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GUIDANCE for National Labour Inspectors on the interaction of the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (REACH) (Regulation (EC) No. 1907/2006), the Chemical Agents Directive (CAD) and the Carcinogens and Mutagens Directive (CMD)

Senior Labour Inspector's Committee (SLIC)

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Employment, Social Affairs and Inclusion

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1. Introduction

1.1 Context of this Document

This document is intended as guidance for National Labour Inspectorates (NLI's) and their Inspectors. It is not intended as guidance for manufacturers and users of chemicals. SLIC CHEMEX Working Group work stream 2 (WS2) document (ref: 2009_0239_edited) set out to establish a framework for NLI arrangements for managing REACH enforcement, this document focuses on the practical enforcement by providing guidance for inspectors on the requirements of REACH and the interfaces with the enforcement of requirements under the Chemical Agents Directive (CAD) and the Carcinogens and Mutagens Directive (CMD).

1.2 How to use this Guidance

The first part of this guidance, sections 1.3 to 8 inclusive, sets out the requirements of REACH and highlights areas where both duties under REACH and duties under CAD/CMD coexist.

The second part, sections 9 to 12, puts the guidance into context and provides NLIs and their inspectors with tools they can use to assist in assessing compliance with REACH and in making enforcement decisions over priorities between REACH and CAD/CMD. It includes suggestions of questions that can be used and adapted by Inspectors to assess compliance with REACH as well as worked case studies to support the enforcement decision making process. It is not exhaustive and is not intended to give a definitive guide to the enforcement action to take. Included is a glossary of terms used in this guidance but for consistency the terms substance, mixture and hazardous have been used and have the same meaning as the Classification, Labeling and Packaging Regulation (EC) No 1272/2008 (CLP).

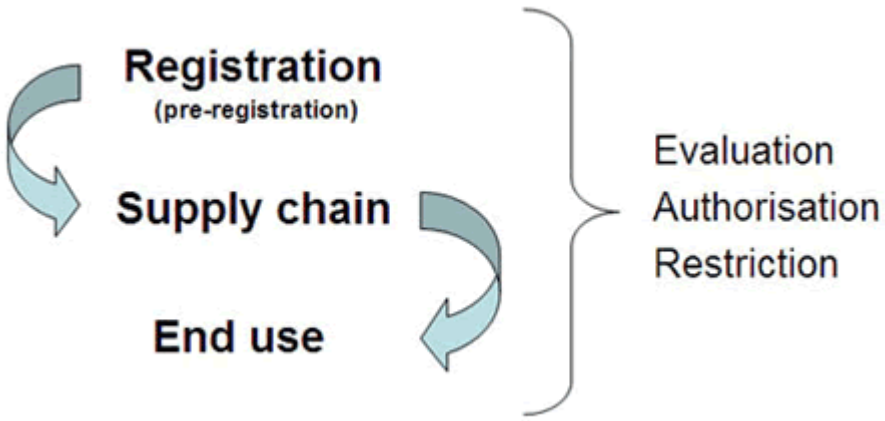
Each member state may have arrangements that differ in relation to the inspection of occupational health and safety and the market surveillance regulation of REACH duties and NLIs should provide the information to the relevant agency with responsibility within their state. For example the market surveillance aspects refering to the monitoring of compliance with authorisation and quality and accuracy of the supply information requirements may be carried out by organisations other than the NLI within individual member states. The NLI being only responsible for the practicle application of measures to protect people in the workplace.

1.3 Overview of REACH

REACH applies to most businesses, however, the extent of the duties it imposes will vary significantly, depending on the dutyholder's activities. REACH places duties on **actors in the supply chain**, such as **manufacturers**, **importers**, **suppliers** and **downstream users** of chemicals.

REACH requires any **manufacturer** or **importer** of a substance in quantities of one or more tonnes per year to **register** that substance with the European Chemicals Agency (ECHA). Registration involves submitting a dossier of information to ECHA on the substance's properties, uses and risk management measures. REACH also puts duties on **suppliers** and **users** of chemicals, primarily to ensure that the information gained through registration is passed down the supply chain, and effectively applied to control risks. REACH also places duties on downstream users to inform their supplier about new information on hazards and if the risk control measures are not appropriate.

