 shown by the analysis of saliva samples and of 75% - 85% (1995-2004) according respectively to scalp hair and pubic hair samples analysis. The reduction over a period of 21 years (1984-2004) has been of over 90% according to the analysis of saliva, scalp hair and pubic hair samples from one single location (Münster).



[85] For the specific conditions of restriction, please consult entry 23 of the Annex XVII of the REACH Regulation.

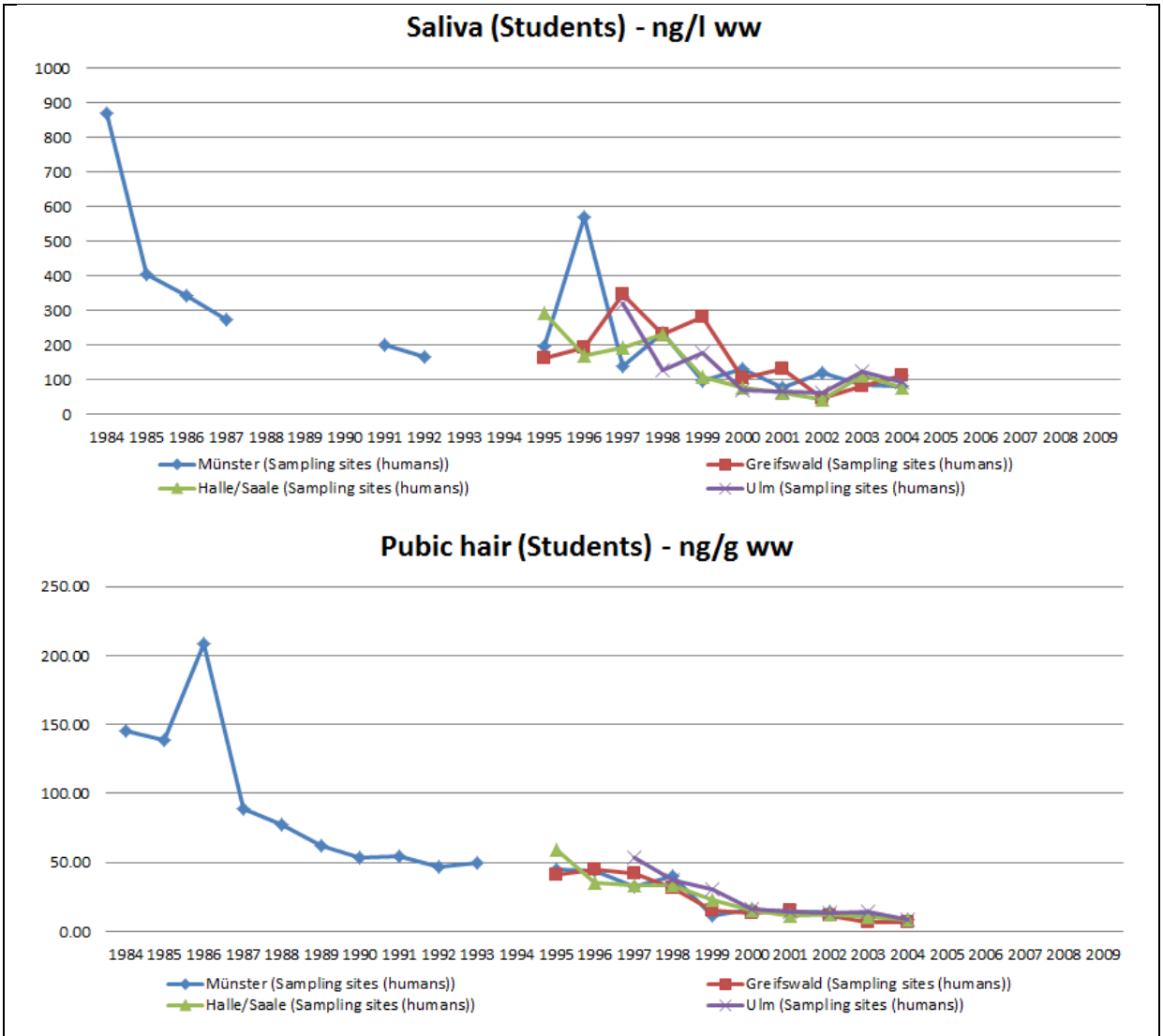


Figure 3-4: - Cadmium in whole blood, saliva, scalp hair and pubic hair samples in four different locations in Germany - *Source: UBA Umweltprobenbank*

Mercury

Mercury is a metal with a wide range of applications (chlor-alkali production, lamps, batteries, dentistry, measuring equipment, electrical components, catalysts, disinfectant). Its health and environmental hazard profile (classified for acute toxicity, toxic to reproduction, specific target organ toxicity and acute and chronic toxicity to the aquatic environment) led to the development of international strategies for its reduction.[86]

The EU Mercury strategy was adopted in 2005 and renewed in 2010, resulting in the restriction on the sale of measuring devices containing mercury, a ban on exports of mercury from the EU that came into force in 2011 and new rules on storage requirements.[87] Moreover, several different EU

[86] COWI (2008): Options for reducing mercury use in products and applications, and the fate of mercury already circulating in society, Report for the European Commission, DG Environment. Available at: http://ec.europa.eu/environment/chemicals/mercury/pdf/study_report2008.pdf

[87] http://ec.europa.eu/environment/chemicals/mercury/strategy_en.htm

Directives have been introduced to reduce mercury emissions in specific environmental media (e.g. Directive 2004/107/EC relating to the arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient and Directive 84/156/EEC on limit values and quality objectives for mercury discharges by sectors other than the chlor-alkali electrolysis industry).

Figure 3-5 presents the HBM data on mercury from the German ESB.

Whole blood samples show a decrease in mercury concentration of around 60% over nine years (2001-2010), while urine samples show a decrease of over 90% over 19 years (1995-2013).

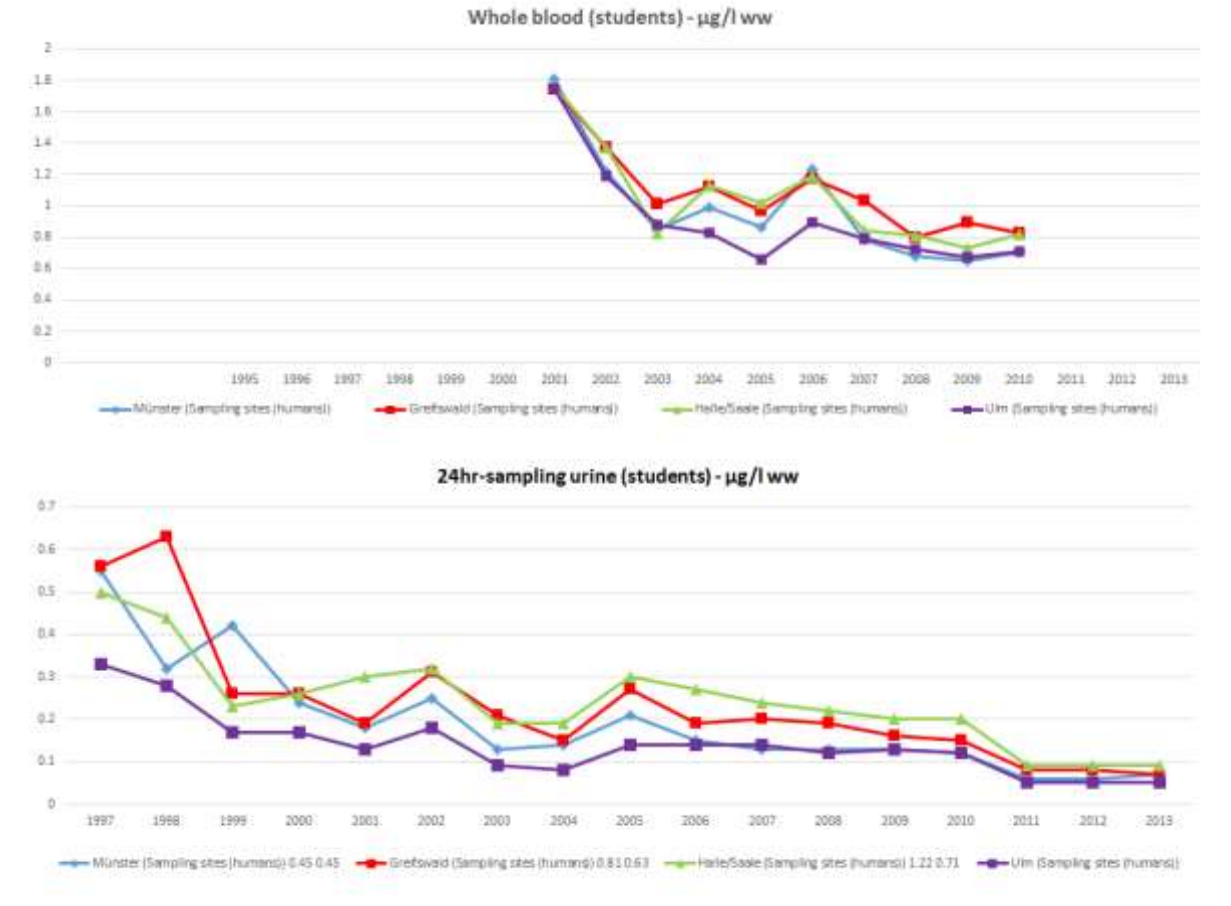


Figure 3-5: Mercury in whole blood and urine samples in four different locations in Germany – *Source: UBA Umweltprobenbank*

Lead (Pb)

Lead is an element that occurs naturally in the environment. Lead and its compounds have been used in a wide range of applications, due to their desirable properties. Their environmental and human health risks have been reviewed extensively by a number of authoritative bodies in recent years and have harmonised classification and labelling and self-classifications for acute toxicity, reproductive toxicity, carcinogenicity, specific target organ toxicity, acute and chronic toxicity to the aquatic environment. Lead is also a neurotoxic substance.

In recent decades, in response to a growing awareness of the need to control Pb exposure, there has been increasing national and international emphasis on establishing appropriate regulatory measures to control its use. Thus, for example, extensive European legislation is now in place to regulate the level of Pb in petroleum, pipes, electrical goods and many other potential sources of exposure. Among many other legislative initiatives, lead and its compounds are restricted in jewellery and in consumer articles.

HBM data from the German ESB show an average decrease in internal exposure to lead of around 60% over the period 1995-2013. For the population sample in Münster, the reduction was of around 85% in the period 1981-2013.

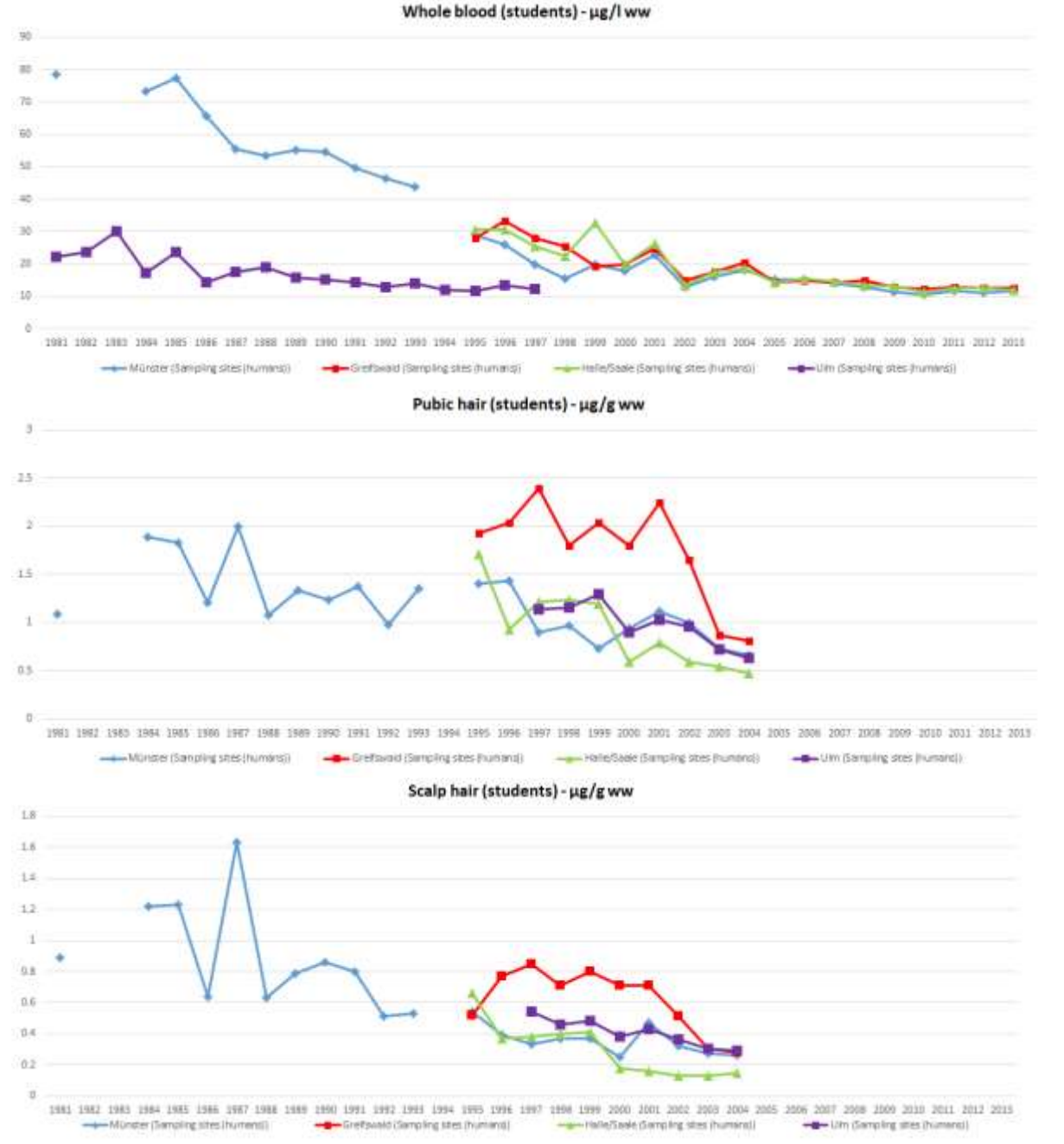


Figure 3-6: Lead in whole blood, scalp hair and pubic hair samples in four different locations in Germany – *Source: UBA Umweltprobenbank*

Hexachlorobenzene (HCB)

Introduced as an agricultural pesticide in 1945, HCB was banned in 1981 for agricultural use in the EU. It may still be used to some extent as an industrial chemical and is still released to the environment during incineration and, to some extent, as a by-product from the manufacture of industrial chemicals and several pesticide formulations.

HCB is included in the Stockholm Convention on persistent organic pollutants and the United Nations Economic Commission for Europe (UNECE) Convention on long-range trans-boundary air pollution protocol on POPs.

The legislative measures have contributed to the reduction of around 80% in internal exposure of the German population to HCB in the period 1995-2010.

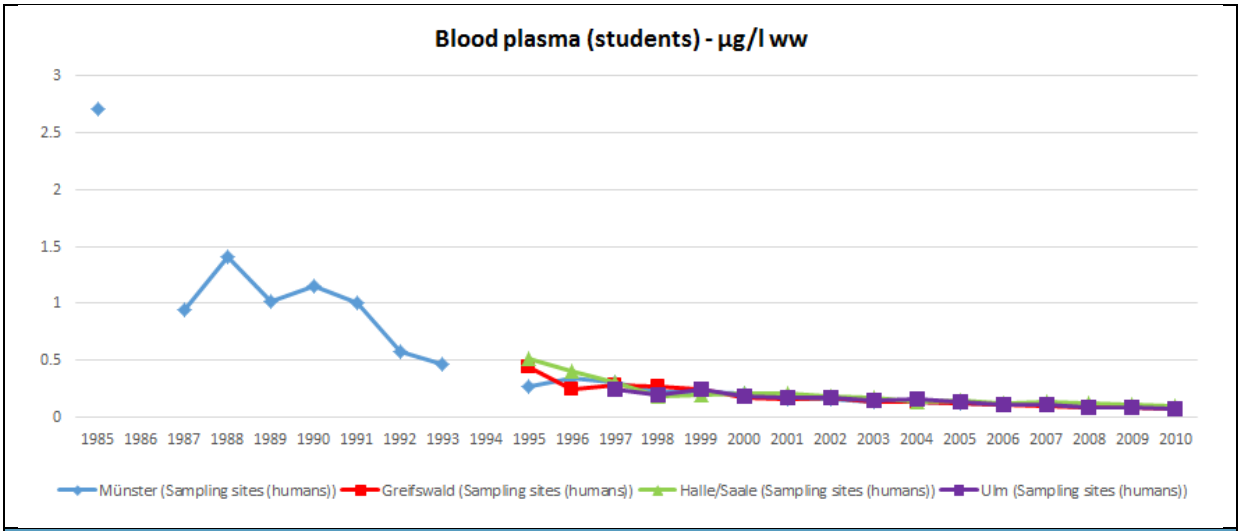


Figure 3-7: Hexachlorobenzene in blood plasma samples in four different locations in Germany – *Source: UBA Umweltprobenbank*

Pentachlorophenol

Pentachlorophenol was widely used as active substance in plant protection products. It is almost always contaminated with dioxins and furans. It has harmonised classifications of H301 (Toxic if swallowed), H311 (Toxic if in contact with skin), H315 (causes skin irritation), H319 (causes serious eye irritation), H330 (fatal if inhaled), H335 (may cause respiratory irritation), H351 (suspected of causing cancer), H400 (toxic to the aquatic environment) and H410 (toxic to the aquatic environment with long lasting effects).

Its production was banned in Germany in 1986 while trading and use were banned in 1989. Pentachlorophenol is included in Annex XVII of REACH and cannot be therefore placed on the market as a substance or as constituent in other substances, or in mixtures, in a concentration equal to or greater than 0.1% by weight. Since 2002, it has not been approved as active substance in plant protection products. These legislative measures have contributed to a decrease in internal exposure of around 90% over the period 1995-2010.

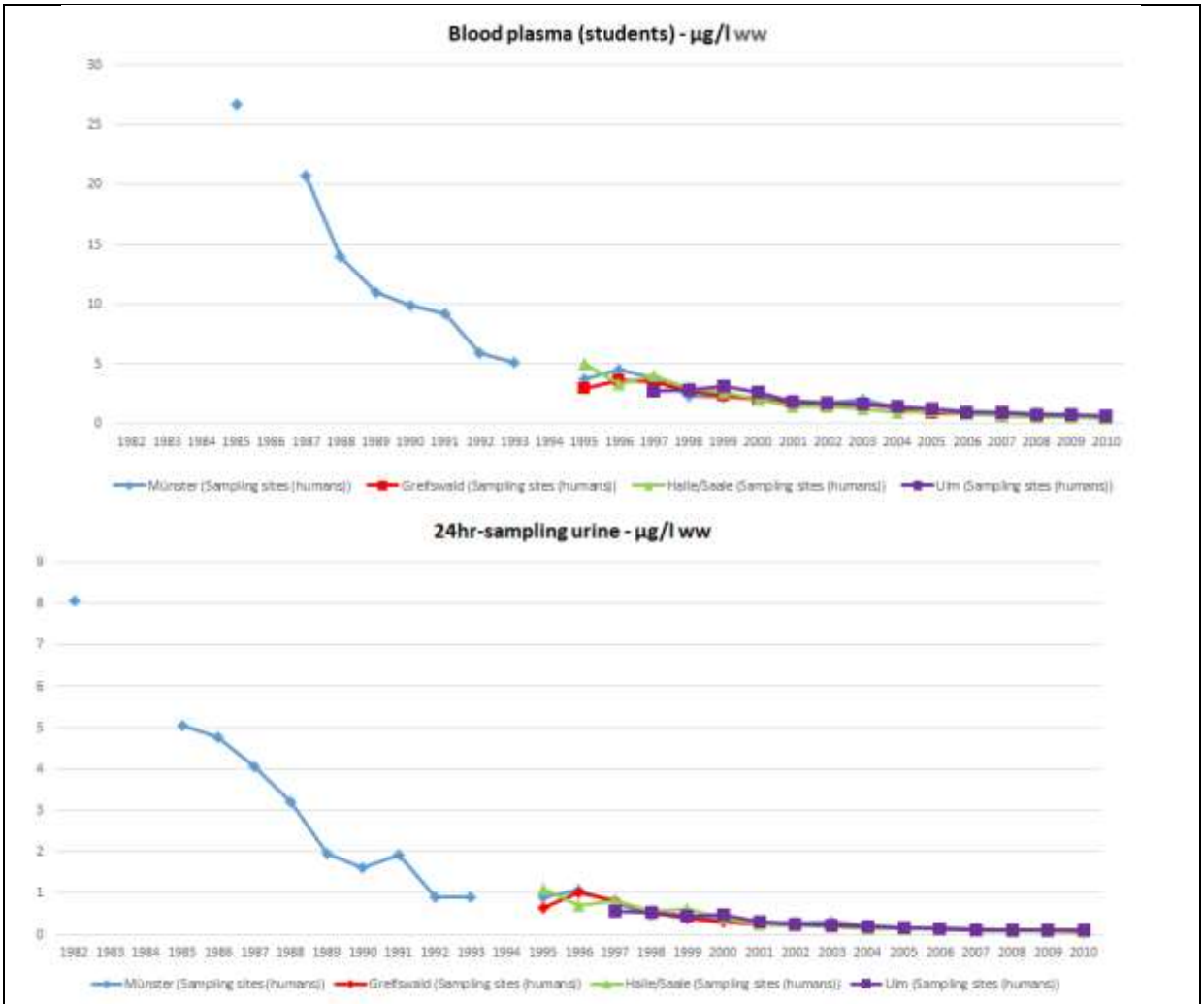


Figure 3-8: Pentachlorobenzene in blood plasma and urine samples in four different locations in Germany – *Source: UBA Umweltprobenbank*

Polychlorinated biphenyls (PCBs)

PCBs are a class of 209 chlorinated hydrocarbons which have been widely used as hydraulic fluids, lubricating oils, plasticisers and flame retardants in paints and plastics.[88] This group of substances has harmonised classification for specific target organ toxicity (H373), acute and chronic toxicity to the aquatic environment (H400, H410) and is in the list of substances with clear evidence of endocrine activity.

Their manufacture has been banned in Germany since 1983 and worldwide since 2004 (Stockholm Convention).

HBM data from the German ESB show a decrease of around 65% - 80% in internal exposure of the German population to PCBs over the period 1995-2010.

[88] https://www.umweltprobenbank.de/en/documents/profiles/analytes/10062

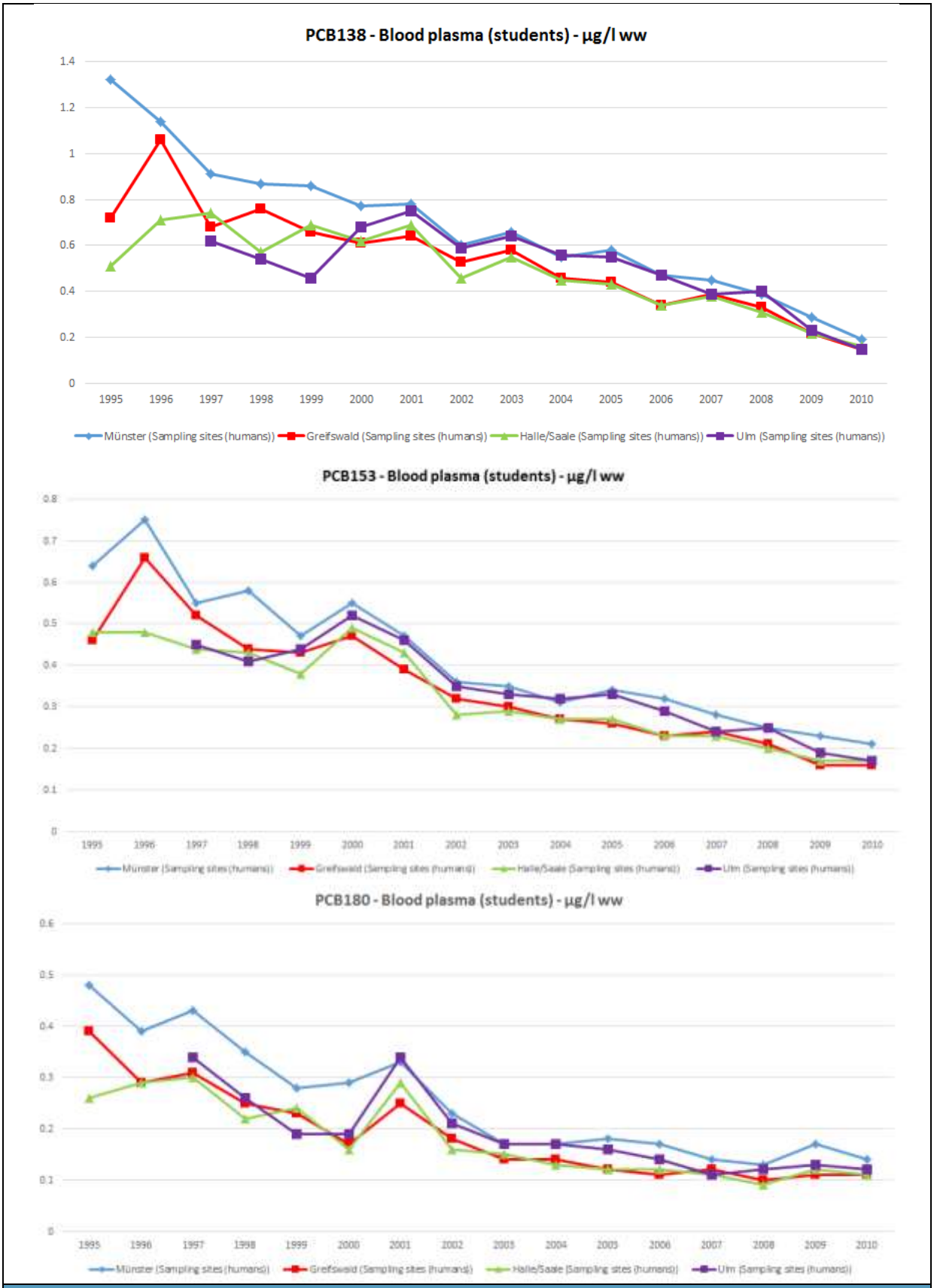


Figure 3-9: PCB138, PCB153 and PCB180 in blood plasma samples in four different locations in Germany – *Source: UBA Umweltprobenbank*

Phthalates

The German ESB provides interesting data on five different phthalates:

- Diethylhexyl phthalate (DEHP);
- Di-n-butyl phthalate (DnBP);
- Diisobutyl phthalate (DiBP);
- Butylbenzyl phthalate (BBP); and
- Diisononyl phthalate (DiNP).

DEHP has a harmonised classification and labelling for reproductive toxicity (H360FD - May damage fertility. May damage the unborn child) and acute and chronic toxicity to the aquatic environment (H400 - Very toxic to aquatic life; H410 - Very toxic to aquatic life with long lasting effects). It is also included in the list of substances with clear evidence of endocrine activity.

At the time of the 2002 RAR and Draft RRS of 2003, DEHP was widely used as a plasticiser in polymer products, mainly PVC with content varying in flexible polymer materials but around 30 % (w/w). DEHP and other phthalates accounted 92% of plasticiser consumption in Western Europe (2003 RRS). The 2003 draft RRS estimated European consumption of DEHP to be 476,000 tpa in 2003, representing 51% of all phthalate plasticiser use. It estimated that 97% of the DEHP consumption (462,000 tpa) was as a plasticiser in polymers (mainly soft-PVC) and the remaining 3% was used in non-polymer applications such as adhesives and sealants, paints and lacquers, printing inks and capacitors as well as in advanced ceramic materials for electronic and structural applications.

In the late 1980s DEHP was suspected as being toxic for reproduction and in the 1990s it was also suspected to have an oestrogenic effect. For some years, it was also a suspected human carcinogen and classified as possibly carcinogenic to humans by the US EPA the International Archives of Cancer but, after it was re-evaluated by IARC in 2000 it was downgraded and declared to be not classifiable in terms of carcinogenicity to humans[89].

Owing concerns over its properties and widespread use, in 1995 DEHP was added to the second priority list of substances under ESR and Sweden (as rapporteur) initiated work on the RAR. In the meantime:

- In 1998 the first OSPAR List of Substances for Priority Action was established. DEHP was listed amongst the 30 priority substances /groups of substances in this list (OSPAR, 2000); and
- On 7 December 1999 the European Commission (Decision 1999/815/EC) adopted measures under the Directive on General Product Safety (92/59EEC) on certain phthalates in toys and childcare articles. Thereby, the placing on the market was prohibited for toys and childcare articles that are intended to be put into the mouth by children under three years age and made of soft PVC containing DEHP or five other phthalates (DIDP, DINP, DBP, BBP and DNOP). The duration of the decision under this mechanism was limited to three months with the possibility for repeat renewals. Repeated renewals were applied while a permanent solution was sought under ESR.

[89] Rank, J (2005): Classification and Risk Assessment of Chemicals: The Case of DEHP in the Light of REACH, The Journal of Transdisciplinary Environmental Studies vol. 4, no. 3, 2005, http://www.journal-tes.dk/vol_4_no_3/no2_hoj.pdf

The RAR under ESR was finalised in September 2001 and the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) delivered its opinion on the risk assessment in January 2002. A draft RRS was produced in 2003 and coincided with the proposals for REACH set out in the White Paper (which offered the possibility of new legislative mechanisms for control of the risks. A final RAR was produced in 2008 and, on the basis of this, in 2009 DEHP was included in the list of substances requiring authorisation under Annex XIV of REACH and Restrictions under Annex XVII were also applied.

During the timescale of the RAR process, DEHP was not yet classified at Community level and the self-classification applied by the manufacturers was reproduction category 3 (under DSD). A harmonised classification under DSD as toxic to reproduction (both fertility and developmental toxicity) in category 2 was agreed and was implemented by 30 July 2002.

In addition to the action taken under the General Product Safety Directive in 1999, the change in classification to toxic for reproduction category 2 triggered actions to control risks and exposure under parallel regulation including:

- Directive on Cosmetic Products (76/768/EEC) – where, in November 2002, amendments to restrict the use of CMR substances via the Cosmetics Directive were agreed;
- Directive on Plastic Materials and Articles Intended to Come in Contact with Foodstuffs (90/128/EEC);
- Directive on Medical Devices (93/42/EEC);
- Directive on Pregnant Workers and Workers who have Recently Given Birth or are Breastfeeding (92/85/EEC);
- Directive on Waste (91/689/EEC); and
- Directive on Integrated Pollution Prevention and Control (96/61/EC).

Legislative and non-legislative initiatives on DEHP have contributed so far to a reduction of around 70% over 21 years (1988-2008) in concentration of DEHP metabolites in urine (proxy of the median daily intake) of German students in Münster (Germany). Concentration of DEHP metabolites in urine had a peak in 1991 (increase of around 30% in three years (1988-1991)).

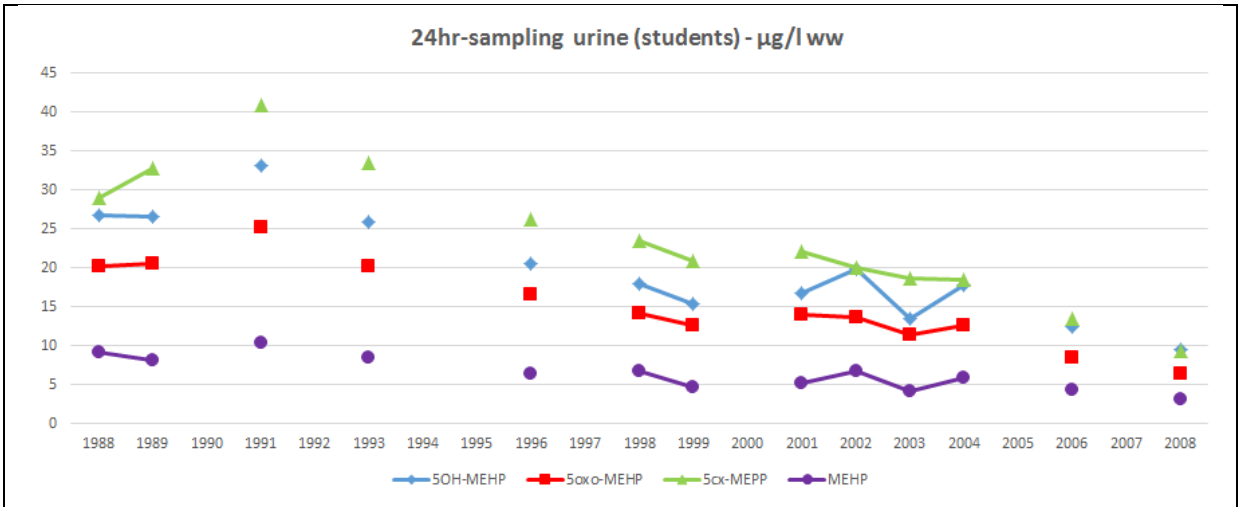


Figure 3-10: DEHP primary and secondary metabolites (MEHP, 5OH-MEHP, 5oxo-MEHP and 5cx-MEPP) in 24 hours-sampling urine in Münster (Germany) – *Source: UBA Umweltprobenbank*

Di-n-butyl phthalate (DnBP or DBP) has harmonised classification and labelling for reproductive toxicity (H360Df - May damage the unborn child. Suspected of damaging fertility) and acute toxicity to the aquatic environment (H400 - Very toxic to aquatic life). It is also included in the list of substances with clear evidence of endocrine activity.

DBP is mainly used as plasticiser in PVC and other polymers and has a wide range of applications in consumer products. It is present in floor coverings, adhesives and as a solvent in plant protection products and paints. It is also used as a gallant in plastisols and for encapsulating drugs to resist gastric juice[90]. It was widely used in cosmetic products.

Its use in childcare articles and toys and in cosmetic products has been banned in the EU. It has been identified as a SVHC in October 2008 and included in the authorisation list with the sunset date of February 2015. Uses in the immediate packaging of medicinal products are exempted from authorisation. A draft PBT-assessment has been developed but the activity has been postponed without concluding on the properties.

Production of dibutyl phthalate decreased between 1994 and 1998 of around 45% (from 49,000 tonnes to 26,000 tonnes per year)[91]. Following the restrictions on its use, internal exposure to DBP is decreased by around 90% in the period 1988-2008[92]. Wittassek et al (2007) noted that in 14% of the sampled German population, daily intakes above the tolerable daily intake (TDI) deduced by EFSA were observed, although the frequency of the exceedance has decreased during the years and was not above 2%[93].

[90] https://www.umweltprobenbank.de/en/documents/profiles/analytes/11051

[91] ECB (2003): European Union Risk Assessment Report on Dibutyl phthalate (DBP), Institute for Health and Consumer Protection – Joint Research Centre, Ispra (Italy). Available at: http://echa.europa.eu/documents/10162/ba7f7c39-dab6-4dca-bc8e-dfab7ac53e37

[92] Göen T et al (2011): Trends of the internal phthalate exposure of young adults in Germany—Follow-up of a retrospective human biomonitoring study, International Journal of Hygiene and Environmental Health, Volume 215, Issue 1, December 2011, Pages 36–45. Available at: http://www.sciencedirect.com/science/article/pii/S1438463911001039

[93] Wittassek et al (2007): Internal phthalate exposure over the last two decades – A retrospective human biomonitoring study, International Journal of Hygiene and Environmental Health, Volume 210, Issues 3–4, 22 May 2007, Pages 319–333. Available at: http://www.sciencedirect.com/science/article/pii/S1438463907000491

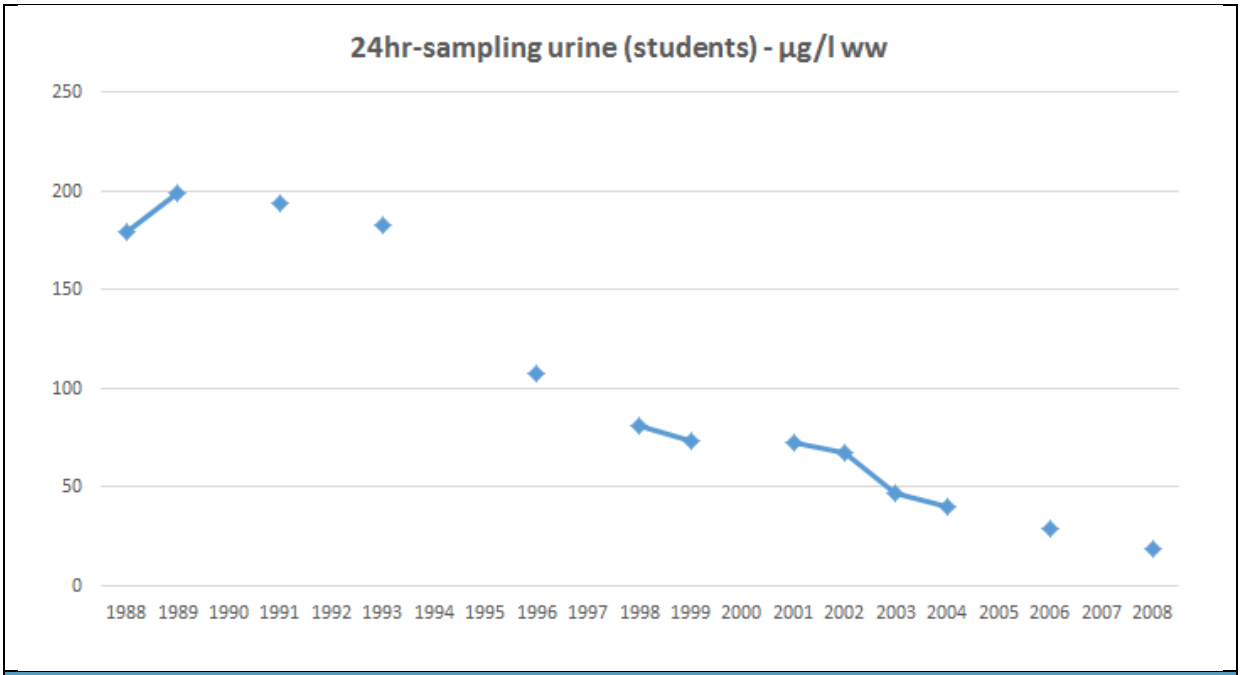


Figure 3-11: DnBP metabolite (MnBP) in 24 hours-sampling urine in Münster (Germany) – *Source: UBA Umweltprobenbank*

Diisobutyl phthalate (DiBP) has harmonised classification and labelling for reproductive toxicity (H360Df – May damage the unborn child. Suspected of damaging fertility) and has self-classifications for acute and chronic aquatic toxicity (H400 and H410). It has also been found to be a PBT substance.

DiBP is used as plasticiser in different polymers and is present in different applications, such as floorings, adhesives, lacquers, inks, hydraulic fluids and lubricants.[94]

As DEHP, BBP and DBP, DiBP has been included in the Authorisation list with a sunset date of 21 February 215.

According to the HBM data from the ESB, the internal exposure to DiBP remained stable between 1998 and 2008.

[94] https://www.umweltprobenbank.de/en/documents/profiles/analytes/10286

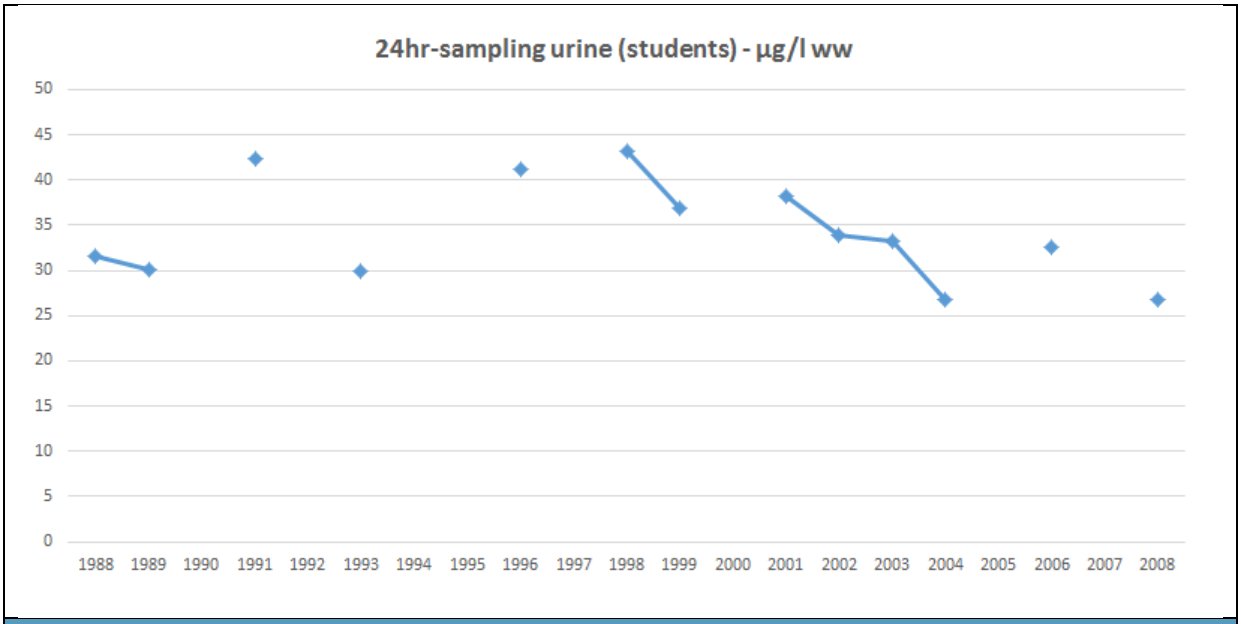


Figure 3-12: DiBP metabolite (MnBP) in 24 hours-sampling urine in Münster (Germany) – *Source: UBA Umweltprobenbank*

Butylbenzyl phthalate (BBP) has harmonised classification and labelling for reproductive toxicity (H360Df - May damage the unborn child. Suspected of damaging fertility) and acute and chronic toxicity to the aquatic environment (H400 - Very toxic to aquatic life; H410 - Very toxic to aquatic life with long lasting effects). It is also included in the list of substances with clear evidence of endocrine activity.

According to the European Union Risk Assessment Report on BBP[95], use of BBP in Europe decreased of around 50% in the period 1997 to 2004 (from 36,000 tonnes to 19,500 tonnes per year). In 2004, BBP was mainly used (95%) as plasticiser of PVC or other polymers. More precisely, 40% of the total was used as plasticisers of PVC flooring.

The marketing and use of BBP and preparations containing BBP in toys and childcare articles was prohibited in 2005 while its marketing and use in consumer products was prohibited in 2006, through the amendment of Directive on Restrictions on the Marketing and Use of Certain Substances and Preparations (76/769/EEC). Since 2005, it is also banned from cosmetic products and since 2004 from food contact materials.

In October 2008 it has been identified by the Member States Committee as a SVHC and included in the Authorisation list with the sunset date of February 2015. Uses in the immediate packaging of medicinal products are exempted from authorisation.

Legislative initiatives and non-legislative measures have contributed to a decrease of around 50% in the concentration of BBP in the urine of German students in Münster (Germany) over a 21 years period (1988-2008).

[95] ECB (2007): European Union Risk Assessment Report on Benzyl butyl phthalate (BBP), Institute for Health and Consumer Protection – Joint Research Centre, Ispra (Italy). Available at: http://echa.europa.eu/documents/10162/bad5c928-93a5-4592-a4f6-e02c5e89c299

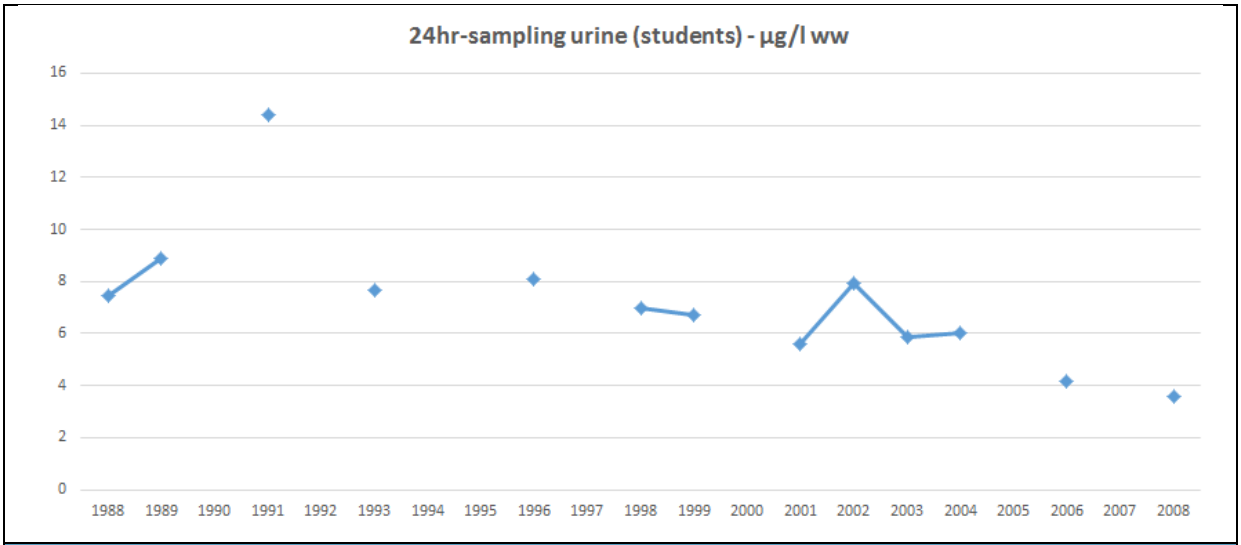


Figure 3-13: BBP metabolite (MBzP) in 24 hours-sampling urine in Münster (Germany) – *Source: UBA Umweltprobenbank*

Diisononyl phthalate (DiNP) has self-classifications for acute toxicity 4 (H332: harmful if inhaled) and acute aquatic toxicity 1 (H400). It is mainly used as plasticiser for PVC and other polymers (95% of the total volume).

In 2005, the use of DiNP (and DiDP and DnOP) has been restricted in toys and childcare articles which can be placed in the mouth by children. Following the restrictions on low molecular weight phthalates (DEHP, DBP and BBP), DiNP has become the preferred substitute for these substances, as its performance in the applications is similar to that of DEHP, with the exception of medical devices[96].

Human biomonitoring data can also be used to verify the substitution of SVHCs with safer alternatives. In the period 1988-2008, the internal exposure to DiNP has increased by a factor of 4.[97]

Göen et al (2011) note that metabolites of all five phthalates were detectable in over 98% of the urine samples, indicating the ubiquitous exposure of the German population to these substances. The authors highlight that further investigations will verify the effectiveness of the recent REACH measures (both restrictions and authorisations) on the substances.

[96] ECHA (2010): Evaluation of new scientific evidence concerning the restrictions contained in Annex XVII to Regulation (EC) no 1907/2006 (REACH), Review of new available information for di-'isononyl' phthalate (DINP). Review report. Available at: https://echa.europa.eu/documents/10162/13641/dinp_echa_review_report_2010_6_en.pdf

[97] Göen T, Dobler L, Koschorreck J, Müller J, Wiesmüller GA, Drexler H, Kolossa-Gehring M., Trends of the internal phthalate exposure of young adults in Germany--follow-up of a retrospective human biomonitoring study. Int J Hyg Environ Health. 2011 Dec;215(1):36-45. doi: 10.1016/j.ijheh.2011.07.011. Epub 2011 Sep 1. Available at: http://www.ncbi.nlm.nih.gov/pubmed/21889907

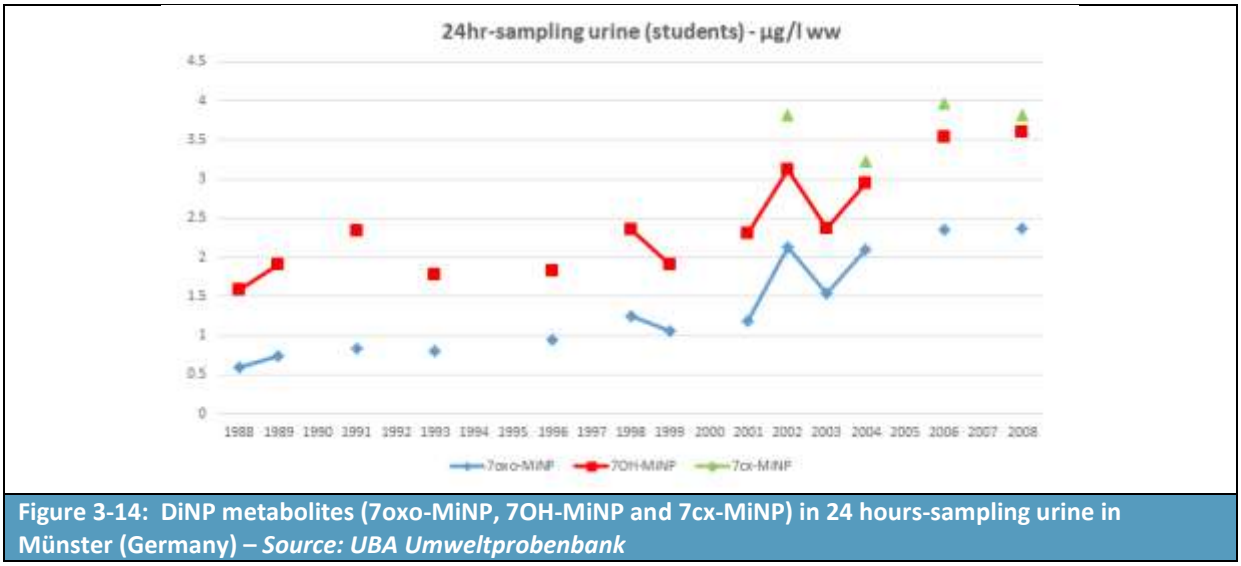


Figure 3-14: DiNP metabolites (7oxo-MiNP, 7OH-MiNP and 7cx-MiNP) in 24 hours-sampling urine in Münster (Germany) – *Source: UBA Umweltprobenbank*

Bisphenol A (BPA)

BPA has harmonised classification and labelling for skin sensitisation (H317), eye damage (H318), specific target organ toxicity (H335) and reproductive toxicity (H361f). It is also included in the list of the substances with clear evidence of endocrine activity.

BPA is mainly used in the manufacture of polycarbonates and epoxy resins, it is present in plasticisers and thermal paper and is the parent compound of the flame retardant TBBPA.[98]

A restriction submitted by France in 2014 is currently being considered by the European Commission.[99]

HBM data from the German ESB show a decrease of BPA in 24 hours-sampling urine of students in Münster (Germany) of around 35% over the period 1995-2009.

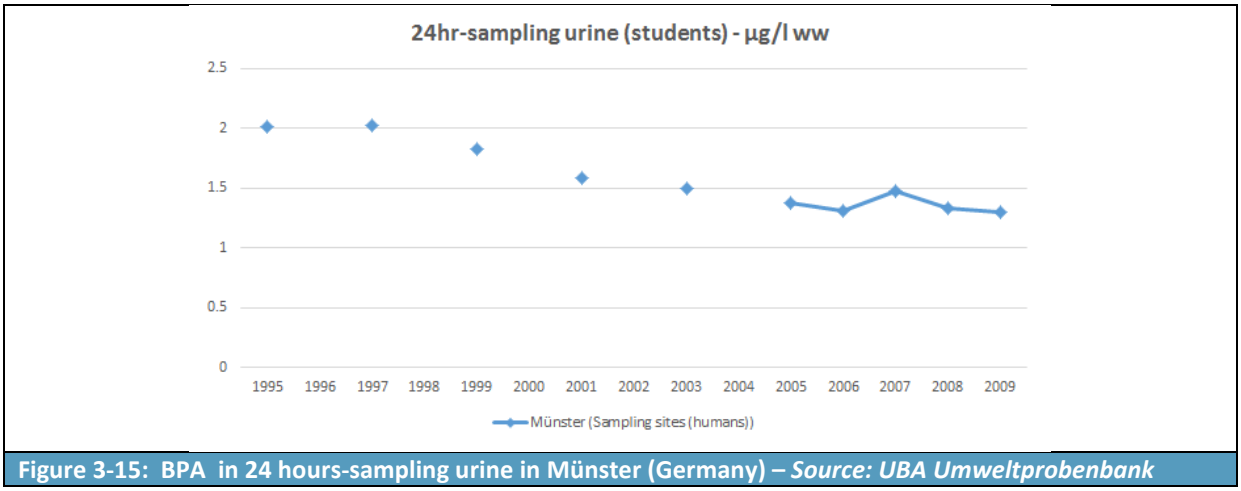


Figure 3-15: BPA in 24 hours-sampling urine in Münster (Germany) – *Source: UBA Umweltprobenbank*

[98] https://www.umweltprobenbank.de/en/documents/profiles/analytes/18564

[99] http://echa.europa.eu/view-article/-/journal_content/title/echas-committees-finalise-evaluation-of-bisphenol-a-restriction-proposal

PFOA and PFOS

Perfluorooctane sulphonate (PFOS) is a fully fluorinated anion, the related compounds of which are members of the large family of perfluoroalkyl sulphonate substances (PFAS). PFOS have harmonised classification and labelling for acute toxicity 4 (H302), eye damage (H318), carcinogenicity (H351), reproductive toxicity (H360D and H362), specific target organ toxicity (H372 – liver) and chronic toxicity to the aquatic environment (H411).

The 2004 RAR and RRS under ESR identified that, historically within the EU, former uses of PFOS had included:

- Carpets;
- Leather/apparel;
- Textiles/upholstery;
- Paper and packaging;
- Coatings and coating additives;
- Industrial and household cleaning products; and
- Pesticides and insecticides.

Consultation for the RRS suggested that use in the above applications had ceased but that use was ongoing for the following five sectors industrial and professional uses:

- Use in metal plating;
- Use in PFOS based fire-fighting foams, where these foams are held in current stocks;
- Use by the photographic industry;
- Use in semiconductors and in photolithography; and
- Use in hydraulic fluids for the aviation industry.

As a result of work on the RAR and RRS, marketing and use restrictions on PFOS under Directive 76/769/EEC were introduced by the adopting of Directive 2006/122/EC. The marketing and use restrictions can be summarised as follows:

- PFOS and related substances were banned from 27 June 2008 as substances or constituents of preparations in concentrations equal to or higher than 0.005%, in semifinished products and articles at a level of 0.1% except for textiles or coated materials in which the restricted amount of PFOS is 1 $\mu g/m^2$;
- Exemptions for some PFOS uses, as well as for the substances and preparations needed to produce them:

  - photo-resist or anti-reflective coatings for photolithography processes;
  - industrial photographic coating;
  - mist suppressants for chromium plating and other electroplating applications;
  - aviation hydraulic fluids; and

- Stocks of PFOS-based fire-fighting foams supplied on or before the date 12 months before the legislation comes into force could be used for a period of 54 months until 27 June 2011.

The EU 2004 RAR/RRS under ESR was preceded by (and initiated because of) action in the US and investigations by OECD on hazards and risks of PFOS that culminated in the major global

manufacturer (3M) announcing in May 2000 that it would phase-out the manufacture and use of PFOS voluntarily from 2001 onwards (and production ceased in 2003).

In the late 1990's, the US EPA had received information indicating that PFOS was widespread in the blood of the general population and in wildlife and presented concerns for persistence, bioaccumulation and toxicity. Following discussions between EPA and 3M, the company terminated production of these chemicals. EPA took regulator action in 2002 and 2007 to limit any future manufacture or importation of 271 PFAS chemicals, essentially encompassing all PFAS chemicals on the US market.

Findings on PFOS and PFAS led EPA to review similar chemicals to determine whether they might present similar concerns and the EPA began investigating PFOA in 1990s and found that it, too, is very persistent in the environment, is found at very low levels both in the environment and in the blood of the general US population, and causes developmental and other adverse effects in laboratory animals[100].

In May of 2009 PFOS was added to the Annex B of the Stockholm Convention and classified as a Persistent Organic Pollutant (POP). In 2012 the Chemical Review Committee of the Rotterdam convention recommended that perfluorooctane sulfonic acid, perfluorooctanesulfonates, perfluorooctanesulfonamides and perfluorooctanesulfonyls should be listed under Annex III of the Convention. These compounds are now subject to PIC under Annex III of the Rotterdam Convention.

Perfluorooctanoic acid (PFOA) have harmonised classification and labelling for acute toxicity 4 (H302), eye damage (H318), carcinogenicity (H351), reproductive toxicity (H360D and H362) and specific target organ toxicity (H372 – liver). Due to its water-repellent and fat-repellent properties, it is used in textiles, leather articles, paper and as a sealant.

PFOS is on the candidate list of SVHCs under REACH and in September 2015 RAC had adopted its opinion in support of the proposal by Germany and Norway to restrict the manufacture, manufacture and marketing of PFOA, its salts and PFOA related substances[101].

In terms of the effect of concerns and regulatory activity on PFOS (and PFOA/PFAS more widely), Figure 3-9 provides measurements of PFOS and PFOA in the blood plasma of German students from 1982 to 2010.

As can be seen from Figure 3-16, until the late 80s and early 90s, the trajectory was one of an increase in the levels of PFOS and PFOA in blood plasma where this is consistent with the wide range of historical uses of PFOS. The rising concerns associated with PFOS in the US and elsewhere (culminating in the announcement of voluntary withdrawal of the substance by 3m in 2000) produced a reduction in the number and nature of the uses with an accompanying reduction in levels detected in blood plasma. Thereupon there is a sharp reduction in levels with the announcement of and completion of cessation of production followed by a slow reduction in levels after marketing and use restrictions were put in place (2006).

[100] http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/perfluorooctanoic-acid-pfoa-perfluorooctyl-sulfonate

[101] ECHA. RAC concludes on PFOA restriction ECHA/NA/15/30: http://echa.europa.eu/documents/10162/13579/annex_to_rac_news_alert_15_september_2015.pdf

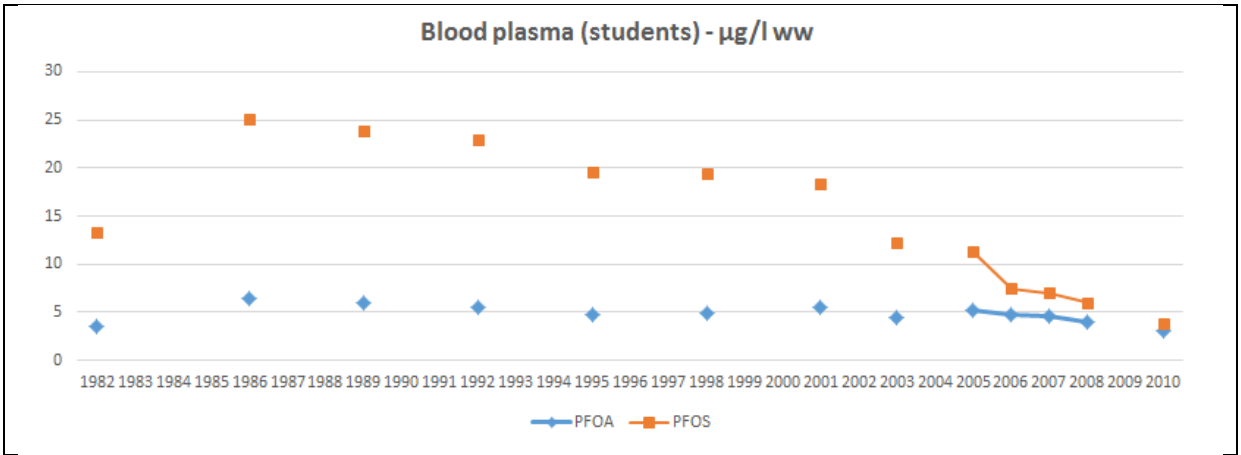


Figure 3-16: PFOA and PFOS in blood plasma in Münster (Germany) – *Source: UBA Umweltprobenbank*

Result indicator 2 – Change in the concentration level of selected chemicals in animal and plant tissues

Both the European Environment Agency and the German UBA provide interesting biomonitoring data on concentrations of selected chemicals in animal and plant tissues.

Biomonitoring data on Cadmium, Mercury, Lead, HCB, lindane, DDT, Polychlorinated biphenyls (PCB) and Benzo[a]pyrene

Data on the concentrations of these hazardous substances in marine organisms are made available by the European Environment Agency[102]. Data trends are available for the North-East Atlantic and the Baltic Sea only, while concentration values are available for the other European seas too.

As noted by the EEA, HCB, PCB, lindane and DDT are synthetic substances that are not naturally found in the environment, while cadmium, lead, mercury and polycyclic aromatic hydrocarbons, such as benzo[a]pyrene, occur naturally but human activity contribute to the general mobilisation of these pollutants. All these substances are highly toxic and tend to bioaccumulate in fish and shell fish. They are all designated as priority substances or priority hazardous substances under the Water Framework Directive and, although severely restricted or banned, they are still found in all the European seas.

In the North-East Atlantic, all concentrations in mussels and fish with exception of mercury decreased in the period 2003-2012. Concentrations of lindane and PCB have decreased in the same period in the Baltic Sea too.

[102] http://www.eea.europa.eu/data-and-maps/indicators/hazardous-substances-in-marine-organisms/hazardous-substances-in-marine-organisms-1

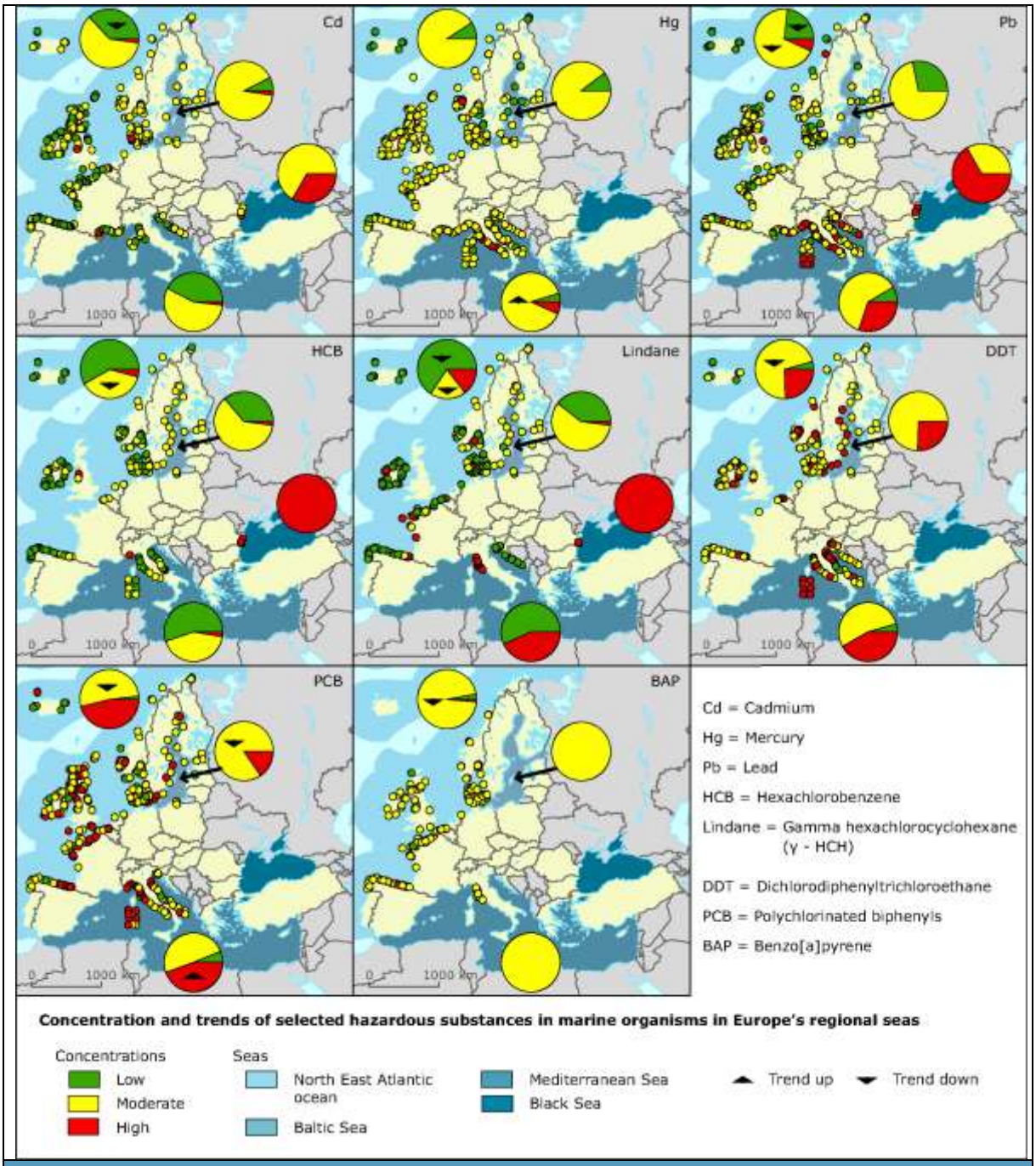


Figure 3-17: Concentrations and trends of selected hazardous substances in marine organisms (2003-2012) - *Source: European Environment Agency*

Biomonitoring data on Hexabromocyclododecane (HBCD)

HBCD has harmonised classifications of H361 (suspected of damaging the fertility of the unborn child) and H362 (may cause harm to breast-fed children). It is also classified as very toxic to aquatic life (H400) and very toxic to aquatic life with long lasting effects (H410).

HBCD's main use is as a flame retardant in Expanded and Extruded Polystyrene (EPS and XPS) insulation foam boards in the construction sector. It can also be applied in the back-coating of textiles, mainly for upholstered furniture. A minor application is in HIPS used in electrical and electronic equipment and appliances such as audio visual equipment. HBCD was placed on the

second list of priority substances under ESR in September 1995 with Sweden designated as the Member State "rapporteur". The Risk Assessment (RA) was initiated in 1996 and by 2002 a risk assessment report had been submitted for discussion by Member State authorities, industry and other stakeholders. The Risk Assessment Report (RAR) was finalised in May 2008. In 2006 the Bromine Science and Environmental Forum (BSEF) extended its voluntary programme for emissions control in textiles and also downstream uses in EPS and XPX to HBCD.

The RAR identified that by 2008 HBCD was only produced at one site in the EU15 located in the Netherlands with total annual production (in 2005) of 6,000 tons. Two other production sites were closed in the autumn of 2003 and in June 1997 respectively. It also identified that HBCD is imported to (and probably exported from) the EU both as a chemical (on its own or in formulations) and in articles. In June 2007, the Technical Committee on ESR determined that HBCD was a PBT and HBCD was added to the UN Stockholm Convention and restricted under Annex A (parties must take measures to eliminate production and use) with continued use in EPS and XPS permitted in buildings by Parties listed in the Register of Specific Exemptions. In October 2008 HBCD was identified as Substance of Very High Concern (SVHC) meeting criteria of a PBT substance under REACH and was therefore included in the candidate list for authorisation. In May 2009 HBCD was added to the list of substances subject to authorisation (Annex XIV).

German monitoring data on HBCD in herring gull eggs (provided in Figure 3-18) shows a rise in content from 1994 to 2000 followed by a decline owing to increased regulatory interest and activity in relation to the production and use of the substance in the preparation of the RAR under ESR and subsequently the decision that HBCD was a PBT (which was finally determined in June 2007). Further reduction could be anticipated owing to the inclusion of HBCD on substances subject to Authorisation under REACH in May 2009; a Decision was adopted on 8 January 2016[103] granting an authorisation to the site in the Netherlands for the use of HBCDD for two years, although the applicant is not expected to request a revision of the review period after this time since technical and economic feasible alternatives are available already on the market and that the two years period should be sufficient to undertake the substitution.

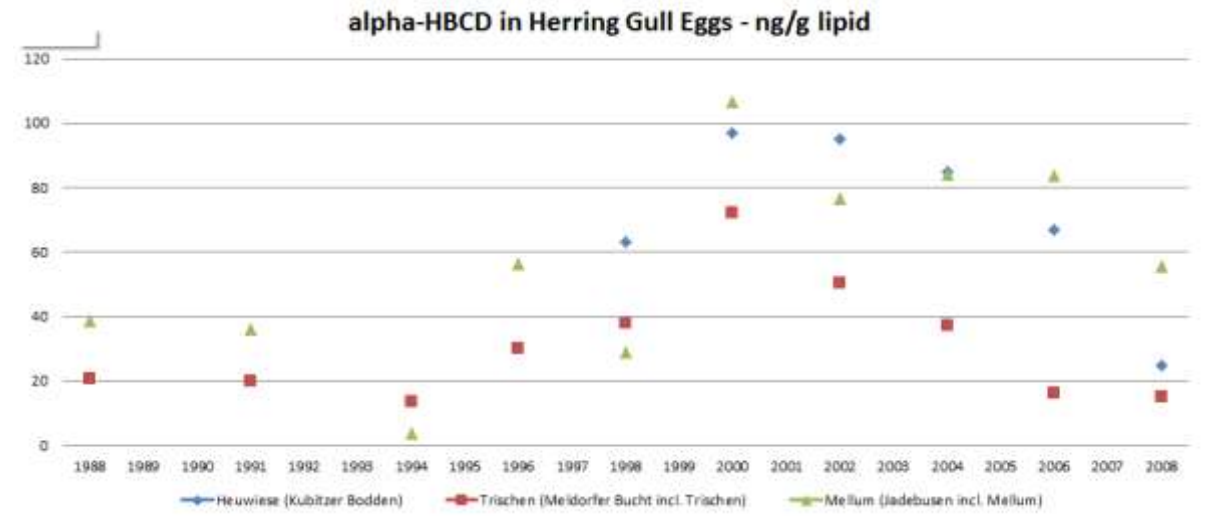


Figure 3-18: **HBCD in herring gull eggs - *Source: UBA Umweltprobenbank***

[103] http://ec.europa.eu/DocsRoom/documents/14945

Biomonitoring data on Nonylphenol (NP) and Ethoxylates (NPE)

NP has harmonised classifications of H302 (harmful if swallowed), H314 (causes severe skin burns and eye damage), H361fd (suspected of damaging fertility. Suspected of damaging the unborn child), H400 (very toxic to aquatic life) and H410 (very toxic to aquatic life with long lasting effects). It is also classified as skin corrosive (H314) and as causing serious eye damage (H318). NPE have classifications for acute toxicity (H302), skin and eye irritation (H315, H318 and H319), specific organic toxicity (H335) and aquatic toxicity (H411). Nonylphenol is included in the list of substances with clear evidence of endocrine activity (medium concern).

NP was used almost exclusively as an intermediate in the production of various NP derivatives including NPEs used in domestic and industrial cleaning agents and also production of resins plastics and stabilisers and phenolic oximes (minor use).

Owing to concerns on the effects of NP and the breakdown of NPE into NP in the environment several initiatives were introduced to reduce emissions. The most significant of these was the 1992 Paris Commission (PARCOM) commitment on the part of members to "take concerted action within the framework of the competent international forums to substitute the use of the following substances (with the list including NPs, NPEs and related substances) by less hazardous or preferably non-hazardous substances where these alternatives are available".

Under PARCOM Recommendation 92/8, contracting parties agreed (amongst other things) that the use of NPEs as cleaning agents for domestic uses be phased out by 1995 and for industrial uses by 2000.

Efforts to develop the PARCOM recommendation towards a binding decision were postponed pending the completion of work on the RAR and Risk Reduction Strategy (RRS) under ESR. The final RRS was completed in 1999 by which time significant reductions in use of NPEs had already occurred owing to the activity of contracting parties under PARCOM and other initiatives such that, by 1999 virtually all domestic uses of NPE based cleaning products had been phased out.

In a report to PARCOM in March 1998, the Swedish EPA summarised actions taken within Member States which can be summarised as follows:

- Austria - not used;
- Belgium - use of NPEs in domestic cleaning products phased out by 1995. Use of NPEs in industrial cleaning products reduced and industry committed to a phase out of use by 2000;
- Denmark - In 1998 there was no consumption of NPEs among trade association members in Denmark;
- Finland - In 1994, use was estimated at 7.4t, declining to 0.6t in 1996;
- Germany - By 1995, virtually all domestic use of alylphenol ethoxylates (APEs) in detergents had been phased out and use in industrial cleaning agents reduced by about 90% from around 11,000 tpa in 1986 to around 1,000 tpa in 1997;
- Netherlands - NPEs had not been used in household cleaning agents since 1988. Use in industrial cleaning had been substantially diminished.
- Spain - steps to replace NPEs with other surfactants, and substitution should be completed in 1998
- Sweden - initiatives to phase out NPEs began in 1972, when their use ceased in household detergents. In the late 1980s it was agreed that the use of NPEs in industrial and

institutional cleaning products would be reduced by 90% between February 1989 and January 1991. In 1992, use of NPEs in other household cleaners was phased-out.

- UK - in 1976 when it was agreed to phase out the use of NPEs in domestic cleaning products. In 1996-97, there was an agreement to remove all APEs from industrial and institutional detergents by 1998.

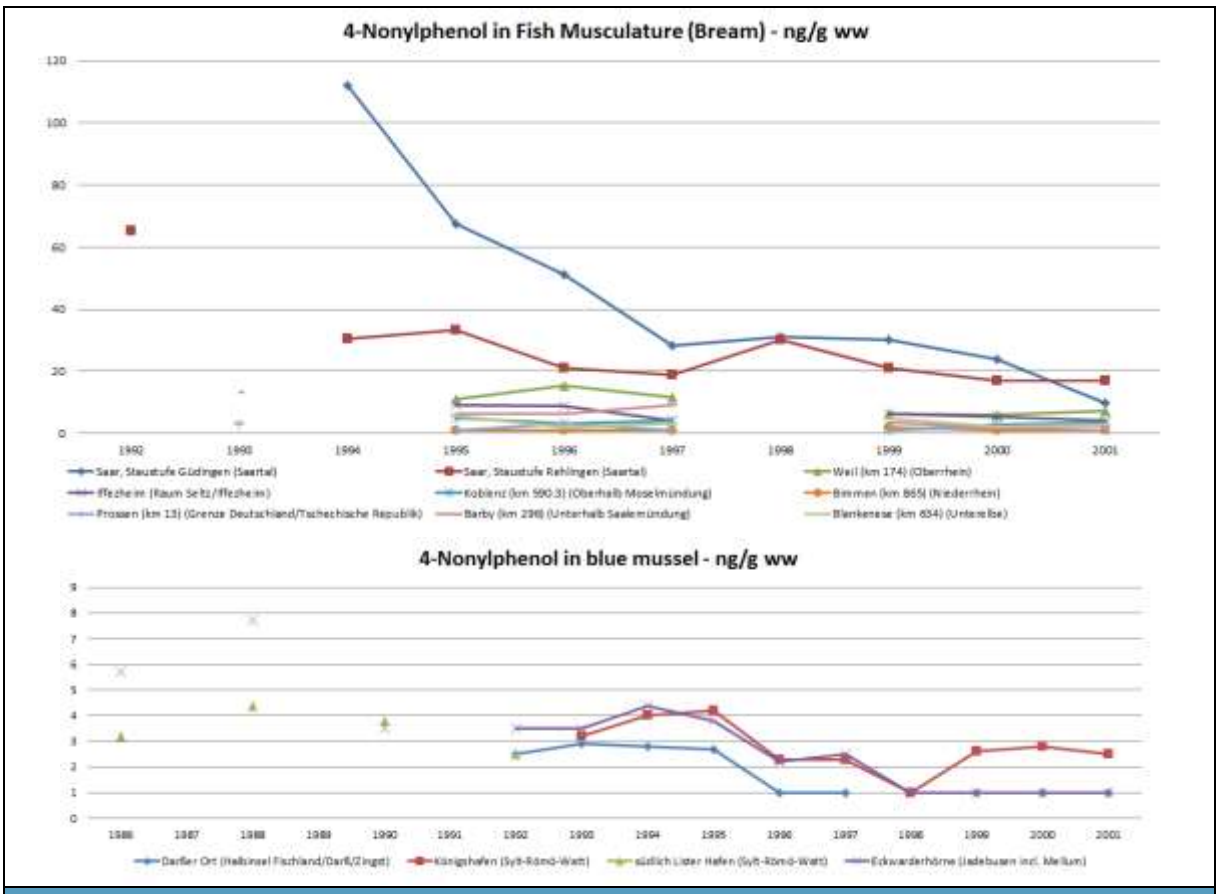


Figure 3-19: Nonylphenol in fish musculature (bream) and blue mussel soft body tissue - *Source: UBA Umweltprobenbank*

Based on the risks identified in the RAR under ESR all isomers (linear and branched) of nonylphenol and their ethoxylates were included in the list of substances subject to restriction under REACH (Annex XVII) by 2009. In April 2015 NP work on a PACT RMOA for PBT was initiated.

The effect of actions taken in Germany following the 1992 PARCOM recommendation and subsequent regulatory activity are clearly visible in monitoring data for both NP and NPE. Figure 3-19 and Figure 3-20 provide data on measurements of NP and NPE respectively in fish musculature and blue mussel soft tissue (for NP). The timing and level of reductions is broadly consistent with the phase out of domestic use of alkylphenol ethoxylates (APEs) in detergents by 1995 and the 90% reduction in industrial use from 1986 to around 1997.

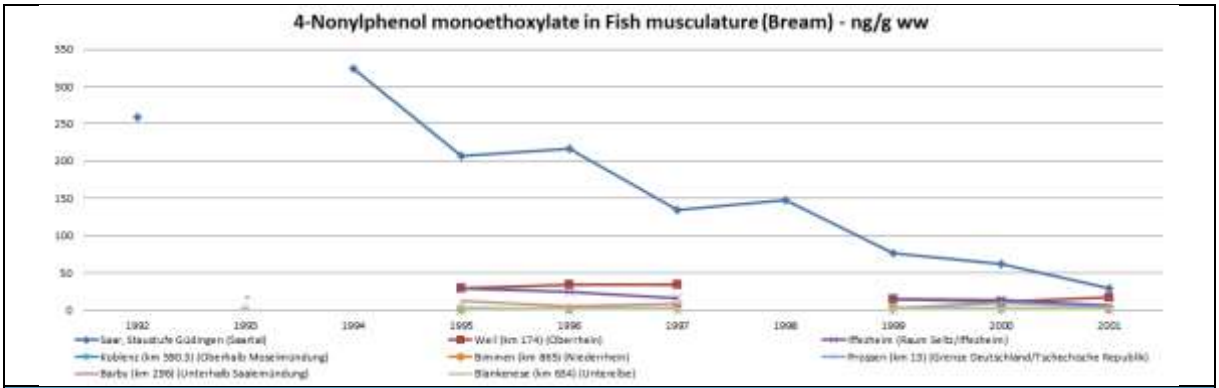


Figure 3-20: NPE in fish musculature (bream) - *Source: UBA Umweltprobenbank*

Biomonitoring data on Hexachlorobenzene (HCB)

As regulation has been in force for some time, HCB biomonitoring data is of limited interest as an ongoing indicator. However, in spite of the PBT properties of HCB, the German biomonitoring data in Figure 3-21 and Figure 3-22 illustrates the impact of regulatory activity on HCB since the mid-1980s to near the present day. These trends are confirmed by the data published by the EEA[104].

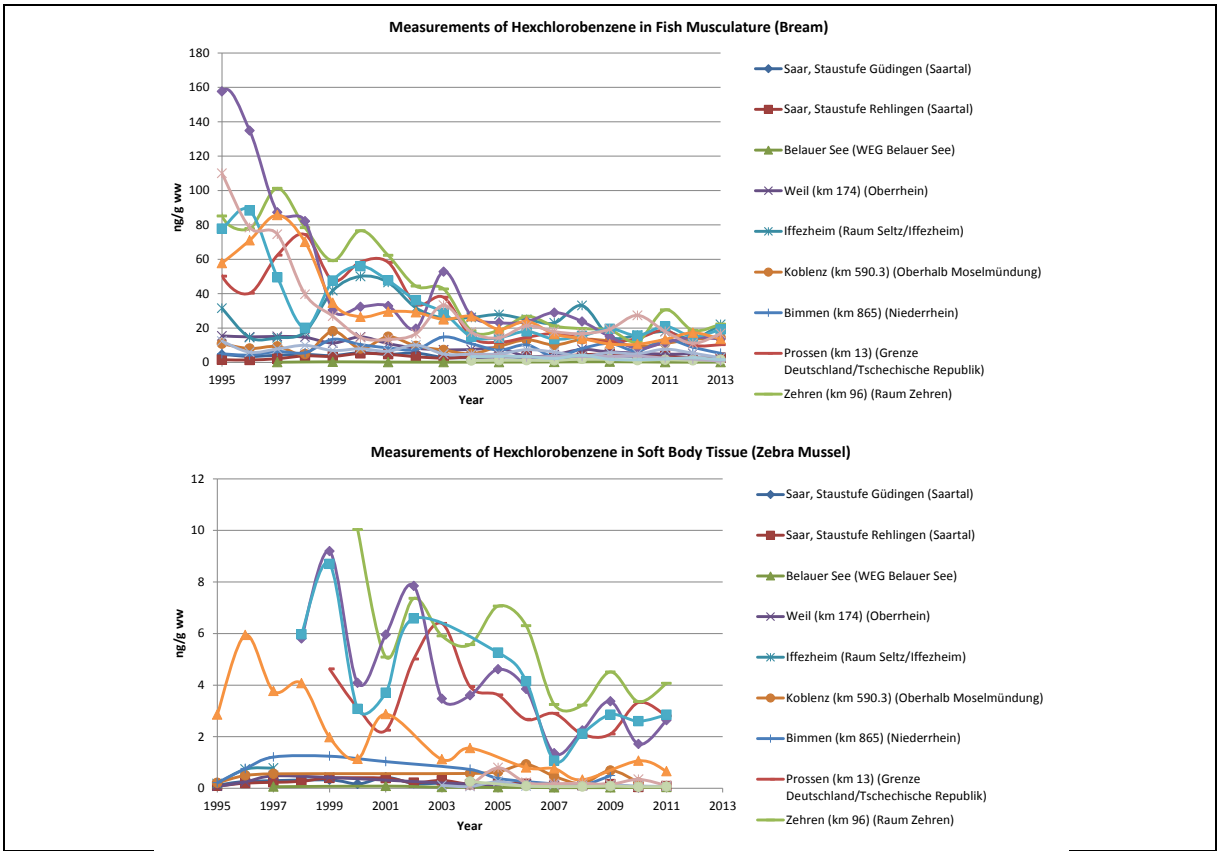


Figure 3-21: German biomonitoring data on HCB in fish and shellfish body tissue - *Source: UBA Umweltprobenbank*

104 http://www.eea.europa.eu/data-and-maps/indicators/hazardous-substances-in-marine-organisms/hazardous-substances-in-marine-organisms-1

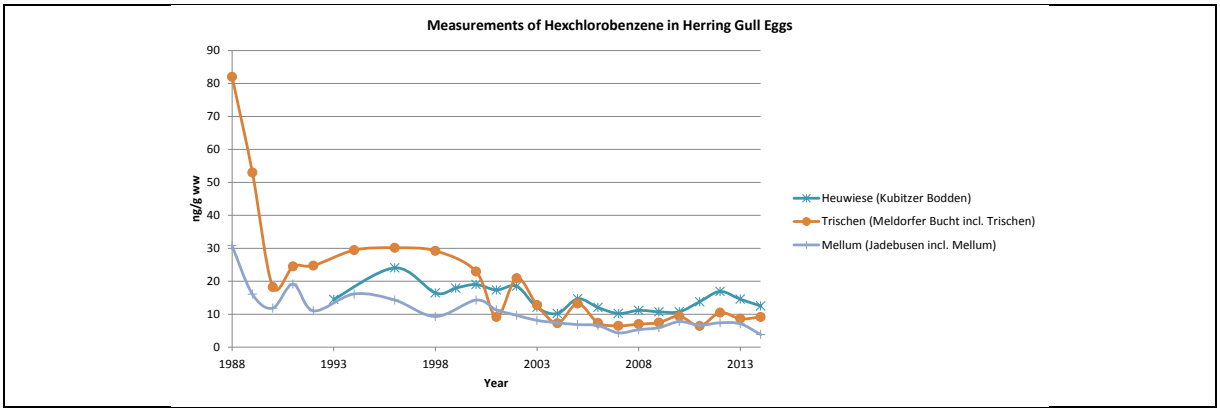


Figure 3-22: German biomonitoring data on HCB in Herring gull eggs - *Source: UBA Umweltprobenbank*

Biomonitoring data on methylmercury

Methylmercury is a reaction by-product. It is most commonly released as a result of burning waste containing inorganic mercury or the burning of fossil fuels.

Point sources of CH_3Hg include:

- Coal-fired power stations;
- Coal-fired industrial boilers;
- Smelting and roasting processes used in the production of non-ferrous metals;
- Waste incineration facilities;
- Cement clinker production facilities.

Various regulatory instruments on methylmercury have been in place for some time (e.g. Minamata and Basel Conventions). Biomonitoring data on methylmercury are of limited interest, owing to the persistent and bioaccumulative nature of the substance. Levels in the biomonitoring data broadly oscillate around a constant but perhaps slightly declining level. There is no increase however (which is the most that one could expect from regulating uses/emissions given the properties of methylmercury).

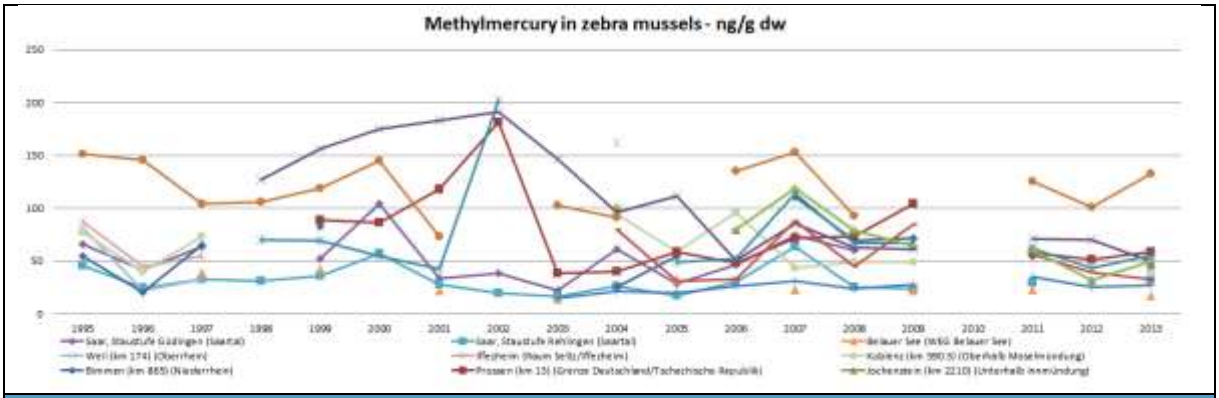


Figure 3-23: German biomonitoring data on methylmercury in shellfish - *Source: UBA Umweltprobenbank*

Biomonitoring data on tributyltin and triphenyltin

Tributyltin has harmonised classifications of H301 (toxic if swallowed), H312 (Harmful in contact with skin), H315 (causes skin irritation), H319 (causes serious eye irritation), H372 (causes damage to organs), H400 and H410 (very toxic to aquatic life and very toxic to aquatic life with long lasting effects). Triphenyltin compounds have harmonised classifications for H301 (toxic if swallowed), H311 (toxic in contact with skin), H331 (toxic if inhaled), H400 and H410 (very toxic to aquatic life and very toxic to aquatic life with long lasting effects).

Tributyltin and Triphenyltin were used as pesticides and tributyltin mainly as biocide in anti-fouling paints for ship hulls and appliances and equipment submerged in coastal or marine environments.

Tributyltin is still used in material and wood preservatives as a slimicide.

Various (and International) regulatory instruments have been in place for some time (Rotterdam Convention, Annex XVII of REACH) and the German biomonitoring data suggests a significant decline overall since data collection began but there is no data post 2003-2005.

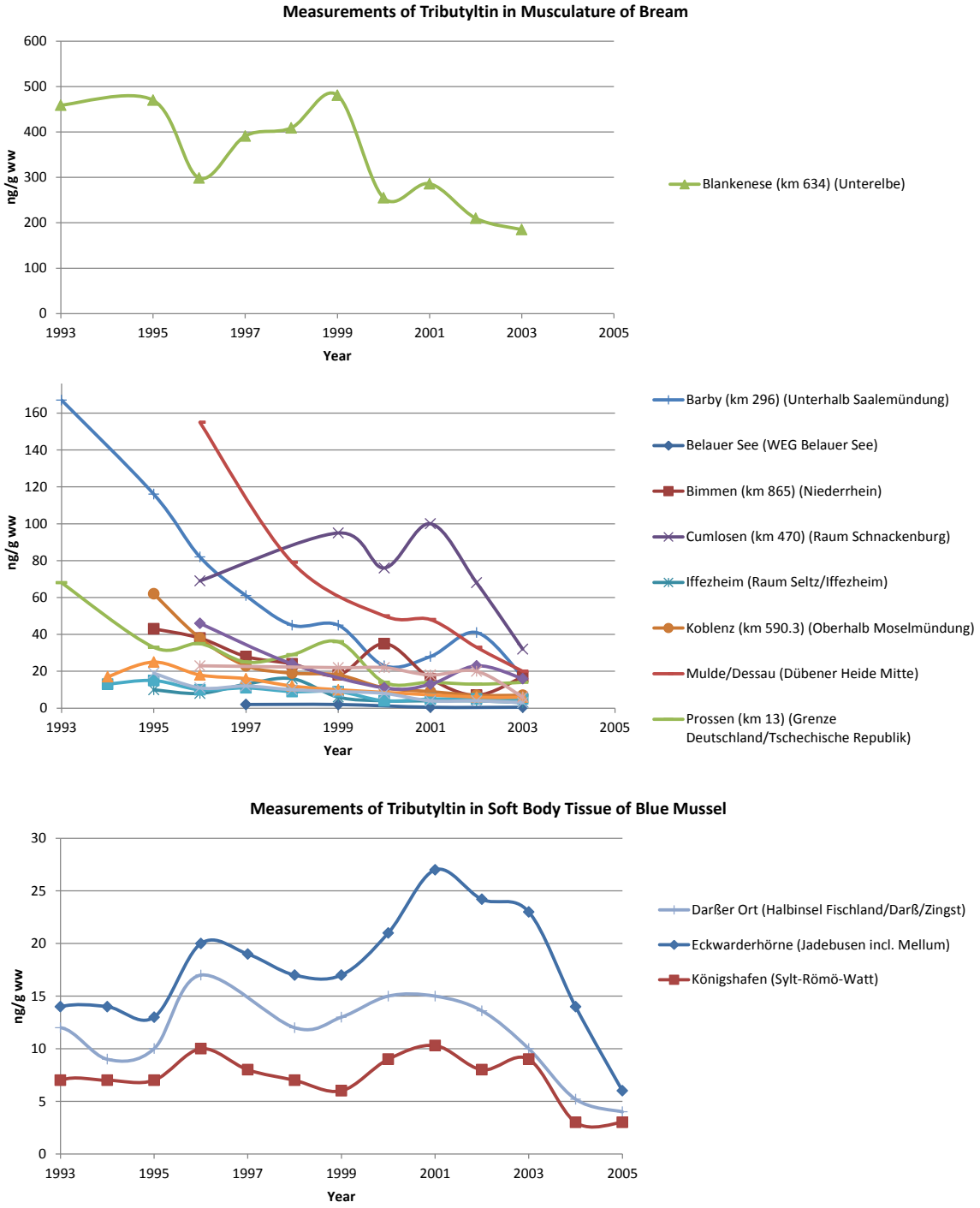


Figure 3-24: German biomonitoring data on tributyltin in fish and shellfish - *Source: UBA Umweltprobenbank*

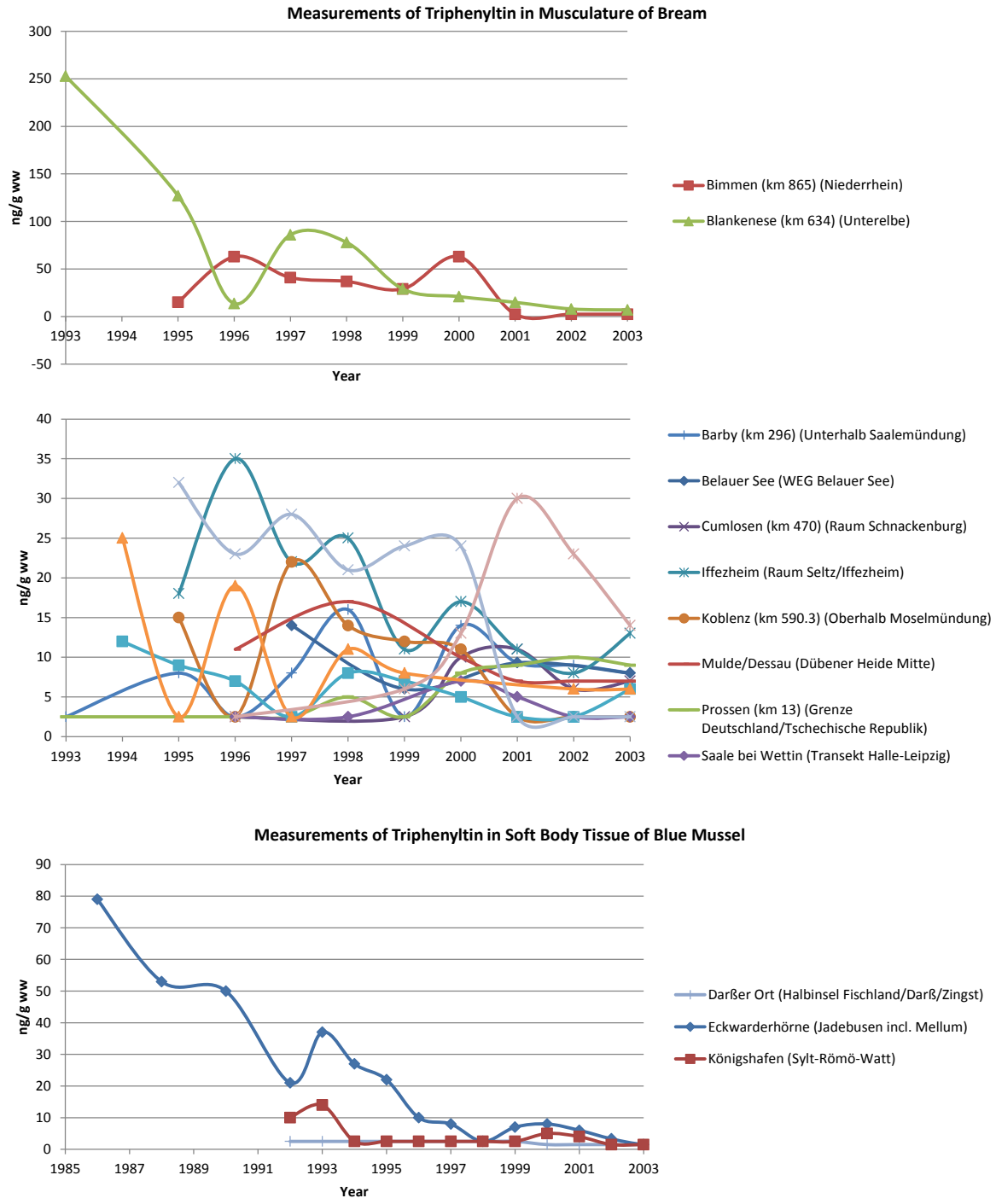


Figure 3-25: German biomonitoring data on triphenyltin in fish and shellfish - *Source: UBA Umweltprobenbank*

Result indicator 3 – Change in the concentration level of selected chemicals in air, water and soil samples

With regard to the result indicator 3, the possibility to use the results of the monitoring programme required by the Water Framework Directive was explored. The WFD monitoring programme results have the advantage of being more easily linked to chemicals legislative action, as the classification of

substances with respect to environmental hazards is based on aquatic chronic and acute toxicity. A comparison of the water chemical status across Europe available from the first and second round (and future rounds) of River Basin Management Plans (RBMPs) could be carried out and the change monetised using WTP values for the improvement of the water status by European citizens, thus enabling the estimation of the benefits of chemicals legislation. Unfortunately, the second round of RBMPs is not yet published. Moreover, during the Experts Workshop (see Section 5), it was noted that the information from the WFD monitoring programme cannot be used to inform a system of indicators in the short-medium term, as water sampling and analysis methods have changed between the sampling periods and differ by location and Member State. Moreover, the frequency of the sampling does not guarantee that anomalous results (due to, for example, floods or storms provoking the recirculation of pollutants in the sediments) are treated accordingly.

In terms of concentrations of chemical substances in air, monitoring is usually carried out on main urban pollutants such as particulate matters (PM2.5 and PM10), nitrogen dioxide, ozone, benzo[a]pyrene and sulphur dioxide.

With regard to soil, samples are usually analysed for heavy metals, mineral oil, PAHs, aromatic hydrocarbons, chlorinated hydrocarbons, phenols and cyanides, in particular in sites where contamination has occurred.

The German ESB holds data on the concentration of different metals, non-metals, chlorohydrocarbons and polycyclic aromatic hydrocarbons in the suspended particulate matter (limnetic samples), in the organic layer/root network, in the topsoil and subsoil for different locations in the country. Some examples are presented below for illustrative purposes.