A good way of illustrating how these duties apply is to put them in the context of a simple chemical supply chain:



- Those at the top of the chemical supply chain will be subject to registration related duties – these will be either **manufacturers** of substances or mixtures in the EU, **importers** of substances or mixtures into the EU, or the **only representatives** of non-EU manufacturers.
- Those in the middle of the supply chain must pass on safety, health and environmental information, typically via the safety data sheet. Such dutyholders include **distributors** and **retailers** but may include any **supplier** of substances, mixtures or articles.
- Those using substances or mixtures in an industrial or professional capacity are expected to apply the risk management information provided to them to control risks to human health and the environment. Businesses using substances or mixtures are referred to as **downstream users** under REACH.

These actors in the supply chain can be either **natural or legal persons** (limited companies, partnerships, sole traders, the self-employed etc) but must be **established in the Community**.

Downstream Users of Chemicals

There are many different types of business that fall under the REACH definition of a downstream user, for example:

- **formulator**: someone who mixes substances together to produce a product, but which does not involve the (intentional) creation of a new substance, e.g. a paint manufacturer;
- **industrial user**: someone who uses a substance or mixture in the course of their industrial activities which does not remain in their product, for example as a processing aid such as a degreaser or a metalworking fluid;
- **end user**: a person using substances or mixtures in an industrial or professional activity (e.g. not a consumer or a distributor) who does not supply it further downstream, so that it is either incorporated into an article (see article producer) or is consumed in the activity (see professional user);
- **article producer**: an end-user incorporating substances / mixtures into articles which become an integral part of such articles, e.g. inclusion into the article such as dying of textile fibres, or application onto the article's surface such as powder coating;
- **professional users**: users who apply substances in a professional capacity not regarded as an industrial use. This could involve craftsmen and service providers such as flooring contractors, mobile cleaning companies, professional painters, construction companies and so on;
- **re-fillers**: a person who transfers substances or mixtures from one container to another, e.g. aerosol producers;
- **re-importer**: a person who imports a substance into the EU that was originally manufactured in the EU and has already been registered by someone else (in such cases that person is then exempt from re-registering it themselves and instead becomes a downstream user);
- **importers covered by an only representative**: An importer covered by an only representative is regarded as a downstream user in the context of that particular supply chain. i.e. the importer is only classed as a downstream user in relation to the tonnage imported from the non-EU manufacturer that appointed the only representative. If the importer also imports the substance from different non-EU suppliers, he still has to register the tonnage imported from each of these sources, unless they have also appointed different only representatives.

A downstream user under REACH may therefore be quite different from who we may regard as a user under CAD/CMD. Or perhaps more pertinently, some of those listed above might be traditionally regarded as suppliers rather than users under CAD/CMD, e.g. formulators, re-fillers, re-importers etc.

A REACH downstream user's main duty is to ensure they use chemicals safely. While this is of course what they should already be doing under other occupational health and safety legislation, there are key differences. Under REACH:

- there are duties on downstream users to communicate information back up the supply chain in certain circumstances;
- there are also duties when using chemicals outside the conditions of the registration, or otherwise against the advice of their supplier; and
- duties on end use apply to the potential environmental releases and impact during use.

As well as the three general areas described above, REACH also imposes other types of duties on the chemical industry. Registered substances can be subject to **evaluation**, of the quality of the information submitted in the registration dossiers or testing proposals or to clarify whether a specific substance poses a risk to human health or the environment. REACH also **restricts** the use of certain very hazardous substances, and for other substances of very high concern, use-specific **authorisation** may be required.

1.4 REACH and CAD/CMD

REACH and CAD/CMD all impose requirements on the use of hazardous chemicals in the workplace, and employers will now find themselves faced with two sets of duties. Although REACH and CAD/CMD should ultimately complement one another, their requirements overlap to some extent and this has the potential to give rise to inconsistencies in their application.

Article 2(4) of REACH states that it applies 'without prejudice' to existing Community workplace and environmental protection legislation, and so employers will have to meet the requirements of both REACH and CAD/CMD. Compliance with one regime cannot justify failure to comply with the other.