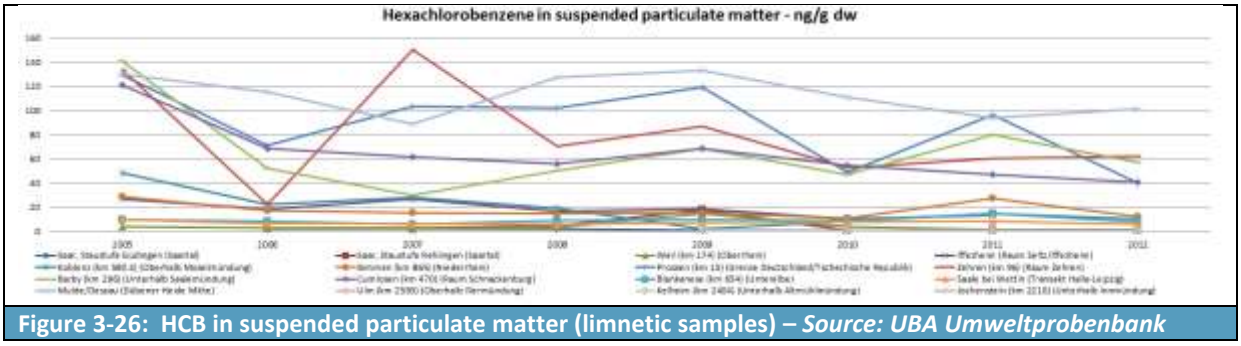
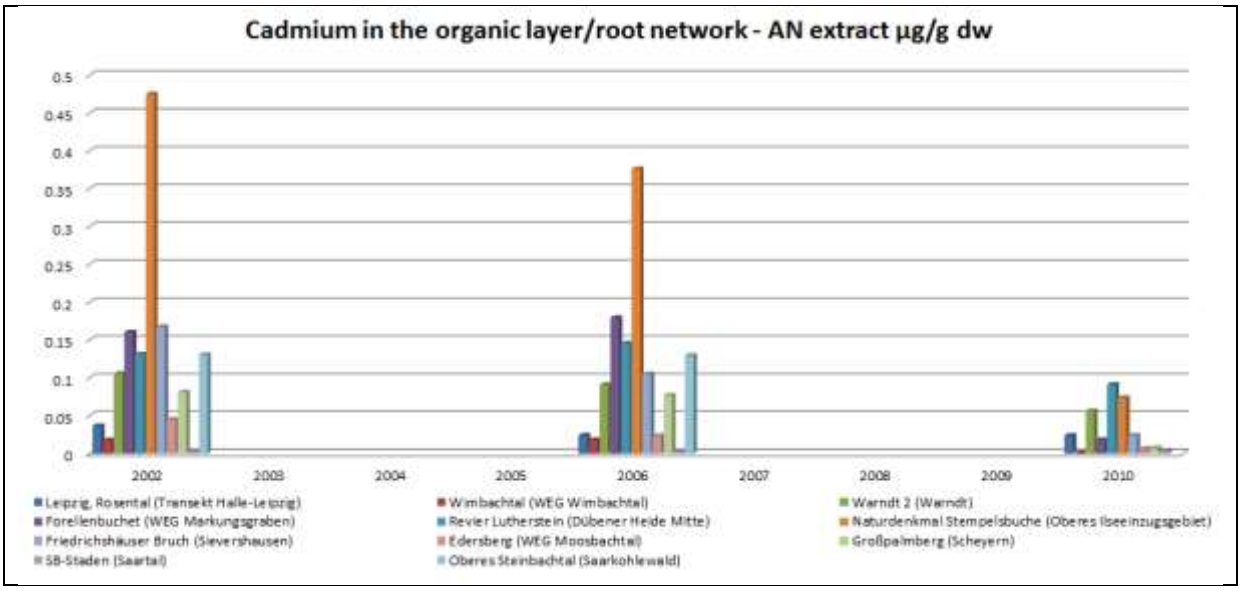


Figure 3-26: HCB in suspended particulate matter (limnetic samples) – *Source: UBA Umweltprobenbank*



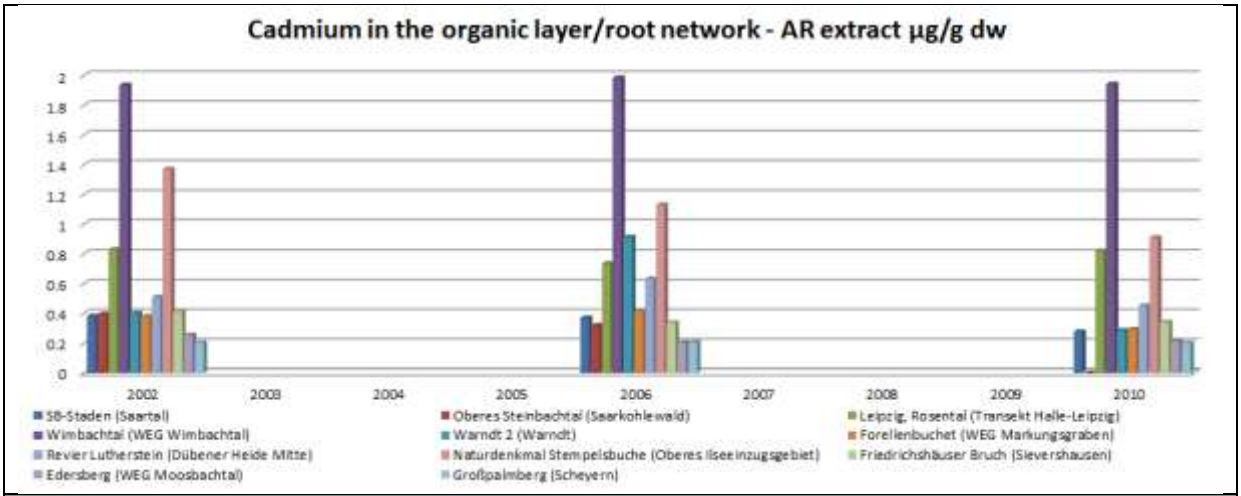


Figure 3-27: Cadmium in the organic layer/root network in 11 locations in Germany (two decomposition methods: AN extract and AR extract) – *Source: UBA Umweltprobenbank*

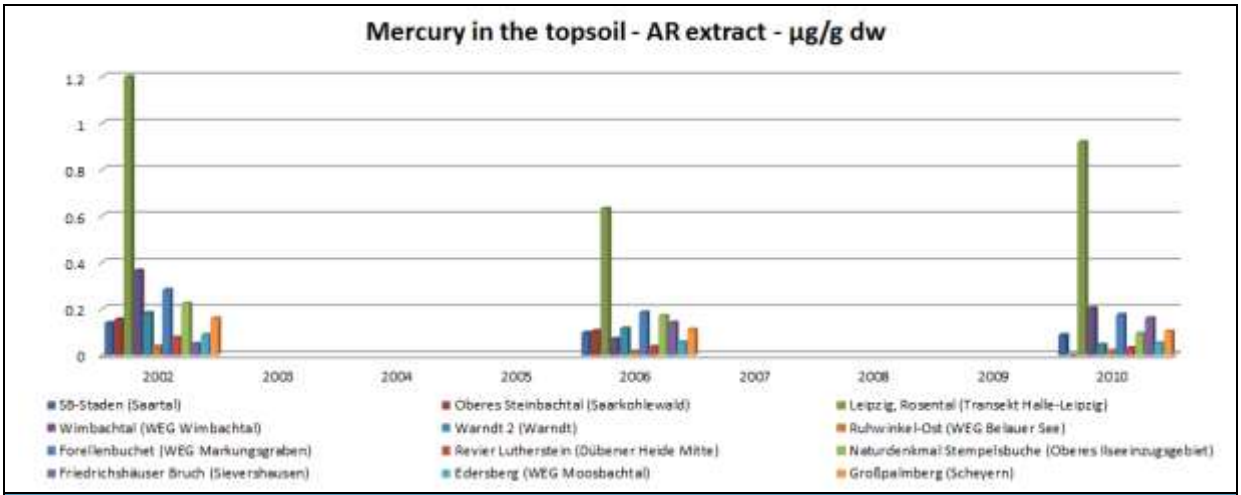


Figure 3-28: Mercury in the topsoil in 12 locations in Germany (decomposition method: AR extract) – *Source: UBA Umweltprobenbank*

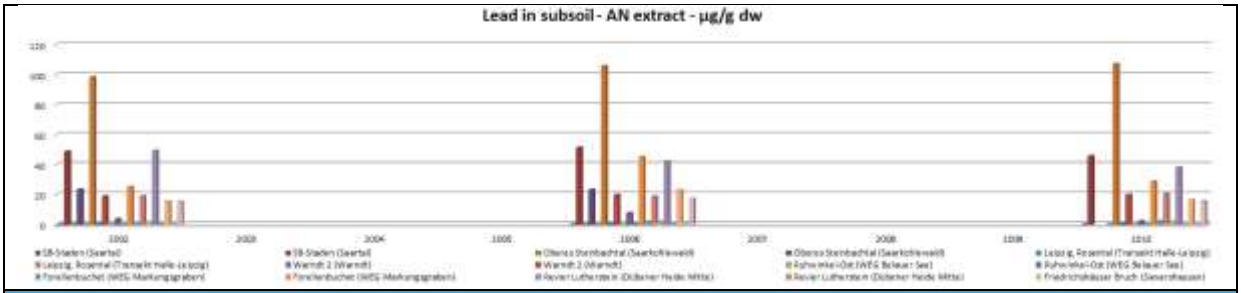


Figure 3-29: Lead in subsoil in 15 locations in Germany (decomposition method: AN extract) – *Source: UBA Umweltprobenbank*

Result indicator 4 – Change in emissions of selected chemicals in air, water and soil

Data for the result indicator 4 are available at European level through the E-PRTR maintained by the EEA for the period 2007-2013. Releases and transfers of the pollutants reported are mainly regulated by the Industrial Emissions Directive and the indicator is sensitive to variations in the macroeconomic situation.

The indicator may provide some indications on the effectiveness of the chemicals legislation, in particular of the IED and of the different sectorial legislative acts regulating specific chemicals.

Another source of information is the European Environment Agency.

Emission trends of persistent organic pollutants

The European Environment Agency has developed the indicator "*Persistent organic pollutants emissions*"[105]. The indicator reports the changes in anthropogenic emissions to air of POPs against the baseline year 1990 and covers the EEA-33 country grouping (EU27 plus Iceland, Liechtenstein, Switzerland, Norway and Turkey). It currently reports on hexachlorobenzene, hexachlorocyclohexane, polychlorinated biphenyl, dioxins and furans and PAHs.

POPs have been strictly regulated at international level by a number of legislative measures (the UNECE Convention on Long-range Transboundary Air Pollution, 1998 Aarhus Protocol on Persistent Organic Pollutants, 2001 Stockholm Convention, Directive 2001/80/EC on the limitation of emissions of certain pollutants to the air from large combustion plants, Directive 2008/50/EC on ambient air quality and cleaner air for Europe, the Water Framework Directive, the Industrial Emissions Directive). As a result, emissions have consistently decreased during the last 25 years (Figure 3-30).

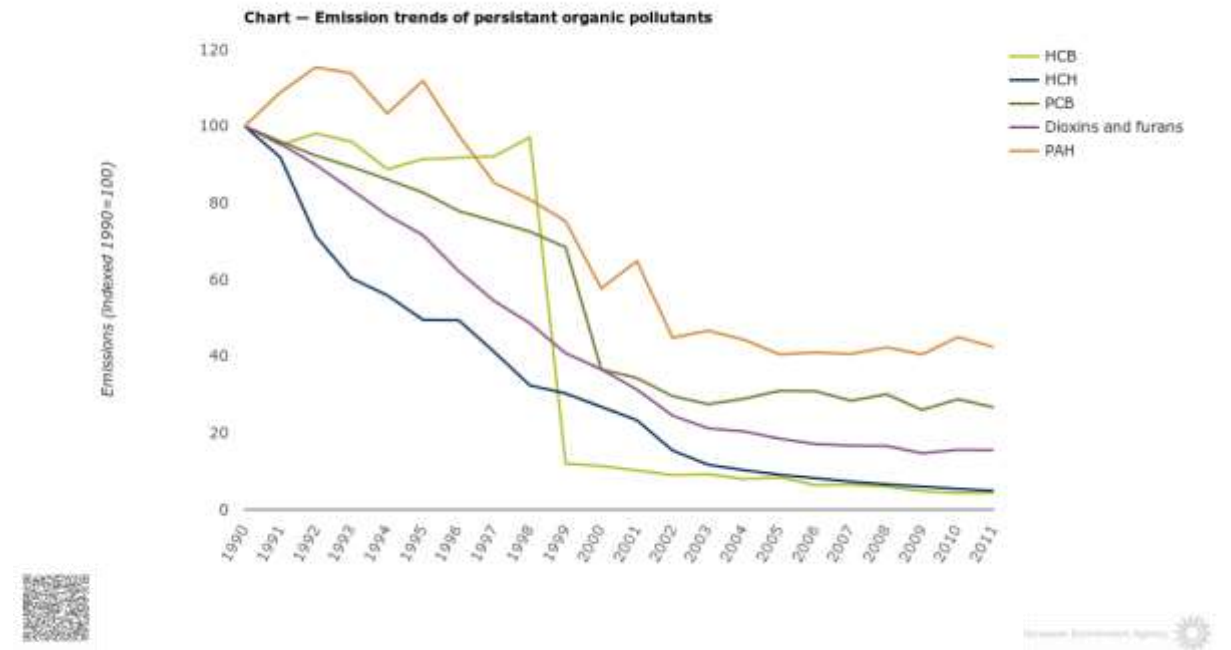


Figure 3-30: Emission tends of POPs (1990-2011) - *Source: European Environment Agency*

Result indicator 5 – Change in production volume of selected chemicals

Data to inform result indicator 5 are not easily collected. Although Eurostat provides statistics on the total production of certain chemicals and group of chemicals (PRODCOM list), the information is too

[105] http://www.eea.europa.eu/data-and-maps/indicators/eea32-persistent-organic-pollutant-pop-emissions-1/assessment-4

aggregated. Ideally, as suggested during the Experts Workshop, information should be collected by CAS number. The indicator is very sensitive to changes in the macroeconomic situation. Any judgement on the effectiveness of the chemicals legislation based on information on the production volumes of specific chemicals, especially for the baseline period 2004-2013, needs to consider the effect of the 2007-2009 economic crisis.

Production of hazardous substances

Eurostat developed two indicators based on industrial production statistics, one focusing on the potential human health impact of some hazardous substances (and included among the Sustainable Development Indicators) and the other one focusing on the potential impacts of toxic chemicals on the aquatic environment:

- Production of toxic chemicals, broken down by toxicity class;
- Production of environmentally harmful substances.

The toxicity classes, as explained in Section 2.3.3, have been derived from the risk phrases (Annex 6 of the old Dangerous Substance Directive, now repealed by CLP) assigned to the substances. As clear from Figure 3-31 and as reiterated by Eurostat, the indicators defined on production volumes can hardly be used as indications of changes in exposure to chemicals or as proxies of the effects of the chemicals legislation. All the trends for the different toxicity classes follow the same pattern of the trend for the total EU production of chemicals, characterised by a significant decrease in coincidence with the 2007-2009 economic crisis, followed by a moderate recovery in 2010 and a general light reduction in production levels between 2010 and 2013. This downward trend may be capturing the shift of manufacturing of chemicals to Asia.

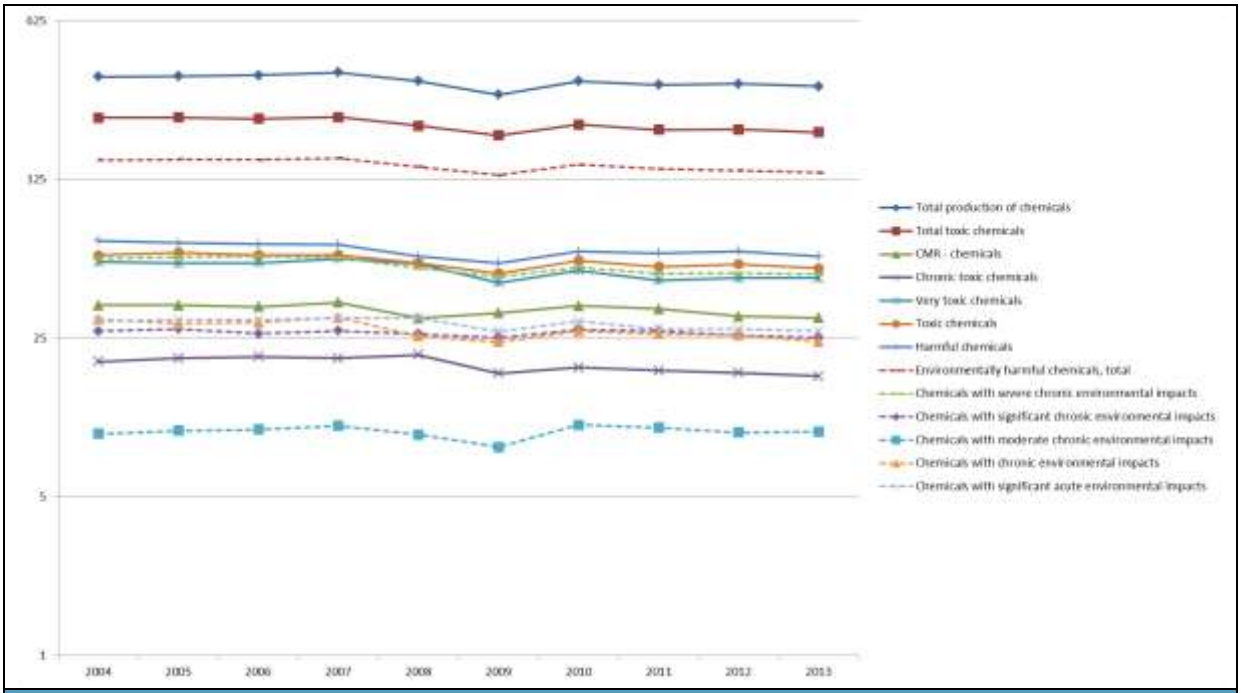


Figure 3-31: Production of toxic chemicals and of environmentally harmful substances (2004-2013) (million tonnes - logarithmic scale) – *Source: Eurostat*

Conclusions

Table 3-13 summarises the average changes (in percentage) of the concentration of specific chemicals in Germany in different samples (human, animal and plant tissues, soil samples).

Table 3-13: Summary of the average changes (in percentage) of the concentration of specific chemicals in Germany in different samples (human, animal and plant tissues, soil samples)

Substances	Sample	Average Δ %	Period
Cadmium	Whole blood (Students) – µg/l ww	+33%	2000-2009
	Saliva (Students) – ng/l ww	-58%	1995-2004
	Scalp hair (Humans) – ng/g ww	-75%	1995-2004
	Pubic hair (Students) – ng/g ww	-83%	1995-2004
	Organic layer/root network – AN extract µg/g dw	-75%	2002-2010
	Organic layer/root network – AR extract µg/g dw	-11%	2002-2010
Mercury	Whole blood (Students) – µg/l ww	-57%	2001-2010
	24h-sampling urine (Students) - µg/l ww	-92%	1995-2013
	Topsoil – AR extract - µg/g dw	-30%	2002-2010
Lead	Whole blood (Students) – µg/l ww	-58%	1995-2013
	Whole blood (Students - Münster) – µg/l ww	-85%	1981-2013
	Pubic hair (Students) – µg/g ww	-62%	1995-2004
	Scalp hair (Students) - µg/l ww	-57%	1995-2004
	Subsoil – AN extract - µg/g dw	+3%	2002-2010
Hexachlorobenzene	Blood plasma (Students) - µg/l ww	-79%	1995-2010
	Suspended particulate matter – ng/g dw	-66%	2005-2012
Pentachlorophenol	24h-sampling urine (Students) - µg/l ww	-92%	1995-2010
	Blood plasma (Students) - µg/l ww	-87%	1995-2010
PCB138	Blood plasma (Students) - µg/l ww	-81%	1995-2010
PCB153	Blood plasma (Students) - µg/l ww	-66%	1995-2010
PCB180	Blood plasma (Students) - µg/l ww	-68%	1995-2010
Phthalates			
DEHP	24h-sampling urine (Students) - µg/l ww	-67%	1988-2008
DINP	24h-sampling urine (Students) - µg/l ww	+67%	1988-2008
BBP	24h-sampling urine (Students) - µg/l ww	-52%	1988-2008
DnBP	24h-sampling urine (Students) - µg/l ww	-90%	1988-2008
DiBP	24h-sampling urine (Students) - µg/l ww	-15%	1988-2008
Bisphenol A	24h-sampling urine (Students) - µg/l ww	-36%	1995-2009
PFOA	Blood plasma (Students) - µg/l ww	-13%	1982-2010
PFOS	Blood plasma (Students) - µg/l ww	-71%	1982-2010
Hexabromocyclododecane	Herring Gull Eggs – ng/g lipid	+8%	1988-2008
Nonylphenol	Fish musculature (Bream) – ng/g ww	-65%	1995-2001
	Soft body (Blue mussel) – ng/g ww	-47%	1992-2001
Nonylphenol ethoxylates	Fish musculature (Bream) – ng/g ww	-70%	1995-2001
Methylmercury	Soft body (Zebra mussel) – ng/g dw	-33%	1995-2013
	Soft body (Blue mussel) – ng/g ww	-20%	1992-2013
Tributyltin	Fish musculature (Bream) – ng/g ww	-73%	1995-2003
	Soft body (Blue mussel) – ng/g ww	-50%	1992-2005

Source: Own elaboration on German ESB data

Almost all the data in the German ESB refer to substances with regulation spanning across one or more decades. Nevertheless, they provide indications on how the regulatory pressure and other factors such as technological progress, voluntary initiatives, increased consumers' awareness, research and development of suitable alternatives, have contributed in lowering the exposure to hazardous chemicals. The data also help in identifying potential issues with the persistence and bioaccumulation of certain substances in different samples (e.g. cadmium in whole blood, lead in

subsoil). Human biomonitoring data can also be used to verify the substitution of certain hazardous chemicals with less (or not) hazardous substances (e.g. substitution of DEHP, DBP and BBP with DiNP).

3.4.4 Impact Indicators

Introduction

The aim of impact indicators is to provide a measure of the consequences of a legislative act beyond its direct interaction with the recipients. Within the context of this study, this has been interpreted as moving from changes in exposures to changes in effects, either in terms of chemicals related diseases or chemicals related impacts on environmental ecosystems and biota.

Health and environmental outcomes are the results of the synergies of multiple factors (see for example: Tomasetti and Vogelstein, 2015)[106] and scientists have tried to quantify the effects of exposures to chemicals for several decades. In 1981 the Institute of Medicine developed a new methodology to estimate the "attributable fraction" of the environment to causation of illness, where "*attributable fraction"* is intended as *"the percentage of a particular disease category that would be eliminated if environmental risk factors were reduced to their lowest feasible concentrations*".

Studies have been undertaken to try and establish the role of chemical exposures as environmental risk factors (e.g. Murray and Lopez, 1997 and Prüss Üstun, 2011), with this work leading to estimates of the burden of disease attributable to chemical exposures. Knowing the attributable fraction, the disease rate, the population size and the cost per case, it is possible to calculate the attributable costs, where these refer to discounted lifetime expenditures attributable to a particular disease, expressed in terms of health care costs, the costs of rehabilitation and lost productivity, as well as the "human" or intangible costs of illness (i.e. individual's willingness to pay to avoid a disease or a day's illness).

Following such an approach impact indicators can be defined as those that reflect a:

- Change in incidence, prevalence and mortality following a change in chemicals' exposure due to chemicals legislation requirements per disease group;
- Change in environmental impacts (defined on ecosystem services or number of species) following a decrease in exposures due to chemicals legislation requirements.

However, only the impact indicator on human health has been carried forward for the monetisation of the benefits and for two occupational health endpoints only. Statistics on the incidence of occupational diseases caused by some specific chemicals in Germany are also presented for illustrative purposes. With regard to the indicator on the environmental impacts, a discussion on the methodology followed and on the data needs to develop a meaningful indicator is provided below.

Change in incidence, prevalence and mortality following a change in chemicals' exposure due to chemicals legislation requirements per disease group

The indicator has been classified using the screening criteria and the "classification card" is presented in Annex 3.8.3.

[106] Tomasetti C. and Vogelstein B. Cancer etiology. Variation in cancer risk among tissues can be explained by the number of stem cell divisions. Science. 2015 Jan 2;347(6217):78-81. doi: 10.1126/science.1260825

The main issue in defining impact indicators is the availability of suitable datasets (at national and, most importantly for this study, at European level) to quantify the chemicals' attributable fractions and the availability of historic data trends to assess the effects of chemicals legislation.

As presented in Section 2.3.4, human health statistics relative to the European Union are available from different sources (i.e. WHO, OECD and Eurostat). However, changes in the health statistics at national population level, as recorded by these organisations, depend on a large number of factors such that the effects of the chemicals legislation cannot be singled out. Occupational health and safety statistics are more likely to register changes in health outcomes due to the reduction of the exposure to chemicals thanks to the implementation of risk management measures required by the legislation. The project team identified two national OSH databases (the UK HSE and the German DGUV) reporting systematically the causative (chemical) factors for certain occupational diseases, namely occupational dermatitis and occupational asthma. DGUV reports also suspected and recognised cases of occupational diseases caused by some specific chemical compounds.

With regard to skin diseases and asthma, health practitioners can attribute these outcomes to the exposure of certain chemical substances with a certain degree of certainty because of their short latency. Data from the UK HSE and the DGUV have been used to populate the indicator for these two health end-points and the results are presented in Section 4.

With regard to attribution to specific chemicals, this is possible for certain groups of workers particularly exposed to chemicals which hazardous properties are well studied and known. For long latency diseases (e.g. chronic obstructive pulmonary diseases, cancers), attribution is more complex[107] and requires assumptions such that nullify the value of any indicator trying to measure the marginal contribution of chemicals legislation in lowering exposure. Although relative risks[108] to develop cancer due to high level of exposure to particular substances have been estimated, data are also necessary on the proportion of the population ever exposed to each carcinogenic agent in the risk exposure period (REP). Rushton et al (2012) use a latency of 10-50 years for solid tumours and 0-20 years for haematopoietic[109] neoplasms; for the baseline period 2004-2013 would mean respectively a REP of 1954-2003 and 1984-2013. In order to estimate the population exposed during these exposure periods, the authors used a range of datasets and assumptions relevant for Great Britain that would not be valid at European level.

DGUV presents statistics on malignant neoplasms caused by specific chemicals too, but statistics on incidence, prevalence and mortality reflect past exposure (e.g. the time from exposure to asbestos to the diagnosis of mesothelioma is on average greater than 40 years and incidence is expected to peak in developing countries before 2030[110]). Trends on the incidence, prevalence and mortality of cancer and other long-latency diseases will reflect the action (or inaction) of legislation prior to the implementation of the REACH and CLP Regulations.

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[107] Even for cancer statistics, quality and completeness of registry data may vary and the international comparability of cancer incidence data can also be affected by differences in medical training and practice – Source: OECD (2014): Health at a Glance: Europe 2014, OECD Publishing, page 40. Available at: http://ec.europa.eu/health/reports/docs/health_glance_2014_en.pdf

[108] Ratio of the incidence rate among individuals with a given risk factor to the incidence rate among those without it – Source: Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health, Seventh Edition, 2003 by Saunders, an imprint of Elsevier, Inc.

[109] Pertaining to the formation of blood or blood cells – Source: Based on WordNet 3.0, Farlex clipart collection, 2003-2012 Princeton University, Farlex Inc.

[110] Robinson BM (2012): Malignant pleural mesothelioma: an epidemiological perspective, Ann Cardiothorac Surg. 2012 Nov; 1(4): 491–496. doi: 10.3978/j.issn.2225-319X.2012.11.04. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3741803/

DGUV statistics are presented below for illustrative purposes, as they cannot be considered representative of the European situation. However, they provide an example of how impact indicators have been defined at national level and used to highlight successes and failures in addressing health problems related to exposure to chemicals.

The Annex to the German ordinance on occupational diseases[111] list different groups of diseases attributable to chemicals agents (group 1), physical impact (group 2), infectious agents or parasites (group 3), diseases of the respiratory tract, lungs pleura and peritoneum caused by inorganic and organic dust, allergic agents and chemical agents (group 4), skin diseases (group 5) and diseases caused by other factors (group 6). The subgroups relevant to this study and the associated data are presented in Table 3-14.

While occupational diseases linked to exposure to metals and metalloids, asphyxiating gases and solvents, pesticides and other chemical agents have decreased to none or fewer than 5 cases per year (notable exceptions: 17 cases of diseases caused by chromium or its compounds in 2014, but overall decrease in the period 1995-2014 of around 47%; 12 cases of diseases caused by carbon monoxide in 2014, but overall decrease in the period 1995-2014 of around 70%; 16 cases of diseases caused by halogenated hydrocarbons in 2014, but overall decrease in the period 1995-2014 of around 84%; 27 cases of diseases caused by isocyanates in 2014, but overall decrease in the period 1995-2014 of around 54%; 9 cases of polyneuropathy or encephalopathy caused by organic solvents or their mixtures 2014, but overall decrease in the period 2000-2014 of around 47%; 180 cases of mucosal changes, cancer or other neoplasms of the urinary tract caused by aromatic amines with an increase in the period 1995-2014 of around 173%[112]), the incidence and mortality of diseases linked to exposure to asbestos are on the rise and still have to reach the peak.

Data on occupational asthma and occupational skin diseases are discussed in the following Section.

[111] http://www.dguv.de/medien/content/facts_figures/begriffe/BKV2009engl.pdf

[112] According to DGUV, aromatic amines are "*constituent of coal tar products which up until the 1960s and 1970s were used as work materials in the plants of member companies of the German Social Accident Insurance Institution for the building trade. Known examples are the hot processing of road tar and the sealing of flat roofs with tar adhesives and tar papers*". It is possible that the incidence of bladder neoplasms caused by exposure to aromatic amines still has to reach the peak. *Source:* http://www.dguv.de/ifa/Forschung/Projektverzeichnis/IFA_2079-2.jsp

Table 3-14: DGUV statistics on recognised cases of occupational diseases linked to chemicals' exposure						
Disease group	1995	2000	2005	2010	2014	Variation (1995 baseline)
1 Diseases caused by chemical agents						
11 Metals and metalloids						
1101 Diseases caused by lead or its compounds	17	8	5	5	3	-82% (low number of cases)
1102 Diseases caused by mercury or its compounds	3	5	2	–	–	No recognised cases since 2010
1103 Diseases caused by chromium or its compounds	32	32	24	13	17	-47%
1104 Diseases caused by cadmium or its compounds	3	2	2	1	3	Steady Low number of cases
1105 Diseases caused by manganese or its compounds	2	1	–	–	–	No recognised cases since 2005
1106 Diseases caused by thallium or its compounds	–	–	–	–	–	No recognised cases
1107 Diseases caused by vanadium or its compounds	2	–	–	–	–	No recognised cases since 2000
1108 Diseases caused by arsenic or its compounds	5	2	3	3	5	Steady Low number of cases
1109 Diseases caused by phosphorus or its inorganic compounds	1	18	1	2	–	Low number of cases (outlier value in 2000)
1110 Diseases caused by beryllium or its compounds	1	1	1	3	3	Slight increase in number of cases (low number of cases)
12 Asphyxiating gases						
1201 Diseases caused by carbon monoxide	40	20	102	46	12	-70%
1202 Diseases caused by hydrogen sulphide	8	3	7	–	2	-75%
13 Solvents, pesticides and other chemical agents						
1301 Mucosal changes, cancer or other neoplasms of the urinary tract caused by aromatic amines	66	93	107	152	180	173%
1302 Diseases caused by halogenated hydrocarbons	97	83	24	11	16	-84%
1303 Diseases caused by benzene and its homologues or by styrene	88	61	35	27	4	-95%
1304 Diseases caused by nitro or amino compounds of benzene or its homologues or their derivatives	1	1	2	1	–	Steady Low number of cases

Table 3-14: DGUV statistics on recognised cases of occupational diseases linked to chemicals' exposure						
Disease group	1995	2000	2005	2010	2014	Variation (1995 baseline)
1305 Diseases caused by carbon disulphide	8	–	2	–	–	No recognised cases since 2005
1306 Diseases caused by methyl alcohol (methanol)	2	–	–	–	–	No recognised cases since 2000
1307 Diseases caused by organic phosphorus compounds	1	2	1	–	–	No recognised cases since 2005
1308 Diseases caused by fluorine or its compounds	25	3	1	–	1	-96%
1309 Diseases caused by nitric acid esters	–	–	–	–	–	No recognised cases
1310 Diseases caused by halogenated alkyl oxide, aryl oxide or alkyl aryl oxide	41	13	7	2	–	No recognised cases in 2014 from 41 cases in 1995
1311 Diseases caused by halogenated alkyl sulphide, aryl sulphide or alkyl aryl sulphide	–	2	–	–	1	Low number of cases
1312 Dental diseases caused by acids	59	10	2	1	6	-90%
1313 Lesions to the cornea of the eye caused by benzoquinone	–	–	–	–	–	No recognised cases
1314 Diseases caused by para-tertiary-butylphenol	–	–	–	–	–	No recognised cases
1315 Diseases caused by isocyanates	59	45	35	30	27	-54%
1316 Liver diseases caused by dimethyl formamide	–	–	–	1	–	No recognised cases
1317 Polyneuropathy or encephalopathy caused by organic solvents or their mixtures	–	17	18	8	9	-47% (2000 baseline)
1318 Diseases of blood, blood generating and lymphatic system caused by Benzol	–	–	–	159	265	Occupational disease newly defined in 2009*
4 Diseases of the respiratory tract, lungs, pleura and peritoneum						
41 Diseases caused by inorganic dust						
4101 Silicosis	2,652	1,627	1,013	1,618	758	-71%
4102 Silicosis combined with active pulmonary tuberculosis (silico-tuberculosis)	59	27	20	7	6	-90%
4103 Asbestosis or diseases of the pleura caused by asbestos dust	2,175	1,813	2,178	1,749	1,956	-10%
4104 Lung or larynx cancer - combined with asbestosis - combined with diseases of the pleura caused by asbestos dust or - if there is evidence of cumulative exposure to asbestos dust in the workplace of at least 25 fibre years {25*106 [(fibre/m3)*years]}	647	734	791	719	832	+29%
4105 Mesothelioma of the pleura, the peritoneum or the pericardium caused by asbestos	501	699	904	931	1,040	+108%
4106 Diseases of the lower respiratory tract and the lungs caused by aluminium or its compounds	2	6	2	2	5	Steady (low number of cases)
4107 Pulmonary fibrosis caused by metallic powder present in the production or processing of hard	7	3	1	3	1	Slight decrease

Table 3-14: DGUV statistics on recognised cases of occupational diseases linked to chemicals' exposure						
Disease group	**1995**	**2000**	**2005**	**2010**	**2014**	**Variation (1995 baseline)**
metals						(low number of cases)
4108 Diseases of the lower respiratory tract and the lungs caused by dust from basic slag (Thomas phosphate)	1	–	–	–	–	No recognised cases
4109 Malignant neoplasms of the respiratory tract and the lungs caused by nickel or its compounds	9	4	2	5	3	Slight decrease (low number of cases)
4110 Malignant neoplasms of the respiratory tract and the lungs caused by crude coke oven gas	17	17	12	21	7	-59%
4111 Chronic obstructive bronchitis or emphysema in underground hard coal miners if there is evidence of exposure to a cumulative dose of generally 100 fine dust years [(mg/m3)* years]	–	325	336	1,095	255	Access to compensation was granted in 2009**
4112 Lung cancer caused by silica dust where there is accompanying silicosis or silico-tuberculosis	–	–	46	61	41	Added to the list in 2001***
4113 Lung cancer caused by polycyclic aromatic hydrocarbons if there is evidence of exposure to a cumulative dose of generally 100 Benzo[a]pyrene years [(µg/m3) x years]	–	–	–	9	20	Occupational diseases newly defined in 2009*
4114 Lung cancer caused by simultaneous exposure to asbestos fibre dust and polycyclic aromatic hydrocarbons if there is evidence of exposure to a cumulative dose corresponding to a causative probability of at least 50 % according to annex 2	–	–	–	15	23	
4115 Lung fibrosis caused by extreme and long lasting exposure to welding fumes and gases (Sidero-fibrosis)	–	–	–	10	8	
43 Obstructive diseases of the respiratory tract						
4302 Obstructive diseases of the respiratory tract caused by chemical irritants or agents with a toxic effect	316	236	171	141	173	-45%
5 Skin Diseases						
5101 Severe or recurrent skin diseases	2,232	1,634	877	559	565	-75%
5102 Skin cancer or skin alterations showing a cancerous tendency caused by soot, paraffin, sludge, tar, anthracene, pitch or similar substances	16	19	18	25	81	+406%
Notes: **Source: https://www.researchgate.net/publication/287347297_New_occupational_diseases_in_Germany* *** Source: http://www.dguv.de/de/Presse-Aktuelles/Pressearchiv/2009/3.-Quartal/3.-Quartal-Details_21729.jsp* **** Source: http://www.dguv.de/ifa/Forschung/Projektverzeichnis/BGFA_EPIDZELL001-2.jsp*						

Change in environmental impacts (defined on ecosystem services or number of species) following a decrease in exposures due to chemicals legislation requirements

With regard to environmental impacts, the quality and completeness of data are even more of an issue than for human health impacts. There is a tendency for studies to focus on the local (or case study), regional and national scale with fewer studies undertaken at the European scale (particularly in relation to the impact of chemical substances on habitats/ecosystems). Data trends on environmental impacts are missing and for those recorded, their changes cannot easily be attributed to the effectiveness of the legislation in lowering exposure to chemical substances. In order to identify potential impact indicators that could be used to estimate the benefits of chemicals legislation, a formalised approach was followed by the project team (Figure 3-32). The first step within this process was to identify the measure of the impacts of chemicals on the environment. If an appropriate measure could be identified (or a suitable surrogate was available) then the next stage involved identifying suitable datasets at the EU/national level to enable measurement of the baseline situation. If a suitable dataset was available at the EU level to enable measurement of the baseline, then the next stages involved identifying datasets that enable changes over time to be linked to chemicals/chemical properties and to chemicals legislation specifically. If information could be identified at each of these stages then an indicator could be suggested. Following on from this was the identification of values that could be used to monetise the damages caused by exposure to chemicals.

Although some measures of environmental impacts were identified (e.g. number of species threatened by chemical pollution), datasets that would enable to estimate the benefits of the chemicals legislation are not available. For example, the Species Survival Commission at the European regional office of the International Union for Conservation of Nature (IUCN) publishes the European Red List, a review of the status of the European species[113]. Each species is assessed and coded against the IUCN Threats Classification Scheme. Table 3-15 reports the number (and in some cases the percentages) of species and the number of species classified as threatened that are affected by pollution.

Table 3-15: Number of European species impacted by pollution

	Number or % of species impacted by pollution (proportion of species classified as threatened)
Amphibians	72 (10 threatened)* [83 species assessed]
Bees	259 (7 threatened) [1,101 total species]
Birds	239 (39 threatened, 20 by pesticides and herbicides and 19 marine species by industrial effluents, mainly oil spills) [530 species]
Butterflies	18 (12 threatened) [482 total species]
Dragonflies	60 (17 threatened) [5,680 total species]
Freshwater fish	81 (55 threatened) [382 total species]
Mammals	38 (4 threatened) [228 total species]
Marine fish	52 (5 threatened) [1,256 total species]
Medicinal plants	41 (8 threatened) [400 taxa]
Freshwater molluscs	302 (170 threatened) by agriculture and forestry sources of pollution, 245 (145 threatened) by domestic and urban sources of pollution, 40 (15 threatened) by industrial and military sources of pollution, 25 (23 threatened) by other sources of pollution [854 species assessed]
Terrestrial molluscs	30 (15 threatened) [1,233 species assessed]
Reptiles	35 (12 threatened)* [139 species assessed]
Saproxylic beetles	8 (2 threatened) [431 species assessed]

[113] http://ec.europa.eu/environment/nature/conservation/species/redlist/index_en.htm

Table 3-15: Number of European species impacted by pollution	
	Number or % of species impacted by pollution (proportion of species classified as threatened)
Vascular (policy) plants	148 (52 threatened) [891 species assessed]
Crop wild relatives	22 (4 threatened) [572 species assessed]
Aquatic plants	55 (11 threatened) by agricultural water pollution, 13 (6 threatened) by domestic and urban water pollution, 9 (5 threatened) by industrial water pollution, 7 (5 threatened) by garbage and solid waste [393 species assessed]
Notes: *Include the impacts of climate change *Source: RPA analysis on data from the European Red List - DG Environment (last update: October 2015)*	

The assessment is not comprehensive, as many of the species identified are listed as data deficient (e.g. 20.6% of the European marine fishes[114]), but it provides an idea of the challenges in preserving biodiversity in Europe. However, the definition of major threat used by the IUCN (pollution can refer to sewage, run offs, oil spills, nutrient loads, sedimentation, pesticides, noise pollution, etc.; sometime its effects are presented together with climate change impacts) does not allow discerning the contribution of the chemicals legislation in lowering the chemicals' exposure and therefore in reducing the number of species impacted by pollution. Moreover, in the majority of cases there is no single source of threats to each species, but usually a series of threats combined that lead to declining populations and the contribution of pollution cannot be singled out. Nevertheless, chemicals legislation has been proven to be beneficial in recovering the populations of many species. For example, a study commissioned by Rewilding Europe indicates that a ban on the use of organochlorine chemicals in agriculture, along with a drive to reduce illegal nest robbing and the introduction of protection legislation, has resulted in an increase in populations of Peregrine falcon and white-tailed eagle in many parts of Europe[115].

As a consequence of the lack of suitable data and of the level of uncertainty in establishing and measuring the link between the action of the chemicals legislation and the changes in human health and environmental statistics, monetary valuation has been possible only for:

- Change in incidence and prevalence of occupational dermatitis; and
- Change in incidence and prevalence of occupational asthma.

The results are presented in Section 4.

[114] See for example the European bee species: http://ec.europa.eu/environment/nature/conservation/species/redlist/bees/major_threats.htm

[115] Deinet et al (2013): Wildlife comeback in Europe – The recovery of selected mammal and bird species. The Zoological Society of London (ZSL), Birdlife International and the European Bird Census Council for Rewilding Europe. Available at: http://rewildingeurope.com/wp-content/uploads/2013/11/Wildlife-Comeback-in-Europe-the-recovery-of-selected-mammal-and-bird-species.pdf

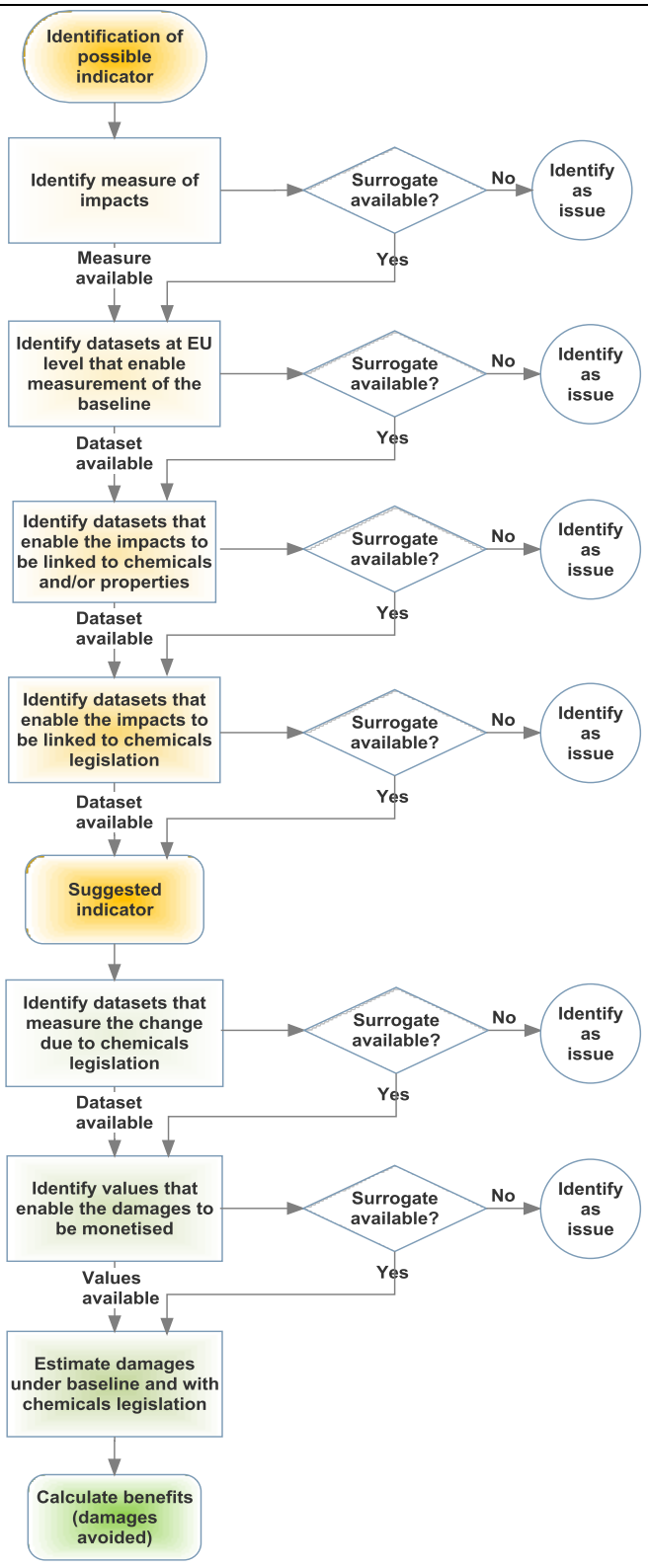

Figure 3-32: Overview of approach used to identify indicators to determine the environmental benefits of chemicals legislation

4 Monetisation of the Benefits of the Chemicals Legislation

4.1 Introduction

Based on the differentiation between output, result and impact indicators proposed by the Better Regulation guidelines, output indicators were used to evaluate the level of activity for each main legislative mechanism considered to deliver human health and environmental benefits (e.g. classification, authorisation and restriction). Result indicators have been used to evaluate the change in chemicals' exposure attributable to the action of the chemicals legislation. Finally, impact indicators have been used to evaluate the change in human health and environmental impacts attributable to the chemicals legislation.

The information needed to feed this system of indicators is:

- Toxicological and ecotoxicological properties of the chemical substances;
- Level of activities required to stakeholders by the chemicals legislation (e.g. number of substances registered, restrictions implemented, etc.);
- Historic trends of chemicals' exposure;
- Data enabling a direct association to be made between chemical exposures and human health or environmental damages (e.g. dose response functions, attributable fractions);
- Health statistics (e.g. incidence and prevalence rates of certain diseases associated to chemicals' exposure);
- Values for the monetisation of the benefits (medical treatment costs, data on productivity loss, Willingness-To-Pay values, etc.).

Information for the output indicators is normally available and easily collected: toxicological and ecotoxicological properties of the chemical substances are being generated through the information requirements for registration under REACH and are being made publicly available through the Classification and Labelling Inventory. Information on the other activities resulting in the likely reduction of chemicals' exposure can be easily found on the ECHA website (information on harmonised classifications, authorisations, restrictions, etc.).

Information for the result and impact indicators is instead scarce and of more difficult collection: data on exposure to chemicals are available on specific chemical substances only and are often limited in terms of time and geographic area, requiring important assumptions for their extrapolation to the EU level. Health statistics are often collected, aggregated and presented in ways that made them not suitable for the purposes of this study. Even occupational health and safety statistics, that are usually the most complete and for which in some cases is possible to estimate the attributable fraction to chemicals' exposure, are not fully harmonised in the European Union[116].

Owing to the quality of the information available on chemicals' exposure and associated human health and environmental impacts, monetisation of the benefits of the chemicals legislation has been possible for short latency diseases and for the workers' population only, where effects have

[116] One of the seven strategic objectives of the EU Occupational Safety and health Strategic Framework 2014-2020 is to improve statistical data collection to have better evidence and for developing monitoring tools. Source: http://ec.europa.eu/social/main.jsp?catId=151&langId=en

been attributed to the exposure to certain chemicals by health practitioners (namely occupational skin diseases and occupational asthma). In valuing the impacts on human health, the project team followed a Cost of Illness approach. In particular, we calculated the medical treatment costs, the productivity loss and the Willingness to Pay (WTP) to avoid the disease. For the environment, different "benefits transfer" approaches have been explored, but due to the limitations in data availability, monetisation of the benefits can be carried out only by making assumptions that invalidate the reliability of the estimates.

4.2 Skin Diseases

4.2.1 Introduction

Skin diseases or skin disorders can be defined as any medical condition affecting the skin. Although skin cancers are within the skin disease definition, statistics on skin cancers are usually compiled separately. When referring to the workers population, occupational (or work-related) skin diseases "*may be defined as any disorder of the skin which is caused by or made worse by work or workplace activity*"[117].

The British Skin Foundation presents details on 37 different skin diseases[118], which may be of varying aetiology. Among the most common skin diseases that can be linked to the exposure to chemicals there are contact dermatitis, which may be defined as inflammation of the skin resulting from the contact with a chemical or physical agent.

4.2.2 Indicators and linkage

For the WHO ICD-10 "diseases of the skin and subcutaneous tissue", we considered substances classified for skin sensitisation (1, 1A or 1B).

At March 2016, there are 1,149 substances with harmonised classification and labelling for skin sensitisation. Thirty-seven of these CLH have been implemented after the entry into force of CLP (output indicator 1 - Table lists the substances).

Among those substances that were already listed in IUCLID (2005), in the last ten years there has been an increase of 132% in self-classifications for skin sensitisation (from 903 to 2,905 substances), owing to new and better toxicological data (output indicator 2).

There are 15 substances restricted on their own, in mixtures or in articles with classification for skin sensitisation. Two restrictions have been implemented after the entry into force of REACH (placing on the market of articles containing dimethylfumarate and placing on the market of leather products containing chromium VI - Table) (output indicator 3).

Although substances have been put in Annex XIV mostly for their carcinogenicity and toxicity to reproduction, as for Annex XVII, 12 of these substances have also been classified for skin sensitisation (Table - output indicator 4). In preparing the applications for authorisation, stakeholders ensure that the risks arising from the exposure to the substances are adequately controlled. This process and the eventual phase out of the substances should guarantee some benefits also in terms of a decrease in the occurrence of skin diseases.

[117] HSE (2014): Work-related skin disease in Great Britain 2014. Health and Safety Executive. Available at: http://www.hse.gov.uk/statistics/causdis/dermatitis/skin.pdf

[118] http://www.britishskinfoundation.org.uk/SkinInformation/AtoZofSkinDisease.aspx

It should be noted that, although it is not possible to attribute the decrease in occupational skin diseases to the action of the REACH and CLP Regulations only, the output indicators above provide an indication of what has been done during the last years to tackle substances linked to skin diseases.

4.2.3 Data availability

Both the UK and Germany have detailed statistics on occupational diseases and, to a certain extent, data allowing estimating the attributable fraction to chemicals' exposure.

The UK HSE maintains a database with information on occupational skin disorders.

Statistics on the incidence[119] of occupational skin disease are available in Great Britain through the EPIDERM scheme of the Health and Occupation Research Network (THOR), in which dermatologists report new cases. Data are also available through the THOR-GP scheme, where general practitioners (GPs) report the cases for which enough concern triggered a visit to the GP and that were subsequently diagnosed and attributed to work. Information on prevalence[120] is based on the Self-reported Work-related Illness (SWI) annual survey and from assessments for Industrial Injury and Disablement Benefit (IIDB) (HSE, 2014).

According to the HSE, "*EPIDERM provides by far the largest numbers of actual reported cases of skin disease and, though restricted to more severe cases and subject to a degree of underreporting, provides the best basis for more detailed analyses such as by occupational group or causal agent*". With regard to THOR-GP, due to the small sample of GPs participating in the scheme, the overall estimates of the burden of the occupational skin diseases in Great Britain is imprecise.

The data on the incidence of occupational skin diseases gathered by the different sources, although varying considerably, are consistent. The IIDB scheme typically identifies only the most severe cases of dermatitis for which a disablement benefit is granted. Statistical analysis of the self-reported occupational skin diseases suggests that there are around 5,000 new cases per year[121], while dermatologists diagnosed around 1,300 new cases in 2013. However, EPIDERM "*inevitably substantially underestimates the true incidence of work-related disease – particularly for those conditions such as contact dermatitis where there may be substantial numbers of less serious cases*" (HSE, 2014).

In terms of skin diseases prevalence, HSE statistical analysis of the data suggests that there are around 12,000 workers[122] with skin problems caused or made worse by their work.

For the monetisation of the benefits, of interest are also the data on the sickness absence days certified due to occupational skin diseases (around 1% of the total sickness absence days)[123].

The German Social Accident Insurance (Deutsche Gesetzliche Unfallversicherung – DGUV) is "*the umbrella association of the accident insurance institutions for the industrial and public sectors*"[124]

[119] Number of new cases occurring each year.
[120] The proportion of the population currently with the disease.
[121] 95% Confidence Interval: 3000-7000. Source: HSE (2014)
[122] 95% Confidence interval 9,000 to 15,000. Source: HSE (2014).
[123] http://www.hse.gov.uk/statistics/causdis/dermatitis/skin.pdf
[124] http://www.dguv.de/de/Wir-%C3%BCber-uns/index-2.jsp

and represents their interests and the interests of their members when dealing with public institutions, employers' and employees' representative bodies.

Since 1969, facts, figures and long term trends on occupational diseases in Germany have been published by the associations responsible for the industrial sectors and the public sector, merged in 1993 to form the DGUV.

Scope and categorisation of the statistics have been reformed through the years, but consistent occupational skin diseases statistics are available since 1995. According to Annex 1 of the Occupational Diseases Ordinance listing the recognised occupational diseases, occupational skin diseases are "*severe or recurrent skin diseases which have forced the person to discontinue all activities that caused or could cause the development, worsening or recurrence of the disease*" (occupational disease number 5101), "*skin cancer or skin alterations showing a cancerous tendency caused by soot, raw paraffin, tar, anthracene, pitch or similar substances*" (occupational disease number 5102) and "*squamous cell carcinoma or multiple actinic keratosis of the skin caused by natural ultraviolet irradiation*" (occupational disease number 5103).[125] For the purpose of this exercise, the project team considered statistics referring to the group 5101 only.[126]

4.2.4 Human health benefits of the chemicals legislation – Occupational skin diseases

UK Health and Safety statistics

The HSE reports statistics on occupational skin disorders by cause for the years 1998 to 2013 (reproduced in Table 4-1).

Table 4-1: Statistics on occupational skin disorders by cause, average annual estimates over 3-year and 16-year periods

Cause	1999-2001	2002-2004	2005-2007	2008-2010	2011-2013	1998-2013
Soaps and cleaners	219	307	317	314	245	279
Wet work	281	254	263	348	228	272
Rubber chemicals and materials	361	293	243	175	163	251
Nickel	168	215	148	116	106	154
Personal protective equipments (PPE)	140	133	138	181	126	141
Preservatives	92	150	122	78	81	109
Resins and acrylics	136	108	97	62	67	97
Foods and flour	100	118	128	54	56	95
Aromatic amines (PPD)	90	80	113	115	45	88
Chromium and chromates	114	119	126	41	17	87
Hairdressing chemicals	78	82	85	96	56	79
Fragrances and cosmetics	75	79	64	56	84	75
Other biological substances	73	78	88	50	74	75
Bleaches and sterilisers	43	59	97	75	94	72
Cobalt and compounds	55	105	99	43	24	66
Petroleum and products	100	83	66	34	27	64
Aldehydes	58	79	47	30	28	51

[125] http://www.baua.de/en/Topics-from-A-to-Z/Occupational-Diseases/pdf/Occupational-Diseases.pdf;jsessionid=12442AECEAFCCB302DFAC89321D42D36.1_cid333?__blob=publicationFile&v=4

[126] The other two groups refer to skin cancers: their incidence, prevalence and latency are completely different from other skin diseases.

Table 4-1: Statistics on occupational skin disorders by cause, average annual estimates over 3-year and 16-year periods						
Cause	**1999-2001**	**2002-2004**	**2005-2007**	**2008-2010**	**2011-2013**	**1998-2013**
Solvents and alcohols	69	59	63	26	11	49
Friction	63	57	50	45	33	49
Irritants (unspecified)	84	43	34	47	14	48
Colophony and flux	79	46	46	30	21	45
Cutting oils and coolants	74	51	34	28	17	44
Glues and paints	30	37	28	25	17	29
Metals and compounds	16	16	48	22	17	23
Cements, plaster and masonry	33	33	11	14	23	23
Temperature and humidity	14	14	25	19	27	20
Medications	20	22	25	15	8	19
Acids and caustics	9	10	21	12	3	12
Other substances	145	129	126	82	71	118
Other unspecified chemicals	29	17	14	1	1	14
Not known	44	45	39	36	10	38
Total number of known causative substances*	2674	2730	2626	2151	1712	2414
Total number of cases**	2014	1804	1613	1343	1110	1607
Total number of known and unknown causative substances	**2,892**	**2,921**	**2,805**	**2,270**	**1,794**	**2,586**
Total number of cases attributed to chemicals**	**1,983**	**2,054**	**1,909**	**1,439**	**1,160**	**1,743**

Notes: Data referring to the following causes have not being considered because not directly related to chemical factors (in red): wet work, personal protective equipment (PPE), food and flour, other biological substances, friction, temperature and humidity, medications.
Some physicians report on a sample basis, for one month in each year. Estimated totals for these are calculated by multiplying the actual number of cases reported by 12.
Figures shown in light type are based on fewer than 10 actual cases.
*(Total – other substances, other unspecified substances and not known).
**Some cases may have more than one causative substance.
2013 statistics are provisional.
Source: Adapted and elaborated from UK HSE THORS06 statistics (http://www.hse.gov.uk/statistics/tables/index.htm)

In order to deal with cases with more than one causative substance, we calculated the percentage of cases attributed to chemicals, non-chemical factors (in red in Table 4-1) and unknown causes and applied these to the total number of cases reported (Table 4-2).

Table 4-2: Percentage and number of occupational cases per causative factors (diagnosed by practitioners)	
Cause	**1998-2013**
Percentage of cases attributed to chemical substances	67.4 %
Percentage of cases attributed to non-chemical causative factors	25.9 %
Percentage of cases with unknown or unspecified causative factors	6.6 %

We then applied the percentage of cases attributed to chemical substances to the total number of individuals with diagnosed work-related skin conditions between 1998 and 2013[127]. The results are presented in Figure 4-1. It highlights a decrease of around 50% of the cases of occupational skin

[127] UK HSE THORS01 statistics. Cases reported by dermatologists to EPIDERM. Available at: http://www.hse.gov.uk/Statistics/tables/index.htm

diseases attributed to chemicals in the UK during this period. The decrease may be associated to a decrease in the workforce; however, in the period 1998-2013, according to Eurostat data, employment in the UK kept growing apart from a sharp decrease in 2008 (decrease of around 500,000 workers), decrease that have been reabsorbed by 2012.

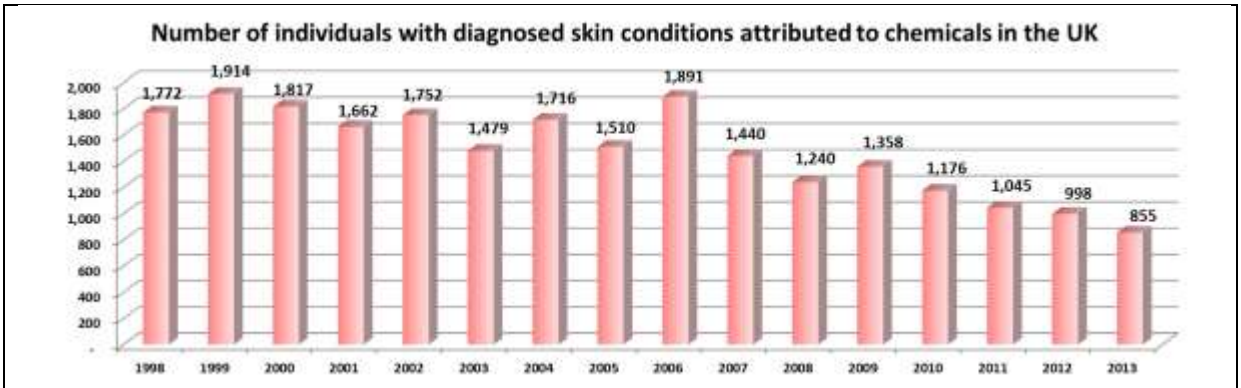

Figure 4-1: Number of individuals with diagnosed work-related skin conditions attributed to chemicals in the UK

As mentioned, EPIDERM data are likely to underestimate the true incidence of work-related disease. The Self-reported Work-related Illness (SWI) annual survey presents data on incidence and prevalence for the years 2006-2013 in the UK.

Deutsche Gesetzliche Unfallversicherung statistics

With regard to the DGUV statistics on occupational skin diseases in Germany, Table 25 of DGUV (2015)[128] presents the number of recognised cases[129] of occupational diseases. The data are reproduced in Table 4-3.

Table 4-3: DGUV statistics on occupational skin diseases – suspected cases and recognised cases

	1995	2000	2005	2010	2014
Recognised cases of occupational skin diseases	2,232	1,634	877	559	565
Variation in percentage (baseline 1995)					**-75%**

Although the number of notified suspected cases increased by 16% between 1995 to 2014, the recognised cases dropped by 75% in the same period, broadly confirming the trend shown by the UK data (50% decrease between 1998 and 2013).

[128] DGUV (2015): DGUV Statistics 2014 – Figures and long-term trends, Deutsche Gesetzliche Unfallversicherung e.V., Berlin. Available at: http://www.dguv.de/de/zahlen-fakten/index.jsp

[129] Recognised cases are defined as: "*Of all reports of suspected occupational disease, all those cases in which it has been proved in an adjudication procedure that the person is indeed suffering from the occupational disease. For some diseases, the confirmation of the occupational causation must coincide with additional insurance conditions, e.g. some diseases must have forced the person to refrain from all activities which led or could lead to the development, aggravation or recurrence of the illness. If such conditions are not fulfilled, a formal OD recognition is not possible. Nevertheless, extensive benefits for prevention, curative treatment and vocational help are often granted in these cases*." (DGUV, 2015).

Extrapolation to the EU level

Although the German and the UK statistics cannot be considered representative of the situation in the other 26 Member States, for illustrative purposes the project team proceeded in extrapolating these national statistics on the EU level. Differences in the incidence and prevalence of occupational skin diseases across Member States may depend on e.g. the relative importance of certain industrial sectors where workers are particularly exposed to skin sensitisers or the level of compliance to the occupational health and safety legislation and the chemicals legislation.

In terms of incidence, we applied the incidence average rates per 100,000 workers[130] from the UK HSE data to the EU28 workers population in each year (period 2004-2013)[131] and multiplied the results by the percentage of cases attributed to chemical substances (65%[132]). Assuming that the incidence of skin disorders in the EU28 is equal to the incidence in the UK and that the number of self-reported new cases would follow the same pattern, the number of new self-reported skin conditions in the EU28 in 2013 would be 24,000 (95% C.I.: 14,000 (lower) - 35,000 (upper)).

In terms of prevalence (the proportion of the population currently with the disease), statistics on the rates of self-reported skin conditions caused or made worse by work for people working in the last 12 months are available for the UK for the period 2005-2012[133]. The average rates per 100,000 workers have been applied to the EU28 workers population in each year (period 2004-2013) and multiplied by the percentage of cases attributed to chemical substances, resulting in around 54,000 workers with occupational skin disorders in the EU28 in 2013. Estimates for incidence and prevalence of occupational skin disorders in the EU28 for the period 2004-2013 are presented in Table 4-4[134] and Figure 4-2.[135]

Table 4-4: Estimates of the incidence and prevalence of occupational skin diseases in the EU28

Year	Incidence rate	Prevalence rate	UK workers population[136]	EU28 workers population	New cases of occupational skin diseases in the EU28***	EU28 population with occupational skin diseases***
2004	43*	85**	28,369,400	208,900,600	**58,000**	**120,000**
2005	41*	74	28,666,400	211,991,000	**56,000**	**102,000**
2006	34	76	29,040,700	216,155,800	**48,000**	**107,000**
2007	36	72	29,260,700	220,363,100	**52,000**	**103,000**

[130] In 2013, incidence central average rate of 17 per 100,000 cases. Source: Table HSE UK SWIT6w12_3yr.xls. Available at: http://www.hse.gov.uk/statistics/lfs/index.htm

[131] Eurostat statistics – Employment – Labour Force Survey (lfsa_emp), year 2013 (http://ec.europa.eu/eurostat/data/database). Average rate per 100,000 workers x (EU28 workforce/100,000).

[132] Rounded to the nearest multiple of 5.

[133] HSE UK SWIT3W12_3YR provides the averaged 3 year estimates based on overlapping time periods (preferred to the annual estimates because the latter are not available for some years). It has been assumed that the rates presented refer to the central year period. Available at: http://www.hse.gov.uk/statistics/lfs/index.htm

[134] For completeness of information, we reported the UK workers population statistics, showing that the decrease in incidence and prevalence rates are not linked to the workers population.

[135] *"(…) prevalence includes new and pre-existing cases whereas incidence includes new cases only."* Source: U.S. Centers for Diseases Control and Prevention - Principles of Epidemiology in Public Health Practice, Third Edition, An Introduction to Applied Epidemiology and Biostatistics. Available at: http://www.cdc.gov/ophss/csels/dsepd/ss1978/lesson3/section2.html

[136] Eurostat statistics – Employment – Labour Force Survey (lfsa_emp), year 2013 (http://ec.europa.eu/eurostat/data/database).

Table 4-4: Estimates of the incidence and prevalence of occupational skin diseases in the EU28						
Year	Incidence rate	Prevalence rate	UK workers population[136]	EU28 workers population	New cases of occupational skin diseases in the EU28***	EU28 population with occupational skin diseases***
2008	36	65	29,520,200	222,875,500	**52,000**	**94,000**
2009	33	64	29,058,700	218,952,200	**47,000**	**91,000**
2010	31	50	29,125,000	216,843,300	**44,000**	**70,000**
2011	24	49	29,282,100	216,218,500	**34,000**	**69,000**
2012	22	39	29,596,200	215,807,100	**31,000**	**55,000**
2013	17	37**	29,952,500	215,398,500	**24,000**	**54,000**
Notes: *Values interpolated from 2006-2013 incidence rates. **Values interpolated from 2005-2012 prevalence rates. ***Rounded to the nearest multiple of 1,000.						

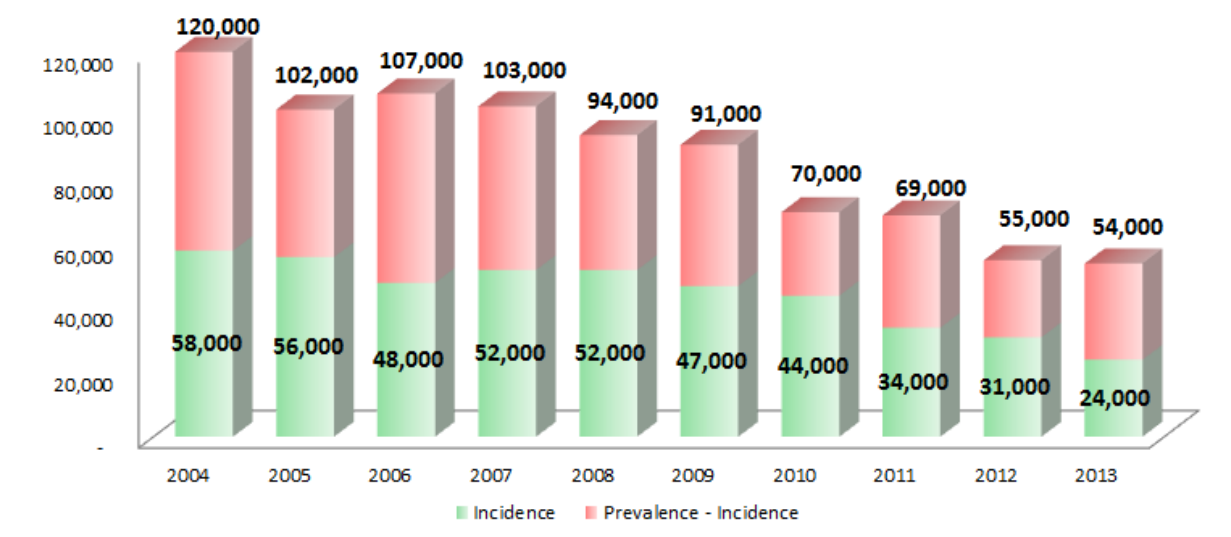

Figure 4-2: Incidence and prevalence estimates of occupational skin disorders in the EU28

Monetisation of the impact

In order to monetise the impact of occupational skin disorders, we calculated the medical treatment costs and the productivity loss due to skin conditions. The UK National Health System (NHS) reference costs[137] are a solid source to calculate the unit cost for the treatment of skin disorders. Reference costs are the average unit cost to the NHS of providing secondary healthcare to NHS patients. The unit costs and the number of treatments in 2013 and 2014 are presented in Table 4-5.

Table 4-5: Unit costs and number of treatments for skin disorders in the UK in 2013 and 2014			
Currency*	Currency description	Activity	Unit cost in GBP
JD07A	Skin Disorders with Interventions, with CC** Score 12+	2,271	£8,054
JD07B	Skin Disorders with Interventions, with CC Score 8-11	2,534	£5,510
JD07C	Skin Disorders with Interventions, with CC Score 4-7	5,494	£3,719
JD07D	Skin Disorders with Interventions, with CC Score 0-3	20,661	£1,876
JD07E	Skin Disorders without Interventions, with CC Score 19+	835	£3,907
JD07F	Skin Disorders without Interventions, with CC Score 14-18	6,390	£3,322

[137] Available at: https://www.gov.uk/government/collections/nhs-reference-costs

Table 4-5: Unit costs and number of treatments for skin disorders in the UK in 2013 and 2014			
Currency*	Currency description	Activity	Unit cost in GBP
JD07G	Skin Disorders without Interventions, with CC Score 10-13	15,305	£2,450
JD07H	Skin Disorders without Interventions, with CC Score 6-9	31,285	£1,803
JD07J	Skin Disorders without Interventions, with CC Score 2-5	57,114	£1,187
JD07K	Skin Disorders without Interventions, with CC Score 0-1	55,443	£678
*Notes: *Currencies are defined as the units of healthcare for which a payment is to be made.* ***CC stands for "complications or comorbidities" and each CC recorded is assigned a score in order to reflect the increment in complexity and treatment costs.*			

The weighted average treatment unit cost for skin disorders has been calculated weighting the average unit cost for the number of treatments. This is equal to £1,598 or €2,157[138]. The average unit cost for diagnosing a skin disorder[139] is £122 or €165.

Assuming that these average unit costs for diagnosing and for treating skin disorders are the same in the EU28, the benefits of the decrease (resulting in 335,000 cases avoided between 2004 and 2013)[140], accrue to around €722.6 million[141] in the period 2004-2013 only in treatment cost savings. Diagnose cost savings for the same period accrue to around € 22.1 million[142].

In order to calculate the productivity loss savings, we applied the average days lost per worker in the UK to the EU28 workers population, obtaining the days lost for all illness and injuries in the EU28 per year[143]. To calculate the days lost due to skin conditions, we applied the one percent value estimated by HSE (2015). The reduction in the occurrence of occupational skin diseases resulted in a total of 5.6 million working days lost avoided over the period 2004-2013. These have been multiplied by the average daily gross earnings in the EU28, resulting in a total of around €769.8 million in productivity loss savings over the period 2004-213. Table 4-6 present the calculations and results.

Table 4-6: Productivity loss savings						
Year	Average days lost per worker*	Days lost in the EU28**	Days lost due to skin conditions***	Days lost avoided****	EU28 Gross earnings per year*****	Productivity loss savings******
2004	1.62	338,418,972	3,384,190	-	€ 29,776	€ -
2005	1.49	315,866,590	3,158,666	225,524	€ 31,057	€ 30,400,000
2006	1.28	276,679,424	2,766,794	617,396	€ 31,386	€ 84,000,000
2007	1.49	328,341,019	3,283,410	100,780	€ 32,187	€ 14,100,000
2008	1.39	309,796,945	3,097,969	286,221	€ 31,362	€ 38,900,000
2009	1.22	267,121,684	2,671,217	712,973	€ 30,148	€ 93,400,000
2010	1.19	258,043,527	2,580,435	803,755	€ 30,388	€ 106,100,000
2011	1.1	237,840,350	2,378,404	1,005,786	€ 31,153	€ 135,800,000
2012	1.13	243,862,023	2,438,620	945,570	€ 32,774	€ 134,300,000

[138] Exchange rate GBP/EUR: 1.35.

[139] JC45A - Standard Patch Test (NHS Reference costs 2013-2014).

[140] The cumulative sum of the differences between the prevalence in 2004 and the prevalence in years 2005-2013.

[141] Total number of cases avoided (335,000) x Average unit cost for skin disorders (€2,157). Rounded to the nearest multiple of 100,000.

[142] Number of new cases avoided (134,000) x Average unit cost for diagnosing a skin disorder (€ 165). This is an underestimate, as it does not include the cases where the result of the diagnosis would have been negative.

[143] The underlining assumption is that the yearly average lost days per worker in the other Member States are equal to the UK ones.

Table 4-6: Productivity loss savings						
Year	Average days lost per worker*	Days lost in the EU28**	Days lost due to skin conditions***	Days lost avoided****	EU28 Gross earnings per year*****	Productivity loss savings******
2013	1.14	245,554,290	2,455,543	928,647	€ 32,944	€ 132,800,000
			Total	**5,600,000**	**Total**	**€ 769,800,000**

*Notes: *All illness and injuries - UK values – UK HSE Table SWIT1 – Annual (http://www.hse.gov.uk/statistics/lfs/index.htm#illness)*
***Calculated multiplying the average days lost per worker for the number of workers in the EU28.*
*** *Skin diseases account for around 1% of total sickness absence days certified due to occupational illnesses in 2012-2014 (source: HSE, 2015 – Work-related skin disease in Great Britain 2014; available at: http://www.hse.gov.uk/statistics/causdis/dermatitis/skin.pdf). This same value has been applied for each year.*
*****Calculated as the difference between the days lost due to skin conditions in 2004 and in years 2005-2013.*
******Eurostat labour market statistics (http://ec.europa.eu/eurostat/data/database).*
*******EU28 average gross earnings per day have been calculated assuming 230 working days per year in all Member States and multiplied per the days lost avoided to estimate the productivity loss savings. Values rounded to the nearest multiple of 100,000.*

To the treatment, diagnosis and productivity loss savings, the willingness to pay (WTP) to avoid a skin disease should be added. ECHA has recently published a study on the willingness to pay to avoid certain health impacts[144]. With regard to skin sensitisation, the authors provide a range of WTP values to avoid dermatitis, depending on its nature (acute or chronic), intensity (mild or severe), occurrence frequency in one year and over two, five and ten years. Values range from €227 for a single episode of mild acute dermatitis to €1,055 for severe chronic dermatitis[145]. Multiplying these values by the number of case of occupational skin diseases avoided (335,000), we obtain the range €76-€353.4 million.

The progressive reduction in the occurrence of occupational skin diseases attributed to the exposure to chemical substances has resulted in **total cost savings of around €1.59-1.87 billion over the period 2004-2013 in the EU28.**

These figures are based on UK statistics that cannot be considered representative of the EU situation. However, they provide indication of the order of magnitude of the accrued benefits.

These are the likely result of multiple factors, such as an increased awareness on health and safety in the workplaces, the adoption of better risk management measures, the restriction/withdrawal of some skin sensitisers, the reduction of the workforce in sectors where workers are particularly exposed to skin sensitisers[146] and the technological progress in the production processes.

However, the chemicals legislation is a determinant and confounding factor of many of these aspects and has played a major role in reducing the number of cases of occupational skin diseases.

[144] Charles University in Prague and VU University Amsterdam (2015): Stated-preference study to examine the economic value of benefits of avoiding selected adverse human health outcomes due to exposure to chemicals in the European Union. Report prepared for the European Chemicals Agency, Helsinki.

[145] Table 1 in ECHA (2015): Valuing selected health impacts of chemicals: Summary of the results and a critical review of the ECHA study. Available at: http://echa.europa.eu/documents/10162/13630/echa_review_wtp_en.pdf

[146] It should be noted that the results have been normalised to consider the variations in the overall workforce.

4.3 Occupational Asthma

4.3.1 Introduction

Respiratory diseases can be defined as any medical condition affecting the respiratory system. Occupational respiratory diseases are medical conditions caused by, or made worse by, something that is breathed in at work, such as dusts, fumes and gases. Although lung cancers are within the respiratory disease definition, statistics on cancers are usually compiled separately. However, since data on prevalence and incidence refer to "breathing problems" in general, these include people with respiratory cancers.

According to the UK HSE, "*the most prevalent of these diseases are chronic obstructive pulmonary disease (COPD), asthma and silicosis*"[147].

In particular:

- "*Chronic Obstructive Pulmonary Disease (COPD) is a serious long-term lung disease in which the flow of air into the lungs is gradually reduced by inflammation of the air passages and damage to the lung tissue. Chronic bronchitis and emphysema are common types of COPD. A wide range of vapours, dusts, gases and fumes potentially contribute to causing the disease or making it worse.*
- *Occupational asthma can be defined as adult asthma that is specifically caused by agents that are present in the workplace, however, a wider definition of work-related asthma includes all cases where there is an association between symptoms and work, including cases that are exacerbated by work.*
- *Pneumoconiosis is a long-term and irreversible disease characterised by scarring and inflammation of the lung tissue. The main types of pneumoconiosis are defined in terms of their causative agents: coal worker's pneumoconiosis due to coal dust exposure, asbestosis due to exposure to asbestos fibres, and silicosis due to silica dust exposure.*
- *Other non-cancerous respiratory diseases include diffuse pleural thickening and pleural plaques (non-malignant diseases of the lung lining caused by asbestos), allergic alveolitis (inflammation of the air sacs within the lungs due to an allergic reaction to organic material), allergic rhinitis (inflammation within the nose, mouth or throat that can be caused by an allergic reaction to a range of agents), and byssinosis (an asthma like disease in which the air passages become constricted in reaction to exposure to cotton dust).*"[148]

For the purpose of this study, COPD, pneumoconiosis and other non-cancerous respiratory diseases have not been considered:

- COPD is a long-latency disease, or in other words cases tend to develop a number of years after first exposure to the causative agents. According to the HSE, "*the most important causative factor is smoking – but others include occupational exposures to fumes, chemicals*

[147] http://www.hse.gov.uk/aboutus/occupational-disease/respiratory-disease.htm

[148] HSE (2015): Work-related respiratory disease in Great Britain 2014 – An overview of the current burden of disease in Great Britain. Available at: http://www.hse.gov.uk/statistics/causdis/respiratory-diseases.pdf

and dusts, as well as genetic susceptibility and environmental pollution".[149] Recent epidemiological studies in various countries estimate the proportion of occupational COPD in 15%. Although the causative substances of COPD tend to be the same as for occupational asthma, the identification of a particular causative substance for COPD diagnosis is more difficult. Moreover, any change in the number of cases of COPD is more likely to reflect the decrease in coal mining activity in Europe than any improvement in the working conditions introduced and promoted by the chemicals' legislation.

- Pneumoconiosis is linked to exposure to coal dust, silica dust and asbestos fibres. Although legislative acts aiming at minimising exposure to silica dust and asbestos fibres can be broadly considered as chemicals legislation, since the focus of the study is on REACH and CLP and that silica and asbestos have been regulated by specific OSH legislative acts predating REACH, silicosis and asbestosis cases have not been considered for the monetisation of the benefits of the chemicals legislation;
- Allergic alveolitis, rhinitis and byssinosis are linked to exposure to biological factors (e.g. dust or spores arising from mouldy hay, grain and straw, plant pollen and cotton dust).

The project team has therefore focused on asthma, estimating the chemicals' attributable fractions for the disorder.

4.3.2 Indicators and linkage

For the WHO ICD-10 "Diseases of the respiratory system", we considered substances classified for respiratory sensitisation 1, 1A and 1B - may cause allergy or asthma symptoms or breathing difficulties if inhaled.

At March 2016, there are 193 substances with harmonised classification and labelling for respiratory sensitisation, but none has been implemented after the entry into force of the REACH and CLP Regulations (output indicator 1).

Among those substances that were already listed in IUCLID (2005), in the last ten years there has been an increase of 538% in self-classifications for respiratory sensitisation (from 208 to 1,326 substances), owing to new and better toxicological data (output indicator 2).

There are 6 substances restricted on their own, in mixtures or in articles with classification for respiratory sensitisation. One restriction has been implemented after the entry into force of REACH (placing on the market of leather products containing chromium VI - Table) (output indicator 3).

Although substances have been put in Annex XIV mostly for their carcinogenicity and toxicity to reproduction, as for Annex XVII, 12 of these substances have also been classified for respiratory sensitisation (Table - output indicator 4). In preparing the applications for authorisation, stakeholders ensure that the risks arising from the exposure to the substances are adequately controlled. This process and the eventual phase out of the substances should guarantee some benefits also in terms of a decrease in the occurrence of occupational asthma.

It should be noted that, although it is not possible to attribute the decrease in occupational asthma to the action of the REACH and CLP Regulations only, the output indicators above provide an

[149] HSE (2015): Work-related Chronic Obstructive Pulmonary Disease (COPD) in Great Britain in 2014. Available at: http://www.hse.gov.uk/statistics/causdis/copd/copd.pdf

indication of what has been done during the last years to tackle substances linked to occupational asthma.

4.3.3 Data availability

Most of the respiratory diseases, with the exception of occupational asthma and other allergic respiratory diseases, are long latency diseases, meaning that the consequences of the first exposure become apparent many years after (UK HSE, 2015). Therefore, the Self-reported Work-related Illness (SWI) survey conducted every year in Great Britain tend to capture cases of long latency diseases reflecting the effects of past working conditions.

It is important to note that occupational and non-occupational exposures work together to cause disease, therefore the number of occupational respiratory diseases represents the number of cases that would not have occurred had the workplace exposures not occurred. The same is valid for the occupational respiratory diseases attributable to chemicals' exposure.

Prevalence is estimated from the results of the SWI annual survey: considering the number of workers reporting to be ill at some point during the previous 12 months in different years, the HSE estimated that around 141,000 people who have ever worked currently have breathing or lung problems caused or made worse by work.

Incidence is estimated from different sources: the SWI surveys, the THOR-GP reporting scheme, the THOR-SWORD[150] and the IIDB, with the last two providing more detailed information but substantially underestimating the incidence.

DGUV provides data on "*obstructive diseases of the respiratory tract caused by chemical irritants or agents with a toxic effect which have forced the person to discontinue all activities that caused or could cause the development, worsening or recurrence of the disease"* (occupational disease 4302). It should be noted that obstructive lung diseases comprehend asthma, bronchiectasis, bronchitis and COPD.

4.3.4 Human health benefits of the chemicals legislation – Occupational asthma

UK HSE statistics

The HSE reports statistics on occupational asthma by causative substances (diagnosed by chest physicians) for the years 1998-2014 (reproduced in Table 4-7). In order to deal with cases with more than one causative substance, we calculated the percentage of cases attributed to chemicals (in grey cells), non-chemical factors and unknown causes. The percentage of cases attributed to chemical and non-chemical factors are presented in Table 4-8.

We then applied the percentage of cases attributed to chemical substances (40%[151]) to the total number of individuals with asthma caused or made worse by work diagnosed by chest physicians between 1998 and 2014[152]. HSE paper on occupational asthma[153] suggests that THOR-SWORD

[150] THOR-SWORD is the reporting scheme for consultant chest physicians, opposed to the THOR-GP that is the scheme for general practitioners. THOR-SWORD tends to capture only the more severe cases that were referred to chest physicians.

[151] Rounded to the nearest multiple of 5.

[152] UK HSE THORS01 statistics. Available at: http://www.hse.gov.uk/Statistics/tables/index.htm

statistics may underestimate the incidence of occupational asthma even by an order of magnitude. Figure 4-3 presents the estimates according to the different sources of information (chest physicians - TOHR-SWORD, general practitioners - THOR-GP, self-reporting workers – LFS).

Table 4-7: Occupational asthma - average annual estimates over 3-year and 16-year periods							
	Cause	2000-2002	2003-2005	2006-2008	2009-2011	2012-2014p	1998-2014p
Organic	Laboratory animals	15	13	11	5	4	10
	Flour	47	33	23	23	18	28
	Enzymes, amylase	9	8	8	5	6	9
	Solder/colophony	38	8	8	7	6	14
	Latex	13	7	2	1	1	6
	Wood dusts	18	14	4	8	12	14
	Grains	13	10	5	2	5	7
	Other creatures (mites, dogs, horses)	10	4	2	0	6	6
	Vegetables, spices and tea dusts	6	0	4	0	1	3
	Fish & crustaceans	5	1	1	1	1	4
	Other biological substances	4	1	4	1	1	2
	Fungi and moulds	4	9	5	2	2	4
Chemical	Isocyanates	57	55	48	28	21	45
	Glutaraldehyde	7	5	1	0	0	4
	Medicines, antibiotics	2	1	1	1	2	2
	Formaldehyde	19	1	1	3	1	5
	Chlorine	1	6	1	4	8	5
	Pesticides, herbicides and insecticides	5	1	4	1	0	2
	Sulphur dioxide	0	0	4	0	0	2
	Ammonia	0	0	4	0	0	2
Metallic	Chrome compounds	10	15	0	1	1	5
	Cobalt and compounds	3	6	1	2	0	3
	Other welding fumes	15	4	4	2	6	7
	Zinc compounds	3	3	1	0	0	3
	Aluminium salts	3	5	4	1	0	3
	Stainless steel welding fumes	3	0	5	0	1	2
	Platinum salts	1	1	1	2	1	1
	Nickel and compounds	8	1	0	4	0	2
Miscellaneous	Cutting oils and coolants	8	32	15	9	5	13
	Epoxy resins, other resins and hardening agents	13	6	2	2	2	7
	Acrylics and acrylates	8	11	6	2	2	6
	Paints	10	20	3	1	6	9
	Cleaning products	11	2	6	13	15	8
	Glues and adhesives	5	5	9	1	4	5
	Inks	1	1	12	5	0	4
	Reactive dyes	0	0	0	0	0	0
	Hair products unspecified	0	1	2	1	1	1
	Unspecified chemicals	7	9	4	0	0	5
	Other specified agents	62	89	173	49	38	87

[153] HSE (2015): Occupational asthma in Great Britain 2014. Available at: http://www.hse.gov.uk/statistics/causdis/asthma/asthma.pdf

Table 4-7: Occupational asthma - average annual estimates over 3-year and 16-year periods							
	Cause	2000-2002	2003-2005	2006-2008	2009-2011	2012-2014p	1998-2014p
	Agent unknown	27	19	18	2	12	17
	Total number of known causative substances	375	288	213	138	138	252
	Total cases	435	370	336	182	166	326
	Total number of known and unknown causative agents	471	405	408	189	188	361
	Total number of cases attributed to chemicals	200	191	139	83	76	151

Notes:
Some physicians report on a sample basis, for one month in each year. Estimated totals for these are calculated by multiplying the actual number of cases reported by 12.
*Some cases may have more than one causative substance.
2014 statistics are provisional.
Source: adapted from UK HSE THORS06 statistics (http://www.hse.gov.uk/statistics/tables/index.htm).

Table 4-8: Percentage and number of occupational cases per causative factors (diagnosed by practitioners)	
Cause	1998-2014p
Percentage of cases attributed to chemical substances	41.8 %
Percentage of cases attributed to organic substances	29.6 %
Percentage of cases attributed to unknown agents or other non-chemical agents	28.8 %

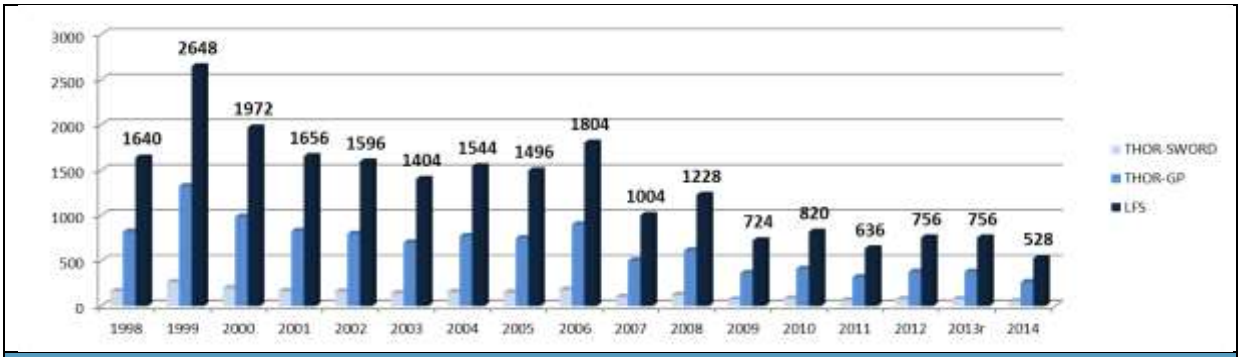

Figure 4-3: New cases of occupational asthma attributable to chemicals in the UK

Deutsche Gesetzliche Unfallversicherung statistics

With regard to the DGUV statistics on occupational obstructive diseases of the respiratory tract caused by chemical irritants or agents with a toxic effect in Germany, Table 25 of DGUV (2015) presents the number of recognised cases of occupational diseases. The data are reproduced in Table 4-9.

Table 4-9: DGUV statistics on occupational obstructive diseases of the respiratory tract caused by chemical irritants or agents with a toxic effect – suspected cases and recognised cases					
	1995	2000	2005	2010	2014
Recognised cases	316	236	171	141	173
Variation in percentage (baseline 1995)					**-45%**

Number of notified suspected cases decreased by 34% between 1995 to 2014 while recognised cases decreased by 75%, broadly confirming the trend shown by the UK data (68% decrease between 1998 and 2014).

Extrapolation to the EU level

Although the German and the UK statistics cannot be considered representative of the situation in the other 26 Member States, for illustrative purposes the project team proceeded in extrapolating these national statistics on the EU level. For consistency, we used incidence and prevalence rates from the Labour Force Survey. These rates refer to a generic "Breathing and lungs problems"; therefore we had to calculate the percentage of occupational asthma reported in different years. The UK HSE Table THORR01[154] reports estimated number of cases of occupational respiratory diseases reported by chest physicians between 1998 and 2014. Table 4-11 reproduces the number of cases estimated by the HSE for the period 2004-2013 while Table 4-11 presents the percentages of the different respiratory diseases compared to the total number of diagnoses.

Table 4-10: Estimated number of cases of occupational respiratory diseases by diagnostic category (2004-2013)

Diagnostic category	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Allergic alveolitis	32	43	47	19	87	39	29	25	56	53
Asthma	386	374	451	251	307	181	205	159	189	189
Bronchitis / emphysema	113	123	65	15	18	69	18	52	19	26
Infectious diseases	26	37	49	28	24	25	2	60	25	14
Inhalation accidents	24	45	16	5	38	50	3	14	3	1
Lung cancer	131	101	82	104	91	86	71	133	16	88
Malignant mesothelioma	819	754	637	884	611	559	522	472	577	658
Benign pleural disease	1120	1481	1281	1008	1114	893	790	831	711	708
Pneumoconiosis	107	222	194	167	145	208	110	224	159	276
Other	134	49	53	81	56	100	61	105	61	105
Total diagnoses	2892	3229	2875	2562	2491	2210	1811	2075	1816	2118

Table 4-11: Percentages of different respiratory diseases on the total diagnoses for the period 2004-2013

Diagnostic category	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Allergic alveolitis	1.11%	1.33%	1.63%	0.74%	3.49%	1.76%	1.60%	1.20%	3.08%	2.50%
Asthma	**13.35%**	**11.58%**	**15.69%**	**9.80%**	**12.32%**	**8.19%**	**11.32%**	**7.66%**	**10.41%**	**8.92%**
Bronchitis / emphysema	3.91%	3.81%	2.26%	0.59%	0.72%	3.12%	0.99%	2.51%	1.05%	1.23%
Infectious diseases	0.90%	1.15%	1.70%	1.09%	0.96%	1.13%	0.11%	2.89%	1.38%	0.66%

[154] THOR - Voluntary reporting of occupational diseases by specialist doctors: Index of THOR - Respiratory (Cases reported by consultant chest physicians to SWORD) - Last updated 10/15. Available at: http://www.hse.gov.uk/statistics/tables/index.htm#thor

Table 4-11: Percentages of different respiratory diseases on the total diagnoses for the period 2004-2013										
Diagnostic category	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Inhalation accidents	0.83%	1.39%	0.56%	0.20%	1.53%	2.26%	0.17%	0.67%	0.17%	0.05%
Lung cancer	4.53%	3.13%	2.85%	4.06%	3.65%	3.89%	3.92%	6.41%	0.88%	4.15%
Malignant mesothelioma	28.32%	23.35%	22.16%	34.50%	24.53%	25.29%	28.82%	22.75%	31.77%	31.07%
Benign pleural disease	38.73%	45.87%	44.56%	39.34%	44.72%	40.41%	43.62%	40.05%	39.15%	33.43%
Pneumoconiosis	3.70%	6.88%	6.75%	6.52%	5.82%	9.41%	6.07%	10.80%	8.76%	13.03%
Other	4.63%	1.52%	1.84%	3.16%	2.25%	4.52%	3.37%	5.06%	3.36%	4.96%

In order to extrapolate to the EU level, we applied the average incidence and prevalence rates per 100,000 workers from the Labour Force Survey to the EU28 workers population and multiplied the result by the percentage of cases attributed to chemical substances (40%) and by the different percentages of occupational asthma cases reported per year (Table 4-12).

Assuming that the incidence and prevalence of the different respiratory diseases in the EU28 is equal to the incidence and prevalence in the UK and that the number of self-reported cases would follow the same pattern, the incidence of occupational asthma in the EU28 equates 2,000 new cases in 2013, while the prevalence equates 7,000 cases. Estimates for incidence and prevalence of occupational asthma in the EU28 are presented in Table 4-13 and Figure 4-4.

Table 4-12: Estimates of the incidence and prevalence of occupational asthma in the EU28						
Year	Incidence average rate per 100,000 workers employed in last 12 months (breathing problems)*	Prevalence average rate per 100,000 workers employed in last 12 months (breathing problems)**	UK workers population***	EU28 workers population	Chemicals attributable fraction	% of cases of asthma
2004	60****	170	28,369,400	208,900,600	40%	13.35%
2005	60****	150	28,666,400	211,991,000	40%	11.58%
2006	61	140	29,040,700	216,155,800	40%	15.69%
2007	53	130	29,260,700	220,363,100	40%	9.80%
2008	52	130	29,520,200	222,875,500	40%	12.32%
2009	54	120	29,058,700	218,952,200	40%	8.19%
2010	56	120	29,125,000	216,843,300	40%	11.32%
2011	51	110*****	29,282,100	216,218,500	40%	7.66%
2012	42	110****	29,596,200	215,807,100	40%	10.41%
2013	34	100****	29,952,500	215,398,500	40%	8.92%

Notes: *UK HSE Table SWIT6W12_3YR
**UK HSE Table SWIT3W12_3YR (http://www.hse.gov.uk/statistics/lfs/index.htm)
***Eurostat statistics – Employment – Labour Force Survey (lfsa_emp), year 2013 (http://ec.europa.eu/eurostat/data/database).
****Values interpolated from 2006-2013 incidence rates.
*****Values interpolated from 2004-2010 prevalence rates.

Table 4-13: Incidence and prevalence estimates of occupational asthma in the EU28 (2004-2013)		
Year	New cases of occupational asthma in the EU28*	EU28 population with occupational asthma*
2004	7,000	19,000
2005	6,000	15,000
2006	8,000	19,000
2007	5,000	11,000
2008	6,000	14,000
2009	4,000	9,000
2010	5,000	12,000
2011	3,000	7,000
2012	4,000	10,000
2013	3,000	8,000
*Notes: *Rounded to the nearest multiple of 1,000.*		

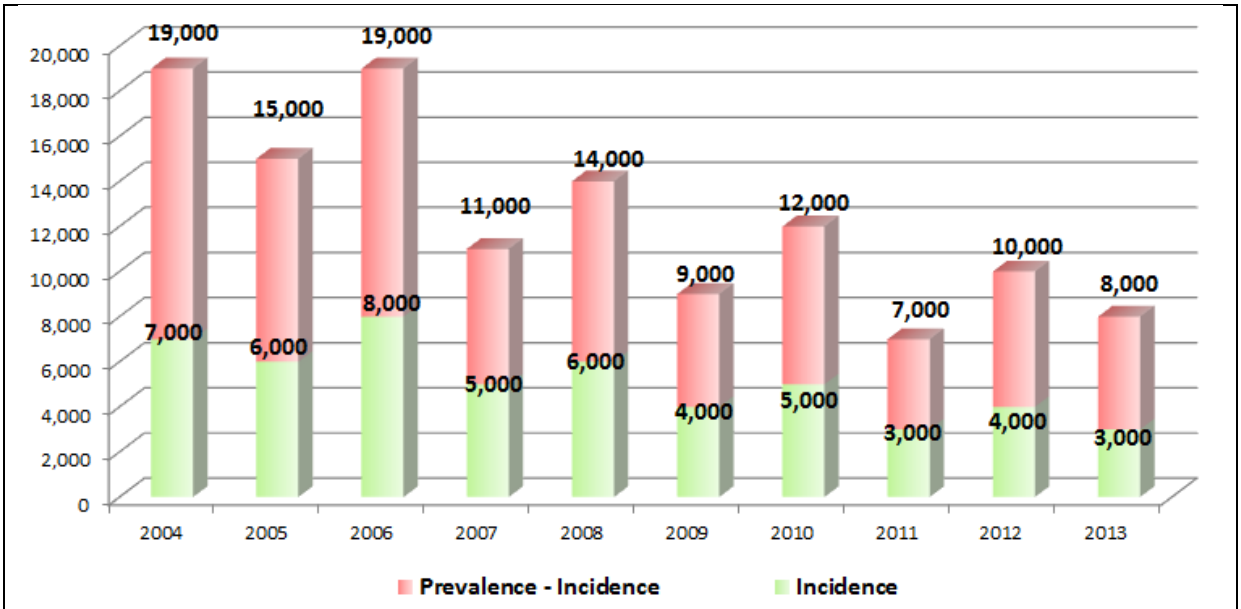

Figure 4-4: Incidence and prevalence estimates of occupational asthma in the EU28 (2004-2013)

Monetisation of the impact

In order to monetise the impact of occupational asthma, we calculated the medical treatment costs and the productivity loss in terms of sick leaves. As for the skin disorders treatment, we used the UK National Health System (NHS) reference costs to calculate the unit cost for the treatment of asthma. The unit costs and the number of treatments in 2013 and 2014 are presented in Table 4-14.

Table 4-14: Unit costs and number of treatments for skin disorders in the UK in 2013 and 2014			
Currency*	Currency description	Activity	Unit cost in GBP
DZ15G	Asthma with Intubation	167	£2,266
DZ15H	Asthma without Intubation, with CC Score 9+	1,666	£2,385
DZ15J	Asthma without Intubation, with CC Score 6-8	4,518	£1,389
DZ15K	Asthma without Intubation, with CC Score 3-5	14,480	£1,025
DZ15L	Asthma without Intubation, with CC Score 0-2	38,712	£695
*Notes: *Currencies are defined as the units of healthcare for which a payment is to be made. **CC stands for "complications or comorbidities" and each CC recorded is assigned a score in order to reflect the increment in complexity and treatment costs.*			

The weighted average treatment unit cost for asthma has been calculated weighting the average unit cost for the number of treatments. This is equal to £880 or €1,188[155].

Assuming that these average unit costs for treating asthma are the same in the EU28, the benefits of the decrease (resulting in 66,000 cases avoided between 2004 and 2013), accrue to around €78.4 million[156] in the period 2004-2013 only in treatment cost savings.

In order to calculate the productivity loss savings, we applied the average days lost for breathing or lung problems[157] in the UK to the number of cases of occupational asthma extrapolated at the EU28 level, obtaining the days lost for breathing and lung problems in the EU28 per year[158]. The reduction in the occurrence of occupational asthma resulted in a total of 1.7 million working days lost avoided over the period 2004-2013. These have been multiplied by the average daily gross earnings in the EU28, resulting in a total of around €168.2 million in productivity loss savings over the period 2004-2013. Table 4-15 presents the calculations and results.

Table 4-15: Productivity loss savings

Year	Average days lost per case*	Days lost in the EU28	Days lost avoided	EU28 Gross earnings per year**	Productivity loss savings***
2004	**18.2****	237,500	-	€ 29,776	€-
2005	**17.5**	262,500	83,300	€ 31,057	€11,200,000
2006	**17.7**	336,300	9,500	€ 31,386	€1,300,000
2007	**17.8**	195,800	150,000	€ 32,187	€21,000,000
2008	**19.9**	278,600	67,200	€ 31,362	€9,200,000
2009	***15.5***	139,500	206,300	€ 30,148	€27,000,000
2010	**21.6**	259,200	86,600	€ 30,388	€11,400,000
2011	***17.4***	121,800	224,000	€ 31,153	€30,300,000
2012	***18.1***	181,000	164,800	€ 32,774	€23,500,000
2013	***14.2***	113,600	232,200	€ 32,944	€33,300,000
	Total	2,100,000	1,200,000	**Total**	**€168,200,000**

*Notes: *Breathing and lung problems - UK values (UK HSE Table SWIT1 - http://www.hse.gov.uk/statistics/lfs/index.htm).*
***Eurostat labour market statistics (http://ec.europa.eu/eurostat/data/database).*
****EU28 average gross earnings per day have been calculated assuming 230 working days per year in all Member States and multiplied per the days lost avoided to estimate the productivity loss savings.*
*****Estimated as average value between years 2003 and 2005.*

To the treatment and productivity loss savings, the willingness to pay (WTP) to avoid occupational asthma should be added. Máca et al (2014)[159] suggest using €50 as central EU-wide WTP value for avoiding asthma discomfort. Multiplying this value by the number of cases of occupational asthma avoided (66,000), we obtain a total of around €3.3 million.

[155] Applying an exchange rate GBP/EUR: 1.35.
[156] Total number of cases avoided (99,000) x Average unit cost for the treatment of asthma (€1,188). Rounded to the nearest multiple of 100,000.
[157] Table SWIT1 available at: http://www.hse.gov.uk/statistics/lfs/index.htm
[158] The underlining assumption is that the average lost days per case in the other Member States are equal to the UK ones and that breathing and lung problems account for occupational asthma only. This could result in an overestimate of days lost for occupational asthma.
[159] Máca V. et al (2014): Appendix: Willingness to pay for avoiding respiratory sensitisation outcomes. Report prepared for the European Chemicals Agency, Helsinki, page 10. Available at: http://echa.europa.eu/documents/10162/13630/appendix_study_economic_benefits_avoiding_adverse_health_outcomes_1_en.pdf

The progressive reduction in the occurrence of occupational asthma attributed to the exposure to chemical substances has resulted in **total cost savings estimated in around €249.9 million over the period 2004-2013 in the EU28.**

These figures are based on UK statistics that cannot be considered representative of the EU situation. However, they provide indication of the order of magnitude of the accrued benefits.

As for the decrease in cases of occupational skin diseases, the benefits are the likely result of multiple factors, such as an increased awareness on health and safety in the workplaces, the adoption of better risk management measures, the legislative restriction and/or voluntary withdrawal of some respiratory sensitisers, the reduction of the workforce in sectors where workers are particularly exposed to respiratory sensitisers[160] and the technological progress in the production processes.

However, the chemicals legislation is a determinant and confounding factor of many of these aspects and has played a major role in reducing the number of cases of occupational asthma.

[160] It should be noted that the results have been normalised to consider the variations in the overall workforce.

5 The Expert Workshop

5.1 Introduction

The expert workshop[161] was a one day event, aimed at gaining the views of socio-economic and risk assessment experts in the fields of public health, environmental protection and occupational health and safety on the methodology followed by the project team, on the work carried out to the date (November 2015) and on the problems and possible solutions for the better development of a system of indicators and for the quantification of the benefits of the chemicals legislation. Around fifty-five experts attended the workshop: members of the ECHA Socio-Economic Assessment and Risk Assessment Committees, representatives of the Member States Competent Authorities, as well as representatives of trade unions, NGOs, research centres, academia, European industry associations and industry.

This Section summarises the main conclusions and remarks of the participants to the workshop. More details are provided in Annex 6 of this report.

5.2 Structure of the Workshop and Main Discussions

The Project Manager and the project team welcomed and introduced the participants to the context, the methodology and the proposed system of indicators. The key issues in developing such a system were highlighted, such as the challenges in ascribing changes in exposures and hence benefits to REACH or CLP, and the paucity of harmonised or comparable data on chemicals' exposure and health statistics across the EU Member States.

The morning session explored different stakeholders' views on potential indicators, as well as outputs of work carried out by other organisations to develop indicators of the effects of chemicals' exposure on human health and the environment, and methods for measuring the benefits accruing from the chemicals legislation. Speakers in the first panel were:

- Mr Vito Buonsante, Law and Policy Advisor, Health and Environment, ClientEarth;
- Dr Annette Prüss-Üstun, Team Leader, Assessment of Environmental Health Impacts Department of Public Health, Environmental and Social Determinants of Health, World Health Organization;
- Dr Tony Musu, Senior Researcher, Health and Safety, Working Conditions, ETUI;
- Mr Kalle Kivelä, Risk Management Implementation unit, European Chemicals Agency.

Following these presentations, the audience was invited to pose questions to the panellists and to respond to some additional research and validation questions developed by the study team to elicit views on the value of different types of indicators and on methodological issues.

With regard to the adequacy of the system of indicators proposed, the audience was of the opinion that the project team should focus on result and impact indicators rather than on output indicators; although output indicators were recognised as being an invaluable component of any overall system of indicators, there was a fear that consideration of too many of these may distract from putting sufficient emphasis on the results and impacts of chemicals legislation. In terms of output indicators, it was stressed that the study team should consider both self-classification data as well as

[161] Workshop website: http://www.euconf.eu/chemicals_legislation_workshop/en/registration/index.html

harmonised classifications, as the former will have changed more over time and may be more informative (bearing in mind difficulties in establishing before and after REACH data on these).

On impact indicators, the audience suggested that, given the lack or paucity of evidence on impacts, the project team should avoid proposing measures of impacts and instead should complement result indicators (measuring changes in exposures) with qualitative information on impacts. With regard to the overall scope of the system of indicators, the audience suggested that the team should focus on result indicators (chemicals' exposure level) and then link any changes identified by these to particular regulations, maybe working with validation cases (specific substances). A question remained unanswered, i.e. on how to capture the benefits of the new information generated by REACH, although it was also suggested that it was too early to quantify these benefits given that not all substances will have been registered until 2018.

The afternoon started with the second set of presentations with this then followed by the second panel discussion. This session explored further methodologies for calculating the benefits of chemicals legislation. The second panel was formed by:

- Dr Matti Vainio, Head of the Risk Management Implementation Unit at ECHA;
- Dr Stavros Georgiou, Economic Analysis Unit at the UK Health and Safety Executive;
- Ms Meg Postle, Project Director for Risk & Policy Analysis.

Questions and answers on the presentations was followed by a second session involving additional research and validation questions for the audience on the indicators and on methodological issues.

In general, participants indicated that it would be appropriate for any system of indicators to include both general indicators that operated at the EU level, as well as 'case study' indicators linked to specific chemicals. This was deemed to be especially true when considering cancers. The audience also suggested the use of indicators at the national level as exemplars of benefits, where extrapolation to the EU28 may not be possible. Extrapolation to the European level should be carried out only when available data refer to at least two or more Member States characterised by a diverse for geography (e.g. North, South Europe), economic situation or specific chemical industry characteristics.

Following the second panel discussion session, the audience was invited to divide into three groups (environment, human health, workers' health) for more detailed discussions, according to the preferences they expressed during their registration for the workshop. The groups were moderated by the morning speakers and by one project team member. The objective was to discuss the results of the key points from the morning and afternoon panel discussions as well as, methodological issues and possible solutions. Specific research questions were posed to each group in order to trigger the discussions.

The workers' health group reinforced the view that the project team should look into self-classifications. Another useful output indicator could be the number of OELs proposed by Member States and implemented due to the new information being generated and made available by REACH. With regard to result indicators, the project team should define an indicator referring to the quantities of hazardous substances used and/or put in the market, ideally by CAS number. Since this type of information is not available[162], it was suggested that the project team should recommend to the European Commission to engage with industry in order to systematically gather this information. Another useful indicator could be to systematically collect data on the number of workers exposed

[162] In the registration dossiers, manufacturers and importers are required to specify tonnage bands only.

to toxic chemicals. Although this information is currently available only for one Member State and the definition of "toxic chemical" may need to be improved (substances with at least one hazardous classification? Substances of very high concern?), it was suggested that similar surveys could be launched in other Member States. This triggered a discussion on what type of data could be gathered through EU-wide surveys, considering the data missing for the best functioning of a system of indicators. The group then suggested consideration of a few other national databases that could be of relevance for the purposes of the study. Finally, it was reiterated that the project team should avoid extrapolating from national statistics to the EU level without validation (meaning similar data from other Member States). When not possible, all assumptions should be made as transparent as possible.

The general human health group discussed the relevance of the different types of indicators. The results indicators are the most important type based on data on exposure/level of chemical substances in human body tissues in the EU population. With regards to impact indicators, only obvious ones should be used. Furthermore, the group discussed the possibility to set up output indicators. A systematic recording of substances in articles is missing, but would be valuable as a tool for quantification of substances imported into EU in articles and materials. Some studies at the National level are existing, but these are not robust enough. The notification of substances in articles to ECHA is only for the uses of articles not included in the registration and therefore not satisfactory. The RAPEX system will also give some information on exposure to the general public, but again this is not satisfactory as not all products posing a risk are reported in the RAPEX system. The number of substances in Annex VXII Entry 28-30[163] could be used as an indicator for changes in the number of CMR substances that the general public can be exposed to.

The environment group started by considering what types of result indicators may be of value in addition to those discussed earlier in the day. Key recommendations were information on production volumes for priority substances under the WFD, production volumes for other ecotoxic substances (and in particular PBTs and vPvBs), import data for SVHC and potentially for a set of substances with certain (unspecified but assumed to be aquatic toxicity or similar) harmonised classifications.

It was also suggested that there may be merit in collating data on inputs (influents) to sewage treatment works; the Environment Agency for England and Wales carried out a study in 2008/09 which it is currently repeating and the data may be of value in indicating the reductions in environmental concentrations of regulated chemicals. Similarly, EurEau may hold data on the presence of regulated substances in inputs to drinking water treatment plants across Europe (although it was unclear whether there was consistent reporting on this across Member States). There was also discussion on the use of water quality and biota monitoring under the WFD, but it was felt that there may be too many uncertainties and other factors affecting the ability to use these in the short term as indicators; in the longer term it should be possible. Similar comments were made with regard to the types of data held on the E-PRTR.

Other key suggestions to be explored further included:

[163] Only substances listed in the relevant Appendices (1 - 6) of Annex XVII are covered by the restrictions in entries 28 - 30. When substances are classified for the first time as CMR and included in an ATP of the CLP Regulation, the European Commission prepares a draft amendment to include these substances in the Appendices of REACH Annex XVII. The amendment then has to be adopted in accordance with Article 68(2) of REACH, before the new substances are covered by entries 28-30. – Source: http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/reach/restrictions

- Data on plant protection products and tonnages of active ingredients applied, which is available for selected countries (e.g. Sweden and maybe Denmark and the UK);
- EEA data sets showing trends for certain pollutants;
- Neonicotinoids and bee populations;
- Use of public health indicators as illustrative of changes in environmental exposures;
- Trace element levels in food products;
- Diffuse metal apportionments developed for ESR risk assessments and use in REACH CSRs; and
- Macro-invertebrate monitoring data.

It should be noted however that plant protection products (and among them neonicotinoids) are not within the scope of the REACH Regulation.

5.3 Remarks and Conclusions

At the end of the breakout session, Richard Dubourg and Finn Pedersen, the external reviewers of the study, were called on the stage to wrap up the workshop and summarise the main conclusions.

Richard Dubourg started by stating that the indicators which are most appropriate for the study depends on what the objectives of the study are and what the indicators are intended to do. He identified three different types of objective which he felt had been proposed (explicitly or implicitly) for the current project:

1. Performance measurement and performance indicators – Is legislation doing it is supposed to do from an operational perspective?
2. Impact evaluation – Is legislation having the intended effect in terms of its overall objectives?
3. Benefits estimation – What has been the value of the legislation in terms of change in 'societal wellbeing'?

He then made the point that no single outcome measure or indicator can answer all three of these objectives (effectively), so that some compromise will be necessary either in relation to the objectives of the indicators/study or the accuracy of the indicators in measuring what they are intended to measure. In that respect, it should be remembered that the term 'indicators', by its very nature, implies imperfect and partial coverage of an objective, which in turn suggests how useful indicators might be for meeting the three objectives just outlined.

For instance, he explained, one of the principal issues encountered in impact measurement, broadly defined, is that of 'confounding'. Regulations have effects on their intended (and possibly some unintended) outcomes through 'pathways' which link the various policy 'levers' to those outcomes. These pathways can involve several steps governing the physical, chemical and economic relationships between different endpoints, and get more complex as the 'distance' between endpoints and the number of steps increase. Longer and more complex pathways mean that the number of factors potentially affecting a final outcome also increases and the relative influence of a particular policy lever is likely to decline.

Simply put, he summarised, this means that, when pathways are long, an outcome can change as a result of a multitude of different factors, not just because of the effects of a policy lever. Moreover, an outcome could deteriorate because of these other factors, even if the effect of the policy lever is positive; conversely, an outcome could improve even if a policy lever is ineffective or even counterproductive. Clearly, therefore, unless these additional ('confounding') factors are taken into

account, an incorrect conclusion could be reached about the effectiveness (and value) of regulation. But 'indicators' are generally simplified representations of relationships between policies and outcomes. They are, by design, unable to control for a large number of possible influences on a particular outcome. If indicators are used to track the movement of outcomes which are the result of complex relationships, it must be in the knowledge that the interpretation of this movement is subject to uncertainty and possible error.

Mr Dubourg argued that a useful indicator is one which generally moves in the 'right direction' in comparison with the true underlying relationship which it is trying to summarise. So, for instance, if the impact of regulation on an outcome is positive over a period, the indicator should show a positive result. According to Mr Dubourg, in the presence of multiple potentially confounding factors, this is not as simple as it sounds. To increase the chances of being useful, he suggested that indicators used in this project should generally:

- Relate to relatively controlled or simple relationships, and outcomes which are relatively close to the policy levers of interest. This will limit the number of confounding factors which could interfere with the movement and interpretation of the indicator;
- Be geographically representative. It is unlikely to be feasible, due to data limitations, that an indicator will cover all countries of the EU, and not all countries are equally important when it comes to a particular policy problem (due, e.g., to geographical concentrations of industry) it should nevertheless strive to cover as much of the 'policy problem' as possible. Certainly, any implied extrapolation from a limited set of countries to the EU level needs to be justified;
- Be regularly updated. If the desire is to measure the performance of regulation over time, which is implicit in an indicators framework, there is no point in using data which is updated only infrequently or inconsistently;
- Cover short-term relationships. Although one major objective of REACH and chemicals regulation generally is to reduce, for instance, the incidence of chemicals-related cancer, the time frames over which it takes exposures to cancer-causing chemicals to manifest themselves in actual cancers mean that a cancer-based indicator cannot provide a timely measure of regulatory performance. It is quite possible that no change in recorded cancers has yet happened as a result of the introduction of REACH, and no such change might be observed for another 10 years. However, changes in cancer-related chemicals exposure have taken place, and such a shorter-term indicator is a better way of measuring REACH impact on cancer than a cancer indicator itself. (This is clearly related to the first point above regarding 'simple' relationships);
- Relate to the major sources of potential benefit. An indicator which perfectly tracks a chemicals-related health impact of only minor concern is clearly not useful in saying whether REACH is generating significant benefits (unless it can be demonstrated that this particular health impact is highly correlated with a broader class of REACH benefits which means that it can serve as a reasonable indicator of these). A related question is where the costs are incurred as a result of REACH, and whether those costs can be linked to any specific benefit;
- Be objective, in the sense that it is based on data and information which are generated independently of the measurement process, rather than as a result of subjective judgement.

Finally, Mr Dubourg made the observation that previous exercises to generate benefits indicators and estimates have been hampered by a lack of widespread and consistent data on relevant factors such as exposures, use volumes etc., but that repeated recommendations to fill these gaps have not generally been acted upon. Until this changes, this and future indicators exercises will struggle to be successful.

Finn Pedersen used as his point of departure the cause-effect relationship of chemicals regulation, namely that implementation of chemicals regulation is supposed to lead to lower exposure of humans (workers and the general public) and the environment, which is supposed to reduce the burden of disease for humans and ecosystem effects. Seen from a top-down perspective, it was obvious that chemicals regulation can be determined with high precision; however, the direct effect on exposure levels could only be determined with some uncertainty and determination of the impact on human health and ecosystems could only be established with high uncertainty. Seen from a bottom-up perspective, at least for human health effects, rather detailed statistics are available in many Member States of diseased that may be attributed to exposure to chemicals; however, it would normally only be possible to estimate with some uncertainty how large a fraction of the diseases that can be assumed to be caused by exposure to chemicals. And as the effect of chemicals regulation on the exposure level is uncertain, estimates of the direct relationship between chemicals regulation and disease levels are rather uncertain.

In his recommendations to the project group, Mr Pedersen suggested that as chemicals regulation is expected to lead to reduced exposure of humans and the environment and as this parameter is the connection between chemicals regulation and impact on humans and the environment, chemicals exposure could be used as a key indicator for the benefits. Another advantage is that, as explained, the inherent uncertainty of determining this indicator would probably be at a medium level compared to other indicators, where the uncertainty in establishing the link between regulation and benefits would be higher. The challenge with using exposure data as a key indicator would be that biomonitoring or environmental monitoring data would only be available for a limited number of often rather well-known substances. However, as registrants under REACH are obliged to prepare a Chemical Safety Report including exposure estimates for all substances manufactured or imported in quantities of greater than 10 tonnes per year and classified as hazardous, it should be possible to dig out this information from the ECHA database.

The workshop was closed by Bjorn Hansen, Head of the Chemicals Unit at DG Environment, who thanked the participants, provided his views on the next steps to be taken and made some closing remarks. Mr Hansen stressed the importance of the study in the context of the Regulatory Fitness Programme (REFIT) for the chemicals area, noting that the assessment of the costs and the benefits of the European legislation is high up in the agenda of all the Member States, as it was also demonstrated by the level of participation during the workshop.

He acknowledged the challenge in quantifying the benefits of the chemical legislation but noted that several useful indicators were suggested and discussed during the panel discussions and break-out sessions. In particular, some of the human biomonitoring data presented highlighted how the legislation is having an impact in lowering the exposure to certain chemicals of concern and the use of monitoring data in informing policy evaluation and policy-making should be therefore further explored.

6 Conclusions and Recommendations

The two main challenges in developing a system of indicators for the assessment of the benefits of the chemicals legislation are:

- The availability of historic data on trends in exposures to chemical substances and on the impacts attributable to the chemicals exposures; and
- The extent to which any change in trends can be attributable to the action of chemicals legislation, as opposed to technical or economic factors.

Information for output indicators is available from ECHA databases and other databases maintained by the Commission services. As the ease of searching data in these databases is being constantly improved, it may be possible to define more refined indicators in the future. For example, it may be possible to compare the registered substances database and the Classification and Labelling Inventory in order to determine the extent to which registration under REACH has resulted in the identification of new and revised hazardous classifications for substances. This would require comparison of the records on the CLI before and after the registration of a substance.

In this regard, an analysis of a sample of substances has been carried out in the context of the REACH Baseline study. However, the complete assessment will be possible after 2018, when all substances will have been registered. Importantly, any future comparison (post-2018) would need to draw on current/historical records for the classification of each substance. This means that it will be essential to ensure that current and previous images of the CLI (and of the registered substances database) are preserved (and in a format that allows comparisons to be made in future).

Whilst it will be relatively easy to make a comparison between substance classifications before and after REACH registration, it may be more difficult to assess the impact of REACH on uses, changes of use and on the implementation of more effective risk management measures for those substances with hazardous properties. The registered substances database records information on the product category, sector of use, process category, and environmental release category for each registered substance. Comparison of this information with information on the same categories before registration would, in theory, enable one to determine how uses have changed with registration under REACH and the role that identification of hazardous properties may have played in that change. In practice, however, it is doubtful that historical information comparable to the use and exposure information on the registered substances database exists and so no comparison will be possible (now or in the future). Thus, other instruments need to be explored in order to establish indicators able to identify:

- The number of substances and/or former uses that have not been registered and, hence, the benefits of eliminating those uses from the perspective of human health and the environment; and
- The number of substances for which there has been a change in the RMMs to be applied for registered uses and hence the benefits of improving risk management for those substances.

During the Experts workshop, EU-wide surveys have been suggested as potential tools to collect such information. Moreover, it was suggested that the European Commission could further engage with industry in order to systematically gather information on the quantities of hazardous

substances used and/or put on the market, ideally by CAS number[164]. Other information of value that should be gathered through surveys is improved data on the number of workers exposed to toxic chemicals.

It should be noted that some of this information has been collected recently during the survey of European companies for the monitoring of the impacts of REACH on innovation, competitiveness and SMEs. According to this report, "*around 53% of the respondents reported to have improved risk management procedures because of REACH, with another 39% reporting to have improved the management of environmental emissions and waste*". Among the companies that reported to have had to improve their Risk Management Measures (RMMs), most had to change personal protection equipment and had to adopt new safety instructions, with some having to invest in emission reduction technologies or to change products/articles compositions. The improvement of RMMs leads to lower levels of exposure to chemicals and, ultimately, results in a reduction of impacts on the human health and the environment.

With regard to result indicators, the data from the German Environmental Specimen highlight their importance for the assessment of the chemicals and environmental legislation and for identifying threats to the human health and the environment. The European Commission is aware of the need to develop an EU-wide human biomonitoring initiative and has set aside €50 million to fund this action. The information generated by this initiative will be of vital importance for the policy-making process in a wide variety of sectors, one of the most important being the EU chemicals legislation.

Similar initiatives (e.g. the EU Occupational Safety and Health Strategic Framework 2014-2020) are also ongoing for the systematic collection and harmonisation of occupational health and safety statistics throughout the EU. This should ensure the availability of better information to quantify the attributable fraction of human health impacts that can be linked to chemical exposures.

With respect to the environmental impact of chemicals on the environment, more work is required to develop better information on the effects of changes in chemical concentrations on environmental populations; the systematic collection of changes in species populations and in biomonitoring data will help in this regard.

With respect to translating impact indicators into monetary terms, this is currently possible for short latency diseases only. For both long latency diseases and environmental impacts, valuation is much more difficult and requires either case study based approaches or large scale valuation studies. In particular with regard to the effects on the environment, there is a paucity of studies on hazardous industrial chemicals; in this respect, chemicals that are persistent and bioaccumulative pose particular valuation difficulties with this being an area requiring much further research given the regulatory priority for addressing such chemical hazards.

It is important to note that this study had the objective of developing indicators to monitor the benefits of the chemicals legislation. Monetary estimates can be provided, but their suitability as indicators is very limited, as they rely on assumptions that are likely to be (and should be) changed over time.

[164] Currently, manufacturers and importers need to indicate the tonnage bands only.

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Annex 1 Literature Review

A1.1 Introduction

Table A1-1 presents the list of articles and reports reviewed in the context of this project.

Table A1-1: List of reviewed studies
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Charles University in Prague and VU University Amsterdam. Stated-preference study to examine the economic value of benefits of avoiding selected adverse human health outcomes due to exposure to chemicals in the European Union, Service contract for the European Chemicals Agency No. ECHA/2011/123, Helsinki, November 2014. Available at: http://echa.europa.eu/support/socio-economic-analysis-in-reach/willingness-to-pay-to-avoid-certain-health-impacts
Trasande L et al, Public health and economic consequences of methyl mercury toxicity to the developing brain, Environ Health Perspect. 2005 May; 113(5): 590–596. Published online 2005 Feb 28. doi: 10.1289/ehp.7743. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1257552/ Legler J, Fletcher T, Govarts E, Porta M, Blumberg B, Heindel JJ, Trasande L. Obesity, Diabetes and Associated Costs of Exposure to Endocrine Disrupting Chemicals in the European Union, J Clin Endocrinol Metab. 2015 Apr;100(4):1278-88. doi: 10.1210/jc.2014-4326. Epub 2015 Mar 5. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4399302/ Hauser R, Skakkebaek NE, Hass U, Toppari J, Juul A, Andersson AM, Kortenkamp A, Heindel JJ, Trasande L. Male Reproductive Disorders, Diseases, and Costs of Exposure to Endocrine-Disrupting Chemicals in the European Union, J Clin Endocrinol Metab. 2015 Apr;100(4):1267-77. doi: 10.1210/jc.2014-4325. Epub 2015 Mar 5. Available at: http://www.ncbi.nlm.nih.gov/pubmed/25742517 Bellanger M, Demeneix B, Grandjean P, Zoeller RT, Trasande L. Neurobehavioral Deficits, Diseases and Associated Costs of Exposure to Endocrine Disrupting Chemicals in the European Union, J Clin Endocrinol Metab. 2015 Apr;100(4):1256-66. doi: 10.1210/jc.2014-4323. Epub 2015 Mar 5. Available at:

Table A1-1: List of reviewed studies
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4399309/
Plas et al. REACH – Evaluation of the impact on the affected industries and the whole economy in Austria. Report prepared for Austrian Federal Ministry of Agriculture, Forestry, Environment and Water, 2015.
EC. Better Regulation guidelines, 2015. Available at: http://ec.europa.eu/smart-regulation/guidelines/toc_guide_en.htm

The following subsections present the in-depth review of the most relevant reports on the benefits of the chemicals legislation on human health and the environment, summarise the different methodologies applied by the authors and pull out monetary values and indicators.

Of the studies that were initially selected for review:

- The USEPA (2000) study "White Paper on Valuing the Benefits of Fatal Cancer Risk Reduction" is not available online anymore. Instead, USEPA (2004) "Value of Statistical Life Analysis and Environmental Policy: A White Paper" has been reviewed;
- The IVM study "Benchmark development for the proportionality assessment of restriction proposals and authorisation applications for PBT and vPvB substances" is ongoing and not available online yet;
- Eurostat (2012) is an update of Eurostat (2009) and have been reviewed together.

Moreover, the following papers have been consulted and considered not relevant for the purpose of the study (identifying past indicators and methodologies for linking the impacts to chemicals and the action of the chemicals legislation to the impacts), therefore an in-depth review has not been included in the Annex:

- FEI (2004): Remediation costs of contaminated sites in Finland;
- KPMG (2005): REACH - further work on impact assessment - A case study approach;
- Heinzerling et al (2005): Applying Cost-Benefit to Past Decisions: Was Environmental Protection Ever a Good Idea?
- Alpha-Gamma (2006): Morbidity and Mortality: How Do We Value the Risk of Illness and Death?
- COM (2006): The impact assessment for a Regulation replacing Directive 91/414/EEC on Plant Protection Products, Commission Staff Working Document
- Chemsec (2006): Implications of REACH for the developing countries
- RPA (2006): Impact Assessment of implementing the GHS
- Clapp et al (2007): Environmental and Occupational Causes of Cancer, New Evidence, 2005–2007
- IMV (2007): Challenges for Economic Analysis under REACH
- Chestnut et al (2009): Economic Valuation of Mortality Risk Reduction Review and Recommendations for Policy and Regulatory Analysis
- WRc (2013): Extended impact assessment study of the human health and environmental criteria for endocrine disrupting substances proposed by HSE, CRD
- FERA (2013): Agronomic and economic impact assessment for possible human health and ecotoxicology criteria for endocrine disrupting substances
- RIVM (2013): Verification of a REACH Environmental Prioritization System against Regulatory Risk Indices.

A1.2 WHO (2000): Methodology for assessment of Environmental burden of disease

WHO (2000) provides an overview of the methodologies used for calculating environmental burden of disease (EBD). The paper is based on consultation with 39 environmental health experts and discusses the various concepts, frameworks and challenges associated with deriving EBD. It also provides examples of previous EBD estimates and considers levels of evidence and uncertainty surrounding the estimates.

The authors offer several recommendations for future EBD assessments with a focus on risk factor categorisation, scenario analysis and determining causation. Nevertheless, the key value of the paper is within the accompanying annexes, which provide different methodologies and indicators that could be applied within the context of this study.

The paper focuses on four thematic areas for which work groups were assigned[165]: water and sanitation, air quality, global environment, and chemicals. The findings of the chemicals work group[166] list four groups of chemical risk factors to be considered in EBD assessments; these include: metals, pesticides, other organochlorines and related compounds, solvents and volatile organic compounds (VOCs). The work group also suggests that the most reliable indicator of actual human exposure is a biological measure of body burden.

More specifically, the work group mentions two studies that could provide indicators of chemical exposure:

- An analysis of breast milk samples from 19 countries for dioxin and PCBs;
- Long-term study of arsenic exposures and health effects in a district in Slovakia.

While these studies could provide useful insights into the levels of exposure at the European level (especially for dioxin and PCBs), it is likely that the findings are outdated. However, a recent literature search indicates that more recent data may be available (e.g. the WHO's Global Environment Monitoring System)[167].

A1.3 Nunes et al (2001): Ecological-Economic Analysis and Valuation of Biodiversity

This paper provides an overview of economic and ecological indicators of biodiversity as well as the underlying valuation approaches. In terms of indicators the paper presents two approaches to measuring biodiversity: biotic-richness and ecosystem health/integrity.

In assigning a value to biodiversity, the biotic-richness approach considers the magnitude of biological products and services flows provided by nature. Under this approach the measurement of biological diversity is typically undertaken with the use of genetic, species, and ecosystem richness or variety indices. The identified indicators and indices are listed in Table A1-2.

[165] Each work group was asked to consider risk factors, the strength of evidence, and relevant alternative scenarios for each of their thematic areas.
[166] Annex 5.2 to the report.
[167] Available at: http://www.who.int/foodsafety/areas_work/chemical-risks/gems-food/en/

The authors present some specific examples of measures of species diversity such as Red Data Books and the Comparative Biological Value Index (CBVI). Red Data Books (RDBs) classify species in one of eight different categories: extinct, extinct in wild, critically endangered, endangered, vulnerable, lower risk, data deficient and not evaluated. RBDs are often used by governments for policy guidance due to their ability to convey information in a simple format. However, the authors highlight that RBDs are difficult to use as measures because the definitions of each category are based on subjective views.

Table A1-2: Biological diversity indicators (biotic-richness approach)		
Type of diversity	**Indicator**	**Description**
Genetic	Phenetic diversity	Measurement of the variance of certain traits and, in general, involves readily measurable morphological and physiological characteristics of the individual.
Species	α, β and γ diversity	α diversity - assesses the number of species (using only their presence and not abundance) in a given area. β diversity - estimates average changes in species in response to site or habitat heterogeneity γ diversity - measures the turnover of species between local areas Red Data Books
Ecosystem	Bio-geographical realms or provinces	Based on the distribution of species
	Eco-regions or eco-zones	Based on physical attributes such as soils and climates

The Comparative Biological Value Index (CBVI) uses a multi-criteria rating method to evaluate coastal habitats. The index takes into account different aspects of a particular site such as (among others) physiochemical features, optimum populations, education and research use, purity and geographical size. These factors are combined to give a total CBVI rating, the higher the rating the greater the requirement for site protection. Nonetheless, the paper acknowledges that this index still relies on some input criteria which require subjective valuation and thus diminish its value for policy making.

The ecosystem health/integrity approach assesses the complex interactions between biotic and abiotic environments, based on the assumption that the variety of abiotic conditions is equally important as the variety of species. The approach measures value in terms of how well an ecosystem is functioning compared to its own potential and the degree to which this functioning impacts upon other ecosystems. Ecosystem health is considered an overall indicator of ecosystem functioning (or integrity).

Nunes et al. (2001) highlight the general methodology used for constructing ecosystem health indices and provides some specific examples of implementation. Such indices typically include three dimensions: biotic and abiotic parameters (e.g. soil, flora and fauna); indicators of scale or system hierarchy (e.g. geographical and temporal boundaries) and economic activities/target groups (e.g. consumers and industry). The indices use inputs from either monitoring activities or integrated modelling techniques that allow for different conversation scenarios to be analysed.

The paper highlights two particular indexes: Ulanowicz's ascendency index (measures any degradation of a system) and the Ecological capital index (assess state of both natural and cultural ecosystems in relation to human activities). However, sufficient detail is not provided on each index to allow for an assessment of their applicability within the context of this study. Nevertheless further investigation could be warranted.

Lastly, Nunes et al. (2001) provide a broad overview of the economic valuation literature with regards to biodiversity. One valuation method reviewed by the paper is total economic value (TEV). The TEV of an environmental resource is defined by two components – its use value (UV) and non-use value (NUV). Use values can be further subdivided into direct (DUV), indirect (IUV) and option values (OV) while non-use values can also be further defined by bequest value (BV) and an existence value (XV). TEV, its value components and valuation methods are described further in Table A1-3.

Table A1-3: TEV components, examples and methods

Uses			Examples	Valuation methods
Total economic value (TEV)	Use value (UV)	Direct use value (DUV)	Recreation benefits e.g. sight-seeing, fishing, swimming	Travel cost, contingent valuation
		Indirect use value (IUV)	Ecosystem functional benefits e.g. regulating local chemical composition of the water	Production function, averting behaviour, hedonic price
		Options value (OV)	Insurance for having the asset on stand-by e.g. future visits, future genetic manipulation	Contingent valuation
	Non-use value (NUV)	bequest value (BV)	Legacy benefits e.g. habitat conservation for future generations	Contingent valuation
		existence value (XV)	Existence benefits e.g. knowledge of existence of marine wildlife diversity	Travel cost, contingent valuation

Source: Nunes et al (2001): Ecological-Economic Analysis and Valuation of Biodiversity

With regards to the empirical literature, the paper reviews a series of studies and presents a value range for each biodiversity component. Table A1-4 presents these ranges alongside studies and the valuation methodologies used.

Table A1-4: Biodiversity value component ranges

	Study	Method
Single species		
Minimum range: $5	Stripped Shiner, endangered species in Wisconsin, US *Boyle and Bishop (1987)*	Contingent Valuation
Maximum range $126	Wolf, endangered species in Sweden Boman and *Bosdedt (1995)*	Contingent Valuation
Multiple species		
Minimum range: $18	Preservation of threatened and endangered species populations in the US, *Hageman (1985)*	Contingent Valuation
Maximum range: $194	Preservation of 300 endangered species in Sweden, *Johnansson (1989)*	Contingent Valuation
Habitat: Terrestrial (non-use)		
Minimum range: $27	Protection of the Nadgee Nature Reserve, Australia, *Bennett (1984)*	Contingent Valuation
Maximum range: $101	Desert Protection in California, US *Richer (1995)*	Contingent Valuation
Habitat: Coastal (non-use)		
Minimum range: $10	Protection of New Jersey beaches, US, *Silberman et al. (1992)*	Contingent Valuation
Maximum range: $51	Protection of a wilderness coastal area, Portugal, *Nunes (2000b)*	Contingent Valuation
Habitat: Wetland (non-use)		

Table A1-4: Biodiversity value component ranges		
	Study	**Method**
Minimum range: $8	Protection of the Norfolk Broads, UK, *Batemann et al. (1992)*	Contingent Valuation
Maximum range: $96	Enhancing wetland habitat in California, US *Hoehn and Loomis (1993)*	Contingent Valuation
Habitat: Ecosystem space (recreation)		
Minimum range: $23/trip	Forest recreation activities in Flanders, Belgium *Moons (1999)*	Travel cost
Maximum range: $23 million/year	Tourism in Ecuador, *WTO (1997)*	Tourism revenue
Ecosystems functions		
Minimum range: $1.2 million	Life-support value of a wetland ecosystem in the a Swedish island, Baltic Sea, *Turner et al. (1995)*	Production function
Maximum range: $4.4 billion	Water ecosystem benefits in ten regions in US *Ribaudo (1989)*	Averting behaviour
Source: Nunes et al (2001): Ecological-Economic Analysis and Valuation of Biodiversity		

The valuations provided above could be of particular use to the study with regards to quantifying the potential biodiversity benefits that may arise from chemicals regulation. On the other hand, it should be recognised that these values are context specific and extrapolating these results to the wider European level may pose difficulties. In addition, all of the studies were undertaken over 15 years ago and this may further limit their applicability in this study.

A1.4 EC (2003): Extended Impact Assessment

The Commission's Extended Impact Assessment focused on the quantification of the costs of REACH for the Chemicals Industry, providing a qualitative description of the potential health and environmental benefits and some illustrative quantitative figures. It identified four benefit drivers[168]:

- The generation of information about the properties of the chemicals and the potential risks that they may pose for health and the environment, and to develop strategies to manage these risks;
- The availability and accessibility to this information to downstream users, the authorities and the general public;
- The replacement of substances of very high concern by new substances less dangerous for health and the environment; and
- Faster action by authorities when risk reduction measures are needed.

Testing and registration costs could lead to the withdrawal of some substances that may no longer be profitable, for example due to low demand as a result of their hazardous properties. In addition, in light of the information gathered, users would adopt greater risk management measures with the aim of reducing risk of exposure to hazardous chemicals.

The Extended IA noted that estimating the benefits of REACH requires assumptions regarding:

- The amount of disease that is due to chemicals;
- The proportion of this unknown amount of disease that will be identified by REACH;

[168] EC (2003): *Extended Impact Assessment,* Commission staff working paper, SEC (2003) 1171/3, 29/10/2003.

- The proportion that will be tackled through risk management measures after socio-economic assessments have been carried out;
- The number of lives subsequently saved and other health improvements; and
- The monetary value attached to these.

The Extended Impact Assessment recognised that, at the time, a comprehensive quantitative assessment of the health and environmental impacts of REACH would have been impossible. This was mainly due to the lack of basic information about the effects of the chemicals that REACH was being introduced to regulate. It noted the complications arising from cocktail effects, non-linear dose-response functions, poor aggregate data and underreported health problems. Notwithstanding, it concluded that the evidence available to support the conclusion that the health burden related to chemicals was considerable, and that the four main drivers within REACH should have helped in reducing this health burden.

The inability to provide a comprehensive quantitative assessment of current impacts meant that it was also impossible to apportion environmental impacts between historical and on-going emissions and to establish how much of the benefits would be delivered by REACH and how much from existing legislation. For example, regarding occupational health impacts, the Extended IA stated that the benefits would be delivered in synergy with the existing legislation, e.g. the Chemical Agents Directive 98/24/EC and/or Directive 2004/37/EC on the Protection of Workers from Occupational Exposure to Carcinogens or Mutagens.

This will also be an issue for the upcoming study, in terms of assessing the benefits delivered from legislation which has been active since 2007. In this case though, it may be possible to consider a series of specific and more concrete actions e.g. substance specific measures, introduction of specific types of protection measures etc.

Given the lack of information, the Impact Assessment adopted a conservative figure of 1% as representing the proportion of all diseases (measured in Disability Adjusted Life Years - DALYs) due to agro-industrial chemicals and chemical pollution from diffuse sources; this was based on the estimated range of 0.6% to 2.5% by Murray and Lopez (1996)[169]. The proportion of diseases that will be identified and tackled by REACH was then assumed to be 10%[170]. It was then further assumed that 10 DALYs are equivalent to 1 life saved[171] with the value of a statistical life assumed to be €1 million. It was also assumed that REACH would start to deliver benefits after 10 years of implementation and that these would continue for another 20 years. The magnitude of the estimated benefits from this assessment is similar to that derived by RPA (2003) at €50 billion.

A1.5 WWF (2003): The Social Cost of Chemicals

WWF (2003) uses three different modelling approaches to assess the benefits of REACH regulation. The first two models use Disability Adjusted Life Years (DALYs) to estimate the burden of disease and premature mortality. The models adopt estimates of DALYs for Established Market Economies (EMEs) from the WHO/World Bank database and then apply World Bank estimates of the proportion of DALYs in EMEs judged to be due to agro-industrial pollution, which range from a low of 0.6% to a high of 2.5%. It is then assumed that REACH will reduce the proportion of DALYs resulting from chemical exposure by 10%, based on insights from the available literature.

[169] Murray and Lopez (1996): *The global burden of disease,* World Health Organisation, 1996.
[170] RPA (2003): *Assessment of the impact of the new Chemical Policy on Occupational Health*, 2003.
[171] WHO (2002): *World Health Report,* 2002.

However, the two models differ in their approach to valuing an individual DALY. The first model calculates health expenditure per DALY, using data from the UK and EU. This ratio is then applied to the number of DALYs avoided through REACH to give an estimate of total healthcare expenditure savings. Meanwhile, the second model takes into account that the value of DALY may be greater than the healthcare costs incurred. As a result, it applies willingness to pay (WTP) estimates (i.e. value of statistical life and value of a life year) to the proportion of DALYs saved by the REACH regulation[172].

The third model takes a different approach and estimates the medical costs and forgone productivity associated with specific diseases or health end-states. The model uses data from a US study (Muir and Zegarac, 2001)[173] that estimates social healthcare costs plus productivity effects of toxic substances in the USA for 1997[174]. The data from this study is then applied within the UK and EU contexts, assuming the same level of incidence among the respective populations and making adjustments for EU incomes.

Overall, WWF (2003) provides two possible indicators of exposure that could be used for this study:

- World Bank estimates of DALYs due to agro-industrial pollution;
- Incidence and cost estimates from the Muir and Zegarac (2001) study.

Furthermore, in terms of the valuation methodology it provides different values for individual DALYs:

- Model I – €5,624 per DALY (healthcare expenditure approach);
- Model II - €90,000 per DALY (WTP approach).

A1.6 Rice et al (2003): Exposure Assessment for Endocrine Disruptors: Some Considerations in the Design of Studies

This paper discusses the various approaches for assessing exposure to endocrine disruptors and as such no specific data are given. Nevertheless, the paper provides insights into potential indicators of endocrine disruptor exposure. It states that in order to gather the information required for exposure and risk assessment, a combination of environmental and biological data are needed. In particular, the paper highlights that data on dietary intake are crucial for an accurate assessment of exposure to endocrine disruptors. It is pointed out that this information can be collected and analysed from a number of sources including breast milk, dietary history questionnaires and duplicate diet or split-plate collection and analysis of food.

The paper also draws attention to the various difficulties associated with assessing exposure to endocrine disruptors. For instance, it states that different life stages may be more susceptible to endocrine disruption than others (the embryo/foetus life stage is the most vulnerable). As a result, the authors recommend that study designs should aim to capture data on the timing of exposure in the course of a child's development in addition to frequency and intensity. Further issues highlighted within the paper include routes of exposure, sample collection and storage.

[172] The model uses €90,000 per DALY (specific currency units are not given.

[173] Muir and Zegarac (2001) Societal costs of exposure to toxic substances: economic and health costs of four case studies that are candidates for environmental causation. Environmental Health Perspectives, 109, Supp.6, 885-903.

[174] The study covers diseases such as diabetes, Parkinson's disease, neurodevelopmental effects & hyperthyroidism, and deficiencies in IQ.

A1.7 RPA and BRE Environment (2003): The Impact of the New Chemicals Policy on Health and the Environment

The study aimed to illustrate how the new proactive approach proposed by REACH may have improved the human health and the environment. Four case studies were examined:

- Nonylphenol;
- Short-chained chlorinated paraffins;
- Tributyltin;
- Tetrachloroethylene.

In order to determine whether the new legislation would have required additional data and recommended stricter risk management measures than the previous legislation (the Existing Substance Regulation), REACH dossiers were developed for each case study chemical. Moreover, the damages arisen over time due to the failure to control the risks were identified.

The authors concluded that, although for the four chemicals considered, there was already an understanding of their impacts, REACH would have ensured more rigorous testing and risk assessment requirements that would have provided better information to trigger more restrictive regulatory measures.

The impacts were defined in terms of:

- Number of EU water bodies likely to exceed the no effect concentration level for nonylphenol;
- Costs to remediate contamination of groundwater resources per tetrachloroethylene;
- Detection in animal tissues and human breast milk for SCCPs;
- Commercial loss due to negative impacts on harvested shell fisheries.

A1.8 RPA (2003): Assessment of the Impact of the New Chemicals Policy on Occupational Health

This study started with an extensive review of the health and safety legislation already in place that would interact with REACH and provide an enhanced level of protection to workers against occupational diseases that may arise from exposure to chemicals. The study highlighted that the health impact reductions and the associated economic benefits will not be delivered by REACH alone, but that REACH is expected to accelerate the introduction of risk management measures, including: improvements in classification and labelling, the adoption of new occupational exposure limits under other legislation, bans on the use of substances of very high concern, etc.

The authors identified the generation of new and additional information on the health risks arising from chemicals, whose properties are currently poorly understood, as a main driver of benefits. It took as its basis White Paper predictions setting out a Strategy for a Future Chemicals Policy that REACH would result in the identification of some 500 new carcinogenic, mutagenic and reproductive (CMRs) toxic substances (the continued use of which would have to be authorised for specific applications). The identification and authorisation of these currently unknown CMRs, together with other chemicals posing human health hazards, as predicted will lead to a reduction in the incidence of work-related occupational health effects in the future and to savings in the economic costs associated with medical treatment and recovery.

Five groups of disease were analysed:

- Skin: eczema, allergic contact dermatitis, irritant contact dermatitis;
- Respiratory System: asthma, allergic rhinitis, and other respiratory illnesses;
- Eyes: conjunctivitis;
- Central Nervous System: CNS disorders; and
- Cancer: various end-points, with a focus on those that stem from general chemicals exposure (as opposed to cancers arising from exposure to known carcinogens).

The approach adopted in the study identified and reviewed the published data on the numbers of occupational diseases associated with exposure to "specific", "unspecified" and "unknown" chemicals. The availability of data[175] on occupational diseases varied at the Member State level, with a good range being available for Germany, the UK and a few other EU countries. The data also varied in terms of the disease end-points that were covered and the degree to which the data separated chemicals-related cases from other causal agents or activities. As the data became more specific to chemical-related diseases, the number of countries for which detailed figures were available decreased, in particular for data on numbers of occupational diseases associated with "unspecified" or "unknown" chemicals.

Data on exposure to carcinogens across all workers in the EU were provided by the CAREX database (for the years 1990-1993). These data and other estimates of health experts on the number of cancers that are due to occupational exposure reflect cases related to known or suspected carcinogens. No reliable statistical data were found on the numbers of cancers resulting from exposure to unknown carcinogens.

The study also reviewed the literature on the economic costs of ill-health and combined different approaches to economic valuation (direct and indirect resource costs, human costs) considering:

- The costs of medical treatment;
- The value of lost output; and
- The human costs, where these reflect an individual willingness to pay to avoid a particular health effect.

All of the figures for the health care costs, hospital treatment costs for respiratory diseases, the value of a statistical life and the willingness to pay to avoid morbidity related health effects and to reduce the risk of fatality were taken from different studies, among them: Pearce (2000)[176] and the values from the European project ExternE (1997).

The study combined information from different sources and generalised at EU level the validity of data coming from specific countries with the help of adjustment factors. The approach that was adopted for extrapolation was based on estimating incidence rates amongst the worker population for individual countries and then using the average figure to predict the number of cases at the EU level.

[175] Annex I to the study reports a large list of statistical data sources to the date (2003), among them Eurostat, the World Health Organisation and the International Labour Organisation databases, plus the Health and Safety Authorities datasets across the EU.

[176] Pearce (2000): *Valuing Risks to Life and Health, Towards Consistent Transfer Estimates in the European Union and Accession States*, paper prepared for the European Commission (DGXI), Workshop on Valuing Mortality and Valuing Morbidity, November 13, 2000, Revised December 2000, Brussels.

In order to account for uncertainty as to the impacts of REACH, varying assumptions were made resulting in benefit estimates under low to high scenarios. For example, assumptions were made regarding the effectiveness of REACH (1/3 to 2/3 decrease of health effects by unknown chemicals) and the value of a human life (low and best value):

- Lower bound: one third of the diseases can be avoided. For cancer this is 2,167 cases, which is 0.23 % of the total cancer deaths per year in the EU;
- Upper bound: two thirds of the diseases can be avoided. For cancer this is 4,333 cases or 0.47% of the total cancer deaths per year in the EU.

Once the estimates of the number of disease cases avoided for worker populations were developed, the study then valued these in monetary terms. It used as its lower estimate €0.65 million (based on the willingness of individuals to pay to avoid the risk of fatality, no medical costs are included in this estimate) and its higher estimate €1.0 million (human costs and some elements of medical costs and lost output).

The resulting estimates of the benefits for occupational health were that these would fall between €18 billion and €54 billion, depending on assumptions concerning the number of disease cases avoided and the choice of the value of a statistical life. These are not the total benefits of REACH, because other potential benefits in relation to consumer and public health and the environment have not been taken into account.

The estimates assumed that the benefits would be realised over a 30-year time period, with the time when reductions in diseases would begin to occur linked to the specific end-point. A 3% discount rate was assumed for consistency with the Business Impact Assessment carried out for REACH (RPA and Statistics Sweden, 2002).

A1.9 Nordic Council of Ministers (2004): The True Costs of REACH

This paper compares the cost of REACH with a proposed variant *'REACH Plus'*[177]. While this paper does not explicitly provide any indicators of chemical exposure, it does provide some insights into the costs that may be incurred from regulation as well as estimations of the total number of substances that will be registered under REACH.

For example, the paper recalculates previous European Commission estimates of the number of substances that will be registered under REACH by accounting for several factors, these include: rationalisation (i.e. chemicals that are likely to be withdrawn from the market in the face of new regulation); repeat registrations and formation of consortia; and turnover in chemical usage. The authors then calculate the cost per substance for testing and registration in each volume tier and multiply this by the total number of chemical substances expected to be affected.

In addition to these direct costs, the paper also considers the potential price impacts of the REACH regulation. Using a single market model, the authors calculate that REACH would increase prices by 0.03% and decrease output by nearly 0.06%. Similarly, they find that consumer and producer surplus, for the whole of the European chemical industry, would each decline by €45,000 per year. Finally, the paper points out that the cost impacts of REACH would not be outside the normal cost fluctuations experienced by the chemicals industry (e.g. the price of crude oil).

[177] Defined as a version that restores some features of an older version of REACH

A1.10 COWI (2004): Valuation of Chemical related health impacts for the Danish EPA

A study carried out by COWI (2004) for the Danish EPA also applied a cost of illness approach to value the direct and indirect costs of five diseases (asthma, headache, contact allergy, lung cancer and skin cancer). Direct costs were calculated using data available from the literature and expert judgments, with a patient's own lost earnings included in the calculation (i.e. well-being forgone). In this case, as the aim was to value the costs associated with the burden of disease, estimates were based on the prevalence of the disease in the general population. Transition probabilities were used to estimate the migration of patients from one disease state to another, based on survival data given in the literature. Rates are then multiplied by individual disease 'state' costs of treatment, etc. to generate the direct costs. Social welfare costs are estimated based on a benefits transfer approach using available willingness to pay values.

A1.11 Pearce, Koundouri (2004): Regulatory assessment for chemicals a rapid appraisal

This paper was written by the same authors of WWF (2003) and adopts a similar methodology. Once again the authors only consider the potential health benefits that could arise from the REACH regulation; environmental benefits are not considered. DALYs from WHO/World Bank datasets are used and a 10% reduction in exposure levels is assumed. In contrast with the last paper, the authors only use two approaches (as opposed to three in the WWF paper) to value a DALY: one based on medical expenditure and another using WTP values. However, the same values are as in the previous paper. As a result, this paper does not yield any new insights with regards to potential indicators.

A1.12 ECORYS (2004): The impact of REACH, overview of 36 studies

As stated in the title, this paper reviews 36 studies that have attempted to estimate the impacts of REACH. In terms of indicators, the paper does provide an overview of the different methods used to estimate the benefits of the REACH regulation. In total, it summarises three general methodologies for assessing direct benefits to human health and the environment:

- Assessment of the time saved between establishing the dangerous properties of chemicals and implementing risk reducing measures;
- Estimation of the number of illnesses, which are caused by exposure to chemicals, and the application of different models to calculate the benefits (e.g. DALYs and WTP values); and
- Calculation of the costs for rectifying the damage caused by substances that are released in the environment.

In spite of this, the paper does not provide further details with regards to the data sources used for the indicators (although references to the individual papers are included). It can therefore be argued that while the paper provides some useful insights and a summary of previous results, it does not have much value for the purpose of the identification of indicators.

A1.13 Eftec (2004): The health benefits of pollution control - a review of the literature on mortality and morbidity

While no indicators are provided in the paper, it does review the valuation literature for mortality and morbidity, with a focus on the Value of Statistical Life (VOSL) and Value of a Life Year (VOLY) approaches. It also discusses the issues surrounding the use of those approaches, such as the effects of age and income.

The VOSL estimates provided in the paper could be of some use to this study (see Table A1-5). For the UK, the paper highlights that VOSL values derived from stated preference studies are largely invariant with context and are typically around £1-1.2 million[178]. Nevertheless, all of the values included in the paper are taken from studies published pre-2004 and it is likely that more recent estimates have become available. The applicability of the values must therefore be treated with caution.

Table A1-5: Estimates of the VOSL

Study	Country	Risk Context	Type of study	VOSL £M (2002 prices)
Costa & Kahn (2002)	USA	Fatality rates over time	Wage risk	3.9 – 5.0
Viscusi & Aldy (2003)	USA	Various occupational risks	Wage risk	5.2
Viscusi (2004)	USA	Occupational-industry risk measure	Wage risk	3.5
Hammitt (2000)	USA	Various	Various	2.8 – 6.6
Alberini et al (2001)	USA Canada	Context free reduction in mortality risk between ages of 70 and 80	CV CV	1.1 – 3.6 0.7 – 2.7
Krupnick et al (1999)	Japan	Context free reduction in mortality risk between ages of 70 and 80	CV	0.1 – 0.3
Persson et al (2001)	Sweden	Road traffic risks	CV	2.0
Markandya et al (2004)	UK	Context free reduction in mortality risk between ages of 70 and 80	CV	0.9 – 2.1 (mean WTP) 0.5 – 0.6 (median WTP) 0.7 – 1.4 (pooled)
Chilton et al (2004)	UK	Mortality (impacts from air Pollution)	CV	0.2 - 1.1
Chilton et al (2004)	UK	Roads (R), Rail (Ra), Domestic fires (Fd) and public fires (Fp)	CV	Ratios: Ra/R =1.003 Fd/R = 0.890 Fp/R = 0.960
Beattie et al (1998)	UK	Roads (R) and domestic fires (F)	CV	4.2 (R) for 10^{-5} 9.4 (R) for 3.10^{-5} 6.3 (F)
Carthy *et al* (1999)	UK	Roads	CV / standard gamble	1.1 - 1.7
Siebert and Wei (1994)	UK	Occupational risk	Wage risk	9.7
Elliott and Sandy (1996)	UK	Occupational risk	Wage risk	0.9
Arabsheibani and Marin (2000)	UK	Occupational risk	Wage risk	7.9

Source: Reproduced from Eftec (2004)

[178] If hedonic wage risk studies are considered this changes

A1.14 Ostertag *et al* (2004): Analysis of the costs and benefits of the new EU chemicals policy

This paper concentrates on three different types of benefit associated with REACH; these include the extent to which REACH:

- Improves existing foundation for assessment and communication of substance-oriented risks in the supply chain;
- Contributes to improved knowledge management with regard to assessing old substances;
- Contributes to the prevention of chemicals-related harm costs.

The paper offers few indicators of relevance to this study. However, it does provide some useful valuations and insights into past levels of environmental exposure to chemicals in the German context. For instance, the paper reviews the literature and finds that the cost of PCB remediation in public buildings[179] is equivalent to €25 per resident. Moreover, the paper presents data on the costs of removing pesticides from drinking water at the European level (see Table A1-6).

Table A1-6: Costs of pollution of water with pesticides

	Costs in € millions/a	Euros per capital and year	Source
Costs for the removal of pesticides from drinking water (including monitoring)	162	2.75	UK Water Industry Research (2003); costs Survey
	240 in 10a	1.6	Netherlands Water Association (2004), costs survey
Costs for removal of pesticides from drinking water (including monitoring) and costs of preventive measures	65 - 95	0.78 – 1.16	Hanover University (1998), calculation model

Source: taken from Ostertag et al (2004)

The paper also presents data for Germany on chemicals-related industrial diseases; contact eczema and skin cancer. One key finding is that dangerous substances contribute some 7 % to the unfitness to work in Germany and generate approximately 3 billion euros in direct (illness treatment) and 2.7 billion in indirect (disability) costs per year.

A1.15 Norden (2004): Cost of Late Action - the Case of PCB

Norden (2004) estimates the environmental costs to society across the EU-25 of a PCB misstep. Firstly, the paper uses Swedish data to estimate a total social cost associated with a PCB misstep, these data include future estimates up to 2018. The data variables include:

- Amount of money that society has paid to research and monitor PCB;
- Costs associated with handling PCB contaminated waste;
- Cost of replacing PCB contaminated parts in buildings; and
- Cost of an eagle conversation project to counteract the effects of PCB.

[179] In particular schools and kindergartens.

The data for Sweden are then extrapolated to the EU level using an indicator of PCB production in five Member States - assumptions are made on the level of production for the remaining twenty Member States. This extrapolation is conducted using the average PCB cost[180] per tonne produced in Sweden, estimated at around SEK 0.6 – 1.25 million (€0.07 – 0.14 million). The authors also factor in different societal levels of ambition among countries with regards to dealing with PCB.

Table A1-7: PCB production in five EU member states	
Member State	**Production (thousand tonnes)**
Germany	155
France	118
United Kingdom	67
Spain	28
Italy	27
Source: Inchem cited by Norden (2004)	

A1.16 WORKHEALTH (2004): Indicators for work-related health monitoring in Europe

In response to a political request for practical, quick and easy to handle basic health monitoring system on European level, WORKHEALTH (2004) provides a shortlist of indicators or work-related health monitoring in Europe (see Table 2-8). The indicators were selected from a comprehensive list compiled by the report and were based on professional opinion of all the project partners reflecting the public health, occupational health and safety, work inspectorate, and social insurance perspectives.

Table A1-8 shows that, in 2004, data were available for five of the eleven listed indicators, while it was fragmented for two of the indicators and for four no data were available. Due to the age of this report, it is not possible to assess whether the continued availability of these data sets is assured. Nonetheless, a literature search has indicated that recent data are still available for some of the indicators from the European Statistics on Accidents at Work (ESAW) database[181].

Table A1-8: WORKHEALTH shortlist of indicators				
Indicators	**Operational indicators**	**Data source**	**Data holder**	**Data availability**
Accidents at work	Incidence rate of serious accidents at work in comparison to 1998 (=100) with incidence rate = (no. of accidents at work with > 3 days' absence that occurred during the year/number of persons in employment in the reference population) x 100 000	ESAW	Eurostat	Available
Occupational diseases	No. of recognised occupational diseases by economic activity and disease per 100.000 workers covered by the recognition system	EODS	Eurostat	Available
Work-related health risks	% of employees thinking that their health or safety is at risk because of work	European Survey on Working	European Foundation	Available

[180] This is the total social cost not the cost to decontaminate one tonne.

[181] For example see: http://www.emsa.europa.eu/retro/Docs/marine_casualties/ESAW_methodology_2012_edition.pdf

Table A1-8: WORKHEALTH shortlist of indicators				
Indicators	**Operational indicators**	**Data source**	**Data holder**	**Data availability**
		Conditions		
Sickness absence (by diagnosis)	% of employed people absent from work in reference week due to own illness, injury or temporary disability	Labour Force Survey	Eurostat	Available
Disability	% of employees stating that they have a longstanding health problem or disability by occupational class	European Community Household Panel Labour Force Survey: ad hoc module 2002	Eurostat	Available
Disease occurrence**	Morbidity (prevalence or incidence) by ICD main groups stratified by occupations and economic sectors	-	-	Not available
Job quality	Indices on several aspects of working conditions (physical working conditions, psychological working conditions, work autonomy, work intensity)	Eurobarometer 56.1 European Survey on Working Conditions	Eurostat European Foundation	fragmented
Health promotion activities at the workplace	% of enterprises carrying out workplace health promotion activities	-	-	Not available
Reintegration - rehabilitation	% of enterprises/institutions providing action on reintegration of staff (especially disabled staff) when they return to work after a longer-term period of sick-leave	-	-	Fragmented
Compliance with OSH regulations	% of ILO OHS conventions ratified by the Member States % of enterprises complying with a legal provision	ILO	ILO	Not available
Expenditures on occupational health & safety measures	% of total health expenditure or % of GNP/GDP	-	-	Not available
Source: WORKHEALTH (2004)				

A1.17 WHO (2004): Occupational carcinogens: Assessing the environmental burden of disease at national and local levels

This paper provides guidance on assessing the current burden of disease from past and current occupational exposures to carcinogens of which the outcomes include lung cancer, leukaemia and malignant mesothelioma. The paper shows how workforce and exposure data can be used

alongside relative risk factors from the literature to estimate the impact (in terms of DALYs) of occupational exposures to carcinogens.

The paper assesses a number of selected occupational carcinogens and outcomes, these include:

- Arsenic, asbestos, beryllium, cadmium, chromium, diesel exhaust, nickel, silica (cancer of the trachea, bronchus, or lung);
- Benzene, ethylene oxide, and ionizing radiation (leukaemia); and
- Asbestos (malignant mesothelioma).

To estimate the proportion of workers exposed to carcinogens for lung cancer and leukaemia, the paper uses the exposed proportions of workers in the industrial sectors or occupations who were exposed to the carcinogens from CAREX survey. CAREX is a survey of 139 carcinogens and presents data on the proportion of workers in the European Union exposed to higher-than-background levels of the carcinogens (IARC Class 1, 2A, and selected 2B agents) between 1990 and 1993. This is the main indicator used within the paper. However, the indicator itself has not been updated with more recent data at the time of writing[182]. As a result, it has limited applicability to this current study.

A1.18 Sundberg and Söderqvist (2004): The economic value of environmental change in Sweden

Sundberg and Söderqvist (2004) built upon the existing environmental valuation literature by conducting a comprehensive survey and subsequently summarising a number of Swedish valuation studies. One of the main outputs of the paper is a database of more than 170 valuation studies of environmental change in Sweden – ValueBase[SWE]. The database categorises these evaluation studies in terms of the type (e.g. journal, report, conference paper etc.), valuation method (e.g. revealed and standard preferences) and what type of environmental change is being valued.

Annex 2 provides a summary of each of the studies (around 170) included within the database with regards to the methods used and values obtained. The database is still available and could provide a valuable source of information for this study, although the fact that the database was last updated in December 2003[183] may diminish its relevance.

A1.19 US EPA (2004): Value of Statistical Life Analysis and Environmental Policy: A White Paper

US EPA (2004) is a background paper on the value of statistical life (VOSL) used by the United States Environmental Protection Agency (US EPA). Since 1999, the US EPA has used a central VOSL estimate of $6.2 million (in 2002 dollars) for the majority of its economic analyses. This value is derived from 26 estimates compiled for EPA's first retrospective analysis of the Clean Air Act[184]. The estimates are taken from different studies published between 1976 and 1991 - 21 from hedonic wage studies and the other five studies emanating from contingent valuation studies. The overall estimates range from $0.9 million to $20.9 million (2002 dollars). The EPA has since made a number of adjustments to the central value to account for time effects and income.

182 18 March 2015

183 At the time of writing, 18 March 2015

184 USEPA (1997): The Benefits and Costs of the Clean Air Act, 1970 to 1990, accessed on 10/03/15 at: http://www.epa.gov/cleanairactbenefits/1970-1990/contsetc.pdf

The US EPA (2004) paper reviews three EPA funded studies (intended to examine various segments of the mortality risk valuation literature) in conjunction with three meta-analyses that derive VOSL estimates. This review is used to construct a set of questions for future discussion on the US EPA's VOSL. The paper concludes that the literature has grown considerably since the EPAs default estimate was derived and that the 'the time is ripe for revisiting the VOSL estimate(s) used in EPA policy analysis'. This assessment, in addition to the fact that the estimate is derived from US studies, indicates the US EPA's VOSL will have limited applicability for this study.

A1.20 DHI (2005): The Impact of REACH on Environment and Human Health

The DHI study identified three approaches for assessing the potential benefits of REACH on the environment and humans exposed via the environment. The aim of applying all three approaches was to circumvent the lack of suitable data. The three approaches were:

- Use of WTP estimates – with this based on benefits transfer of willingness to pay among the broad population for avoiding impacts of chemicals (weaker approach);
- Damage function approach (weakest approach) with this applied to four specific cases. Then, through a system of scoring, the amount of substances with a higher score was estimated and an assumed benefit of 10% of the costs was calculated; and
- Avoided or saved costs approach (most robust approach).

Although the use of WTP estimates was considered the theoretically correct approach to assessing benefits, its application was limited by a lack of relevant studies, with only estimates of benefits in relation to drinking water quality derived.

The damage function approach was applied using a risk ranking type of system based on the EURAM[185] method to provide the basis for assessing the likely changes in exposure to hazardous substances, which could then be linked to valuation. The scores that were estimated are measures of environmental exposure (EEX-values), environmental effects (EEF-values) or measures combining exposure and the toxic properties of the chemicals (environmental scores, ES-values). Persistent toxic substances that are produced in large amounts were ranked very high. Although the method resulted in a very high number of substances being ranked similarly, and the DHI study team urged caution in the use of the results, the approach provided a means of benchmarking substances in terms of their relative risks which could then be used to develop an overall indicator of more general shifts in risks.

The study also used the avoided costs approach (a form of market-based approach) to estimate the benefits from chemicals regulation. Saved costs included the costs of water purification, sludge and dredged sediment disposal and cleaning of fish. The starting point was that excess levels of chemicals in a specific environmental compartment would restrict the possibilities of using it, thereby implying a loss of potential future income or value and/or costs for treatment or cleaning. The avoided costs approach generated the smallest estimates of environmental benefits but was also considered the most robust of the methods applied (as opposed to WTP values where only limited studies were available).

The benefit drivers discussed in the study were ranked in order of decreasing importance:

[185] European Union Risk Ranking Method, which was developed for prioritising EU high production volume chemicals for risk assessment.

- Industry introduces additional Risk Management Measures (RMM) as a consequence of either having re-classified substances as a result of additional information on substance properties leading to additional S-phrases, or having identified risks by preparing a Chemical Safety Assessment (CSA) in relation to the registration of their chemicals;
- Use conditions are imposed as a result of an Authorisation obtained for certain uses of prioritised substances of very high concern; and
- Restrictions on manufacturing, marketing and/or use as a result of the Restriction procedure.

The authors viewed the Restriction procedure as essentially a continuation of the Marketing and Use Directive (76/769/EEC), so they assumed that REACH would have no or only minor influence on releases to the environment through this instrument. The main benefits of REACH were then assumed to be related to registration of phase-in (existing) substances manufactured or imported in a quantity of more than 10 tonnes per year and meeting the criteria for classification as dangerous or the PBT/vPvB criteria.

We assume that, as this study is not attempting to develop a marginal analysis of the pre-REACH to REACH situation, the benefits from Restriction and Authorisation are relevant.

The input data for the study were obtained from the European Commission's IUCLID database and from the Danish EPA QSAR2 database. The information from the IUCLID database was restricted to substances manufactured or imported in quantities above 10 tonnes/year and information on properties and amounts was collated for 8,031 substances. The following data were extracted:

- CAS numbers;
- DSN number coding for the registrant;
- Quantities manufactured or imported per year;
- Main Categories of use (per entry); and
- Hazard classification.

All of the input data were uncertain and the authors noted that it could only be used with caution.

The study highlighted the level of uncertainty associated with all of the data which it relied upon:

- The majority of the information in IUCLID submitted by industry on the quantity of chemicals manufactured or imported was for the years 1991-1995 although some entries have been updated since then;
- Information on main categories of use was on the one hand based on information available to the registrant and on the other hand specified by a number of main categories of uses, which are a weak basis for estimating releases; and
- The QSAR models used for estimating biodegradation and aquatic toxicity had not been subject to an external validation and peer review (although a comprehensive internal validation has taken place).

Assumptions regarding the efficiency of REACH in reducing the burden of chemicals were the same as in the Extended IA, fixed at a level of 10%.

A1.21 Pickvance *et al* (2005): The Impact of REACH on Occupational Health

The aim of the study carried out by the University of Sheffield for the ETUI was to complement the set of estimates produced by RPA (2003) study on occupational health benefits. As a result, it did not cover cancers but focused on two broad groups of occupational diseases: non-malignant diseases of the skin (dermatitis) and diseases of the respiratory system (asthma and chronic obstructive pulmonary disease).

The authors combined a range of techniques to calculate the direct and/or indirect health benefits of REACH, calculating the burden of occupational disease from the information obtained on incidence rates, estimating the proportion of cases attributable to exposure to substances affected by the Regulation and using this estimate to calculate preventable disease for the EU-25 workforce (200 million). Then they analysed the costs associated with skin and respiratory diseases in terms of the associated health service costs, productivity costs, and the value of the lost health-related quality of life to the individual using QALYs.

To determine the disease burden, three databases - PubMed, NIOSHTIC, and CISDOC - were searched for relevant peer-reviewed publications using a range of search terms including: occupational dermatitis/eczema, asthma, chronic obstructive lung/pulmonary/airways disease, burden, prevalence, incidence, compensation, cost, outcome, name of EU state. All reference citations were followed up and data were compared with the information from the public health organisations in the EU Member States and with occupational disease data from the EODs, EUROSTAT[186], MISSCEEC[187], EUROGIP[188] and RIDDOR[189] databases.

Health service costs were calculated using evidence from other studies in the published literature. For valuing production losses, two alternative methods were used: the human capital approach (the traditional approach) and the friction-cost method. The monetary values of the prevention of reductions in health-related quality of life for individuals with occupational asthma, COPD, and dermatitis was approximated by multiplying an estimated utility decrement over an assumed duration of symptoms by the value of a QALY (assumed to be between €28,000 - €43,000, see also discussion below under cost-benefit analysis). The mid-point estimates of costs incurred due to productivity losses, health care costs, and monetary valuations of the impact of lost health relating to chemicals covered by REACH were calculated for 10-year and 30-year time horizons following implementation of REACH, compared to a scenario in which REACH had not been implemented.

The data regarding the chemical substances produced and marketed in the EU were collected from the EINECS, ELINCS and IUCLID databases.

The adopted approach required several assumptions to be made by the authors. It was assumed that the effects of REACH are likely to be proportional to the theoretical and actual effects of chemical substances wherever they fit into the existing framework of chemical legislation. Given the impact of the assumptions built into the estimates of the number of cases of disease, the authors preferred to set upper and lower bounds based on a range of estimates for the burden of disease

[186] http://europa.eu.int/comm/eurostat/newcronos/reference/sdds/en/health/occ_dis_base.htm
[187] http://ec.europa.eu/employment_social/missceec/index_en.html
[188] http://www.eurogip.fr/en/bref/index.htm
[189] http://www.riddor.gov.uk

rather than for the scope of REACH. These estimates of burden took into account both the case count and the case severity for each disease.

A1.22 Entec UK ltd. (2006) New approaches to evaluating and quantifying the benefits of chemicals regulation.

A1.22.1 Background

This report was submitted to Defra before REACH had been implemented. At this time, the UK had a hierarchy of legislation which was aimed at regulating the production, marketing, use, disposal and release of chemicals to the environment. Enforcement of such regulations were carried out by various executives and government agencies. Compliance was evaluated by approval of chemical products through assessing their predicted and monitored exposure levels of release to the environment and evaluating release levels against guidance and standards on permitted emission vales and environmental concentrations.

Protection of the environment was usually measured by comparison of exposure levels with level at which effects on the environment and humans are predicted to occur. This is carried out through risk assessment or comparing environmental levels with standards or guideline values. Limiting environmental exposure to guideline levels is assumed to afford adequate environmental protection. The goal of chemicals legislation is to protect from harm and reducing the environmental burden of chemicals in the environment, but there has been no quantification of the economic cost of the impact or the benefit of avoidance of such impacts.

Problems associated with assessing and evaluating the economic benefit of chemicals regulation are:

- There is no direct link established between increasing environmental concentration and the magnitude of the impact on the environment above the no adverse effect level.
- Due to the number of chemicals released to the environment, it is difficult to attribute the observed environmental impacts to a particular chemical substance.
- The environment has not previously been subject to economic market valuations and so it has not been given a specific value. Therefore, the cost of the depletion of this resource has not been linked to a value that can be easily quantified in terms of a monetary value.

A1.22.2 Scope of report

The objectives of this report are:

- To identify two chemicals of concern, based on historical evidence, to use as case studies and collect evidence establishing a link between the substance and effects reported on the environment and human health.
- Quantify (and where possible monetise) the link between the substances hazardous characteristics and the effects reported in the environment. This was to be addressed by the development of dose-response functions for the selected substances and then the monetisation of the environmental impacts.
- Develop a generic model to estimate the potential costs of implementing further chemicals legislation. The model should be able to be used for any chemical, not just ones which have demonstrated a historical environmental impact, as it is more useful to be able to predict

the benefit of regulation of all chemicals, as opposed to only those for which environmental impacts have been attributed.

A1.22.3 Methodology

Exposure, effects and environmental impacts

Selection of data

Data on substances were selected from data sources which have been subject to risk assessment under ESR. Under ESR, substances had already been prioritised and subject to extensive data gathering and analysis had been carried out on environmental emissions, exposure concentrations and hazardous impacts on the environment and humans.

Selection of chemicals

Substances considered had to have been identified as a risk to the environment under Existing Substances Regulation (ESR) and considered for assessment for the UK Government by the Advisory Committee on Hazardous Substances. A shortlist was drawn up of chemicals known to cause a risk to the environment and are subject to a risk management process through a risk reduction strategy. The exposure data required for the study had already been generated and peer reviewed for those chemicals which had been prioritised under ESR. The substances selected for this study were trichloroethylene and diphenyl ether perntabromo derivative.

Definition of effect levels

Within the model, each substance assessed had a series of theoretical bands of effect. PNEC and NEL values are used to generate and extrapolate percentage effect values, with concentrations set at specific points above the no effect concentration. For the environment, effects at 0, 5, 50, 95 and 100% correspond to the PNEC, 10x PNEC, 31.5x PNEC, 100x PNEC and 1000X PNEC respectively. PNEC values represent the Risk Characterisation Ratio (RCR) values. For environmental effects, a level of effect is assumed from above the band, up until the next threshold band.

For human health the bands range from no effects to 50%, instead of up to 95%. This is due to the exposure of humans via the environment is generally lower than that of exposure in other environmental compartments. In the model, five effect bands are used to represent adequate definition. RCRs are comprised of total daily intake (TDI) to the no effect level (NEL). It is assessed as a percentage of the population at risk from adverse effects as humans can, to a certain extent, avoid exposure.

Predicted environmental concentrations (PECs)

PECs were generated using the EUSES model. By altering the inputs on use patterns, PECs for different scenarios can be generated. Comparing PECs to PNECs, or TDIs to NELs, RCRs can be generated, the magnitude of which reflects the risk of a substance to an environmental compartment or human health.

Generating impacts from effects - environment

To allow for the valuation of benefits, the effects on the environment or to human health have been translated to possible impacts. An example of the translation of effect to impacts is given in table A1-

9. The impact sores allow for the impact to be scaled which is important for the economic valuation of benefits.

Table A1-9: Determining impact from effects for the environment: freshwater fisheries			
Impact category: marker of impact:		Surface water: freshwater – impact on fisheries Toxicity estimates for freshwater fish species	
Impact levels description	Impact score	Effects category	Risk characterisation ratio
No impact	0	No effect	<1
Sensitive species (salmonids) populations impacted	1	5% species	>1-10
Effects on coarse fishery	2	10% species	>10-50
Impacted – sensitive species in decline or absent	3	20% species	>50-100
Poor or unviable fishery	4	50% species	>100-500
No fishery or very few species	5	95% species	>500-1000

Under the EU risk assessment framework, each environmental compartment is assumed to be representative of an ecosystem. In this study the ecosystems represented in the EU risk assessment framework for chemicals are balanced against valuations for impacts to those ecosystems. In order for valuations to be made, the environmental compartments from the EU risk assessment framework are split into representative groups, such as fish and invertebrates.

Impacts for each set of effects were derived from balancing known and scalable impacts with those for which known valuations exist or valuations could be adapted. In order to assign an impact score to an effect level, an indication of possible effects at this level are given so that an economic valuation of the impact, or the value of the willingness to pay for avoiding such an impact, can be derived.

Generating impacts from effects – human health

Impacts on human health via the environment are based on effects which have been tested for, within the EU risk assessment framework for chemicals. The effects used within the model are not relevant to all chemicals, for example not all chemicals are carcinogens. For each effect, the impact is the risk of the effects manifesting a proportion of the population.

The diseases and conditions used are representative of effects which may be expected and are not inclusive of all effects which can be caused by chemical exposure.

Scaling of impacts and standardisation

In order to evaluate the magnitude of impacts on a countrywide scale, the number of local environments effected is estimated to calculate the total impact. Each use pattern is assumed to occur in a single local environment, with the local environment being a standard. The standard comes from data relating to the UK environment.

A number of assumptions are made in the methodology for deriving the environmental impacts from PNEC and NEL values.

Table A1-10: Determining impact from effects on human health			
Impact category: marker of impact:		Man via the environment Acute toxicity estimate for human health	
Impact levels description	Impact score	Effects category	Risk characterisation ratio
No impact	0	No effect	<1
Very low risk of impacts on health	1	0.1% population at risk	>1-10
Low risk of health impacts (sensitive populations)	2	0.2% population at risk	>10-20
Elevated risk of health impacts (wider population)	3	0.5% population at risk	>20-40
Health risk of significant impacts on health	4	1% population at risk	>40-60
Very high risk of serious or severe health impacts	5	5% population at risk	>60-90

A1.22.4 Economic valuation of benefits

The valuation of environmental and human health impacts is a function used to broadly assess the potential magnitude of benefits of chemicals regulation within the standardised UK environment. This model relies on studies which measure welfare from human health and environmental quality.

The valuation approach

This model includes primary valuation (marketed goods are directly impacted and easily estimated), and benefit transfer (non-marketed goods impacted). Benefit transfer estimates the economic values for environmental and human health goods through transferring available information from studies which have been completed in another location or context. Dose-response was used as the first level of screening for studies.

Total economic value

This includes two key components; the use and non-use of environmental quality. The model covers value from impacted areas, those which are considered most significant in terms of severity and additionality, those which are exclusively attributable to chemical pollution. Therefore, a number of impact areas are left un-quantified and un-valued.

Gaps include:

- Non-crop marketed goods
- Municipal water supply
- Education
- Property
- Marine commercial fisheries
- Bequest and option value.

For human health coverage, a wide inventory of specific illnesses is not included due to the need for broad applicability to a range of chemicals. Therefore, representative illnesses are used to reflect the typical categories of health effects expected from chemical exposure.

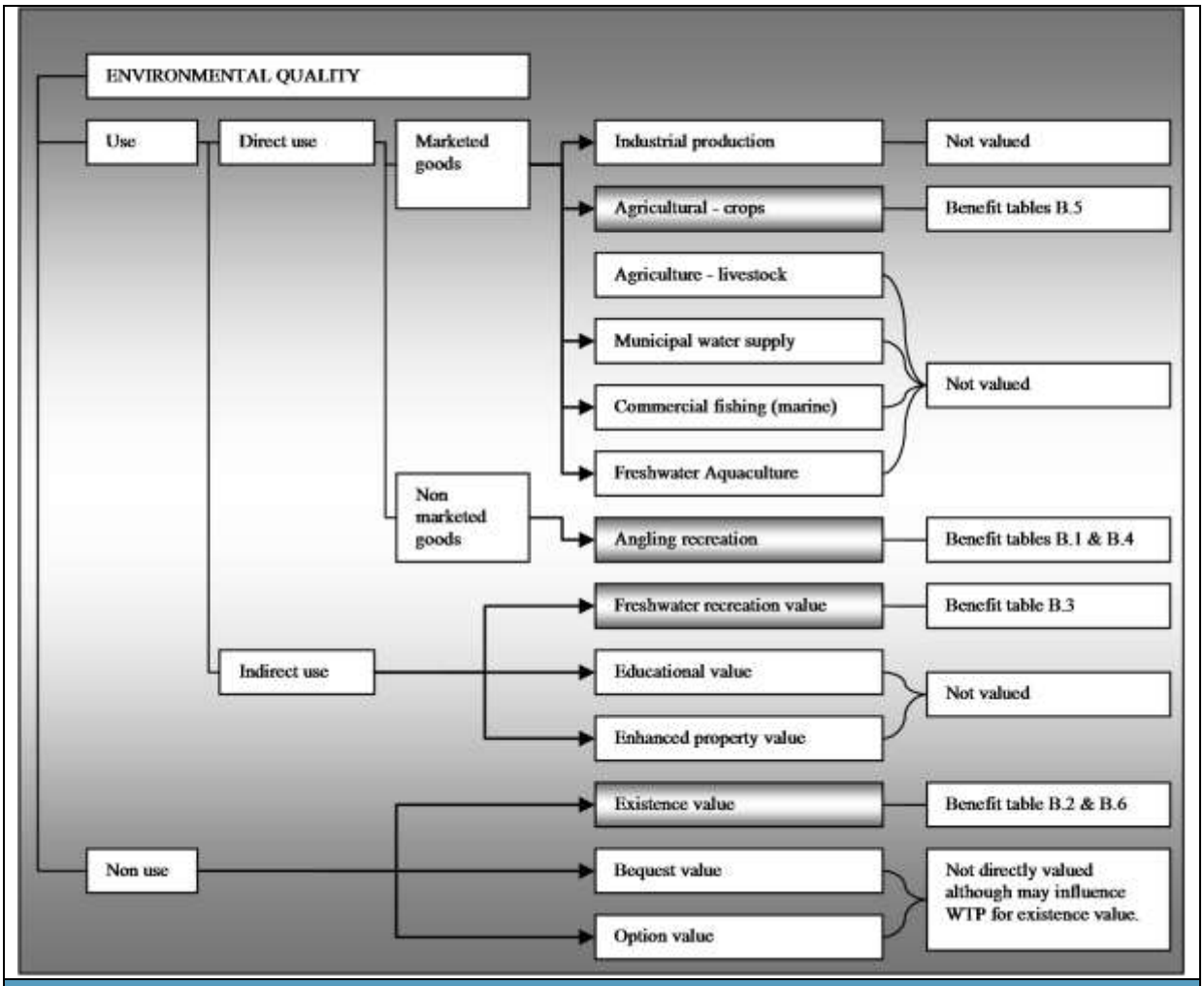


Figure A1-1: total economic value of land and aquatic environmental quality

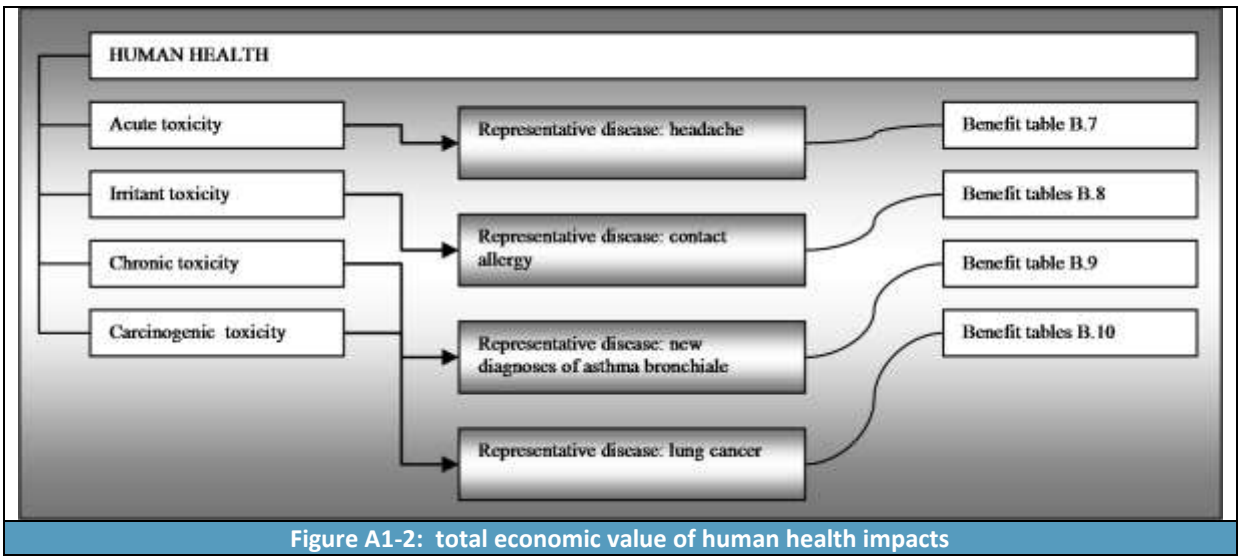


Figure A1-2: total economic value of human health impacts

A1.22.5 Model

The model structure is developed using a modular spreadsheet, to improve transparency and improve user interface.

Module 1 (scenario and benefits summary), Module 2 (scenario definition), Module 3 (toxicity data), Module 4 (standardised impact category tables), Module 5 (risk characterisation ratios), Module 6 (standardised benefits transfer tables), Module 7 (benefits monetisation), Module 8 (local environment), Module 9 (calculations).

A1.22.6 Results

By comparing two scenarios, the net benefit of chemicals regulations can be evaluated. For trichloroethylene, it can be observed that the benefit of chemicals regulations is largely seen in marine waters, crops and terrestrial biodiversity. The uses responsible for the impacts are metal degreasing and production. The sensitivity of the model depends upon the data used to define each module of the model. If the changes in risk ratios are not great enough to change the impact category then the model will not register a change in impact.

Environmental Compartment	Scenario A (baseline) Benefit (£k/year)	Scenario B (future) Benefit (£k/year)	Net Benefit of Chemical Regulation (£k/year)	Proportion of Total Net Benefit (%)
Freshwater: angling	47,182	47,200	18	0.5%
Freshwater: use value	2,123	2,124	0	0.0%
Freshwater: non-use value	538	538	0	0.0%
Marine: angling	31,075	33,767	2,692	79.0%
Marine: use value	101	110	9	0.3%
Marine: non-use value	27	28	2	0.1%
Air and soil: impact on crops	565,820	566,342	521	15.3%
Terrestrial: biodiversity	633,049	633,215	165	4.8%
Secondary poisoning : human health	n/a	n/a	n/a	n/a
Totals (£k/year)	**1,279,915**	**1,283,323**	**3,408**	**100%**
Present Value (£k)	**14,741,310**	**14,780,560**	**39,250**	

Figure A1-3: scenario benefits results (by environmental compartment)

Chemical Use Category	Application	Scenario A (baseline) Benefit (£k/year)	Scenario B (future) Benefit (£k/year)	Net Benefit of Chemical Regulation (£k/year)	Proportion of Total Net Benefit (%)
Production	Production of solvent	595	985	390	11.4%
Formulation	Production intermediates	776	985	210	6.2%
Formulation	Adhesives	982,741	985,400	2,659	78.0%
Industrial use	Metal degreasing	294,818	294,822	4	0.1%
Formulation	Consumer products	985	1,130	145	4.3%
Service use	n/a	n/a	n/a	n/a	n/a
Waste disposal	n/a	n/a	n/a	n/a	n/a
Totals (£k/year)		**1,279,915**	**1,283,323**	**3,408**	**100%**
Present Value (£k)		**14,741,310**	**14,780,560**	**39,250**	

Figure A1-4: scenario benefits results (by chemical use category)

A1.22.7 Conclusions

The significance of this model is that it may be used to determine the relative benefits of regulations by comparing two scenarios for a substance. It is a single approach based on extrapolating effects from previous predicted NELs and relating them to a possible impact. The impacts are then used to derive the benefits of those impacts being avoided. In order to assess the benefits of regulation, a scenario where a substance has restricted use and production is compared with a scenario prior to restriction. The benefits of regulating trichloroethylene were estimated to be £39.3 million per year. This model is theoretical which means the valuations are not based on actual observed impacts on the environment and at the time of publication there were no other valuations to compare the benefits values to. The substances selected for this study did not trigger an impact for the effect on human health, and so the valuations are based solely on the effects on the environment.

This model may act as a tool to assist in the identification of substances of concern that will derive the most benefit from restriction.

A1.23 Okopol (2007): Analysis of studies discussing benefits of REACH

Okopol (2007) reviews various studies that have been carried out to determine the costs and benefits of REACH. The key aim of the paper is identify the various types of benefits described in existing studies as well as the quantification methods used. It also aims to ascertain how particular benefits have been linked to the mechanisms of REACH.

Overall, the paper provides useful information on the benefits of REACH for business, the environment and occupational and public health. It also matches these benefits to the specific mechanisms of REACH. For example, less public spending for public health is a benefit associated with the greater control of substance use and better information on substance properties. The paper goes on to list the methodologies and results of previous studies in a tabular format, which contains some examples of the indicators used.

The paper summarises the different assessment approaches used for each type of benefit. For environmental benefits, the paper highlights three key methodologies that have been used by previous studies, these include:

- Case studies analysing (clean-up) costs for remediation;
- Assessment of costs incurred for preventing substance-related environmental damage;
- Assessment of willingness to pay for certain environmental goods.

Among the types of studies reviewed, the paper highlights that data for occupational disease and worker health is available at a greatest level of detail. On the other hand data pertaining to environmental and public health benefits is not immediately available and accurate. For instance, the paper hypothesises that public health benefits are least explored because exposure data is lacking and the cause-effect links are often complex.

A1.24 The Benefits of Chemicals Regulation, Lancaster University (2006)

The aim of the Lancaster University (2006) study was twofold. Firstly, it set out to identify suitable substances that could be used as case studies to assess the links between substances and effects reported in the environment. Secondly, the study aimed to quantify the links between the substances and the reported environmental and human health impacts. The study anticipated that the monetary valuations derived from these substances could be used in future studies to assess the economic value of regulating chemicals with similar impacts.

In total, four substances were chosen for the final case studies: tributytin (TBT); methiocarb; DDT and polychlorinated biphenyls (PCBs). These substances were chosen based on a number of factors such as the available information, range of complexities (e.g. sources/pathways/endpoints) and expertise within the assembled team.

Each case study followed a similar methodology. Firstly, hazard data on the selected substance were collected, including information on toxicity, physiochemical properties, persistence and bioaccumulation. Next, the environmental/human impacts of each substance were analysed. Where possible the studies aimed to gather quantitative data on the adverse impacts of each substance (e.g. number of species affected, proportion of the population affected etc.). The studies then applied monetary evaluations to the identified impacts, with an emphasis on the use of willing to pay values and avoided costs. However, it was not possible to quantify the size of some impacts and, as a result, only the proposed methodology was presented.

For the economic assessment of environmental services/goods the study utilised the concept of Total Economic Value (TEV). The TEV of a species is calculated by summing its *direct use*, *indirect use*, *option* and *non-use* values. An example of this is provided by the TBT case study which looked at the TEV of marine invertebrates. Many marine invertebrates have a *direct use* value as a consumptive resource and an *indirect use* value through nutrient cycling. They also have an *option value* to pharmaceutical companies as valuable commercial applications may be discovered from further research. On the other hand, the case study found that invertebrates have a small *non-use* value as individuals do not place a significant value on the survival of small invertebrates relative to mega-fauna such as the blue whale.

For the assessment of the economic costs associated with a change in human health due to chemical exposure, the study utilised a number of concepts. Firstly, the authors measured the direct medical costs associated with cancer cases (e.g. National Health Service treatment costs). However, the authors noted that these costs only form part of the total social cost as they fail to take into account

the pain, suffering, reduced quality of life, and loss of earnings associated with the disease. To capture the fatal aspect of these elements the study employed the value of statistical life (VOSL) and in the case of morbidity, quality adjusted life years were used (monetised using willing to pay estimates). The study also looked at the perception of health risks and the effect this may have on different goods and activities. For instance, in the DDT case study qualitative arguments were made regarding whether recreational fishing would decrease due to the perception of increased levels DDT in caught fish (therefore making caught fish less attractive to eat due to the possible health risks).

Table A1-11 provides a summary of the methodologies used in each case study. As shown, the methodologies can be split into the physical and economic components. The physical component reflects the approach used to quantify the impact of substance upon the environment and human health. The economic approach shows the methodology used to monetise this impact.

Table A1-11: Summary of case study methodologies

Study	Impacts considered	Physical component	Economic component
TBT	Commercial shellfisheries	Landing data on different types of shellfish	Market prices
	Invertebrates nutrition cycling	Expert judgement	Benefit transfer value, time and income adjustments made
	Dredging disposal costs	Level of sediment highly contaminated by TBT	Dredging disposal costs (avoided costs approach)
Methiocarb	Small mammals (e.g. wood mice, badgers)	Poisoning incidents	Market prices and benefit transfer values
DDT	Observed impacts upon three bird predator species	Expert judgement	Benefit transfer value, time adjustment made
	Potential impacts (avian species, marine mammals and polar bears)	No data available	Benefit transfer values methodology presented only
PCB	Human health	Dose response model	NHS costs, benefit transfer values for VOSL and loss of quality of life/non-fatal cancers
	Potential impacts (avian species, marine mammals and polar bears)	No data available	Benefit transfer values methodology presented only

Source: Based on information from University of Lancaster (2006)

The following sections also provide a brief description of the methodologies used. It should be noted that each case study focused on the UK and **only benefits to the UK economy and society are considered.**

TBT

This case study examined the economic impact of TBT on commercial shellfisheries using a landings revenue approach. Species examined included cockles, pacific/native oysters, periwinkles, mussels, scallops and whelks. The overall impact of the TBT ban in the UK on landings of these species was then calculated against a baseline and the estimated benefits were valuated using market prices and revenue data.

The study then quantified the ecological benefit of nutrient recycling performed by TBT affected invertebrate species. Economic valuations from Costanza *et al* (1997)[190] were used alongside assumptions on:

- How much of the nutrient cycling function performed by estuarine ecosystems was carried out by the TBT-affected invertebrate species; and
- How much TBT affects the ability of these species to carry out the nutrient cycling function.
- The information was then combined with data on the total area of UK estuaries to calculate the ecological benefits of TBT regulation in terms of nutrient recycling.

The final valuation made by the study, looked at the issue of sediment contamination and the additional costs associated with the disposal of TBT-contaminated dredgings[191]. The case study used the avoided costs approach to estimate the economic benefits of TBT regulation. Data on the amount of sediment that is too contaminated by TBT for normal marine disposal, and the cost of disposing contaminated dredgings in the UK, were utilised to provide the final economic valuation.

Methiocarb

For the Methiocarb case study, the key impact considered was on mammals such as mice, deer and badgers (among others). The study used data from the Wildlife Incident Investigation Scheme (WIIS) to obtain annual rates of mortality due to methiocarb poisoning for different species. Use and non-use values were then calculated for each species and aggregated. The study used both market data (e.g. the price of venison) and WTP estimates (e.g. in terms of an increased badger population) to place an economic value on the potential benefit of Methiocarb regulation.

DDT

The first stage of the DDT case study focused on the impairment of the reproductive system in three predatory bird species: the merlin, sparrow hawk and peregrine falcon. The study noted that these three bird species would have been at certain risk of extinction if the DDT ban had been delayed. However, due to a lack of data on the dose response relationships for these species, expert judgements were used for the physical component (i.e. the impact due to DDT exposure). The economic valuation of these impacts used two separate WTP studies to account for the embedding effect[192] and estimate the economic benefit of the ban on DDT.

It should be noted that the case study also attempted to estimate the impact of DDT on the reproduction of other avian species and freshwater fisheries/marine mammals. However due to a lack of robust data, the estimations displayed a high level of uncertainty and were therefore not included in the final valuation.

[190] Costanza, R, d'Arge, R, de Groot, R, Farber , S, Grasso, M, Hannon, B, Limburg, K, Naeem, S, O'Neill, R V, Paruelo, J, Raskin, R G, Sutton, P and van de n Belt, M (1997). The value of the world's ecosystem services and natural capital. Nature 387, 253-260.

[191] TBT contaminated harbour dredgings are seen as special waste that cannot be disposed of at sea like ordinary dredged sediments.

[192] The embedding effect, which is observed in some contingent valuation survey responses, is the observation that people are apparently willing to pay the same amount of money for a good as for a larger number of the same good.

PCB

As dose-response relationships for top animal predators were unavailable, the PCB case study was limited to an estimation of human health benefits. The study attempted to quantify the economic benefits of reduced cancer risk for the UK general population, due to the PCBs ban in 1977. A dose response model was adopted to quantify the change in cancer cases at different possible introduction times of the ban. The impacts associated with these delays in the ban were then compared with the baseline (introduction of the ban in 1977) to calculate the excess lifetime cancer risk.

The calculated excess lifetime cancer risk was then used to estimate the total economic cost in terms of mortality, morbidity and medical treatment costs. Benefit transfer values were used to proxy the VOSL (value of statistical life) for fatal cancer cases and loss of quality of life for non-fatal cases. NHS costs were derived for both fatal and non-fatal cancer cases.

Availability of data

For each case study a wide variety of data sources were consulted, nonetheless the scope of the studies remained at the UK level and potential benefits for other EU countries were not analysed[193]. The authors pointed out several data availability issues in the study that influenced their final choice of methodology for each case study.

The lack of dose response relationships was highlighted a major limitation to their ability to monetise the impacts of chemicals regulation. While the environmental pathways of chemicals were relatively well known in qualitative terms, the quantitative relationships were far more uncertain. As a result the benefits of improved animal health in some cases were estimated using different causality levels and expert judgement rather than the preferred dose-response relationship approach.

Moreover, due to time and budget constraints the study was unable to gather primary data on the implicit values of some natural and human resources. The study thus had to rely on the use benefit transfer (BT) values. These are values derived from previous stated/revealed preference studies and then transferred to evaluate a similar situation in a separate study. However, by using BT values instead of primary data a higher degree of uncertainty is generated. This is because the characteristics of the two studies and the situation being evaluated may differ significantly.