While REACH and CAD/CMD share the same philosophy with respect to worker protection and have as their objectives the better protection of human health, there are a number of differences in how they set about achieving those ends:

- REACH is a very broad ranging Regulation, and its requirements encompass occupational health and safety, environmental protection and consumer protection; CAD/CMD are focused solely on the first of these.
- CAD/CMD require all employers to assess the risks to employees' health created by working with hazardous substances, and to identify the necessary controls. Whereas REACH places the onus of risk assessment and the identification of the necessary controls much higher up the supply chain (on the manufacturer or importer). Because of this, CAD/CMD risk assessments are more likely to be workplace-specific, while the risk management measures identified by REACH are likely to be broader.
- CAD/CMD cover all work activities involving hazardous substances and mixtures at a workplace, including processes that generate substances and mixtures that are hazardous to health e.g. welding fumes, wood dusts, diesel engine exhaust fume etc. REACH does not cover these type of process generated substances and mixtures and therefore no Chemical Safety Report (CSR) or Chemical Safety Assessment (CSA) (and resulting exposure scenarios) will be required.
- REACH is substance-driven, and the REACH risk assessments will relate to the use of that substance throughout the supply chain. It is unlikely that the REACH risk assessments will take into account the other substances or mixtures in use on any one particular site or the interactions or combined health effects of different substances in certain processes. CAD/CMD tend to be more process-driven (or

workplace specific), i.e. the employer looks at the process being carried out, including the existing controls, and also at all the substances used in the process.

Article 2 of REACH exempts a number of substances or mixtures entirely, for example, waste, or substances covered by legislation on the transport of hazardous substances or mixtures. Other substances or mixtures have partial exemptions from REACH, for example, the requirements imposed on downstream users by Title V do not apply to the extent that a substance or mixture is used in medicinal products or food. Annexes IV and V of REACH also contain a range of substances to which Title V requirements do not apply. However, these substances or mixtures will still be covered by CAD / CMD and will require consideration of the required control arrangements to protect occupational health and safety.

2. Risk assessments and 'exposure scenarios' under REACH

Every **registration** of a substance under REACH requires the submission of a technical dossier to the ECHA. For substances imported or manufactured in quantities of 10 tonnes or more per year, the registration must also be accompanied by a chemical safety report (CSR). The CSR is the documentation concerning the registrant's chemical safety assessment (CSA), essentially a risk assessment, for that substance. The CSA contains a detailed summary of information on the properties of the substance that is hazardous to human health and the environment. For substances classified as "hazardous" according to CLP, an assessment of exposure and risk is also required; This is called an Exposure Scenario (ES) and includes the operational conditions and risk management measures required to control health and safety risks from the use of the substance or mixture.

REACH also introduced a new type of exposure control benchmark to protect human health known as the derived no-effect level (DNEL). The DNEL must be established by the registrant as part of their chemical safety assessment (CSA). DNELs must reflect the likely routes, duration and frequency of exposure, and, if more than one route of exposure is likely to occur (oral, dermal or inhalation) then a DNEL must be established for each route of exposure. It may also be necessary to identify different DNELs for each relevant human population (e.g. workers, consumers, and humans liable to exposure indirectly via the environment) and possibly for certain vulnerable sub-populations (e.g. children, pregnant women).

A REACH 'exposure scenario' (ES) specifies the conditions of use (the operational conditions and risk management measures) necessary to ensure health and safety risks are adequately controlled. The exposure scenario is communicated to downstream users by being annexed to an extended safety data sheet (SDS) provided when the substance is supplied. The risk management measures should be designed to ensure that the relevant DNEL(s) can be complied with. Registrants are required to provide ESs for all relevant identified uses. An 'identified use' of a substance or mixture is a use that is intended by an actor in the supply chain, or a use that is made known to a supplier by a downstream user.

Given the phased introduction of the registration-related requirements in REACH, the introduction of ES will not be complete until 2018. Even after that, they will only be required for substances or mixtures subject to registration and manufactured or imported in quantities of 10 tonnes or more per year per registrant and classified as hazardous. Nevertheless, when they are available, the ES should provide a downstream user with improved information about hazards, uses and risk management measures on which a risk assessment under CAD / CMD can be based.

When information generated by REACH is received by downstream users via an extended SDS, it is important that this triggers a review of existing risk assessments and controls. The downstream user should also check that their intended use of the substance is covered by ES and the risk management measures are identified.