Indicators suggested

A wide range of indicators were adopted by the authors to assess the impacts of the respective chemicals. Where possible the study attempted to find quantitative estimates of the impacts of each substance on the environment and human health. However, in some cases where adequate data were not available the studies relied on assumptions, proxies or expert opinion. For instance, in the TBT case study, data on changes in landings were used as a proxy for dose response relationships between different species and TBT.

However, the main goal of the study was to provide estimations of the economic benefits of four chemicals, which could thus be used to derive the benefits of regulating chemicals with similar

[193] The study does however acknowledge and discuss that regulations placed on chemicals used/produced in the UK may impact on ecosystems outside the UK territory (in particular for DDT and PCBs).

impacts. This is based on the idea that if two chemicals generate the same impact, and the combined magnitude of these impacts along with economic value of one chemical's impact are known, then it is possible derive the economic benefit of the chemical in question (see equation 1).

$$(1) \quad Cost_i = \frac{IMPACT_i}{IMPACT_r} \cdot Cost_r$$

Where $IMPACT_r$ is the impact on the environment or human health from exposure to the reference chemical (i.e. TBT, methiocarb, DDT or PCB) and $Cost_r$ is the economic value of this impact. While $IMPACT_i$ is the same type of impact on the environment or human health derived from exposure to the chemical *i* and $Cost_i$ is the corresponding economic value of the impact.

As chemical exposure may lead to more than one impact, the study states that the above formula could be used to generate a matrix of impacts for a set of chemicals. However, as discussed throughout the study, finding data on the impact of a particular chemical is often difficult and may require the use of expert judgment.

Due to data availability issues the individual case studies made a number of assumptions. For instance, the lack of dose response functions for animal species meant that many of the studies had to rely on expert judgment and thus assumptions on the different causality levels associated with chemical exposure. The lack of dose response functions also meant that the final estimations only consider a small proportion of the overall affected animal species and thus the estimations can be viewed as conservative in nature.

Furthermore, the study assumed that stated/revealed preference values could be transferred across studies (known as benefit transfer values). As discussed earlier the use of such values could lead to an increased level of error in the final estimations and this is highlighted in the individual case studies.

The study also favours WTP over willing to accept (WTA) valuations: WTA estimations are typically higher than WTP equivalents due to loss aversion (ranging from four to fifteen times larger). WTP values were adopted to provide a conservative estimation.

The study found overall that the more a chemical persists and travels in the environment, the larger the benefits are from regulating it. For instance, the four substances analysed in the case studies ranged from a low level of persistency and bioaccumulation, such as Methiocarb, to high levels of persistency and bioaccumulation, as found with PCBs. This pattern is reflected by the results shown in Table A1-12.

Table A1-12: Summary of economic valuations by case study and impact

Case Study	Impact	Social benefit/cost per year
TBT	Commercial shellfisheries	£1.5 – 15.2 million
	Invertebrates nutrition cycling	£8.7 – 87 million
	Dredging disposal costs	£60,000
Methiocarb	Small mammals (e.g. wood mice, badgers)	£308,583
DDT	Observed impacts upon three bird predator species	£19 – 279 million
	Potential impacts (otters, other avian species, marine mammals and polar bears)	-
PCB	Human health	£429 million – 1.5 billion
	Potential impacts (otters, other avian species, marine mammals and polar bears)	-

Source: University of Lancaster (2006)

The table also shows that human health impacts are relatively important. However, the authors acknowledge that the small size of the environmental impacts was mainly due to data limitations and thus an inability to quantify them.

Lastly, the results show that there are large costs associated with the ecosystem functioning (e.g. invertebrates nutrition cycling). Yet, the authors explain that there is a high level of uncertainty based around this estimate. This is because robust economic unit values and relevant dose response relationships were unavailable.

A1.25 RIVM (2008): Health impact assessment of policy measures for chemicals

RIVM (2008) use a case study analysis to assess the total health gain of measures on chemicals in consumer products. The case studies focus on a number of substances, products and control measures (see Table A1-13).

Table A1-13: Overview of exposure estimates of all investigated case studies

Compound	Product	Legal measure	Year	Measure
Acrylamide	Cosmetics	Cosmetics Directive 76/768/EC and 2002/304/EC	2002	0.1 mg polyacrylamides/kg product (non-rinse) 0.5 mg/kg products in other cosmetics
Azo dyes	Textiles	Council directive 76/769/EC	1996	Ban
	Tattoos			
Dichloromethane	DIY	Directive 76/765/EC	Proposal	Total restriction in paint stripper/glue remover
Formaldehyde	Chipboard	Dutch 'Warenwet'	1987	10 mg/100g
	Cosmetics	EU Directive 76/768/EC	1995 1998	0.2% for cosmetics and 5% for nail hardeners 0.1% oral hygiene products
	Textile	Dutch 'Warenwet'	2001	120 ppm
Lamp oil	Household	Directive 76/769/EC Dutch 'Warenwet'	1997 2000	Ban on coloured and scented lamp oil
Nickel	Jewellery	Nickel Directive 94/27/EC	1994	Migration limit 0.5 g/cm^2/week
Nitrosamines	Teats/soothers	Directive 93/11/EC (Food and Commodies Act)	1992	Migration limit of 0.01 mg nitrosamines/ kg product an d 0.1 mg precursors/kg product
	Cosmetics	Cosmetics Directive 76/768/EC	1993	Not contain nitrosamines or secondary dialkanolamines
	Balloons		2004	Warning not to take into the mouth and limit of 0.01 mg/kg rubber
Toluene	DIY	Directive 76/679/EC	2005	Limit of 0.1% toluene in adhesives and spraying paints
Volatile Organic Compounds (VOC)	DIY	Council Directive 2004/42/CE	2001-2007-2010	

Source: RIVM (2008)

Table A1-14: Overview of exposure estimates of all investigated case studies				
Compound	**Product**	**Exposure before the measure**	**Exposure after the measure**	**Background exposure**
Acrylamide	Cosmetics	0.36 µg/kg bw/day	0.004 µg/kg bw/day	0.6 µg/kg bw/day
Azo dyes	Textiles	8 ng/kg bw/day benzidine 0.2 ng/kg bw/day 2,4-TDA	0 - 5 ng/kg bw/day benzidine 0 - 0.1 ng/kg bw/day 2,4-TDA	n.d
	Tattoos	-	-	-
Dichloromethane	DIY	660 ppm (average)	assumed to be zero	n.a
Formaldehyde	Chipboard	0.25 mg/m^3	0.06 mg/m^3	-
	Cosmetics	Not known	0.2 mg/kg bw/day	
	Textile	6 µg/kg bw/day	5 µg/kg bw/day	
Lamp oil	Household	n.a[1]	n.a[1]	n.a[1]
Nickel	Jewellery	n.a[2]	n.a[2]	n.a[2]
Nitrosamines	Teats/soothers*	8 ng/kg bw/day	0.39 ng/kg bw/day	20 ng/kg bw/day
	Cosmetics**	5.3 ng/kg bw/day	1.2 ng/kg bw/day	
	Balloons***	0.001 ng/kg bw/day	0.0009 ng/kg bw/day	
Toluene	DIY	27,000 µg/kg bw/event	220 µg/kg bw/event	9-29 µg/kg bw/day
Volatile Organic Compounds (VOC)	DIY	660 mg/m^3 white spirit (SB) with peak of 5880 mg/m^3 10 mg/m^3 (WB)	165 mg/m^3 white spirit (SB) with peak of 1420 mg/m^3 3 mg/m^3 (WB)	-

Source: RIVM (2008)
[1] *in this case it concerns lamp oil intoxications, no exposure can be stated*
[2] *in this case, calculations are performed using incidence numbers, no exposure can be stated*
* *data given for children 0-6 months*
** *data given for adults*
*** *data given for children 2-4 years of age*
n.d not determined
n.a not applicable

For each case study, exposure is estimated before and after the implementation of a specific measure. The paper uses measured data from the literature to estimate the levels of exposure before and after the implementation of a measure. Where data are not available, the exposure is estimated using a calculation or the modelling program ConsExpo. The paper assumes zero exposure in some case studies where measures have been recently implemented or will be implemented in the future. In addition, the paper considers background exposure (i.e. exposure outside of the products assessed) from sources such as the air and water supply using data from the available literature. Table A1-14 presents an overview of the exposure estimates for each case study.

In addition the study provides estimates of the incidence of cancers linked with each substance before and after measures are implemented (see Table A1-15). The estimates show large reductions in the incidence of particular effects such as CNS depression linked to dichloromethane and irritation/headache/dizziness associated with VOCs.

Table A1-15: Overview of the decrease in incidence of effect in all investigated case studies				
Compound	Product	Effect	Incidence before	Incidence after
Acrylamide	Cosmetics	Cancer (thyroid, adrenals,	2,880	32

Table A1-15: Overview of the decrease in incidence of effect in all investigated case studies				
Compound	Product	Effect	Incidence before	Incidence after
		testis)		
Azo dyes	Textiles	Cancer (bladder)	35,000	0/21,000
	Tattoos		-	-
Dichloromethane	DIY	Central Nervous System (CNS) depression	83,000	0
Formaldehyde	Chipboard	Nasal tumours	0	0
	Cosmetics	Contact dermatitis	-	-
	Textile		0	0
Lamp oil	Household	Vomiting, nausea to chemical pneumonitis	254	87
Nickel	Jewellery	Newly sensitized persons Prevention of complaints of contact dermatitis	24,000 200,000	17,100 140,000
Nitrosamines	Teats/soothers	Liver and nasal tumours in animals, stomach/colorectal cancer in humans	0.03 - 100	0.003 - 10
	Cosmetics		2.2 - 7900	0.4 - 1600
	Balloons		negligible	negligible
Toluene	DIY	Headache/dizziness	5,000	0
Volatile Organic Compounds (VOC)	DIY	Irritation/headache/dizziness	1,200,000	0/240,000
Source: RIVM (2008)				

These indicators could be potentially valuable to the current study as few studies have attempted to assess the total health gain of measures on chemicals in consumer products. In fact, the authors state that their work is the first attempt aimed at quantifying such benefits. On the other hand, the paper itself focuses only on the Dutch population and not the broader European context. The use of such indicators within the framework of this study would thus require cross country extrapolation, which may impact upon the robustness of any conclusions made.

A1.26 RFI (2008): Baseline Estimates Report for Selected Draft Indicators Proposed for Voluntary Reporting to the ICCM on SAICM

With regards to measuring progress with chemicals management against internationally agreed goals, a set of draft indicators for reporting by stakeholders on progress in the implementation of SAICM were developed under the guidance of an International Project Steering Committee. In a 2008 report titled "*Baseline estimates report for selected draft indicators proposed for voluntary reporting to the ICCM on SAICM*", Resources for the Future (RFI) presented available baseline data for the time period 2002-2007 against these draft indicators to provide an estimated overview of the state of chemicals management in countries that are Parties to SAICM. Since then, the SAICM Secretariat has used these indicators to prepare a baseline estimates report for the period 2006-2008 and a report on progress in implementation from 2009 to 2010. In addition, a simple electronic reporting tool was developed for the period 2009 to 2010 and the results of this data analysis can be down-loaded from the SAICM website, in the form of aggregated data for each group of stakeholders.

RFI used the period 2002-2007 as their baseline, allowing them to use data series from different sources. Their initial idea was to establish the baseline in 2006, but the team soon found that data for that single year were not sufficient to complete a meaningful exercise. Even over the period

2002-2007, there was a lack of quantifiable and comparable data on the different categories of possible indicators. The study concluded that new approaches are needed for the assessment of the contribution of SAICM towards the achievement of the WSSD 2020 chemicals goal.

Four different sets of possible indicators were developed, each corresponding to a different stakeholder group: Governments, NGOs, industry and intergovernmental organisations. The indicators were in the form of questions organised in seven sections, corresponding to the categories of the objectives defined in the SAICM Overarching Policy Strategy. The drafting of the indicators was then followed by pilot testing by nine Governments, all representatives of different United Nations Regional Groups, including the Czech Republic and Romania for Eastern Europe and Germany for Western Europe. Germany provided several pieces of additional information, including the relevance of the indicators in the regional context for reporting on the progress of the implementation of the Strategic Approach.

The outcome of the pilot testing was that the set of indicators needed to be refined for their successful application. The problems were related to difficulties in accessing the data needed to answer the questions; the number of indicators and sub-indicators considered and the format of the questionnaire, which was considered unsuitable to be efficiently analysed. An overall report on the pilot testing findings has been prepared by the secretariat, highlighting the aspects to be considered in the modification of the possible indicators. These are:

- The narrative text allows misinterpretation of the questionnaire;
- Unclear questions and terms;
- Duplication of questions;
- Choice of answers not relevant in all the cases;
- Misuse of chemical categories;
- Need for a better balance of indicators in the different sections.

A1.27 Eurostat (2009) REACH Baseline study

The REACH Baseline Study set out a system of indicators to monitor the impact of REACH on human health and the environment over time based on a series of specifically-developed surrogate markers and other indicators related to the quality of the information available for risk assessment purposes. Eurostat started the development of its approach to assessing the impacts of REACH with the development of a 'snap shot' of data for the year 2007. The intention was that this would provide the baseline against which future comparisons could be made. While seeking to establish a wider set of metrics than just the impact of chemicals on human health and the environment, the Eurostat baseline system was never intended as a comprehensive tool to address **all** potential benefits that could arise from REACH implementation. Rather, it sought to establish a number of metrics which could be grouped under the three different types (or 'pillars' as described in Eurostat, 2009) of indicators.

The system is composed of:

- **Administrative indicators:** used to monitor the REACH process. These refer to the registration, evaluation, authorisation and restriction steps defined by REACH and include, for example, the numbers of substances registered and of chemical safety reports documented by ECHA;
- **Risk and quality indicators:** intended to link two of the main aims of REACH, the reduction in nominal risks of chemicals for humans and the environment and the improvement in the

quality of publicly available data. These indicators are assessed on the basis of a defined sub-set of 237 substances; and

- **Supplementary indicators:** these relate to those REACH objectives not covered by the other two indicator types, including increase in the quality of safety data sheets and the use of alternative test methods.

The Risk and Quality Indicator System, the core part of the Eurostat methodology, was developed to determine not the "real" but a "nominal" risk, as the real risk is currently not known (and will only partially be known after the implementation of REACH). The quality indicators define the "robustness" of the calculation of the nominal risk in terms of number of assumptions that have to be included for the determination of the risk. The value of the Risk and Quality Indicator System was designed so as to grow with the repetition of the exercise over the years as new data for a larger subset of substances becomes available. However, the study acknowledged that these indicators could not be easily used by other studies. Instead, it was proposed that the administrative and supplementary indicators could be used to develop an alternative methodology for the quantification of the environmental and human health benefits delivered by REACH.

Thus, only a subset of the overall indicator set developed for the Baseline Study is of relevance to the assessment to be carried out for this study, although the full set of indicators is likely to be of value to future evaluations of the health and environmental benefits of REACH. The potential value of the indicators considered under each pillar with respect to this study is summarised below.

Administrative Indicators

The administrative indicators are aimed at monitoring progress with REACH implementation with regard to registration (including total numbers of registrations and within different production classes), evaluation (e.g. numbers of testing proposals examined, registration dossiers evaluated and substances evaluated), and progress in authorisation and restriction (e.g. number of substances placed on the candidate list, number of Annex XV dossiers, number included in Annex XIV, number of authorisations granted, etc.). While these measures do not directly inform on either health or environmental impacts, they may be of value in establishing changes in the extent of the use of chemicals of various toxicities against which changes in health and environmental burdens should be measured.

Risk and Quality Indicators

Indicators included in the Eurostat baseline study under this pillar should be those of greatest value to this study, since the system developed by Eurostat is intended to provide information on:

- Impacts on workers;
- Direct impacts on consumers;
- Impacts on the environment; and
- Impacts on humans via the environment.

The problem with these indicators lies with the assumptions and data sources needed to derive a measure of the real change in risk, as explained above. For this reason, it was suggested that as part of future evaluations, it might be easier to gather information on the supplementary indicators listed below.

Supplementary Indicators

A number of 'supplementary' indicators were identified in the Baseline study that could be derived from existing statistics and other data sources that may be available at the Member State (rather than EU) level. Those of potential relevance to this study include:

- Relating to protection of human health (workers and consumers) and the environment:
  - Changes in quality of safety data sheets;
  - Dangerous (toxic) chemicals in households;
  - Production of toxic chemicals;
  - Cross-border transport of toxic chemicals;
  - Occupational skin diseases; and
  - Changes in chemical use patterns in Scandinavia and Germany based on information from their product registers.
- Improvement in knowledge of chemical properties and their safe use:
  - Availability of hazard data;
  - Availability of use and exposure data;
  - Changes in classification and labelling;
  - Assessment of existing and new chemicals within a single, coherent system;
  - Registration of new chemicals as a proxy.

A problem with some of the above indicators is that supporting data still remain unavailable. This includes, for example, the number of dangerous substances in the households.

The system is based on the premise that neither the calculation of risk, nor the understanding of changes in data quality and provision, are manageable for all (approximately 30,000) substances falling within the scope of REACH. Instead, the impact assessment system focuses on the detailed statistical analysis of only a very small subset of the chemicals on the European market, with these acting as a surrogate of the wider chemical use situation across Europe. Thus, a stratified subset of 237 substances was randomly selected from approximately 10,000 existing substances considered to be of high, medium or low production volume, as well as the selective inclusion of some Substances of Very High Concern (SVHC).

For each selected reference substance, a "Risk Score" (of between 1 and 1000 or greater) was calculated using criteria specifically developed for the baseline study; this draws on estimates of exposure and toxicity. The toxicity assessment for worker scenarios draws on occupational exposure limit (OEL) values and, for other scenarios, on tolerable daily intake (TDI)-type values or derived no-effect levels (DNELs) where these were available. Where such estimates were not readily available, analogous values were developed for the chemical. Characterisation of environmental effects was similarly achieved by using actual or surrogate values for predicted no effect concentration (PNEC) or no-observed-effect-concentration (NOEC) values for relevant media. Exposure was based upon an exposure assessment that sought to define the 90^{th} or 95^{th} percentile exposure for a given scenario, i.e. a "reasonable worst case". Data gaps were addressed through use of assessment factors (AFs) to address data uncertainty or route-to-route extrapolations or adoption of the medium hazard category via the oral route from the GLEV or OIRIS datasets for non-carcinogens or CMR (Category 1 and 2) substances respectively.

The exposure and toxicity metrics were then used to derive a Risk Score, i.e. a weighted risk characterisation ratio through multiplication of a risk characterisation ratio (RCR) by a population

risk modifier and an optional severity of effect modifier. It should be noted that any shift in the level of modelled risk thus derived does not represent a change in "real-world" risk but in the "nominal" risk based on the changes in the pattern of the set of Risk Scores.

The degree of uncertainty surrounding the available datasets was also assessed for each chemical and used to derive a "Quality Score". This was based upon consideration of the extent (size of database) and nature (use of robust studies, reliance of QSARs, etc.) of the available toxicity and environmental toxicity datasets. Consideration of the quality of the exposure data encompassed both human and environmental aspects.

The data thus derived were used to construct a series of 'snapshots' of each of the proposed indicators as of the year 2007, with each sample chemical assigned to one of four categories:

- High Production Volume Chemicals (more than 1 000 tonnes/year; HPV);
- Medium Production Volume Chemicals (1 000 >> 100 tonnes/year; MPV);
- Low Production Volume Chemicals; (100 >> 10 tonnes/year; LPV); or
- Substances of Very High Concern (SVHC).

Modelling was conducted for each of the impact classes of interest. The intention was to characterise the 'baseline' situation as the basis for future comparison.

The assumption underlying the Baseline study model is that, as REACH implementation progresses, the quality of data will improve leading to more informed knowledge and awareness of the risks relating to chemicals and consequently changes in industry practice regarding the use of chemicals. It is therefore intended that comparisons over time against the 2007 baseline estimates for the subset of chemicals might enable prediction of changes in the overall pattern of the Risk Scores across the chemicals used by industry (i.e. a progressive move away from the use of toxic substances to less harmful alternatives and gradual improvement in quality of data available). The intention is to complement the assessment of changes in Risk Scores by comparison to changes in other metrics relating to workers and consumers over time by reference to data from the pre-existing reporting systems in Germany (BfR consumer products database) and Scandinavia (SPIN data).

The baseline study approach was therefore developed to indirectly inform on the degree of REACH's success in ensuring a high level of protection through information provision throughout the supply chain. The Risk and Quality indicator system constitutes the core element of the assessment but – importantly – provides a mechanism for the future prediction of impacts using surrogates of real-world risk (based on scientific approximation and agreed conventions relating to uncertainty) rather than directly measuring 'real' changes in burdens.

Table A1-16 sets out the indicators most relevant for this study as developed by the Baseline study and links them to the benefits drivers of REACH.

Table A1-16: Eurostat Baseline Study, Drivers and Indicator systems

Baseline Study Indicator System	Pathway
Administrative indicators system	
Registration of chemicals	Better information through registration
Evaluation of chemicals	Enhancement of registration; better information (substance evaluation)
Authorisation and restriction of chemicals	Control of uses through authorisation and restriction.
Establishment of a central agency	Consolidated way of gathering data and assessment
R&Q indicator system	

Table A1-16: Eurostat Baseline Study, Drivers and Indicator systems	
Baseline Study Indicator System	**Pathway**
Protection of human health and the environment	Implementation of risk management measures and control of uses through authorisation and restriction
Improvement of knowledge on properties and safe uses of chemicals	Reclassification, effects through (new) coverage by downstream legislation, improved information for safe use and potential re-formulation
Assessment of existing and new chemicals in a single, coherent system	
Increased transparency and consumer awareness	
Promotion of alternative methods for assessment of hazards of chemicals	
Supplementary indicators system	
Changes in quality of safety data sheets	Better information on substance properties and safe conditions of use
Toxic chemicals in households	Reduced exposure through reduction of toxic chemicals – health benefits through the environment
Production of toxic chemicals	Reduced exposure through reduction of toxic chemicals and benefits to the environment from reduced emissions
Cross-border transport of toxic chemicals	
Occupational skin diseases	Reduced skin exposure from RMM
Changes in use patterns in Scandinavia and Germany	
Availability of hazard data	Better information on substance properties and safe conditions of use
Availability of use and exposure data: *Total number (and percentages) of substances with information on use pattern; Total number (and percentages) of substances with a CSR; Total number (and percentages) of substances with a CSR including exposure assessment and risk characterisation*	Better information on substance properties and safe conditions of use
Changes in classification and labelling	Effects on coverage by downstream legislation and for use in (consumer) mixtures
Registration of new chemicals as a proxy	

A1.28 Remoundou, Koundouri (2009): Environmental Effects on Public Health: An Economic Perspective

The authors critically review the literature on the contribution of the environmental factors on the global burden of disease and deaths. They describe the different economic valuation techniques and present some of the applications of these techniques that have been carried out to estimate the social benefits associated with increased quality of the environmental media.

The appendix to the study provides a useful summary of valuation studies and benefits of environmental legislation estimated using the different techniques.

A1.29 RPA (2009): Scoping Study for the Evaluation of the EU REACH Regulation and CLP Regulations

The principal aim of the study was to provide an overview of how the impact of REACH and CLP in the UK might be evaluated in a manner that is suitable to meet the short-term need for appropriate information with which to complete the UK's first quinquennial reports to the EC. The study also aimed to establish, in outline, a specification for a monitoring programme over the longer-term. In this way, the specific objectives of the scoping study were to:

- Ascertain the feasibility of obtaining information on how the principal objectives of REACH and CLP are being delivered, and how baselines for each of these may be established for evaluation purposes;
- Identify possible options for data-gathering methodologies; and
- Propose possible options for longer-term monitoring, evaluation and reporting of REACH and CLP impacts.

In order to achieve this, a staged approach was applied involving the identification of objectives/sub-objectives (for which indicators might be sought); identification of indicators and data sets; and repeated iterations of these two activities until a 'master list' of possible indicators matched to objectives/sub-objectives was identified. Using a transparent scoring process, indicators were then screened and scored according to a range of different criteria to allow the identification of suitable candidates for indicators relevant to different options (in terms of effort required to satisfy data requirements and level of detail/coverage of indicators).

The initial step in establishing the identity of suitable sub-objectives was to review the REACH and CLP Regulations and the REACH and CLP Technical Guidance Documents to gain additional insights on possible sub-objectives that might support the established aims and objectives of REACH and CLP. Once a consolidated list of sub-objectives had been developed and discussed with the Steering Group, the various information sources were reviewed to establish possible indicators that might inform on the sub-objectives and help determine the current and likely future availability (or otherwise) of data sets that could serve to support such indicators. During this review, particular attention was given to establishing for each data set:

- The nature, quality and source of the data set;
- The extent to which the continued availability of the data set was assured;
- If suitable baseline information is currently available or if this would need to be established;
- The extent to which the data set might be subject to confounding by factors other than those related to REACH and CLP; and
- The frequency of the recording of data.

Once the long list of possible indicators was developed, some means of screening these and prioritising those for future consideration was required. To aid this process, a simple scoring and weighting system was developed to allow the different indicators to be compared against one another in a consistent and transparent manner. Four criteria were chosen against which to score each indicator, namely:

- Specificity: how closely does the indicator match to the sub-objective?
- Quality of Information: is the data robust based upon its source and the extent of quality control that is apparent within data sets?
- Cost: how easy will it be to collect the data and what extent of additional analysis will be required?

- Confounding Factors[194]: how extensive and significant are the confounding factors, and to what extent can these be adjusted for?

For each of these factors scores were assigned according to a series of definitions (summarised in Table A1-17). Scores for each criterion were assigned to each indicator during a brainstorming session focused on each objective. Summaries of the reasoning behind the assigned scores were recorded for each indicator (other than where a score of one or five was assigned, where the rational was considered self-evident from the definition).

Table A1-17: Scoring Criteria for Indicators

Specificity: How closely does the indicator match to the sub-objective at UK level?	Quality of information: Is the data source robust?	Cost: How easy will it be to collect the data and what extent of additional analysis is required?	Confounding Factors: How significant are the confounding factors and how easily can these be addressed?
1.**Questionable**: tenuous fit with the sub-objective and will inform on a non-UK level only	1. **Unreliable**: no apparent quality control in place	1. **Very high**: requires collection of new data through extensive monitoring/analysis (possibly with development of new methodologies) or extensive surveys specifically to gather data	1.**Very high confounding**: many confounding factors that it will be difficult to address
2. **Limited**: limited fit with sub-objective and may inform only on a non-UK level	2.**Borderline**: collecting organisation has some quality control measures in place, but no cross-checking is possible	2. **High**: requires collection of new data through additional monitoring/analysis (using existing methodologies) or surveys in co-operation with other organisations	2. **Some confounding**: some confounding factors with limited potential for correction
3.**Moderate**: reasonable fit with sub-objective but may inform only on a non-UK level	3. **Reasonable**: some independent cross-checking of information is possible	3. **Medium**: requires collection of new data (monitoring or surveys) but this can be undertaken at little or no cost to Defra, or may involve addition of some questions to existing questionnaire survey	3. **Moderate**: some confounding factors but with some potential for correction
4.**Good fit**: reasonable fit with sub-objective and relates to UK relevant data	4. **High**: information collected by authoritative source but quality control unspecified	4. **Moderate**: data already collected, but significant additional analysis required	4. **Quite specific:** some confounding factors but they can be largely corrected
5. **Specific**: excellent fit for the sub-objective	5. **Robust**: information collection by	5. **Very low**: already collected on on-going	5. **No confounding:** no confounding factors

[194] Confounding factors relate to objectives where there is crossover with other changes that may also have caused or contributed to that effect, such as other legislation which may have come into force or common practices may have changed thus contributing towards the effect.

Table A1-17: Scoring Criteria for Indicators			
Specificity: How closely does the indicator match to the sub-objective at UK level?	**Quality of information: Is the data source robust?**	**Cost: How easy will it be to collect the data and what extent of additional analysis is required?**	**Confounding Factors: How significant are the confounding factors and how easily can these be addressed?**
and relates to UK specific data	authoritative source and is subject to recognised quality control	basis in a usable format from a reliable source with no data protection issues. May need some reformatting or limited additional analysis	

Scores were weighted according to the importance of each criterion and weighted scores were summed together to provide an overall score for each indicator. This approach provides a transparent means of identifying the indicators that best satisfied requirements in terms of: specificity; quality of information: cost; and confounding factors.

This was subsequently used to inform the development of the options proposed in the scoping exercise for the UK monitoring and evaluation system. These ranged from 'Option 1', which included only those indicators that were expected to fulfil the Commission (legal) requirements for Member State reporting (any additional aspects agreed between Member States would need also to be included in this indicator set), to 'Option 4', which would include all indicators considered of potential value irrespective of cost implications.

A1.30 EC (2009a): Accompanying document to the Proposal for a Regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products, Impact Assessment, Commission Staff Working Document

COM (2009) assesses the impact of proposed revisions to the Directive 98/8/EC, which seeks to) seeks to harmonise the placing of biocidal products on the market whilst guaranteeing a high level of protection for humans, animals and the environment. The report considers the potential costs and benefits that may arise from various options under five policy areas. It estimates that the total costs of all preferred options to the industry would amount to a range from €193.6 to 706 million spread over a period of 10 years. These costs are mainly attributable to an extensive of the scope of the Directive to include treated materials (e.g. the costs of the authorisation of additional products and the labelling costs of treated materials).

The report also estimates that the total cost savings of all preferred options for industry could range from €2.7 billion to 5.7 billion spread over a period of 10 years. It states that the majority of these savings would be realised under the obligatory sharing of test data involving vertebrate animals at the substance evaluation and authorisation stage. All of the savings are calculated against a baseline of no policy change.

The report also states that monitoring and evaluation of the policy outcomes will take place through a variety of channels. For instance, Article 24 of the Directive states that Member States have to monitor whether biocidal products placed on the market comply with the requirements of the Directive. This means that every three years the Member States send a report to the commission on

their actions taken on this matter together with information on any poisonings involving biocidal products. The commission then compiles and publishes a composite report, which could be a valuable source of information. Table A1-15: provides a full list of the policy objectives, indicators and data sources associated with the monitoring and evaluation process.

Table A1-18: Core indicators for the general policy objectives		
Objective	**Indicator**	**Data source**
Facilitate the harmonisation of the EU market for biocidal products	Number of active substances evaluated	Progress report extracted from DG ENV's database
	Speed of product authorisation	Community Register For Biocidal Products
	Number of conflicts in Mutual Recognition that require resolution at Community level	The Commission/Agency will keep track of the number of conflict resolutions
Continue to provide high level of protection for humans, animals and the environment	Number of biocidal products on the market	Reporting obligation from MS to the Commission. Community Register for Biocidal Products
	Number of poisoning incidents	Reporting obligation from MS to the Commission under Article 24 of the Directive.
	Number of low risk biocidal products	The Agency will keep track of the decisions about low risk biocidal products
	Number of data sharing failures (linked to animal testing)	The Commission/Agency are informed when there is no agreement.
Increase the competitiveness of the EU industries affected by this Directive	Number of new active substances	Agency
	Number of unfavourable controls/inspections in the market surveillance activities in particular for the treated materials	Member States
Source: COM (2009)		

A1.31 EC (2009b) Commission Impact Assessment Guidelines

The Commission's Impact Assessment (IA) Guidelines, revised in 2009, give general guidance to the Commission services for assessing the potential impacts of different policy options. Public health and safety is included under the Guidelines, including a number of questions aimed at assessing whether there are changes in health risks in the workplace and with respect to the general public via the environment. It also includes public health risks associated with waste disposal and some stages of the life-cycle, like energy use.

In terms of the valuation of health impacts, the Guidelines suggest quantification whenever possible by using the Healthy Life Years indicator[195], or measuring both quality and quantity of life using QALYs (quality adjusted life years) or DALYs (disability adjusted life years). Monetary valuation is also recommended although the guidance acknowledges the problems in doing so. Approaches suggested in Annex 9 to the Guidelines include market based approaches, such as the Cost of Illness

[195] The Healthy Life Years (HLY) indicator is in the core set of the European Structural Indicators as its importance was recognised in the Lisbon Strategy.

(COI) or human capital approach, revealed preferences based approaches, such as Willingness to Pay (WTP) or Willingness to Accept (WTA), and related units based on these, such as Value of Statistical Life (VOSL) and Value of Statistical Life Year (VOLY)[196]. Annex 9 suggests a range of values for different units of measurement, as:

- 50.000 – 80.000 Euros for a QALY (although this could be adjusted for a concrete policy proposal to reflect the specific context);
- 1-2 million Euros for VOSL; and
- 50.000-100.000 Euros for VOLY in Europe.

Life-cycle approaches are also recognised as potentially useful tools to assess the environmental impacts through the different stages of a product's life. As for environmental impacts, monetisation is also recommended. Examples are given of a range of EU-funded environmental impact assessment models, e.g. ECOSENSE; FUND; IMAGE; RAINS; and SMART. These consider environmental and man via the environment health impacts but vary in their focal point, e.g. pollutants to the atmosphere, climate change, acid deposition, etc. Of all the examples given, SMART may be the most applicable to the chemical context, as it focuses on long-term chemical changes and pollution in soil and water but only from atmospheric deposition. Other modules from the models also may be transferable, such as the maps on environmental sensitivities from RAINS.

In summary, although the Impact Assessment Guidelines favour the use of monetisation and go on to suggest some values, the applicability of these values to chemicals legislation will always be limited to the extent to which it is possible to quantify the changes in environmental or health impacts, e.g. reductions in exposures and hence the burden of certain types of diseases for workers, consumers or the general public.

A1.32 EU-OSHA (2010): Socio-economic costs of accidents at work and work-related ill health

The report presents the results of the benOSH (Benefits of Occupational Safety and Health) project, aiming at evaluating the costs of accidents at work and work-related ill health and at demonstrating the incremental benefit to enterprises in developing an effective prevention policy in Occupational Safety and Health. The researchers followed a two-track approach, carrying out desk research and field research based on multiple case studies. Eurostat data were used for the determination of the global burden of accidents at work and work-related ill health in Europe. Information is presented by sector of activity (where the data on the chemical sector are not necessarily linked to the effects of certain chemicals but could refer to accidents of other nature and where data referring to other sectors might refer to the effects due to workers' exposure to chemicals).

In terms of data availability, the authors highlighted the difficulties encountered in:

- Involving small-medium enterprises and receiving the necessary data;
- Gathering information concerning work related diseases on company level;
- Obtaining the necessary data to make the economic valuations;
- Assessing the effectiveness of the OSH measures.

[196] For more discussion on the individual units, please refer to: http://ec.europa.eu/governance/impact/commission_guidelines/docs/iag_2009_annex_en.pdf

Interestingly for this study, the report suggests consideration of different variables at three different levels:

- The employee;
- The company;
- The society.

Moreover, the consequences on the family, friends and colleagues need to be considered as well. Table A1-19 presents some of these parameters that could be used as proxies or indicators.

Table A1-19: Consequences of accidents at work and work-related ill-health for different groups		
Level	**Non tangible**	**Quantifiable**
Victim	Pain and suffering Moral and psychological suffering (especially in the case of permanent disability) Lowered self-esteem, self confidence Strain on relationships Lifestyle changes	Loss of salary and premiums Reduction of professional capacity Medical costs Loss of time (medical treatments)
Family and friends	Moral and psychological suffering Medical and family burden Strain on relationships	Financial loss Extra costs
Colleagues	Psychological and physical distress Worry or panic (in case of serious or frequent accidents/cases of ill-health)	Loss of time and possibly also of premiums Increase of workload Training of temporary workers
Company	Presenteeism Company image Working relations and social climate	Internal audit Decrease of the production Damage to equipment, material Quality losses Training of new staff Technical disturbances Organisational difficulties Increase of production costs Increase of the insurance premium or reduction of the discount Early retirement Administrative costs Legal sanctions
Society	Reduction of the human labour potential Reduction of the quality life	Loss of production Increase of social security costs Medical treatment and rehabilitation costs Early retirement Decrease of the standard of living
Source: De Greef and Van den Broek, 2004 (as reproduced in COM, 2011)		

Related to the different levels identified, different perspectives can be applied for the monetisation of the indirect cost of illness. Table A1-20 reports on the definition of these perspectives and possible calculation methods.

Table A1-20: Indirect cost of illness from the individual, societal and employer perspectives			
	Individual perspective	**Societal perspective**	**Employer perspective**
Definition			
	Value of human life in terms of a person's	Value of a human life in terms of a person's	Cost of the disease to the employer from

	income and value of leisure time	potential income generation	illness and/or death
Calculation			
Mortality	The ultimate loss Effect on family	Present value of forgone future income	Cost of replacing workers (hiring and training)
Morbidity	Loss of income (e.g. unpaid sick-leave days, decrement in income when on disability) and loss of leisure time	Loss of income from missed work	Work-loss, idle assets, and non-wage costs (e.g. benefits and fixed payroll costs)
Source: Berger et al, 2001 (as reproduced in COM, 2011)			

More importantly, the report links cost variables with data sources (Table A1-21). The authors also review some methodologies for the monetisation of the benefits stemming from the implementation of a better OSH strategy. In summary, the report is a precious source of indicators and data on occupational health effects of chemicals (although it is not limited to the chemicals field); in particular the section on respiratory, skin problems and infectious diseases provides information on the most affected sectors and on the hazardous chemicals associated with those effects. On the other hand it has limited value with regard to the assessment of the effects on the non-workers population's health and on the environment.

Table A1-21: Cost variable and how to obtain monetary value		
Variable	**Description**	**How to obtain monetary value**
Effects of incidents that cannot directly be expressed in monetary value		
Fatalities, deaths	Number of fatalities	Sum of costs of subsequent activities, fines and payments
Absenteeism or sick leave	Amount of work time lost due to absenteeism	Sum of costs of activities to deal with effects of lost work time, such as replacement and lost production; indirect effect is that sick leave reduces flexibility or possibilities to deal with unexpected situations
Personnel turnover due to poor working environment, or early retirement and disability	Percentage or number of persons (unwanted) leaving the company in a period of time	Sum of costs of activities originated by unwanted turnover, such as replacement costs, additional training, productivity loss, advertisements, recruitment procedures
Early retirement and disability	Percentage or number of person s in a period of time	Sum of costs of activities originated by disability or early retirement, fines, payments to the victim
Source: Mossink and De Greef, 2002 (adapted from COM, 2011)		

A1.33 OECD (2010): Valuing mortality risk reductions in regulatory analysis of environmental, health and transport policies: Policy implications

The authors analysed the differences in the approaches followed by different countries in establishing the Value of Statistical Life (VSL). While in the US the most common approach is to rely on Revealed Preference methods in terms of wage risk, in Europe the Stated Preferences methods are the mainstream, eliciting people's Willingness to Pay (WTP) for changes in mortality risks.

The authors provide useful recommendations on how to adjust VSL base values for differences in population, risk characteristics and other differences. These recommendations may be of value in the monetisation stage of the present study.

A1.34 COWI *et al* (2011): The costs of not implementing the environmental acquis

Aim of the study was to quantify the costs deriving from the non-full implementation of the EU environmental acquis. For this reason, the report considers wider legislation and does not focus exclusively on chemicals. As first step, the authors looked at different environmental sectors, namely:

- Waste;
- Biodiversity and nature;
- Water;
- Air;
- Chemicals; and
- Noise.

Due to the very high number of directives and regulations (more than three hundreds legislative acts), the identification of the implementation gaps was carried out through the assessment of the overall policy objectives and targets and their comparison with the actual scenario.

With regard to the chemicals sector, the REACH Regulation, the Seveso II Directive and other chemicals legislation (Biocides, Pesticides etc.) were examined in order to determine the compliance status and identify quantifiable targets. The general target was defined by the authors as "*Safe use of chemicals and phase-out of most hazardous ones*". It should be stressed that the costs of non-full implementation have been defined in the study as comprising not only the environmental and health costs but also the uncertainty, innovation and competition costs, the spill over effects, the administrative costs to industry and the litigation costs. The data sources considered for the quantification of the implementation gaps were generally identified as ECHA and Eurostat; however, the early stage of implementation of the REACH Regulation and the few specific targets defined led to a high level of uncertainty. The authors did not try to quantify the environmental and health costs, instead referring to previous studies (namely to the Extended Impact Assessment by the Commission and the DHI (2005) report).

A1.35 Prüss-Ustün et al (2011) Knowns and unknowns on burden of disease due to chemicals

Prüss-Ustün et al (2011) applied the standard methodology of the Global Burden of Disease developed by the World Health Organisation to chemicals' exposure. The authors undertook a systematic review of previous studies looking into the burden attributable to exposure to chemicals and concluded that the unknown aspects were still prevailing on what was already known. The article first describes how human exposure to chemicals occurs, identifying the chemical groups of most concerns, the processes that provoke the exposure, the life-cycle stages of the chemicals when the exposure might occur and the legislative areas in which policies to reduce the exposure are implemented (Figure A1-5).

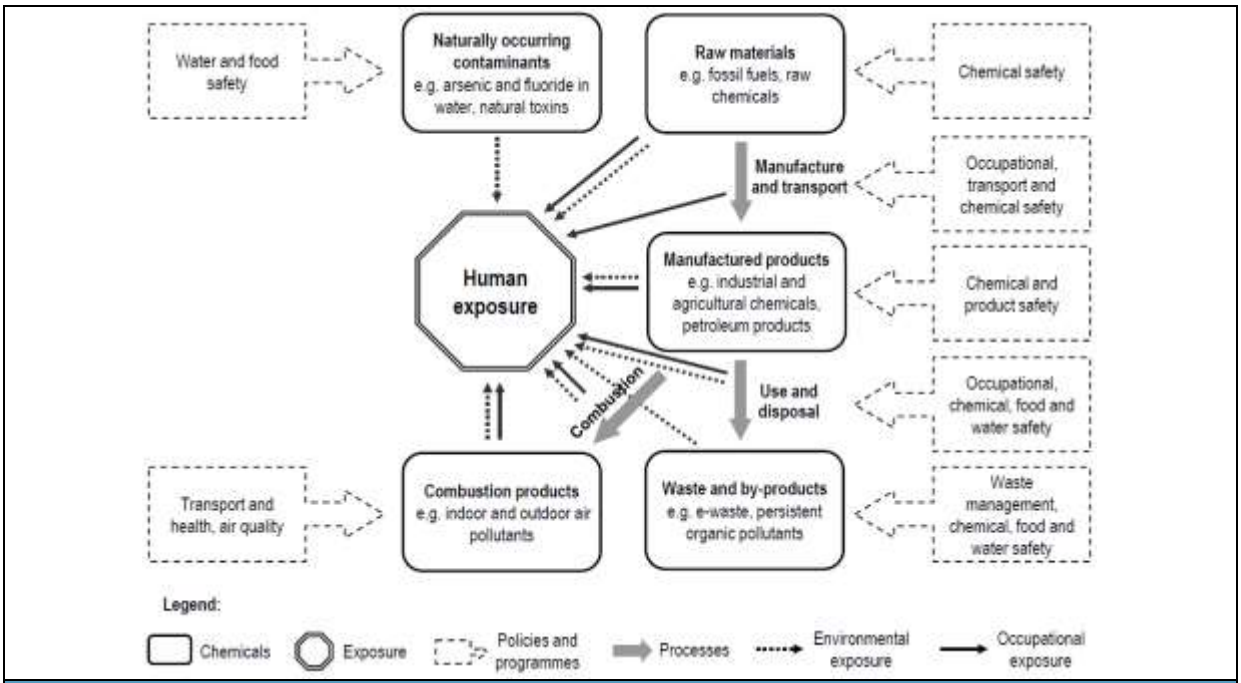


Figure A1-5: Human exposure to chemicals throughout their life-cycle and selected programmes relevant to their prevention - *Source: Prüss-Ustün et al (2011)*

The study also provides examples of sources and pathways of human exposure to a few selected chemicals (figure A1-6).

Exposure media	Example sources of exposure and exposure pathways	Examples of chemicals
Outdoor air	Inhalation of toxic gases and particles from vehicle and industrial emissions, or naturally occurring sources such as volcanic emission or forest fires.	Sulfur dioxide, nitrogen oxides, ozone, suspended particulate matter, lead, benzene, dioxins and dioxins-like compounds
Indoor air	Inhalation of pollutants released during indoor combustion of solid fuels, tobacco smoking, or from construction materials and furnishings, contaminants in indoor air and dust.	Suspended particulate matter, nitrous oxide, sulfur oxides, carbon monoxide, formaldehyde, polyaromatic hydrocarbons (PAH), mercury, lead dust from lead-based paints, benzene, asbestos, mycotoxins, phtalates, polybrominated diphenyl ether fire retardants (PBDEs)
Drinking water	Ingestion of drinking water contaminated with toxic chemicals from industrial effluents, human dwellings, agricultural runoff, oil and mining wastes, or from natural sources.	Pesticides, herbicides, fertilisers, metals (copper, lead, mercury, selenium, chromium), arsenic, fluoride, nitrate, cyanide, industrial solvents, petroleum products, disinfection by-products.
Food	Consumption of food contaminated with chemicals at toxic levels through agricultural practices, industrial processes, environmental contamination, and natural toxins.	Pesticides, methylmercury, lead, cadmium, dioxins, aflatoxin.
Non-food consumer products	Exposure by ingestion, inhalation or dermal exposure to toxic chemicals contained in toys, jewellery and decoration items, textiles, or food containers, consumer chemical products	Lead, mercury, cadmium, phthalates, formaldehyde, dyes, fungicides or pesticides.
Soil	Ingestion (particularly for children) or inhalation of soil contaminated through industrial processes, agricultural processes or inadequate household and industrial waste management.	heavy metals, pesticides, and persistent organic pollutants.
Occupational exposure	Chronic or acute exposures through inhalation, dermal absorption, or secondary ingestion of toxic chemicals or by-products of industrial processes such as agriculture, mining or manufacturing.	Pesticides, benzene, heavy metals, solvents, suspended particulate matter.
Human to human	Foetal exposure to toxic chemicals during pregnancy (through placental barrier) or through consumption of contaminated breast milk.	Heavy metals, pesticides, benzene, etc.

Figure A1-6: Examples of sources and pathways of human exposure to a few selected chemicals
Source: Prüss-Ustün et al (2011)

The authors analysed a number of sources from the WHO and peer reviewed journals. In total, relevant estimates were found for the following chemicals or groups of chemicals:

- Chemicals involved in unintentional acute poisonings;
- Chemicals involved in unintentional occupational poisonings;
- Pesticides involved in self-inflicted injuries;
- Asbestos;
- Occupational lung carcinogens;
- Occupational leukaemogens;
- Occupational particulates;
- Outdoor air pollutants;
- Indoor air pollutants from solid fuel combustion;
- Second-hand smoke;
- Lead and arsenic in drinking water.

The estimates were compiled and have been reproduced for convenience in Table 2-20.

Moreover, in order to compare the available estimates to the total burden of disease from chemicals, the authors reviewed the literature and listed the main health outcomes associated with exposure to toxic chemicals (Figure A1-7).

Diseases/disease groups	Examples of exposures	Examples of associated outcomes [22,66,67]
Respiratory infections and chronic respiratory diseases	Occupational exposures to dusts, gases, irritant chemicals, fumes	Chronic Obstructive Pulmonary Disease (COPD) [68,69]
	Second-hand smoke; occupational exposures to cleaning-agents, pesticides, hairdressing chemicals etc.	Asthma onset and exacerbation [28,70-72]
	Second-hand smoke	Acute lower respiratory infections [28]
	Occupational exposure to asbestos Metal dusts, particulate matter	Asbestosis Bronchitis, pneumoconiosis, silicosis
Perinatal conditions	Maternal exposure to pesticides or other chemicals	Low-birth-weight and preterm infants [73-76]
Congenital anomalies	Maternal exposure to pesticides, polychlorinated biphenyls (PCBs), polychlorinated dibenzofurans (PCDFs), lead, mercury, other endocrine disruptors	Various birth defects [77,78]
Diseases of the blood	Lead, arsine, naphthalene, benzene	Anaemia, methaemoglobinemia
Cancers	Occupational exposures to carcinogens, aflatoxins in food, second-hand smoke, outdoor air pollution by carbon particles associated with polycyclic aromatic hydrocarbons, asbestos, arsenic; volatile organic compounds such as benzene, pesticides, dioxins. etc.	Numerous cancer sites, including of the lung, skin, liver, brain, kidney, prostate, bone marrow, bladder [79-82]
Neuropsychiatric and developmental disorders	Lead, methylmercury, polychlorinated biphenyls (PCBs), arsenic, toluene etc.	Cognitive development, mental retardation, Parkinson disease, Attention-deficit disorder, Minamata disease [51,78,83,84]
Sense organ diseases	Carbon disulfide, mercury, lead	Hearing loss
Cardiovascular diseases	Ultrafine particles in polluted air, lead, arsenic, cadmium, mercury, pollutant gases, solvents, pesticides, second-hand smoke	Ischaemic heart disease, cerebrovascular disease [28,49,85]
Diabetes mellitus	Arsenic, N-3-pyridylmethyl-N'-p-nitrophenyl urea (rodenticide), 2,3,7,8-Tetrachlorodibenzo-p-dioxin.	Diabetes Type II [86-89]
Systemic auto immune diseases	Crystaline silica dust	Systemic sclerosis, systemic lupus erythematosus, rheumatoid arthritis, systemic small vessel vasculitis [90]
Endocrine diseases	Ethanol, hexachlorobenzene	Porphyria
Genito-urinary diseases	Beryllium, cadmium, lead	Calculus of kidney, chronic renal disease
Digestive diseases	Ethanol, chloroform, carbon tetrachloride, manganese	Hepatitis, cholestasis, pancreatitis
Skin diseases	Antiseptics, aromatic amines, cement, dyes, formaldehyde, artificial fertilizers, cutting oils, fragrances, glues, lanolins, latex, metals, pesticides, potassium dichromate, preservatives	Atopic dermatitis, allergic and irritant contact dermatitis, chloracne, hyperkeratosis [91]
Musculoskeletal diseases	Cadmium, lead	Osteoporosis, gout
Oral conditions	Fluoride	Dental fluorosis
Poisonings	Accidental ingestion of household products, occupational exposures and accidents, intentional self-harm by ingestion of pesticides	Unintentional poisonings, self-inflicted injuries [92-94]

Figure A1-7: Main disease groups with suspected or confirmed linkage to chemicals
Source: Prüss-Ustün et al (2011)

The authors found that the global burden of disease attributable to environmental exposure and management of selected chemicals amounts to 4.9 million deaths (86 million DALYs) per year. This accounts for approximately 8.3% of the total deaths and 5.7% of the total burden of disease in DALYs worldwide. These figures refer only to a number of chemicals for which data are available and for which the causal link with the health outcomes is solidly proven. As successfully presented in Figure A1-8 (reproduced from Prüss-Ustün et al (2011) as adapted from de Hollander et al (2000)) only a small fraction of health outcomes can easily be linked to chemicals' exposure. Therefore, the estimated burden is likely to be an underestimate.

Of interest, Figure A1-9 reproduced the distribution of known burden of disease in DALYs as estimated by Prüss-Ustün et al (2011).

The population attributable fraction methodology described in the paper might prove valuable for the purpose of the present study.

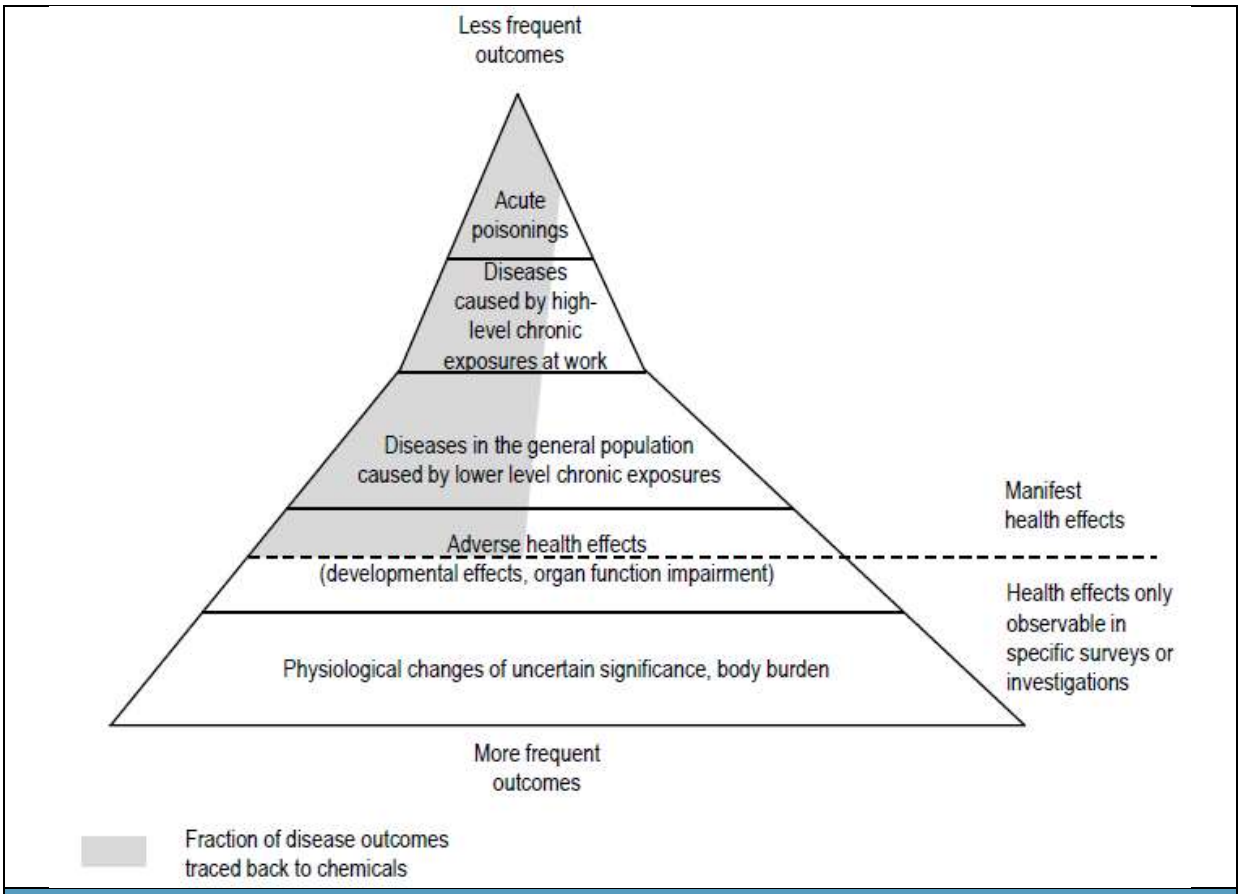


Figure A1-8: Occurrence and detection of health impacts from chemicals
Source: Prüss-Ustün et al (2011)

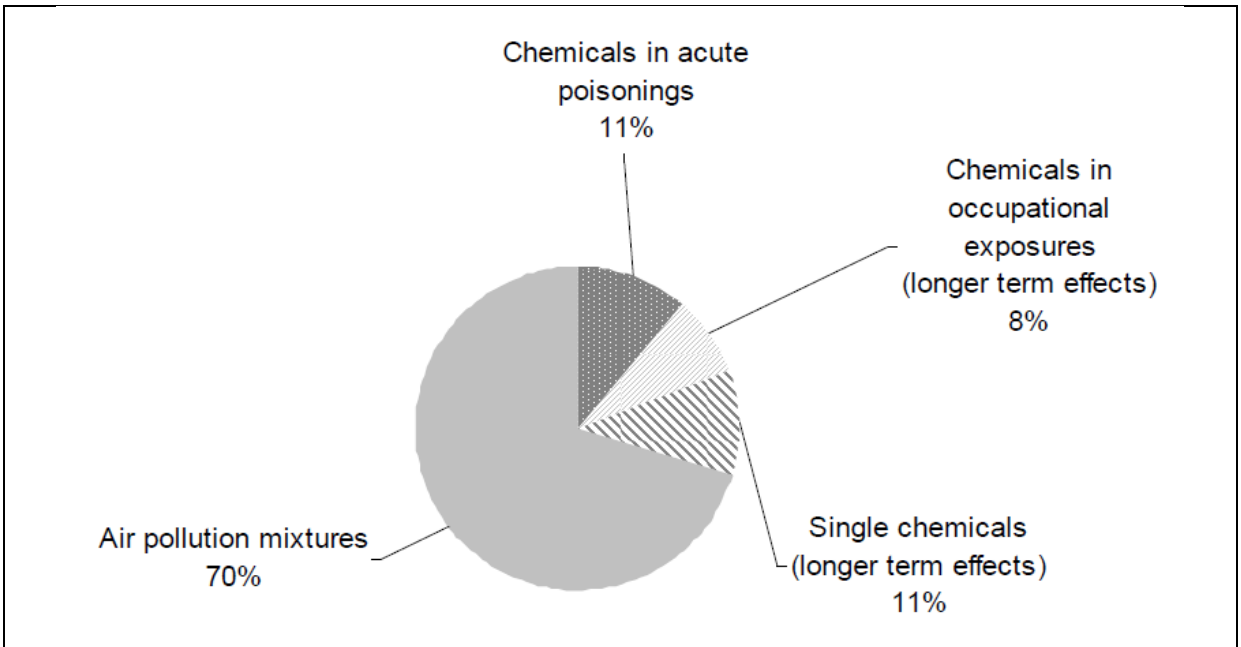


Figure A1-9: Distribution of known burden of disease (in DALYs)
Source: Prüss-Ustün et al (2011)

Table A1-22: Overview of available disease burden estimates attributable to chemicals				
Chemicals/Groups of chemicals	**Disease outcomes considered (attributable fraction)**	**Deaths**	**DALYs**	**Data year**
Chemicals in acute poisonings				
Chemicals (including drugs) involved in unintentional acute poisonings (methanol, diethylene glycol, kerosene, pesticides etc.)	Unintentional poisonings (71%)	240,000	5,246,000	2004
Chemicals involved in unintentional occupational poisonings	Unintentional poisonings (occupational) (8.6%)	30,000	643,000	2004
Pesticides involved in self-inflicted injuries	Self-inflicted injuries (23%)	186,000	4,420,000	2002
Chemicals in occupational exposures (longer term effects)				
Asbestos	Malignant mesothelioma (NA); trachea, bronchus, lung cancer (0.3%); asbestosis (NA)	107,000	1,523,000	2004
Occupational lung carcinogens (arsenic, asbestos, beryllium, cadmium, chromium, diesel exhaust, nickel, silica)	Trachea, bronchus, lung cancer (8.6%)	111,000	1,011,000	2004
Occupational leukaemogens (benzene, ethylene oxide, ionizing radiation)	Leukaemia (2.3%)	7,400	113,000	2004
Occupational particulates - causing COPD (dusts, fumes/gas)	COPD (13%)	375,000	3,804,000	2004
Occupational particulates - other respiratory diseases than COPD (silica, asbestos and coal mine dust)	Asbestosis (NA); silicosis (NA); pneumoconiosis (NA)	29,000	1,062,000	2004
Air pollutant mixtures				
Outdoor air pollutants (particulate matter, sulfur dioxide, nitrogen oxides, benzo[a]pyrene, benzene, others)	Lung cancer (7.9%); acute respiratory infections (1.6%); selected cardiopulmonary diseases (3.4%)	1,152,000	8,747,000	2004
Outdoor air pollutants emitted from ships (particulate matter, sulfur dioxide, nitrogen oxides, benzo[a]pyrene, benzene, others)	Lung cancer (0.3%); selected cardiopulmonary diseases (0.4%)	60,000	n/a	2002
Indoor air pollutants from solid fuel combustion (carbon monoxide, nitrogen oxides, sulfur oxides, benzene, formaldehyde, polyaromatic compounds, particulates, others)	Lung cancer (2.9%); acute respiratory infections (33%); COPD (33%)	1,965,000	41,009,000	2004
Second-hand smoke (nicotine, formaldehyde, carbon monoxide, phenols, nitrogen oxides, naphthalenes, tar, nitrosamine, PAHs, vinyl chloride, various metals, hydrogen cyanide, ammonia, others)	Lower respiratory infections (6.3%); otitis (1.7%); asthma (11%); lung cancer (1.8%); ischaemic heart disease (4.5%)	603,000	10,913,000	2004
Single chemicals with mostly longer term effects				
Lead	Mild mental retardation; Cardiovascular diseases	143,000	8,977,000	2004
Arsenic in drinking-water	Diabetes mellitus (0.04%) ischemic heart disease (0,11%); lung cancer (0.25%); bladder cancer (1.2%); kidney cancer (NA); skin cancer (0.30%)	9,100	125,000	2001
Source: Prüss-Ustün et al. (2011)				

A1.36 RPA *et al* (2011): Assessing the Health and Environmental Impacts in the Context of Socio-economic Analysis under REACH

RPA developed logic frameworks for the assessment of human health and environmental impacts, using the ECHA Guidance on SEA for restrictions as the starting point[197]. The aim of the frameworks was not to invent a new approach but to provide further suggestions and refinements as to how health and environmental impacts in particular could be assessed within the overall SEA process for restriction and authorisation as envisaged by ECHA.

The frameworks set out a step-by-step approach, from impact characterisation to assessment, including valuation and comparison with impacts from the alternatives. The approach is based on a qualitative assessment followed by a more quantitative assessment where appropriate and of value to decision makers. Two case study applications were undertaken of the proposed methods (on TCEP for human health and HBCDD for the environment, two substances of very high concern (SVHC) under REACH).

The study suggests the use of different tools for benchmarking human health impacts as well as, of relevance for this tender, proxy indicators for impacts, e.g.:

- Changes in exposure level and/or frequency;
- Changes in concentration of a chemical of consumer products;
- Changes in emissions.

Fuller quantification may be possible (e.g. where it is possible to use the methods commonly applied as part of health impact assessment to quantify changes in disease cases or disease burden) but should be accompanied by information and the level and sources of uncertainty. The approaches to valuation are those included in the earlier guidelines, namely the use of QALYs or DALYs, the use of VOSL estimates and the use of cost of illness or resource cost estimates.

In comparison with the ECHA guidance for restrictions, the framework suggests the use of data from the chemical safety assessment, supported by other information, to infer environmental impacts. However, the framework highlights that care is needed in doing this, to avoid over-estimating the impacts (as a risk assessment will be generally based on worst-case scenarios). Thus, for example, a smaller sub-set of data may be sufficient to quantify the benefits to the environment. On the other hand, it is recognised that data not included in the CSA may be needed to produce robust information suitable for use by decision makers, e.g. relating to tonnages used, the efficiency of emissions control equipment, local environmental factors (e.g. actual receiving water dilution rates), species sensitivity distribution, etc.

A1.37 Defra (2011): The costs and benefits of Defra's regulatory stock

Defra (2011) estimates the costs and benefits of chemicals regulation for business in the UK. These impacts are derived over a 10 year period from the baseline year 2011. The estimates are taken from a variety of sources such as regulatory impact and compliance cost assessments; Defra's internal value for money analyses and a paper on administrative burdens conducted by Price

[197] At the time of preparation, the ECHA guidance on SEA and authorisation was not available yet.

Waterhouse Coopers. In total, seventeen policy areas are considered ranging from climate change to animal health and welfare.

The key value of this paper is that estimates the costs and benefits of chemicals and genetically modified organisms (GMO) regulation in the UK for businesses over a ten year period starting from 2011. With regards to benefits, the paper only considers those arising from the REACH and Mercury regulations, which are estimated to be around £17 million per annum. The paper goes on to state that the benefit cost ratio of chemicals regulation is 38:1.

This data could be used as an indicator within the study as the information is held in an excel database and 'continues to be improved and updated'. However, it is unclear whether this database is publicly available and no link is provided within the paper. Furthermore, the estimates are based on UK data and may prove difficult to extrapolate to the EU level. A full list of the results for the chemicals and GMOs policy area is provided in Table A1-23.

Table A1-23: Summary of Defra's Chemicals and GMOs regulation	
Variable	**Value**
Number of EU regulations	9
Number of domestic regulations	2
Direct costs to business £m p.a.	15
Direct benefits to business £m p.a.	17
Net costs to business £m p.a.	-2
Costs to other parties £m p.a.	1
Other benefits £m p.a.	0
Admin burden as % of business cost	58%
Benefit cost ratio	38.4
Benefits included in BCR, £m p.a.	17
Costs included in BCR, £m p.a.	0
% of costs EU	28%
Reliability of cost estimates (1-5)	3.0
Source: Defra (2011) *Note: Benefits estimates are only available for some regulations and the benefit-cost ratios reported only include those regulations for which both benefits and costs estimates are available.*	

A1.38 ECHA (2011): ECHA's Guidance on Socio-Economic Analysis

Guidance on socio-economic analysis (SEA) was issued by ECHA in 2008 and 2011, on Restriction and Authorisation, respectively.

Both guidance documents propose a stepwise approach (Figure A1-10) whereby the assessment focuses on those health and environmental impacts that are considered to be significant, with the level of detail and quantification applied determined by the extent to which further information contribute to developing a robust SEA. Throughout the process, judgements need to be made (drawing on the expertise of others as appropriate) on what impacts are likely to be significant and how these can best be assessed.

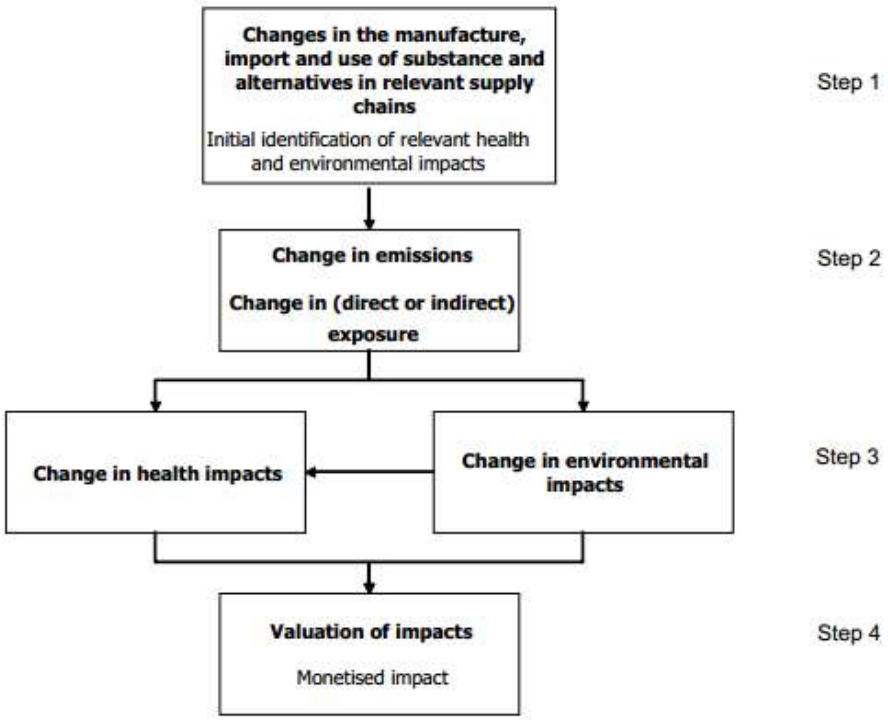


Figure A1-10: Scheme for assessment of health and environmental impacts
Source: ECHA (2008): Guidance on Socio-Economic Analysis - Restrictions

The ECHA Guidance documents highlight the importance of moving from qualitative to quantitative assessment and acknowledge the difficulties in quantification when assessing environmental and human health impacts. The guidelines provide some examples on the types of impacts that should be considered:

- Human health
  - Morbidity
    - Acute effects (e.g. sneezing, skin or lung irritation);
    - Chronic effects (e.g. asthma or reproductive disorders);
  - Mortality (e.g. premature death due to cancer);
  - Morbidity or mortality due to different explosive characteristics of the substance;
- Environmental
  - Ecological impairment (i.e. biodiversity and functioning);
  - Habitat destruction;
  - Water quality impairment;
  - Air quality impairment;
  - Soil quality impairment;
  - Other impacts, such as
    - Climate change (e.g. greenhouse gas emissions);
    - Water consumption/abstraction;
    - Landscape/aesthetic quality of environment;

- Resilience and vulnerability to environmental impacts.

Importantly, the guidance stresses the types of data that are likely to be needed for a proper quantification:

- "*Quantitative estimates of the relationship between individual exposure and the incidence of a defined health effect and derivation of a probability of that effect being manifested (i.e. a dose-response relationship);*
- *Assessment of exposure, including the frequency and duration of exposure, the rate of uptake of the substance by the relevant route (e.g. inhalation, oral, dermal) in order to be able to estimate and average dose or a range of doses;*
- *A measure of actual impact of the health effect (e.g. numbers of life years lost due to contracting cancer);*
- *An estimate of the total population exposed (and if possible the distribution of exposures within that population)"* (ECHA, 2008).

The units of measurements are similar to those set out in the IA Guidelines.

A1.39 RPA *et al* (2012): Assessment of the Health and Environmental Benefits of REACH

The aim of the REACH Benefits Study was to provide an understanding of the benefits to human health and the environment stemming from the implementation of REACH to date. It included the development of a framework for assessing the human health and environmental benefits of REACH.

The proposed framework draws on a review of the methodologies that have been used in the past (or that could otherwise be used) to provide qualitative or quantitative information on the benefits of REACH, including the economic value of human health (mainly workers and the general public) and environmental benefits. A key conclusion from this work is that, in the implementation of REACH, it was not possible to quantify benefits and the assessment had to rely on the use of a series of qualitative information together with a limited set of quantitative indicators; the latter are the types of indicators being reported on by the REACH Baseline Study[198]. As a follow-up to the Eurostat study of 2009 which was published with data before REACH was in place, the 2012 comprehensive report presents the results and the methodology of the update and the assessment of the main changes from the first study in 2009 to its update in 2012.

The framework for assessing the benefits of REACH proposed in the study started with the identification of:

- The **drivers of benefits** within REACH, where these are the set of legal provisions which are expected to trigger direct or indirect human health and/or environmental benefits. The drivers considered within the study were registration, requirements for information through the supply chain, authorisation and restrictions;
- The **pathways** through which the drivers deliver these benefits, in other words they describe the cause and effect links between the drivers and benefits;
- **Indicators** of benefits, which can act as a direct measure or a proxy of the effects stemming from any cause-effect link; and

[198] Oko-Institut, FoBiG, DHI and INERIS (2011): REACH Baseline Study: 5 Years Update, Progress Report IV, Eurostat study Reference No 2010/S 167-255573, Freiburg, December 2010.

- **Enhancers**, which are those provisions that help to realise the benefits through support, control and enforcement and thus assist or ensure compliance with the main obligations. The study considered the provision of guidance, evaluation, inspection and enforcement activities.

The key indicators of benefits used for the **registration** driver were:

- Number of newly classified substances and number of substances which have changed classification as a result of new information (new data on substance properties lead to new classifications or changes in existing substance classifications, higher data quality and re-assessment of risks);
- Changes in DNELs, PNECs, etc. (the degree to which information on previously unknown uses became known to registrants; linked to this is the number of uses subsequently 'advised against' as they are not/no longer considered 'safe');
- Changes in recommended risk management measures (the extent to which reach may have triggered the implementation of more stringent operating conditions or RMMs);
- The number of substances withdrawn from the market due to hazardous properties (where the use of alternatives does not lead to an increase in exposure to other hazardous substances);
- Linked to the above is information on the number of new, non-hazardous (or potentially low hazard) substances added to the market and the degree to which this varies from the numbers and hazard profiles of such substances being newly notified before reach; and
- The number of newly identified PBTs or vPvBs.

Potential indicators of benefits were also identified to act as proxies for the impacts that the **communication** of safety data may have in terms of realising health and environmental benefits. These include:

- The extent to which ES set out more stringent use conditions (operational conditions and/or RMM) to be implemented by Downstream Users in their processes;
- Queries and information provision to suppliers from Downstream Users;
- The number of Downstream User chemical safety assessments (although it may be too early for there to be many of these); and
- Queries from consumers about the content of substances of very high concern in articles.

The indicators related to **authorisations** identified were:

- Number of substances identified as meeting the criteria as a SVHC;
- Number of chemicals included in the candidate list (Art.58), and as a % of those meeting criteria as a SVHC;
- Number of substances (and % of all SVHCs) subject to authorisation (inclusion in Annex XIV);
- % of substances with SVHC properties listed in Annex IV of CLP and in Annex XIV compared to the total expected number of SVHCs;
- % of Annex XIV substances for which safe alternatives are introduced over specified time frames (e.g. First 10 years of REACH);
- Number of applications for the continued use of substances and the associated percentage of the total volume pre-candidate listing;
- Number of decisions taken regarding Article 60 using the adequate control route or the socio-economic route.

With regard to **restrictions**, they were:

- Number of restriction proposals introduced for substances, mixtures or articles;

- Number of new restrictions adopted on uses of substances and mixtures, and on articles;
- Average (and minimum/maximum) time taken to reach regulatory decision on a restriction proposal.
- The study identified four main enhancers within REACH: Evaluation; Inspection and enforcement; Synergies with other legislation; and Guidance and other support, including the dissemination of information to external stakeholders.

With regard to dossier **evaluation** the indicators listed below were considered:

- Number of dossiers opened;
- Draft decisions sent to registrant;
- Final decisions;
- Quality observation letters sent;
- Compliance checks concluded without further action.

With regard **to inspection and enforcement** the indicators considered were:

- Number of inspection performed by Member States and different categories of actors;
- Number of measures due to non-compliance.

A1.40 Rushton et al (2012): The burden of occupational cancer in Great Britain

The United Kingdom Health and Safety Executive commissioned to the Health and Safety Laboratory, the Institute of Environment and Health, the Institute of Occupational Medicine and to the Imperial College London a study to estimate the burden of occupational cancer in Great Britain and to develop a methodology for predicting the future burden of occupational cancer.

The work was organised accordingly, with the first phase aiming to quantify the current cancer burden and the second aiming to look at the future cancer burden. A first interim report (RR 595) on the first phase was published in 2007, containing provisional estimates for the burden of six of the most common cancer sites. Individual reports were published for each of these cancer sites[199]. The estimates presented in Rushton et al (2007)[200] and Rushton et al (2010)[201] have been updated in Rushton et al (2012)[202].

The authors followed the attributable fractions (AC) method ("*that is the proportions of cases that would not have occurred in the absence of exposure*" (Hutchings and Rushton, 2011)). For the prediction of the future burden of occupational cancer, three possible approaches were scrutinised during a workshop with international expert held in 2008; these were:

- To estimate attributable fractions (AC), "*using an extension of the methodology developed to estimate current burden*" (Hutchings and Rushton, 2011);

[199] And can be found at: http://www.hse.gov.uk/cancer/research.htm

[200] Rushton et al (2007): The burden of occupational cancer in Great Britain, Report RR595 for the UK HSE, available at: http://www.hse.gov.uk/research/rrhtm/rr595.htm

[201] Rushton et al (2010): The burden of occupational cancer in Great Britain, Overview Report RR800 for the UK HSE, available at: http://www.hse.gov.uk/research/rrpdf/rr800.pdf

[202] Rushton et al (2012): The burden of occupational cancer in Great Britain, Overview Report RR931 for the UK HSE, available at: http://www.hse.gov.uk/research/rrpdf/rr931.pdf

- To estimate the "lifetime risk" of a cohort of newly exposed workers, applying national incidence rates to the future person-years-at risk and excess risk from the occupational exposure of the cohort;
- To estimate attributable numbers (AN), differentiating projected cancer numbers for occupational and non-occupational risk factors through a structural regression model.

For the measurement of the current burden, the authors uses UK data on incidence (2004 data), mortality (2005 data) and survival trends for each cancer site. After identifying known and suspected occupational exposures, the authors derived attributable fractions in order to estimate the attributable numbers.

Cancer sites were linked to the exposure to determined factors (such as ionising radiation, environmental tobacco smoke, diesel engine exhaust, etc.) and, more importantly for this project, to determined chemical substances in different occupational settings (chemicals manufacturing, agricultural workers and farmers , hair-dressing, embalmers, etc.). Relative risk factors for high and low exposure were compiled from different scientific articles, differentiating for the strength of evidence ("strong" or "suggestive"). The quality of the literature considered was determined taking into account sample size, extent of control for confounders, adequacy of exposure assessment and clarity of case definition.

Relevant exposure periods (REP) and levels of exposure were estimated using national data sources such as the CARcinogen Exposure database (CAREX), the UK Labour Force Survey and the Census of Employment).

The authors estimated that the proportion of cancer deaths in 2004 attributable to occupation was 8.0% for men and 1.5% for women with an overall estimate of 4.9% for men plus women. The estimated numbers of deaths attributable to occupational cancer were 6,259 for men and 1,058 for women (a total of 7,317).

Table A1-24 presents the results with regards to the estimated attributable fractions and deaths. Figure A1-11 shows the estimated occupational cancer deaths by cause in Great Britain in 2005.

Table A1-24: Estimated attributable fractions and deaths, 2004

	Attributable fraction (AF)			Attributable deaths	
	Male	Female	Total	Male	Female
Established carcinogens only (IARC Group 1 and 2A, strong human evidence)					
Bladder	1.3%	0.6%	1.0%	40	10
Leukaemia	0.3%	0.5%	0.2%	4	5
Lung	16.5%	4.5%	11.6%	3,137	599
Mesothelioma	85-90%	20-30%	74-80%	1,450	75
NMSC	11.8%	3.0%	8.4%	38	6
Sinonasa	34.1%	10.8%	23.4%	24	6
Established + Uncertain carcinogens (IARC Group 1 and 2A, strong and suggestive human evidence)					
Bladder	11.6%	2.0%	8.3%	362	32
Leukaemia	2.7%	0.8%	1.7%	58	11
Lung	21.6%	5.5%	15.0%	4,106	728
Mesothelioma	98%	90%	97%	1,650	270
NMSC	11.8%	3.0%	8.4%	38	6
Sinonasa	64.3%	18.4%	43.3%	45	11
Total				6,259	1,058
Total all cancers in the UK				78,237	71,666
AFs for six cancers combined (out of all GB cancers)				8.0%	1.5%
Source: Rushton et al (2007)					

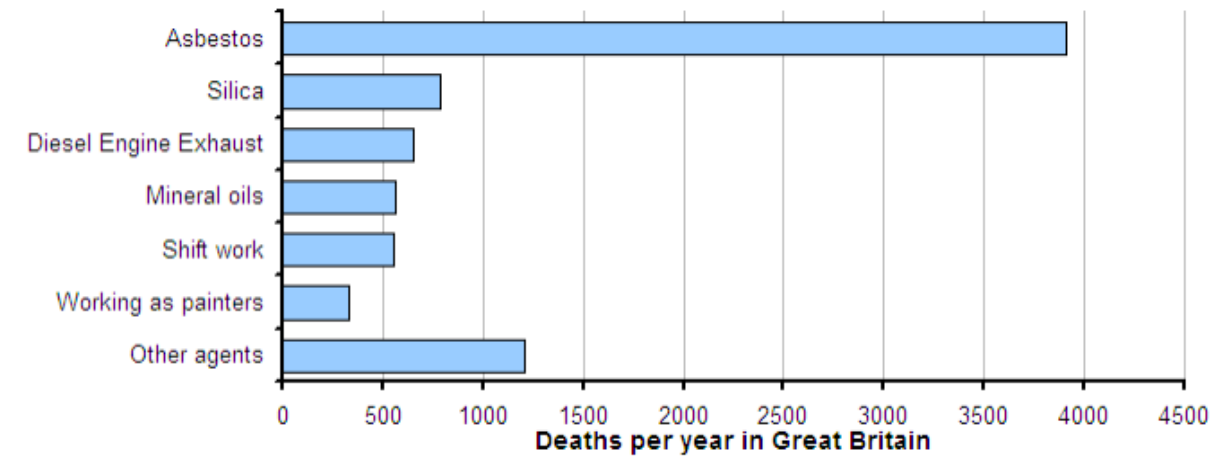


Figure A1-11: Estimated occupational cancer deaths by cause in Great Britain in 2005
Source: HSE (2014): Occupational cancer in Great Britain (available at: http://www.hse.gov.uk/Statistics/causdis/cancer/cancer.pdf)

Although, it is important to note that many non-work related factors can cause cancer and not all occupational cancers are related to chemicals' exposure (there are biological carcinogens such as viruses, physical carcinogens such as ultraviolet radiation, but also occupational circumstances that might increase the risk such, as shift (night) work), the methodology followed by the authors could be of value for the development of indicators aiming to establish and measure the link between substances and health effects, such as "**Number of occupational cancers due to chemicals' exposure**".

A1.41 UNEP (2013): Costs of inaction

Scope, objectives and methodology

Aim of the study was to provide a pragmatic and useful assessment on the economic impacts of chemicals upon human health and the environment. It also aimed to show how these information sources could be used to extrapolate costs to the national, regional and global levels.

The first part of the study provided a broad literature review of past studies that have attempted to measure and quantify the impact of chemicals upon the environment and human health. In total, the authors reviewed 281 documents for the study, of which 75 sources contained relevant monetised or quantified primary research data. The data covered 28 countries, including six OECD countries, representing approximately 65% of the world's total population. Through the literature review the authors identified significant gaps or weaknesses in the information and assessed the quality and usefulness of the data for policy makers.

The second part of the study demonstrated how to estimate health costs due to harmful chemicals when existing data is minimally adequate, fragmentary or difficult to compare. By gathering data on pesticide poisonings in certain sub-Saharan countries, the study showed how it is possible to extrapolate health costs to the entire sub-Saharan region. The basic methodology is summarised below.

To calculate baseline estimates for 2005, incident and cost data from Tanzania and Zambia, respectively, were used and then extrapolated to the other 35 countries in the study[203]. Data were also collected from supporting sources such as the World Bank and the CIA World Factbook. The variables included in the study and relationships between them are shown in Figure A1-12.

The study assessed the impacts of pesticide use over the period 2005-2020. Cumulative costs were calculated for two separate scenarios. The first scenario considered a constant usage of pesticides (2005 level) over the period in question. The second scenario looked at an increase in pesticide use over the years 2005-2008 (using a World Bank Pesticides import index) followed by a constant use thereafter[204]. These costs were then compared again the average per capita medical expenditure and net official development assistance in the region.

Data availability

As highlighted in the previous section the initial literature review consulted a number of sources. From the 75 sources of primary data listed in the references, the study found that 57 of the sources presented human health effects, including 15 that presented health effects of acute pesticide poisonings, 8 that showed data on children's health effects, and 14 quantified in DALYs. In comparison only 24 sources presented data on environment effects, including 10 related to ecosystem services and biodiversity, and 11 water related studies (e.g. fisheries and water drinking water).

Figure A1-12: Relationships between the variables included in the study
Source: from UNEP (2013)

In general, a number of issues were highlighted with regards to data availability. For instance, the review found that the literature is very fragmented with little data on chemical specific effects. Furthermore, the review showed that the available literature only covered a small spectrum of

[203] Industrial or service based economies were excluded from the study using data from the CIA World Factbook. Estimations were provided for 37 countries in total.

[204] All over key variables were kept constant in both scenarios.

issues, suffered from a lack of general comparability (in terms of methodology and coverage) and failed to take into consideration future risk scenarios.

Indicators suggested

The literature review looked at a number of indicators adopted in various studies. One of the key studies identified is a WHO study[205] described as "*the only attempt so far to quantify the health effects of chemicals generally and on a global scale*"[206]. The WHO study presented data from 2004 on the number of DALYs (disability adjusted life years) and deaths attributable to different chemicals including lead, occupational lung carcinogens, occupational leukaemogens, occupational particulates, outdoor air pollutants and asbestos. The authors suggested that the study could be used in future extrapolation studies.

For the sub-Saharan Africa extrapolation study, the authors used incidence data from a Tanzanian survey of smallholder agricultural pesticide users. These incidence data were then monetised using cost data from Zambia on daily wages, days of work lost, medical cost per incident and hospital cost per incident. These data were then extrapolated to all sub-Saharan African countries included in the study. The authors asserted that such extrapolations could be very useful in order to assess the impacts across sectors and different geographical regions.

Overall, the study highlighted the need for indicators that are specific to certain chemicals or chemical groups in order to accurately estimate costs to human health and environment. This is because past studies looking at environmental impacts have tended to assess general pollution sources (i.e. air and water), which does not allow for identification of component chemicals. In addition, the authors argue that assessing specific chemicals/groups of chemicals would allow for a more integrated assessment of both human and environmental effects.

Assumptions

For the calculation of the human health impacts of pesticide use in sub-Saharan Africa, the study adopted a number of key assumptions. As an extrapolation study, the key assumption was that the results from studies conducted in Tanzania and Zambia could be applied to a broader range of countries in the sub-Saharan Africa region. This meant that percentages from the studies were applied to all countries for a number of variables. For example, the reference survey conducted in Tanzania found that 1.2% of smallholder agricultural users of pesticides experienced serious incidents that required hospital treatment. This percentage was then extrapolated to all countries in the study.

Perhaps the strongest assumptions are those on the expected increases in pesticide use over the period 2005-2020. The extrapolation considers two different scenarios: one where pesticide use is constant over the years 2005-2020 and a second where pesticide use increases over the years 2005-2008 and thereafter remains constant. It is also assumed that there is a direct link between increasing pesticide use volumes and human health costs. The authors state that these assumptions may be weak as pesticide use volumes may increase or, alternatively, the incidence of pesticide poisonings and costs may be offset by improved future chemical management strategies.

[205] Prüss-Ustün A, Vickers C, Haefliger P, and Bertollini R. (2011). "Knowns and unknowns on burden of disease due to chemicals: a systematic review". Environmental Health, 2011, 10:9. Available at: http://www.ehjournal.net/content/10/1/9

[206] UNEP (2013), page 25

Results

The literature review presented estimations on the extent of human health and environmental costs due to harmful chemicals. The authors handpicked two key studies that underlined the magnitude of these costs at the global level. For human health costs, the authors chose the WHO Study, which found that a subset of chemicals accounted for 964,000 deaths (1.6% of total deaths) and 20,986,153 DALYs (1.4% of total DALYs) globally in 2004. However, the study did not attempt to monetise these impacts.

For environmental costs, the authors emphasised that UNEP FI and PRI (2010)[207] study gave an initial view of global costs of environmental effects due to chemicals. In this study, it was found that VOCs (volatile organic compounds) and mercury emissions account for USD 236.3 billion and USD 22 billion, respectively, of environmental costs due to human activity.

The extrapolation exercise found that the baseline costs associated with pesticide poisonings in sub-Saharan Africa were around USD 4.4 billion in 2005. Using this figure the authors calculated the cumulative costs over two future risk scenarios. The first scenario, which assumed the use of pesticides remains constant, found that the cumulative costs would be approximately USD 66 billion over the period 2005-2020. The second scenario, which assumed an increase in pesticide use during the years 2005-2008 and constant use thereafter, calculated that the cumulative costs would rise to USD 97 billion over the same period.

A1.42 UNEP (2013b): Global Chemicals Outlook – Towards Sound Management of Chemicals

UNEP (2013b) provides a detailed analysis of the global chemicals industry and reviews the available literature to assess its human and environmental impacts. The report is organised into three chapters. The first analyses the trends within the global chemicals market and its sub-sectors. It also looks at trends associated with the human and environmental impacts of chemicals with an extensive focus on the developing world. The second chapter assesses the economic implications of the trends in production, trade and use of synthetic and toxic chemicals. More specifically, the paper looks at the potential costs associated with chemicals mismanagement; these include the financial implications for industry (e.g. costs of environmental accidents) and the broader impacts on human health and the environment in monetary terms. The final chapter analyses the various instruments and approaches to promote the sound management of chemicals with examples from government, civil society and business.

Chapter I has the most relevance to this study as it presents a range of indicators on the chemicals industry and its impacts on human health and the environment. The initial sections provide global level data on the production, trade and use of bulk chemicals, metals, fibres and agriculture chemicals. The environmental impacts section (sub-section 10) covers a range of resources including air, water, soil and wildlife. However, no useful indicators are provided within the framework of this study. The human health impacts section provides more insight with indicators taken from various studies these include, but are not limited to, pesticide poisonings in developing and transitioning countries; human milk bio-monitoring data for dioxins/furans and PCBs; data from the Prüss-Ustün et al (2011) study on the global burden of disease due to chemicals (see previous section);

[207] UNEP FI and PRI (2010): UNEP Finance Initiative and the Principles for Responsible Investment (PRI): Universal Ownership. Why environmental externalities matter to institutional investors. Available at: http://www.unepfi.org/fileadmin/documents/universal_ownership.pdf

cardiopulmonary health effects associated with chemicals and studies of cancer associated with chemical exposure in developing/transition countries.

Overall, the indicators provided in the paper have limited applicability to the European context. This is because the data is typically presented at either the global level or for developing/transition countries. Furthermore, the studies on human milk bio-monitoring and the global burden of disease are based on data from years 1998 and 2004 respectively and thus has little relevance to this current period.

A1.43 EEA (2013): Late lessons from early warnings: science, precaution, innovation

This study has been produced by the European Environment Agency as follow up to the first report published in 2001, looking at a selection of occupational, public health and environmental problems occurred in the past years and trying to determine whether the authorities could have done better, reading the early signs of hazard and acting early enough to prevent the problems.

The first part of the report focus on the human health effects of some of the most studied and well documented cases of non-action by authorities in the presence of early signs of problems. The second chapter "The precautionary principle and false alarms – lesson learned" deals with the regulatory actions that were taken based on the precautionary principle and turned out to be unnecessary. After an analysis of 88 false positives identified, the authors concluded that most of these are not genuine cases but rather due to a deliberate strategy in risk communication, further concluding that fear of false positives is not a rationale for avoiding precautionary actions. The third chapter presents the evidence on the several errors committed by the authorities in, first, allowing the use of lead in petrol, when its neurotoxic effects were widely recognised and scientists warned of the likely health impacts as early as 1925 and, second, in failing to address the problem in the following decades. The fourth chapter discusses the use of perchloroethylene (PCE), a substance with known toxic effects that lately have been suspected to be a carcinogen and teratogen even at low levels, in producing plastic linings for drinking water distribution pipes. The fifth chapter presents the battle for justice of the population living in Minamata bay that were exposed to high levels of methylmercury emitted by the largest Japanese chemicals manufacturer Chisso. The sixth chapter discusses how industry shaped the scientific literature for their advantage, denying that exposure to beryllium below the regulatory standard was the cause of the chronic beryllium disease diagnosed on workers employed in nuclear weapons production. The seventh chapter focuses on the strategies followed by the tobacco industry to dismiss the growing evidence that environmental tobacco smoke causes lung cancer and other effects in non-smokers. The eighth chapter presents the case of the human health effects of vinyl chloride and how the first evidence on these impacts was initially hidden from workers and regulators, focusing the discussion on corporations' and trade associations' behaviour. The ninth chapter deals with the pesticide dibromochloropropane and its effect on male infertility, the first well documented case of reproductive damage to workers who manufactured and used a synthetic chemical. The tenth chapter focuses on the different approaches to risk assessment of bisphenol A by different authorities, resulting in different evaluations and regulatory actions and making a strong argument about the precautionary principle. The eleventh chapter presents the case of DDT and its effects on human health and the environment, focusing on the difficult balancing of costs and benefits and on the sharing of information to make the right decisions.

The twelfth chapter is the first of the second part of the report, looking into the emerging lessons from ecosystems, focusing on biocide antifoulants. These have been promoted as effective alternatives to tributyltin (TBT), banned in 1989 due to its effects on the aquatic life. However, some

biocide antifoulants have been discovered to be PBTs and to have wider ecological effects that are far less studied than effects of TBT, raising concern on their impact on marine food chains. The thirteenth chapter discusses again the problems in balancing costs and benefits of using effective chemicals but with proven toxic and ecotoxic effects, this time presenting the case of ethinyl oestradiol (EE2; active ingredient in the birth control pill) and its impact on the aquatic environment. The fourteenth chapter summarises "*the history of growing knowledge about human-induced climate change and of the main actions, or inactions that accompanied it*" and the fifteenth chapter presents the challenges faced by scientists and policy regulators in flood management. The sixteenth chapter analyses the ways in which scientific evidence is used by stakeholders and decision-makers to influence policy during the controversy over the use of neonicotinoid insecticides and their effects on honeybees. The seventeenth chapter discusses the reasons why institutions fail to understand and act on environmental problems, arguing about the current inadequacy of policy-making, unfit to deal with the complexity of ecosystems and focused on short-term effects and decisions.

The third part of the study looks into the emerging issues, discussing about nuclear energy (chapter 18), genetically modified crops and agroecological methods (chapter 19), the threat posed by invasive alien species (chapter 20), the discussion around mobile phone use and brain tumour risk (chapter 21) and the case of nanotechnology (chapter 22).

The fourth part of the report looks into costs, justice and innovation. Of particular interest for the current study is chapter 23, discussing about the methodological challenges involved in producing credible and appropriate estimates of the costs of inaction. Some case studies are presented: nitrates in drinking water, ozone-depleting substances and emission level for air pollutants.

In conclusion, the report focuses on the dynamics between science, risk communication, risk management and policy-making. In making their arguments, the different authors used case studies in which several measures have been used as indicators of costs (that can be translated into indicators of benefits) of late action. Many case studies focuses on the effects of chemical substances on human health and environment, substantiating the evidence with indicators that have been suggested in the other reports reviewed, e.g. BPA or lead concentration in human tissues, emissions of mercury or lead, concentration of pesticides in pollen or nectar.

A1.44 Trasande et al (2014): Estimating Burden and Disease Costs of Exposure to Endocrine-Disrupting Chemicals in the European Union

Overview of Methodology

Trasande et al (2014) reports on estimated disease burden and costs of EDCs in relation to obesity & diabetes, reproductive disorders and neurobehavioural deficits. The following papers:

- Legler et al (2014): Obesity, Diabetes and Associated Costs of Exposure to Endocrine Disrupting Chemicals in the European Union;
- Hauser et al (2015): Male Reproductive Disorders, Diseases, and Costs of Exposure to Endocrine-Disrupting Chemicals in the European Union;
- Bellanger et al (2014): Neurobehavioral Deficits, Diseases and Associated Costs of Exposure to Endocrine Disrupting Chemicals in the European Union.

Being all part of the same overall study, apply the same approach, each providing detail in relation to each of the diseases/disorders/deficits.

The same general methodological approach was applied in all studies. In summary, a Delphi expert elicitation was used to hone estimates of the probability that different EDCs contribute to the different outcomes considering the toxicological and epidemiological evidence and the nature of the association between exposures and outcomes. The disease/disorder/deficit burden attributable to the different EDCs was estimated for different percentiles of affected population and rates of exposure giving priority to dose-response relationships from the epidemiological literature but also considering trends that would be difficult to attribute to genetics accompanied by information on likely causal mechanisms or data from genetic studies that permit quantification of the remaining environmental contribution and portion attributable to EDCs.

The analysis allows prediction of the numbers of cases attributable to the named EDC to which was applied a human capital approach to calculate the direct and indirect costs of illness applying a Monte Carlo simulation approach to produce ranges of probable costs across all of the exposure-outcome relationships considering uncertainties/probabilities for causation/not causation, cost given causation, and sensitivities from the expert panel.

Comments on presence or relevance in terms of indicators

The studies consider the burden attributable to the (relatively small number of) EDCs for which there sufficient toxicological/epidemiological information on which to judge. In theory (at least) it might be possible to apply some of the values to new monitoring data on exposure/concentration in body tissues. However, just as these will change with time so will the information used to generate the Delphi estimates suggesting that the whole exercise would have to be repeated. One might expect that new information would also include new information on substances newly (or recently) identified as potential EDCs to which fractions might also be attributable. Over time, then, estimates of the direct and indirect costs attributable to EDCs might increase simply because there is more information available on a greater number of substances to which cases could also be attributed.

In short, there is no information suitable for use as an indicator. There are values applied to different disorder that may be of use but only for some there is a description as to how these individual values were derived. The table below sets out values applied to specified cases. These have been calculated from the totals combined with the number of cases calculated.

Table A1-25: Values from Trasande et al (2014)	
Legler et al (2014): Obesity, Diabetes and Associated Costs of Exposure to Endocrine Disrupting Chemicals in the European Union	
Childhood obesity- DDE	€15,800 per case
Adult diabetes – DDE	€29,600 per case
Direct cost adult obesity - Phthalates	€21,500 per case*
Indirect cost adult obesity - Phthalates	€268,000 per case*
Adult diabetes - Phthalates	€29,600 per case
Direct costs of childhood obesity (?*) - BPA	€48,700 per case
Indirect costs of childhood obesity (?*) – BPA	€17,800 per case
Hauser et al (2015): Male Reproductive Disorders, Diseases, and Costs of Exposure to Endocrine-Disrupting Chemicals in the European Union	
Cryptorchidism - PBDE	€28,170 per case
Cost of ART attributable to phthalate exposure	€7,600 per case
Testicular Cancer –PBDE	€125,000 per case
Decreases in serum T – Phthalate	€320,700 per case
Bellanger et al (2014): Neurobehavioral Deficits, Diseases and Associated Costs of Exposure to Endocrine Disrupting Chemicals in the European Union	
Lost productivity per IQ point lost	€9,600 Per IQ point lost
Social costs of intellectual disability – PBDE	€361,000 per case

Table A1-25: Values from Trasande et al (2014)	
Autism – EDCs	€632,330 per case
ADHD - EDCs	€62,300 – €91,660 per case
** Explanation of monetary values applied is not clear for any of the above and, for those marked with a "*" it is not clear why there is variation between the estimates used.*	

A1.45 HEAL (2014): Health costs in the European Union – How much is related to EDCs?

The report was commissioned by the Health and Environmental Alliance in order to estimate the costs of the health impacts from exposure to endocrine disrupting chemicals (EDCs). The authors focused on the following conditions:

- Reproductive and fertility problems;
- Abnormalities of the penis and testicles in baby boys;
- Cancer of the breast, prostate, testes;
- Children's behavioural disorders, such as autism and attention deficit hyperactivity disorder (ADHD);
- Obesity and diabetes.

They then associated treatment costs available for the above conditions and multiplied these for the number of cases attributable to exposure to EDCs in the European Union, using an Attributable Fraction of 2-5%.

Total costs are extrapolated to the European level multiplying the treatment costs for a member states by a scaling factor defined on population size. As highlighted by the authors, this methodology oversimplifies the reality, not taking into account differences in treatment costs and in incidence rates between countries.

A1.46 Oltmanns et al (2014): The impact of REACH on classification for human health hazards

The authors compared information from REACH registration dossiers with harmonised classifications of 142 substances produced at very high tonnages and for which assessments were already carried out in the past. They found that 12 substances lacking a harmonised classification were classified in the registration dossiers submitted by the manufacturers/importers. Thirty-seven substances had stricter classifications and twenty-nine of these were classified for an additional end-point.

These findings led the authors to conclude that REACH is improving the hazard characterisation even for those substances supposed to have a good data basis.

Although the study does not point to any indicator in particular, it does reinforce the validity of some of the proxies that might be used as indicators of human health and environmental benefits, such as "number of companies that had to improve risk management measures as result of REACH" or "expenditure in risk management measures".

A1.47 ECHA (2014): Willingness to pay to avoid certain health impacts

The authors conducted a stated-preference study "*to estimate the willingness to pay to avoid selected adverse human health outcomes due to exposure to chemicals in the European Union and to derive representative EU-wide benefit estimates reference values*" to be used by ECHA and other bodies when performing and evaluating socio-economic analyses in the context of REACH, in particular of authorisation applications and restriction proposals.

The health end-points and outcomes considered were:

- Skin sensitisation (mild acute dermatitis, severe chronic dermatitis);
- Acute kidney injury and chronic kidney disease;
- Respiratory sensitisation (asthma and acute respiratory sensitisation);
- Infertility and fertility problems;
- Developmental toxicity (minor birth defects, birth defects of internal organs, metabolic and genetic disorders, birth defects of external body parts, very low birth weight);
- Cancer.

Table A1-26 presents the recommended values.

Table A-1-26: Estimates of EU-wide WTP for different health outcomes - Recommended values

Health outcome	Recommended value
Acute mild dermatitis	€222-€227
Episodes of acute mild dermatitis (4 over 1 year)	€295-€329
Episodes of acute mild dermatitis (1/yr over 5 years)	€292-€352
Episodes of acute mild dermatitis (4/yr over 10 years)	€473-€615
Chronic dermatitis	€908-€1,055
Acute kidney injury	€473-€532
Chronic kidney disease	€2,375-€2,761
Asthma episode	€50
Respiratory sensitisation	€17.5
Value of statistical pregnancy	€21,600-€34,700
Value of statistical case of healthy child: minor birth defects	€4,300-€12,100
Value of statistical case of healthy child: defects in internal organs	€128,200-€178,000
Value of statistical case of healthy child: defects on external body parts	€25,700-€108,300
Value of statistical case of very low birth weight	€126,200
Value of statistical infertility (in vitro fertilisation treatment)	€29,400
Value of a statistical case of a cancer (VSCC)	396,000
Value of a Statistical Life for cancer	5,000,000

A1.48 Plas et al (2015): REACH – Evaluation of the impact on the affected industries and the whole economy in Austria

In terms of the benefits delivered by the Regulation on human health and the environment, the authors apply conservative values of the burden of disease due to chemicals' exposure and of the reduction owing to REACH estimated in other previous studies on Austrian data.

In particular, the following burdens were attributed to chemicals' exposure:

- 25% of the occupational skin and respiratory diseases;
- 4% of all cancers;
- 0.5% of the multiple chemical sensitivity cases;
- 3% of all sick leave cases of poisoning and burns at home.

A 5% reduction was applied and labelled as the "REACH effect".

Monetary values in terms of treatment costs, sick leaves and hospital stay were then applied together with the value of statistical life for cancer estimated in the ExternE project and summed to the remediation costs of contaminated sites and to water cleaning costs. The resulting total value was finally compared to the costs, resulting in a present value of net benefits of about €2.5 billion.

Annex 2 Databases and Information Sources

A2.1 Introduction

Table A2-1 lists the databases and information sources that have been screened for the purpose of the study.

Table A2-1: Available databases and information sources

Source and Access	Description
Climate and Pollution Agency http://www.klif.no	Monitoring surveys on environmental pollutants such as PCB, heavy metals, PBDE, siloxanes, PFC, chlorinated paraffins, nitrogen and carbon
COPHES http://www.eu-hbm.info/cophes/human-biomonitoring	Consortium to perform human bio-monitoring on a European scale. National surveys. Biomarkers for chemicals of concern were measured in the hair and urine of almost 4000 mothers and children in 17 European countries.
Danish EPA database on substances in consumer products http://www.mst.dk	Web-portal with overview and access to product mapping studies carried out for the Danish EPA.
Database on air quality http://envs.au.dk/en/knowledge/air/monitoring/programmes/	National monitoring of air quality in Denmark
ECHA CLI http://echa.europa.eu/information-on-chemicals/cl-inventory-database	Classification and Labelling Inventory: It also includes the list of harmonised classifications. The database is refreshed regularly with new and updated notifications. Unfortunately, updated notifications are not be specifically flagged.
ECHA registered substances database http://echa.europa.eu/information-on-chemicals	ECHA database on registered substances: It provides updated information on substance ID, tonnages, exposure scenarios (system of descriptors) and PBT assessment outcomes. The registration dossiers are publicly available.
EEA AirBase http://www.eea.europa.eu/data-and-maps/data/airbase-the-european-air-quality-database-8	**AirBase** is the European air quality database maintained by the EEA through its European topic centre on Air pollution and Climate Change mitigation
EEA Hazardous substances in marine organisms and loads to coastal waters http://www.eea.europa.eu/data-and-maps/indicators/hazardous-substances-in-marine-organisms-1	Data on concentrations of some hazardous substances in marine organisms.
EEA Persistent Organic Pollutants Emissions http://www.eea.europa.eu/data-and-maps/indicators/eea32-persistent-organic-pollutant-pop-emissions-1/assessment-3#data_specifications	The EEA POPs emissions database addresses the following policy issue: What progress is being made in reducing emissions of persistent organic pollutants?
EEA river classification scheme http://www.eea.europa.eu/data-and-maps/indicators/national-river-classification-schemes	The **EEA river classification scheme** addresses whether good surface water ecological status is being achieved

Table A2-1: Available databases and information sources	
Source and Access	**Description**
EEA Waterbase http://www.eea.europa.eu/data-and-maps/data/waterbase-lakes-10	**Waterbase** is the EEA's databases on the status and quality of Europe's rivers, lakes, groundwater bodies and transitional, coastal and marine waters
Environmental Specimen Bank (ESB) http://www.umweltprobenbank.de/en/documents/investigations/analytes	Describe time trends of human and environmental exposure. Annual measurement of heavy metal contents and organics in hair, blood, blood plasma, and urine as well as heavy metal contents and organics in the environment
European Pollutant Release and Transfer Register (E-PRTR) http://www.eea.europa.eu/data-and-maps/data/member-states-reporting-art-7-under-the-european-pollutant-release-and-transfer-register-e-prtr-regulation-9	The E-PRTR was established by Regulation (EC) No 166/2006 and provides data on emissions and transport of pollutants for 2007 to 2011.
Eurostat database on chemicals production: Eurostat>Data>Database>Tables by themes>Environment and energy>Environment> Production of environmentally harmful chemicals, by environmental impact class (ten00011) Eurostat>Data>Database>Tables by themes>Environment and energy>Environment> Production of toxic chemicals, by toxicity class (tsdph320) Eurostat>Data>Database>Tables on EU policy>Sustainable development indicators>Public health>Determinants of health> Production of toxic chemicals, by toxicity class (tsdph320) **Dedicated section 'Environment' at the Eurostat website:** Eurostat >Environment>Hazardous substances: http://ec.europa.eu/eurostat/web/environment/hazardous-substances **Statistics Explained articles:** http://ec.europa.eu/eurostat/statistics-explained/index.php/Chemicals_production_statistics http://ec.europa.eu/eurostat/statistics-explained/index.php/Chemicals_-_monitoring_REACH_with_indicators	Official statistics (Data) on the total production of industrial chemicals, of environmentally harmful chemicals, and of substances that harm human health (toxic chemicals). Production volumes are weighted according to the toxicity of the chemicals (both for human health and environmental endpoints).
Foregs http://weppi.gtk.fi/publ/foregsatlas/ForegsData.php	FOREGS-EuroGeoSurveys Geochemical Baseline Database
ICES data portal http://ecosystemdata.ices.dk/inventory/index.aspx?Param=0&Area=Parameter	Includes monitoring data for several year and for a large number of chemicals (e.g. dioxins, chlorinated hydrocarbons, PAHs, pesticides, heavy metals)

Table A2-1: Available databases and information sources	
Source and Access	**Description**
IPCheM for monitoring data (Information Platform for Chemical Monitoring) http://ipchem.jrc.ec.europa.eu/	Access point to chemical monitoring data in Europe
KemI Commodity Guide http://webapps.kemi.se/varuguiden/Default.aspx	The Commodity Guide provides an overview of commodities and material used in Sweden. Searches can also be made for single materials and substances
KemI Pesticide register http://www.kemi.se/en/Content/Databases/	Information on more than 2,000 approved (and previously approved) pesticide preparations in Sweden
KemI Statistics for chemicals http://apps.kemi.se/flodessok/floden/flodessok.cfm?lang=eng	This portal provides flow analyses for a list of chemicals, with data on quantities manufactured, imported and exported in Sweden
KemI-stat http://apps.kemi.se/kemistat/start.aspx?sprak=e	KemI-stat is a tool for compiling statistical information from 1992 on from the Swedish Chemicals Agency´s (KemI) products register and pesticides register
Nordic Council of Ministers H-Class Database http://apps.kemi.se/hclass/	H-Class primarily concerns classification and labelling of health effects
OECD Statistics http://www.oecd.org/statistics/	The OECD data portal provides a list of key indicators: e.g. environmental pollution, cause of death, etc.
OSH Monitoring Systems https://osha.europa.eu/en/topics/osm/reports/country.stm	The OSH Monitoring System database is a meta database providing links to European monitoring systems (country-wise) can be found.
RAINS http://www.iiasa.ac.at/web/home/about/achievements/scientificachievementsandpolicyimpact/cleaningeuropeair/The-RAINS-Model.en.html	The **RAINS model** organizes key information on science, policy options, and costs
SPIN http://195.215.202.234/fmi/xsl/spin/SPIN/maininfo.xsl?-db=SPINstof&-lay=SPINnavn&-max=1&-findall	**SPIN** contains current and historical data on Nordic (Norway, Sweden, Finland, Denmark) consumption of classified substances for several years.
TEEB Ecosystem Service Valuation Database http://www.fsd.nl/esp/80763/5/0/50	Database on monetary values of ecosystem services which now contains over 1350 data-points from over 300 case studies
The Danish Natural Environment Portal http://www.miljoeportal.dk/English/Sider/default.aspx	Environmental data for Denmark. Need access code Data on nature, soil pollution and water quality (surface water, groundwater).
The European Health Examination Survey (EHES) http://www.ehes.info/	A collaboration to collect nationally representative, high quality health data which are comparable between countries and over time.
The German Environmental Survey (GerES) http://www.umweltbundesamt.de/en/topics/health/assessing-environmentally-related-health-risks/german-environmental-survey-geres	The German Environmental Survey (GerES) is a nationwide population representative study on HBM and external human exposure.
TNO-report R 2004/493 Man-made chemicals in human blood http://www.greenpeace.org/eu-unit/Global/eu-unit/reports-briefings/2009/3/man-made-chemicals-in-human-bl.pdf	Dutch study for Greenpeace on man-made chemicals in human blood (2004)
UK HSE Hands-On Statistics Data Tool http://www.hse.gov.uk/statistics/hands-on/index.htm	HandS-On is a free-to-use service that allows visitors to view, manipulate, create and export tables from UK Health and Safety Executive's injury and ill health data.

Table A2-1: Available databases and information sources	
Source and Access	**Description**
UNEP - United Nations Environment Programme Division of Technology, Industry and Economics Chemicals Branch http://www.chem.unep.ch/	UNEP webpage gives information on the implementation of SAICM, on Mercury, metal programme, persistent organic pollutants, pesticide activities and on mainstreaming of chemicals
WHO European Environment and Health Task Force (EHTF) http://www.euro.who.int/en/data-and-evidence/environment-and-health-information-system-enhis/activities/human-biomonitoring-survey	Human bio-monitoring survey. Indicators to measure prenatal exposures to selected priority chemicals and tobacco smoke and children's exposure to priority environmental risks at schools. ENHIS Database
WHO International Programme on Chemical Safety http://www.who.int/ipcs/assessment/en/	Relevant databases on environmental health criteria, pesticides and endocrine disruptors.
WHO Regional Office for Europe – Databases http://www.euro.who.int/en/data-and-evidence/databases	This is the portal to health statistics for Europe. Among the relevant for the purpose of this study: • European Health for All database (HFA-DB) • Mortality indicator database: mortality iindicators by 67 causes of death, age and sex (HFA-MDB) • European detailed mortality database (DMDB) • European hospital morbidity database (HMDB)

The following subsections present the description of the most relevant databases, highlighting the availability and the usefulness of the data for the purpose of the assessment of the chemicals legislation benefits via the system of indicators and providing some examples on the types of data available.

A2.2 The Norwegian Climate and Pollution Agency

A2.2.1 Introduction

The Norwegian Climate and Pollution Agency (www.klif.no) provides monitoring surveys on environmental pollutants such as PCB, heavy metals, PBDE, siloxanes, PFC, chlorinated paraffines, stable isotopes of nitrogen and carbon.

The Norwegian Agency has developed a web-portal with information and statistics on the state of the environment in Norway (available at: www.environment.no). The content is organised by topics, of which of relevance for this study is "Hazardous chemicals". Since 1997, Norway has developed a list of priority substances (including about 30 substances or groups of substances) for which releases have to be completely eliminated or substantially reduced.

The portal is also very informative with regard to the sources of chemical pollution, the impacts observed and the confounding factors in the changes of the impacts.

A2.2.2 Potential Indicators

Below, a list of potential indicators that could be developed with the data available from this source:

- Change in emissions[208];
- Changes in levels of selected chemicals in water and sediment samples[209];
- Changes in levels of selected chemicals in soil samples[210];
- Changes in levels of selected chemicals in aquatic species;
- Number of sites with severe contaminated sites.

With regard to the "Change in emissions" indicator, the portal reports the different national and international legislative initiatives that might have contributed to the changes in emissions' trends.

With regard to the levels of selected chemicals in different sub-targets (fresh water, coastal water, sediment, soil etc.), the portal content is organised in four different sections:

1. State;
2. Impact;
3. Pressure/driving forces;
4. Response.

A2.2.3 Substances and Available Data

The portal contains various links to statistics and reports on the state of the environment (**target**) in Norway. Data are available for different **sub-targets** (such as fresh water, coastal water, soil, sediment, fresh water fish and shellfish) and are presented as concentration or emission levels (**type of samples**). With regard to soil pollution, the number of severely contaminated sites is available. Most of the data are georeferenced at local and regional level (**spatial level**) and, for most of the substances, information is available for the period 1995-2010 (**temporal level**).

Table A2-2 presents the list of substances/groups of substances that have been prioritised in Norway and the changes in emissions since 1995.

Table A2-2: Change in emissions

Substance	Emissions 1995 (t)	Emissions 2010 (t)	Reduction
Arsenic	36	31	15%
Bisphenol A	Not known	1.7	-
Brominated flame retardants	79 (consumption)	299 (consumption)	-
DEHP	285	~123	60%
Certain surfactants (DTDMAC, DSDMAC, DHTDMAC)	8	0.8	90%
1,2-Dichloroethane (EDC)	33	14	58%
Dioxins and furans (amounts in I-TEQ/g)	73 (grams)	26 (grams)	64%
Cadmium	5	1.5	72%
Chlorinated alkyl benzenes (CABs)	0.08	0.002	98%
Chromium	100	47	53%
Hexachlorobenzene	0.09	0.009	91%
Lead	600	119	80%
Medium-chain chlorinated paraffins	27	17	39%
Mercury	2.5	0.9	63%

[208] http://www.environment.no/Topics/Hazardous-chemicals/Hazardous-chemical-lists/List-of-Priority-Substances/

[209] http://www.environment.no/Topics/Freshwater/
http://www.environment.no/Topics/Marine-areas/Hazardous-chemicals-in-coastal-waters/

[210] http://www.environment.no/Topics/Air-pollution/Deposition-of-heavy-metals/

Table A2-2: Change in emissions			
Musk xylenes	0.6	0.1	83%
Nonyl/octylphenol and its ethoxylates	25	4.7	81%
PAHs	268	104	61%
Pentachlorophenol (PCP)	10	0.002	>99%
Polychlorinated byphenyls (PCBs)	487	125	74%
PFOA	Not known	~0.021	-
PFOS	22	0.002	>99%
Short-chain chlorinated paraffins	1	0.3	73%
Siloxanes (D4 and D5)	Not known	8.5	-
TCEP (tris(2-chloroethyl) phosphate)	Not known	Not known	-
Tetrachloroethane (PER)	367	13	96%
Trybutyl tin compounds	29	0	100%
Trichlorobenzene	~0.021	0.07	-
Trichloroethene (TRI)	620	26	96%
Triclosan	Not known	1.5	-
2, 4, 6 Tri-ter-buthylphenol	Not known	Not known	-
Source: http://www.miljodirektoratet.no/Documents/publikasjoner/M210/m210.pdf			

A2.3 The European Pollutant Release and Transfer Register (E-PRTR)

A2.3.1 Introduction

The European Pollutant Release and Transfer Register (E-PRTR - http://prtr.ec.europa.eu/Home.aspx) is the Europe-wide register that provides key environmental data (pollutant releases and waste transfers) from industrial facilities in European Union (EU) Members States and in Iceland, Liechtenstein, Norway, Serbia and Switzerland. The E-PRTR replaced and improved upon the previous European Pollutant Emission Register (EPER).

The E-PRTR was established by Regulation (EC) No 166/2006 which implements the United Nations Economic Commission for Europe (UNECE) PRTR Protocol and contains data reported annually by more than 30,000 industrial facilities covering 65 economic activities across Europe. Each facility reports information regarding the amounts of pollutant releases to air, water and land as well as off-site transfers of waste and pollutants in waste water from a list of 91 key pollutants, including heavy metals, pesticides, greenhouse gases and dioxins (see Table 3-1 below). Data are available from the year 2007 onwards with some information on releases from diffuse sources also available, which will be gradually enhanced. The database allows information to be searched at the facility level, by country/region, industrial activity, pollutant and environmental medium. Comparisons of pollutant emissions/waste transfers can also be made between reporting years.

A2.3.2 Potential Indicators

The following provides a list of potential indicators that could be developed using the data contained within the E-PRTR database to assist in informing the benefits that can be attributed to chemicals legislation:

- Change in pollutant emissions over time by industrial activity/economic sector;
- Change in pollutant emissions over time by country/region;

- Change in pollutant emissions over time by environmental medium (i.e. air, water and soil); and
- Change in pollutant emissions over time at the facility level (where reporting occurs over multiple years).

A2.3.3 Substances included in the Database

The substances included in the E-PRTR database are grouped into seven categories. These along with the substances themselves are summarised in Table A2-3. The database contains information on the annual emissions (in kg and tonnes) of these substances to air, water and soil between 2007 and 2012 (currently) and the number of facilities emitting these pollutants. It is also possible to group emissions by industrial activity, namely:

- Energy sector;
- Production and processing of metals;
- Mineral industry;
- Chemical industry;
- Waste and waste water management;
- Paper and wood production processing;
- Animal and vegetable products from the food and beverage sector; and
- Other activities.

Table A2-3: Substances included in the E-PRTR database

Pollutant group	Pollutant
Chlorinated organic substances	Brominated diphenylethers (PBDE)
	Chloro-alkanes C10-C13
	1,2-dichloroethane (EDC)
	Dichloromethane (DCM)
	Dieldrin
	Halogenated organic compounds (as AOX)
	Hexabromobiphenyl
	Hexachlorobenzene (HCB)
	Hexachlorobutadiene (HCBD)
	PCDD + PCDF (dioxins + furans) (as Teq)
	Pentachlorobenzene
	Pentachlorophenol (PCP)
	Polychlorinated biphenyls (PCBs)
	Tetrachloroethylene (PER)
	Tetrachloromethane (TCM)
	Trichlorobenzenes (TCBs)
	1,1,1-trichloroethane
	1,1,2,2-tetrachloroethane
	Trichloroethylene
	Trichloromethane
	Vinyl chloride
Greenhouse gases	Carbon dioxide (CO_2)
	Hydro-fluorocarbons (HFCs)
	Methane (CH_4)
	Nitrous oxide (N_2O)
	Perfluorocarbons (PFCs)
	Sulphur hexafluoride (SF_6)
Heavy metals	Arsenic and compounds (as As)
	Cadmium and compounds (as Cd)

Table A2-3: Substances included in the E-PRTR database	
Pollutant group	**Pollutant**
	Chromium and compounds(as Cr)
	Copper and compounds (as Cu)
	Lead and compounds (as Pb)
	Mercury and compounds (as Hg)
	Nickel and compounds (as Ni)
	Zinc and compounds (as Zn)
Inorganic substances	Asbestos
	Chlorides (as total Cl)
	Cyanides (as total CN)
	Fluorides (as total F)
	Particulate matter (PM10)
	Total nitrogen
	Total phosphorus
Other gases	Ammonia (NH_3)
	Carbon monoxide (CO)
	Chlorine and inorganic compounds (as HCl)
	Chlorofluorocarbons (CFCs)
	Fluorine and inorganic compounds (as HF)
	Halons
	Hydrochlorofluorocarbons (HCFCs)
	Hydrogen cyanide (HCN)
	Nitrogen dioxides (NO_X/NO_2)
	Non-methane volatile organic compounds (NMVOC)
	Sulphur oxides (SO_x/SO_2)
Other organic substances	Anthracene
	Benzene
	Benzo(g,h,i)perylene
	Di-(2-ethyl hexyl) phthalate (DEHP)
	Ethyl benzene
	Ethylene oxide
	Fluoranthene
	Naphthalene
	Nonylphenol and Nonylphenol ethoxylates (NP/NPEs)
	Octylphenols and Octylphenol ethoxylates
	Organotin compounds (as total Sn)
	Phenols (as total C)
	Polycyclic aromatic hydrocarbons (PAHs)
	Toluene
	Total organic carbon (TOC) (as total C or COD/3)
	Xylenes
Pesticides	Alachlor
	Aldrin
	Atrazine
	Chlordane
	Chlordecone
	Chlorfenvinphos
	Chlorpyrifos
	DDT
	Diuron
	Endosulphan
	Endrin
	Heptachlor

Table A2-3: Substances included in the E-PRTR database	
Pollutant group	**Pollutant**
	1,2,3,4,5,6-hexachlorocyclohexane (HCH)
	Isodrin
	Lindane
	Mirex
	Simazine
	Toxaphene
	Isoproturon
	Tributyltin and compounds
	Triphenyltin and compounds
	Trifluralin
Source: http://prtr.ec.europa.eu/pgLibraryPollutants.aspx	

A2.3.4 Data Trends

As indicated in the previous sections, the E-PRTR database contains a significant quantity of information regarding releases of pollutants to air, water and soil. As an example of the type of data that is included, information relating to emissions of zinc (and its compounds), chromium (and its compounds) and nonylphenol (including nonylphenol ethoxylates) has been extracted to provide an indication of the information available.

Zinc Emissions

Table A2-4 and Figure A2-1 provide details of the total emissions of zinc to air, water and soil from all reporting states between 2007 and 2012.

Table A2-4: Zinc emissions from all E-PRTR reporting states				
Year	**Number of facilities**	**Emissions (tonnes)**		
		Air	**Water**	**Soil**
2007	2,234	1,346	2,430	431
2008	2,417	1,184	2,046	356
2009	2,373	867	2,496	222
2010	2,331	937	2,541	124
2011	2,225	904	2,017	351
2012	2,279	801	2,074	8.05
Source: http://prtr.ec.europa.eu/PollutantReleases.aspx				

The data from the E-PRTR database indicates that there has been an overall decrease in emissions of zinc to air between 2007 and 2012. In the case of zinc emissions to soil an overall decrease can be observed between 2007 and 2010, followed by a marked increase in 2011. However, in 2012, emissions of zinc to soil have fallen to their lowest level in any of the six reporting years. There is a much less definitive trend with regards emissions of zinc to water as the highest levels were reported in 2009 and 2010 followed by a reduction in emissions in 2011 and a small increase in 2012.

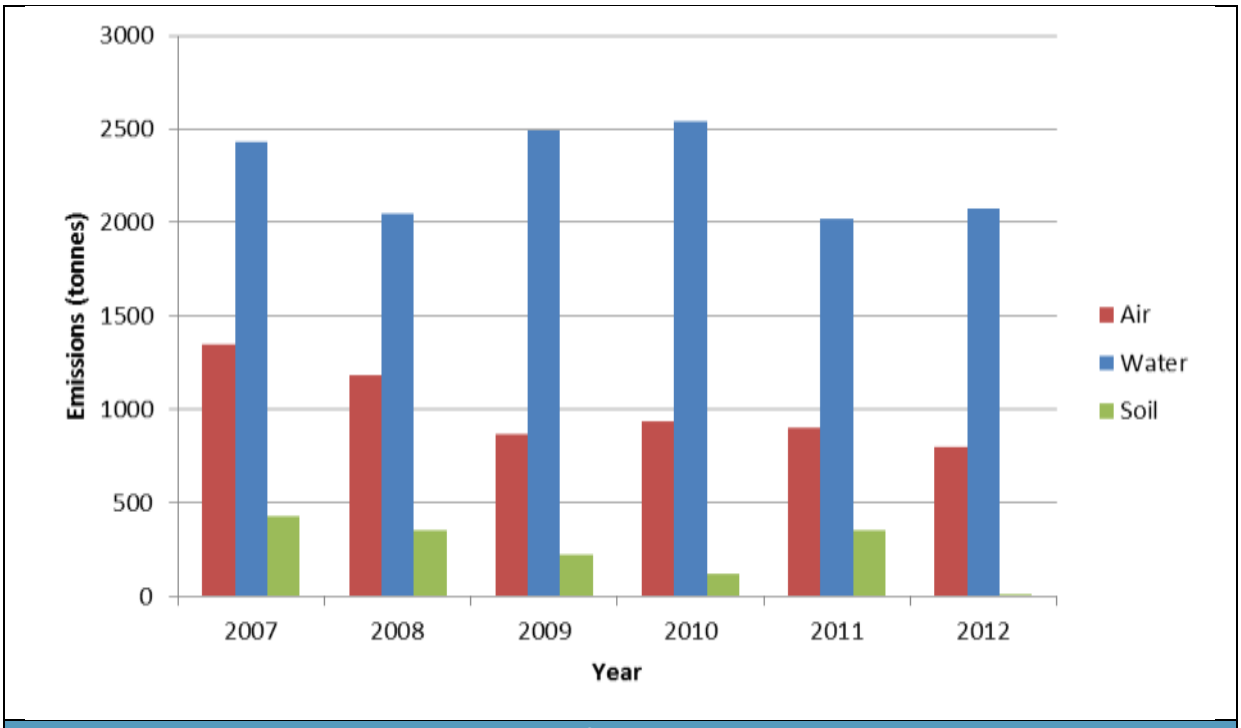


Figure A2-1: Zinc emissions to environment media from all E-PRTR reporting states

Chromium Emissions

Table A2-5 and Figures A2-2, A2-3 and A2-4 provide details of the total emissions of chromium to air, water and soil from all reporting states between 2007 and 2012.

Table A2-5: Chromium emissions from all E-PRTR reporting states

Year	Number of facilities	Emissions (tonnes)		
		Air	Water	Soil
2007	707	138	666	10.4
2008	667	121	633	17.5
2009	601	80.7	501	18.6
2010	629	104	288	7.18
2011	564	76.7	523	5.74
2012	537	77.3	520	0.46

Source: http://prtr.ec.europa.eu/PollutantReleases.aspx

As indicated in Figure A2-2, there is a general trend that emissions of chromium to air (from all states reporting to the E-PRTR) have decreased between 2007 and 2012. Emissions of chromium to air remained relatively stable in 2009, 2011 and 2012, but increased in 2010. The main cause of this spike in emissions is the release of chromium from the production and processing of metals sector in 2010, which can be predominantly attributed to emissions from the production of pig iron/steel.

In the case of releases to water, chromium emissions reduced on an annual basis between 2007 and 2010 (see Figure A2-3). However, emissions of chromium increased in 2011 to above 2009 levels and remained relatively stable in 2012. The main reason for the difference in chromium emissions to water in 2010 compared to 2011 and 2012 is the significant reduction in emissions from the production and processing of metals sector in 2010 (20.6 tonnes emitted in 2010 compared to 372 tonnes and 308 tonnes in 2011 and 2012 respectively).

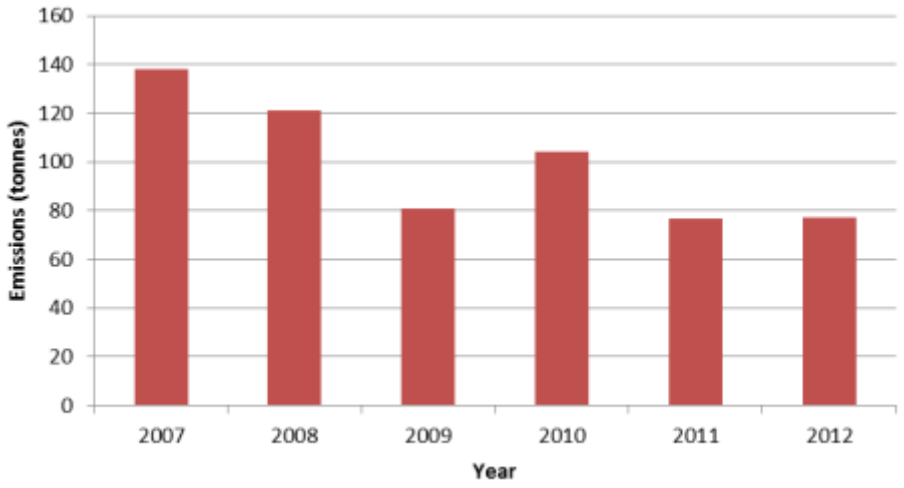


Figure A2-2: Chromium emissions to air from all E-PRTR reporting states

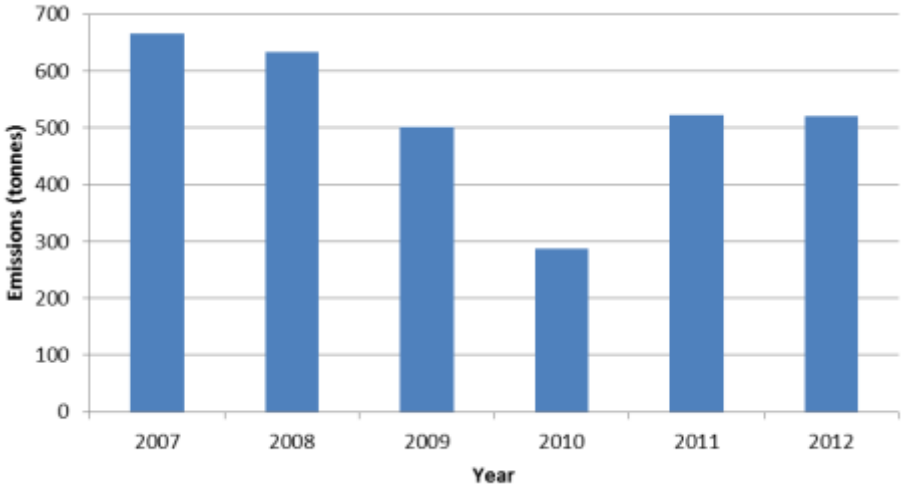


Figure A2-3: Chromium emissions to water from all E-PRTR reporting states

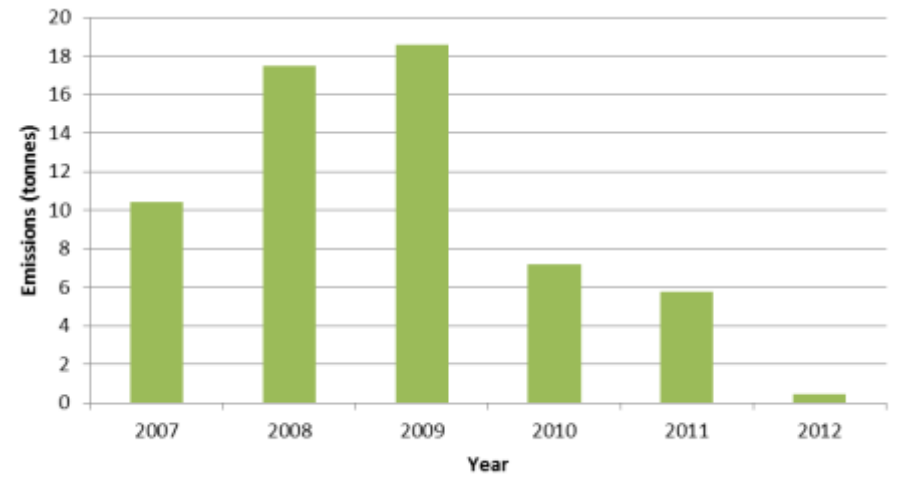


Figure A2-4: Chromium emissions to soil from all E-PRTR reporting states

Emissions of chromium to soil across the states reporting to the E-PRTR increased between 2007 and 2009, peaking at 18.6 tonnes (in 2009). However, in 2010 emissions of chromium to soil reduced considerably (to less than half of 2009 releases) and continued to decrease in 2011 and 2012. The main reason for the decrease in chromium releases to soil in 2010 compared to 2009 is the reduction in emissions from the production and processing of metals sector and the waste and waste water management sector. In 2012, emissions of chromium to soil were less than 0.5 tonnes.

Nonylphenol and Nonylphenol Ethoxylates (NP/NPEs) Emissions

Table A2-6 and Figure A2-5 provide details of the total emissions of nonylphenol and nonylphenol ethoxylates to water from all reporting states between 2007 and 2012. There were no emissions of these substances to air between 2007 and 2012 and only 1.4 kg were emitted to soils in 2010 (from the animal and vegetable products from the food and beverage sector).

Table A2-6: Nonylphenol and nonylphenol ethoxylates emissions from all E-PRTR reporting states

Year	Number of facilities	Emissions (tonnes)		
		Air	Water	Soil
2007	196	-	115	-
2008	267	-	116	-
2009	205	-	32.3	-
2010	268	-	37	-
2011	255	-	37.4	0.0014
2012	249	-	44.8	-

Source: http://prtr.ec.europa.eu/PollutantReleases.aspx

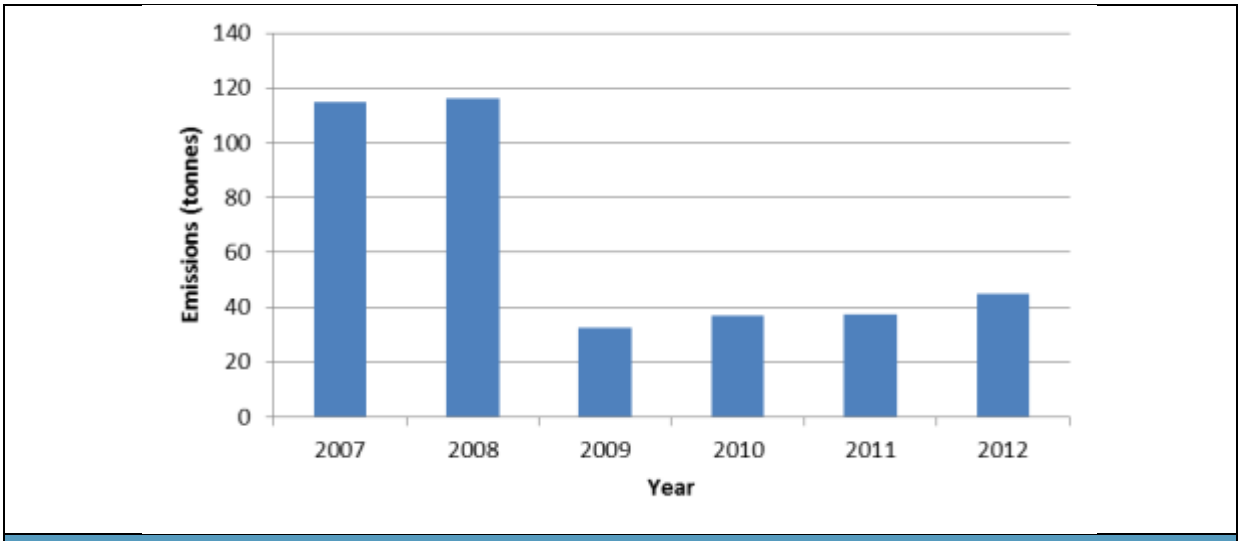


Figure A2-5: Nonylphenol and nonylphenol ethoxylates emissions to environment media from all E-PRTR reporting states

As indicated in Table A2-6 and Figure A2-5, emissions of nonylphenol and nonylphenol ethoxylates to water from all states reporting to the E-PRTR remained relatively stable in 2007 and 2008 (at 115 tonnes and 116 tonnes respectively). However, emissions decreased considerably in 2009 to around a quarter of 2008 levels. The main reason for this reduction is the decrease in emissions from the waste and waste water management sector (112 tonnes of nonylphenol and nonylphenol ethoxylates emitted in 2008 compared to 30.7 tonnes in 2009). Although in subsequent years

emissions of nonylphenol and nonylphenol ethoxylates have remained considerably lower than the peak of 2009, an increase in emissions can be observed between 2009 and 2012.

A2.4 Eurostat - Chemicals Production Statistics

A2.4.1 Introduction

Work on European (EU) statistics concerning hazardous substances began in the mid-1990s when a set of Environmental Pressure Indicators (EPIs) related to chemicals was developed. More recently, a set of indicators to monitor the effectiveness of the Regulation on the registration, evaluation, authorisation and restriction of chemicals (REACH) have been developed. The Statistics explained article is produced on an annual basis providing an analysis of indicators that have been developed by Eurostat covering the production of industrial chemicals[211]. Statistics Explained is an official Eurostat website presenting statistical topics in an easily understandable way. This article focusses specifically on the total production industrial chemicals in the EU-28 compared to the reference year (2004), the production of environmental harmful chemicals (focussing on those that are harmful to the aquatic environment) and the production of toxic chemicals. . The statistical information may be used to measure the progress towards the headline objective for 'public health' established in the EU - Sustainable Development Strategy and towards the long term vision of a non-toxic environment as set out in the 7th Environmental Action Programme for the European Union.

The indicators presented in the Statistics Explained article 'Chemicals production statistics' are derived from annual statistics on the production of manufactured goods (Prodcom). Statistics are available from 1995 onwards in principle, while statistics on toxic chemicals as well as environmentally harmful chemicals are available from 1996. Aggregated data for the EU-28 are only available from reference year 2004 onwards. The information presented on the production of chemicals harmful to the aquatic environment and the production of toxic chemicals has been compiled from detailed product statistics. As well as providing total production figures, the data are also aggregated into five effect classes. These classes of aquatic environmental effects and toxicity to human health follow official classifications in EU legislation based on scientific expert judgement. It is important to note that the indicators do not describe the actual risks associated with the use of chemicals, but their level of production in quantity terms. With the introduction of REACH, the classification system was updated according to the environmental classification of substances/globally harmonised system of classification and labelling of chemicals (CLP/GHS) system.

Table A2-7 provides details of the five classes of environmental harmful chemicals based on their effects on the aquatic environment, starting with the most harmful. Table A2-7 also presents the trend in aggregated production volumes of toxic chemicals, broken down into five classes, starting with the most dangerous.

[211] http://ec.europa.eu/eurostat/statistics-explained/index.php/Chemicals_management_statistics#Further_Eurostat_information
http://ec.europa.eu/eurostat/statistics-explained/index.php/Chemicals_production_statistics

Table A2-7: Five classes of environmental harmful chemicals and toxic chemicals	
Classes of environmental harmful chemicals[1]	**Classes of toxic chemicals[2]**
• Severe chronic effects • Significant chronic effects • Moderate chronic effects • Chronic effects • Significant acute effects	• Carcinogenic, mutagenic and reprotoxic (CMR) chemicals • Chronic toxic chemicals • Very toxic chemicals • Toxic chemicals • Hazardous chemicals
Note: *[1] Based on their effects on the aquatic environment. These are categorised with the most harmful at the top and reducing harmfulness down the list.* *[2] These are categorised in terms of danger to human health with the most dangerous at the top of the list.*	

A2.4.2 Potential Indicators

The Eurostat's Statistics Explained article "Chemicals production statistics" (old title "Chemicals management statistics") presents an analysis of indicators that have been developed, covering the production of industrial chemicals with a particular focus on substances being toxic to human health or harmful to the environment.

The indicator "Production of toxic chemicals" is a Sustainable Development Indicator (SDI)[212] and related to the theme ´Public health´ of the Sustainable Development Strategy. This indicator presents the trend in aggregated production volumes of toxic chemicals, broken down into five toxicity classes. The methodology uses the hazard statements according to the CLP Regulation (Regulation (EC) 1272/2008 of the EP and of the Council of 16.12.2008 on classification, labelling and packaging of substances and mixtures). The CLP Regulation describes hazardous properties by hazard statements (H statements) that replace the risk phrases. Both the Sustainable Development Strategy and the REACH-Regulation encourage the substitution of chemicals of high concern by chemicals with a lower toxic impact.

The Environmental Pressure Indicator "Production of chemicals harmful to the aquatic environment" focuses on impacts to aquatic toxicity. This indicator shows the trend in aggregated production volumes of environmentally harmful chemicals, broken down into five classes of environmental effects. The methodology follows the methodology for the SDI and also uses the hazard statements according to the CLP Regulation.

Both indicators are based on official statistics on the production of industrial chemicals, compiled by National Statistical Institutes and Eurostat. Production volumes are weighted according to the toxicity of the chemicals. These indicators are based on hazard information for specific substances derived from the PRODCOM list of chemicals but do not provide information on changes in the exposures related to the use of these chemicals.

The related indicators on the "apparent consumption" of toxic and of environmentally harmful chemicals are under development.

[212] **Eurostat publication: 'Sustainable development in the European Union — 2015 monitoring report of the EU Sustainable Development Strategy'**, Chapter 5 'Public Health', 'Determinants of health', 'Production of toxic chemicals': http://ec.europa.eu/eurostat/documents/3217494/6975281/KS-GT-15-001-EN-N.pdf/5a20c781-e6e4-4695-b33d-9f502a30383f

The information provided in the article enables comparison of chemical production in the EU-28 as a whole between the years 2004 and 2013 (currently). The annual figures are also disaggregated into the classes presented in Table A2-7 and can therefore be used to identify changes in production of chemicals that are harmful to the aquatic environment and toxic to human health over time. Therefore, the data can be used as an indicator of the potential benefits of chemicals legislation as follows:

- Analysis of the production of chemicals harmful to the aquatic environment can be used to monitor developments in shifting production from more harmful to less harmful chemicals; and
- Analysis of the production of toxic chemicals can be used to monitor developments in moving production from more toxic to less toxic chemicals and to assess the effect of production changes to public health outcomes, especially the shift from high to lower toxicity substances.
- Development of the additional indicators 'Apparent consumption of toxic chemicals' and 'Apparent consumption of environmentally harmful chemicals' to support the indicators based on production by adding data from official foreign trade statistics. The both indicators will follow the methodology with five classes and will cover EU-28 from 2004 onwards.
- The indicator on "Toxic chemicals in households" is under development.

A2.4.3 Substances included in the Database

The data used in developing the chemicals production statistics is based on the total production of all chemicals within the EU-28. The total production of toxic chemicals and environmental harmful chemicals (in relation to their effects on the aquatic environment) is also obtained at the EU-28 level and disaggregated based on the five classes presented in Table A2-7. The data are only presented at the EU level and cannot be further separated by country or specific chemical substance.

A2.4.4 Data Trends

The Statistics Explained article "Chemicals production statistics" provides three main types of findings. Firstly, the article provides the annual change in total production of chemicals compared to the base year (2004). Secondly, the article compares production of environmentally harmful chemicals (in relation to the aquatic environment) between 2004 and 2013 (currently) and, thirdly, comparison is made regarding the annual production of toxic chemicals between 2004 and 2013. A brief summary of the data in each of three cases is presented below.

Total Production of Chemicals

Figure A2-6 presents the development of the production of chemicals in the EU-28 since 2004 using an index on the level (or quantity) of output. This indicates that the production of chemicals in the EU-28 increased each year between 2005 and 2007 reaching a peak production of 371 million tonnes in 2007. During the financial and economic crisis, production fell by 31 million tonnes (or 8.4%) in 2008 and by a further 43 million tonnes (or 12.8%) in 2009. There was a rebound in production in 2010 followed by a decrease in production in 2011 and stabilisation during the 2011 to 2013 period. The latest data available for 2013 suggests that chemicals production fell slightly compared to 2012

and was the second lowest production value during the period 2004-2013 period (year 2009 has the lowest value recorded).[213]

The production of chemicals was predominantly concentrated in Western Europe, with Germany the largest producer in the EU-28 followed by France, Italy and the United Kingdom.

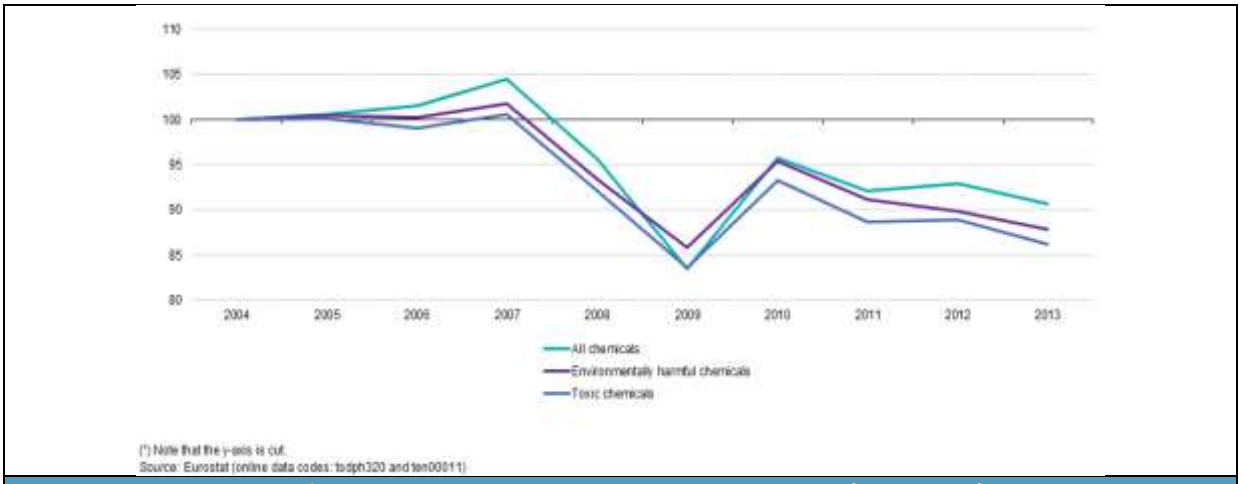


Figure A2-6: Production of chemicals in the EU-28 between 2004 and 2013 (2004 = 100)
***Source*: Chemicals production statistics: tables and figures**

Production of Environmentally Harmful Chemicals

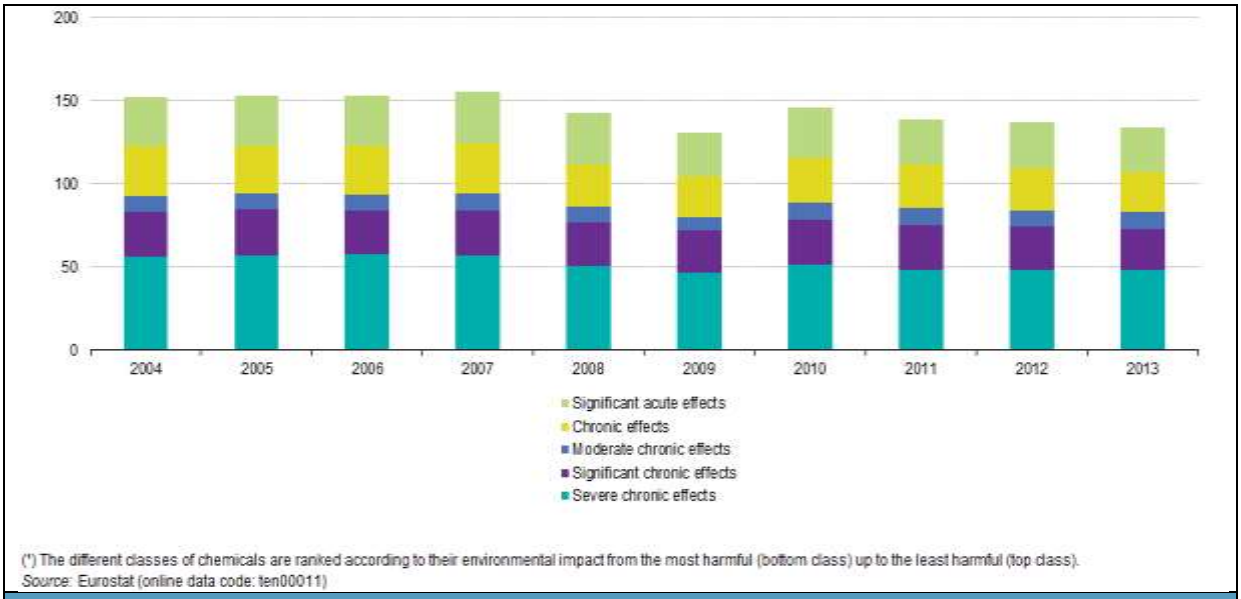
Figure A2-7 presents the change in production of chemicals that were harmful to the aquatic environment between 2004 and 2013 (according to five classes of environmental effects). The aggregated production of the five classes of chemicals in the EU-28 grew by 1.8% between 2004 and 2007 reaching a peak of 155 million tonnes. The production of chemicals that are harmful to the aquatic environment fell by 24 million tonnes during the next two years to a low of 131 million tonnes in 2009. In 2010, there was a strong rebound in production followed by three consecutive year-on-year reductions between 2011 and 2013. By 2013, 134 million tonnes of chemicals that were harmful to the aquatic environment were produced in the EU28, which was lower than every year during the period 2004-2013 other than 2009.

The share of chemicals that were harmful to the aquatic environment in comparison to the total chemicals production was relatively consistent over the period 2004-2013 in the EU28, fluctuating between 41.5% and 44.2%. Having peaked at 44.2% in 2009 (when the overall production of chemicals was at its lowest level), the share fell during the three subsequent years reaching 41.6% in 2013.

There was a wide degree of variation in the production of chemicals that were harmful to the aquatic environment in the five different classes. The largest overall increase in EU-28 output between 2004 and 2013 was recorded for chemicals with moderate chronic effects (as the volume of production rose by 2.17% over this period). However, there was a significant decline in the

[213] Chemicals production statistics: tables and figures: http://ec.europa.eu/eurostat/statistics-explained/index.php/Chemicals_production_statistics

production of chemicals with chronic environmental impacts (-20.4%) and chemicals with severe chronic effects (-14.3%).[214]



(*) The different classes of chemicals are ranked according to their environmental impact from the most harmful (bottom class) up to the least harmful (top class).
Source: Eurostat (online data code: ten00011)

Figure A2-7: Production of chemicals harmful to the aquatic environment in the EU-28 between 2004 and 2013 (million tonnes)
Source: **Chemicals production statistics: tables and figures**

Production of Toxic Chemicals

Figure A2-8 presents the change in production of toxic chemicals produced in the EU-28 member states. The chemicals are assigned to the five classes according to their specific toxicity (as presented in Table A2-7). Total production of toxic chemicals in the EU-28 increased by 0.6% between 2004 and 2007 reaching a peak of 235 million tonnes. Production fell by 20 million tonnes in 2008 (or by 8.4%) and by the same amount in 2009 (or 9.3%) to a level of 196 million tonnes. In 2010, there was a rebound in production (an increase of 11.7%), but this was followed by further reductions in 2011 (-5.0%) and 2013 (-3.0%). As a result of these developments, the EU28 level of production of toxic chemicals in 2013 was 202 million tonnes, some 32 million tonnes less than in 2004.

In the EU-28, the share of all toxic chemicals in total EU-28 chemicals production generally followed a gradual downward trend between 2004 and 2013. There was a peak in the proportion of toxic chemicals (compared to total chemicals production) of 66% in 2004 with this falling to 62.7% in 2013.

Production of the most toxic chemicals (carcinogenic, mutagenic and reprotoxic (CMR) chemicals) in the EU-28 fluctuated between 34 and 36 million tonnes between 2004 and 2007. Production fell by 5.3 million tonnes (or 14.8%) between 2007 and 2008 to 30.6 million tonnes. The production of CMR increased in 2009 and 2010, but since 2010 has declined at a steady rate to 30.7 million tonnes in 2013. The relative share of CMR chemicals in total EU-28 chemical production decreased from 9.9% in 2004 to 9% in 2008. A rebound in production resulted in an increase to 10.9% in 2009 followed by a reduction to 9.5% in 2013.

[214] http://ec.europa.eu/eurostat/statistics-explained/index.php/Chemicals_production_statistics

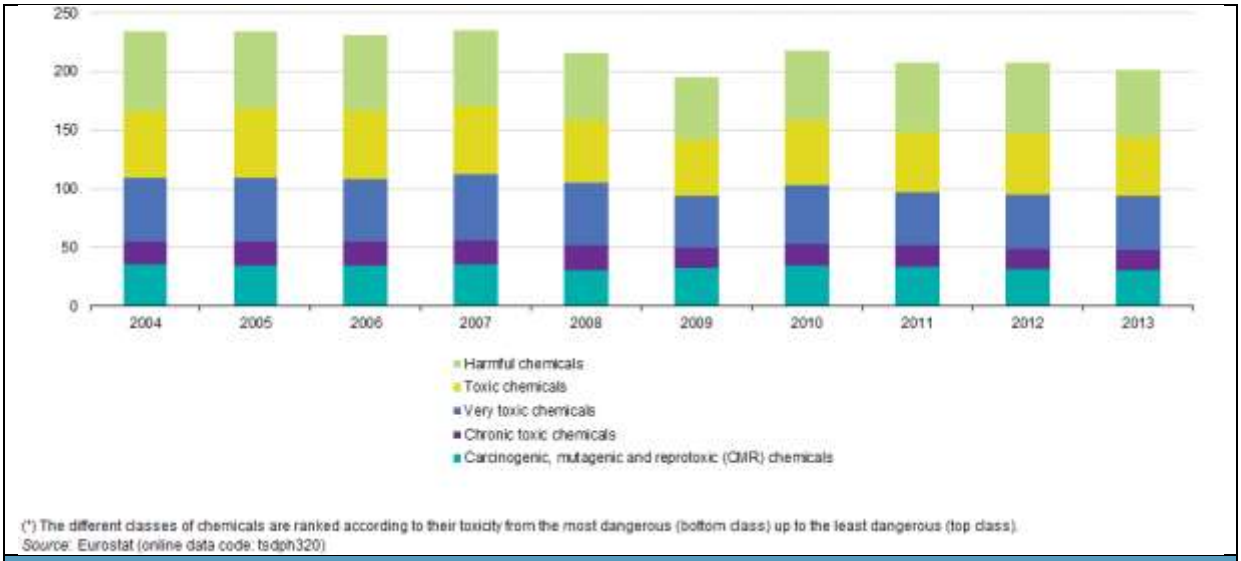


Figure A2-8: Production of toxic chemicals in the EU-28 between 2004 and 2013 (million tonnes)
Source: **Eurostat (online data code : tsdph320)**

A2.5 KemI Commodity Guide

A2.5.1 Introduction

The Swedish Chemicals Agency (KemI) has developed a Commodity Guide[215] in an attempt to place commodities in a system for spreading knowledge about how chemical substances are used in clothing, furniture and other products. The Commodity Guide therefore identifies what substances and materials may be included in commodities on the Swedish market.

Information on the type of material included in different commodities is based in the Danish Environmental Protection Agency Miljøprojekt 281/1995, where a comprehensive survey was undertaken by asking manufacturers about the composition of their products. The intention is to update the Commodity Guide when there is reason to believe that the composition of a commodity has changed considerably.

In the Commodity Guide it is possible to search different types of commodities, the materials they usually consist of and substances that may be included in these materials. Searches can also be made for single materials and substances to identify what commodities and groups of commodities these are used in. Examples of different chemical substances that can be part of materials that are plastics, rubbers and textile fibres have been retrieved from KemI reports and from handbooks. Information on the quantities of commodities produced, imported and exported is retrieved from Statistics Sweden data and is available for the years 1996, 2001 and 2007.

Table A2-8 provides an overview of the searches that can be undertaken using the KemI Commodity Guide.

Table 3-8: Overview of searches that can be undertaken using the KemI Commodity Guide

Type of Search	Purpose of Search	Data Retrieved
1) Substances that may be	To find examples of substances	Data can be searched by year

[215] http://webapps.kemi.se/varuguiden/Default.aspx

Table 3-8: Overview of searches that can be undertaken using the KemI Commodity Guide		
Type of Search	**Purpose of Search**	**Data Retrieved**
contained in a commodity group	that can be contained in certain commodity groups	(1996, 2001 and 2007), product type and commodity group. Information is retrieved on the quantity of substance used in the selected commodity group, the material(s) in which the substance is used, the content of the substance in the material (in % terms) and the quantity of substance in the material. The content/quantity data is given as a range
2) Commodity groups that may contain a certain substance	To search for substances and identify the commodity group and material in which they are used	Data can be searched by year (1996, 2001 and 2007), substance or CAS number. Information is retrieved on the commodity groups and materials in which the substance is used, the content of the substance in the material (in % terms) and the quantity of substance in the material.
3) Materials that may be used in a commodity group	To search product types and commodity groups and identify the quantities of materials produced, imported and exported within the product group	Data can be searched by year (1996, 2001 and 2007), product type and commodity group. Information is retrieved on the materials used in each product group, the production/import/ export of materials (in tonnes) and the net amount (production/ import minus export)
4) Commodity groups that may contain a certain material	To search materials and identify types of commodities in which the material is used and the quantity of material produced, imported and exported within the commodity groups	Data can be searched by year (1996, 2001 and 2007), material group and material. Information is retrieved on the commodity groups in which the material is used, the production/import/ export of materials (in tonnes) and the net amount (production/ import minus export)
5) Substances that may be used in a material	To search material groups (animal material, plastic, rubber, wood and vegetable material) and specific materials within these to identify the substances that may be included in the materials	Data can be searched by material group and material. Information is retrieved on the substances that may be included in the material and the content of the substance in the material (in % terms)
6) Materials where a certain substance may be used	To search for substances and identify which materials they may be included in	Data can be searched by substance and CAS number. Information is retrieved on the materials in which the substance may be included and the content of the substance in the material (in % terms)
Source: http://webapps.kemi.se/varuguiden/Default.aspx		

A2.5.2 Potential Indicators

The following provides a list of potential indicators that could be developed using the data contained within the Commodity Guide to assist in informing the benefits that can be attributed to chemicals legislation:

- Change in the content of substances within certain materials over time;
- Change in the amount of each material used in different commodities over time;
- Change in the production, import and export of materials over time; and
- Change in the production, import and export of materials used in different commodities over time.

A2.5.3 Substances included in the Database

Table A2-9 provides an overview of the types of commodity and examples of specific commodities included in the KemI Commodity Guide.

Table A2-9: Types of commodity and materials included in the KemI Commodity Guide

Types of Commodity	Commodity Examples
1) Live animals; animal products	Various living animals, smoked fish, cheese, honey
2) Vegetable products	Living plants, fresh vegetables, rice, coffee
3) Animal or vegetable fats and oils, their cleavage products and waxes	Various oil-containing seeds and fruits, cooking oil, margarine and other fat mixtures
4) Prepared foodstuffs; beverages, spirits and vinegar; tobacco and manufactured tobacco substitutes	Sausages, preserved fish, sugar, pasta, tobacco
5) Mineral products	Salt, quartz, slate, lime, crude oil
6) Chemical products and similar	Oxygen, rare gases, copper sulphate, waste, inks
7) Plastics and plastic articles; rubber and rubber articles	Various plastic and plastic goods, used tyres
8) Skin and leather articles, saddlery, travel goods, handbags and similar containers, article of animal guts	Various leather articles and travelling items; cases, trunks, suitcases etc. of leather/plastic
9) Wood and wood articles, charcoal, cork and articles of cork, straw, plaiting material, basketware and wickerwork	Various wood and wood articles and charcoals, chipboard, fibreboards, articles of agglomerated and natural cork
10) Pulp of wood, recovered paper and paperboard, articles of paper and paper board	Pulp of wood, books and leaflets, newspapers and journals, carbon paper
11) Textile and textile articles	Various natural silk, various wool and fine and coarse animal hairs, cotton yarn, overcoats and jackets, tents
12) Footwear, headgear, umbrellas, sun umbrellas, sticks, whips, prepared feathers, artificial flowers, articles of human hair	Various footwear, waterproof footwear of rubber, clogs, umbrellas, artificial flowers, foliage and fruits
13) Articles of stone, plaster, cement, asbestos, mica or similar materials; ceramic products; glass and glassware	Various articles of stone, plaster, cement, asbestos and similar materials, worked slate, glazed pottery
14) Pearls, precious or semi-precious stones, precious metals, metals clad with precious metal and articles thereof; imitation jewellery; coins	Various natural pearls, precious metals etc.
15) Base metals and articles of base metal	Various iron and steel, reinforcement bar, cookers, radiators, articles of nickel/lead/zinc/tin
16) Machinery and mechanical appliances, electrical equipment	Heating boilers, steam turbines, fuel pumps, burners, winches, ploughs, fuses
17) Vehicles, aircraft, vessels and associated	Various locomotives, train coaches etc.; goods vans,

Table A2-9: Types of commodity and materials included in the KemI Commodity Guide	
Types of Commodity	**Commodity Examples**
transport equipment	military vehicles, bicycles, fishing vessels, motor boats
18) Optical, photographic, cinematographic, measuring, checking, precision, medical or surgical instruments and apparatus; clocks and watches; musical instruments; parts and accessories thereof	Various optical and photographic instruments, photocopying apparatus, pressure gauges, thermometers
19) Arms and ammunition	Weapons and ammunition, steel and lead shots
20) Furniture, toys and other miscellaneous manufactured articles	Office chairs, mattresses, toy cars, toothbrushes, ballpoint pens
Source: http://webapps.kemi.se/varuguiden/Tabeller/Varugrupper.aspx	

Table A2-10 provides an overview of the material groups and examples of specific materials that are included in the KemI Commodity Guide.

Table A2-10: Groups of materials included in the KemI Commodity Guide	
Material Group	**Material Examples**
1) Animal material	Meat from mammals, fish and shellfish, egg, fat
2) Glass	Floatglass, container glass (pressed), glass wool
3) Iron and steel	Structural steel (high-alloy), magnetic steel
4) Plastic	Epoxy, melamine plastic, polyethene
5) Chemical products	Carbon, waxes, bitumen, bases, acids
6) Metals (except iron)	Aluminium, lead, cadmium, zinc
7) Coatings and adhesives	Paint and varnishes (water/solvent based), chromium coating
8) Stone materials	Granite, marble, cement, gypsum, sand and gravel
9) Rubber	Natural rubber, butyl rubber, urethane rubber
10) Wood and vegetable material	Soft/hard wood (roughly pretreated), cork, cotton, sugar, coffee
11) Recovered materials	Aluminium (recirculated), waste paper, ashes and slag
12) Others	Other
Source: http://webapps.kemi.se/varuguiden/Tabeller/Materialslag.aspx	

The substances presented in the Commodity Guide are examples of substances used in plastics, rubber and textiles of synthetic, vegetable and animal origin. At present there are approximately 900 substances included in the database. It is likely that other substances are included in the materials that are used in the various commodities included in the database (some of which are identified in Tables A2-7 and A2-8).

A2.5.4 Data Trends

To provide an example of the type of data that can be extracted from the Commodity Guide database, information regarding the quantity of specific substances within a specific commodity group has been obtained for the three reporting years (1996, 2001 and 2007). For the purpose of providing an example, the type/category of commodity selected is 'chemical products and similar' and the commodity group selected is 'inorganic bases'. Table A2-11 provides a summary of the quantity of certain substances within the commodity group as recorded in 1996, 2001 and 2007. This suggests that, in all four of the examples selected, the quantity of the substances in the commodity group has increased over time.

Table A2-11: Change in quantities of certain substances in the inorganic bases commodity group over time				
Substance Name	CAS No.	Quantity of substance in the 'Inorganic Bases' Commodity Group (tonnes)		
		1996	2001	2007
Calcium stearate	1592-23-0	5 - 83	5 - 86	9 - 138
Glycerol distearate	1323-83-7	1 - 17	1 - 18	2 - 29
Mica	12001-26-2	229 - 458	239 - 478	384 - 768
Zinc oxide	1314-13-2	2 - 9	2 - 10	4 - 15
Source: http://webapps.kemi.se/varuguiden/VarugrupperAmne.aspx				

It is also possible to identify the quantity of a substance (as a range) used in a particular material and how this has changed over time. Using zinc oxide as an example, Table 3-12 outlines the amount of this substance used in various materials and how this has changed over the three reporting years. The data indicates that polyethene and natural rubber are used in mattresses and that zinc oxide was used in these materials in quantities of between 3 to 14 tonnes and 51 to 127 tonnes in 1996 respectively. The information obtained for 2001 and 2007 suggests that the quantity of zinc oxide used in polyethene and natural rubber (which is subsequently used in mattresses) has increased over time. The data also suggests that the quantity of zinc oxide used in natural rubber and butadiene rubber (which is subsequently used in new tyres) has also increased between 1996 and 2007.

In the case of butadiene rubber and other rubber materials used in paper and paperboard coated with kaolin, the quantity of zinc oxide used these materials may have increased between 1996 and 2001, but decreased considerably in 2007 with no zinc oxide considered to have been used. The use of zinc oxide in polyethene (which is subsequently used for frozen vegetables) appears to have remained relatively stable across the reporting years.

Table A2-12: Change in quantities of zinc oxide in certain materials over time				
Commodity Group	Material	Quantity of Zinc oxide in the Material (tonnes)		
		1996	2001	2007
Mattresses	Polyethene	3 - 14	4 - 15	8 - 30
	Natural rubber	51 - 127	56 - 139	113 - 283
New rubber tyres of a kind used on cars, buses etc.	Natural rubber	94 - 234	126 – 314	205 – 512
	Butadiene rubber	386 - 965	518 – 1,296	845 – 2,112
Paper and paperboard coated with kaolin	Butadiene rubber	106 - 265	114 - 284	0 - 0
	Other rubber materials	106 - 265	114 - 284	0 - 0
Frozen vegetables	Polyethene	3 - 14	4 - 15	3 - 11
Source: http://webapps.kemi.se/varuguiden/VarugrupperAmne.aspx				

A2.6 KemI Statistics for Chemicals

A2.6.1 Introduction

The Swedish Chemicals Agency (KemI) developed a database of flow cards[216], which provide statistics relating to specific chemicals. The database includes 1,068 flow cards for 258 substances

[216] http://apps.kemi.se/flodessok/floden/flodessok.cfm

and allows searches to be made using substance name or CAS number. The search results provide links to information relating to general facts about each of the chemical substances included in the database. This information includes details of the substance structure, physical data (e.g. melting point, boiling point etc.) and key uses. In addition, a series of flow cards are provided for the searches substances with each relating to a specific year. For certain chemicals, flow cards are only available for a single year, whereas for others flow cards are available for multiple years (e.g. in the case on nonylphenol ethoxylates flow cards are available on an annual basis from 1994 to 2012 – 19 in total).

The flow cards provide details of the amount of each substance imported into Sweden and exported out of Sweden as a raw material. They also provide information relating to how the raw material is used. In addition, the flow cards also provide information on the quantity of the specific substance in question contained in chemical products that are imported and manufactured in Sweden as well as the amount in chemical products that are exported out of Sweden.

A2.6.2 Potential Indicators

The following provides a list of potential indicators that could be developed using the data contained within the KemI statistics for chemicals flow cards to assist in informing the benefits that can be attributed to chemicals legislation:

- Change in the quantity of raw material imported and exported over time;
- Change in the quantity of the raw material used in downstream applications over time; and
- Change in the amount of a substance in chemical products that are manufactured and imported into Sweden over time.

A2.6.3 Substances included in the Database

The substances/groups of substances included in the statistics for chemicals flow card are provided in Table A2-13 along with the years for which data on quantities of the substances that were manufactured/imported/exported is available.

Table A2-13: Substances included in the KemI Statistics for Chemicals Database

Substance Name	Years in which Information is available
Acetic acid	1998, 2004, 2010
Acetone	2001, 2006
Acrylic acid	1993, 2001, 2004, 2008
Acrylonitrile	1993, 1998, 2004, 2008
Adipic acid	1993, 1998
Alcohol (C6-C18) ethoxylates	1996, 1998, 2000, 2003, 2005, 2010
Aliphatic light solvent naphtha	1993, 1995, 1998, 2001, 2004, 2007, 2010
Aliphatic heavy solvent naphtha	1993, 1995, 1998, 2001, 2004, 2007, 2010
Aliphatic medium solvent naphtha	1993, 1995, 1998, 2001, 2004, 2007, 2010
Alkyl phosphates	1998, 2000, 2003, 2005, 2006, 2007, 2009
Alkylaryl- and aryl phosphates	1998, 2000, 2003, 2005, 2006, 2007, 2009
Alkylbenzyldimethylammonium salts	1993, 1995, 2001, 2004, 2008, 2009
Aluminium fluoride	1993
Aluminum compounds, inorganic	2005
Amines	2000, 2004, 2008
Ammonia	1993, 1995, 1998, 2003, 2008
Ammonium chloride	1993, 2001, 2006
Ammonium fluoride	1993

Table A2-13: Substances included in the KemI Statistics for Chemicals Database	
Substance Name	**Years in which Information is available**
Ammonium hydrogen fluoride	1993
Ammonium hydrogen nitrate	2010
Antimony trioxide	1998, 2001, 2002, 2003, 2005, 2007, 2009
Aromatic heavy solvent naphtha	1993, 1995, 1998, 2001, 2004, 2007, 2010
Aromatic medium solvent naphtha	1993, 1995, 1998, 2001, 2004, 2007, 2010
Barium sulfate	2005
Benzene	1998
1,2-Benzisothiazol-3(2H)-one, 1,1-dioxide incl. Salts	2005, 2008
1,2-Benzisothiazole-3(2H)-one, incl. Salts	2005, 2008
2(2H-Benzotriazol-2-yl)-phenol	1999, 2001, 2002, 2003, 2006, 2012
Benzotriazoles	2008
Benzyl alcohol	2003, 2006, 2010
Benzyl butyl phthalate	1993, 1995, 1996, 1997, 1998, 1999, 2001, 2003, 2005, 2007, 2009, 2011
Bisphenol A	1994, 1995, 1997, 1999, 2001, 2004, 2006, 2008, 2009, 2010, 2011, 2012
Bisphenol A-diglycidyl ether resins	2004, 2006, 2010, 2011
Bisphenol A-diglycidyl ether	1994, 1995, 1996, 2001, 2004, 2006, 2009, 2011, 2012
Boric acid and sodium borates	2000, 2003, 2005, 2007, 2009, 2011
2-Bromo-2-nitropropane-1,3-diol	1998, 2001, 2003, 2005, 2007, 2009
Butanols	2004, 2008
2-Butanone	2004, 2008
2-Butoxy ethanol	1993, 1995, 1997, 2001, 2004, 2006, 2009
2-Butoxy(2-ethoxy)ethanol	1993, 1995, 1997, 2001, 2004, 2006, 2009
2-Butoxyethyl acetate	1999, 2004, 2006, 2009
Butoxypropanol	2003, 2006, 2009
Butyl acetate	2001, 2006
Butyl metacrylate & 2-hydroxyethyl metacrylate	1994
Butyl phenols	1998, 2001, 2004, 2007, 2010
Butyl acrylate	1994, 1995, 1996, 2001, 2004, 2007
1,4-Butylene glycol diglycidyl ether	1994, 1995
gamma-Butyrolactone	1998, 1999, 2003, 2005, 2006, 2008, 2010, 2012
Calcium carbonate	1999, 2009
Calcium dioctadecanoate	2005
Calcium hydroxide	2005
Carbendazim	1998, 2003, 2006, 2009
Carbon black	2004, 2009
Chlorinated alkyl phosphates	1998, 2003, 2005, 2006, 2008, 2009, 2010
Chlorinated paraffins	1995, 1996, 1997, 1998, 1999, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2012
Chlorine	1993
Chloroform	1993, 1994, 1995, 1996
Chloroisocyanuric acids and salts	1993, 1995, 1998, 2001, 2004, 2006, 2010
5-Chloro-2-methyl-4-isothiazolin-3-one	1994, 1997, 2000
Chromium salts, inorganic	2000, 2005, 2010
Citric acid	2005
Coal tar	1994, 1996, 2003
Cobalt compounds, inorganic	2003, 2008
Coco amidopropyl betaine	2005, 2010
Coco diethanolamides	2005, 2010

Table A2-13: Substances included in the KemI Statistics for Chemicals Database	
Substance Name	**Years in which Information is available**
Colophony	1997, 2001, 2004, 2006, 2009, 2012
Copper compounds, inorganic	2004, 2009
Copper phthalocyanines	2001, 2004, 2007, 2010
Creosote	1994, 1998, 2003, 2006, 2008, 2011
Cyanides	1994, 1997, 2001, 2004, 2007, 2010
Dearomatised heavy solvent naphtha	1993, 1995, 1998, 2001, 2004, 2007, 2010
Dearomatised light solvent naphtha	1993, 1995, 1998, 2001, 2004, 2007, 2010
Dearomatised medium solvent naphtha	1993, 1995, 1998, 2001, 2004, 2007, 2010
Decanedicarboxylic acid esters	1998, 2000, 2003, 2006, 2009
Dialkyldimethylammonium-earth complexes	1993, 1995, 1998, 2001, 2004, 2006, 2009
Dialkyldimethylammonium salts	1993, 1994, 1995, 1996, 1997, 2001, 2003, 2006, 2009
4,4'-Diaminodiphenylmethane	1994, 1997, 2003, 2006, 2010
Dibenzoyl peroxide	1994, 1998, 2002, 2003, 2007
Dibutyl phthalate	1993, 1995, 1996, 1997, 1998, 1999
Dibutyl phthalates	2001, 2002, 2003, 2005, 2008, 2011
Dibutyltin compounds	2000, 2002, 2003, 2005, 2006, 2008, 2010, 2012
Dibutyltin dilaurate	1998, 200
Dichloromethane	1993, 1994, 1995, 1996, 1997, 1998, 1999, 2000, 2003, 2007
Diethanolamine	1993, 1996, 2000
Diethyl ether	2004, 2008
Diethylene glycol dibenzoate	2000, 2004, 2008
Diethylenetriamine	1994, 1997, 2000, 2004, 2008
Diethylenetriamine pentaacetetic acid including sodium salts	1997, 2001, 2004, 2007, 2008
N,N-Di (2-ethylhexyl)-?-methyl-1H-benzotriazole-1-methanamines	2000, 2004, 2008, 2012
Di(2-ethylhexyl)-phthalate	1995, 1996
Diisobutyl phthalate	1999
Diisodecyl phthalates	1997, 1999, 2001, 2003, 2005, 2007, 2009, 2012
Diisopropyl naphthalene	1999, 2003, 2007, 2010
Dimethyl ether	2005
Dimethyl formamide	2003, 2006, 2008, 2010
Dimethyl phthalate	1997, 1998, 2012
Dimethylesters of C4-C6 dicarboxylic acids	1993, 1996, 1998, 2000, 2004, 2008
Di(nonylphenyl) amine	2000, 2003, 2006, 2009
Dioctyl phthalates	1993, 1997, 1998, 1999, 2001, 2003, 2005, 2007, 2009, 2011
Di(1,2,2,6,6-pentamethyl-4-piperidinyl)decanodioate	1998
Diphenylmethane diisocyanates	1994, 1996, 1998, 2001, 2004, 2007, 2010
2,6-Di(tert-butyl)-4-methyl phenol	1994, 1996, 1998, 2001, 2004, 2005, 2008
Dodecyl phenol	2001, 2004, 2007, 2010
Enzymes	1998, 2004, 2007, 2010
Etanolamines	2000, 2003, 2005, 2007, 2009
1,2-Ethanediamine	1997, 2000, 2005, 2009
1,2-Ethanediol	2001, 2004, 2007, 2009
Ethanol	1999, 2004, 2009
2-Ethoxy ethanol	1995, 1996, 1997, 2003, 2007
2-Ethoxyethyl acetate	1994, 1995, 1996, 1997, 1999, 2003, 2007
Ethoxylated quaternary ammonium compounds	1993, 1995, 2001, 2004, 2007, 2009, 2010
Ethyl acetate	2004, 2009

Table A2-13: Substances included in the KemI Statistics for Chemicals Database	
Substance Name	**Years in which Information is available**
Ethylbenzene	2005
Ethylene glycol diformal	1998, 2001, 2004, 2007, 2010
Ethylene oxide-propylene oxide copolymer	2005
Ethylenediamine tetraacetic acid including sodium salts	1997, 2001, 2004, 2007, 2010
2-Ethylhexanoic acid metal salts	2000, 2002, 2003, 2006, 2009
2-Ethylhexyl acrylate	1993
Fluorides	1993
Fluorosilicic acid	1993
Fluorspar and calcium fluoride	1993
Formaldehyde	1993, 1995, 1999, 2003, 2006, 2009
Formic acid	2000, 2004, 2008
Glutaraldehyde	1994, 1997, 2001, 2005, 2008
Glycidyl(C12-14)alkyl ether	1994, 1996, 1998
Hexamethylenetetramine	1994, 1997, 2001, 2004, 2008
Hexanes	1998, 2004, 2009
Hydrazine	1993, 2003, 2006, 2009
Hydrochloric acid	2003, 2008
Hydrofluoric acid	1993, 1995, 1997, 1999, 2001, 2004, 2007, 2010
Hydrogen peroxide	1993, 1995, 1997, 1998, 2003, 2005, 2007, 2009
Hydroquinone	1993, 1999, 2004, 2006, 2008
4-Hydroxybenzoates (Parabens)	2003, 2007, 2010
2-(2-Hydroxyethoxy)-ethanol	2004, 2007, 2009
N-Hydroxyethylenediamine acetate trisodium salt	1997
Hydroxyl ammoniumsulfate	1997
Inorganic phosphates	2008
3-Iodo-2-propynyl butyl carbamate	1999, 2003, 2006, 2010
Iron oxide	2005
Isoparaffins	1993, 1995, 1998, 2001, 2004, 2007, 2010
Isophorone diamine	1994, 1997, 2001, 2004, 2007, 2010
Isophorone diisocyanate	1994, 1996, 1998, 2001, 2004, 2007
Isotiazolines	1997, 2000, 2003, 2005, 2006, 2008
Lead naphthenates	2004
Lignosulphonates	2005, 2010
Limonene	1994, 1996, 1999, 2004, 2008
Linear alkylbenzene sulfonates	2001, 2003, 2004, 2007, 2010
Metacrylic acid	1993, 2005
Metal naphthenates	1993, 1999, 2004, 2009
Methanol	1995, 1998, 2004, 2009
2-Methoxy ethanol	1994, 1997, 1999
Methoxy methylethoxy propanol	2004, 2006, 2009
2-(Methoxyethoxy)ethanol	2003, 2008
4-Methoxyphenol	2000, 2005, 2009
Methoxypropanol	1993, 1994, 1995, 1996, 1997, 1998, 1999, 2001, 2004, 2006, 2009
Methyl ethyl ketoxime	1994, 1996, 2001, 2004, 2007, 2009, 2012
2-Methyl-4-isothiazoline-3-one incl. chlorine derivate	2005, 2006, 2008
Methyl metacrylic acid	1993, 1995, 1996, 2001, 2004, 2007, 2009
4-Methyl-2-pentanone	2004, 2008
2-Methyl-4-isothiazolin-3-one	1994, 1997, 2000, 2004, 2006, 2008
2-Methyl-2,4-pentanediol	2005
N-Methyl-2-pyrrolidone	1994, 1996, 1998, 2001, 2004, 2007, 2008

Table A2-13: Substances included in the KemI Statistics for Chemicals Database	
Substance Name	**Years in which Information is available**
Monobutyl phenols	1998, 2001, 2004, 2007, 2010
Monoethanol amine	1993, 1996, 2000
Nickel salts, inorganic	1999, 2003, 2008
Nitric acid	2004, 2009
Normal paraffins	1993, 1995, 1998, 2001, 2004, 2007
Nonylphenol	1994, 1995, 1996, 1997, 1998, 2001, 2004, 2007, 2009, 2011, 2012
Nonylphenol derivatives sulfides	1998, 1999, 2000, 2004, 2008
Nonylphenol ethoxylates	1994, 1995, 1996, 1997, 1998, 1999, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012
Nonylphenol phosphite (3:1)	1998, 2001, 2004, 2007, 2008
2-Octyl-2H-isothiazol-3-one	1994, 1998, 2005
Octylphenol	2003, 2007, 2010
Octylphenol etoxylate	2010
Organic phosphates	1993, 1996
Oxalic acid	1993, 1999, 2004, 2009
Oxirane	1993, 1996
Pentaerythritol tetrakis(3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate	2008
Pentaethylene hexamine	1994, 1997, 2000, 2004, 2008
n-Pentane	1994, 2001
Pentanes	2004, 2009
Peracetic acid	1998, 2003, 2006, 2009
Phenol	1993, 1996, 1999, 2003, 2006, 2009, 2012
2-Phenoxy ethanol	2005
Phosphoric acid	2003, 2008
Poly(oxy-1,2-ethanediyl), .alpha.-(nonylphenyl)-.omega.-hydroxy-, phosphates	2012
Poly(oxy-1,2-ethanediyl), .alpha.-sulfo-.omega.-(nonylphenoxy)-	2012
Polyalkylbutyl phenols	1998, 2001, 2004, 2007, 2010
Polybutenes	2010
Polydimethyl siloxane	1998, 2003
Polydimethyl siloxanes	2003
Polyethene	2001, 2006, 2011
Polyethylene glycol	2005
Polypropylene glycol	2010
Polyvinyl chloride	2004, 2008, 2011
Potassium hydroxide	2005
Proppane/butane	2008
1,2-Propanediol	2001, 2004, 2007, 2010
1,2,3-Propanetriol	2004, 2007, 2010
2-Propanol	1998, 2004, 2009
1-Propanol	2008
Propylene glycol methyl ether acetate	1995, 1996, 1997, 1998, 2001, 2004, 2006, 2009
Quaternary ammonium compounds	1993, 1995, 1999, 2001
Silica	2004, 2009
Siloxanes (Si2-Si6)	2003, 2005, 2007, 2009
Silver salts, inorganic	2003, 2010
Sodium benzoate	2004, 2007, 2010
Sodium carbonate	2001, 2006

Table A2-13: Substances included in the KemI Statistics for Chemicals Database	
Substance Name	**Years in which Information is available**
Sodium chloride	2001, 2006
Sodium dodecyl ether sulphate	2004, 2006, 2009
Sodium dodecyl sulphate	1996, 2004, 2007, 2010
Sodium fluoride	1993, 1995, 1998, 2001, 2004, 2007, 2010
Sodium hydroxide	1999, 2004, 2009
Sodium hypochlorite; calcium hypochlorite	1998, 2001, 2003, 2006, 2009, 2012
Sodium metasilicate	1996, 1999, 2001, 2006
Sodium nitrite	1994, 1998, 2005, 2008
Sodium perborate (including mono- & tetrahydrates)	1996, 1998, 2002, 2003, 2006, 2009
Sodium silicates	1996, 1999, 2001, 2006
Sodium sulfate	2004, 2009
Sodium tripolyphosphate	2005
Styrene	1993, 1996, 2000, 2005, 2010
Sulfuric acid	2003, 2008
Talc	1999, 2004, 2010
Tetrachloroethene	1994, 1995, 1996, 1997, 1998, 1999, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010
Tetrachloromethane	1993, 1994, 1995, 1996
Tetraethylen pentamine	1997
2,4,7,9-Tetramethyl-5-decyne-4,7-diol	2005
Thiram, Ziram, TMTMS	1994, 1998, 2002, 2003, 2006, 2009
Tiourea	1993, 1996, 2001, 2004, 2007, 2010
Titanium dioxide	1998, 2004, 2009
Toluene	1993, 1994, 1995, 1996, 1998, 2001, 2004, 2007, 2010
Toluene diisocyanate	1994, 1996, 1998, 2001, 2004, 2007, 2010
Tolylfluanid	1994, 1996, 1998, 2000, 2003, 2006
Tolylfluanide and dichlofluanide	2009
1,1,1-Trichloroethane	1993, 1994, 1995, 1996
Trichloroethene	1993, 1994, 1995, 1996, 1997, 1998, 1999, 2000, 2001, 2002, 2003, 2004, 2006, 2008, 2010
Tricresyl phosphate	1996
Triethanolamine	1993, 1996, 2000
Trietylenetetraamine	1997, 2000, 2004, 2008
2,2,4-Trimethyl-1,6-hexamethylenediamine	1994
2,4,4-Trimethyl-1,6-hexamethylenediamine	1994
Trimethylhexanediamines	1997, 2000, 2004, 2008
Triphenyl phosphates	1996
Tris(2-hydroxiethyl)-sym-hexahydrotriazine	1994, 1998, 2001, 2004, 2007, 2008
Trisodium nitrilotriacetate	1997, 1998, 2001, 2004, 2007
Turpentine	1994, 1996, 2003, 2004, 2009
Urea	2005
Xylene	1993, 1994, 1995, 1996, 1998, 2001, 2004, 2007, 2010
Zeolites	1993, 1994, 1995, 1996, 1998, 2004, 2007, 2010
Zinc chloride	1998, 2006, 2010
Zinc dialkyldithiophosphate	1999, 2003, 2006, 2010
Zinc dialkyl(C3-C6)ditiophosphate	1998
Zinc salts, inorganic	2000, 2003, 2006
Source: https://apps.kemi.se/flodessok/floden/flodessok.cfm	

A2.6.4 Data Trends

To provide an example of the type of data that can be extracted from the KemI statistics for chemicals flow cards, information regarding the quantity of inorganic chromium salts (as a raw material and contained in chemical products) imported to and exported from Sweden has been extracted. Table A2-14 provides details of the amount of inorganic chromium salts imported and exported as a raw material to and from Sweden in the reporting years (2000, 2005, and 2010). This indicates that the quantity of chromium salts manufactured in Sweden has decreased over the reporting period with 16 tonnes of raw material produced in 2000 and none in 2005 and 2010. The data suggest that between 2000 and 2010 the quantity of inorganic chromium salts imported into Sweden has increased from 775 tonnes to 815 tonnes, although a smaller quantity of material was exported in 2005. The quantity of inorganic chromium salts exported from Sweden has increased in each of the reporting years from <1 tonne in 2000 to 37 tonnes in 2010.

Table A2-14: Amount of inorganic chromium salts (raw material) manufactured, imported and exported in/to/from Sweden

Manufacture/Import/Export	Quantity (tonnes)		
	2000	2005	2010
Manufactured	16	0	0
Imported	775	670	815
Exported	<1	31	37

Source: https://apps.kemi.se/flodessok/floden/_flodenbild/floden.cfm?ID=412 (2000)
https://apps.kemi.se/flodessok/floden/_flodenbild/floden.cfm?ID=855 (2005)
https://apps.kemi.se/flodessok/floden/_flodenbild/floden.cfm?ID=1292 (2010)

Table A2-15 provides details on the quantity of inorganic chromium salts imported and exported in chemical products to/from Sweden. This indicates that between 2000 and 2010, the amount of inorganic chromium salts imported and exported in chemical products has decreased. Imports have decreased from 1,326 tonnes in 2000 to 865 tonnes in 2010 and exports have decreased from 365 tonnes in 2000 to 305 tonnes in 2010.

Table A2-15: Amount of inorganic chromium salts in chemical products that are imported and exported to/from Sweden

Import/Export	Quantity (tonnes)		
	2000	2005	2010
Imported	1,326	793	865
Exported	326	329	305

Source: https://apps.kemi.se/flodessok/floden/_flodenbild/floden.cfm?ID=412 (2000)
https://apps.kemi.se/flodessok/floden/_flodenbild/floden.cfm?ID=855 (2005)
https://apps.kemi.se/flodessok/floden/_flodenbild/floden.cfm?ID=1292 (2010)

Table A2-16 provides data on the types of products imported and manufactured that contain inorganic chromium salts and the quantity of this substance within these products. The data indicates that in 2000 the largest amount of inorganic chromium salts were imported into Sweden in wood preservation coatings, however, by 2010 the largest amount of inorganic chromium salts were imported in paints (including raw material). The data also suggests that the amount of inorganic chromium salts imported in products has increased in four of the product types between 2000 and 2010 (namely, paints (including raw material), metal surface coating agents, products to building industry and catalytic agents). The quantity of inorganic chromium salts imported in products has

decreased in four of the product types between 2000 and 2010 (namely, refractory concrete and cement, tanning agents, printing inks and other types of products).

In the case of products that are manufactured in Sweden and contain inorganic chromium salts, the quantity of this material has increased in three of the product types between 2000 and 2010 (namely, metal surface coating agents, products to building industry and catalytic agents) and decreased in five (namely, paints (including raw material), wood preservation coatings, tanning agents, printing inks and other types of products).

Table A2-7-16: Amount of inorganic chromium salts in specific chemical products that are manufactured and imported in/to Sweden

Product Type	Quantity Imported (tonnes)			Quantity Manufactured (tonnes)		
	2000	2005	2010	2000	2005	2010
Paints incl. raw material	139	33	359	465	470	442
Wood preservation coatings	418	185	No data	<0.1	0	0
Refractory concrete & cement	378	191	163	No data	No data	<0.1
Tanning agents	276	152	28	<0.1	0	0
Metal surface coating agents	55	46	69	58	57	91
Raw material to plastic	11	163	No data	23	7	No data
Printing inks	<1	0	0	<1	0	0
Other types of products	40	22	4	2	7	<0.1
Products to building industry	0	0	4	0	0	5
Catalytic agents	0	0	5	0	0	<1

Source: https://apps.kemi.se/flodessok/floden/_flodenbild/floden.cfm?ID=412 (2000)
https://apps.kemi.se/flodessok/floden/_flodenbild/floden.cfm?ID=855 (2005)
https://apps.kemi.se/flodessok/floden/_flodenbild/floden.cfm?ID=1292 (2010)

A2.7 COPHES

A2.7.1 Introduction

The Consortium to Perform Human Monitoring on a European scale (COPHES)[217] and the feasibility study DEMOCOPHES (DEMOnstration of a study to COordinate and Perform Human bio-monitoring on a European Scale) provides data from national surveys that took place between September 2010 and November 2012. In the surveys, biomarkers for chemicals of concern were measured in the hair and urine of almost 400 mothers and children in 17 European countries. The COPHES and the feasibility study DEMOCOPHES have been able to demonstrate that a more coordinated and harmonised approach to Human Bio-Monitoring (HBM) in Europe is possible and can become an important tool to monitor the exposure of Europeans to chemical substances and address potential health effects that may derive from this exposure.

The results are reported in a final report and a technical report and published in the scientific literature (www.eu-hbm.info/euresult).

A2.7.2 Potential Indicators

The data from the study represent a snapshot for the years 2010 to 2012. The data can be used as a background level if future measurements are undertaken. Potential indicators are:

[217] www.eu-hbm.info/cophes

- Levels of mercury in human hair; and
- Levels of cadmium, bisphenol A and metabolites of phthalates in urine.

A2.7.3 Substances and Available Data

The **target** of the survey is the exposure of humans to chemical substances. The exposure is monitored by measuring the concentration of the selected chemicals in urine and hair (**subtargets**) with the data representing a snapshot for the years 2010 to 2012 (**temporal level**). So far, the HBM survey has been conducted at the national level or lower scale in 17 European countries (**spatial level**).

The following biomarkers have been surveyed as part of the DEMOCOPHES study:

- Mercury in hair;
- Cadmium in urine;
- Phthalates Metabolites: DEHP metabolites, MnBP, MBzP, MEP, MiBP in urine; and
- Bisphenol A in urine (only measured in 5 countries).

A2.8 Danish EPA Database on Substances in Consumer Products

A2.8.1 Introduction

The Danish Environmental Protection Agency (EPA) has constructed a database[218] of the Danish surveys of chemical substances in consumer products. In this database it is possible to search for reports made on a specific substance or for results within a given product type.

A2.8.2 Potential Indicators

The surveys are based on spot checks of products available on the Danish consumer market. The data are very scattered and not suitable as indicators.

A2.9 The Danish Database on Air Quality

A2.9.1 Introduction

Data from national monitoring of air quality in Denmark is collected by the Danish Centre for Environment and Energy (DCE) at Aarhus University under contract to the Danish Environmental Protection Agency[219].

The database contains results of measurements of various pollutants, namely NO_2, NO, CO, O_3, SO_2, particulates, As, Cd, S, Ni, Mn, Se, Pb, Benzene and Toluene at stations in Denmark, with these representing different locations/levels (street, forest, urban background, country, regional and coast).

[218] eng.mst.dk/topics/chemicals/consumers--consumer-products
[219] envs.au.dk/en/knowledge/air/monitoring/programmes/

A2.9.2 Potential Indicators

The air quality measurements could be used as a potential indicator, however, the measurement programme for data on air quality is set up with the purpose to obtain information on the pollutions from vehicle traffic. The data source is therefore not suitable to describe the air quality related to the use and emissions of chemicals specifically.

A2.10 The German Environmental Specimen Bank (ESB)

A2.10.1 Introduction

The Environmental Specimen Bank (ESB) is a tool to describe time trends of human and environmental exposure. The data bank is managed by the German Umweltbundesamt (UBA)[220] and based on results from analyses of the exposure of humans and the environment to chemicals in different ecosystems. Analyses have been undertaken annually since 1981 including measurements of heavy metal contents and organics in hair, blood, blood plasma, and urine as well as the measurement of heavy metal contents and organics in environmental species and compartments.

A2.10.2 Potential Indicators

The following provides a list of potential indicators that could be developed using the data bank to assist in informing the benefits that can be attributed to chemicals legislation:

- Changes in level of selected chemicals in humans (blood, blood plasma, urine, hair);
- Changes in level of selected chemicals in aquatic organisms; and
- Changes in level of selected chemicals in terrestrial organisms.

A2.10.3 Substances and Available Data

Data are available for 6 ecosystem types (**target**):

- Agrarian ecosystems;
- Ecosystems close to conurbations;
- Forestry ecosystems;
- Marine ecosystems;
- Nearly natural terrestrial ecosystems; and
- Riverine ecosystems.

The specimen types covered include (**subtargets**):

- Limnetic samples;
- Marine samples;
- Terrestrial samples; and
- Human samples.

A total of 15 sampling areas in Germany cover the major types of ecosystems in Germany and take into account the varying intensities of anthropogenic impact and land use (**spatial level**).

[220] www.umweltprobenbank.de/en/documents/investigations/analytes

Analytes that are the subject of investigation have been chosen to represent substances or groups of substances that describe either a basic physiological state or else toxic or carcinogenic conditions. The analytes include:

- Metals;
- Non-metals;
- Organometallic compounds;
- Chlorohydrocarbons;
- Polycyclic Aromatic Hydrocarbons;
- Phthalates;
- Bisphenol-A;
- Biocides;
- Perfluorinated compounds;
- Polycyclic musks;
- Alkylphenol compounds; and
- Hexabromocyclodecane.

Sampling has been undertaken annually since 1981 (**temporal level**) with quantitative measurements (**type of samples**) of relevant analytes for selected targets and specimens.

Metals (as Pb, Cd, Hg, Au, Pt and Ni), non-metals, phthalates, bisphenol-A, perfluorinated compounds, chlorohydrocarbons have been measured in humans (blood, blood plasma, urine, hair) over time. This includes quantitative measurements of metabolites of phthalates in urine. Figure A2-9 shows the results from 24h-sampling urine (Students) on Mono-(2-ethylhexyl) phthalate MEHP, a metabolite of DEHP.

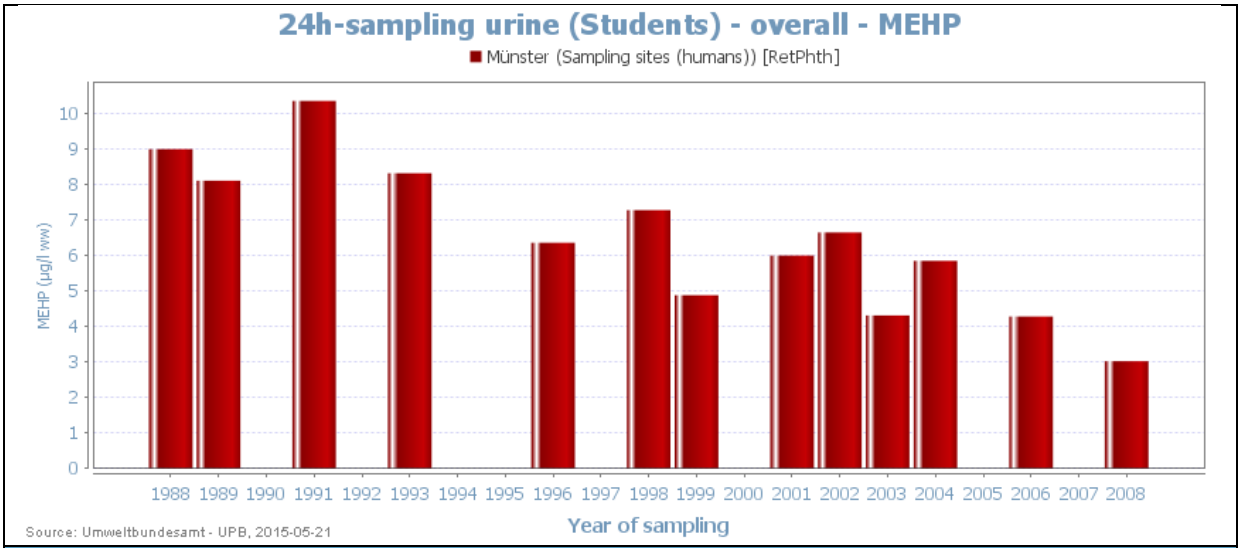


Figure A2-9: 24 hour Sampling of MEHP Urine of Students

Metals (as Cr, Fe, Co, Ni, Cu, Zn, Cd, Hg, Tl and Pb), non-metals, organometallic compounds, chlorohydrocarbons, polycyclic aromatic hydrocarbons, biocides, polycyclic musks, and alkylphenol compounds have been measured in limnetic ecosystems over time.

As an example, the presence of cobalt in the aquatic environment is monitored based on quantitative analysis of freshwater species in the river Donau, the second largest river in Europe. The analysis is undertaken on the soft body of zebra mussel and liver of bream and the

measurement unit is µg/g dw. Each measurement is based on 4-6 counts and results are given as arithmetic mean with standard deviation (as indicated in Figures A2-10 and A2-11).

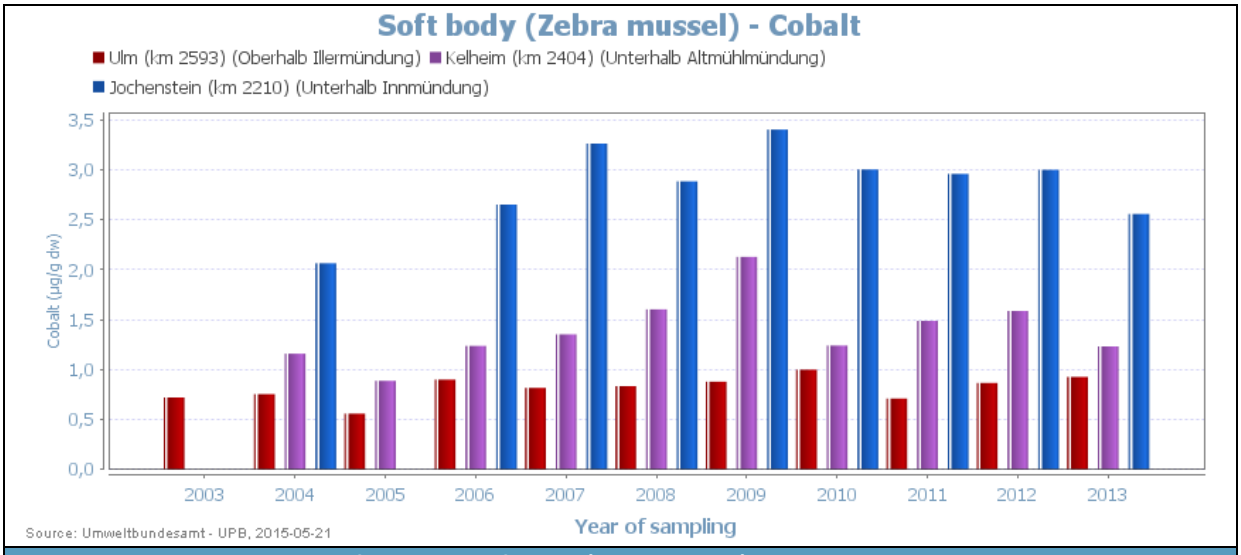


Figure A2-10: Measurement of Cobalt in Soft Body (Zebra mussel)

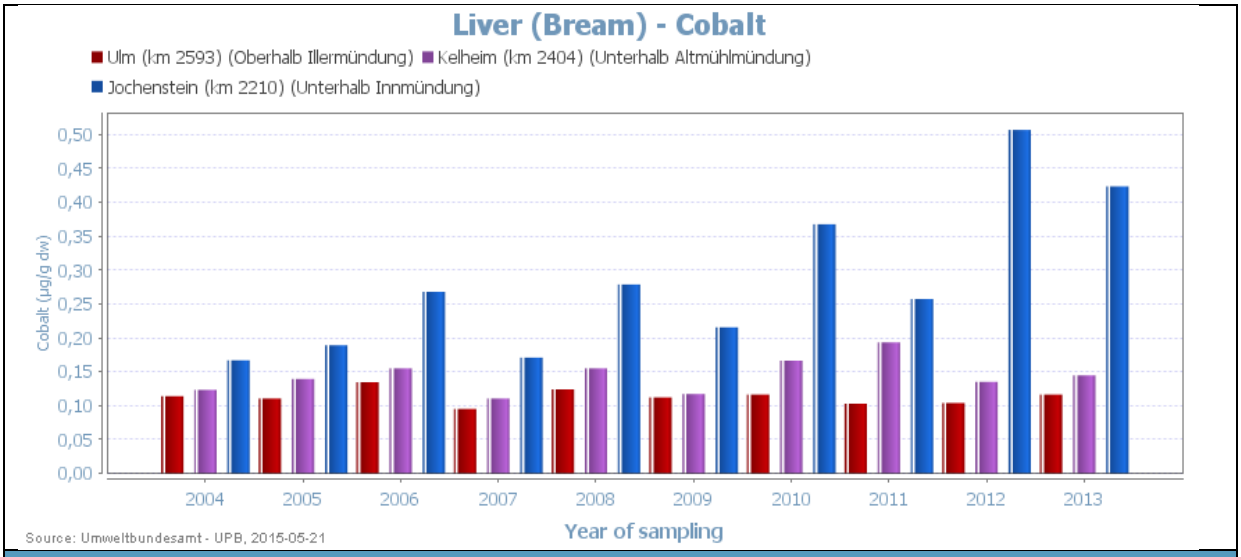


Figure A2-11: Measurement of Cobalt in Liver (Bream)

A2.11 FOREGS

A2.11.1 Introduction

The FOREGS - EuroGeoSurveys Geochemical Baseline Database[221] contains monitoring data for a number of European countries. Compartments included in the database include: stream water (filtered and unfiltered), stream/bank/floodplain sediment – mineral sediment, soil and humus.

It is not clear, if the database is updated on regular basis as there are no dates specified. The FOREGS database is therefore not straight-forward to use as an indicator, but it may well serve as a

[221] http://weppi.gtk.fi/publ/foregsatlas/index.php

good baseline study. A comparison of these data with a later similar monitoring study could be a very good indicator for legislation on emission reductions of heavy metals.

A2.12 ICES data portal

A2.12.1 Introduction

The International Council for the Exploration of the Sea (ICES) is a global organisation that develops science and advice to support the sustainable use of the oceans. The strategic partnership aims to understand the marine ecosystems in the Atlantic Ocean and in the Arctic, the Mediterranean Sea, the Black Sea, and the North Pacific Ocean. The ICES network includes over 350 marine institutes in 20 member countries. The ICES data portal[222] includes monitoring data from several years and for a large number of parameters (with a function allowing data to be searched and exported.

A2.12.2 Potential Indicators

The extensive datasets allow a range of potential environmental indicators to be developed. These include:

- Changes in biological communities;
- Changes in concentration levels of chemicals in marine organisms and sub-compartments; and
- Changes in biological effects.

A2.12.3 Substances and Available Data

Data are available for the Atlantic Ocean and in the Arctic, the Mediterranean Sea, the Black Sea, and the North Pacific Ocean (**spatial level**). Relevant data sets include (**targets, temporal level**):

- Biological communities (1979 to 2013);
- Contaminants and biological effects (1977 to 2014); and
- Eggs and larvae (1862 to 2013).

Matrices covered include water, sediment, organisms such as mussels and fish, organs of the organism (**sub targets**). The data sets represent data on a range of chemicals e.g. dioxins, chlorinated hydrocarbons, PAHs, pesticides and heavy metals. The parameter groups include the biological effects such as endocrine effects and toxicity.

A2.13 The Danish Natural Environment Portal

A2.13.1 Introduction

The Danish Natural Environmental Portal[223] holds data on the nature and the natural environment in Denmark. The portal is where data from the Danish authorities concerning nature and the natural environment is collected, presented and shared between different stakeholders.

[222] ecosystemdata.ices.dk/inventory/index.aspx
[223] http://www.miljoeportal.dk/English/Sider/default.aspx

The data includes area information, data on nature, soil pollution and water quality (surface water, groundwater). In order to obtain access to the database it is necessary to contact the Danish Natural Environmental Portal.

A2.13.2 Potential Indicators

Potential indicators include:

- Changes in concentration levels of chemicals in surface water, groundwater and in the terrestrial environment.

A2.13.3 Substances and Available Data

In order to obtain access to the database it is necessary to contact the Danish Natural Environmental Portal. Access to the database will reveal which substances are measured and for which targets.

A2.14 The European Health Examination Survey (EHES)

A2.14.1 Introduction

The European Health Examination Survey (EHES)[224] is a collaboration to collect nationally representative, high quality health data which are comparable between countries and over time. In the survey, information on key health indicators is collected. In the framework of the EHES pilot, 13 European Union Member States and one EFTA/EEA country have started preparing for a standardised national HES. During the pilot phase (2010 to 2011) these countries conducted a HES pilot to test the EHES standards in their country. The pilot survey was undertaken in 12 countries during July 2010 to May 2011.

A2.14.2 Potential Indicators

The key health indicators could be used potential indicators; however, health conditions are affected by many factors that are unrelated to chemicals regulation. Therefore these are not considered suitable as indicators for determining the benefits from chemicals regulation.

A2.15 The European Core Health Indicators (ECHI)

A2.15.1 Introduction

Under the Second Programme of Community Action in the Field of Health 2008-2013, the EU funded the Joint Action (JA) on European Community Health Indicators Monitoring (ECHIM). The ECHIM JA built on previous achievements and developed more precise definitions of the indicators and continued the implementation of the indicators in the Member States. One of the aims of the ECHIM was to consolidate and expand the ECHI[225] indicator system towards a sustainable health monitoring system in Europe supporting the EU Health Strategy. The work was carried out in close collaboration with Member States, the European Commission, Eurostat, WHO, OECD and other international

[224] www.ehes.info/index.html
[225] http://ec.europa.eu/health/indicators/echi/list/index_en.htm

organisations. The JA came to an end in June 2012 were the main result was a shortlist of 88 health indicators classified by policy areas, including environmental health.

A2.15.2 Potential Indicators

The environmental health indicators from the ECHI shortlist could be used as potential indicators in particular:

- Particulate Matter (PM) exposure implemented for PM10 and PM2.5 (ECHI 55).

Some more general health indicators could be used as potential indicators like:

- Disease-specific mortality implemented for death due to malignant neoplasms and all childhood cancer for age group 0-14 years (ECHI 13).

A2.16 The German Environmental Survey (GerES)

A2.16.1 Introduction

The German Environmental Survey (GerES)[226] is a nationwide population representative study on human bio-monitoring and external human exposure. The first German Environmental Survey took place between 1985 and 1986 and the latest study, GerES IV during the period 2003 to 2006[227]. The study GerES-V is currently taking place during the period 2014 to 2017.

A2.16.2 Potential Indicators

Potential indicators that could be used in determining the benefits of chemicals regulations are:

- Trends in internal human exposure to metals and xenobiotics;
- Trends of the present of xenobiotics in indoor air and dust; and
- Environmental impacts on the population as a whole.

A2.16.3 Substances and Available Data

The **target** of the surveys is humans with the focus changing from the exposure to pollution of adults to that of children (**subtargets**). The young generation, as represented by children and adolescents, is the target in the current environmental survey, GerES V.

The current GerES V study includes monitoring and investigation of the following (**type of samples**):

- Parabens, mercaptobenzothiazole, arsenic, metallic and inorganic mercury in urine;
- Metabolites of phthalates, PAHs, organophosphates and pyrrolidones in urine;
- Metals and organic substances in drinking water;
- Plasticisers and flame retardants in the vacuum cleaner bag;
- Volatile organic compounds (VOCs), formaldehyde and other carbonyls in the air;

[226] http://www.umweltbundesamt.de/en/topics/health/assessing-environmentally-related-health-risks/german-environmental-survey-geres

[227] Results are published in a report after end of study. The recent report, GerES IV, is available at: www.umweltbundesamt.de/en/publikationen/german-environmental-survey-for-children-200306

- Particulate matter in the indoor environment and outdoor air;
- PAH analysis of particulate matter indoors;
- Ultra-fine particles in the indoor environment; and
- Potential effects of dust particles in the indoor environment.

Children and adolescents aged 3 to 17 from more than 160 German cities and municipalities (**spatial level**) have been invited to participate in the survey in the period 2014 to 2017 (**temporal level**).

The **type of samples** is for example quantitative measurements of metals and xenobiotics including the measurements of metabolites of xenobiotics excreted with morning urine of 3 to 17 years old children.

A2.17 TNO-report R 2004/493

A2.17.1 Introduction

The TNO-report "R 2004/493 Man-made chemicals in human blood"[228] is a reported study sponsored by Greenpeace and completed in 2004. The objective of this study was to determine the presence of a number of chemicals in blood samples of volunteers in the Netherlands.

A2.17.2 Potential Indicators

The study reports the results of man-made chemicals in blood samples as a snapshot in 2004. The data can be used as a background level for future measurements; therefore the following information can be used as a potential indicator for determining the benefits of chemicals regulation:

- Level of man-made chemicals in human blood.

A2.17.3 Substances and available data

Samples of human blood (**sub-target**) collected from 100 volunteers in the Netherlands (**spatial level**) were analysed in 2004 (**temporal level**) for the following man-made chemicals:

- Bromated flame retardants (polybromated diphenyl ethers, hexabromocyclodecane, tetrabromobisphenol-A);
- Phthalates;
- Musk compounds (nitro musks, polycyclis musks);
- Organotin compounds;
- Alkylphenols;
- Alkylphenol ethoxylates; and
- Bisphenol-A.

[228] http://www.greenpeace.org/eu-unit/Global/eu-unit/reports-briefings/2009/3/man-made-chemicals-in-human-bl.pdf

Annex 3 The Brainstorming Workshop

A3.1 Structure of the Workshop

Presentations were given by the DG Environment Project Manager on the aims of the study, and by the study team on the progress made to date. The Project Manager set the context for the study, noting that it had been commissioned to help the balanced assessment of EU chemicals legislation, given that there are currently three studies underway focusing on the costs and the economic impacts of the legislation (cumulative costs assessment for the chemicals industry, impacts of REACH on international competitiveness of the EU industry and study on the regulatory fitness of the legislative framework (excluding REACH) governing the risk management of chemicals); moreover, the present project would stand alongside the REACH baseline study and will feed the REACH review process scheduled for 2017.

The project team then gave an overview of the methodology for the study and of the findings to date, highlighting key issues such as the challenges in ascribing changes in exposures and hence benefits to REACH or CLP given the interactions with other legislation. In addition, the team presented an overview of the types of databases and other information sources that are available to support the quantification of impacts across the different indicators.

A presentation was then given on the two different groupings identified by the study team for the indicators, in terms of their being top-down or bottom-up. It was explained that the top-down indicators reflected the legal provisions in place and tried to define indicators that provide an insight into whether a particular legal provision is delivering benefits; the bottom-up approach looks at the available statistics and data on the impacts of chemicals on human health and environment and tries to establish backwards linkages to the legal provisions.

A3.2 Break-out Session

The workshop then divided into four groups for a break-out session, facilitated by the study team. During this session, the Commission services participants were asked to rate the relative importance of the different criteria set out in Table 2-2, by allocating a total of 100 points. As a background to this exercise, the Likert scale set out in Table A3-1 was included in the background paper provided to participants prior to the workshop.

Participants were then asked as a group to score the indicators in terms of their "performance" against each criterion, on a scale from 1 to 5, with 1 "Poor" and 5 "Excellent". A short description of each indicator was made available to each group. The groups were asked to reach a consensus on the weights for the criteria, while for the scoring of the indicators a consensus was not required. Each group was asked to scrutinise around 15 indicators, with there being some overlap in the indicators considered by the groups. For example, all the groups discussed indicators referring to the REACH registration process and its generation of information: group 1 considered "availability of hazard data" and "No. of uses advised against" as specific and relatively relevant, while scoring high against all the other criteria; group 2 had to analyse "Changes in classification and labelling", "Number of new RMMs of increased stringency" and "Changes in PNECs", scoring all three indicators relatively high; group 3 discussed "Availability of use and exposure data", "Number of substances reclassified with a 'higher' or 'lower' classification" and "No. of newly identified PBTs or vPvBs"; Group 4 looked at "Registration of new chemicals" and "Changes in DNELs". Equally, all groups had

to discuss indicators referring to measurements of exposure to chemicals and indicators of the impacts of the chemicals' exposure in terms of human health and the environment.

The aim of the exercise was to generate discussion on what types of criteria should be given the most importance, and on how well the different indicators then performed against these criteria. The study team hoped that these discussions would help inform how they would further develop the analysis of the indicators before making final recommendations to the Commission.

Commission services representatives were also invited to suggest any indicator that had not yet been identified by the study, as well as any database / source of information that might be important for the success of this study.

Table A3-1: Scoring system for indicators

Specificity: How closely does the indicator match to the objective at EU level?	Quality of information: Is the data source robust?	Cost: How easy will it be to collect the data and what extent of additional analysis is required?	Confounding Factors: How significant are the confounding factors and how easily can these be addressed?
1. **Questionable**: tenuous fit with the objective and will inform on a non-EU level only	1. **Unreliable**: no apparent quality control in place	1. **Very high**: requires collection of new data through extensive monitoring/analysis or extensive surveys specifically to gather data	1. **Very high confounding**: many confounding factors that it will be difficult to address
2. **Limited**: limited fit with objective and may inform only on a non-EU level	2. **Borderline**: collecting organisation has some quality control measures in place, but no cross-checking is possible	2. **High**: requires collection of new data through additional monitoring/analysis (using existing methods) or surveys in co-operation with other organisations	2. **Some confounding**: some confounding factors with limited potential for correction
3.**Moderate**: reasonable fit with objective but may inform only on a non-EU level	3. **Reasonable**: some independent cross-checking of information is possible	3. **Medium**: requires collection of new data (monitoring or surveys) but this can be undertaken at little or no cost	3. **Moderate**: some confounding factors but with some potential for correction
4. **Good fit**: reasonable fit with objective and relates to EU relevant data	4. **High**: information collected by authoritative source but quality control unspecified	4. **Moderate**: data already collected, but significant additional analysis required	4. **Quite specific:** some confounding factors but they can be largely corrected
5. **Specific**: excellent fit for the objective and relates to EU specific data	5. **Robust**: information collection by authoritative source and is subject to recognised quality control	5. **Very low**: already collected on on-going basis in a usable format from a reliable source with no data protection issues.	5. **No confounding:** no confounding factors

A3.3 Importance of the Different Criteria

Within the time available for the scoring and weighting exercise, the groups were only able to complete the weighting component of the task. Although each group started the scoring part of the exercise, this was approached differently by the groups and was not completed. This was not considered to be an issue by the study team as the aim was not to generate an "answer" as to the most appropriate indicators, but to generate discussion on the indicators. The key conclusions of the group discussions are summarised below. The results of the weighting exercise are presented in Figure A3-1.

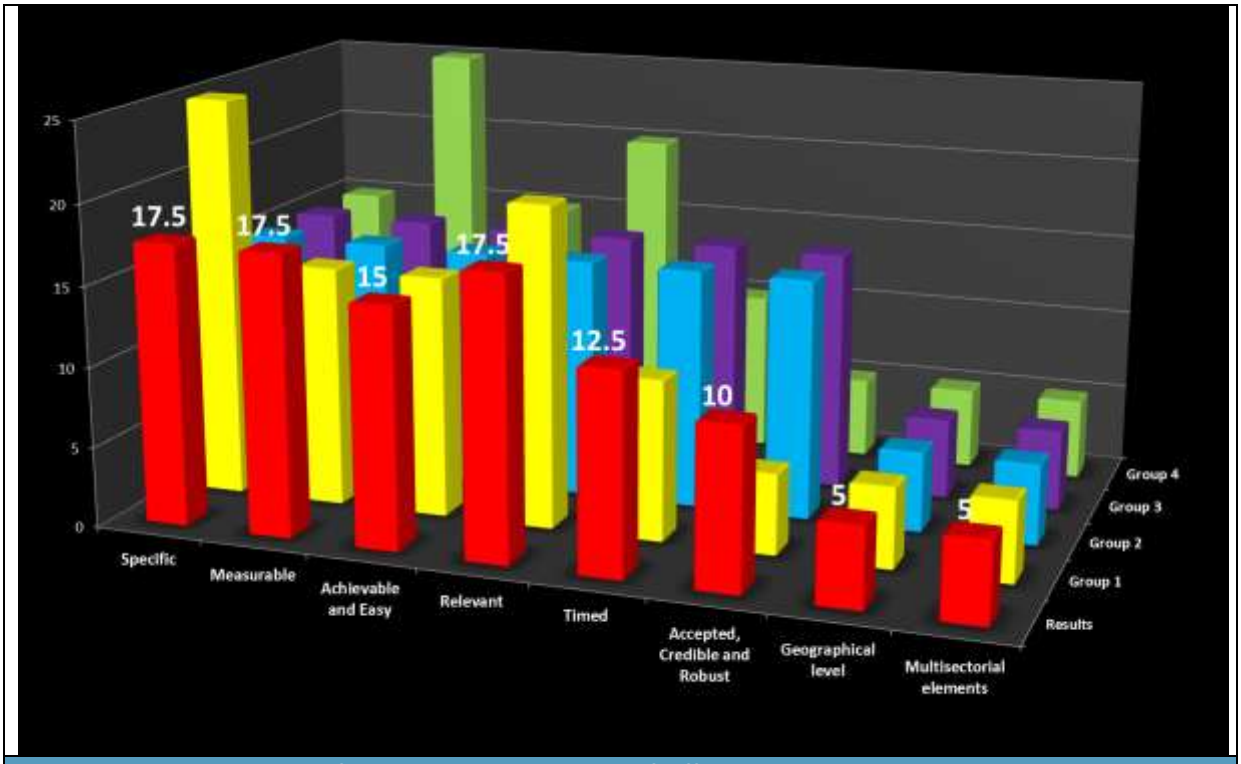


Figure A3-1: Group 1 results for the relative importance of different indicator selection criteria

Group 1 identified "specific" and "relevant" as the two most important criteria (at 25 and 20 out of 100 respectively, but also had difficulty in separating out the two concepts when discussing some of the indicators). "Measurable" and "achievable" were then the next important set of criteria (and of equal importance at 15 out 100) followed by "timed", "accepted" and "geographic level" (which were also considered of equal importance, at 10, 5 and 5 out of 100 respectively). With respect to "timed", it was noted that it is necessary to determine whether one wants to provide a one-off estimate of benefits or to establish longer term indicators, before finally agreeing on its importance. "Accepted" was noted as depending on whether one was focused on acceptability within the Commission Services (which may be important as it will be up to the Commission to communicate any indicator) or outside the Commission. The two criteria considered least relevant were multi-sectorial elements and geographic level. It was suggested that multi-sectorial elements should actually be combined into the criterion on specificity, and removed as a separate indicator. Geographic level was considered to have two components, one related to coverage and the other related to the resolution of the data (i.e. not just reflecting a generalised average).

Groups 2 and 3 also believed that the geographical level and the multi-sectorial elements should have a very low weight. They felt that all of the other criteria are important, and thus should be assigned similar weights.

There was a general consensus within Group 4 that the last three criteria (acceptability, credibility and robustness, geographical level and multisectoral elements) were of less importance than the other criteria. This group felt that measurability was the most important criterion (weight of 25), followed by relevance and specificity. The group decided not to assign a very high weight to "relevance" in order not to eliminate some of the indicators, which may be important in specific cases.

Based on the views expressed by the four groups, specificity, measurability and relevance (with an average weight of 17.5) would appear to be the three most important criteria for the selection of the indicators, followed by achievability, ease of gathering the necessary data (with an average weight of 15) and the time dimension of the data (criterion closely linked to the data availability). Acceptability, credibility and robustness characteristics of the indicators were considered of relative importance as they are dependent on the performance of the indicators against the other criteria.

A3.4 Scoring the Indicators Against the Criteria

Although not all of the groups completed the scoring exercise, all of the groups discussed the nature of the indicators proposed, how to better define them and whether data were available or achievable and easy to obtain.

Group 1 and 4 completed the scoring exercise, although when an indicator was considered to score very low against a key criterion, the scoring was not completed against all the criteria. For example, group 1 did not score change in soil biodiversity, as it was agreed quickly that this was not measurable, specific or an achievable indicator. Group 2 and 3 preferred not to proceed with the scoring of each indicator, while still discussing their performance against the criteria.

Group 1 felt that some of the top-down administrative indicators were actually very important and that they should be included within the overall set of indicators. It was agreed that there was a need for both process (top-down) and impact (bottom-up) indicators, and that these should complement each other. Group 3 reached a similar conclusion, highlighting that there is a need to strike a balance between these two types of indicators. Group 1 also argued that the scope of the indicators should be broadened beyond REACH and CLP, as this would enable the use of a wider set of environmental monitoring data. In particular, it would enable the use of data that reflected performance of combined legislation where these worked together with REACH and CLP, with a key example being the Water Framework Directive and the water quality and biota monitoring that is to be undertaken at the MS level as part of compliance.

Group 2 concluded that the more specific an indicator is, the more credible it is. They also felt that the indicators should be widely accepted by experts rather than easy to interpret for non-experts. In this respect, the indicators should be specific targeted indicators and not debatable. Furthermore, the group believed it was important for there to be indicators for which trend data existed. If one is to clearly demonstrate the benefits of chemicals legislation, then the availability of comparable data/figures over time are important. In addition, it was agreed that indicators on exposure levels are preferable to those that cannot easily be linked to exposures. However, the group also felt that indicators on the related impacts may be affected by confounding factors and, therefore, should be investigated in separate epidemiology studies; for specific regions though, it may be possible to link effects to the exposure.

This latter set of views has some implications for this study. If the study does not try and make linkages between exposures/emissions and effects, then it is not possible to provide quantitative estimates of impacts, and to then value these in monetary (or other terms). Such an approach is in contrast with part of the aims of this study, which is to provide quantitative monetary estimates of the benefits of chemicals legislation. It therefore suggests that it may be important for this study to recommend exposure/emission indicators regardless of whether they can or cannot be valued in monetary terms; The project team could define sub-indicators referring to specific chemicals for which there is enough evidence to support linkages between exposures/emissions and effects.

Group 3 concluded that there is a need for indicators that reflect both outputs of the regulatory processes (based on a top-down approach) and impacts/results (reflecting a bottom-up approach). They also noted that there is a need to strike a balance between these two types, as they are both important. As for Group 2, the time aspect is also considered to be important when selecting indicators to benchmark benefits / impacts of chemicals legislation.

Group 4 discussed the potential of some of the output indicators that were suggested. For example, the indicators "Registration of new chemicals" and "Changes in DNELs", although scored highly for most of the criteria, were deemed of poor relevance for the purpose of establishing a causal link between chemicals legislation and the reduced effects on the environment and/or the human health. In contrast, of more value along the same lines would be a results-based indicator on the "production of environmentally harmful chemicals, by environmental impact class" if it referred to SVHCs. With regard to impact indicators, "occupational skin diseases" was considered to be a good indicator, as it is more closely correlated to exposure to chemicals than other indicators defined in relation to other health end-points. Other impact indicators were rejected for being too broad, not directly reflecting impacts, etc.

Table A3-2 provides the outputs of the scoring exercise. Group 1 and 4 scores are those that have been discussed during the brainstorming workshop, while the scores presented for group 2 and 3 have been assigned by the project team on the basis of the conclusions of those groups.

A3.5 Further assessment by the study team

Indicatively, we have taken 300 as a cut-off value in terms of the resulting total weighted scores for identifying those indicators that may be the most useful for the purposes of this study. However, it is important to note that the weighting and scoring exercise has been used by the project team as a mean for triggering the discussion over the indicators rather than as the final tool for their selection and prioritisation.

Moreover, although some of the indicators as defined and presented during the workshop did not score highly, the groups discussed how to improve them, for example by better defining their specificity or suggesting the necessary data that, if available or achievable, would make them very relevant for the scope of the study. For example, group 1 assigned poor scores to "Death caused by cancer" and "Change in incidence of chemically-related occupational disease". In particular, "Death caused by cancer" was considered too broad and unspecific, as it may be more influenced by medical innovations and interventions (and lifestyle factors) rather than chemicals legislation. However, the group highlighted that, if better defined (considering both morbidity and mortality, and making explicit links between specific types of cancer and exposures to specific substances), the indicator could provide a good illustration of the effects of the chemicals on human health and the environment and, subsequently, of the benefits of chemicals legislation in avoiding/reducing these effects.

In contrast, although some indicators resulted in high total weighted scores, they were considered not to be as valuable for the purposes of this study, scoring highly against less important criteria but scoring poorly against one of the key criteria, as identified during the brainstorming workshop. For example, "Incidence of childhood leukaemia", although very specific and measurable thanks to timed data already being available on the regional geographic level, scored poorly on relevance and therefore on acceptability, credibility and robustness, as the linkage between childhood leukaemia and chemicals' exposure is still debated[229].

Table A3-2 highlights in green those indicators to be considered further based on their scoring and the discussions of the groups during the brainstorming workshop; indicators highlighted in pale red are those that received low overall scores or that have been discarded because they perform poorly against some of the key criteria.

[229] Known risk factor is ionizing radiation. There are several studies linking pesticides' exposure of parents and children to leukaemia (e.g. Van Maele-Fabry, Lantin, Hoet Lison, 2011; Turner, Wigle and Krewski, 2009; Menegaux et al, 2006). Other studies suggest exposure to solvents, paints and benzene as potential risk factors (e.g. Ross et al, 1994; Colt and Blair, 1998).

Table A3-2: Indicators scoring for potential use as a Key Indicator or as part of a Key Indicator									
	Weighted score	Specific	Measurable	Achievable and Easy	Relevant	Timed	Accepted, Credible and Robust	Geographical level	Multisectorial element
Group 1 - weights	**Total**	**25**	**15**	**15**	**20**	**10**	**5**	**5**	**5**
1 Availability of hazard data	455	5	5	5	3	5	4	5	5
2 Risk and Quality Indicator System	-	0	-	-	-	-	-	-	-
3 No. of "uses advised against"	380	4	4	2	4	5	2	5	5
4 Death caused by cancer	280	1	2	5	2	5	2	5	5
5 Change in incidence of chemically-related occupational disease	200	3	2	1	2	2	2	1	1
6 Change in industry expenditure on local and general ventilation equipment	390	3	4	5	4	5	4	3	3
7 Percentage of employed people absent from work in reference week due to own illness, injury or temporary disability	-	0	-	-	0	-	-	-	-
8 Changes in use patterns in Scandinavia	390	3	4	5	4	5	4	3	3
9 Change in tissue levels of chemicals of concern in the EU population	450	5	5	5	5	3	5	2	2
10 POPs level in breast milk (DDE, DDT, HCB, PBDE, PCB, and PCN)	440	5	5	5	5	2	5	2	2
11 Animal testing: use of QSARs, read-across and waiving options	-	-	-	-	0	-	-	-	-
12 Species diversity	265	4	3	1	2	3	2	3	2
13 Change in population / numbers of species with established susceptibility to chemical pollution	-	-	0	0	-	-	-	-	-
14 Change in levels of selected chemicals in tissue samples of aquatic species	450	5	5	5	5	3	5	2	2
15 Change in soil biodiversity	-	0	0	0	-	-	-	-	-
Group 2 - weights		**15**	**15**	**15**	**15**	**15**	**15**	**5**	**5**
1 Changes in classification and labelling	315	4	2	2	5	2	5	1	1
2 Concentration of dioxins in breast milk and blood	345	5	5	3	2	2	2	3	3
3 No. of substances withdrawn from the market due to hazard properties	250	2	2	1	5	2	2	3	2
4 Change in number and consumption levels of substances of concern	255	1	2	3	5	2	3	2	2
5 Change in number of prescriptions for chemically-related occupational diseases	370	5	4	2	5	2	4	2	1
6 Number of new RMMs of increased stringency	330	3	3	2	5	3	4	3	3
7 Production of toxic chemicals	365	4	4	4	3	4	2	4	3

Table A3-2: Indicators scoring for potential use as a Key Indicator or as part of a Key Indicator									
	Weighted score	Specific	Measurable	Achievable and Easy	Relevant	Timed	Accepted, Credible and Robust	Geographical level	Multisectorial element
8 Estimate of the burden of disease	270	3	2	2	4	2	2	2	3
9 Number of national emergency actions taken relating to human health (under Article 129)	355	4	5	3	3	4	2	4	1
10 Levels of lead in children´s blood	450	5	5	3	5	4	5	5	3
11 Changes in PNECs	370	5	3	3	5	2	5	1	1
12 A - Pollutants in the terrestrial urban environment; B - Bioaccumulative toxic organic pollutants and mercury in birds and eggs	290	3	3	3	3	2	3	3	3
13 Change in population levels of chemical induced non-lethal effect in wildlife species	290	3	3	2	4	2	3	2	3
14 Change in levels of selected chemicals in waste sludge samples	460	5	5	4	5	4	4	4	4
Group 3 - weights		15	15	15	15	15	15	5	5
1 Availability of use and exposure data	325	4	3	3	4	3	3	1	1
2 Number of substances reclassified with a 'higher' or 'lower' classification	315	4	2	2	5	2	5	1	1
3 No. of hazardous substances removed from articles due to "announcement effect"	285	5	1	1	5	1	2	1	1
4 Changes in quality of safety data sheets	200	2	1	1	4	2	2	1	1
5 Change in the number of chemical accidents involving exposure of workers	225	2	2	2	3	2	3	2	2
6 Proportions of workers in the industrial sectors or occupations who were exposed to carcinogens	185	2	2	1	2	2	2	2	2
7 Cross-border transport of toxic chemicals	115	1	2	1	1	1	1	1	1
8 Change in the numbers of the public affected by chemical incidents	235	4	1	1	2	3	1	3	3
9 Phthalates in humans	440	5	5	3	5	4	5	5	1
10 Incidence of childhood leukaemia	370	5	5	4	2	4	1	4	1
11 No. of newly identified PBTs or vPvBs	460	5	5	5	5	5	5	1	1
12 River quality; lead, cadmium, chromium and copper	500	5	5	5	5	5	5	5	5
13 Change in levels of selected chemicals in ambient air samples	425	4	5	5	3	5	3	5	5
14 Change in levels of selected chemicals in tissue samples of terrestrial species	415	4	5	3	5	3	5	4	4

Table A3-2: Indicators scoring for potential use as a Key Indicator or as part of a Key Indicator									
	Weighted score	Specific	Measurable	Achievable and Easy	Relevant	Timed	Accepted, Credible and Robust	Geographical level	Multisectorial element
Group 4 - weights		15	25	15	20	10	5	5	5
1 Registration of new chemicals	420	5	5	5	1	5	5	5	5
2 Changes in DNELs	365	5	5	5	1	5	2	1	1
3 Introduction of alternative substances to replace chemicals of concern	-	4	5	1	0	0	-	-	-
4 Occupational skin diseases	425	4	4	4	5	5	5	5	1
5 Change in industry expenditure on protective gloves	-	0	1	1	1	1	1	-	-
6 Percentage of employees thinking that their health or safety is at risk because of work	-	1	-	-	-	-	-	-	-
7 Toxic chemicals in households	-	-	-	-	0	-	-	-	-
8 Change in usage of chemicals of concern in consumer products	230	3	2	2	3	1	2	2	1
9 Metals, phthalates, parabens, polycyclic aromatic hydrocarbons (PAH) and pyrrolidones in humans over time	415	5	5	3	5	2	5	3	2
10 Production of environmentally harmful chemicals, by environmental impact class	-	-	-	-	1	-	-	-	-
11 Cobalt in the aquatic environment (fresh water)	-	-	-	-	-	-	-	-	-
12 Development of concentration level of organofluorines in marine organisms	-	-	-	-	-	-	-	-	-
13 Change in levels of selected chemicals in water and sediment samples	425	5	5	3	5	3	4	3	3
14 Change in levels of selected chemicals in tissue samples of aquatic species	405	5	5	3	4	3	4	3	3

A3.6 List of Indicators

This Annex presents the list of indicators presented at the brainstorming workshop and identified through the screening of the literature and the data sources. The indicators have been grouped by impact area (general, workers' health, public human health and the environment) for presentation purposes, however many of them overlap and it was one of the objectives of this workshop to define how to better group the indicators to ensure the full coverage of the impact areas and to minimise overlaps.

General indicators

1. Availability of hazard data
2. Changes in classification and labelling
3. Availability of use and exposure data
4. Registration of new chemicals
5. Risk and Quality Indicator System
6. Concentration of dioxins in breast milk and blood
7. Number of substances/ mixtures reclassified with a 'higher' or 'lower' classification
8. Changes in DNELs
9. No. of "uses advised against"
10. No. of substances withdrawn from the market due to hazard properties
11. No. of hazardous substances removed from articles due to "announcement effect"
12. Introduction of alternative substances to replace chemicals of concern
13. Death caused by cancer
14. Change in number and consumption levels of substances of concern

Workers' health indicators

15. Changes in quality of safety data sheets
16. Occupational skin diseases
17. Change in incidence of chemically-related occupational disease
18. Change in number of prescriptions for chemically-related occupational diseases
19. Change in the number of chemical accidents/ incidents involving exposure of workers
20. Change in industry expenditure on protective gloves
21. Change in industry expenditure on local and general ventilation equipment
22. Number of new RMMs of increased stringency
23. Proportions of workers in the industrial sectors or occupations who were exposed to the carcinogens
24. Percentage of employees thinking that their health or safety is at risk because of work
25. Percentage of employed people absent from work in reference week due to own illness, injury or temporary disability

Public human health indicators

26. Production of toxic chemicals
27. Cross-border transport of toxic chemicals
28. Toxic chemicals in households
29. Changes in use patterns in Scandinavia
30. Estimate of the burden of disease

31. Change in the numbers of the public affected by chemical incidents
32. Change in usage of chemicals of concern in consumer products
33. Change in tissue levels of chemicals of concern in the EU population
34. Number of national emergency actions taken relating to human health (under Article 129)
35. Phthalates in humans
36. Metals, phthalates, parabens, polycyclic aromatic hydrocarbons (PAH) and pyrrolidones in humans over time
37. POPs level in breast milk (DDE, DDT, HCB, PBDE, PCB, and PCN)
38. Levels of lead in children´s blood
39. Incidence of childhood leukaemia

Environmental indicators

40. Production of environmentally harmful chemicals, by environmental impact class
41. Animal testing: use of QSARs, read-across and waiving options
42. Changes in PNECs
43. No. of newly identified PBTs or vPvBs
44. Cobalt in the aquatic environment (fresh water)
45. Species diversity
46. A - Pollutants in the terrestrial urban environment; B - Bioaccumulative toxic organic pollutants and mercury in birds and eggs
47. River quality; lead, cadmium, chromium and copper
48. Development of concentration level of organofluorines in marine organisms
49. Change in population / numbers of species with established susceptibility to chemical pollution
50. Change in population levels of chemical induced non-lethal effect in wildlife species to chemical pollution
51. Change in levels of selected chemicals in ambient air samples
52. Change in levels of selected chemicals in water and sediment samples
53. Change in levels of selected chemicals in soil samples
54. Change in levels of selected chemicals in waste sludge samples
55. Change in levels of selected chemicals in tissue samples of terrestrial species
56. Change in levels of selected chemicals in tissue samples of aquatic species
57. Change in soil biodiversity

A3.7 Classification of Indicators

The "indicator classification cards" (presented below) were provided by the project team to the participants to the brainstorming workshop to facilitate the weighting and scoring exercise. Some fields were intentionally left blank, as their completion will be one of the outputs of the workshop (for example, with regard to the acceptability, credibility and robustness of the indicators).

Therefore, the list of indicators and their classifications should not be considered as definitive.

1. Name of indicator: Availability of hazard data	
Short description: Refers to all substances that have to be registered according to REACH.	
Data needed: The REACH Baseline study uses the following data: • Total number (and %) of substances for which data on toxicity and/or PBT properties are available. • Substances with a production volume between 1 and 10 tonnes/year: number (and percentage) of substances with the complete Annex V data set/number (and percentage) of substances with a reduced data set (PC properties only) (section 7). • The baseline (situation 2007) uses endpoint-specific availability of data according to Allanou et al, 1999/RPA & Statistics Sweden 2002.	
Type of data	Quantitative
Specific	Hazard data are provided on the human health and environmental impacts of registered chemicals.
Measurable	ECHA stores all hazard data on its website portal.
Achievable and Easy	Data available from European Chemicals Agency (ECHA), IT tools REACH-IT and IUCLID 5.
Relevant	Focuses on REACH.
Timed	Aim to measure the improvement introduced by REACH.
Accepted, Credible and Robust	Proposed in the REACH Baseline study.
Geographical level	EU-28.
Multisectorial elements	-

2. Name of indicator: Changes in classification and labelling	
Policy issue: Classification and labelling of hazardous chemicals	
Short description: Classification and labelling data for different substances	
Data needed: The proportions of new and existing substances classified as dangerous	
Type of data	Quantitative with elements of qualitative.
Specific	An increase in data on the properties of substances due to REACH will lead to an increase in classification and labelling.

2. Name of indicator: Changes in classification and labelling	
Measurable	Classification and labelling data is stored and monitored by the European Chemicals Agency (ECHA).
Achievable and Easy	Data sources include the European Chemicals Agency (ECHA), IT tools REACH-IT and IUCLID 5. REACH Baseline study indicates that there is poor availability of data on existing substances.
Relevant	This indicator is directly related to various EU Chemicals regulation (e.g. CLP/GHS).
Timed	This indicator is timed in that first notifications made to the Inventory (2010 latest) can act as a starting point, with further deadlines in 2015 and then in line with the 2018 REACH registration date.
Accepted, Credible and Robust	Proposed by the REACH Baseline study.
Geographical level	Regional.
Multisectorial elements	-

3. Name of indicator: Availability of use and exposure data	
Policy issue: Regulation of harmful substances	
Short description: REACH requires an exposure assessment and a risk description within the chemical safety report.	
Data needed: The REACH Baseline study uses the following information for this indicator: • Total number (and percentages) of substances with information on use pattern • Total number (and percentages) of substances with a CSR • Total number (and percentages) of substances with a CSR including exposure assessment and risk Characterisation.	
Type of data	Quantitative
Specific	The indicator relates directly to the number of substances which have an exposure assessment and risk characterisation.
Measurable	See *data needed.*
Achievable and Easy	Data is available from European Chemicals Agency (ECHA), IT tools REACH-IT and IUCLID 5.
Relevant	The indicator is directly linked to the REACH requirements. Due to these requirements, a large increase in the amount und quality of data on use and exposure is expected.
Timed	Indicators can be linked to key REACH registration deadlines.
Accepted, Credible and Robust	Proposed by the REACH Baseline study.
Geographical level	EU-28
Multisectorial elements	-

4. Name of indicator: Registration of new chemicals
Policy issue: Chemicals regulation

4. Name of indicator: Registration of new chemicals	
Short description: Registration of new or existing chemicals under REACH	
Data needed: Number of registrations	
Type of data	Quantitative
Specific	Refers to the registration of new and existing chemicals. However, from registrations alone it is not possible to specify the hazardous properties of such chemicals. This indicator will therefore have to be used conjointly with other indicators that inform of the properties of such chemicals.
Measurable	The number of registrations are recorded by ECHA and published through its website
Achievable and Easy	Data available from European Chemicals Bureau (ECB), in future: European Chemicals Agency (ECHA).
Relevant	The trend in the number of registrations is directly related to the REACH chemicals regulation. This indicator is intended to provide an indication of whether the regulation has impacted upon the introduction of new chemicals.
Timed	Indicators can be linked to key REACH registration deadlines.
Accepted, Credible and Robust	Proposed by the REACH Baseline study.
Geographical level	EU-28
Multisectorial elements	-

5. Name of indicator: Risk and Quality Indicator System	
Policy issue: Increased risk due to exposure to harmful chemicals	
Short description: Intended to link two of the main objectives of REACH, the reduction in nominal risks of chemicals for humans and the environment and the improvement in the quality of publicly available data. The system is assessed on the basis of a defined sub-set of 237 substances. The system comprises two scores (risk and quality) for different impact areas (e.g. consumers, environment etc.) and is based on a number of individual indicators.	
Data needed: The Risk and Quality Indicator System is based on the evaluation of data from registration dossiers: • information on toxicity data: usually reference doses/concentrations (DNELs and PNECs) or classification and labelling information • exposure data for the four impact areas, assessed in Chemical Safety Reports (CSRs) • the basis for these data in order to assess the quality • tonnage and detailed use information. The risk and quality scores are provided in the REACH Baseline reports.	
Type of data	Quantitative in the form of nominal risk scores: Nominal Risk Score = RCR x Population Risk Modifier (x Severity Modifier*)
Specific	The Risk and Quality Indicator system is specific to the REACH chemicals regulation
Measurable	It is measured and published in REACH baseline reports. These reports also provide annexes with information regarding the

5. Name of indicator: Risk and Quality Indicator System	
	derivation of risk and quality scores
Achievable and Easy	The Risk and Quality scores are aggregates based on a number of different individual indicators. While the papers provide information on the methodology used to calculate the scores, it could be a very time consuming process and may not be justified by the insights gained. So far only two REACH Baseline studies have been published that provide risk and quality scores.
Relevant	Focuses on REACH.
Timed	Unclear as only two studies have been published: one in 2009 (using data from 2007, the baseline) and another in 2012 (5 year update)
Accepted, Credible and Robust	Proposed by the REACH Baseline study.
Geographical level	Regional (EU)
Multisectorial elements	Covers different areas

6. Name of indicator: Concentration of dioxins in breast milk and blood	
Policy issue: Regulation of environmental pollutants	
Short description: Dioxins are a group of chemically-related compounds that are persistent environmental pollutants (POPs). More than 90% of human exposure is through food, mainly meat and dairy products, fish and shellfish. Many national authorities have programmes in place to monitor the food supply.	
Data needed: Samples of breast milk and blood	
Type of data	Quantitative
Specific	The indicator relates directly to EU regulations on the limits of dioxins in foodstuffs.
Measurable	The indicator is based on measured data, and also will reflect temporal changes.
Achievable and Easy	Data sources are known, reliable and publicly available. Examples of data sources: WHO is responsible for the Global Environment Monitoring System's Food Contamination Monitoring and Assessment Programme. Commonly known as GEMS/Food, the programme provides information on levels and trends of contaminants in food through its network of participating laboratories in over 50 countries around the world.
Relevant	It is relevant for establishing the link between chemicals legislation and reduced effects on the environment and human health.
Timed	Regular annual sampling periods.
Accepted, Credible and Robust	Data derived directly from WHO sources that are subject to rigorous quality assurance procedures.
Geographical level	Regional, over 50 countries participating in the WHO data collection.
Multisectorial elements	Looks at a variety of products from meat products to fruit and vegetables.

7. Name of indicator: Number of substances/ mixtures reclassified with a 'higher' or 'lower' classification
Policy issue: Regulation of chemicals through CLP

7. Name of indicator: Number of substances/ mixtures reclassified with a 'higher' or 'lower' classification	
Short description: The CLP Regulation ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the European Union through classification and labelling of chemicals. This indicator looks at the number of substances that have been reclassified under this regulation.	
Data needed: Data on the number of substances reclassified	
Type of data	Quantitative
Specific	CLP specific indicator
Measurable	No existing collated data is available and would be difficult to measure from the C & L database or supplemented with a survey.
Achievable and Easy	Data is available from C&L Database. Very few confounding factors. However, as mentioned it would be very difficult (and possibly unfeasible) to analyse all changes in classification.
Relevant	The data would be directly relevant to the CLP regulation; however it would be difficult to ascertain and quantify the potential benefits
Timed	Database is updated regularly but changes in classification are not timed/dated
Accepted, Credible and Robust	-
Geographical level	Regional (EU-28)
Multisectorial elements	-

8. Name of indicator: Changes in DNELs	
Policy issue: Chemicals regulation under REACH and improved information on chemicals risks	
Short description: Under REACH there is a requirement for health-based derived no-effect levels (DNELs) to be established for occupational (and non-occupational) exposure to chemicals produced or imported into Europe in annual quantities above 10 tonnes. The DNELs apply to all routes of exposure (oral, dermal or inhalation) and all populations (workers, consumers, people indirectly exposed like children or pregnant women). They are used to establish risk management measures that must be communicated to the downstream users.	
Data needed: Quantitative estimates of the changes in DNELs	
Type of data	Quantitative
Specific	REACH specific indicator
Measurable	No existing collated data is available. Measurement would require analysis of a large number of safety datasheets which could be deemed unfeasible.
Achievable and Easy	As no existing collated data is available and measurement is particularly difficult, this indicator can be deemed relatively unfeasible
Relevant	This indicator is relevant to the REACH Regulation but it is not possible to accurate determine the benefits that arise from changes in DNELs
Timed	Safety datasheets are uploaded regularly but it is not possible to determine the timing of changes
Accepted, Credible and Robust	-
Geographical level	Regional (EU-28)
Multisectorial elements	-

9. Name of indicator: No. of "uses advised against"	
Policy issue: Chemicals regulation under REACH and improved information on chemicals risks	
Short description: As a requirement for safety datasheets, suppliers must indicate the relevant identified uses of a substance. Uses advised against and reasons why must be given if applicable.	
Data needed: Quantitative estimates of the change in the number of uses advised against derived from safety data sheets	
Type of data	Quantitative
Specific	REACH specific indicator
Measurable	The large number of safety datasheets makes measurement unfeasible
Achievable and Easy	As stated this indicator is difficult to measure and therefore not easily achievable
Relevant	Somehow relevant for establishing the link between the chemicals legislation and the reduction in chemicals' exposure
Timed	Safety Data Sheets are uploaded regularly but it is not possible to determine the timing of changes
Accepted, Credible and Robust	-
Geographical level	Regional (EU-28)
Multisectorial elements	-

10. Name of indicator: No. of substances withdrawn from the market due to hazard properties	
Policy issue: Chemicals regulation under REACH and improved information on chemicals risks	
Short description: REACH aims to restrict chemicals from the market with properties that are hazardous to human health and the environment. This indicator aims to measure the number of substance that have been withdrawn from the market prior as a result of the REACH regulation.	
Data needed: Quantitative estimates of the number of substances withdrawn from the market due to their hazardous properties	
Type of data	Quantitative
Specific	REACH specific indicator
Measurable	Very difficult to measure as there are a number of reasons why substances are withdrawn from the market
Achievable and Easy	As stated this indicator is difficult to measure and therefore not easily achievable
Relevant	This indicator could help in establishing the link between the action of the chemicals legislation and the reduction in chemicals' exposure
Timed	The next registration deadline is 31 May 2018. The previous deadline was 2010, so it may be possible to measure some difference between these dates.
Accepted, Credible and Robust	-
Geographical level	Regional (EU-28)
Multisectorial elements	-

11. Name of indicator: No. of hazardous substances removed from articles due to "announcement effect"	
Policy issue: Chemicals regulation under REACH and improved information on chemicals risks	
Short description: Announcement of potential substances for authorisation on a publicly available candidate list might provide an incentive for producers and users of these substances to start proactively looking for safer substitutes.	
Data needed: Quantitative estimates of the number of substances removed from articles due to the "announcement effect"	
Type of data	Quantitative
Specific	REACH specific indicator
Measurable	Very difficult to measure as there are a number of reasons why substances are withdrawn from the market
Achievable and Easy	As stated this indicator is difficult to measure and therefore not easily achievable
Relevant	This indicator could help in establishing the link between the action of the chemicals legislation and the reduction in chemicals' exposure
Timed	May be difficult to ascertain when substances were withdrawn from the market due to the announcement effect
Accepted, Credible and Robust	-
Geographical level	Regional (EU-28)
Multisectorial elements	-

12. Name of indicator: Introduction of alternative substances to replace chemicals of concern	
Policy issue: Chemicals regulation under REACH	
Short description: One of the key aims of REACH is to move towards the use of alternative chemicals that have no/reduced impact on human health and the environment. This indicator aims to measure the number of alternatives introduced as a result of REACH.	
Data needed: Estimates of the number of hazardous chemicals replaced by safer alternatives	
Type of data	Quantitative
Specific	While this indicator is related to REACH, it may be difficult to ascertain whether chemicals are substituted due to the regulation or not
Measurable	The large number of substances on the EU market makes measurement of this indicator particularly difficult
Achievable and Easy	As stated this indicator is difficult to measure and it is not easily applicable to a specific regulation. As a result it can be considered not easily achievable. A new survey or case study approach may be the only way forward as suggested in RPA (2009)
Relevant	This indicator could help in establishing the link between the action of the chemicals legislation and the reduction in chemicals' exposure
Timed	It cannot easily be tracked through the time period
Accepted, Credible and Robust	-
Geographical level	Regional

12. Name of indicator: Introduction of alternative substances to replace chemicals of concern	
Multisectorial elements	-

13. Name of indicator: Death caused by cancer	
Policy issue: Regulation of carcinogenic substances (REACH Regulation (Authorisation, Restriction), CLP, and regulation on use of carcinogenic substances in the working environment).	
Short description: This indicator presents data on deaths from cancer.	
Data needed: Data on mortality rates and cause of death	
Type of data	Registration of numbers of deaths caused by cancer
Specific	The numbers of deaths caused from cancer is related to the number of cancer incidents. There are many sources to the development of cancer incidents and one is the exposure to carcinogenic substances.
Measurable	The original source of the data is the WHO Mortality Database. This indicator is presented as a total and by gender. Cancer mortality is measured per 100 000 inhabitants (total), per 100 000 men and per 100 000 women. There are more than 100 different types of cancers. For a large number of cancer types, the risk of developing the disease rises with age. Mortality rates are based on numbers of deaths registered in a country in a year divided by the size of the corresponding population. The rates have been directly age-standardised to the 2010 OECD population to remove variations arising from differences in age structures across countries and over time.
Achievable and Easy	Data are retrieved from OECD Statistics. Database is available at https://data.oecd.org/healthstat/deaths-from-cancer.htm
Relevant	The trend in the number of death caused by cancer is related to the regulation of carcinogenic substances.
Timed	Annual registrations, 1961-2012
Accepted, Credible and Robust	To be discussed
Geographical level	EU 28
Multisectorial elements	Human health, occupational health

14. Name of indicator: Change in number and consumption levels of substances of concern	
Reference for indicator: Based on the review of data sources (present study).	
Policy issue: Reduction of the negative impacts on the environment and humans arising from chemicals. Several chemicals legislations relate to this purpose.	
Short description: This indicator decribes the temporal changes in the number of substances of concern - here defined by number of sensitizers, CMRs, PBTs and vPvBs.	
Data needed: Calculated data on the basis of the classification and reported tonnages of substances (registration dossier).	
Type of data	Calculated data. Suggestion for data sources: ECHA CLI; ECHA registered substances database
Specific	This indicator relates to at least two purposes of REACH: 1)Better data and knowledge on the handled chemicals substances. This may lead to the identification of properties of concern for a substance, which again may increase the number of substance of co

14. Name of indicator: Change in number and consumption levels of substances of concern	
Measurable	See data needed.
Achievable and Easy	Data need for the calculations is available via the registration dossiers and the notified classifications. The indicator is thus both achievable and easy to calculate.
Relevant	If the right substances are selected, the indicator is considered relevant as it reflects one of the purposes with the chemicals regulation - namely the reduction of emissions of hazardous substances into the environment.
Timed	The time scale depends on the time scale of the applied data source(s).
Accepted, Credible and Robust	To be discussed.
Geographical level	This indicator works on the EU-level.
Multisectorial elements	Environment and humans.

Workers' Health Indicators

15. Name of indicator: Changes in quality of safety data sheets	
Policy issue: Communication of safe use across the supply chain	
Short description: Extended safety data sheets for substances and for preparations contain additional information on substance properties (e.g. DNEL values, DMEL values, PNEC values) and appropriate risk management measures.	
Data needed: Compilations of safety data sheets	
Type of data	Qualitative
Specific	The safety data sheets contain information on various substance properties alongside the appropriate risk management measures.
Measurable	The REACH Baseline study uses two indicators: • Indicator regarding DNELs, DMELs and PNECs – this monitors in how many cases these reference values for the risk characterisation are included in the chemical safety report • "Share-of" indicator regarding exposure scenarios - this monitors in how many cases exposure scenarios have been developed
Achievable and Easy	Assessment of SDSs at the baseline and at future points in time would mean a multidimensional detailed evaluation, which would generate a voluminous workload and cannot be meaningfully aggregated into indicator-type of information
Relevant	The requirements for the compilation of the safety data sheets are specified in Annex II of REACH
Timed	SDS will be updated overtime as new information becomes available but 2010, 2015 in relation to CLP and 2018 could be taken as key dates.
Accepted, Credible and Robust	Proposed in the REACH Baseline study.
Geographical level	Covers the EU-28
Multisectorial elements	-

16. Name of indicator: Occupational skin diseases	
Policy issue: Workers' exposure	
Short description: The occurrence of occupational skin diseases in Europe such as contact dermatitis	
Data needed: Incidence data	
Type of data	Quantitative.
Specific	This indicator relates directly to the number of occupational skin diseases.
Measurable	Measured in a variety of ways including diagnosis by physicians, self-reporting and sickness absences.
Achievable and Easy	Data is available at the UK level from HSE from 1996-2013. A number of national occupational disease databases also exist, which may provide information.
Relevant	It is considered relevant as it gives the change in incidence over time, which can be linked to the implementation of regulation.
Timed	Yearly data is available for the UK.
Accepted, Credible and Robust	Also proposed in the REACH Baseline study.
Geographical level	National level data is available.
Multisectorial elements	Covers a range of sectors.

17. Name of indicator: Change in incidence of chemically-related occupational disease	
Policy issue: Occupational exposure to chemicals	
Short description: Agglomeration of different diseases including skin, asthma, chronic obstructive pulmonary and cancer.	
Data needed: Data on chemically related occupational disease	
Type of data	Quantitative
Specific	Includes quantitative estimates of the prevalence and rates of self-reported problems caused or made worse by work (e.g. skin). It may be difficult to attribute these estimates directly to specific chemicals regulation.
Measurable	Work-related ill health and workplace injuries are self-reported to the HSE. Data specifies the type of illness, occupation, industry as well as the gender/age of those reporting.
Achievable and Easy	Data are already collected and collated. Minimal costs will be incurred to extract and format required data. HSE Statistics: Labour Force Survey - Self-reported Work-related Illness survey (SWI), the Health and Occupation Reporting network (THOR), Voluntary reporting of occupational diseases by General Practitioners (THOR-gP), Occupational skin surveillance (EPI-DERM), Occupational Physicians Reporting Activity (OPRA)
Relevant	Directly relevant to occupational health but not particularly specific to REACH or to CLP
Timed	Most data is measured annually by the HSE
Accepted, Credible and Robust	Occupational incidence data derived directly from UK government sources that are subject to rigorous quality assurance procedures
Geographical level	National (UK), unclear whether other Member States report data in the same manner but can be investigated
Multisectorial elements	Data reported across a range of industries

18. Name of indicator: Change in number of prescriptions for chemically-related occupational diseases	
Policy issue: Occupational exposure to chemicals	
Short description: Agglomeration of different diseases including skin, asthma, chronic obstructive pulmonary and cancer	
Data needed: Data from survey of appropriate health professionals	
Type of data	Quantitative
Specific	Quantitative estimates of the number of prescriptions for chemically-related occupational diseases. It may be difficult to attribute these estimates directly to specific chemicals regulation.
Measurable	Data would need to be collected from a survey of appropriate health care professionals. RPA (2009) states that there is a wide range of confounding factors including changes in medical practice, general improvements in occupational hygiene, changes in industrial practice. These could be addressed by careful study design.
Achievable and Easy	New data would need to be generated from a survey of appropriate health professionals. However, RPA (2009) deemed that the collection of this data would be costly but could be limited by using established HSE data gathering systems
Relevant	Directly relevant to occupational health but not particularly specific to REACH or to CLP
Timed	Not applicable as data is currently unavailable
Accepted, Credible and Robust	Not applicable as data is currently unavailable
Geographical level	National (UK)
Multisectorial elements	-

19. Name of indicator: Change in the number of chemical accidents/ incidents involving exposure of workers	
Policy issue: Occupational exposure to chemicals	
Short description: A chemical incident is when a chemical is released into the environment either accidentally or deliberately. This indicator assesses exposure to workers through such instances.	
Data needed: Data on the number of chemical accidents/incidents and resulting levels of exposure	
Type of data	Quantitative
Specific	Quantitative estimates of exposure through chemical accidents are gathered through a number of means such as self-reporting and recorded information from physicians. It may be difficult to attribute these estimates directly to specific chemicals regulation.
Measurable	Incidents are reported through a number of systems in place through the UK. For instance, The TOXBASE database provides information about routine diagnosis, treatment and management of patients suffering from exposure to a wide range of pharmaceuticals, chemicals (agricultural, household and industrial), plants and animals.

Achievable and Easy	Data are already collected and collated. Minimal costs will be incurred to extract and format required data Health Protection Agency: Chemicals and Poisons Division (CHaPD) chemical incident surveillance systems. Local and Regional Services (LaRS) National Poisons Information Service (NPIS), National Chemical Emergency Centre (NCEC)
Relevant	Directly relevant to occupational health but not particularly specific to REACH or to CLP
Timed	Annual updates for most databases
Accepted, Credible and Robust	Data derived directly from UK government sources that are subject to rigorous quality assurance procedures
Geographical level	National (UK) but systems may be in place among other Member States
Multisectorial elements	Covers chemicals across a variety of sectors

20. Name of indicator: Change in industry expenditure on protective gloves	
Policy issue: Occupational exposure to chemicals	
Short description: Industry expenditure on protective gloves could be linked to varying extents to different chemicals regulation	
Data needed: Expenditure data on protective gloves for high risk industries	
Type of data	Quantitative
Specific	Could be linked as an induced effect of chemicals regulation through improved risk management measures
Measurable	Estimates may be derivable from Eurostat Prodcom data
Achievable and Easy	No existing data collated. RPA (2009) states that a survey of either glove manufacturers or purchasers in relevant industry sectors of numbers/types of glove purchased would need to be carried out. Eurostat prodcom data on 'Protective gloves, mittens and mitts for all trades, of leather or composition leather' could be possibly used to derive estimates
Relevant	Directly relevant to occupational health and could be linked to varying extents to REACH and/or CLP
Timed	No existing collated data is available; however Eurostat data is published annually.
Accepted, Credible and Robust	No existing collated data is available
Geographical level	No existing collated data is available; however Eurostat data is generally available for all countries
Multisectorial elements	Covers a variety of different sectors

21. Name of indicator: Change in industry expenditure on local and general ventilation equipment
Policy issue: Occupational exposure to chemicals
Short description: Expenditure by industry on local and general ventilation equipment could be linked to varying extents to different chemicals regulation
Data needed: Expenditure data by industry on local and general ventilation equipment

Type of data	Quantitative
Specific	Could be linked as an induced effect of chemicals regulation through improved risk management measures
Measurable	May be derivable from Eurostat prodcom data. RPA (2009) suggests a survey based approach
Achievable and Easy	No existing collated data. RPA (2009) suggests a survey of either equipment manufacturers or purchasers in relevant industry sectors of numbers/types of equipment purchased
Relevant	Directly relevant to occupational health and could be linked to varying extents to REACH and/or CLP
Timed	Due to the type of investment, the time nature of the data would be sporadic and difficult to assess in terms of the impact of chemicals regulation
Accepted, Credible and Robust	No existing collated data is available
Geographical level	No existing collated data is available; however Eurostat data is generally available for all countries
Multisectorial elements	Covers a range of different sectors

22. Name of indicator: Number of new RMMs of increased stringency	
Policy issue: Chemicals exposure	
Short description: Risk Management Measures' (RMM) appear in the REACH Safety Data Sheet for a substance or product. Industry introduces additional Risk Management Measures (RMM) as a consequence of either having re-classified substances as a result of additional information on substance properties leading to additional S-phrases, or having identified risks by preparing a Chemical Safety Assessment (CSA) in relation to Registration of their chemicals. This indicator measures the degree to which new RMMs are more stringent.	
Data needed: Qualitative assessments of RMMs in safety datasheets	
Type of data	Qualitative
Specific	REACH specific indicator
Measurable	Difficult to measure due to the large number of safety data sheets and the subjective nature of the indicator i.e. what is more stringent?
Achievable and Easy	As stated this indicator is difficult to measure and therefore not easily achievable
Relevant	Focuses on the effects of the REACH Regulation
Timed	Safety datasheets are uploaded regularly but it is not possible to determine the timing of changes
Accepted, Credible and Robust	-
Geographical level	Regional (EU-28)
Multisectorial elements	-

23. Name of indicator: Proportions of workers in the industrial sectors or occupations who were exposed to the carcinogens
Policy issue: Occupational exposure to carcinogens

23. Name of indicator: Proportions of workers in the industrial sectors or occupations who were exposed to the carcinogens	
Short description: A carcinogen is any substance, radionuclide, or radiation that is an agent directly involved in causing cancer. This indicator measures the proportion of workers that have been exposed to carcinogens across industrial sectors or occupations	
Data needed: Monitoring data for workers exposed to carcinogens	
Type of data	Quantitative
Specific	Specific to the REACH and CLP regulations (Annex VI)
Measurable	This indicator is measured in a number of ways. For example, in Finland employers are to report annually the carcinogens used, the amount of each compound used and the names of the employees exposed to carcinogens.
Achievable and Easy	There are three types of data sources that provide information about occupational exposure to carcinogens: a) national registers, b) exposure measurement databases and c) exposure information systems National registers include Finnish Register of Workers Exposed to Carcinogens (ASA Register), the Italian Information System for Recording Occupational Exposures to Carcinogens (SIREP) and the German ODIN Register.
Relevant	This is a relevant indicator as it looks at carcinogens, which have been categorised as substances of very high concern by REACH. Furthermore, the European Agency for Safety and Health at Work (EU - OSHA) regards work - related cancer as a major issue for occupational safety and health (OSH).
Timed	Most registers record data annually
Accepted, Credible and Robust	-
Geographical level	National
Multisectorial elements	Human health impacts across different industries

24. Name of indicator: Percentage of employees thinking that their health or safety is at risk because of work	
Policy issue: Occupational health and safety	
Short description: The indicator "work-related health risks" reflects the subjective assessment of risks at the workplace	
Data needed: Survey data on work-related health risks	
Type of data	Quantitative
Specific	This indicator is not specific as it takes into account a range of factors and is not solely limited to chemicals
Measurable	The indicator is measurable through surveys of workers and is thus subjective in nature
Achievable and Easy	Data sources are known. The European Working Conditions Survey (EWCS) is the longest running survey, and has become an established source of information about working conditions and the quality of work and employment. Themes covered include employment status, working time arrangements, work organisation, learning and training, physical and psychosocial risk factors, health and safety, worker participation, work-life balance, earnings and financial security, as well as work and health.
Relevant	The indicator will give some indication of whether risks have increased/decreased in the workplace over time. Nevertheless, it will

24. Name of indicator: Percentage of employees thinking that their health or safety is at risk because of work	
	be difficult to attribute this change to chemicals regulation as the surveys take into account a range of factors.
Timed	Five waves having been implemented since 1990, it enables monitoring of long-term trends in working conditions in Europe
Accepted, Credible and Robust	This indicator was shortlisted and selected by the WORKHEALTH (2004) study, which aimed to establish indicators for work-related health monitoring in Europe.
Geographical level	Regional – the sixth survey (currently on-going) will interview more than 43,000 workers in 35 different European countries
Multisectorial elements	Human health across a range of industries

25. Name of indicator: Percentage of employed people absent from work in reference week due to own illness, injury or temporary disability	
Policy issue: Occupational health and safety	
Short description: Sickness absence is an indicator which provides information on the health status of the employees. Sickness absence figures are often used for example to reveal the need for preventive activities if absence rates are high.	
Data needed: Data on the incidence of absenteeism	
Type of data	Quantitative
Specific	An indicator of the health status of employees but not specific to chemicals regulation
Measurable	Measurable through surveys and self-reporting. At a national level, absence rates are usually examined according to economic sectors to determine what action is necessary. It is also common to consult absence rates at company level in order to determine which departments should be targeted by health promotion activities.
Achievable and Easy	On European level, data should be used from the European Labour Force Survey for monitoring of sickness as social insurance data are hardly comparable across the Member States. It assesses, with regard to a reference week, if employees were absent from a job or business due to "own illness, injury or temporary disability". The illness is not further specified, i.e. no diagnosis etc.is given. There may also be a range of confounding factors meaning that sickness absence rates do not only reflect the actual health status of employees. For example, they can reflect macroeconomic changes as well, as sickness absence rates usually drop with high unemployment rates. This can be attributed to the fact that older and less healthy workers are no longer in employment and that people choose to go to work feeling ill rather than risk losing their job.
Relevant	The indicator will give some indication of whether risks have increased/decreased in the workplace over time. Nevertheless, it will be difficult to attribute this change to chemicals regulation as the surveys take into account a range of factors.
Timed	Data for the Labour Force Survey is updated annually
Accepted, Credible and Robust	This indicator was shortlisted and selected by the WORKHEALTH (2004) study, which aimed to establish indicators for work-related health monitoring in Europe.
Geographical level	Regional and national
Multisectorial elements	Human health across a range of industries

Public Human Health Indicators

26. Name of indicator: Production of toxic chemicals	
Policy issue: Production of toxic substances	
Short description: The indicator 'Production of toxic chemicals' draws on a selection of 162 identified toxic chemicals out of a total of 387 chemicals from the European production statistics database (Prodcom). The indicator presents the trend in aggregated production volumes of toxic chemicals, broken down into five toxicity classes: Carcinogenic, Mutagenic and Reprotoxic (CMR-chemicals); Chronic toxic chemicals; Very toxic chemicals; Toxic chemicals and chemicals classified as harmful	
Data needed: Production data of toxic substances	
Type of data	Quantitative
Specific	The indicator relates directly to the production of toxic chemicals. The Eurostat indicator is not disaggregated at either the individual chemical or country levels. Prodcom data is available at the individual country level (except when confidential) and for some individual chemicals (more frequently groups of chemicals).
Measurable	Unit of measurement is tonne (or millions of tonnes). The indicator will reflect temporal changes in production patterns.
Achievable and Easy	Data source is known, reliable and publicly available. The classifications in Prodcom are standardised across countries. Nonetheless, identifying all toxic chemicals through the database could be a difficult task. The aggregation of chemicals under different groups also hinders the identification of toxic substances. Furthermore, the Eurostat indicator does not provide the names of its selected chemicals for confidentiality reasons.
Relevant	It is considered a relevant indicator, as it gives an indication of increases/decreases in the production of toxic chemicals. These changes could be attributed to the different regulation.
Timed	Every year
Accepted, Credible and Robust	This is an official indicator used in the REACH Baseline study and is also one of Eurostat's Sustainable Development Indicators.
Geographical level	The indicator covers the EU-28 while Prodcom data cover the regional and country levels.
Multisectorial elements	The indicator focuses on the European chemicals sector. Prodcom data cover all industry classifications.

27. Name of indicator: Cross-border transport of toxic chemicals	
Policy issue: Trade and geographical spread of toxic chemicals	
Short description: The amount of toxic chemicals is calculated as the sum of imports (intra-EU and extra-EU) for every Member State	
Data needed: Foreign Trade Statistics (Eurostat)	
Type of data	Quantitative
Specific	This indicator relates to the movement of toxic chemicals across borders. It also gives an indirect indication of the production levels of toxic chemicals.
Measurable	Foreign Trade Statistics are measured annually.

27. Name of indicator: Cross-border transport of toxic chemicals	
Achievable and Easy	Toxic chemicals need to be selected from the Foreign Trade Statistics database (Comext). REACH baseline study uses 189 chemicals from the 27.07.x, 28.x and 29.x classifications. However it is not specified which chemicals are used.
Relevant	It is considered a relevant indicator, as it gives an indication of the geographical spread of toxic chemicals as well as increases/decreases in the production.
Timed	Comext statistics are updated yearly.
Accepted, Credible and Robust	Comext is Eurostat's primary Foreign Trade Statistics database. The indicator was proposed as supplementary indicator for the REACH Baseline study.
Geographical level	Regional and country level data available.
Multisectorial elements	A variety of sectors can be considered through the Comext database.

28. Name of indicator: Toxic chemicals in households	
Policy issue: Exposure to toxic chemicals in households	
Short description: Information, documentation and assessment of poisonings from primary substances, cleaning products, disinfectants, paint and related materials, building materials and glues.	
Data needed: Consumer product data base	
Type of data	Reported poisonings from substances.
Specific	This indicator relates directly to the number of poisonings from toxic substances.
Measurable	Measured by reported number of poisoning cases.
Achievable and Easy	Accessing relevant data may be difficult. For example, The German BfR (Bundesinstitut für Risikobewertung) owns a consumer product database but access to the database is restricted.
Relevant	It is considered relevant as it gives a change in poisonings over time, which can be linked to changes in regulation.
Timed	Unclear how often the German database is updated.
Accepted, Credible and Robust	Proposed in the REACH Baseline study.
Geographical level	The database consulted for the REACH Baseline study only covers Germany.
Multisectorial elements	Only considers consumer products.

29. Name of indicator: Changes in use patterns in Scandinavia	
Policy issue: Consumption of chemicals in Sweden, Denmark, Finland and Norway	
Short description: The SPIN database publishes yearly the consumption of approx. 20 000 chemicals in the Scandinavian countries Sweden, Denmark, Finland and Norway	
Data needed: Data on consumption of chemicals by type in Scandinavia	
Type of data	Quantitative.

29. Name of indicator: Changes in use patterns in Scandinavia	
Specific	Focuses specifically on chemical use within the Scandinavian countries.
Measurable	The SPIN database uses data from the Product Registries of Norway, Sweden, Denmark and Finland.
Achievable and Easy	The data is freely available to access.
Relevant	This data is specific to Scandinavian countries and provides an indication of changes in the use of different chemicals. These changes could be linked back to chemicals regulation.
Timed	Yearly.
Accepted, Credible and Robust	This indicator is used as part of the REACH Baseline study.
Geographical level	Scandinavian countries only.
Multisectorial elements	Data is presented by NACE sector.

30. Name of indicator: Estimates of the burden of disease	
Policy issue: Public health	
Short description: DALYs, YLLs and YLDs for each country due to disease	
Data needed: Data on the incidence of DALYs, YLLs and YLDs in each country	
Type of data	Quantitative
Specific	This indicator is not specific to any particular chemicals regulation, nevertheless it has been used by past studies to attribute a fraction of DALYs, YLLs or YLDs to chemical exposure (see WWF, 2003).
Measurable	The indicator is based on measured data, and also will reflect temporal changes in use pattern.
Achievable and Easy	Data sources are known, reliable and publicly available. The most comprehensive data set provided by the WHO.
Relevant	The indicator is relevant because it can be used to derive the impact of chemicals on human health through the environment. Nevertheless, it will be difficult to relate this indicator to a specific piece of chemicals regulation.
Timed	The data is published for the years 2000 and 2012 by country.
Accepted, Credible and Robust	Data derived directly from WHO sources that are subject to rigorous quality assurance procedures.
Geographical level	WHO Member States
Multisectorial elements	Disease burden can be linked to a number of sectors but requires further sector specific information (e.g. the proportion of disease attributable to chemicals in the agricultural uses).

31. Name of indicator: Change in the numbers of the public affected by chemical incidents
Policy issue: Public health and exposure to chemicals
Short description: A chemical incident is when a chemical is released into the environment either accidentally or deliberately. This indicator assesses exposure to general public through such instances.
Data needed: Data on the numbers of the public affected by chemical incidents

31. Name of indicator: Change in the numbers of the public affected by chemical incidents	
Type of data	Quantitative
Specific	Will be difficult to attribute changes in this indicator to a specific chemicals regulation
Measurable	Estimates can be derived from a number of sources. Data is typically self-reported or recorded by physicians.
Achievable and Easy	Data is already collected from a number of sources, including Chemicals and Poisons Division (CHaPD) chemical incident surveillance systems, Local and Regional Services (LaRS), National Poisons Information Service (NPIS), National Chemical Emergency Centre (NCEC), environment agencies. Wide range of confounding factors including other legislation and general improvements in industrial practice.
Relevant	Chemical incidents and resulting public exposure are low probability events. Consequently this indicator would not add much to the final analysis
Timed	Many of the data sources provide and update datasets annually
Accepted, Credible and Robust	Some data derived directly from UK government sources that are subject to rigorous quality assurance procedures
Geographical level	National (UK) unclear whether other systems of data collection are in place within other Member States
Multisectorial elements	Human health

32. Name of indicator: Change in usage of chemicals of concern in consumer products	
Policy issue: Hazardous chemicals in consumer products	
Short description: This indicator measures the usage of hazardous chemicals in consumer products	
Data needed: Quantitative estimates of the use of hazardous chemicals in consumer products	
Type of data	Quantitative
Specific	Informative of public exposure to chemicals of concern; any changes are likely to be related to the implementation of both REACH and CLP
Measurable	Data is recorded on hazardous substances within different consumer products through the SPIN database
Achievable and Easy	The Nordic product registers SPIN database is a good source of information for the changes in use of hazardous chemicals in consumer products
Relevant	Consumer products are used by a wide range of the population. This indicator therefore has particularly relevance as the benefits from the reduced use of hazardous chemicals in consumer products could be large
Timed	SPIN database is updated annually
Accepted, Credible and Robust	Data from SPIN is subject to rigorous quality assurance procedures and is considered credible/robust
Geographical level	Scandinavian countries
Multisectorial elements	-

33. Name of indicator: Change in tissue levels of chemicals of concern in the EU population	
Policy issue: Public exposure to hazardous chemicals	
Short description: This indicator measures change in tissue levels of hazardous chemicals among the EU population	
Data needed: Tissue monitoring data	
Type of data	Quantitative
Specific	Monitoring for targeted substances selected for monitoring in the UK population will be highly REACH specific.
Measurable	Measurable through tissue samples and monitoring
Achievable and Easy	Some tissue archives already exist (e.g. MRC Biobank, and others might require establishment), access to tissues would have to be negotiated and quality criteria agreed
Relevant	Relevant as the benefits could be large from reductions in exposure to the EU population. Also relates directly to the REACH regulation
Timed	Unsure as data is not publicly available
Accepted, Credible and Robust	-
Geographical level	National?
Multisectorial elements	-

34. Name of indicator: Number of national emergency actions taken relating to human health (under Article 129)	
Policy issue: Public health	
Short description: When a Member State has justifiable grounds for believing that urgent action is essential to protect human health or the environment in respect of a substance, on its own, in a preparation or in an article, even if satisfying the requirements of this Regulation, it may take appropriate provisional measures under article 129. This indicator aims to measure the number of times national emergency actions have been taken.	
Data needed: Estimates of the number of hazardous chemicals replaced by safer alternatives	
Type of data	Quantitative
Specific	Addresses a specific REACH-relevant endpoint. Not relevant to CLP.
Measurable	-
Achievable and Easy	-
Relevant	-
Timed	-
Accepted, Credible and Robust	-
Geographical level	National (UK)
Multisectorial elements	-

35. Name of indicator: Phthalates in humans

35. Name of indicator: Phthalates in humans	
Policy issue: Regulation of phthalates in consumer products (REACH Regulation (Authorisation, Restriction); specific legislations on substances in consumer products)	
Short description: Phthalates are mainly used in the production of plasticized polyvinyl chloride to soften the PVC. Phthalates are not chemically bound to PVC. Due to their wide use, phthalates are thus ubiquitous in the environment and they have a high potential for bioaccumulation. Some phthalates are endocrine disruptors and are suspected to be toxic for reproduction and development. Phthalates are degraded when entering the body. Therefore only their degradation products (metabolites) can be analysed. The first metabolites are monoesters which are further degraded to other metabolites.	
Data needed: Data on phthalates in humans	
Type of data	Quantitative measurements of metabolites of phthalates in urine
Specific	Quantitative measurements of metabolites of phthalates excreted with urine in 24H sampling from young adults. The presence of metabolites of phthalates in human urine is related to the exposure to and accumulation in humans of phthalates during use of phthalates and articles containing phthalates.
Measurable	The internal phthalate exposure in young adults is monitored based on quantitative analysis of metabolites excreted in the urine, reported as µg/l ww in 24H sampling. The metabolites of DnBP, DiBP, BBzP, DEHP and DiNP are measured. Approximately 60 counts per metabolites. Results are given as geometric mean with 95% confidence intervals.
Achievable and Easy	Data can be retrieved from the Environmental Specimen Bank (ESB). The ESB is a tool to describe time trends of human exposure. Annual measurement of heavy metal contents and organics in hair, blood, blood plasma, and urine. The database is available at http://www.umweltprobenbank.de/en/documents/investigations/analytes.
Relevant	The trends in internal human exposure to phthalates can be related to the regulation of phthalates.
Timed	Series of measurements 2002, 2004, 2006 and 2008 plus 1988-2003
Accepted, Credible and Robust	To be discussed
Geographical level	Students in Muenster, Germany representative for EU
Multisectorial elements	Exposure to humans, human health, consumers

36. Name of indicator: Metals, phthalates, parabens, polycyclic aromatic hydrocarbons (PAH) and pyrrolidones in humans over time.	
Policy issue: Regulation of chemical substances in consumer products (REACH Regulation (Authorisation, Restriction); specific legislations on substances in consumer products)	
Short description: Humans are exposed to xenobiotics through activities and via the environment. The metals or their ions penetrate into the organism, for example, through the ingestion of food or via dental implants, and accumulate there over time. Phthalates and their substitutes are used as plasticisers in PVC and can be found, for instance, in toys, food packaging films, floor coverings, hoses, seals or carpeted floors. Parabens are used as a preservative and are found, among other places, in cosmetic products such as creams or shampoos; some may also be used in medicines and foodstuffs. Polycyclic aromatic hydrocarbons (PAH) are created when organic material, such as wood, coal, or oil, fails to combust fully. They also occur in used motor oils, tar and soot. The pyrrolidones NMP (N-methyl-2-Pyrrolidone) and NEP (N-ethyl-2-Pyrrolidone) are used as solvents and found in automotive coatings, paint removers, and non-stick coatings.	
Data needed: Monitoring data of metals, phthalates, parabens, polycyclic aromatic hydrocarbons (PAH) and pyrrolidones in urine	
Type of data	Quantitative measurements

36. Name of indicator: Metals, phthalates, parabens, polycyclic aromatic hydrocarbons (PAH) and pyrrolidones in humans over time.	
Specific	The presence in human urine of chemical substances or metabolites of substances being transformed in the human body is related to the exposure to humans during use of the substances or exposure to articles containing the substances. Quantitative measurements of metals and parabens and measurements of metabolites of phthalates, PAHs and pyrrolidones excreted with morning urine of 3-17 years old children are related to the exposure of the children to the metals and the xenobiotics.
Measurable	The internal xenobiotics exposure in humans is monitored based on quantitative analysis of the substances and metabolites excreted in the urine. In the 5th German Environmental Survey (GerES) measurements in the morning urine are done to determine the exposure of the children and adolescents to plasticisers, polycyclic aromatic hydrocarbons (PAHs), metals, parabens, certain pesticides, pyrrolidones, and active and passive smoking (cotinine). The quantities of metabolites from more than ten phthalates and phthalate substitutes are measured. PAH are detected in the urine through the concentration of metabolites of 1-Hydroxypyrene and four Hydroxyphenanthrenes. The parabens and the degree of metal contamination in the body is determined directly from the urine. NMP and NEP are broken down in the body to form metabolites. Quantities of the NMP metabolites are found in urine.
Achievable and Easy	The German Environmental Survey (GerES) is a nationwide population representative study on human biomonitoring and external human exposure. Quantitative measurements of metals and parabens and measurements of metabolites of phthalates, PAHs and pyrrolidones excreted with morning urine of 3-17 years old children are included in the current study, GerES V. Results are published in a report after end of study. The recent report, GerES IV, is available at http://www.umweltbundesamt.de/en/publikationen/german-environmental-survey-for-children-200306
Relevant	The trends in internal human exposure to metals and xenobiotics can be related to the regulation of the chemical substances
Timed	The first German Environmental Survey took place between 1985 and 1986 and the latest study, GerES IV during the period 2003-2006. The study GerES-V is taking place during the period 2014-2017
Accepted, Credible and Robust	The studies contain extensive data sets subject to quality assurance and statistical analysis.
Geographical level	Germany
Multisectorial elements	Exposure to humans, human health, consumers

37. Name of indicator: POPs level in breast milk (DDE, DDT, HCB, PBDE, PCB, and PCN)	
Policy issue: Regulation of PBT/vPvB substances by REACH is of relevance (authorisation, restriction).	
Short description: POPs are a group of organochlorine and related chemicals. They are lipophilic and resistant to both physicochemical and biological degradation and thus accumulate in living organisms and subsequently in humans via the food chain.	
Data needed: Data on concentrations of various persistent organic pollutants (POPs) in breast milk	
Type of data	Quantitative measurements of POPs in human breast milk
Specific	The indictor relates indirectly to regulations on POPs and regulations on PBT and vPvB substances.
Measurable	Studies with concentrations of POPs in µg/kg (or an alternative mass/mass unit) in milk fat are available.

37. Name of indicator: POPs level in breast milk (DDE, DDT, HCB, PBDE, PCB, and PCN)	
Achievable and Easy	One data set is available covering the period 1972-2001. The data are available through the database Environment and Health Information System (ENHIS) provided by WHO: http://data.euro.who.int/eceh-enhis/Default2.aspx
Relevant	Levels in human milk fat are a good indicator of levels in the population as a whole. This measure is also relevant in measuring the developmental exposure of unborn children.
Timed	1971-2008, frequency varies
Accepted, Credible and Robust	To be discussed
Geographical level	Sweden
Multisectorial elements	Exposure to humans, human health, consumer

38. Name of indicator: Levels of lead in children´s blood	
Policy issue: Regulation of substances of very high concern by REACH is of relevance (authorisation, restriction). Also relevant is European policy initiatives on reducing the amount of leaded petrol which are in place in the Member States.	
Short description: The phasing out of lead from petrol, first in western Europe and later in central and eastern Europe, has resulted in a significant fall in blood lead levels in children over the last two decades. Since lead was phased out from petrol, other sources of exposure to lead that had previously been ignored have become increasingly significant. Industrial emissions remain important local sources of lead exposure in some countries.	
Data needed: Data on the mean blood lead levels in children of various age groups in European countries	
Type of data	Quantitative measurements of lead in blood samples
Specific	Lead in the environment has multiple sources, including petrol, industrial processes, paint, solder in canned foods and water pipes, and reaches people via a number of pathways (such as air, household dust, street dirt, soil, water and food). Consequently, evaluation of the relative contribution of different sources is complex and is likely to differ between areas and population groups. Lead-containing petrol remains the most important source of atmospheric lead and is a significant contributor to the lead burden in the body in the countries where it is still used. Industrial emissions are also important sources of lead contamination of the soil and ambient air. Lead from atmospheric air or flaked paint deposited in soil and dust may be ingested by children and may substantially raise their blood lead levels. In addition, food and water may also be important media of baseline exposure to lead. In children, the potential for adverse effects of exposure to lead is increased because (a) the intake of lead per unit of body weight is higher for children than for adults; (b) young children often place objects in their mouths, resulting in the ingestion of dust and soil and, possibly, increased intake of lead; (c) physiological uptake rates of lead in children are higher than in adults; and (d) young children are undergoing rapid development, their systems are not fully developed, and consequently they are more vulnerable than adults to the toxic effects of lead (WHO).
Measurable	The levels of lead in children's blood were determined mostly from venous blood samples using atomic absorption spectrometry or inductively coupled plasma mass spectroscopy (ICP-MS). Three countries reported the use of capillary samples and blood test kits (based on electrochemistry). According to the comparison tests performed in each case, these data were claimed to be comparable

38. Name of indicator: Levels of lead in children´s blood	
	with the results produced by the above-mentioned methods. Levels of lead in the blood were provided in the form of arithmetic and/or geometric means. One country presented only the percentages of lead in children's blood.
Achievable and Easy	One data set is available covering the period 1991-2008. The time period differs from country to country. The data are available through the database Environment and Health Information System (ENHIS) provided by WHO: http://data.euro.who.int/eceh-enhis/Default2.aspx
Relevant	The indictor relates indirectly to regulations on lead
Timed	1991-2008, frequency not defined
Accepted, Credible and Robust	To be discussed
Geographical level	Belgium, Bulgaria, the Czech Republic, France, Germany, Hungary, Israel, Poland, Romania, the Russian Federation, Sweden, the former Yugoslav Republic of Macedonia and Ukraine
Multisectorial elements	Exposure to humans, human health, consumer

39. Name of indicator: Incidence of childhood leukaemia	
Policy issue: Regulation of carcinogenic substances by REACH is of relevance (authorisation, restriction). Also relevant is the Council Directive 97/43/Euratom (19) which aims to protect patients from excessive exposure to radiation for medical use and to ensure that there is minimum radiation exposure during pregnancy and early childhood. Environmental issues are often discussed in relation to childhood leukaemia, but the causes of the majority of cases are unknown and there is a lack of major multinational programmes fostering research into potential risk factors for leukaemia in Europe. As a result, there is also a lack of policies aimed directly at reducing the incidence of leukaemia.	
Short description: Leukaemia is the most common childhood malignancy. It accounts for over 30% of all cancers diagnosed in children less than 15 years of age in the WHO European Region. In2012, the average annual incidence rate for this age group in the European Region was 4.4 cases per 100 000. European population-based cancer registries show an average increase in the incidence of childhood leukaemia of 0.7% per year between 1970 and 1999.	
Data needed: National estimates of leukaemia incidence in children aged 0-14 years	
Type of data	Registration of diagnosis of leukaemia
Specific	In the majority of cases of childhood leukaemia, the cause is unknown. While a number of causes and highly suspected risk factors have been identified, reviews stress that these are responsible for only a very small number of cases. The known and highly suspected causes include genetic factors (2–3% of cases are associated with Down syndrome) and exposure to ionizing radiation in utero and after birth. Infectious diseases are likely to have a role in the etiology of childhood leukaemia. Delayed exposure to infection during early infancy could result in an abnormal response, leading to the development of leukaemia. Leukaemia could also be a rare response to a specific although unidentified infectious agent. Other environmental risk factors have been less clearly identified. The International Agency for Research on Cancer has concluded that extremely low-frequency electromagnetic fields are possibly carcinogenic to humans, based on consistent statistical associations of high-level residential magnetic fields with a doubling of risk of childhood leukaemia (9). Several studies suggest that children

39. Name of indicator: Incidence of childhood leukaemia	
	exposed to certain hazardous chemicals have an increased risk of leukaemia, with benzene being the most frequently suspected causal agent. A number of papers have shown statistically significant associations between the risk of childhood leukaemia and exposure to pesticides during pregnancy or childhood. The risks associated with environmental leukaemogens may be modified by genetic susceptibility (WHO).
Measurable	Incidence of leukaemia is given as the number of new cases per 100 000 children per year in children aged 0–14 years. Incidence of leukaemia in children aged 0-14 years for countries of the European Region with population-based data are registered and reported for 2008 and 2012. The median incidence in the Region for 2012 was 4.4 cases per 100 000 per year. In 2012, national estimates ranged from 2.5 cases per 100 000 per year in Montenegro to 7.0 cases per 100 000 per year in Germany.
Achievable and Easy	The data for 2008 and 2012 are available through the database Environment and Health Information System (ENHIS) provided by WHO: http://data.euro.who.int/eceh-enhis/Default2.aspx?indicator_id=15
Relevant	The indictor relates indirectly to regulations on carcinogenic substances.
Timed	2018 and 2012 based on data from 1990-2009 , every five year
Accepted, Credible and Robust	To be discussed
Geographical level	40 countries in the WHO EU region
Multisectorial elements	Exposure to humans, human health, consumer

Environmental Indicators

40. Name of indicator: Production of environmentally harmful chemicals, by environmental impact class	
Policy issue: Production of environmentally harmful substances	
Short description: Aggregated production of chemicals that were harmful to the aquatic environment, analysed according to five classes of environmental effects: significant, chronic, moderate, significant and severe effects.	
Data needed: Production data	
Type of data	Quantitative
Specific	The indicator relates directly to the production of substances that are harmful to the aquatic environment.
Measurable	The indicator is based on measured data, and also will reflect temporal changes in production pattern.
Achievable and Easy	Data source is known, reliable and publicly available. However, the data is not disaggregated at the individual country or at chemical substance.
Relevant	It is considered a relevant indicator, as it gives an indication of increases/decreases in the production of harmful chemicals. These changes could be attributed to the different regulations.
Timed	Every year.
Accepted, Credible and Robust	Derived from Eurostat prodcom data. The indicator was proposed as supplementary indicator for the REACH Baseline study.

Geographical level	Aggregated at the EU-28 level.
Multisectorial elements	-

41. Name of indicator: Animal testing: use of QSARs, read-across and waiving options	
Policy issue: Chemical testing	
Short description: An indicator to analyse the increase/decrease in different types of testing as a result of chemicals regulation.	
Data needed: Incidence of animal testing, QSARs, read-across and waiving options	
Type of data	Quantitative
Specific	Quantitative measurements of animal testing incidence alongside raw data on the use of QSARs, read-across and waiving options.
Measurable	The European Union records and reports statistics on "protection of animals used for experimental and other scientific purposes, the statistical data on the number of animals used for experimental and other scientific purposes in the Member States of the EU", according to Article 26 of Directive 86/609/EEC of 24 November 1986. Data is also stored in IUCLID 5 regarding the use of QSARs, read-across and exposure-based waiving.
Achievable and Easy	Data is available from European Union reports (for animal testing) and from IUCLID 5 (for QSARs, read-across and waiving options).
Relevant	In preparing the registration dossier, several options exist in REACH for using all adequate existing knowledge in order to avoid unnecessary testing of animals (here and in the context of REACH, "animals" refers only to vertebrates) and also to reduce costs. All these possibilities are presented in the REACH Regulation either in column 2 of tables setting out testing requirements for the different tonnage bands (Annexes VII to X) or in Annex XI presenting the general rules for adaptation of the standard testing regime.
Timed	Indicators can be linked to key REACH registration deadlines.
Accepted, Credible and Robust	Proposed by the REACH Baseline study.
Geographical level	EU-28
Multisectorial elements	Animal welfare

42. Name of indicator: Changes in PNECs	
Policy issue: Improved information on chemicals properties	
Short description: The Predicted No Effect Concentration or PNEC is the concentration of a substance in any environment below which adverse effects will most likely not occur during long term or short term exposure. Under REACH, there is a requirement to provide information on the PNECs for a substance in the chemical safety sheet. This indicator measures the changes in PNECs	
Data needed: Data on changes in PNECs from chemical safety datasheets	
Type of data	Quantitative
Specific	REACH specific indicator
Measurable	No existing collated data is available. Measurement would require analysis of a large number of safety datasheets which could be

42. Name of indicator: Changes in PNECs	
	deemed unfeasible.
Achievable and Easy	As no existing collated data is available and measurement is particularly difficult, this indicator can be deemed relatively unfeasible
Relevant	This indicator is relevant to the REACH regulation but it is not possible to accurate determine the benefits that arise from changes in DNELs
Timed	Safety datasheets are uploaded regularly but it is not possible to determine the timing of changes
Accepted, Credible and Robust	-
Geographical level	Regional (EU-28)
Multisectorial elements	-

43. Name of indicator: No. of newly identified PBTs or vPvBs	
Policy issue: Improved information on hazardous chemicals	
Short description: Very Persitent and Very Bioaccumulative substances (vPvBs) and Persistent, Bioaccumulative and Toxic substances (PBTs) are generally considered to be substances of very high concern. This indicator assesses the number of newly identified PBTs or vPvBs to provide an indication of increased awareness of hazardous chemicals through regulation.	
Data needed: Data on newly identified PBTs or vPvBs	
Type of data	Quantitative
Specific	PBT/vPvB substances are defined in REACH Annex XIII in relation to their persistent, bioaccumulative and/or toxic properties.
Measurable	Data on classification as a PBT or vPvB should be available from the CLI
Achievable and Easy	-
Relevant	Defined in REACH Annex XIII but similar substances have also been targeted in other legislative frameworks such as the OSPAR Convention and the two POP conventions , i.e. the UNECE LRET Air Protocol and the Stockholm Convention.
Timed	-
Accepted, Credible and Robust	-
Geographical level	-
Multisectorial elements	-

44. Name of indicator: Cobalt in the aquatic environment (fresh water)
Policy issue: Regulation of the use and discharge of cobalt (REACH Regulation (Registration, Authorisation, Restriction); waterframe directive, etc.)
Short description: Applications of cobalt include alloys and pigments in glass-, ceramics-, and enamel production. It is also used as catalyst, as component in batteries and as micronutrient in medicine and agriculture. Cobalt is released into the environment mainly by weathering of rocks and minerals, volcanic action and anthropogenic activities. Cobalt is an essential element for all higher animals and for humans, but high concentrations of cobalt are toxic. Cobalt compounds are classified as carcinogenic and

44. Name of indicator: Cobalt in the aquatic environment (fresh water)	
mutagenic. Many organisms are able to accumulate cobalt (bioaccumulation).	
Data needed: Data on cobalt in fresh water organisms	
Type of data	Quantitative measurements of cobalt in zebra mussels and bream from the Donau, Germany
Specific	Quantitative measurements of cobalt in freshwater organisms represented by zebra mussel and freshwater bream. Zebra mussel is a common mussel species as invasive animal in rivers and lakes with high information level for water pollution; bream is species of fish used as bioindicator in rivers and lakes due to it's widespread presence and substantial biomass availability.
Measurable	The presence of cobalt in the aquatic environment is monitored based on quantitative analysis of freshwater species in the river Donau, the second largest river in Europe. The analysis is done on soft body of zebra mussel and liver of bream. The measurement unit is µg/g dw. Each measurement is based on 4-6 counts. Results are given as arithmetic mean with standard deviation.
Achievable and Easy	Data can be retrieved from the Environmental Specimen Bank (ESB). The ESB is a tool to describe time trends of environmental exposure. Annual measurement of heavy metal contents and organics in environmental species and compartments. The database is available at http://www.umweltprobenbank.de/en/documents/investigations/analytes.
Relevant	The presence of cobalt in freshwater organisms is related to the discharge of cobalt compounds to the aquatic environment. Trends in discharge of cobalt compounds into rivers and lakes can be related to regulation of the production and use of cobalt compounds.
Timed	Annual measurements 2003-2013
Accepted, Credible and Robust	To be discussed
Geographical level	Donau, the second largest river in Europe, Germany representative for EU
Multisectorial elements	Exposure to the aquatic environment, freshwater organisms

45. Name of indicator: Species diversity	
Policy issue: Legislations covering the air emissions, releases and waste	
Short description: The species diversity is described by three different figures: α diversity - assesses the number of species (using only their presence and not abundance) in a given area. β diversity - estimates average changes in species in response to site or habitat heterogeneity γ diversity - measures the turnover of species between local areas	
Data needed: Number and changes in number of species in given areas	
Type of data	Quantitative
Specific	The indicators relate to the environmental conditions for living and survival of the individual species. The indicators relate indirectly to chemicals emissions and releases into the environment, but the environmental conditions are a result of many impacts.
Measurable	The indicator is based on registration of number of species

45. Name of indicator: Species diversity	
Achievable and Easy	Data is provided through the International Union for Conservation of Nature programmes with the goal to provide information and analyses on the status, trends and threats to species in order to inform and catalyse action for biodiversity conservation. The results are published in The IUCN Red List of Threatened Species (Red Data Books, RDB). RDBs classify species in one of eight different categories extinct, extinct in wild, critically endangered, endangered, vulnerable, lower risk, data deficient and not evaluated. Data for geographical Europe and EU27 are available from the European Red List (EC Environment) providing data on the number of threatened species within mammals, amphibians, bees, reptiles, freshwater fishes, butterflies, dragonflies, beetles, molluscs and vascular plants. The data consist of a review of the conservation status of approx. 6,000 European species. The data are easy to achieve and available at: http://ec.europa.eu/environment/nature/conservation/species/redlist/index_en.htm The OECD data portal provides data on the state of threatened species build on country replies to the Annual Quality Assurance (AQA) of OECD environmental reference series. These data are harmonised through the work of the OECD Working Party on Environmental Information (WPEI). The data refer to the latest year available which corresponds to the late 2000s for most countries http://stats.oecd.org/
Relevant	The indicator is only relevant if the review of the conservation status is repeated.
Timed	The reviews are reported during 2009-2012
Accepted, Credible and Robust	RBDs are often used by governments for policy guidance due to their ability to convey information in a simple format. According to a paper by Nunes et al (2001), RBDs are difficult to use as a measure because the definitions of each category are based on subjective views.
Geographical level	Geographical Europe and EU27
Multisectorial elements	The indicator is related to environmental impacts from climate change, air emissions, releases and waste.

46. Name of indicator: A - Pollutants in the terrestrial urban environment; B - Bioaccumulative toxic organic pollutants and mercury in birds and eggs	
Policy issue: Legislations covering the air emissions and releases of pollutants as well as ban and use restrictions of chemical substances (e.g. the POP regulation and REACH)	
Short description: 1. Environmental indicator for contaminants as PCBs, brominated flame retardants (PBDE), perfluorinated alkylated substances (PFAS) and metals in eggs of the terrestrial bird species golden eagle and pied flycatcher as well as liver from urban brown rats and urban and rural earthworms 2. Environmental indicator for monitoring bioaccumulative, toxic organic substances and mercury; Organic pollutants in bird of prey eggs, mercury content in feathers and eggshell thickness. Non-broken eggs and myth feathers are collected from nests in connection with various monitoring projects. Contaminants measured are PCBs, brominated flame retardants (PBDE), perfluorinated alkylated substances (PFAS) and mercury in addition to several pesticides and plant protection substances.	
Data needed: Monitoring data of pollutants in terrestrial animals, birds and eggs of bird of prey.	
Type of data	Quantitative measurements
Specific	The indicators relate to the exposure and bioaccumulation of pollutants in terrestrial organisms.
Measurable	The indicators are based on the monitoring of organic pollutants in land-living animals and in birds.

46. Name of indicator: A - Pollutants in the terrestrial urban environment; B - Bioaccumulative toxic organic pollutants and mercury in birds and eggs	
Achievable and Easy	The monitoring is done as part of survey programmes conducted by NILU and NINA on behalf of The Norwegian Environment Agency. The results from the survey programmes are reported annually or every 5 year for pollutants in bird of prey eggs. The results from the Norwegian survey studies are published and available at http://www.miljodirektoratet.no/no/. Reports are in English or Norwegian. 1. D. Herzke, T. Nygård, E. S. Heimstad, H. Uggerud, L. Hanssen & A. Götsch. 2014 Environmental pollutants in the terrestrial and urban environment. NINA Rapport 261. 113 pp. 2. Nygård, T. & Polder, A. 2012. Environmental pollutants in eggs of birds of prey in Norway. Current situation and time-trends. NINA Rapport 834. 51 pp. (in Norwegian)
Relevant	The indicators are considered as relevant as they indicate the exposure of pollutants to environmental organisms which is directly related to the air emissions and releases of pollutants.
Timed	1. 1995-2011 2. 1992-2012
Accepted, Credible and Robust	The surveys consist of extensive data sets. The data are of high quality and high reliability. 2. Time-trends for pollutants over four to five decades. Some uncertainty with regard to brominated flame retardants and perfluorinated alkyl compounds (PFAS), because the material is still small and the time-series short (1992-2012).
Geographical level	Norway
Multisectorial elements	The indicators are related to air emissions and releases to the environment.

47. Name of indicator: River quality; lead, cadmium, chromium and copper	
Policy issue: Regulation of the use and discharge of heavy metals (REACH Regulation (Registration, Authorisation, Restriction); waterframe directive, etc.)	
Short description: The indicator describes the level of the heavy metals lead, cadmium, chromium and copper in rivers.	
Data needed: Monitoring data of lead, cadmium, chromium and copper in rivers	
Type of data	Quantitative measurements
Specific	These parameters provide information concerning the state and trends of pollution heavy metals and other metals.
Measurable	Data of water quality are available for selected rivers. Water quality is measured in terms of annual mean concentrations of lead, cadmium, chromium and copper. The rivers selected are main rivers draining large watersheds in the European countries; the measurement locations are at the mouths or downstream frontiers of the rivers.
Achievable and Easy	Data are retrieved from OECD Statistics. Database is available at http://stats.oecd.org/
Relevant	The presence of heavy metals in rivers is related to the use and the discharge of the substances into the aquatic environment. Trends in discharge of heavy metals into rivers can be related to regulation of the use and discharge of heavy metals.
Timed	Annually 1980-2011. Ongoing measurements.
Accepted, Credible and Robust	In reading the data, one should compare trends rather than absolute values, since measurement methods vary by country.

47. Name of indicator: River quality; lead, cadmium, chromium and copper	
Geographical level	Selected rivers in European countries. Data sets after 2003 are available for Finland and Germany.
Multisectorial elements	The indicator is related to use and releases to the aquatic environment.

48. Name of indicator: Development of concentration level of organofluorines in marine organisms	
Policy issue: Regulation of substances of very high concern by REACH is of relevance (authorisation, restriction). Regulations applying to offshore activities and discharge to the sea are of very high importance for the level of organofluorines in marine organisms (OSPAR and Helcom).	
Short description: The ICES data portal includes (among other parameters) monitoring data for several year and for a large number of chemicals (e.g. dioxins, chlorinated hydrocarbons, PAHs, pesticides, heavy metals) for parts of Europe, Atlantic ocean, Greenland. Matrices covered include water, sediment, organisms such as mussels and fish, organs of the organism.	
Data needed: Analysis of organofluorines in marine organisms such as herring, cod and whale.	
Type of data	Quantitative measurements
Specific	The indicator relates directly to the regulation of organofluorines and the discharge to sea.
Measurable	The indicator is based on quantitative measurements and reflects temporal changes
Achievable and Easy	The ICES data portal includes (among other parameters) monitoring data for several year and for a large number of chemicals (e.g. dioxins, chlorinated hydrocarbons, PAHs, pesticides, heavy metals) for parts of Europe, Atlantic ocean, Greenland. Matrices covered include water, sediment, organisms such as mussels and fish, organs of the organism. The ICES data portal provides data on the concentration level of organofluorines in marine organisms: herring 2005-2012, cod 2005-2013 or whale 2001-2010. Access to the data portal is available at: http://ecosystemdata.ices.dk/inventory/index.aspx?ParamGR=0&Area=ParamGR&LatN=&LatS=&LonE=&LonW=&Sdate=&Edate=&Filter.
Relevant	The indicator relates to the burden from chemical substances on marine organisms
Timed	2001-2013, ongoing updates
Accepted, Credible and Robust	To be discussed
Geographical level	OSPAR regions, Helcom Sub basins and ICES areas
Multisectorial elements	Marine environment, humans via the environment

49. Name of indicator: Change in population numbers of species with established susceptibility to chemical pollution
Reference for indicator: RPA (2009): Scoping Study for the Evaluation of EU REACH and CLP Regulations. CONTRACT REF: CBO 425. Report Prepared for DEFRA.
Policy issue: Reduction of the negative impacts on the environment arising from chemicals. Several chemicals legislations relate to this purpose. From now on, REACH may be considered the most important legislation.
Short description: This indicator decribes the temporal changes in the population numbers of preselected species. So far, this indicator has not been calculated, even though data for some geographical regions is available.

49. Name of indicator: Change in population numbers of species with established susceptibility to chemical pollution	
Data needed: Time series of measured data on the population number of pre-selected species in pre-selected geographical areas.	
Type of data	Measured (quantitative) data. Suggestion for data sources: WHO International Programme on Chemical Safety; Biodiversity indicator data from government agencies. No central data source identified.
Specific	Temporal changes in this indicator cannot be attributed to only chemicals regulations, as other factors such as habitat loss and climate changes may also have an impact on the observed changes. The species to be used should be selected with great care for
Measurable	The indicator is based on measured data and will also reflect temporal changes.
Achievable and Easy	Data need for the calculations is available in various countries - but not systematized. So far, this indicator has not been calculated. The indicator is considered easy to calculate, once the data has been collected; however the collection of the data is
Relevant	The indicator is considered relevant as it reflects one of the purposes with the chemicals regulation namely the reduction of negative impacts on the environment from chemicals.
Timed	The time scale depends on the time scale of the applied data source(s).
Accepted, Credible and Robust	To be discussed. With respect to robustness, some challenges with respect to data quality and homogeneity in the data sources are expected.
Geographical level	The geographical level depends on the geographical level of the applied data source(s).
Multisectorial elements	Environmental impact

50. Name of indicator: Change in population levels of chemical induced non-lethal effect in wildlife species to chemical pollution	
Reference for indicator: RPA (2009): Scoping Study for the Evaluation of EU REACH and CLP Regulations. CONTRACT REF: CBO 425. Report Prepared for DEFRA.	
Policy issue: Reduction of the negative impacts on the environment arising from chemicals. Several chemicals legislations relate to this purpose. From now on, REACH may be considered the most important legislation.	
Short description: This indicator decribes the temporal changes in the population levels. So far, this indicator has not been calculated.	
Data needed: Time series of measured data on the population levels in pre-selected geographical areas.	
Type of data	Measured (quantitative) data. Suggestion for data sources:
Specific	Temporal changes in this indicator cannot be attributed to only chemicals regulations, as other factors such as habitat loss and climate changes may also have an impact on the observed changes.
Measurable	The indicator is based on measured data and will also reflect temporal changes.
Achievable and Easy	Data need for the calculations is available in various countries - but not systematized. So far, this indicator has not been calculated. The indicator is considered easy to calculate, once the data has been collected; however the collection and systematiz
Relevant	The indicator is considered relevant as it reflects one of the purposes with the chemicals regulation namely the reduction of negative impacts on the environment from chemicals.
Timed	The time scale depends on the time scale of the applied data source(s).

50. Name of indicator: Change in population levels of chemical induced non-lethal effect in wildlife species to chemical pollution	
Accepted, Credible and Robust	To be discussed. With respect to robustness, some challenges with respect to data quality and homogeneity in the data sources are expected.
Geographical level	The geographical level depends on the geographical level of the applied data source(s).
Multisectorial elements	Environmental impact

51. Name of indicator: Change in levels of selected chemicals in ambient air samples	
Reference for indicator: RPA (2009): Scoping Study for the Evaluation of EU REACH and CLP Regulations. CONTRACT REF: CBO 425. Report Prepared for DEFRA.	
Policy issue: Reduction of the negative impacts on the environment arising from chemicals. Several chemicals legislations relate to this purpose. From now on, REACH may be considered the most important legislation.	
Short description: This indicator decribes the temporal changes in the concentrations of selected chemicals in ambient air. So far, this indicator has not been calculated, even though data is available.	
Data needed: Time series of measured data of the concentration in air of pre-selected chemicals.	
Type of data	Measured (quantitative) data. Suggestion for data sources: AirBase; Database on air quality; RAINS/GAINS; IPCheM for monitoring data (Information Platform for Chemical Monitoring)
Specific	Temporal changes in this indicator cannot be attributed to only chemicals regulations, as other factors such as weather situation (wind directions, degree of precipitation), mass flow from countries not covered by legislation also have an impact on the ob
Measurable	The indicator is based on measured data and will also reflect temporal changes.
Achievable and Easy	Data need for the calculations is available for many EU countries and for some substances (but hardly not for all relevant substances), so the indicator is considered both achievable and easy to calculate. It may be relevant to extend the monitoring progr
Relevant	If the right substances are selected, the indicator is considered relevant as it reflects one of the purposes with the chemicals regulation - namely the reduction of emissions of hazardous substances into the environment.
Timed	The time scale depends on the time scale of the applied data source(s), but e.g. yearly average concentrations appears to be appropriate.
Accepted, Credible and Robust	To be discussed.
Geographical level	The geographical level depends on the geographical level of the applied data source(s).
Multisectorial elements	Environmental impact.

52. Name of indicator: Change in levels of selected chemicals in water and sediment samples
Reference for indicator: RPA (2009): Scoping Study for the Evaluation of EU REACH and CLP Regulations. CONTRACT REF: CBO 425. Report Prepared for DEFRA.
Policy issue: Reduction of the negative impacts on the environment arising from chemicals. Several chemicals legislations relate to this purpose. From now on, REACH may be considered the most important legislation.

52. Name of indicator: Change in levels of selected chemicals in water and sediment samples	
Short description: This indicator decribes the temporal changes in the concentrations of selected chemicals in water and sediment samples. So far, this indicator has not been calculated, even though data is available. The water sample concentrations are primarily usefull fo	
Data needed: Time series of measured data of the concentration in water and sediment of pre-selected chemicals at various geographical distributed stations.	
Type of data	Measured (quantitative) data. Suggestion for data sources: IPCheM for monitoring data (Information Platform for Chemical Monitoring); Waterbase; ICES data portal; The Danish Natural Environment Portal; Environmental Specimen Bank
Specific	This indicator relates primarily to the emissions of chemicals discharges into surface water. The substances to be chosen for the sediment could be PBT/vPvB substances and substances to be chosen for the water could be not readily biodegrable, hydrophilli
Measurable	The indicator is based on measured data and will also reflect temporal changes.
Achievable and Easy	Data need for the calculations is available for many EU countries and for some substances (but hardly not for all relevant substances), so the indicator is considered both achievable and easy to calculate. It may be relevant to extend the monitoring progr
Relevant	If the right substances are selected, the indicator is considered relevant as it reflects one of the purposes with the chemicals regulation - namely the reduction of emissions of hazardous substances into the environment.
Timed	The time scale depends on the time scale of the applied data source(s).
Accepted, Credible and Robust	To be discussed.
Geographical level	The geographical level depends on the geographical level of the applied data source(s).
Multisectorial elements	Environmental impact (water and sediment).

53. Name of indicator: Change in levels of selected chemicals in soil samples	
Reference for indicator: RPA (2009): Scoping Study for the Evaluation of EU REACH and CLP Regulations. CONTRACT REF: CBO 425. Report Prepared for DEFRA.	
Policy issue: Reduction of the negative impacts on the environment arising from chemicals. Several chemicals legislations relate to this purpose. From now on, REACH may be considered the most important legislation.	
Short description: This indicator decribes the temporal changes in the concentrations of selected chemicals in soil samples. So far, this indicator has not been calculated, even though data is available. This indicator is primarily usefull for hydrophobic substances and thu	
Data needed: Time series of measured data of the concentration in soil of pre-selected chemicals at various geographical distributed stations.	
Type of data	Measured (quantitative) data. Suggestion for data sources: IPCheM for monitoring data (Information Platform for Chemical Monitoring); Environmental Specimen Bank; The Danish Natural Environment Portal
Specific	This indicator relates primarily to the emissions of chemicals discharges into the sewage and or soil. The substances to be chosen for the indicator could well be PBT/vPvB substances.
Measurable	The indicator is based on measured data and will also reflect temporal changes.

53. Name of indicator: Change in levels of selected chemicals in soil samples	
Achievable and Easy	Data need for the calculations is available for many EU countries and for some substances (but hardly not for all relevant substances), so the indicator is considered both achievable and easy to calculate. It may be relevant to extend the monitoring progr
Relevant	If the right substances are selected, the indicator is considered relevant as it reflects one of the purposes with the chemicals regulation - namely the reduction of emissions of hazardous substances into the environment.
Timed	The time scale depends on the time scale of the applied data source(s).
Accepted, Credible and Robust	To be discussed.
Geographical level	The geographical level depends on the geographical level of the applied data source(s).
Multisectorial elements	Environmental impact (soil).

54. Name of indicator: Change in levels of selected chemicals in waste sludge samples	
Reference for indicator: RPA (2009): Scoping Study for the Evaluation of EU REACH and CLP Regulations. CONTRACT REF: CBO 425. Report Prepared for DEFRA.	
Policy issue: Reduction of the negative impacts on the environment arising from chemicals. Several chemicals legislations relate to this purpose. From now on, REACH may be considered the most important legislation.	
Short description: This indicator decribes the temporal changes in the concentrations of selected chemicals in sewage sludge samples. This indicator is primarily usefull for hydrophobic substances and thus includes one of focus points of REACH - namely the PBT and vPvB subs	
Data needed: Time series of measured data of the concentration in sewage sludge of pre-selected chemicals at various geographical distributed stations.	
Type of data	Measured (quantitative) data. Suggestion for data sources: Danish EPA database on substances in consumer products
Specific	This indicator relates primarily to the emissions of hydrophobic chemicals discharges into the sewage. The substances to be chosen for the indicator could well be PBT/vPvB substances.
Measurable	The indicator is based on measured data and will also reflect temporal changes.
Achievable and Easy	Data need for the calculations is available for many EU countries and for some substances (but hardly not for all relevant substances), so the indicator is considered both achievable and easy to calculate. It may be relevant to extend the monitoring progr
Relevant	If the right substances are selected, the indicator is considered relevant as it reflects one of the purposes with the chemicals regulation - namely the reduction of emissions of hazardous substances into the environment.
Timed	The time scale depends on the time scale of the applied data source(s).
Accepted, Credible and Robust	To be discussed.
Geographical level	The geographical level depends on the geographical level of the applied data source(s).
Multisectorial elements	Environmental impact (sludge, soil).

55. Name of indicator: Change in levels of selected chemicals in tissue samples of terrestrial species
Reference for indicator: RPA (2009): Scoping Study for the Evaluation of EU REACH and CLP Regulations. CONTRACT REF: CBO 425. Report Prepared for DEFRA.

55. Name of indicator: Change in levels of selected chemicals in tissue samples of terrestrial species	
Policy issue: Reduction of the negative impacts on the environment arising from chemicals. Several chemicals legislations relate to this purpose. From now on, REACH may be considered the most important legislation.	
Short description: This indicator decribes the temporal changes in the concentrations of selected chemicals in tissue samples of terrestrial species. So far, this indicator has not been calculated, even though data is available. This indicator is primarily usefull for hydro	
Data needed: Time series of measured data of the concentration in tissue samples from terrestrial species of pre-selected chemicals at various geographical distributed stations.	
Type of data	Measured (quantitative) data. Suggestion for data sources: IPCheM for monitoring data (Information Platform for Chemical Monitoring); Environmental Specimen Bank; Climate and Pollution Agency
Specific	This indicator relates primarily to the emissions of chemicals discharges into the sewage and/or soil. The substances to be chosen for the indicator could well be PBT/vPvB substances. Other factors such as habitat loss and climate changes may also have an
Measurable	The indicator is based on measured data and will also reflect temporal changes.
Achievable and Easy	Data need for the calculations is available for many EU countries and for some substances (but hardly not for all relevant substances), so the indicator is considered both achievable and easy to calculate. It may be relevant to extend the monitoring progr
Relevant	If the right substances are selected, the indicator is considered relevant as it reflects one of the purposes with the chemicals regulation - namely the reduction of emissions of hazardous substances into the environment.
Timed	The time scale depends on the time scale of the applied data source(s).
Accepted, Credible and Robust	To be discussed.
Geographical level	The geographical level depends on the geographical level of the applied data source(s).
Multisectorial elements	Environmental impact (soil).

56. Name of indicator: Change in levels of selected chemicals in tissue samples of aquatic species	
Reference for indicator: RPA (2009): Scoping Study for the Evaluation of EU REACH and CLP Regulations. CONTRACT REF: CBO 425. Report Prepared for DEFRA.	
Policy issue: Reduction of the negative impacts on the environment arising from chemicals. Several chemicals legislations relate to this purpose. From now on, REACH may be considered the most important legislation.	
Short description: This indicator decribes the temporal changes in the concentrations of selected chemicals in tissue samples of aquatic species. So far, this indicator has not been calculated, even though data is available. This indicator is primarily usefull for hydrophob	
Data needed: Time series of measured data of the concentration in tissue samples from aquatic species of pre-selected chemicals at various geographical distributed stations.	
Type of data	Measured (quantitative) data. Suggestion for data sources: IPCheM for monitoring data (Information Platform for Chemical Monitoring); Environmental Specimen Bank; Climate and Pollution Agency; EEA Hazardous substances in marine organisms and loads to coastal waters
Specific	This indicator relates primarily to the emissions of chemicals discharges into the surface water/sewage. The substances to be chosen

56. Name of indicator: Change in levels of selected chemicals in tissue samples of aquatic species	
	for the indicator could well be PBT/vPvB substances. Other factors such as habitat loss and climate changes may also have
Measurable	The indicator is based on measured data and will also reflect temporal changes.
Achievable and Easy	Data need for the calculations is available for many EU countries and for some substances (but hardly not for all relevant substances), so the indicator is considered both achievable and easy to calculate. It may be relevant to extend the monitoring progr
Relevant	If the right substances are selected, the indicator is considered relevant as it reflects one of the purposes with the chemicals regulation - namely the reduction of emissions of hazardous substances into the environment.
Timed	The time scale depends on the time scale of the applied data source(s).
Accepted, Credible and Robust	To be discussed.
Geographical level	The geographical level depends on the geographical level of the applied data source(s).
Multisectorial elements	Environmental impact (water).

57. Name of indicator: Change in soil biodiversity	
Reference for indicator: RPA (2009): Scoping Study for the Evaluation of EU REACH and CLP Regulations. CONTRACT REF: CBO 425. Report Prepared for DEFRA.	
Policy issue: Reduction of the negative impacts on the environment arising from chemicals. Several chemicals legislations relate to this purpose. From now on, REACH may be considered the most important legislation.	
Short description: This indicator describes the temporal changes in the population levels. So far, this indicator has not been calculated.	
Data needed: Time series of measured data on the soil biodiversity in pre-selected geographical areas.	
Type of data	Measured (quantitative) data. Suggestion for data sources:
Specific	Temporal changes in this indicator cannot be attributed to only chemicals regulations, as other factors such as habitat loss and climate changes may also have an impact on the observed changes.
Measurable	The indicator is based on measured data and will also reflect temporal changes.
Achievable and Easy	Data need for the calculations is available in various countries - but not systematized. So far, this indicator has not been calculated. The indicator is considered easy to calculate, once the data has been collected; however the collection and systematiz
Relevant	The indicator is considered relevant as it reflects one of the purposes with the chemicals regulation namely the reduction of negative impacts on the environment from chemicals.
Timed	The time scale depends on the time scale of the applied data source(s).
Accepted, Credible and Robust	To be discussed. With respect to robustness, some challenges with respect to data quality and homogeneity in the data sources are expected.
Geographical level	The geographical level depends on the geographical level of the applied data source(s).
Multisectorial elements	Environmental impact (soil)

A3.8 Classification of the Proposed Key Indicators

A3.8.1 Output indicators

Output indicator 1 - Substances with a harmonised classification and labelling implemented after the entry into force of the REACH and CLP Regulations per hazard class	
Specific	**Is it clear exactly what is being measured? Are there any other confounding factors?** The increase in the number of harmonised classifications denotes an improvement of knowledge on properties and safe uses of chemicals. Harmonised classifications may be proposed by Member States, manufacturers, importers and downstream users to ensure an adequate risk management throughout the European Community. They primarily concern the most hazardous substances, in particular those that are carcinogenic, mutagenic, toxic for reproduction or respiratory sensitisers.[230]
Measurable	**Is it qualitative or quantitative?** Qualitative and quantitative. It quantifies the CLH per hazard class and provides the lists of chemicals with CLH per hazard class.
Achievable and Easy	**Are data publicly available at reasonable cost and effort?** The indicator can be quantified screening the submitted CLH proposals (available at: http://echa.europa.eu/web/guest/registry-of-submitted-harmonised-classification-and-labelling-intentions) by hazard class **How reliable, complete and coherent (i.e. same units) are the data?** The database is maintained by ECHA, therefore its reliability, completeness and coherence should be ensured.
Relevant	**Does the indicator establish and measure either:** **- The causal link between chemical substances and their effects on the environment and/or human health; or** **- The causal link between chemicals legislation and the reduced effects on the environment and/or human health?** The indicator can be used as a basis for establishing the link between the chemical substances regulated and their effect on the human health and the environment.
Timed (timely)	**Are data available for this indicator for today? Are data available for the baseline period (2004-2013)? Are the data regularly updated?** The indicator measures the number of substances with CLH after the entry into force of CLP (2009). The CLI is regularly updated. The indicator could be updated every year or every five years, in coincidence with the REACH review periods.
Accepted, Credible and Robust	**Is the indicator widely accepted, unambiguous and easy to interpret for non-experts?** The indicator is unambiguous but requires a basic understanding of the REACH and CLP Regulations. With a slightly different definition (i.e. not referring to hazard classes), it has been previously proposed in the REACH baseline study.
Geographical level	***e.g. (Global/European/National/Regional)*** European level.

[230] ECHA (2012): CMR substances from Annex VI of the CLP Regulation, European Chemicals Agency, Helsinki, page 7. Available at: http://echa.europa.eu/documents/10162/13562/cmr_report_en.pdf

Output indicator 2 – Change in self-classifications (per hazard class) since the entry into force of the REACH and CLP Regulations	
Specific	**Is it clear exactly what is being measured?** The self-classification of about 7,700 individual substances in 2005 and 2016 has been compared. The number of substances per hazard class increased due to more data becoming available thanks to REACH requirements. Substances subject to parallel OSH and environmental legislation should denote that appropriate risk management measures are introduced to reduce exposure of humans and environmental receptors. **Are there any other confounding factors?** No.
Measurable	**Is it qualitative or quantitative?** Quantitative. It provides the variation (in percentage) of self-classifications for the compared substances.
Achievable and Easy	**Are data publicly available at reasonable cost and effort? How reliable, complete and coherent (i.e. same units) are the data?** Changes in self-classifications can be accounted only comparing the CLI with an old image of it.
Relevant	**Does the indicator establish and measure either:** **- The causal link between chemical substances and their effects on the environment and/or human health; or** **- The causal link between chemicals legislation and the reduced effects on the environment and/or human health?** The indicator can be used as a basis for establishing the link between the chemical substances regulated and their effect on the human health and the environment.
Timed (timely)	**Are data available for this indicator for today? Are data available for the baseline period (2004-2013)? Are the data regularly updated?** The current self-classifications as reported in the CLI have been compared with a pre-CLP IUCLID4 database. Hazard statements were previously expressed as risk phrases. The comparison requires the matching of hazard statements with the equivalent risk phrases. The indicator could be updated at the end of the 2018 registration deadline and, subsequently, in coincidence with the REACH review periods (every five years).
Accepted, Credible and Robust	**Is the indicator widely accepted, unambiguous and easy to interpret for non-experts?** The indicator is unambiguous but requires a basic understanding of the REACH and CLP Regulations. The indicator has been strongly suggested during the Experts Workshop.
Geographical level	***e.g. (Global/European/National/Regional)*** European level.

Output indicator 3 - Restriction dossiers implemented after the entry into force of the REACH and CLP Regulations per hazard class, PBT/vPvB profile and endocrine activity of the substances and groups of substances covered by the dossiers	
Specific	**Is it clear exactly what is being measured?** Restriction dossiers can have different scopes (import, use, placing on the market of all uses or specific uses) and can cover substances or groups of substances. However, the progressive increase of restrictions directly contributes to lowering the human and environmental exposure to substances of very high concern. **Are there any other confounding factors?**

Output indicator 3 - Restriction dossiers implemented after the entry into force of the REACH and CLP Regulations per hazard class, PBT/vPvB profile and endocrine activity of the substances and groups of substances covered by the dossiers	
	No.
Measurable	**Is it qualitative or quantitative?** Qualitative and quantitative. It quantifies the restriction dossiers per hazard class and provides the lists of chemicals restricted per hazard class.
Achievable and Easy	**Are data publicly available at reasonable cost and effort?** The indicator can be quantified comparing the submitted restriction proposals (available at: http://echa.europa.eu/web/guest/registry-of-submitted-restriction-proposal-intentions) with the list of restrictions (Annex XVII of REACH) (available at: http://echa.europa.eu/addressing-chemicals-of-concern/restrictions/list-of-restrictions) **How reliable, complete and coherent (i.e. same units) are the data?** Both databases are maintained by ECHA, therefore their reliability, completeness and coherence should be ensured.
Relevant	**Does the indicator establish and measure either:** **- The causal link between chemical substances and their effects on the environment and/or human health; or** **- The causal link between chemicals legislation and the reduced effects on the environment and/or human health?** The indicator can be used as a basis for establishing the link between the chemical substances regulated and their effect on the human health and the environment.
Timed (timely)	**Are data available for this indicator for today? Are data available for the baseline period (2004-2013)? Are the data regularly updated?** The indicator measures the number of substances restricted after the entry into force of REACH (2007). Data is available on the ECHA website and is regularly updated. The indicator could be updated every year or every five years, in coincidence with the REACH review periods.
Accepted, Credible and Robust	**Is the indicator widely accepted, unambiguous and easy to interpret for non-experts?** The indicator is unambiguous but requires a basic understanding of the REACH and CLP Regulations. With a slightly different definition (i.e. not referring to hazard classes), the indicator has been suggested by DHI (2005); Eurostat (2009); RPA et al (2012)
Geographical level	***e.g. (Global/European/National/Regional)*** European level.

Output indicator 4 - Substances of Very High Concerns included in Annex XIV per hazard class, PBT/vPvB profile or with clear evidence of endocrine activity	
Specific	**Is it clear exactly what is being measured?** The indicator measures the number of SVHC going through the REACH authorisation process, that aims to assure that their risks are properly controlled and the substances progressively replaced by suitable alternatives. For the substances for which applications for authorisation (AfA) are received, applicants need to ensure that the risks are adequately controlled. Substances for which no AfA are received have been effectively replaced by more suitable alternatives or their production may have ceased in the EU. **Are there any other confounding factors?** No.
Measurable	**Is it qualitative or quantitative?** Qualitative and quantitative. It quantifies the number of substances going through authorisation per hazard class and provides the lists of chemicals per hazard class.

Output indicator 4 - Substances of Very High Concerns included in Annex XIV per hazard class, PBT/vPvB profile or with clear evidence of endocrine activity	
Achievable and Easy	**Are data publicly available at reasonable cost and effort?** The authorisation list (Annex XIV) can be found at: http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list **How reliable, complete and coherent (i.e. same units) are the data?** The list is regularly updated by ECHA, therefore its reliability, completeness and coherence should be ensured.
Relevant	**Does the indicator establish and measure either:** **- The causal link between chemical substances and their effects on the environment and/or human health; or** **- The causal link between chemicals legislation and the reduced effects on the environment and/or human health?** The indicator can be used as a basis for establishing the link between the chemical legislation and the reduced effects on the environment and/or human health.
Timed (timely)	**Are data available for this indicator for today? Are data available for the baseline period (2004-2013)? Are the data regularly updated?** The indicator measures the number of SVHCs included in Annex XIV therefore since 2007. Data is available on the ECHA website and is regularly updated. The indicator could be updated every year or every five years, in coincidence with the REACH review periods.
Accepted, Credible and Robust	**Is the indicator widely accepted, unambiguous and easy to interpret for non-experts?** The indicator is unambiguous but requires a basic understanding of the REACH and CLP Regulations. With a slightly different definition (i.e. not referring to hazard classes), the indicator has been suggested by Eurostat (2009) and RPA et al (2012)
Geographical level	***e.g. (Global/European/National/Regional)*** European

A3.8.2 Result indicators

Result indicator 1 – Change in the concentration level of selected chemicals in human body tissues	
Specific	**Is it clear exactly what is being measured?** Human biomonitoring HBM data are the best indicator of exposure to (specific) chemicals. **Are there any other confounding factors?** No, but HBM cannot distinguish between sources of exposure.
Measurable	**Is it qualitative or quantitative?** Quantitative.
Achievable and Easy	**Are data publicly available at reasonable cost and effort?** HBM is expansive and resource intensive. There are data from one-off studies, some at European level (COPHES and DEMOCOPHES), most at national and regional level. The only HBM database able to provide historic trend is the German ESB; ; information is available for students' human samples (blood plasma, whole blood, saliva, urine, scalp hair and pubic hair) for a number of analytes (metals, non-metals, chlorohydrocarbons, phthalates, bisphenol A, perfluorinates compounds) and for four different sites (Münster, Greifswald, Halle/Saale and Ulm).

Result indicator 1 – Change in the concentration level of selected chemicals in human body tissues	
	How reliable, complete and coherent (i.e. same units) are the data? HBM data from different studies, laboratories and different regions cannot be easily compared. There are co-ordinated efforts to create a harmonised European HBM database.
Relevant	**Does the indicator establish and measure either:** **- The causal link between chemical substances and their effects on the environment and/or human health; or** **- The causal link between chemicals legislation and the reduced effects on the environment and/or human health?** HBM data assist in establishing and measuring the link between chemical substances and their effects on human health. Historic trends of HBM data are the best measures of the effectiveness of legislative initiatives in lowering exposure to (specific) chemicals.
Timed (timely)	**Are data available for this indicator for today?** For specific chemicals and regions only. Moreover, only 200 chemicals can currently be assessed by HBM. **Are data available for the baseline period (2004-2013)?** Only for Germany, information available per year since 1981. **Are the data regularly updated?** In Germany only.
Accepted, Credible and Robust	**Are they widely accepted, unambiguous and easy to interpret for non-experts?** HBM data are widely recognised as the best measure of chemicals' exposure. Once analysed, data trends should be easily interpretable by non-experts too.
Geographical level	*e.g. (Global/European/National/Regional)* Currently national (Germany).

Result indicator 2 – Change in the concentration level of selected chemicals in animal and plant tissues	
Specific	**Is it clear exactly what is being measured?** As for HBM, biomonitoring of chemicals in animal species is the best indicator of environmental exposure. The German ESB provides BM data from different animal and plant samples. Moreover, concentrations of eight compounds in marine organisms are made available by the EEA: http://www.eea.europa.eu/data-and-maps/indicators/hazardous-substances-in-marine-organisms/hazardous-substances-in-marine-organisms-1 **Are there any other confounding factors?** No, but biomonitoring cannot distinguish between sources of exposure.
Measurable	**Is it qualitative or quantitative?** Quantitative.
Achievable and Easy	**Are data publicly available at reasonable cost and effort?** Biomonitoring data are expensive and resource intensive. **How reliable, complete and coherent (i.e. same units) are the data?** Only Germany has a centralised system to ensure reliability, completeness and coherence.
Relevant	**Does the indicator establish and measure either:**

Result indicator 2 – Change in the concentration level of selected chemicals in animal and plant tissues	
	- The causal link between chemical substances and their effects on the environment and/or human health; or **- The causal link between chemicals legislation and the reduced effects on the environment and/or human health?** Biomonitoring data assist in establishing and measuring the link between chemical substances and their effects on the environment. Historic trends can help in determining the effectiveness of the chemicals legislation.
Timed (timely)	**Are data available for this indicator for today?** For specific chemicals and regions only. **Are data available for the baseline period (2004-2013)?** For specific chemicals and regions only. **Are the data regularly updated?** Only for specific chemicals and in specific regions.
Accepted, Credible and Robust	**Are they widely accepted, unambiguous and easy to interpret for non-experts?** Concentrations of chemicals in animal samples are recognised as good measures of environmental exposure. Once analysed, data can be easily interpreted by non-experts only.
Geographical level	***e.g. (Global/European/National/Regional)*** One-off studies are available at national level. Germany has the ESB that provides historic data trends from limnetic, marine, terrestrial (and human) samples. EEA has concentration trends (2003-2012) of certain hazardous substances in marine organisms for the North-East Atlantic and Baltic Sea only.

Result indicator 3 - Change in the concentration level of selected chemicals in air, water and soil samples	
Specific	**Is it clear exactly what is being measured?** Concentrations of specific chemicals in environmental media constitute a second-best indicator after biomonitoring data. **Are there any other confounding factors?** Some chemicals, e.g. metals, can have natural background concentrations in the environment. It may be difficult to determine the sources, especially if diffuse.
Measurable	**Is it qualitative or quantitative?** Quantitative.
Achievable and Easy	**Are data publicly available at reasonable cost and effort?** EEA holds data on concentrations of air pollutants (outside the scope of this study), soil contamination and water monitoring programmes results. **How reliable, complete and coherent (i.e. same units) are the data?** Monitoring in environmental media is carried out mainly for the main pollutants. WFD monitoring programme results may provide interesting results but the comparability of the data between different laboratories, Member States and different years is poor.
Relevant	**Does the indicator establish and measure either:** **- The causal link between chemical substances and their effects on the environment and/or human health; or** **- The causal link between chemicals legislation and the reduced effects on the environment and/or human health?**

Result indicator 3 - Change in the concentration level of selected chemicals in air, water and soil samples	
	The indicator is a good measure of the effectiveness of the environmental legislation in reducing the exposure to some main pollutants. However, data are usually available for urban main pollutants and may not be relevant for the assessment of REACH and CLP.
Timed (timely)	**Are data available for this indicator for today?** For specific chemicals only. **Are data available for the baseline period (2004-2013)?** For specific chemicals only. **Are the data regularly updated?** For specific chemicals only.
Accepted, Credible and Robust	**Are they widely accepted, unambiguous and easy to interpret for non-experts?** Concentrations are those at the monitoring stations. Clear changes in historic trends can be easily interpreted by non-experts too.
Geographical level	***e.g. (Global/European/National/Regional)*** European.

Result indicator 4 – Change in emissions of selected chemicals in air, water and soil	
Name	Emissions of selected chemicals to environmental media
Specific	**Is it clear exactly what is being measured?** The indicator is a third-best measure of exposure to specific chemicals. It does not provide information (if not indicatively) on the population that is being exposed. **Are there any other confounding factors?** Effectiveness of emissions control technologies; macroeconomic situation.
Measurable	**Is it qualitative or quantitative?** Quantitative.
Achievable and Easy	**Are data publicly available at reasonable cost and effort?** Data are publicly available through the E-PRTR maintained by the EEA. **How reliable, complete and coherent (i.e. same units) are the data?** The reporting of emissions of selected chemicals is long established, ensuring reliability, completeness and coherence of the data.
Relevant	**Does the indicator establish and measure either:** **- The causal link between chemical substances and their effects on the environment and/or human health; or** **- The causal link between chemicals legislation and the reduced effects on the environment and/or human health?** The reporting of emissions is performed on some chemicals only, which may not be the best chemical substances for the assessment of the effectiveness of REACH and CLP in reducing exposure.
Timed (timely)	**Are data available for this indicator for today?** For selected chemicals only.

Result indicator 4 – Change in emissions of selected chemicals in air, water and soil	
	Are data available for the baseline period (2004-2013)? For selected chemicals only. **Are the data regularly updated?** For selected chemicals only.
Accepted, Credible and Robust	**Are they widely accepted, unambiguous and easy to interpret for non-experts?** Indicators on emissions are used since many years and are widely accepted and easy to interpret.
Geographical level	***e.g. (Global/European/National/Regional)*** European.

Result indicator 5 – Change in production volume of selected chemicals	
Specific	**Is it clear exactly what is being measured?** Lacking biomonitoring data, data on concentrations in the environment or data on emissions, production volumes of specific chemicals may provide indications of the effectiveness of the legislation. **Are there any other confounding factors?** Macroeconomic situation.
Measurable	**Is it qualitative or quantitative?** Quantitative.
Achievable and Easy	**Are data publicly available at reasonable cost and effort?** Eurostat PRODCOM provides statistics on the production of group of chemicals. Ideally, data by CAS number would be very good indicators of changes due to chemicals legislation. **How reliable, complete and coherent (i.e. same units) are the data?** Reliability, completeness and coherence are ensured by Eurostat.
Relevant	**Does the indicator establish and measure either:** **- The causal link between chemical substances and their effects on the environment and/or human health; or** **- The causal link between chemicals legislation and the reduced effects on the environment and/or human health?** The indicator may assist in establishing the effectiveness of the chemicals legislation, in particular of bans and restrictions on specific chemicals. For most of the chemicals however, the effects of the chemicals legislation would not be distinguishable from other confounding factors.
Timed (timely)	**Are data available for this indicator for today?** For selected chemicals only. **Are data available for the baseline period (2004-2013)?** For selected chemicals only. **Are the data regularly updated?** For selected chemicals only.

Result indicator 5 – Change in production volume of selected chemicals	
Accepted, Credible and Robust	**Are they widely accepted, unambiguous and easy to interpret for non-experts?** Although not the best indicator of exposure, during the Experts workshop (see Section 5) the indicator was mentioned various times. Detailed data by CAS number would be very informative. The Eurostat Baseline study has developed an indicator based on production volumes of toxic chemicals by (eco)toxicity (see Section 2).
Geographical level	***e.g. (Global/European/National/Regional)*** European.

A3.8.3 Impact indicators

Impact indicator 1	
Name	Change in incidence, prevalence and mortality following a change in chemicals' exposure due to chemicals legislation requirements per disease group
Specific	**Is it clear exactly what is being measured? Are there any other confounding factors?** Incidence, prevalence and mortality rates of different diseases are reported by national and international organisations. Changes in these rates however are influenced by many confounding factors (socio-economic determinants, dietary habits, hygiene habits, macroeconomic situation, diagnosis practices, etc.) and their attribution to legislative initiatives regulating chemicals can be attempted when a clear linkage between exposure and health impacts is established by health practitioners and for short latency diseases only.
Measurable	**Is it qualitative or quantitative?** Quantitative.
Achievable and Easy	**Are data publicly available at reasonable cost and effort?** Human health statistics (presented in Annex 2) are routinely collected in all Member States and by international organisations. However, data at the level of detail necessary to estimate the chemical attributable fractions are available only from the occupational health and safety area and for few Member States. **How reliable, complete and coherent (i.e. same units) are the data?** Data used for high level health indicators are usually comparable among countries. The data necessary for the estimate of AFs however are available at national level only and a comparison between Member States or extrapolation to the European level can be carried out with several caveats only. Different national organisations use different data gaps fillings.
Relevant	**Does the indicator establish and measure either:** **- The causal link between chemical substances and their effects on the environment and/or human health; or** **- The causal link between chemicals legislation and the reduced effects on the environment and/or human health?** The indicator establishes and measures the link between the chemicals legislation and the reduced effects on the human health
Timed (timely)	**Are data available for this indicator for today? Are data available for the baseline period (2004-2013)? Are the data regularly updated?** Some suitable and regularly updated data are available in the UK and in Germany for the baseline period for occupational skin diseases and occupational asthma only.

Impact indicator 1	
Accepted, Credible and Robust	**Is the indicator widely accepted, unambiguous and easy to interpret for non-experts?** The degree to which a change in incidence, prevalence and mortality of a disease may be attributed to the lowering of chemicals' exposure due to legislative measures cannot be determined with absolute certainty and is therefore debatable.
Geographical level	***e.g. (Global/European/National/Regional)*** National (extrapolation to European level only possible with certain assumptions)

Annex 4 List Of Substances for which Exposure Data are Available

Table A3-1: List of substances for which exposure data are available					
Substance	**CAS Number**	**EC Number**	**Database**	**Type of data**	**Time period**
All chemicals			KEMI	Substance, chemical group, function	1996-2007
			KEMI	Statistics for chemicals - substance flow card	1993-2010 (depending on substance)
			Eurostat	Total production of chemicals, five classes of environmental harmful and toxic chemicals	1995/96 on wards
			Danish natural environment portal (NEED ACCESS)		
Alachlor (pesticide)	15972-60-8	240-110-8	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			ICES	Contaminants and biological effects	2005-2011
			WFD PS		2008 onwards
Aldrin (pesticide)	309-00-2	206-215-8	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			ICES	Contaminants and biological effects	1988-2013
			Environmental Quality Standards Directive 2008/105/EC.		
Aliphatic hydrocarbons			ICES	Contaminants and biological effects	2005-2013
Aluminium	7429-90-5	231-072-3	ICES	Contaminants and biological effects	1977-2013
Anthracene	102-12-7	204-371-1	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			ICES	Contaminants and biological effects	1985-2013
			WFD PS		2008 onwards

Table A3-1: List of substances for which exposure data are available					
Substance	**CAS Number**	**EC Number**	**Database**	**Type of data**	**Time period**
Arsenic	7440-38-2	231-148-6	Environment.no (list of PSs)	Change in emissions	1995-2010
			environment.no	Interactive map, arsenic in moss	1970-2010
			E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			Environmental Specimen Bank (ESB)	Human samples - blood plasma, whole blood, saliva, urine, hair. Limnetic samples - Zebra Mussel, Bream. Marine samples - Common Bladder wrack, blue mussel, Eelpout, Herring Gull. Terrestrial Samples - common spruce, pine, Lombardy poplar, Beech, Roe deer,	1981-2013
			ICES	Contaminants and biological effects	1983-2013
			German Environmental Survey (GerES)	Biomarker - levels in urine (children)	2003-2006
			ENHIS	Intake through food (adults)	2004
Asbestos	1332-21-4	603-721-4	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
Atrazine (pesticide)	1912-24-9	217-617-8	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			WFD PS		2008 onwards
Barium	7440-39-3	231-149-1	ICES	Contaminants and biological effects	1990-2013
Benzene	71-43-2	200-753-7	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			ICES	Contaminants and biological effects	2004-2013
			WFD PS		2008 onwards
Benzo(g.h.i)perylene	91-24-2	205-883-8	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
Bisphenol A	80-05-7	201-245-8	Environment.no (list of PSs)	Change in emissions	1995-2010
			DEMOCOPHES	Biomarker - Bisphenol A in urine (5 countries)	2010-2012
			Environmental Specimen Bank (ESB)	Human samples - blood plasma, whole blood, saliva, urine, hair. Limnetic samples - Zebra Mussel, Bream. Marine samples - Common Bladder wrack, blue mussel, Eelpout, Herring Gull. Terrestrial Samples -	1981-2013

Table A3-1: List of substances for which exposure data are available					
Substance	**CAS Number**	**EC Number**	**Database**	**Type of data**	**Time period**
				common spruce, pine, Lombardy poplar, Beech, Roe deer,	
			TNO-report R 2004/493	Levels in human blood	2004
Boron	7440-42-8	231-151-2	ICES	Contaminants and biological effects	2004-2013
Bromide			ICES	Contaminants and biological effects	1990-1991
Brominated flame retardants	32534-81-9, 32536-52-0	251-084-2, 251-087-9	Environment.no (list of PSs)	Change in emissions	1995-2010
			TNO-report R 2004/493	Levels in human blood (PBDE)	2004
Brominated diphenylethers (PBDE)	N/A	N/A	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			ICES	Contaminants and biological effects	2004-2007/11
			TNO-report R 2004/493	Levels in human blood (PBDE)	2004
			ENHIS	Levels in human breast milk	
			WFD PS		2008 onwards
Cadmium	7440-43-9	231-152-8	Environment.no (list of PSs)	Change in emissions	1995-2010
			Environment.no	Interactive map, cadmium in moss	1970-2010
			E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			DEMOCOPHES	Biomarker - Cadmium in urine (17 countries)	2010-2012
			Environmental Specimen Bank (ESB)	Human samples - blood plasma, whole blood, saliva, urine, hair. Limnetic samples - Zebra Mussel, Bream. Marine samples - Common Bladder wrack, blue mussel, Eelpout, Herring Gull. Terrestrial Samples - common spruce, pine, Lombardy poplar, Beech, Roe deer,	1981-2013
			ICES	Contaminants and biological effects	1977-2013
			German Environmental Survey (GerES)	Biomarker - levels in blood and urine (children)	2003-2006
			ENHIS	Intake through food (adults)	2004
			WFD PS		2008

Table A3-1: List of substances for which exposure data are available					
Substance	**CAS Number**	**EC Number**	**Database**	**Type of data**	**Time period**
					onwards
Calcium	7440-70-2	231-179-5	Environmental Specimen Bank (ESB)	Human samples - blood plasma, whole blood, saliva, urine, hair. Limnetic samples - Zebra Mussel, Bream. Marine samples - Common Bladder wrack, blue mussel, Eelpout, Herring Gull. Terrestrial Samples - common spruce, pine, Lombardy poplar, Beech, Roe deer, Feral Pigeon, Earthworm, Soil	1981-2013
			ICES	Contaminants and biological effects	1977-2011
Carbon-tetrachloride(1)	56-23-5	200-262-8	Environmental Quality Standards Directive 2008/105/EC.		
Cashmeron (musk) [3,4,6,7,8,9-hexahydro-4,6,6,9,9-pentamethyl-1H-naphtho[2,3-c]pyran]	1922-67-4	217-652-9	TNO-report R 2004/493	Levels in human blood	2004
Celestolide (musk) [6-tert-butyl-1,1-dimethylindan-4-yl methyl ketone]	13171-00-1	236-114-4	TNO-report R 2004/493	Levels in human blood	2004
Chlordane (pesticide)	57-74-9	200-349-0	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
Chlorfenvinphos (pesticide)	470-90-6	207-432-0	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			WFD PS		2008 onwards
Chlorides			E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
Chlorine	7782-50-5	231-959-5	ICES	Contaminants and biological effects	1990-2012
Chloroalkanes C10-13	85535-84-8	287-476-5	WFD PS		2008 onwards
Chlorinated alkyl benzenes (cabs)			Environment.no (list of PSs)	Change in emissions	1995-2010
Chlorinated paraffins			ICES	Contaminants and biological effects	2001-2013

Table A3-1: List of substances for which exposure data are available					
Substance	**CAS Number**	**EC Number**	**Database**	**Type of data**	**Time period**
Chlorpyrifos (pesticide) [chlorpyrifos ethyl]	2921-88-2	220-864-4	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			WFD PS		2008 onwards
Chloro-alkanes C10-C13			E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
Chlorobiphenyls			ICES	Contaminants and biological effects	1978-2013
Chlorofluorocarbons (cfcs)			E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
Chlorodecone (pesticide)			E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
Chromium	7440-47-3	231-157-5	Environment.no (list of PSs)	Change in emissions	1995-2010
			environment.no	Interactive map, chromium in moss	1970-2010
			E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			ICES	Contaminants and biological effects	1977-2013
Cobalt	7440-48-4	231-158-0	ICES	Contaminants and biological effects	1977-2013
Copper	7440-50-8	231-159-6	environment.no	Interactive map, copper in moss	1970-2010
			E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			Environmental Specimen Bank (ESB)	Human samples - blood plasma, whole blood, saliva, urine, hair. Limnetic samples - Zebra Mussel, Bream. Marine samples - Common Bladder wrack, blue mussel, Eelpout, Herring Gull. Terrestrial Samples - common spruce, pine, Lombardy poplar, Beech, Roe deer,	1981-2013
			ICES	Contaminants and biological effects	1977-2013
Cyanides			E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
Cyclodienes			ICES	Contaminants and biological effects	1979-2013
Dibutyltin			TNO-report R 2004/493	Levels in human blood	2004

Table A3-1: List of substances for which exposure data are available					
Substance	**CAS Number**	**EC Number**	**Database**	**Type of data**	**Time period**
DDT (pesticide)	50-29-3	200-024-3	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			ICES	Contaminants and biological effects	1978-2013
			ENHIS	Levels in human breast milk	
			Environmental Quality Standards Directive 2008/105/EC.		
Para-para-DDT	50-29-3	200-024-3	Environmental Quality Standards Directive 2008/105/EC.		
1,2-dichloroethane (edc)	107-06-2	203-458-1	Environment.no (list of PSs)	Change in emissions	1995-2010
			E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			WFD PS		2008 onwards
Di- (2-ethyl hexyl) phthalate (DEHP)	117-81-7	204-211-0	Environment.no (list of PSs)	Change in emissions	1995-2010
			E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			DEMOCOPHES	Biomarker, DEHP metabolites in urine (17 countries)	2010-2012
			WFD PS		2008 onwards
Dichlorodiphenyldichloroethylene (DDE)	72-55-9	200-784-6	German Environmental Survey (GerES)	Biomarker- levels in blood (children)	2003-2006
			ENHIS	Levels in human breast milk	
Dichloromethane (DCM)	75-09-2	200-838-9	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			WFD PS		2008 onwards
Dieldrin (pesticide)	60-57-1	200-484-5	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			ICES	Contaminants and biological effects	1979-2013

Table A3-1: List of substances for which exposure data are available					
Substance	**CAS Number**	**EC Number**	**Database**	**Type of data**	**Time period**
			Environmental Quality Standards Directive 2008/105/EC.		
Dioctyltin			TNO-report R 2004/493	Levels in human blood	2004
Dioxins and furans (PCDD, PCDF)			Environment.no (list of PSs)	Change in emissions	1995-2010
			E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			ICES	Contaminants and biological effects	1990-2012
			ENHIS	Total dioxin levels in human breast milk	
			UNEP Chemicals Branch - report UNEP /POPS/COP.6/INF/33	Levels in human breast milk (graph data only)	2000-2012
Diphenyltin			TNO-report R 2004/493	Levels in human blood	2004
Diuron (pesticide)	330-54-1	206-354-4	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			ICES	Contaminants and biological effects	2002-2013
			WFD PS		2008 onwards
Endosulphan (pesticide)	115-29-7	204-079-4	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			WFD PS		2008 onwards
Endrin (pesticide)	72-20-8	200-775-7	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			ICES	Contaminants and biological effects	1985-2013
			Environmental Quality Standards Directive 2008/105/EC.		
Ethyl benzene	100-41-4	202-849-4	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013

Table A3-1: List of substances for which exposure data are available					
Substance	**CAS Number**	**EC Number**	**Database**	**Type of data**	**Time period**
Ethylene oxide	75-21-8	200-849-9	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
Fluoranthenevi	206-44-0	205-912-4	WFD PS		2008 onwards
Fluorides			E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
Fluoranthene	206-44-0	205-912-4	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
Galaxolide (musk)	1222-05-5	214-946-9	TNO-report R 2004/493	Levels in human blood	2004
1,2,3,4,5,6-hexachlorocyclohexane (HCH) (pesticide)			E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
Halogenated organic compounds (AOX)			E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
Heptachlor (pesticide)	76-44-8	200-962-3	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			ICES	Contaminants and biological effects	1988-2013
Hexabromobiphenyl	36355-01-8	252-994-2	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
Hexachlorobenzene	118-74-1	204-273-9	Environment.no (list of PSs)	Change in emissions	1995-2010
			Environmental Specimen Bank (ESB)	Human samples - blood plasma, whole blood, saliva, urine, hair. Limnetic samples - Zebra Mussel, Bream. Marine samples - Common Bladder wrack, blue mussel, Eelpout, Herring Gull. Terrestrial Samples - common spruce, pine, Lombardy poplar, Beech, Roe deer,	1981-2013
			ICES	Contaminants and biological effects	1979-2013
			German Environmental Survey (GerES)	Biomarker - levbels in blood (children)	2003-2006
			ENHIS	Levels in human breast milk	
			WFD PS		2008 onwards
Hexachlorobutadiene	87-68-3	201-765-5	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water	2007-2013

Table A3-1: List of substances for which exposure data are available					
Substance	**CAS Number**	**EC Number**	**Database**	**Type of data**	**Time period**
(HCBD)				and soil. Pollutant transfer to waste water	
			ICES	Contaminants and biological effects	1985-2013
			WFD PS		2008 onwards
Hexachlorocyclohexanes	608-73-1	210-158-9	ICES	Contaminants and biological effects	1979-2013
			German Environmental Survey (GerES)	Biomarker- levels in blood (children)	2003-2006
			WFD PS		2008 onwards
Hexachloroethane	67-72-1	200-666-4	ICES	Contaminants and biological effects	1994-2012
Hydrofluorocarbons (hfcs)			E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
Iron	7439-89-6	231-096-4	ICES	Contaminants and biological effects	1977-2013
Isodrin (pesticide)	465-73-6		E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			Environmental Quality Standards Directive 2008/105/EC.		
Isoproturon (pesticide)	34123-59-6	251-835-4	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			WFD PS		2008 onwards
Lead	7439-92-1	231-100-4	Environment.no (list of PSs)	Change in emissions	1995-2010
			environment.no	Interactive map, lead in moss	1970-2010
			E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			Environmental Specimen Bank (ESB)	Human samples - blood plasma, whole blood, saliva, urine, hair. Limnetic samples - Zebra Mussel, Bream. Marine samples - Common Bladder wrack, blue mussel, Eelpout, Herring Gull. Terrestrial Samples - common spruce, pine, Lombardy poplar, Beech, Roe deer,	1981-2013
			ICES	Contaminants and biological effects	1977-2013

Table A3-1: List of substances for which exposure data are available					
Substance	**CAS Number**	**EC Number**	**Database**	**Type of data**	**Time period**
			German Environmental Survey (GerES)	Biomarker - levels in blood (children)	2003-2006
			ENHIS	Level in children's blood - no selected source and specific source	1990-2007 (depending on country)
			ENHIS	Intake through food (adults)	2004
			WHO - Global Health Obervatory Data Repository	Burden of disease - data by WHO region	2004
			WFD PS		2008 onwards
Lindane (pesticide)	58-89-9	200-401-2	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
Lithium	7439-93-2	231-102-5	ICES	Contaminants and biological effects	1977-2013
Magnesium	7439-95-4	231-104-6	Environmental Specimen Bank (ESB)	Human samples - blood plasma, whole blood, saliva, urine, hair. Limnetic samples - Zebra Mussel, Bream. Marine samples - Common Bladder wrack, blue mussel, Eelpout, Herring Gull. Terrestrial Samples - common spruce, pine, Lombardy poplar, Beech, Roe deer,	1981-2013
			ICES	Contaminants and biological effects	1977-2011
Manganese	7439-96-5	231-105-1	ICES	Contaminants and biological effects	1977-2013
Medium-chain chlorinated paraffins			Environment.no (list of PSs)	Change in emissions	1995-2010
Mercury	7439-97-6	231-106-7	Environment.no (list of PSs)	Change in emissions	1995-2010
			environment.no	Interactive map, lead in moss	1970-2010
			E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			DEMOCOPHES	Biomarker - mercury in hair (17 countries)	2010-2012
			Environmental Specimen Bank (ESB)	Human samples - blood plasma, whole blood, saliva, urine, hair. Limnetic samples - Zebra Mussel, Bream. Marine samples - Common Bladder wrack, blue mussel, Eelpout, Herring Gull. Terrestrial Samples - common spruce, pine, Lombardy poplar, Beech, Roe deer,	1981-2013
			ICES	Contaminants and biological effects	1977-2013

Table A3-1: List of substances for which exposure data are available					
Substance	**CAS Number**	**EC Number**	**Database**	**Type of data**	**Time period**
			German Environmental Survey (GerES)	Biomarker - levels in blood and urine (children)	2003-2006
			ENHIS	Intake through food (adults)	2004
			WFD PS		2008 onwards
Mirex (pesticide)	2385-85-5	219-196-6	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			ICES	Contaminants and biological effects	1988-2012
Monobutyltin			TNO-report R 2004/493	Levels in human blood	2004
Monooctyltin			TNO-report R 2004/493	Levels in human blood	2004
Monophenyltin			TNO-report R 2004/493	Levels in human blood	2004
Musk ambrette	83-66-9	201-493-7	TNO-report R 2004/493	Levels in human blood	2004
Musk ketone	81-14-1	201-328-9	TNO-report R 2004/493	Levels in human blood	2004
Musk moskene	116-66-5	204-149-4	TNO-report R 2004/493	Levels in human blood	2004
Musk tibetene	145-39-1	205-651-6	TNO-report R 2004/493	Levels in human blood	2004
Musk xylenes	81-15-2	201-329-4	Environment.no (list of PSs)	Change in emissions	1995-2010
			TNO-report R 2004/493	Levels in human blood	2004
Naphthalene	91-20-3	202-049-5	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	
			ICES	Contaminants and biological effects	1985-2013
			WFD PS		2008 onwards
Nickel	7440-02-0	231-111-4	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013

Table A3-1: List of substances for which exposure data are available					
Substance	**CAS Number**	**EC Number**	**Database**	**Type of data**	**Time period**
			ICES	Contaminants and biological effects	1977-2013
			German Environmental Survey (GerES)	Biomarker - levels in urine (children)	2003-2006
			WFD PS		2008 onwards
Nitrogen	7727-37-9	231-783-9	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			ICES	Contaminants and biological effects	1994-2013
Nonylphenol and its ethoxylates	25154-52-3	246-672-0	Environment.no (list of PSs)	Change in emissions	1995-2010
			E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			ICES	Contaminants and biological effects	2007-2013
			TNO-report R 2004/493	Levels in human blood	2004
			WFD PS		2008 onwards
(4-nonylphenol)	104-40-5	203-199-4	WFD PS		2008 onwards
Octylphenol and its ethoxylates	1806-26-4	217-302-5	Environment.no (list of PSs)	Change in emissions	1995-2010
			E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			TNO-report R 2004/493	Levels in human blood	2004
			WFD PS		2008 onwards
(4-(1,1',3,3'-tetramethylbutyl)-phenol)	140-66-9		WFD PS		2008 onwards
Organophosphates			German Environmental survey (GerES)	Biomarker - metabolites in urine (children)	2003-2006
Pahs	N/A	N/A	Environment.no (list of	Change in emissions	1995-2010

Table A3-1: List of substances for which exposure data are available					
Substance	**CAS Number**	**EC Number**	**Database**	**Type of data**	**Time period**
			PSs)		
			E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			ICES	Contaminants and biological effects	1985-2013
			German Environmental survey (GerES)	Biomarker - metabolites in urine (children)	2003-2006
			WFD PS		2008 onwards
(Benzo(a)pyrene)	50-32-8	200-028-5	WFD PS		2008 onwards
(Benzo(b)fluoranthene)	205-99-2	205-911-9	WFD PS		2008 onwards
(Benzo(g,h,i)perylene)	191-24-2	205-883-8	WFD PS		2008 onwards
(Benzo(K)fluoranthene)	207-08-9	205-916-6	WFD PS		2008 onwards
(Indeno(1,2,3-cd)pyrene)	193-39-5	205-893-2	WFD PS		2008 onwards
Pentabromodiphenyle ther (congeners 28, 47, 99, 100, 153, 154)	32534-81-9		WFD PS		2008 onwards
Pentachlorobenzene	608-93-5	210-172-5	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			ICES	Contaminants and biological effects	1985-2013
			WFD PS		2008 onwards
Pentachlorophenol (PCP)	87-86-5	201-778-6	Environment.no (list of PSs)	Change in emissions	1995-2010
			E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			Environmental Specimen Bank (ESB)	Human samples - blood plasma, whole blood, saliva, urine, hair. Limnetic samples - Zebra Mussel, Bream. Marine samples - Common Bladder wrack, blue mussel, Eelpout, Herring Gull. Terrestrial Samples -	1981-2013

Table A3-1: List of substances for which exposure data are available					
Substance	**CAS Number**	**EC Number**	**Database**	**Type of data**	**Time period**
				common spruce, pine, Lombardy poplar, Beech, Roe deer,	
			ICES	Contaminants and biological effects	1992-2011
			German Environmental survey (GerES)	Biomarker - levels in urine (children)	2003-2006
			WFD PS		2008 onwards
Perfluorocarbons			E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
Perfluorooctanoic acid	335-67-1	206-397-9	Environmental Specimen Bank (ESB)	Human samples - blood plasma, whole blood, saliva, urine, hair. Limnetic samples - Zebra Mussel, Bream. Marine samples - Common Bladder wrack, blue mussel, Eelpout, Herring Gull. Terrestrial Samples - common spruce, pine, Lombardy poplar, Beech, Roe deer,	1981-2013
			ICES	Contaminants and biological effects	2001-2013
Perflluorooctanesulfonic acid			Environmental Specimen Bank (ESB)	Human samples - blood plasma, whole blood, saliva, urine, hair. Limnetic samples - Zebra Mussel, Bream. Marine samples - Common Bladder wrack, blue mussel, Eelpout, Herring Gull. Terrestrial Samples - common spruce, pine, Lombardy poplar, Beech, Roe deer,	1981-2013
			ICES	Contaminants and biological effects	2001-2013
Polychlorinated biphenyls (pcbs)			E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			Environmental Specimen Bank (ESB)	Human samples - blood plasma, whole blood, saliva, urine, hair. Limnetic samples - Zebra Mussel, Bream. Marine samples - Common Bladder wrack, blue mussel, Eelpout, Herring Gull. Terrestrial Samples - common spruce, pine, Lombardy poplar, Beech, Roe deer,	1981-2013
			German Environmental survey (GerES)	Biomarker - levels in blood (children)	2003-2006
			ENHIS	Levels in human breast milk	
Polychlorinated naphthalene (PCN)			ENHIS	Levels in human breast milk	
Pfoa			Environment.no (list of PSs)	Change in emissions	1995-2010
Pfos			Environment.no (list of PSs)	Change in emissions	1995-2010

Table A3-1: List of substances for which exposure data are available					
Substance	**CAS Number**	**EC Number**	**Database**	**Type of data**	**Time period**
Phenols	108-95-2	203-632-7	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			ICES	Contaminants and biological effects	2006-2008
Phthalates			DEMOCOPHES	Biomarker - mnbp, mbzp, MEP, mibp metabolites in urine (17 countries)	2010-2012
			Environmental Specimen Bank (ESB)	Human samples - blood plasma, whole blood, saliva, urine, hair. Limnetic samples - Zebra Mussel, Bream. Marine samples - Common Bladder wrack, blue mussel, Eelpout, Herring Gull. Terrestrial Samples - common spruce, pine, Lombardy poplar, Beech, Roe deer,	1981-2013
			TNO-report R 2004/493	Levels in human blood	2004
Phosphorous	7723-14-0	231-768-7	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			ICES	Contaminants and biological effects	1994-1998
Potassium		231-119-8	ICES	Contaminants and biological effects	1990-2000
Pyrethroids			German Environmental survey (GerES)	Biomarker - metabolites in urine (children)	2003-2006
Selenium	7782-49-2	231-957-4	Environmental Specimen Bank (ESB)	Human samples - blood plasma, whole blood, saliva, urine, hair. Limnetic samples - Zebra Mussel, Bream. Marine samples - Common Bladder wrack, blue mussel, Eelpout, Herring Gull. Terrestrial Samples - common spruce, pine, Lombardy poplar, Beech, Roe deer,	1981-2013
			ICES	Contaminants and biological effects	1982-2013
Short-chain chlorinated paraffins			Environment.no (list of PSs)	Change in emissions	1995-2010
Silicon	7440-21-3	231-130-8	ICES	Contaminants and biological effects	1977-2013
Siloxane-D4			Environment.no (list of PSs)	Change in emissions	1995-2010
Siloxane-D5			Environment.no (list of PSs)	Change in emissions	1995-2010
Silver	7440-22-4	231-131-3	ICES	Contaminants and biological effects	1992-2013
Simazine (pesticide)	122-34-9	204-535-2	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			ICES	Contaminants and biological effects	2002-2013
			WFD PS		2008

Table A3-1: List of substances for which exposure data are available					
Substance	**CAS Number**	**EC Number**	**Database**	**Type of data**	**Time period**
					onwards
Sodium	7440-23-5	231-132-9	ICES	Contaminants and biological effects	1996-1998
Strontium	7440-24-6	231-133-4	Environmental Specimen Bank (ESB)	Human samples - blood plasma, whole blood, saliva, urine, hair. Limnetic samples - Zebra Mussel, Bream. Marine samples - Common Bladder wrack, blue mussel, Eelpout, Herring Gull. Terrestrial Samples - common spruce, pine, Lombardy poplar, Beech, Roe deer,	1981-2013
			ICES	Contaminants and biological effects	1990-2008
Sulphur	7704-34-9	231-722-6	ICES	Contaminants and biological effects	1990-1991
Surfactants (DTDMAC, DSDMAC, DHTDMAC)			Environment.no (list of PSs)	Change in emissions	1995-2010
TCEP (tris (2-chloroethyl) phosphate)	115-96-8	204-118-5	Environment.no (list of PSs)	Change in emissions	1995-2010
1,1,2,2-tetrachloroethane	79-34-5	201-197-8	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
Tetrachloroethene (PCE)	127-18-4	127-18-4	Environment.no (list of PSs)	Change in emissions	1995-2010
			E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
Tetrachloromethane (TCM) [carbon tetrachloride]	56-23-5	200-262-8	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
Thallium	7440-28-0	231-138-1	Environmental Specimen Bank (ESB)	Human samples - blood plasma, whole blood, saliva, urine, hair. Limnetic samples - Zebra Mussel, Bream. Marine samples - Common Bladder wrack, blue mussel, Eelpout, Herring Gull. Terrestrial Samples - common spruce, pine, Lombardy poplar, Beech, Roe deer,	1981-2013
			ICES	Contaminants and biological effects	1997-1998
Thorium	7440-29-1	231-139-7	ICES	Contaminants and biological effects	1998-1998
Tin	7440-31-5	231-141-8	ICES	Contaminants and biological effects	1990-2013
Titanium	7440-32-6	231-142-3	ICES	Contaminants and biological effects	1977-2005
Tonalide (musk)	21145-77-7	244-240-6	TNO-report R 2004/493	Levels in human blood	2004
Toxaphene (pesticide)	8001-35-2	232-283-3	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water	2007-2013

Table A3-1: List of substances for which exposure data are available					
Substance	**CAS Number**	**EC Number**	**Database**	**Type of data**	**Time period**
				and soil. Pollutant transfer to waste water	
Traseolide (musk)	68140-48-7	268-799-0	TNO-report R 2004/493	Levels in human blood	2004
Tetrachloro-ethylene	127-18-4	204-825-9	Environmental Quality Standards Directive 2008/105/EC.		
Tributyltin compounds	N/A	N/A	Environment.no (list of PSs)	Change in emissions	1995-2010
			TNO-report R 2004/493	Levels in human blood	2004
			WFD PS		2008 onwards
Tributyltin-cation	36643-28-4	N/A	WFD PS		2008 onwards
1,1,1-trichloroethane	71-55-6	200-756-3	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
Trichlorobenzene	12002-48-1	234-413-4	Environment.no (list of PSs)	Change in emissions	1995-2010
			E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			WFD PS		2008 onwards
Trichloroethene (TRI)	79-01-6	201-167-4	Environment.no (list of PSs)	Change in emissions	1995-2010
Trichlorotheylene	79-01-6	201-167-4	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			Environmental Quality Standards Directive 2008/105/EC.		
Trichloromethane	67-66-3	200-663-8	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			WFD PS		2008 onwards

Table A3-1: List of substances for which exposure data are available					
Substance	**CAS Number**	**EC Number**	**Database**	**Type of data**	**Time period**
Triclosan	3380-34-5	222-182-2	Environment.no (list of PSs)	Change in emissions	1995-2010
Trifluralin	1582-09-8	216-428-8	WFD PS		2008 onwards
Triphenyltin			TNO-report R 2004/493	Levels in human blood	2004
2,4,6 Tri-tert-butylphenol	732-26-3	211-989-5	Environment.no (list of PSs)	Change in emissions	1995-2010
Toluene	108-88-3	203-625-9	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			ICES	Contaminants and biological effects	2004-2013
Uranium	7440-61-1	231-170-6	ICES	Contaminants and biological effects	1992-2013
Vanadium	7440-62-2	231-171-1	ICES	Contaminants and biological effects	1977-2013
Vinyl chlroide			E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
Xylenes	1330-20-7	215-535-7	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			ICES	Contaminants and biological effects	2012-2013
Zinc	7440-66-6	231-175-3	E-PRTR	Pollutant releases, region and river basin district. Releases to air, water and soil. Pollutant transfer to waste water	2007-2013
			Environmental Specimen Bank (ESB)	Human samples - blood plasma, whole blood, saliva, urine, hair. Limnetic samples - Zebra Mussel, Bream. Marine samples - Common Bladder wrack, blue mussel, Eelpout, Herring Gull. Terrestrial Samples - common spruce, pine, Lombardy poplar, Beech, Roe deer,	1981-2013
			ICES	Contaminants and biological effects	1977-2013

Annex 5 Pathways and Indicators for the Benefits delivered by the REACH Regulation (RPA et al, 2012)

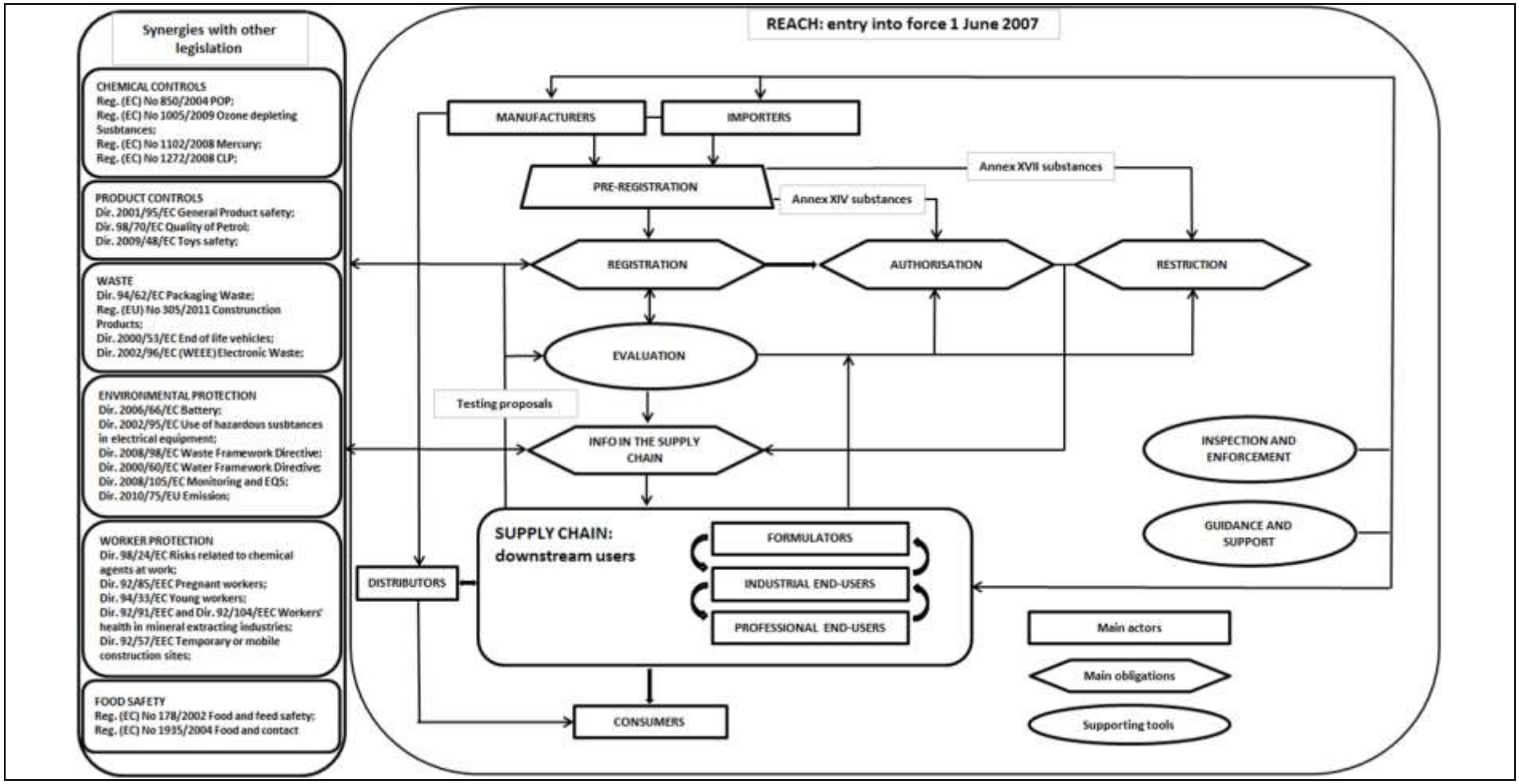


Figure A4-1: Main Actors, Main Obligations, Enhancement Tools and Synergies with Other Legislation

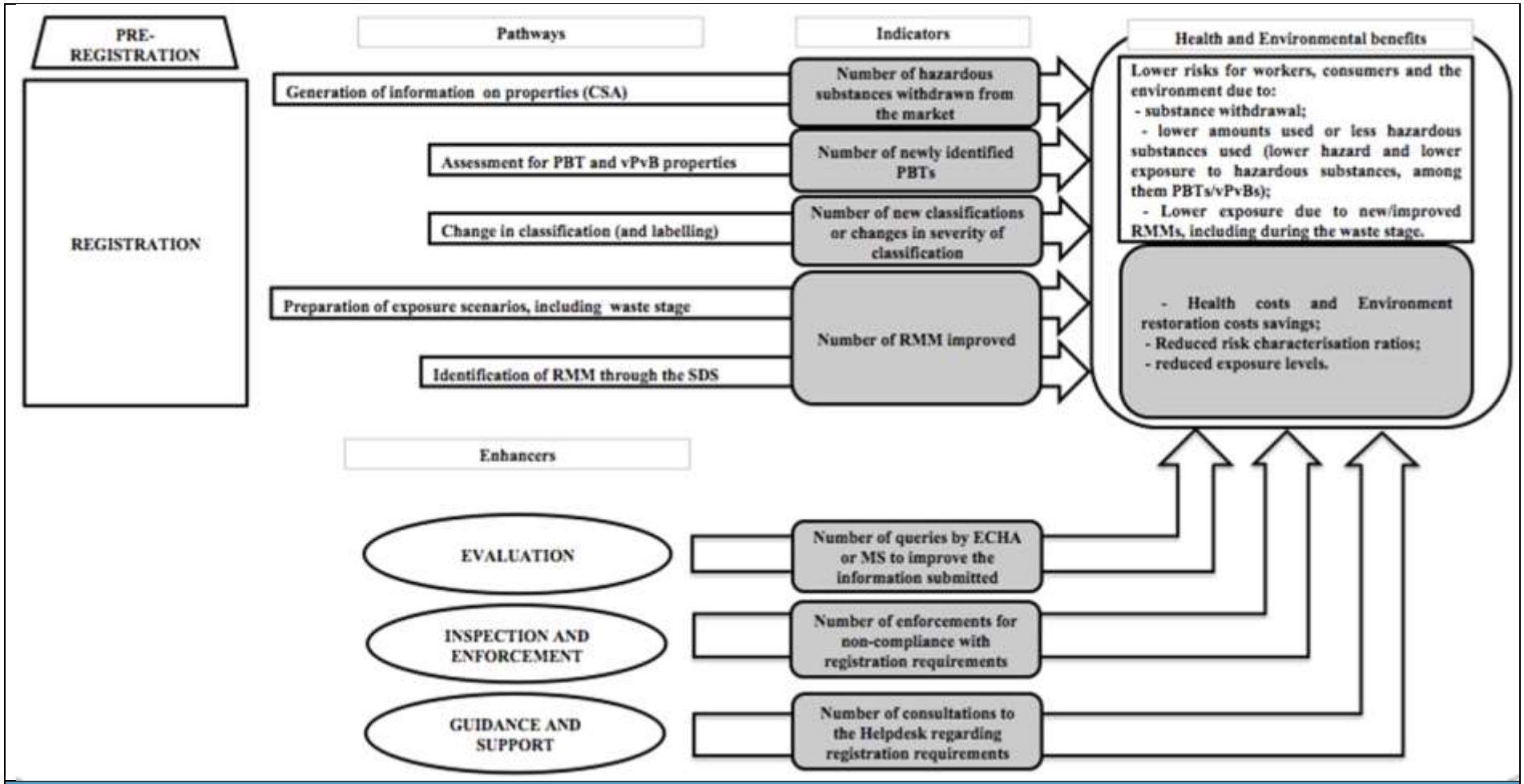


Figure A4-2: The Drivers, Pathways and Indicators of Benefits under Registration

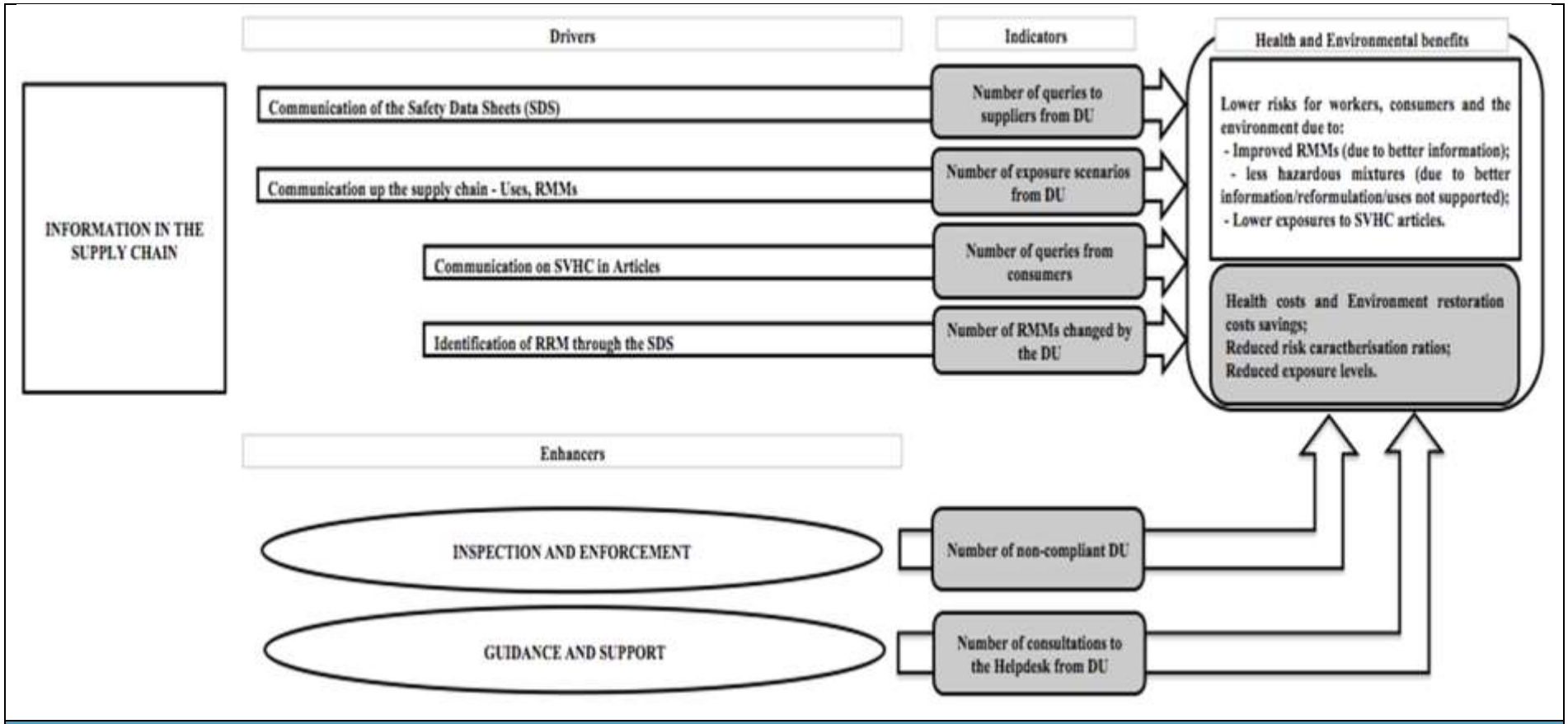


Figure A4-3: The Drivers under Title IV "Information in the Supply Chain" and Title V "Downstream users"

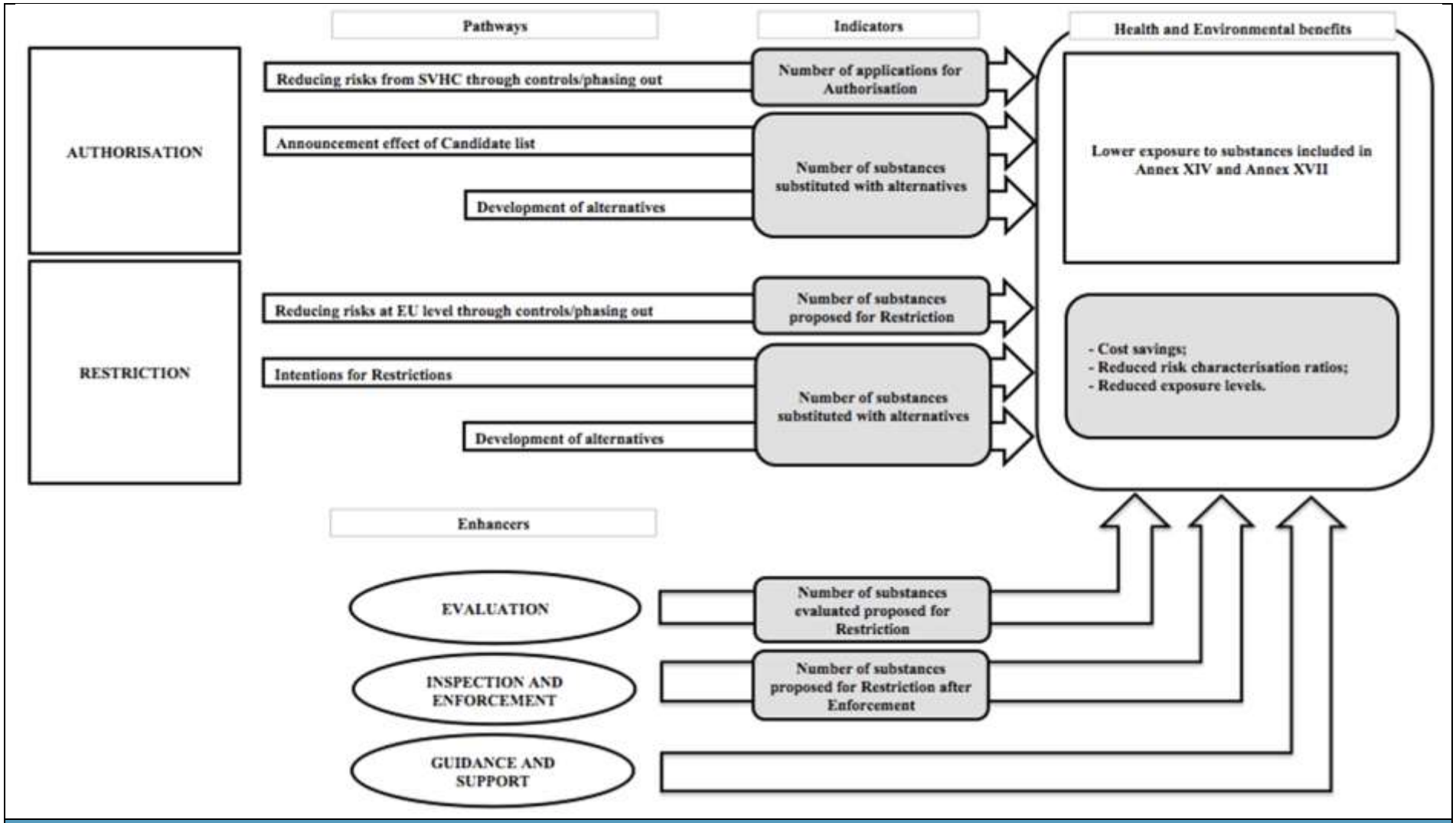


Figure A4-4: The Drivers under Title VII "Authorisation" and Title VIII "Restriction"

Annex 6 The Expert Workshop

A6.1 Organisation of the workshop

The expert workshop[231] was a one day event, aimed at gaining the views of socio-economic and risk assessment experts in the fields of public health, environmental protection and occupational health and safety on the methodology followed by the project team, on the work carried out to the date (November 2015) and on the problems and possible solutions for the better development of a system of indicators and for the quantification of the benefits of the chemicals legislation. Around fifty-five experts attended the workshop: members of the ECHA Socio-Economic Assessment and Risk Assessment Committees, representatives of the Member States Competent Authorities, as well as representatives of trade unions, NGOs, research centres, academia, European industry associations and industry. A fifteen page background paper was prepared and sent out to the participants, which provided a summary of the aims of the workshop, the objectives of the study, the methodology followed, the proposed key indicators, two examples on the quantification of the human health and environmental benefits of chemicals policy and questions that were going to be start discussions during breakout sessions.

All presentations given over the course of the day were made available to participants after the workshop.

A6.2 Welcome and introduction to the study

The welcome to the attendees and a brief introduction to the study were given by the DG Environment Project Manager. The Project Manager set the context for the study, noting that it had been commissioned to help the balanced assessment of EU chemicals legislation, given that there are currently three studies underway focusing on the costs and the economic impacts of the legislation (cumulative costs assessment for the chemicals industry, impacts of REACH on international competitiveness of the EU industry and study on the regulatory fitness of the legislative framework (excluding REACH) governing the risk management of chemicals); moreover, the present project would stand alongside the 10 year update of the REACH baseline study and will feed the REACH review process scheduled for 2017.

The project team then gave an overview of the methodology for the study and on the proposed system of indicators, where this included a system of output, result and impact indicators. The presentation also highlighted some of the key issues facing the study team in trying to develop a system of linked indicators, such as the challenges in ascribing changes in exposures and hence benefits to REACH or CLP, and the paucity of harmonised or comparable data on chemicals' exposure and health statistics across the EU Member States.

[231] Workshop website: http://www.euconf.eu/chemicals_legislation_workshop/en/registration/index.html

A6.3 Panel discussion 1: Indicators – the links between chemicals and the effects on human health and the environment and between regulation and the effects on human health and the environment

Following the introductory presentations, the programme moved to the first set of presentations by invited speakers and the first panel discussion. This session explored different stakeholders' views on potential indicators, as well as outputs of work carried out by other organisations to develop indicators of the effects of chemicals' exposure on human health and the environment, and methods for measuring the benefits accruing from the chemicals legislation. Speakers in the first panel were:

- Mr Vito Buonsante, Law and Policy Advisor, Health and Environment, ClientEarth;
- Dr Annette Prüss-Üstun, Team Leader, Assessment of Environmental Health Impacts Department of Public Health, Environmental and Social Determinants of Health, World Health Organization;
- Dr Tony Musu, Senior Researcher, Health and Safety, Working Conditions, ETUI;
- Mr Kalle Kivelä, Risk Management Implementation unit, European Chemicals Agency.

Mr Buonsante gave ClientEarth's perspective on the benefits of EU chemicals legislation. He highlighted that the REACH Regulation is delivering benefits by increasing (eco)toxicological information on chemicals; ensuring better management of chemicals; establishing the citizens' right to know; requiring the communication of information through the supply chain; and, ultimately, transferring knowledge in developing countries. He then proposed some indicators for use within the EU, focusing on substitution of chemicals of concern, underlining that the legislation delivers business benefits too, in the form of reputational benefits and innovation into new technologies. Finally, Mr Buonsante stressed that uncertainty will continue to characterise knowledge about chemicals' effect and that it will always be difficult, therefore, to establish how much of a specific effect is attributable to chemical exposures. As a result, legislative action should be based on the precautionary principle and there are studies that compare the cost of inaction to the cost of precautionary action. In addition, he noted that monetisation of benefits poses ethical issues, as monetary values reduce complex issues to one dimension and reflect human preferences only.

Dr Prüss-Üstun presented the WHO's work on estimating the burden of disease due to chemical exposures. This was carried out in the framework of the environmental burden of disease series. Her research team has been undertaking a systematic review of the available data on the burden of disease from chemicals, estimating that it is between 2% - 8.3% of global deaths (between 1.7% - 5.7% in terms of disability-adjusted life years (DALYs)), with the low estimate referring to a small number of selected industrial and agricultural chemicals and accidental poisonings and the high estimate considering in addition the impacts of chemicals in air pollution and selected naturally occurring chemicals. She highlighted that the results are likely to underestimate the total burden from chemicals, as the estimates are based on short-term effects (acute diseases) data, the strongest exposure-risk relationships and well-described exposures. For long-term effects, exposure-response relationship and data on levels of exposure for the general population are available for very few substances (e.g. lead) and for certain occupational exposures only.

Dr Musu gave the ETUI's perspective on the development of a system of indicators for the monitoring of the benefits of legislation on workers' health and safety. He started by providing

figures on the number of workers in the chemicals industry and on the proportion of occupational diseases associated with chemical exposures. He then highlighted the interface between the REACH and CLP Regulations with the EU occupational health and safety (OSH) legislation and how these work together to deliver benefits. However, Dr Musu pointed out that it does take time for results to be seen after the implementation of legislation, with the extent of the results depending also on the level of enforcement and the proper training of the employers and workers. Nevertheless, for some occupational diseases, the available statistics allow quantitative assessment and monetisation of the benefits of chemicals legislation and that for skin diseases and respiratory diseases this should be possible. Indicators on cancer would be possible only for some specific cancer sites for which the aetiology has been linked with a certain degree of certainty to chemicals' exposure and would be of limited use, due to the long latency of the disease, that is the period passing between exposure and effect. He also suggested that monitoring changes in workers' exposure to key hazardous chemicals could act as a good indicator of legislative effectiveness.

Mr Kivelä presented a meta-analysis on the costs and benefits of the various REACH restrictions that have been passed by ECHA's Committees (the Risk Assessment and Socio-Economic Analysis Committees). He highlighted that the analysis was carried out on 15 cases and that restriction proposals and opinions provide the best available information on the impacts. In three cases, the benefits were monetised, six presented the benefits in terms of reduced uses and emissions, six dossiers provided semi-quantitative and/or qualitative descriptions and the remaining three did not present any health or environmental benefits. Mr Kivelä stressed that restriction dossiers provide different types of information that could be used to inform a system of indicators, although their systematic extraction poses a challenge, as the information is not provided in a uniform and/or aggregated manner.

Following the above presentations, some time was given to the audience to pose questions to the panellists on particular aspects of their presentations. The audience was then invited to respond to some additional research and validation questions developed by the study team to elicit views on the value of different types of indicators and on methodological issues. The questions were:

1) The study team has based the identification of indicators on the concepts of "output", "result" and "impact", in line with the Commission's Better Regulation guidelines

    - Output: Are the proposed output indicators important to understanding the benefits of chemicals legislation? Should they be given more or less focus compared to the result and impact indicators?

    - Result: Should result indicators be developed for workers or human health more generally? Should these rely on biomonitoring data or other data? Should result indicators be developed for the environment based on the available EU-wide monitoring data?

    - Impact: Are the proposed impact indicators useful? How much focus should be placed on quantifying impacts as opposed to quantifying changes in exposures?

2) Should the indicators be more specific to individual pieces of legislation?

    - Should they be REACH and CLP specific?

    - Or should they relate to a broader set of legislation together?

3) Is it essential to be able to link result and impact indicators to output indicators?

4) Are there key indicators that are missing from the lists proposed here?

The most important points from the discussion triggered by these questions were recorded on a flipchart for further discussion during the break-out sessions in the afternoon. With regard to the adequacy of the system of indicators proposed, the audience was of the opinion that the project team should focus on result and impact indicators rather than on output indicators; although output indicators were recognised as being an invaluable component of any overall system of indicators, there was a fear that consideration of too many of these may distract from putting sufficient emphasis on the results and impacts of chemicals legislation. In terms of output indicators, it was stressed that the study team should consider both self-classification data as well as harmonised classifications, as the former will have changed more over time and may be more informative (bearing in mind difficulties in establishing before and after REACH data on these). Indicators not proposed by the study team were also suggested. For example, a possible indicator could be the number of new DNELs established as a result of REACH (although the problems in setting a baseline for such an indicator were not discussed). On impact indicators, the audience suggested that, given the lack or paucity of evidence on impacts, the project team should avoid proposing measures of impacts and instead should complement result indicators (measuring changes in exposures) with qualitative information on impacts. With regard to the overall scope of the system of indicators, the audience suggested that the team should focus on result indicators (chemicals' exposure level) and then link any changes identified by these to particular regulations, maybe working with validation cases (specific substances). A question remained unanswered, i.e. on how to capture the benefits of the new information generated by REACH, although it was also suggested that it was too early to quantify these benefits given that not all substances will have been registered until 2018.

A6.4 Panel discussion 2: How to calculate the benefits of chemical legislation?

The afternoon started with the second set of presentations with this then followed by the second panel discussion. This session explored further methodologies for calculating the benefits of chemicals legislation. The second panel was formed by:

- Dr Matti Vainio, Head of the Risk Management Implementation Unit at ECHA;
- Dr Stavros Georgiou, Economic Analysis Unit at the UK Health and Safety Executive;
- Ms Meg Postle, Project Director for Risk & Policy Analysis.

Dr Vainio presented an overview of the theory underlying the valuation of human health effects and the techniques that are used in practice for this purpose. He then provided an overview of the results of a study commissioned by ECHA on people's willingness to pay to avoid specific health effects linked to chemical exposures, in order to provide standardised WTP values for selected health endpoints to support socio-economic analyses under REACH. He presented the main results per health outcome covered by the survey, where these included skin diseases, developmental effects, respiratory diseases and cancer.

Dr Georgiou's presentation complemented Dr Vainio's and focused on the use of WTP methods for valuing the avoidance of future environmental damages from chemicals in the environment. He highlighted the main challenges when attempting the valuation of impacts of hazardous chemicals, and in particular PBT and vPvB substances, on the environment: the effects are uncertain and poorly understood; it is unclear how to define the commodities to be valued; human preferences are affected by the nature of the pollutant, the origin of the substance, its persistence and the timing of likely effects, etc. Mr Georgiou then presented the results of a case study on people's WTP to reduce

environmental accumulation of D4 (a PBT substance) and D5 (a vPvB substance) used in personal care products, and discussed the potential relevance of the results from a regulatory perspective.

Ms Postle then gave a second presentation on behalf of the study team, setting out some of the more detailed findings of the study against specific indicators that are likely to be recommended by the study. She highlighted that, with regard to output indicators, simple statistics can be generated, for example on changes in self-classifications, but that it can be difficult to then link these to result and impact indicators. She also noted that it can be difficult to know how to interpret some of the output indicators as there is a lack of baseline information and there is confounding when looking at snapshots over time. However, recommendations can be made for future data collection to bridge some of the data gaps that exist if developing a set of future-looking indicators. With regard to result indicators, trends in human biomonitoring data and environmental concentrations can be produced for specific chemicals to illustrate changes in exposure due to chemicals legislation. An example using human biomonitoring data from Germany and for PFOS and PFOA was provided, together with an example of the type of qualitative narrative that can accompany the use of such data. With regard to human health impact indicators, impacts can be quantified and valued for a subset of human health effects, but it may not always be possible to link these values to result indicators. In this case, an example was given for skin diseases and changes in chemicals related cases over time in the UK. With regard to environmental impact indicators, Ms Postle presented an example indicating the kind of "heroic" assumptions that may have to be used in order to derive economic valuations of changes in environmental impacts, based on an attempt to make a link between impacts on species and environmental monitoring data. Taken together the examples illustrated the possibilities but also the difficulties in finding adequate data to monitor changes and the types of assumptions needed in order to develop monetary values of benefits.

Questions and answers on the presentations was followed by a second session involving additional research and validation questions for the audience on the indicators and on methodological issues. These were:

1) The study team has focused on result and impact indicators that reflect changes in emissions, exposures and concentrations in the environment or humans (e.g. changes in the incidence or prevalence of diseases that can be linked to chemicals exposures) at the EU level, rather than those that could act as the basis for a case study approach.

    - Do you think this is appropriate?

2) If a case study approach were to be adopted, are there certain sets of chemicals that should act as the focus?

3) Is it possible to use a single substance case study as a proxy for the benefits of reducing exposures to other substances with similar properties?

4) How important are confounding factors (e.g. economic situation, technology, working conditions and procedures) arising from the linkages between chemicals legislation and changes that may have occurred due to economic conditions or technological changes?

    - Do you agree that we should ignore their potential influence and highlight the uncertainty that this introduces into end estimates of benefits?
    - Or do you believe that we should only quantify and monetise those benefits where we believe confounding is likely to be minimised?

As in the morning, the most important points of the discussion triggered by these questions were recorded on a flipchart for further discussion as appropriate. In general, participants indicated that it would be appropriate for any system of indicators to include both general indicators that operated at the EU level, as well as 'case study' indicators linked to specific chemicals. This was deemed to be especially true when considering cancers. The audience also suggested the use of indicators at the national level as exemplars of benefits, where extrapolation to the EU28 may not be possible. Extrapolation to the European level should be carried out only when available data refer to at least two or more Member States characterised by a diverse for geography (e.g. North, South Europe), economic situation or specific chemical industry characteristics.

A6.5 Breakout session: the proposed indicators and their quantification

Following the second panel discussion session, the audience was invited to divide into three groups (environment, human health, workers' health) for more detailed discussions, according to the preferences they expressed during their registration for the workshop. The groups were moderated by the morning speakers and by one project team member. The objective was to discuss the results of the key points from the morning and afternoon panel discussions as well as, methodological issues and possible solutions. Specific research questions were posed to each group in order to trigger the discussions.

A6.6 Workers' health

The research questions for the workers' health group were:

1. Are there missing output and result indicators in relation to workers health?
2. An example set of calculations for an impact indicator related to skin diseases is provided in Section 4 above.
    a. Do you think this approach is robust and credible?
    b. Are there alternative approaches?
3. Are there other types of human health effects that should be addressed using this type of approach, taking into account reliability considerations (please refer to Table 3.3)?
4. What sources of data are available that the study team may not have identified from an internet search?
5. Should the project team develop estimates reflecting different sets of assumptions as to the attributable fractions of impacts associated to chemical exposures and reduced by chemicals legislation?
6. Overall, has the study team focused on the right kinds of indicators?

This discussion group reinforced the view that the project team should look into self-classifications. Another useful output indicator could be the number of OELs proposed by Member States and implemented due to the new information being generated and made available by REACH. With regard to result indicators, the project team should define an indicator referring to the quantities of hazardous substances used and/or put in the market, ideally by CAS number. Since this type of information is not available[232], it was suggested that the project team should recommend to the European Commission to engage with industry in order to systematically gather this information. Another useful indicator could be to systematically collect data on the number of workers exposed to toxic chemicals. Although this information is currently available only for one Member State and

[232] In the registration dossiers, manufacturers and importers are required to specify tonnage bands only.

the definition of "toxic chemical" may need to be improved (substances with at least one hazardous classification? Substances of very high concern?), it was suggested that similar surveys could be launched in other Member States. This triggered a discussion on what type of data could be gathered through EU-wide surveys, considering the data missing for the best functioning of a system of indicators. Some ideas for questions to be asked in EU-side surveys[233] were suggested by the group members:

- Did you have to change your Safety Data Sheet?
- If yes, which part of the SDS?
- What type of Risk Management Measure did you have to implement or recommend to downstream users as a result of these changes?

The group then suggested consideration of a few other national databases that could be of relevance for the purposes of the study. Finally, it was reiterated that the project team should avoid extrapolating from national statistics to the EU level without validation (meaning similar data from other Member States). When not possible, all assumptions should be made as transparent as possible.

A6.7 Human health: Consumer and the general population

The research questions for the general human health group were:

1. Are there missing output and result indicators in relation to public and consumer health? Should a distinction be made between consumers and the general population?
2. An example set of calculations for an impact indicator related to skin diseases for workers was provided in Section 4 above. A similar type of approach could be applied to assessing benefits for the general population for a limited set of chemicals based on HBM data.
    a. Do you think this approach is robust and credible?
    b. Are there alternative approaches?
3. Would a case study approach be more appropriate?
4. Are there other types of human health effects that should be addressed using this type of approach, taking into account reliability considerations (please refer to Table 3.3)?
5. Should the project team estimate the benefits of different sets of assumptions as to the attributable fractions of impacts being associated to chemical exposures and reduced by chemicals legislation?
6. What types of human health effects should act as the focus of the assessment to ensure the reliability of the indicators?
7. Overall, has the study team focused on the right kinds of indicators?

The relevance of the different types of indicators was discussed. The results indicators are the most important type based on data on exposure/level of chemical substances in human body tissues in the EU population. With regards to impact indicators, only obvious ones should be used. The impact indicators listed in Table 3-3 should be carefully examined in order to narrow the list and narrow each individual AF/AN to represent only those AF/AN for which evidence on correlation to exposure to specific chemicals is existing and where there is a significant impact. A case study approach could be used in cases where specific studies have been performed, e.g. studies on endocrine-related diseases.

[233] In particular, such questions should be asked to downstream users as it is through their control of use that the biggest benefit for the workers environment would be expected.

Furthermore, the group discussed the possibility to set up output indicators. A systematic recording of substances in articles is missing, but would be valuable as a tool for quantification of substances imported into EU in articles and materials. Some studies at the National level are existing, but these are not robust enough. The notification of substances in articles to ECHA is only for the uses of articles not included in the registration and therefore not satisfactory. The RAPEX system will also give some information on exposure to the general public, but again this is not satisfactory as not all products posing a risk are reported in the RAPEX system.

The number of substances in Annex VXII Entry 28-30 [234]could be used as an indicator for changes in the number of CMR substances that the general public can be exposed to.

A6.8 Environment

The research questions for the environment group were:

1. Are there missing environmental output and result indicators for the environment?
2. Should trend data on environmental concentrations at the EU level be used to act as the basis for environmental 'result' indicators? Or can Member State level data be used as a proxy?
3. An example set of calculations for an impact indicator related to reductions in impacts on the marine environment through chemicals is also provided in Section 4 above.
    a. Do you think that this approach is robust and credible?
    b. Are there alternative approaches?
4. Would a case study approach be better for highlighting environmental benefits?
5. What other types of environmental effects could act as the focus of such a quantitative and monetised assessment, taking into account reliability considerations? Do the data exist to support their use? Would it be possible to use them for illustrating changes in exposure over the period from 2004 to 2013?
6. How should the project team deal with confounding factors arising from the linkages between chemicals legislation and changes that may have occurred due to economic conditions or technological changes?
7. Overall, has the study team focused on the right kinds of indicators?

The discussions within this group started by considering what types of result indicators may be of value in addition to those discussed earlier in the day. Key recommendations were information on production volumes for priority substances under the WFD, production volumes for other ecotoxic substances (and in particular PBTs and vPvBs), import data for SVHC and potentially for a set of substances with certain (unspecified but assumed to be aquatic toxicity or similar) harmonised classifications.

It was also suggested that there may be merit in collating data on inputs (influents) to sewage treatment works; the Environment Agency for England and Wales carried out a study in 2008/09 which it is currently repeating and the data may be of value in indicating the reductions in environmental concentrations of regulated chemicals. Similarly, EurEau may hold data on the

[234] Only substances listed in the relevant Appendices (1 - 6) of Annex XVII are covered by the restrictions in entries 28 - 30. When substances are classified for the first time as CMR and included in an ATP of the CLP Regulation, the European Commission prepares a draft amendment to include these substances in the Appendices of REACH Annex XVII. The amendment then has to be adopted in accordance with Article 68(2) of REACH, before the new substances are covered by entries 28-30. – Source: http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/reach/restrictions

presence of regulated substances in inputs to drinking water treatment plants across Europe (although it was unclear whether there was consistent reporting on this across Member States). There was also discussion on the use of water quality and biota monitoring under the WFD, but it was felt that there may be too many uncertainties and other factors affecting the ability to use these in the short term as indicators; in the longer term it should be possible. Similar comments were made with regard to the types of data held on the E-PRTR.

Other key suggestions to be explored further included:

- Data on plant protection products and tonnages of active ingredients applied, which is available for selected countries (e.g. Sweden and maybe Denmark and the UK);
- EEA data sets showing trends for certain pollutants;
- Neonicotinoids and bee populations;
- Use of public health indicators as illustrative of changes in environmental exposures;
- Trace element levels in food products;
- Diffuse metal apportionments developed for ESR risk assessments and use in REACH CSRs; and
- Macro-invertebrate monitoring data.

It should be noted however that plant protection products (and among them neonicotinoids) are not within the scope of the REACH Regulation.

A6.9 Remarks and conclusions

At the end of the breakout session, Richard Dubourg and Finn Pedersen, the external reviewers of the study, were called on the stage to wrap up the workshop and summarise the main conclusions.

Richard Dubourg started by stating that the indicators which are most appropriate for the study depends on what the objectives of the study are and what the indicators are intended to do. He identified three different types of objective which he felt had been proposed (explicitly or implicitly) for the current project:

4. Performance measurement and performance indicators – Is legislation doing it is supposed to do from an operational perspective?
5. Impact evaluation – Is legislation having the intended effect in terms of its overall objectives?
6. Benefits estimation – What has been the value of the legislation in terms of change in 'societal wellbeing'?

He then made the point that no single outcome measure or indicator can answer all three of these objectives (effectively), so that some compromise will be necessary either in relation to the objectives of the indicators/study or the accuracy of the indicators in measuring what they are intended to measure. In that respect, it should be remembered that the term 'indicators', by its very nature, implies imperfect and partial coverage of an objective, which in turn suggests how useful indicators might be for meeting the three objectives just outlined.

For instance, he explained, one of the principal issues encountered in impact measurement, broadly defined, is that of 'confounding'. Regulations have effects on their intended (and possibly some unintended) outcomes through 'pathways' which link the various policy 'levers' to those outcomes. These pathways can involve several steps governing the physical, chemical and economic relationships between different endpoints, and get more complex as the 'distance' between

endpoints and the number of steps increase. Longer and more complex pathways mean that the number of factors potentially affecting a final outcome also increases and the relative influence of a particular policy lever is likely to decline.

Simply put, he summarised, this means that, when pathways are long, an outcome can change as a result of a multitude of different factors, not just because of the effects of a policy lever. Moreover, an outcome could deteriorate because of these other factors, even if the effect of the policy lever is positive; conversely, an outcome could improve even if a policy lever is ineffective or even counterproductive. Clearly, therefore, unless these additional ('confounding') factors are taken into account, an incorrect conclusion could be reached about the effectiveness (and value) of regulation. But 'indicators' are generally simplified representations of relationships between policies and outcomes. They are, by design, unable to control for a large number of possible influences on a particular outcome. If indicators are used to track the movement of outcomes which are the result of complex relationships, it must be in the knowledge that the interpretation of this movement is subject to uncertainty and possible error.

Mr Dubourg argued that a useful indicator is one which generally moves in the 'right direction' in comparison with the true underlying relationship which it is trying to summarise. So, for instance, if the impact of regulation on an outcome is positive over a period, the indicator should show a positive result. According to Mr Dubourg, in the presence of multiple potentially confounding factors, this is not as simple as it sounds. To increase the chances of being useful, he suggested that indicators used in this project should generally:

- Relate to relatively controlled or simple relationships, and outcomes which are relatively close to the policy levers of interest. This will limit the number of confounding factors which could interfere with the movement and interpretation of the indicator;
- Be geographically representative. It is unlikely to be feasible, due to data limitations, that an indicator will cover all countries of the EU, and not all countries are equally important when it comes to a particular policy problem (due, e.g., to geographical concentrations of industry) it should nevertheless strive to cover as much of the 'policy problem' as possible. Certainly, any implied extrapolation from a limited set of countries to the EU level needs to be justified;
- Be regularly updated. If the desire is to measure the performance of regulation over time, which is implicit in an indicators framework, there is no point in using data which is updated only infrequently or inconsistently;
- Cover short-term relationships. Although one major objective of REACH and chemicals regulation generally is to reduce, for instance, the incidence of chemicals-related cancer, the time frames over which it takes exposures to cancer-causing chemicals to manifest themselves in actual cancers mean that a cancer-based indicator cannot provide a timely measure of regulatory performance. It is quite possible that no change in recorded cancers has yet happened as a result of the introduction of REACH, and no such change might be observed for another 10 years. However, changes in cancer-related chemicals exposure have taken place, and such a shorter-term indicator is a better way of measuring REACH impact on cancer than a cancer indicator itself. (This is clearly related to the first point above regarding 'simple' relationships);
- Relate to the major sources of potential benefit. An indicator which perfectly tracks a chemicals-related health impact of only minor concern is clearly not useful in saying whether REACH is generating significant benefits (unless it can be demonstrated that this particular health impact is highly correlated with a broader class of REACH benefits which means that it can serve as a reasonable indicator of these). A related question is where the costs are incurred as a result of REACH, and whether those costs can be linked to any specific benefit;

- Be objective, in the sense that it is based on data and information which are generated independently of the measurement process, rather than as a result of subjective judgement.

Finally, Mr Dubourg made the observation that previous exercises to generate benefits indicators and estimates have been hampered by a lack of widespread and consistent data on relevant factors such as exposures, use volumes etc., but that repeated recommendations to fill these gaps have not generally been acted upon. Until this changes, this and future indicators exercises will struggle to be successful.

Finn Pedersen used as his point of departure the cause-effect relationship of chemicals regulation, namely that implementation of chemicals regulation is supposed to lead to lower exposure of humans (workers and the general public) and the environment, which is supposed to reduce the burden of disease for humans and ecosystem effects. Seen from a top-down perspective, it was obvious that chemicals regulation can be determined with high precision; however, the direct effect on exposure levels could only be determined with some uncertainty and determination of the impact on human health and ecosystems could only be established with high uncertainty. Seen from a bottom-up perspective, at least for human health effects, rather detailed statistics are available in many Member States of diseased that may be attributed to exposure to chemicals; however, it would normally only be possible to estimate with some uncertainty how large a fraction of the diseases that can be assumed to be caused by exposure to chemicals. And as the effect of chemicals regulation on the exposure level is uncertain, estimates of the direct relationship between chemicals regulation and disease levels are rather uncertain.

In his recommendations to the project group, Mr Pedersen suggested that as chemicals regulation is expected to lead to reduced exposure of humans and the environment and as this parameter is the connection between chemicals regulation and impact on humans and the environment, chemicals exposure could be used as a key indicator for the benefits. Another advantage is that, as explained, the inherent uncertainty of determining this indicator would probably be at a medium level compared to other indicators, where the uncertainty in establishing the link between regulation and benefits would be higher. The challenge with using exposure data as a key indicator would be that biomonitoring or environmental monitoring data would only be available for a limited number of often rather well-known substances. However, as registrants under REACH are obliged to prepare a Chemical Safety Report including exposure estimates for all substances manufactured or imported in quantities of greater than 10 tonnes per year and classified as hazardous, it should be possible to dig out this information from the ECHA database.

The workshop was closed by Bjorn Hansen, Head of the Chemicals Unit at DG Environment, who thanked the participants, provided his views on the next steps to be taken and made some closing remarks. Mr Hansen stressed the importance of the study in the context of the Regulatory Fitness Programme (REFIT) for the chemicals area, noting that the assessment of the costs and the benefits of the European legislation is high up in the agenda of all the Member States, as it was also demonstrated by the level of participation during the workshop.

He acknowledged the challenge in quantifying the benefits of the chemical legislation but noted that several useful indicators were suggested and discussed during the panel discussions and break-out sessions. In particular, some of the human biomonitoring data presented highlighted how the legislation is having an impact in lowering the exposure to certain chemicals of concern and the use of monitoring data in informing policy evaluation and policy-making should be therefore further explored.

Annex 7 Hazard Classes

Table A7-1 sets out the different hazard classes and associated hazard statement codes within CLP which indicate the potential for exposures to cause harm. Moreover, a disease group according to the WHO International Classification of Diseases (ICD - version 10)[235] has been associated to the CLP/GHS hazard classes and statements. The ICD is the standard diagnostic tool for epidemiology, health management and clinical purposes and is used to monitor the incidence and prevalence of diseases and other health problems. The association between ICD codes and CLP classification allow to link statistics on health conditions to specific chemical substances and ultimately to the actions of the REACH and CLP Regulations (e.g. authorisations or restrictions of certain chemical substances, harmonised or self-notified classifications, etc.).

The impacts of chemical pollution and hence the benefits of reducing it can be reflected in different environmental compartments. Environmental benefits can be measured by consideration of changes to the end-points for each of the environmental compartments. For organisms with the freshwater, marine waters and terrestrial environment, plus secondary effects up the food chain, these end-points relate to survival, growth, reproductive ability and abnormalities. For the environmental compartment of air, the end-point relates to change in air quality. For the ozone layer, the end-point is the amount of ozone overhead, measured in Dobson Unit per kilometre. Relevant environmental compartments and end-points are listed in Table A7-1, while Table A7-2 details which environmental compartments and end-points are relevant when considering the impacts of PBT and vPvB substances.

Table A7-1: CLP Hazard classes, codes and statements and associated disease groups

Hazard class and category	HS code	Hazard statement	Disease group (ICD-10)
Acute toxicity, oral 1, 2	H300	Fatal if swallowed	Chapter XIX: Injury, poisoning and certain other consequences of external causes (S00-T98)
Acute toxicity, oral 3	H301	Toxic if swallowed	
Aspiration hazard 1	H304	May be fatal if swallowed and enters airways	
Aspiration hazard 2	H305	May be toxic if swallowed and enters airways	
Acute toxicity, dermal 1, 2	H310	Fatal in contact with skin	
Acute toxicity, dermal 3	H311	Toxic in contact with skin	
Skin corrosion/irritation 1A, 1B, 1C	H314	Causes severe skin burns and eye damage	
Skin corrosion/irritation 2	H315	Causes skin irritation	
Sensitisation, skin 1, 1A, 1B	H317	May cause an allergic skin reaction	Chapter XII: Diseases of the skin and subcutaneous tissue (L00-L99)
Serious eye damage/eye irritation 1	H318	Causes serious eye damage	Chapter XIX: Injury, poisoning and certain other consequences of external causes (S00-T98)
Serious eye damage/eye irritation 2A	H319	Causes serious eye irritation	
Acute toxicity, inhalation 1, 2	H330	Fatal if inhaled	
Acute toxicity, inhalation 3	H331	Toxic if inhaled	
Sensitisation, respiratory 1, 1A, 1B	H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled	Chapter X: Diseases of the respiratory system (J00-J99)

[235] http://www.who.int/classifications/icd/en/

Table A7-1: CLP Hazard classes, codes and statements and associated disease groups			
Hazard class and category	**HS code**	**Hazard statement**	**Disease group (ICD-10)**
Germ cell mutagenicity	H340	May cause genetic defects	Chapter XVII: Congenital malformations, deformations and chromosomal abnormalities (Q00-Q99)
Carcinogenicity 1A, 1B	H350	May cause cancer	Chapter II: Neoplasms (C00-D48)
Reproductive toxicity 1A, 1B	H360	May damage fertility or the unborn child	Chapter XV Pregnancy, childbirth and the puerperium (O00-O99)
Reproductive toxicity, effects on or via lactation	H362	May cause harm to breast-fed children	
Specific target organ toxicity, single exposure 1	H370	Causes damage to organs	Chapter XIX: Injury, poisoning and certain other consequences of external causes (S00-T98)
Specific target organ toxicity, repeated exposure 1	H372	Causes damage to organs through prolonged or repeated exposure	
Environmental Hazard class and category	**HS code**	**Hazard statement**	**Environmental compartments and end-points**
Hazardous to the aquatic environment, acute hazard 1	H400	Very toxic to aquatic life	Fresh and marine water: aquatic organisms and fish Terrestrial environment: earthworm and other invertebrates, soil, plants Secondary Effects (non-compartmental): fish eating predators, worm eating predators, top predators, other mammals and birds End-points: Survival, growth, reproduction, abnormalities End-points air and atmosphere: quality
Hazardous to the aquatic environment, acute hazard 2	H401	Toxic to aquatic life	
Hazardous to the aquatic environment, long-term hazard 1	H410	Very toxic to aquatic life with long lasting effects	
Hazardous to the aquatic environment, long-term hazard 2	H411	Toxic to aquatic life with long lasting effects	
Hazardous to the ozone layer	H420	Harms public health and the environment by destroying ozone in the upper atmosphere	Ozone layer End-points: Quantity (measures in Dobson Unit per km)

Table A7-2: Linking environmental parameters to toxicity, persistence and bioaccumulation			
Environmental parameter	**Chemical property**		
	Acute or chronic Toxicity	**Persistence**	**Bioaccumulation**
Freshwater aquatic organisms and fish (survival, growth, reproduction, abnormalities)	✓		
Marine aquatic organisms and fish (survival, growth, reproduction, abnormalities)	✓		
Terrestrial environment: Earthworm and other invertebrates (survival, growth, reproduction, abnormalities)	✓		
Terrestrial environment: Plants (survival, growth)	✓		
Secondary Effects: Fish eating predators (survival, growth, reproduction, abnormalities)	✓		✓
Secondary Effects: Worm eating predators (survival, growth, reproduction, abnormalities)	✓		✓

Table A7-2: Linking environmental parameters to toxicity, persistence and bioaccumulation			
Environmental parameter	Chemical property		
	Acute or chronic Toxicity	Persistence	Bioaccumulation
Secondary Effects: Top predators, other mammals and birds (survival, growth, reproduction, abnormalities)	✓		✓
Food provision through crops		✓	✓
Food provision from livestock		✓	✓
Wild food provision		✓	✓
Food provision through aquaculture	✓		✓
Drinking water provision	✓		
Provision of water for livestock and industrial processes, etc.	✓		
Regulation of pollution and natural cycles by biota/soil quality linked to biota	✓	✓	
Regulation of pollution and natural cycles by ecosystems/soil quality non-biota	✓	✓	✓
Control of pests and diseases	✓		✓
Buffering of chemical composition		✓	✓
Climate regulation		✓	
Local climate regulation/air quality		✓	
Enjoyment from existence of the natural world and preservation for future generations	✓	✓	✓

Annex 8 Substances by Hazard Class (Output Indicator 1, 3 and 4)

A8.1 Output Indicator 1 - Substances with Harmonised Classification and Labelling Implemented After the Entry into Force of the REACH and CLP Regulations by Hazard Class

Table A8-1: Substances with harmonised classification and labelling for acute toxicity implemented after the entry into force of the REACH and CLP Regulations			
Name	**EC number**	**CAS number**	**Regulatory programme**
Aluminium phosphide	244-088-0	20859-73-8	BPR, PPPR
Dimethyltin bis(2-ethylhexylmercaptoacetate), DMT (EHMA)	260-829-0	57583-35-4	REACH
Dimethyltin dichloride (DMTC)	212-039-2	753-73-1	REACH
Etridiazole	219-991-8	2593-15-9	PPPR
Nitric acid	231-714-2	7697-37-2	REACH
Pyridaben (2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyridazin-3(2H)-one)	405-700-3	96489-71-3	PPPR
Glutaral,Glutaraldehyde,1,5-pentanedial	203-856-5	111-30-8	BPR
Acetochlor (ISO),2-chloro-N-(ethoxymethyl)-N-(2-ethyl-6-methylphenyl)acetamide	251-899-3	34256-82-1	PPPR
Zinc phosphide,Trizinc diphosphide	215-244-5	1314-84-7	PPPR
Propylene oxide,1,2-epoxypropane,Methyloxirane	200-879-2	75-56-9	REACH
Chloralose (INN),(R)-1,2-O-(2,2,2-trichloroethylidene)-α-D-glucofuranose,glucochloralose,anhydroglucochloral	240-016-7	15879-93-3	BPR
Cyanamide	206-992-3	420-04-2	BPR
N,N-diethyl-m-toluamide,deet	205-149-7	134-62-3	BPR
Cyproconazole (ISO); (2RS,3RS;2RS,3SR)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1H-1,2,4-triazol-1-yl)butan-2-ol	-	94361-06-5	BPR
Dichlofluanid (ISO),N-[(Dichlorofluoromethyl)thio]-N',N'-dimethyl-N-phenylsulfamide	214-118-7	1085-98-9	BPR
Metaldehyde; 2,4,6,8-tetramethyl-1,3,5,7-tetraoxacyclooctane	203-600-2	108-62-3	PPPR
Quizalofop-P-tefuryl; (+/-) tetrahydrofurfuryl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenyloxy]propionate	414-200-4	119738-06-6; 200509-41-7	PPPR
2,3-epoxypropyl methacrylate	203-441-9	106-91-2	REACH
Reaction mass 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	-	1085-98-9	BPR
Chlorocresol; 4-chloro-m-cresol; 4-chloro-3-methylphenol	200-431-6	59-50-7	BPR
Maleic anhydride	203-571-6	108-31-6	REACH
Phosmet (ISO),S-[(1,3-dioxo-1,3-dihydro-2H-isoindol-2-yl)methyl] O,O-dimethyl phosphorodithioate	211-987-4	732-11-6	PPPR
Succinic anhydride	203-570-0	108-30-5	REACH
1,2-dihydroxybenzene; pyrocatechol	204-427-5	120-80-9	REACH
Potassium permanganate	231-760-3	7722-64-7	REACH
Hymexazol (ISO); 3-hydroxy-5-methylisoxazole	233-000-6	10004-44-1	PPPR
Nicotine (ISO); 3-[(2S)-1-methylpyrrolidin-2-yl]pyridine	200-193-3	54-11-5	REACH
Spiroxamine (ISO);8-tert-butyl-1,4-dioxaspiro[4.5]decan-2-ylmethyl(ethyl)(propyl)amine	-	118134-30-8	PPPR
Colecalciferol, vitamin D3	200-673-2	67-97-0	BPR

Table A8-1: Substances with harmonised classification and labelling for acute toxicity implemented after the entry into force of the REACH and CLP Regulations			
Name	**EC number**	**CAS number**	**Regulatory programme**
Propiconazole (ISO); 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole	262-104-4	60207-90-1	BPR, PPPR
Trinickel disulfide; nickel subsulfide; [1] heazlewoodite [2]	234-829-6	12035-72-2	REACH
Ethylene oxide; oxirane	200-849-9	75-21-8	REACH
Nickel (II) sulfide; [1] nickel sulfide; [2] millerite [3]	240-841-2	16812-54-7	REACH
Cypermethrin cis/trans +/- 40/ 60; (RS)-á-cyano-3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	257-842-9	52315-07-8	BPR
Penconazole	266-275-6	66246-88-6	PPP
Cymoxanil	261-043-0	57966-95-7	PPPR
Imazalil	252-615-0	35554-44-0	PPPR
Fluazinam	-	79622-59-6	PPPR
Fuberidazole	223-404-0	3878-19-1	PPPR
Fenamiphos	244-848-1	22224-92-6	PPPR
Methyl 2,5-dichlorobenzoate	220-815-7	2905-69-3	PPPR
Ethephon	240-718-3	16672-87-0	PPPR
Tricalcium diphosphide	215-142-0	1305-99-3	PPPR
Tebufenpyrad	-	119168-77-3	PPPR
Tralkoxydim	-	87820-88-0	PPPR
Bendiocarb (ISO),2,2-dimethyl-1,3-benzodioxol-4-yl N-methylcarbamate	245-216-8	22781-23-3	PPPR
Pirimicarb (ISO),5,6-dimethyl-2-dimethylamino-pyrimidin-4-yl N,N-dimethylcarbamate	245-430-1	23103-98-2	PPPR
Chloroform	200-663-8	67-66-3	REACH
Cryolite (Trisodium hexafluoroaluminate)	237-410-6	13775-53-6	REACH
Nitrobenzene	202-716-0	98-95-3	REACH
4-tert-butylbenzoic acid	202-696-3	98-73-7	REACH
Amines, tallow alkyl	263-125-1	61790-33-8	REACH
Amines, coco alkyl (Z)-octadec-9-enylamine	204-015-5	112-90-3	REACH
Ethylbenzene	202-849-4	100-41-4	REACH
2-Ethoxyethanol	203-804-1	110-80-5	REACH
Vinyl acetate	203-545-4	108-05-4	REACH
Pentadecafluorooctanoic acid (PFOA)	206-397-9	335-67-1	REACH
Ammonium pentadecafluorooctanoate (APFO)	223-320-4	3825-26-1	REACH
Lithium sodium 3-amino-10-{4-(10- amino-6, 13-dichloro-4,11-disulfonatobenzo[5,6][1,4]oxazino[2,3 -b]phenoxazine-3-ylamino)-6- [methyl(2-sulfonato-ethyl)amino]- 1,3,5-triazin-2-ylamino}-6,13- dichlorobenzo[5,6][1,4]oxazino[2,3- b]phenoxazine-4,11-disulfonate; Direct Blue FC 57087	418-870-9	154212-58-5	REACH
Bifenthrin	-	82657-04-3	BPR, PPPR
Formaldehyde	200-001-8	50-00-0	BPR, PPPR
Dicopper oxide,copper (I) oxide	215-270-7	1317-39-1	BPR, PPPR
Abamectin	-	71751-41-2	BPR, PPPR
Difenacoum (ISO),3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-	259-978-4	56073-07-5	BPR, PPPR

Table A8-1: Substances with harmonised classification and labelling for acute toxicity implemented after the entry into force of the REACH and CLP Regulations			
Name	**EC number**	**CAS number**	**Regulatory programme**
naphthyl)-4-hydroxycoumarin			
Copper sulphate pentahydrate	231-847-6	7758-99-8	BPR, PPPR
3-Iodo-2-propynylbutylcarbamate	259-627-5	55406-53-6	BPR
chlorfenapyr (ISO)|4-bromo-2-(4-chlorophenyl)-1-ethoxymethyl-5-trifluoromethylpyrrole-3-carbonitrile	-	122453-73-0	BPR
imidacloprid (ISO) 1-(6-chloropyridin-3-ylmethyl)-N-nitroimidazolidin-2-ylidenamine	428-040-8	138261-41-3	BPR
Indoxacarb	-	173584-44-6	BPR
Chlorophacinone (ISO),2-[(4-chlorophenyl)(phenyl)acetyl]-1H-indene-1,3(2H)-dione	223-003-0	3691-35-8	BPR
Flocoumafen (ISO),reaction mass of: cis-4-hydroxy-3-(1,2,3,4-tetrahydro-3-(4-(4-trifluoromethylbenzyloxy)phenyl)-1-naphthyl)coumarin,trans-4-hydroxy-3-(1,2,3,4-tetrahydro-3-(4- (4-trifluoromethylbenzyloxy)phenyl)-1- naphthyl)coumarin	421-960-0	90035-08-8	BPR
Brodifacoum (ISO),4-hydroxy-3-(3-(4'-bromo-4-biphenylyl)-1,2,3,4-tetrahydro-1-naphthyl)coumarin	259-980-5	56073-10-0	BPR
Acrolein	203-453-4	107-02-8	BPR
Etofenprox	407-980-2	80844-07-1	BPR
Coumatetralyl (ISO),4-hydroxy-3-(1,2,3,4-tetrahydro-1-naphthyl)coumarin	227-424-0	5836-29-3	BPR
Iodomethane	200-819-5	74-88-4	BPR
Trimagnesium diphosphide	235-023-7	12057-74-8	BPR

Table A8-2: Substances with harmonised classification and labelling for skin corrosion / skin irritation implemented after the entry into force of the REACH and CLP Regulations			
Name	**EC number**	**CAS number**	**Regulatory Programme**
P-tert-butylphenol	202-679-0	98-54-4	REACH
Dimethyltin dichloride (DMTC)	212-039-2	753-73-1	REACH
Dodemorph	216-474-9	1593-77-7	PPPR
Acetochlor (ISO),2-chloro-N-(ethoxymethyl)-N-(2-ethyl-6-methylphenyl)acetamide	251-899-3	34256-82-1	PPPR
N-methyl-2-pyrrolidone,1-methyl-2-pyrrolidone	212-828-1	872-50-4	REACH
Cyanamide	206-992-3	420-04-2	BPR
N,N-diethyl-m-toluamide,deet	205-149-7	134-62-3	BPR
Isobutyl methacrylate	202-613-0	97-86-9	REACH
2,3-epoxypropyl methacrylate	203-441-9	106-91-2	REACH
Reaction mass 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	-	55965-84-9	BPR
Chlorocresol; 4-chloro-m-cresol; 4-chloro-3-methylphenol	200-431-6	59-50-7	BPR
Succinic anhydride	203-570-0	108-30-5	REACH
1,2-dihydroxybenzene; pyrocatechol	204-427-5	120-80-9	REACH
Sodium hypochlorite, solution ... % cl active	231-668-3	7681-52-9	PPPR
Spiroxamine (ISO);8-tert-butyl-1,4-dioxaspiro [4.5] decan-2-ylmethyl (ethyl) (propyl) amine	-	118134-30-8	PPPR
Ethylene oxide; oxirane	200-849-9	75-21-8	REACH
Amines, coco alkyl	262-977-1	61788-46-3	REACH
(Z)-octadec-9-enylamine	204-015-5	112-90-3	REACH

Table A8-2: Substances with harmonised classification and labelling for skin corrosion / skin irritation implemented after the entry into force of the REACH and CLP Regulations			
Name	**EC number**	**CAS number**	**Regulatory Programme**
nitric acid ... %	231-714-2	7697-37-2	REACH
Amines, tallow alkyl	263-125-1	61790-33-8	REACH
Ethephon	240-718-3	16672-87-0	PPPR
Succinic anhydride	203-570-0	108-30-5	REACH
Formaldehyde	200-001-8	50-00-0	BPR, PPPR
Acrolein	203-453-4	107-02-8	BPR
Nonanoic acid	203-931-2	112-05-0	BPR

Table A8-3: Substances with harmonised classification and labelling for skin sensitisation implemented after the entry into force of the REACH and CLP Regulations			
Name	**EC number**	**CAS number**	**Regulatory Programme**
Dimethyltin bis(2-ethylhexylmercaptoacetate), DMT (EHMA)	260-829-0	57583-35-4	REACH
Dodemorph	216-474-9	1593-77-7	PPPR
Etridiazole	219-991-8	2593-15-9	PPPR
Acetochlor (ISO),2-chloro-N-(ethoxymethyl)-N-(2-ethyl-6-methylphenyl)acetamide	251-899-3	34256-82-1	PPPR
Cyanamide	206-992-3	420-04-2	BPR
Isobutyl methacrylate	202-613-0	97-86-9	REACH
Dichlofluanid (ISO),N-[(Dichlorofluoromethyl)thio]-N',N'-dimethyl-N-phenylsulfamide	214-118-7	1085-98-9	BPR
Quizalofop-P-tefuryl; (+/-) tetrahydrofurfuryl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenyloxy]propionate	414-200-4	119738-06-6; 200509-41-7	PPPR
2,3-epoxypropyl methacrylate	203-441-9	106-91-2	REACH
Reaction mass 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	-	55965-84-9	BPR
Chlorocresol; 4-chloro-m-cresol; 4-chloro-3-methylphenol	200-431-6	59-50-7	BPR
Maleic anhydride	203-571-6	108-31-6	REACH
Succinic anhydride	203-570-0	108-30-5	REACH
Hymexazol (ISO); 3-hydroxy-5-methylisoxazole	233-000-6	10004-44-1	PPPR
Spiroxamine (ISO);8-tert-butyl-1,4-dioxaspiro[4.5]decan-2-ylmethyl(ethyl)(propyl)amine	-	118134-30-8	PPPR
Propiconazole (ISO); 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole	262-104-4	60207-90-1	BPR, PPPR
Trinickel disulfide; nickel subsulfide; [1] heazlewoodite [2]	234-829-6	12035-72-2	REACH
Ethylene oxide; oxirane	200-849-9	75-21-8	REACH
Nickel (II) sulfide; [1] nickel sulfide; [2] millerite [3]	240-841-2	16812-54-7	REACH
Cymoxanil	261-043-0	57966-95-7	PPPR
Fluazinam	-	79622-59-6	PPPR
Fuberidazole	223-404-0	3878-19-1	PPPR
Metazachlor	266-583-0	67129-08-2	PPPR
Sulcotrione	-	99105-77-8	PPPR
Aclonifen	277-704-1	74070-46-5	PPPR
Tebufenpyrad	-	119168-77-3	PPPR
Etridiazole	219-991-8	2593-15-9	PPPR
Dodemorph	216-474-9	1593-77-7	PPPR

Table A8-3: Substances with harmonised classification and labelling for skin sensitisation implemented after the entry into force of the REACH and CLP Regulations			
Name	**EC number**	**CAS number**	**Regulatory Programme**
Acetochlor (ISO),2-chloro-N-(ethoxymethyl)-N-(2-ethyl-6-methylphenyl)acetamide	251-899-3	34256-82-1	PPPR
Pirimicarb (ISO),5,6-dimethyl-2-dimethylamino-pyrimidin-4-yl N,N-dimethylcarbamate	245-430-1	23103-98-2	PPPR
Quizalofop-P-tefuryl; (+/-) tetrahydrofurfuryl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenyloxy]propionate	414-200-4	119738-06-6; 200509-41-7	PPPR
Spiroxamine (ISO);8-tert-butyl-1,4-dioxaspiro[4.5]decan-2-ylmethyl(ethyl)(propyl)amine	-	118134-30-8	PPPR
pyridate	259-686-7	55512-33-9	PPPR
hymexazol (ISO); 3-hydroxy-5-methylisoxazole	233-000-6	10004-44-1	PPPR
Tris(nonylphenyl) phosphite (TNPP)	247-759-6	26523-78-4	REACH
Dimethyltin bis(2-ethylhexylmercaptoacetate), DMT (EHMA)	260-829-0	57583-35-4	REACH
2,3-epoxypropyl methacrylate	203-441-9	106-91-2	REACH
nickel (II) sulfide; [1] nickel sulfide; [2] millerite [3]	240-841-2	16812-54-7	REACH
Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	423-340-5	162881-26-7	REACH
isobutyl methacrylate	202-613-0	97-86-9	REACH
Succinic anhydride	203-570-0	108-30-5	REACH
Maleic anhydride	203-571-6	108-31-6	REACH
nickel bis(sulfamidate)|nickel sulfamate	237-396-1	13770-89-3	REACH
Bifenthrin	-	82657-04-3	BPR, PPPR
Formaldehyde	200-001-8	50-00-0	BPR, PPPR
Acequinocyl	611-595-7	57960-19-7	BPR, PPPR
propiconazole (ISO); 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole	262-104-4	60207-90-1	BPR, PPPR
3-Iodo-2-propynylbutylcarbamate	259-627-5	55406-53-6	BPR
Indoxacarb	-	173584-44-6	BPR
Cis-Tricos-9-ene (Muscalure)	248-505-7	27519-02-4	BPR
Cyanamide	206-992-3	420-04-2	BPR
Dichlofluanid (ISO),N-[(Dichlorofluoromethyl)thio]-N',N'-dimethyl-N-phenylsulfamide	214-118-7	1085-98-9	BPR
Reaction mass 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	-	55965-84-9	BPR
chlorocresol; 4-chloro-m-cresol; 4-chloro-3-methylphenol	200-431-6	59-50-7	BPR

Table A8-4: Substances with harmonised classification and labelling for serious eye damage / eye irritation implemented after the entry into force of the REACH and CLP Regulations			
Name	**EC number**	**CAS number**	**Regulatory Programme**
P-tert-butylphenol	202-679-0	98-54-4	REACH
1,2-epoxybutane (2-ethyloxirane)	203-438-2	106-88-7	REACH
N-methyl-2-pyrrolidone,1-methyl-2-pyrrolidone	212-828-1	872-50-4	REACH
5-chloro-2-(4-chlorophenoxy)phenol	429-290-0	3380-30-1	BPR
Cyanamide	206-992-3	420-04-2	BPR
N,N-diethyl-m-toluamide,deet	205-149-7	134-62-3	BPR
2,3-epoxypropyl methacrylate	203-441-9	106-91-2	REACH

Table A8-4: Substances with harmonised classification and labelling for serious eye damage / eye irritation implemented after the entry into force of the REACH and CLP Regulations			
Name	**EC number**	**CAS number**	**Regulatory Programme**
Reaction mass 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	N/A	55965-84-9	BPR
Chlorocresol; 4-chloro-m-cresol; 4-chloro-3-methylphenol	200-431-6	59-50-7	BPR
Maleic anhydride	203-571-6	108-31-6	REACH
Succinic anhydride	203-570-0	108-30-5	REACH
Acetaldehyde; ethanal	200-836-8	75-07-0	REACH
1,2-dihydroxybenzene; pyrocatechol	204-427-5	120-80-9	REACH
Hymexazol (ISO); 3-hydroxy-5-methylisoxazole	233-000-6	10004-44-1	PPPR
Ethylene oxide; oxirane	200-849-9	75-21-8	REACH
Imazalil	252-615-0	35554-44-0	PPPR
Fluazinam	-	79622-59-6	PPPR
Fenamiphos	244-848-1	22224-92-6	PPPR
Benzoic acid	200-618-2	65-85-0	PPPR
glyphosate (ISO); N-(phosphonomethyl)glycine	213-997-4	1071-83-6	PPPR
Tetrahydrofuran	203-726-8	109-99-9	REACH
Chloroform	200-663-8	67-66-3	REACH
Octadecylamine	204-695-3	124-30-1	REACH
Amines, hydrogenated tallow alkyl	262-976-6	61788-45-2	REACH
Pentadecafluorooctanoic acid (PFOA)	206-397-9	335-67-1	REACH
Ammonium pentadecafluorooctanoate (APFO)	223-320-4	3825-26-1	REACH
1,1',1''-nitrilotripropan-2-ol (TIPA)	204-528-4	122-20-3	REACH
Tetrahydrofurfuryl alcohol (THFA)	202-625-6	97-99-4	REACH
Copper sulphate pentahydrate	231-847-6	7758-99-8	BPR, PPPR
3-Iodo-2-propynylbutylcarbamate	259-627-5	55406-53-6	BPR

Table A8-5: Substances with harmonised classification and labelling for mutagenicity implemented after the entry into force of the REACH and CLP Regulations			
Name	**EC number**	**CAS number**	**Regulatory Programme**
Quizalofop-P-tefuryl; (+/-) tetrahydrofurfuryl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenyloxy]propionate	414-200-4	119738-06-6; 200509-41-7	PPPR
2,3-epoxypropyl methacrylate	203-441-9	106-91-2	REACH
Acetaldehyde; ethanal	200-836-8	75-07-0	REACH
1,2-dihydroxybenzene; pyrocatechol	204-427-5	120-80-9	REACH
Colecalciferol, vitamin D3	200-673-2	67-97-0	BPR
Trinickel disulfide; nickel subsulfide; [1] heazlewoodite [2]	234-829-6	12035-72-2	REACH
Ethylene oxide; oxirane	200-849-9	75-21-8	REACH
Nickel (II) sulfide; [1] nickel sulfide; [2] millerite [3]	240-841-2	16812-54-7	REACH
Di-tert-butyl peroxide	203-733-6	110-05-4	REACH
Leucomalachite Green	204-961-9	129-73-7	REACH
Pitch, coal tar, high temp.	266-028-2	65996-93-2	REACH
nickel bis(sulfamidate)|nickel sulfamate	237-396-1	13770-89-3	REACH
Formaldehyde	200-001-8	50-00-0	BPR, PPPR

Table A8-6: Substances with harmonised classification and labelling for carcinogenicity implemented after the entry into force of the REACH and CLP Regulations

Name	EC number	CAS number	Regulatory Programme
Etridiazole	219-991-8	2593-15-9	PPPR
1,2-epoxybutane (2-ethyloxirane)	203-438-2	106-88-7	REACH
Acetochlor (ISO),2-chloro-N-(ethoxymethyl)-N-(2-ethyl-6-methylphenyl)acetamide	251-899-3	34256-82-1	PPPR
1,2-dichloropropane,propylene dichloride	201-152-2	78-87-5	REACH
Cyproconazole (ISO); (2RS,3RS;2RS,3SR)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1H-1,2,4-triazol-1-yl)butan-2-ol	-	94361-06-5	BPR
Quizalofop-P-tefuryl; (+/-) tetrahydrofurfuryl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenyloxy]propionate	414-200-4	119738-06-6; 200509-41-7	PPPR
2,3-epoxypropyl methacrylate	203-441-9	106-91-2	REACH
Acetaldehyde; ethanal	200-836-8	75-07-0	REACH
1,2-dihydroxybenzene; pyrocatechol	204-427-5	120-80-9	REACH
Colecalciferol, vitamin D3	200-673-2	67-97-0	BPR
Pymetrozine (ISO),(E)-4,5-dihydro-6-methyl-4-(3-pyridylmethyleneamino)-1,2,4-triazin-3(2H)-one	-	123312-89-0	PPPR
Trinickel disulfide; nickel subsulfide; [1] heazlewoodite [2]	234-829-6	12035-72-2	
Ethylene oxide; oxirane	200-849-9	75-21-8	
Nickel (II) sulfide; [1] nickel sulfide; [2] millerite [3]	240-841-2	16812-54-7	
Epoxiconazole	406-850-2	133855-98-8	PPPR
Fuberidazole	223-404-0	3878-19-1	PPPR
Metazachlor	266-583-0	67129-08-2	PPPR
Aclonifen	277-704-1	74070-46-5	PPPR
Proquinazid	-	189278-12-4	PPPR
Tralkoxydim	-	87820-88-0	PPPR
Pirimicarb (ISO),5,6-dimethyl-2-dimethylamino-pyrimidin-4-yl N,N-dimethylcarbamate	245-430-1	23103-98-2	PPPR
isoproturon (ISO); 3-(4-isopropylphenyl)-1,1-dimethylurea	251-835-4	34123-59-6	PPPR
Pymetrozine (ISO),(E)-4,5-dihydro-6-methyl-4-(3-pyridylmethyleneamino)-1,2,4-triazin-3(2H)-one	-	123312-89-0	PPPR
Diantimony trioxide	215-175-0	1309-64-4	REACH
Tris[2-chloro-1-(chloromethyl)ethyl] phosphate (TDCP)	237-159-2	13674-87-8	REACH
Tetrahydrofuran	203-726-8	109-99-9	REACH
Indium phosphide	244-959-5	22398-80-0	REACH
Gallium arsenide	215-114-8	1303-00-0	REACH
Chloroform	200-663-8	67-66-3	REACH
Leucomalachite Green	204-961-9	129-73-7	REACH
Nitrobenzene	202-716-0	98-95-3	REACH
Vinyl acetate	203-545-4	108-05-4	REACH
Pentadecafluorooctanoic acid (PFOA)	206-397-9	335-67-1	REACH
Ammonium pentadecafluorooctanoate (APFO)	223-320-4	3825-26-1	REACH
Pitch, coal tar, high temp.	266-028-2	65996-93-2	REACH
4 vinylcyclohexene (VCH)	202-848-9	100-40-3	REACH
nickel bis(sulfamidate)|nickel sulfamate	237-396-1	13770-89-3	REACH
White spirit type 1, Naphtha (petroleum), hydrodesulphurised heavy	265-185-4	64742-82-1	REACH
Stoddard solvent (US term for white spirit, corresponding to white spirit type 1,see CAS-no. 64742-82-1)	232-489-3	8052-41-3	REACH
Bifenthrin	-	82657-04-3	BPR, PPPR

Table A8-6: Substances with harmonised classification and labelling for carcinogenicity implemented after the entry into force of the REACH and CLP Regulations			
Name	**EC number**	**CAS number**	**Regulatory Programme**
Formaldehyde	200-001-8	50-00-0	BPR, PPPR
Iodomethane	200-819-5	74-88-4	BPR

Table A8-7: Substances with harmonised classification and labelling for reproductive toxicity implemented after the entry into force of the REACH and CLP Regulations			
Name	**EC number**	**CAS number**	**Regulatory Programme**
Trixylyl phosphate	246-677-8	25155-23-1	REACH
P-tert-butylphenol	202-679-0	98-54-4	REACH
Dimethyltin bis(2-ethylhexylmercaptoacetate), DMT (EHMA)	260-829-0	57583-35-4	REACH
Dimethyltin dichloride (DMTC)	212-039-2	753-73-1	REACH
Dodemorph	216-474-9	1593-77-7	PPPR
Spiroxamine (ISO); 8-tert-butyl-1,4-dioxaspiro[4.5]decan-2-ylmethyl(ethyl)(propyl)amine	-	118134-30-8	PPPR
Methanol	200-659-6	67-56-1	REACH
Bisphenol A,4,4'-isopropylidenediphenol	201-245-8	80-05-7	REACH
N-methyl-2-pyrrolidone,1-methyl-2-pyrrolidone	212-828-1	872-50-4	REACH
N,N-dimethylacetamide	204-826-4	127-19-5	REACH
Cyanamide	206-992-3	420-04-2	BPR
2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	400-600-6	71868-10-5	REACH
Cyproconazole (ISO); (2RS,3RS;2RS,3SR)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1H-1,2,4-triazol-1-yl)butan-2-ol	-	94361-06-5	BPR
Quizalofop-P-tefuryl; (+/-) tetrahydrofurfuryl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenyloxy]propionate	414-200-4	119738-06-6; 200509-41-7	PPPR
2,3-epoxypropyl methacrylate	203-441-9	106-91-2	REACH
2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	404-360-3	119313-12-1	REACH
Potassium permanganate	231-760-3	7722-64-7	REACH
Hymexazol (ISO); 3-hydroxy-5-methylisoxazole	233-000-6	10004-44-1	PPPR
Spiroxamine (ISO);8-tert-butyl-1,4-dioxaspiro[4.5]decan-2-ylmethyl(ethyl)(propyl)amine	-	118134-30-8	PPPR
Flumioxazin (ISO); 2-[7-fluoro-3-oxo-4-(prop-2-yn-1-yl)-3,4-dihydro-2H-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1H-isoindole-1,3(2H)-dione	-	103361-09-7	PPPR
Propiconazole (ISO); 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole	262-104-4	60207-90-1	BPR, PPPR
Pymetrozine (ISO),(E)-4,5-dihydro-6-methyl-4-(3-pyridylmethyleneamino)-1,2,4-triazin-3(2H)-one	-	123312-89-0	PPPR
Epoxiconazole	406-850-2	133855-98-8	PPPR
Penconazole	266-275-6	66246-88-6	PPPR
Cymoxanil	261-043-0	57966-95-7	PPPR
Cycloxydim	405-230-9	101205-02-1	PPPR
Fluazinam	-	79622-59-6	PPPR
Sulcotrione	-	99105-77-8	PPPR
isoproturon (ISO); 3-(4-isopropylphenyl)-1,1-dimethylurea	251-835-4	34123-59-6	PPPR
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	278-355-8	75980-60-8	REACH
Indium phosphide	244-959-5	22398-80-0	REACH
Chloroform	200-663-8	67-66-3	REACH
Trichloromethylstannane (MMTC)	213-608-8	993-16-8	REACH

Table A8-7: Substances with harmonised classification and labelling for reproductive toxicity implemented after the entry into force of the REACH and CLP Regulations			
Name	**EC number**	**CAS number**	**Regulatory Programme**
2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-xoethyl]thio]-4-methyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate	260-828-5	57583-34-3	REACH
Nitrobenzene	202-716-0	98-95-3	REACH
4-tert-butylbenzoic acid	202-696-3	98-73-7	REACH
2-Ethoxyethanol	203-804-1	110-80-5	REACH
Pentadecafluorooctanoic acid (PFOA)	206-397-9	335-67-1	REACH
Ammonium pentadecafluorooctanoate (APFO)	223-320-4	3825-26-1	REACH
Pitch, coal tar, high temp.	266-028-2	65996-93-2	REACH
N-ethyl-2-pyrrolidone (NEP)	220-250-6	2687-91-4	REACH
Tetrahydrofurfuryl alcohol (THFA)	202-625-6	97-99-4	REACH
Dioctyltin bis(2-ethylhexyl mercaptoacetate), 2-Ethylhexyl 10-ethyl-4,4- dioctyl-7-oxo-8-oxa-3,5-dithia- 4-stannatetradecanoate	239-622-4	15571-58-1	REACH
Bisphenol A,4,4'-isopropylidenediphenol	201-245-8	80-05-7	REACH
Dihexyl phthalate	201-559-5	84-75-3	REACH
nickel bis(sulfamidate)|nickel sulfamate	237-396-1	13770-89-3	REACH
Abamectin	-	71751-41-2	BPR, PPPR
Warfarin (ISO),4-hydroxy-3-(3-oxo-1-phenylbutyl)-2H-chromen-2-one	201-377-6	81-81-2	BPR, PPPR

Table A8-8: Substances with harmonised classification and labelling for specific target organ toxicity implemented after the entry into force of the REACH and CLP Regulations			
Name	**EC number**	**CAS number**	**Regulatory Programme**
P-tert-butylphenol	202-679-0	98-54-4	REACH
Styrene	202-851-5	100-42-5	REACH
Dimethyltin bis(2-ethylhexylmercaptoacetate), DMT (EHMA)	260-829-0	57583-35-4	REACH
Dimethyltin dichloride (DMTC)	212-039-2	753-73-1	REACH
Etridiazole	219-991-8	2593-15-9	PPPR
Acetochlor (ISO),2-chloro-N-(ethoxymethyl)-N-(2-ethyl-6-methylphenyl)acetamide	251-899-3	34256-82-1	PPPR
N-methyl-2-pyrrolidone,1-methyl-2-pyrrolidone	212-828-1	872-50-4	REACH
Chloralose (INN),(R)-1,2-O-(2,2,2-trichloroethylidene)-α-D-glucofuranose,glucochloralose,anhydroglucochloral	240-016-7	15879-93-3	BPR
Cyanamide	206-992-3	420-04-2	BPR
N,N-diethyl-m-toluamide,deet	205-149-7	134-62-3	BPR
Isobutyl methacrylate	202-613-0	97-86-9	REACH
Cyproconazole (ISO); (2RS,3RS;2RS,3SR)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1H-1,2,4-triazol-1-yl)butan-2-ol		94361-06-5	BPR
Metaldehyde; 2,4,6,8-tetramethyl-1,3,5,7-tetraoxacyclooctane	203-600-2	108-62-3	PPPR
Quizalofop-P-tefuryl; (+/-) tetrahydrofurfuryl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenyloxy]propionate	414-200-4	119738-06-6; 200509-41-7	PPPR
2,3-epoxypropyl methacrylate	203-441-9	106-91-2	REACH
Chlorocresol; 4-chloro-m-cresol; 4-chloro-3-methylphenol	200-431-6	59-50-7	BPR
Maleic anhydride	203-571-6	108-31-6	REACH
Phosmet (ISO),S-[(1,3-dioxo-1,3-dihydro-2H-isoindol-2-yl)methyl] O,O-dimethyl phosphorodithioate	211-987-4	732-11-6	PPPR
Acetaldehyde; ethanal	200-836-8	75-07-0	REACH

Table A8-8: Substances with harmonised classification and labelling for specific target organ toxicity implemented after the entry into force of the REACH and CLP Regulations			
Name	**EC number**	**CAS number**	**Regulatory Programme**
Spiroxamine (ISO);8-tert-butyl-1,4-dioxaspiro[4.5]decan-2-ylmethyl(ethyl)(propyl)amine		118134-30-8	PPPR
Colecalciferol, vitamin D3	200-673-2	67-97-0	BPR
Trinickel disulfide; nickel subsulfide; [1] heazlewoodite [2]	234-829-6	12035-72-2	REACH
Ethylene oxide; oxirane	200-849-9	75-21-8	REACH
Nickel (II) sulfide; [1] nickel sulfide; [2] millerite [3]	240-841-2	16812-54-7	REACH
Cypermethrin cis/trans +/- 40/ 60; (RS)-á-cyano-3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	257-842-9	52315-07-8	BPR
Warfarin (ISO),4-hydroxy-3-(3-oxo-1-phenylbutyl)-2H-chromen-2-one	201-377-6	81-81-2	BPR, PPPR
Difenacoum (ISO),3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin	259-978-4	56073-07-5	BPR, PPPR
Stoddard solvent (US term for white spirit, corresponding to white spirit type 1,see CAS-no. 64742-82-1)	232-489-3	8052-41-3	REACH
White spirit type 0, Solvent naphtha (petroleum), medium aliphatic	265-191-7	64742-88-7	REACH
White spirit type 1, Naphtha (petroleum), hydrodesulphurised heavy	265-185-4	64742-82-1	REACH
isobutyl methacrylate	202-613-0	97-86-9	REACH
Cymoxanil	261-043-0	57966-95-7	PPPR
Fuberidazole	223-404-0	3878-19-1	PPPR
Methyl 2,5-dichlorobenzoate	220-815-7	2905-69-3	PPPR
Benzoic acid	200-618-2	65-85-0	PPPR
Tebufenpyrad	-	119168-77-3	PPPR
glyphosate (ISO); N-(phosphonomethyl)glycine	213-997-4	1071-83-6	PPP
Gallium arsenide	215-114-8	1303-00-0	REACH
Indium phosphide	244-959-5	22398-80-0	REACH
Tetrahydrofuran	203-726-8	109-99-9	REACH
Cryolite (Trisodium hexafluoroaluminate)	237-410-6	13775-53-6	REACH
Cryolite (Trisodium hexafluoroaluminate)	239-148-8	15096-52-3	REACH
Chloroform	200-663-8	67-66-3	REACH
Ethylbenzene	202-849-4	100-41-4	REACH
(Z)-octadec-9-enylamine	204-015-5	112-90-3	REACH
Amines, coco alkyl	262-977-1	61788-46-3	REACH
Amines, hydrogenated tallow alkyl	262-976-6	61788-45-2	REACH
Amines, tallow alkyl	263-125-1	61790-33-8	REACH
Octadecylamine	204-695-3	124-30-1	REACH
4-tert-butylbenzoic acid	202-696-3	98-73-7	REACH
Reaction mass of 2,4,4-Trimethylpent-1-ene and 2,4,4-Trimethylpent-2-ene	246-690-9	25167-70-8	REACH
Nitrobenzene	202-716-0	98-95-3	REACH
Vinyl acetate	203-545-4	108-05-4	REACH
Ammonium pentadecafluorooctanoate (APFO)	223-320-4	3825-26-1	REACH
Pentadecafluorooctanoic acid (PFOA)	206-397-9	335-67-1	REACH

Table A8-8: Substances with harmonised classification and labelling for specific target organ toxicity implemented after the entry into force of the REACH and CLP Regulations			
Name	**EC number**	**CAS number**	**Regulatory Programme**
Styrene	202-851-5	100-42-5	REACH
Dimethyltin bis(2-ethylhexylmercaptoacetate), DMT (EHMA)	260-829-0	57583-35-4	REACH
Dimethyltin dichloride (DMTC)	212-039-2	753-73-1	REACH
Lithium sodium 3-amino-10-{4-(10- amino-6, 13-dichloro-4,11-disulfonatobenzo[5,6][1,4]oxazino[2,3 -b]phenoxazine-3-ylamino)-6- [methyl(2-sulfonato-ethyl)amino]- 1,3,5-triazin-2-ylamino}-6,13- dichlorobenzo[5,6][1,4]oxazino[2,3-b]phenoxazine-4,11-disulfonate; Direct Blue FC 57087	418-870-9	154212-58-5	REACH
N-methyl-2-pyrrolidone,1-methyl-2-pyrrolidone	212-828-1	872-50-4	REACH
Abamectin	-	71751-41-2	BPR, PPPR
nickel bis(sulfamidate)|nickel sulfamate	237-396-1	13770-89-3	REACH
Acequinocyl	611-595-7	57960-19-7	BPR, PPPR
3-Iodo-2-propynylbutylcarbamate	259-627-5	55406-53-6	BPR
chlorfenapyr (ISO)|4-bromo-2-(4-chlorophenyl)-1-ethoxymethyl-5-trifluoromethylpyrrole-3-carbonitrile	-	122453-73-0	BPR
Brodifacoum (ISO),4-hydroxy-3-(3-(4'-bromo-4-biphenylyl)-1,2,3,4-tetrahydro-1-naphthyl)coumarin	259-980-5	56073-10-0	BPR
Perestane	432-790-1	847871-03-8	BPR
Flocoumafen (ISO),reaction mass of: cis-4-hydroxy-3-(1,2,3,4-tetrahydro-3-(4-(4-trifluoromethylbenzyloxy)phenyl)-1-naphthyl)coumarin,trans-4-hydroxy-3-(1,2,3,4-tetrahydro-3-(4-(4-trifluoromethylbenzyloxy)phenyl)-1- naphthyl)coumarin	421-960-0	90035-08-8	BPR
Chlorophacinone (ISO),2-[(4-chlorophenyl)(phenyl)acetyl]-1H-indene-1,3(2H)-dione	223-003-0	3691-35-8	BPR
Indoxacarb	-	173584-44-6	BPR
Coumatetralyl (ISO),4-hydroxy-3-(1,2,3,4-tetrahydro-1-naphthyl)coumarin	227-424-0	5836-29-3	BPR
Iodomethane	200-819-5	74-88-4	BPR

Table A8-9: Substances with harmonised classification and labelling as hazardous to the aquatic environment implemented after the entry into force of the REACH and CLP Regulations			
Name	**EC number**	**CAS number**	**Regulatory Programme**
Aluminium phosphide	244-088-0	20859-73-8	BPR, PPPR
Fenpyrazamine		473798-59-3	PPPR
Tebuconazole	403-640-2	107534-96-3	BPR, PPPR
Dodemorph	216-474-9	1593-77-7	PPPR
Etridiazole	219-991-8	2593-15-9	PPPR
Pyridaben (2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyridazin-3(2H)-one)	405-700-3	96489-71-3	PPPR
Glutaral,Glutaraldehyde,1,5-pentanedial	203-856-5	111-30-8	BPR
Acetochlor (ISO),2-chloro-N-(ethoxymethyl)-N-(2-ethyl-6-methylphenyl)acetamide	251-899-3	34256-82-1	PPPR
Flumioxazin (ISO),N-(7-fluoro-3,4-dihydro-3-oxo-4-prop-2-ynyl-2H-1,4-benzoxazin-6-yl)cyclohex-1-ene-1,2-dicarboxamide		103361-09-7	PPPR
Chloralose (INN),(R)-1,2-O-(2,2,2-trichloroethylidene)-α-D-glucofuranose,glucochloralose,anhydroglucochloral	240-016-7	15879-93-3	BPR
5-chloro-2-(4-chlorophenoxy)phenol	429-290-0	3380-30-1	BPR

Table A8-9: Substances with harmonised classification and labelling as hazardous to the aquatic environment implemented after the entry into force of the REACH and CLP Regulations			
Name	**EC number**	**CAS number**	**Regulatory Programme**
Fenpyrazamine		473798-59-3	PPPR
Cyanamide	206-992-3	420-04-2	BPR
Chlorsulfuron (ISO),2-chloro-N-[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]benzenesulphonamide	265-268-5	64902-72-3	PPPR
2-phenylphenol (ISO),biphenyl-2-ol,2-hydroxybiphenyl	201-993-5	90-43-7	BPR, PPPR
Fipronil (ISO),5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulfinyl]-1H-pyrazole-3-carbonitrile	424-610-5	120068-37-3	BPR
Cyproconazole (ISO); (2RS,3RS;2RS,3SR)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1H-1,2,4-triazol-1-yl)butan-2-ol		94361-06-5	BPR
3,3'-dicyclohexyl-1,1'-methylenebis(4,1-phenylene)diurea	406-370-3	58890-25-8	
Metaldehyde; 2,4,6,8-tetramethyl-1,3,5,7-tetraoxacyclooctane	203-600-2	108-62-3	PPPR
Quizalofop-P-tefuryl; (+/-) tetrahydrofurfuryl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenyloxy]propionate	414-200-4	119738-06-6; 200509-41-7	PPPR
Reaction mass 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)		55965-84-9	BPR
Chlorocresol; 4-chloro-m-cresol; 4-chloro-3-methylphenol	200-431-6	59-50-7	BPR
4-tert-butylphenol	202-679-0	98-54-4	REACH
Phosmet (ISO),S-[(1,3-dioxo-1,3-dihydro-2H-isoindol-2-yl)methyl] O,O-dimethyl phosphorodithioate	211-987-4	732-11-6	PPPR
2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	404-360-3	119313-12-1	REACH
Potassium permanganate	231-760-3	7722-64-7	REACH
Sodium hypochlorite, solution ... % cl active	231-668-3	7681-52-9	PPPR
Hymexazol (ISO); 3-hydroxy-5-methylisoxazole	233-000-6	10004-44-1	PPPR
Nicotine (ISO); 3-[(2S)-1-methylpyrrolidin-2-yl]pyridine	200-193-3	54-11-5	REACH
Spiroxamine (ISO);8-tert-butyl-1,4-dioxaspiro[4.5]decan-2-ylmethyl(ethyl)(propyl)amine		118134-30-8	PPPR
Flumioxazin (ISO); 2-[7-fluoro-3-oxo-4-(prop-2-yn-1-yl)-3,4-dihydro-2H-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1H-isoindole-1,3(2H)-dione		103361-09-7	PPPR
Propiconazole (ISO); 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole	262-104-4	60207-90-1	BPR, PPPR
Thifensulfuron-methyl (ISO); methyl 3-(4-methoxy-6-methyl-1,3,5-triazin-2-ylcarbamoylsulfamoyl)thiophene-2-carboxylate		79277-27-3	PPPR
Pymetrozine (ISO),(E)-4,5-dihydro-6-methyl-4-(3-pyridylmethyleneamino)-1,2,4-triazin-3(2H)-one		123312-89-0	PPPR
Amines, hydrogenated tallow alkyl	262-976-6	61788-45-2	REACH
Penconazole	266-275-6	66246-88-6	PPPR
Bendiocarb (ISO),2,2-dimethyl-1,3-benzodioxol-4-yl N-methylcarbamate	245-216-8	22781-23-3	PPPR
Pirimicarb (ISO),5,6-dimethyl-2-dimethylamino-pyrimidin-4-yl N,N-dimethylcarbamate	245-430-1	23103-98-2	PPPR
isoproturon (ISO); 3-(4-isopropylphenyl)-1,1-dimethylurea	251-835-4	34123-59-6	PPPR
pyridate	259-686-7	55512-33-9	PPP
glyphosate (ISO); N-(phosphonomethyl)glycine	213-997-4	1071-83-6	PPPR
Cryolite (Trisodium hexafluoroaluminate)	239-148-8	15096-52-3	REACH
Cryolite (Trisodium hexafluoroaluminate)	237-410-6	13775-53-6	REACH
Tris(nonylphenyl) phosphite (TNPP)	247-759-6	26523-78-4	REACH

Table A8-9: Substances with harmonised classification and labelling as hazardous to the aquatic environment implemented after the entry into force of the REACH and CLP Regulations			
Name	**EC number**	**CAS number**	**Regulatory Programme**
Nitrobenzene	202-716-0	98-95-3	REACH
Octadecylamine	204-695-3	124-30-1	REACH
Amines, tallow alkyl	263-125-1	61790-33-8	REACH
Thiabendazole (ISO); 2-(1,3-thiazol-4-yl)-1H-benzimidazole	205-725-8	148-79-8	PPPR
Trinickel disulfide; nickel subsulfide; [1] heazlewoodite [2]	234-829-6	12035-72-2	REACH
Nickel (II) sulfide; [1] nickel sulfide; [2] millerite [3]	240-841-2	16812-54-7	REACH
Cypermethrin cis/trans +/- 40/ 60; (RS)-á-cyano-3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	257-842-9	52315-07-8	BPR
Amines, coco alkyl	262-977-1	61788-46-3	REACH
(Z)-octadec-9-enylamine	204-015-5	112-90-3	REACH
Aluminium-magnesium-zinc-carbonate-hydroxide-(hydrate)	423-570-6	169314-88-9	REACH
Pitch, coal tar, high temp.	266-028-2	65996-93-2	REACH
nickel bis(sulfamidate)|nickel sulfamate	237-396-1	13770-89-3	REACH
Flufenoxuron	417-680-3	101463-69-8	BPR, PPPR
Bifenthrin	-	82657-04-3	BPR, PPPR
Tebuconazole	403-640-2	107534-96-3	BPR, PPPR
Dicopper oxide,copper (I) oxide	215-270-7	1317-39-1	BPR, PPPR
Acequinocyl	611-595-7	57960-19-7	BPR, PPPR
Abamectin	-	71751-41-2	BPR, PPPR
Difenacoum (ISO),3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin	259-978-4	56073-07-5	BPR, PPPR
Warfarin (ISO),4-hydroxy-3-(3-oxo-1-phenylbutyl)-2H-chromen-2-one	201-377-6	81-81-2	BPR, PPPR
Copper sulphate pentahydrate	231-847-6	7758-99-8	BPR, PPPR
3-Iodo-2-propynylbutylcarbamate	259-627-5	55406-53-6	BPR
chlorfenapyr (ISO)|4-bromo-2-(4-chlorophenyl)-1-ethoxymethyl-5-trifluoromethylpyrrole-3-carbonitrile	-	122453-73-0	BPR
imidacloprid (ISO) 1-(6-chloropyridin-3-ylmethyl)-N-nitroimidazolidin-2-ylidenamine	428-040-8	138261-41-3	BPR
Indoxacarb	-	173584-44-6	BPR
Chlorophacinone (ISO),2-[(4-chlorophenyl)(phenyl)acetyl]-1H-indene-1,3(2H)-dione	223-003-0	3691-35-8	BPR
Flocoumafen (ISO),reaction mass of: cis-4-hydroxy-3-(1,2,3,4-tetrahydro-3-(4-(4-trifluoromethylbenzyloxy)phenyl)-1-naphthyl)coumarin,trans-4-hydroxy-3-(1,2,3,4-tetrahydro-3-(4-(4-trifluoromethylbenzyloxy)phenyl)-1- naphthyl)coumarin	421-960-0	90035-08-8	BPR
Brodifacoum (ISO),4-hydroxy-3-(3-(4'-bromo-4-biphenylyl)-1,2,3,4-tetrahydro-1-naphthyl)coumarin	259-980-5	56073-10-0	BPR
Acrolein	203-453-4	107-02-8	BPR
Etofenprox	407-980-2	80844-07-1	BPR
Coumatetralyl (ISO),4-hydroxy-3-(1,2,3,4-tetrahydro-1-naphthyl)coumarin	227-424-0	5836-29-3	BPR
Trimagnesium diphosphide	235-023-7	12057-74-8	BPR
Tralkoxydim	-	87820-88-0	PPPR
Epoxiconazole	406-850-2	133855-98-8	PPPR

Table A8-9: Substances with harmonised classification and labelling as hazardous to the aquatic environment implemented after the entry into force of the REACH and CLP Regulations			
Name	**EC number**	**CAS number**	**Regulatory Programme**
Amidosulfuron	407-380-0	120923-37-7	PPPR
Cymoxanil	261-043-0	57966-95-7	PPPR
Imazalil	252-615-0	35554-44-0	PPPR
Fluazinam	-	79622-59-6	PPPR
Fuberidazole	223-404-0	3878-19-1	PPPR
Metazachlor	266-583-0	67129-08-2	PPPR
Sulcotrione	-	99105-77-8	PPPR
Aclonifen	277-704-1	74070-46-5	PPPR
Fenamiphos	244-848-1	22224-92-6	PPPR
Methyl 2,5-dichlorobenzoate	220-815-7	2905-69-3	PPPR
Ethephon	240-718-3	16672-87-0	PPPR
Tricalcium diphosphide	215-142-0	1305-99-3	PPPR
Tebufenpyrad	-	119168-77-3	PPPR
Proquinazid	-	189278-12-4	PPPR

A8.2 Output Indicator 3 – Substances Restricted After the Entry into Force of the REACH and CLP Regulations by Hazard Class

Table A8-10: Substances restricted after the entry into force of the REACH and CLP Regulations with classification for acute toxicity (and scope of the restriction)			
Name	**EC number**	**CAS number**	**Scope of the restriction**
Cadmium and its compounds	231-152-8	7440-43-9	Amendment of the current restriction (entry 23) on use of paints with TARIC codes [3208] & [3209] containing cadmium and cadmium compounds to include placing on the market of such paints and a concentration limit.
Nonylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in positions 2 and/or 3 and/or 4 to phenol, covering UVCB- and well-defined substances which include any of the individual isomers or any combination thereof]	-	-	Placing on the market of textile clothing, fabric accessories and interior textile articles containing NP or NPE that can be washed in water
Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in positions 2 and/or 3 and/or 4 to phenol, ethoxylated with a degree of ethoxylation of ≥ 1, covering UVCB- and well-defined substances,	-	-	

Table A8-10: Substances restricted after the entry into force of the REACH and CLP Regulations with classification for acute toxicity (and scope of the restriction)			
Name	**EC number**	**CAS number**	**Scope of the restriction**
polymers and homologues]			
Nonylphenol	246-672-0	25154-52-3	Placing on the market of textile and leather articles containing NP or NPE
Nonylphenol ethoxylates	-	-	
Chromium VI	-	18540-29-9	Placing on the market of leather articles containing Chromium VI
Mercury	231-106-7	7439-97-6	Placing on the market of measuring devices containing or using Mercury
Phenylmercury 2-ethylhexanoate	231-106-7	13302-00-6	Placing on the market, manufacture and use of Phenylmercury 2-ethylhexanoate and placing on the market of articles containing it
Phenylmercury acetate	200-532-5	62-38-4	
Phenylmercury neodecanoate	247-783-7	26545-49-3	
Phenylmercury propionate	203-094-3	103-27-5	
Dimethylfumarate (DMF)	210-849-0	624-49-7	Placing on the market of articles containing Dimethylfumarate
Lead and its compounds	231-100-4	7439-92-1	Placing on the market of jewellery containing Lead and its compounds; and Placing on the market of consumer articles containing Lead and its compounds

Table A8-11: Substances restricted after the entry into force of the REACH and CLP Regulations with classification for skin corrosion / skin irritation (and scope of the restriction)			
Name	**EC number**	**CAS number**	**Scope of the restriction**
Nonylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in positions 2 and/or 3 and/or 4 to phenol, covering UVCB- and well-defined substances which include any of the individual isomers or any combination thereof]	-	-	Placing on the market of textile clothing, fabric accessories and interior textile articles containing NP or NPE that can be washed in water.
Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in positions 2 and/or 3 and/or 4 to phenol, ethoxylated with a degree of ethoxylation of ≥ 1, covering UVCB- and well-defined substances, polymers and homologues]	-	-	
Nonylphenol	246-672-0	25154-52-3	Placing on the market of textile and leather articles containing NP
Nonylphenol ethoxylates	-	-	Placing on the market of textile and leather articles containing NPE
Chromium VI	-	18540-29-9	Placing on the market of leather articles containing Chromium VI
Phenylmercury acetate	200-532-5	62-38-4	Placing on the market, manufacture and use of Phenylmercury acetate and placing on the market of articles

Table A8-11: Substances restricted after the entry into force of the REACH and CLP Regulations with classification for skin corrosion / skin irritation (and scope of the restriction)			
Name	**EC number**	**CAS number**	**Scope of the restriction**
			containing it
Dimethylfumarate (DMF)	210-849-0	624-49-7	Placing on the market of articles containing Dimethylfumarate

Table A8-12: Substances restricted after the entry into force of the REACH and CLP Regulations with classification for skin sensitisation (and scope of the restriction)			
Name	**EC number**	**CAS number**	**Scope of the restriction**
Chromium VI	-	18540-29-9	Placing on the market of leather articles containing Chromium VI
Dimethylfumarate (DMF)	210-849-0	624-49-7	Placing on the market of articles containing Dimethylfumarate

Table A8-13: Substances restricted after the entry into force of the REACH and CLP Regulations with classification for serious eye damage / eye irritation (and scope of the restriction)			
Name	**EC number**	**CAS number**	**Scope of the restriction**
Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in positions 2 and/or 3 and/or 4 to phenol, ethoxylated with a degree of ethoxylation of ≥ 1, covering UVCB- and well-defined substances, polymers and homologues]	-	-	Placing on the market of textile clothing, fabric accessories and interior textile articles containing NPE that can be washed in water.
Nonylphenol ethoxylates	-	-	Placing on the market of textile and leather articles containing NPE
1,4-Dichlorobenzene (p-dichlorobenzene)	203-400-5	106-46-7	Placing on the market of air fresheners and toilet blocks containing DCB
Dimethylfumarate (DMF)	210-849-0	624-49-7	Placing on the market of articles containing Dimethylfumarate

Table A8-14: Substances restricted after the entry into force of the REACH and CLP Regulations with classification for respiratory sensitisation (and scope of the restriction)			
Name	**EC number**	**CAS number**	**Scope of the restriction**
Chromium VI		18540-29-9	Placing on the market of leather articles containing Chromium VI

Table A8-15: Substances restricted after the entry into force of the REACH and CLP Regulations with classification for mutagenicity (and scope of the restriction)			
Name	**EC number**	**CAS number**	**Scope of the restriction**
Cadmium and its compounds	231-152-8	7440-43-9	Amendment of the current restriction (entry 23) on use of paints with TARIC codes [3208] & [3209] containing cadmium and cadmium compounds to include placing on the market of such paints and a concentration limit.
Chromium VI		18540-29-9	Placing on the market of leather articles containing Chromium VI

Table A8-16: Substances restricted after the entry into force of the REACH and CLP Regulations with classification for carcinogenicity (and scope of the restriction)			
Name	**EC number**	**CAS number**	**Scope of the restriction**
Cadmium and its compounds	231-152-8	7440-43-9	Amendment of the current restriction (entry 23) on use of paints with TARIC codes [3208] & [3209] containing cadmium and cadmium compounds to include placing on the market of such paints and a concentration limit.
1,4-Dichlorobenzene (p-dichlorobenzene)	203-400-5	106-46-7	Placing on the market of air fresheners and toilet blocks containing DCB
Chromium VI		18540-29-9	Placing on the market of leather articles containing Chromium VI
Lead and its compounds	231-100-4	7439-92-1	Placing on the market of jewellery containing Lead and its compounds; and Placing on the market of consumer articles containing Lead and its compounds

Table A8-17: Substances restricted after the entry into force of the REACH and CLP Regulations with classification for reproductive toxicity (and scope of the restriction)			
Name	**EC number**	**CAS number**	**Scope of the restriction**
Cadmium and its compounds	231-152-8	7440-43-9	Amendment of the current restriction (entry 23) on use of paints with TARIC codes [3208] & [3209] containing cadmium and cadmium compounds to include placing on the market of such paints and a concentration limit.
Nonylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in positions 2 and/or 3 and/or 4 to phenol, covering UVCB- and well-defined substances which include any of the individual isomers or any combination thereof]	-	-	Placing on the market of textile clothing, fabric accessories and interior textile articles containing NP or NPE that can be washed in water.
Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in positions 2 and/or 3 and/or 4 to phenol, ethoxylated with a degree of ethoxylation of ≥ 1, covering UVCB- and well-defined substances, polymers and homologues]	-	-	
Lead and its compounds	231-100-4	7439-92-1	Placing on the market of consumer articles containing Lead and its compounds and placing on the market of jewellery containing Lead and its compounds
Nonylphenol	246-672-0	25154-52-3	Placing on the market of textile and leather articles containing NP or NPE
Nonylphenol ethoxylates	-	-	
Chromium VI		18540-29-9	Placing on the market of leather articles

Table A8-17: Substances restricted after the entry into force of the REACH and CLP Regulations with classification for reproductive toxicity (and scope of the restriction)			
Name	**EC number**	**CAS number**	**Scope of the restriction**
			containing Chromium VI
Benzyl butyl phthalate (BBP)	201-622-7	85-68-7	Placing on the market of articles containing BBP for indoor environments and direct exposure
Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	117-81-7	Placing on the market of articles containing DEHP for indoor environments and direct exposure
Dibutyl phthalate (DBP)	201-557-4	84-74-2	Placing on the market of articles containing DBP for indoor environments and direct exposure
Mercury	231-106-7	7439-97-6	Placing on the market of measuring devices containing or using Mercury

Table A8-18: Substances restricted after the entry into force of the REACH and CLP Regulations with classification for specific target organ toxicity (and scope of the restriction)			
Name	**EC number**	**CAS number**	**Scope of the restriction**
Cadmium and its compounds	231-152-8	7440-43-9	Amendment of the current restriction (entry 23) on use of paints with TARIC codes [3208] & [3209] containing cadmium and cadmium compounds to include placing on the market of such paints and a concentration limit.
Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in positions 2 and/or 3 and/or 4 to phenol, ethoxylated with a degree of ethoxylation of ≥ 1, covering UVCB- and well-defined substances, polymers and homologues]	-	-	Placing on the market of textile clothing, fabric accessories and interior textile articles containing NPE that can be washed in water.
Lead and its compounds	231-100-4	7439-92-1	Placing on the market of consumer articles containing Lead and its compounds; and placing on the market of jewellery containing Lead and its compounds
Nonylphenol ethoxylates	-	-	Placing on the market of textile and leather articles containing NPE
Chromium VI		18540-29-9	Placing on the market of leather articles containing Chromium VI
Mercury	231-106-7	7439-97-6	Placing on the market of measuring devices containing or using Mercury
Phenylmercury 2-ethylhexanoate	231-106-7	13302-00-6	Placing on the market, manufacture and use of Phenylmercury 2-ethylhexanoate and placing on the market of articles containing it
Phenylmercury acetate	200-532-5	62-38-4	Placing on the market, manufacture and use of Phenylmercury acetate and placing on the market of articles containing it
Phenylmercury neodecanoate	247-783-7	26545-49-3	Placing on the market, manufacture and

Table A8-18: Substances restricted after the entry into force of the REACH and CLP Regulations with classification for specific target organ toxicity (and scope of the restriction)			
Name	**EC number**	**CAS number**	**Scope of the restriction**
			use of Phenylmercury neodecanoate and placing on the market of articles containing it
Phenylmercury propionate	203-094-3	103-27-5	Placing on the market, manufacture and use of Phenylmercury propionate and placing on the market of articles containing it
Dimethylfumarate (DMF)	210-849-0	624-49-7	Placing on the market of articles containing Dimethylfumarate

Table A8-19: Substances restricted after the entry into force of the REACH and CLP Regulations with classification for aspiration hazard (and scope of the restriction)			
Name	**EC number**	**CAS number**	**Scope of the restriction**
Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in positions 2 and/or 3 and/or 4 to phenol, ethoxylated with a degree of ethoxylation of ≥ 1, covering UVCB- and well-defined substances, polymers and homologues]	-	-	Placing on the market of textile clothing, fabric accessories and interior textile articles containing NPE that can be washed in water.
Nonylphenol ethoxylates	-	-	Placing on the market of textile and leather articles containing NPE

Table A8-20: Substances restricted after the entry into force of the REACH and CLP Regulations with classification for hazardous to the aquatic environment (and scope of the restriction)			
Name	**EC number**	**CAS number**	**Scope of the restriction**
Cadmium and its compounds	231-152-8	7440-43-9	Amendment of the current restriction (entry 23) on use of paints with TARIC codes [3208] & [3209] containing cadmium and cadmium compounds to include placing on the market of such paints and a concentration limit.
Nonylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in positions 2 and/or 3 and/or 4 to phenol, covering UVCB- and well-defined substances which include any of the individual isomers or any combination thereof]	-	-	Placing on the market of textile clothing, fabric accessories and interior textile articles containing NP or NPE that can be washed in water.
Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in positions 2 and/or 3 and/or 4 to phenol, ethoxylated with a degree of ethoxylation of ≥ 1, covering UVCB- and well-defined substances,	-	-	

Table A8-20: Substances restricted after the entry into force of the REACH and CLP Regulations with classification for hazardous to the aquatic environment (and scope of the restriction)			
Name	**EC number**	**CAS number**	**Scope of the restriction**
polymers and homologues]			
Lead and its compounds	231-100-4	7439-92-1	Placing on the market of consumer articles containing Lead and its compounds; and placing on the market of jewellery containing Lead and its compounds
Nonylphenol	246-672-0	25154-52-3	Placing on the market of textile and leather articles containing NP or NPE
Nonylphenol ethoxylates			
1,4-Dichlorobenzene (p-dichlorobenzene)	203-400-5	106-46-7	Placing on the market of air fresheners and toilet blocks containing DCB
Chromium VI		18540-29-9	Placing on the market of leather articles containing Chromium VI
Benzyl butyl phthalate (BBP)	201-622-7	85-68-7	Placing on the market of articles containing BBP for indoor environments and direct exposure
Dibutyl phthalate (DBP)	201-557-4	84-74-2	Placing on the market of articles containing DBP for indoor environments and direct exposure
Mercury	231-106-7	7439-97-6	Placing on the market of measuring devices containing or using Mercury
Phenylmercury 2-ethylhexanoate	231-106-7	13302-00-6	Placing on the market, manufacture and use of Phenylmercury 2-ethylhexanoate and placing on the market of articles containing it
Phenylmercury acetate	200-532-5	62-38-4	Placing on the market, manufacture and use of Phenylmercury acetate and placing on the market of articles containing it
Phenylmercury neodecanoate	247-783-7	26545-49-3	Placing on the market, manufacture and use of Phenylmercury neodecanoate and placing on the market of articles containing it
Phenylmercury propionate	203-094-3	103-27-5	Placing on the market, manufacture and use of Phenylmercury propionate and placing on the market of articles containing it
Mercury	231-106-7	7439-97-6	Placing on the market of measuring devices containing or using Mercury

Table A8-21: Substances restricted after the entry into force of the REACH and CLP Regulations with classification for endocrine activity (and scope of the restriction)			
Name	**EC number**	**CAS number**	**Scope of the restriction**
Nonylphenol	246-672-0	25154-52-3	Placing on the market of textile and leather articles containing NP
Benzyl butyl phthalate (BBP)	201-622-7	85-68-7	Placing on the market of articles containing BBP for indoor environments and direct exposure
Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	117-81-7	Placing on the market of articles containing DEHP for indoor environments and direct exposure
Dibutyl phthalate (DBP)	201-557-4	84-74-2	Placing on the market of articles

Table A8-21: Substances restricted after the entry into force of the REACH and CLP Regulations with classification for endocrine activity (and scope of the restriction)			
Name	**EC number**	**CAS number**	**Scope of the restriction**
			containing DBP for indoor environments and direct exposure

A8.3 Output Indicator 4 – SVHCs in Annex XIV by Hazard Class

Table A8-22: SVHCs included in Annex XIV with classification for acute toxicity		
Name	**EC number**	**CAS number**
2,4 – Dinitrotoluene (2,4-DNT)	204-450-0	121-14-2
Ammonium dichromate	232-143-1	7789-09-5
Arsenic acid	231-901-9	7778-39-4
Chromium trioxide	215-607-8	1333-82-0
Diarsenic pentaoxide	215-116-9	1303-28-2
Diarsenic trioxide	215-481-4	1327-53-3
Formaldehyde, oligomeric reaction products with aniline (technical MDA)	500-036-1	25214-70-4
Pentazinc chromate octahydroxide	256-418-0	49663-84-5
Potassium dichromate	231-906-6	7778-50-9
Potassium hydroxyoctaoxodizincatedichromate	234-329-8	11103-86-9
Sodium chromate	231-889-5	2146108
Sodium dichromate	234-190-3	10588-01-9; 7789-12-0

Table A8-23: SVHCs included in Annex XIV with classification for skin corrosion / skin irritation		
Name	**EC number**	**CAS number**
1,2-Dichloroethane (EDC)	203-458-1	107-06-2
Ammonium dichromate	232-143-1	7789-09-5
Chromium trioxide	215-607-8	1333-82-0
Diarsenic trioxide	215-481-4	1327-53-3
Dichromium tris(chromate)	246-356-2	24613-89-6
Pentazinc chromate octahydroxide	256-418-0	49663-84-5
Potassium chromate	232-140-5	7789-00-6
Potassium dichromate	231-906-6	7778-50-9
Potassium hydroxyoctaoxodizincatedichromate	234-329-8	11103-86-9
Sodium chromate	231-889-5	2146-10-8
Sodium dichromate	234-190-3	10588-01-9; 7789-12-0
Trichloroethylene	201-167-4	79-01-6

Table A8-24: SVHCs included in Annex XIV with classification for skin sensitisation		
Name	**EC number**	**CAS number**
4,4'- Diaminodiphenylmethane (MDA)	202-974-4	101-77-9
Acids generated from chromium trioxide and their oligomers. Group containing: Chromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid	231-801-5; 236-881-5	13530-68-2; 7738-94-5
Ammonium dichromate	232-143-1	7789-09-5
Chromium trioxide	215-607-8	1333-82-0
Dichromium tris(chromate)	246-356-2	24613-89-6
Formaldehyde, oligomeric reaction products with aniline (technical MDA)	500-036-1	25214-70-4
Pentazinc chromate octahydroxide	256-418-0	49663-84-5
Potassium chromate	232-140-5	7789-00-6
Potassium dichromate	231-906-6	7778-50-9
Potassium hydroxyoctaoxodizincatedichromate	234-329-8	11103-86-9

Table A8-24: SVHCs included in Annex XIV with classification for skin sensitisation		
Name	**EC number**	**CAS number**
Sodium chromate	231-889-5	2146-10-8
Sodium dichromate	234-190-3	10588-01-9; 7789-12-0

Table A8-25: SVHCs included in Annex XIV with classification for serious eye damage / eye irritation		
Name	**EC number**	**CAS number**
1,2-Dichloroethane (EDC)	203-458-1	107-06-2
Arsenic acid	231-901-9	7778-39-4
Pentazinc chromate octahydroxide	256-418-0	49663-84-5
Potassium chromate	232-140-5	7789-00-6
Potassium hydroxyoctaoxodizincatedichromate	234-329-8	11103-86-9
Trichloroethylene	201-167-4	79-01-6

Table A8-26: SVHCs included in Annex XIV with classification for respiratory sensitisation		
Name	**EC number**	**CAS number**
Ammonium dichromate	232-143-1	7789-09-5
Chromium trioxide	215-607-8	1333-82-0
Potassium dichromate	231-906-6	7778-50-9
Potassium hydroxyoctaoxodizincatedichromate	234-329-8	11103-86-9
Sodium chromate	231-889-5	2146108
Sodium dichromate	234-190-3	10588-01-9; 7789-12-0

Table A8-27: SVHCs included in Annex XIV with classification for mutagenicity		
Name	**EC number**	**CAS number**
2,4 – Dinitrotoluene (2,4-DNT)	204-450-0	121-14-2
4,4'- Diaminodiphenylmethane (MDA)	202-974-4	101-77-9
Ammonium dichromate	232-143-1	7789-09-5
Chromium trioxide	215-607-8	1333-82-0
Formaldehyde, oligomeric reaction products with aniline (technical MDA)	500-036-1	25214-70-4
Pentazinc chromate octahydroxide	256-418-0	49663-84-5
Potassium chromate	232-140-5	7789-00-6
Potassium dichromate	231-906-6	7778-50-9
Potassium hydroxyoctaoxodizincatedichromate	234-329-8	11103-86-9
Sodium chromate	231-889-5	2146-10-8
Sodium dichromate	234-190-3	10588-01-9; 7789-12-0
Trichloroethylene	201-167-4	79-01-6

Table A8-28: SVHCs included in Annex XIV with classification for carcinogenicity		
Name	**EC number**	**CAS number**
1,2-Dichloroethane (EDC)	203-458-1	107-06-2
2,2'-dichloro-4,4'-methylenedianiline (MOCA)	202-918-9	101-14-4
2,4 – Dinitrotoluene (2,4-DNT)	204-450-0	121-14-2
4,4'- Diaminodiphenylmethane (MDA)	202-974-4	101-77-9
5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene)	201-329-4	81-15-2
Acids generated from chromium trioxide and their oligomers. Group containing: Chromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid	231-801-5; 236-881-5	13530-68-2; 7738-94-5
Ammonium dichromate	232-143-1	7789-09-5
Arsenic acid	231-901-9	7778-39-4
Chromium trioxide	215-607-8	1333-82-0
Diarsenic pentaoxide	215-116-9	1303-28-2

Table A8-28: SVHCs included in Annex XIV with classification for carcinogenicity		
Name	**EC number**	**CAS number**
Diarsenic trioxide	215-481-4	1327-53-3
Dichromium tris(chromate)	246-356-2	24613-89-6
Formaldehyde, oligomeric reaction products with aniline (technical MDA)	500-036-1	25214-70-4
Lead chromate	231-846-0	7758-97-6
Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	235-759-9	12656-85-8
Lead sulfochromate yellow (C.I. Pigment Yellow 34)	215-693-7	1344-37-2
Pentazinc chromate octahydroxide	256-418-0	49663-84-5
Potassium chromate	232-140-5	7789-00-6
Potassium dichromate	231-906-6	7778-50-9
Potassium hydroxyoctaoxodizincatedichromate	234-329-8	11103-86-9
Sodium chromate	231-889-5	2146-10-8
Sodium dichromate	234-190-3	10588-01-9; 7789-12-0
Strontium chromate	232-142-6	2151068
Trichloroethylene	201-167-4	79-01-6
Tris(2-chloroethyl)phosphate (TCEP)	204-118-5	115-96-8

Table A8-29: SVHCs included in Annex XIV with classification for reproductive toxicity		
Name	**EC number**	**CAS number**
2,4 – Dinitrotoluene (2,4-DNT)	204-450-0	121-14-2
Ammonium dichromate	232-143-1	7789-09-5
Arsenic acid	231-901-9	7778-39-4
Benzyl butyl phthalate (BBP)	201-622-7	85-68-7
Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	117-81-7
Bis(2-methoxyethyl) ether (Diglyme)	203-924-4	111-96-6
Chromium trioxide	215-607-8	1333-82-0
Dibutyl phthalate (DBP)	201-557-4	84-74-2
Diisobutyl phthalate (DIBP)	201-553-2	84-69-5
Hexabromocyclododecane (HBCDD), alpha-hexabromocyclododecane, beta-hexabromocyclododecane, gamma-hexabromocyclododecane	221-695-9; 247-148-4	134237-50-6; 134237-51-7; 134237-52-8; 25637-99-4; 3194-55-6
Lead chromate	231-846-0	7758-97-6
Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	235-759-9	12656-85-8
Lead sulfochromate yellow (C.I. Pigment Yellow 34)	215-693-7	1344-37-2
Pentazinc chromate octahydroxide	256-418-0	49663-84-5
Potassium dichromate	231-906-6	7778-50-9
Potassium hydroxyoctaoxodizincatedichromate	234-329-8	11103-86-9
Sodium chromate	231-889-5	2146-10-8
Sodium dichromate	234-190-3	10588-01-9; 7789-12-0
Tris(2-chloroethyl)phosphate (TCEP)	204-118-5	115-96-8

Table A8-30: SVHCs included in Annex XIV with classification for specific target organ toxicity		
Name	**EC number**	**CAS number**
4,4'- Diaminodiphenylmethane (MDA)	202-974-4	101-77-9
Ammonium dichromate	232-143-1	7789-09-5
Chromium trioxide	215-607-8	1333-82-0
Formaldehyde, oligomeric reaction products with aniline (technical MDA)	500-036-1	25214-70-4
Potassium dichromate	231-906-6	7778-50-9

Table A8-30: SVHCs included in Annex XIV with classification for specific target organ toxicity		
Name	**EC number**	**CAS number**
Sodium chromate	231-889-5	2146108
Sodium dichromate	234-190-3	10588-01-9; 7789-12-0

Table A8-31: SVHCs included in Annex XIV with classification for hazardous to the aquatic environment		
Name	**EC number**	**CAS number**
2,2'-dichloro-4,4'-methylenedianiline (MOCA)	202-918-9	101-14-4
2,4 – Dinitrotoluene (2,4-DNT)	204-450-0	121-14-2
4,4'- Diaminodiphenylmethane (MDA)	202-974-4	101-77-9
5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene)	201-329-4	81-15-2
Acids generated from chromium trioxide and their oligomers. Group containing: Chromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid	231-801-5; 236-881-5	13530-68-2; 7738-94-5
Ammonium dichromate	232-143-1	7789-09-5
Arsenic acid	231-901-9	7778-39-4
Benzyl butyl phthalate (BBP)	201-622-7	85-68-7
Chromium trioxide	215-607-8	1333-82-0
Diarsenic pentaoxide	215-116-9	1303-28-2
Diarsenic trioxide	215-481-4	1327-53-3
Dibutyl phthalate (DBP)	201-557-4	84-74-2
Dichromium tris(chromate)	246-356-2	24613-89-6
Formaldehyde, oligomeric reaction products with aniline (technical MDA)	500-036-1	25214-70-4
Lead chromate	231-846-0	7758-97-6
Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	235-759-9	12656-85-8
Lead sulfochromate yellow (C.I. Pigment Yellow 34)	215-693-7	1344-37-2
Pentazinc chromate octahydroxide	256-418-0	49663-84-5
Potassium chromate	232-140-5	7789-00-6
Potassium dichromate	231-906-6	7778-50-9
Potassium hydroxyoctaoxodizincatedichromate	234-329-8	11103-86-9
Sodium chromate	231-889-5	2146108
Sodium dichromate	234-190-3	10588-01-9; 7789-12-0
Strontium chromate	232-142-6	2151068
Tris(2-chloroethyl)phosphate (TCEP)	204-118-5	115-96-8

Table A8-32: SVHCs included in Annex XIV with PBT/vPvB profile		
Name	**EC number**	**CAS number**
5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene)	201-329-4	81-15-2
Chromium trioxide	215-607-8	1333-82-0
Diisobutyl phthalate (DIBP)	201-553-2	84-69-5
Hexabromocyclododecane (HBCDD), alpha-hexabromocyclododecane, beta-hexabromocyclododecane, gamma-hexabromocyclododecane	221-695-9; 247-148-4	134237-50-6; 134237-51-7; 134237-52-8; 25637-99-4; 3194-55-6

Table A8-33: SVHCs included in Annex XIV with clear evidence of endocrine activity		
Name	**EC number**	**CAS number**
Benzyl butyl phthalate (BBP)	201-622-7	85-68-7
Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	117-81-7
Dibutyl phthalate (DBP)	201-557-4	84-74-2

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