3. Substances and Mixtures subject to REACH

REACH requires the registration number of registered substances to be stated in Section 1 of the safety data sheet. This indicates that the substance has been registered. The registration number does not mean that the requirements under CMD / CAD in relation to controlling exposures have been complied with, but the ES requirements in the extended SDS for the substance or mixture do apply starting from the time of registration.

The components of a mixture that have been classified as 'hazardous' (according to CLP) must be listed under Section 3 of the safety data sheet, as well as their registration numbers, if available. No additional REACH obligations for users of mixtures arise from this.

3.1 Authorisation

In order to place on the market or use substances with properties classified as "substances of very high concern" (SVHCs), included on Annex XIV of REACH, dutyholders must apply for an authorisation. However, it does not automatically follow that all substances with such properties will finally be included in Annex XIV and subject to authorisation requirements. An initial list – called the 'candidate list' – is first published by ECHA. This contains substances that are considered for authorisation for certain use or uses, and these are proposed by ECHA, the Commission, or Member States CAs. These substances are then further prioritised with some then transferred to Annex XIV of REACH. This process is repeated so that, over time, the list of substances on both the candidate list and Annex XIV will grow.

These substances or mixtures require authorisation because they are;

- Prioritised from the candidates list for authorisation
- carcinogenic, mutagenic or toxic to reproduction (CMR) category 1A and 1B;

- identified from scientific evidence as being of equivalent concern to those above to humans or the environment on a case-by-case basis, such as endocrine disruptors; or

- persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), based on the criteria in Annex XIII of REACH.

Article 56 of REACH states that a manufacturer, importer or downstream user shall not place a substance listed on Annex XIV on the market for a use, or use it themselves, unless that use has been authorised. The exceptions are detailed in REACH ((EC) No 1907/2006 Article 56).

If a downstream user intends to use a substance which requires authorisation, and an authorisation for the proposed use has already been obtained by an actor further up the supply chain, the downstream user does not have to obtain a separate authorisation. In such circumstances the downstream user must instead notify ECHA of their use (Article 66(1)), and ensure the use of the substance is in accordance with any conditions of authorisation (Article 56(2)).

3.2 Restriction

Article 67(1) of REACH prohibits the use of a substance (on its own, in a mixture or in an article) outside the conditions of a restriction given in Annex XVII. The scope of a restriction can vary from either an outright (or near outright) ban, to setting conditions on certain activities like requiring special occupational safety and health (OSH)/risk reduction measures e. g. closed systems, processes or applications. Restrictions can also be applied to substances within articles. Also see section 9.6

3.3 How is the substance or mixture being used

Use outside the exposure scenario

A proposed use of a substance may be outside the conditions described in an exposure scenario, or otherwise against the advice of the supplier (as communicated on the SDS or otherwise). This may be the case with novel or unusual uses of substances, as these may fall outside the typical uses identified by the exposure scenario. See section 5.3 below for down stream user options in this situation.

Exposure scenarios will not be required for all substances, e.g. substances that are not subject to registration, or substances that are registered but which are manufactured or imported in quantities of less than 10 tonnes per year, or are not classified as ‘hazardous’.

4. Safety Data Sheets

Safety data sheets (SDSs) provide useful information on substances and mixtures, describing the hazards that the substance or mixture presents, and giving information on risk reduction

measures especially recommendations on handling, storage and, emergency measures in case of an accident. In accordance with the REACH Regulation, a safety data sheet (SDS) should be provided with any hazardous substance or mixture. Over the coming years, SDSs will include further information on safe handling, in the form of the exposure scenarios. REACH requires users of hazardous substances or mixtures to follow the advice on risk management measures given in the exposure scenario or to choose one of the other options in 5.3 below.

4.1 Safety Data Sheets must be provided for:

- Substances or mixtures classified as hazardous;
- Substances which are persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) to the environment;
- Substances which appear on ECHA's Candidate List of substances of very high concern (SVHC) for a reason other than either of the 2 points above;
- Mixtures (upon request of the downstream user/distributor) which are not classified as hazardous but which contain at least one substance that is:
    - classified as hazardous to health or the environment at concentrations ≥ 1%w/w (non gaseous mixtures) and ≥0,2%v/w (gaseous mixtures)
    - a PBT or vPvB at a concentration ≥0.1% w/w
    - on the Candidate List of SVHCs at a concentration ≥0.1% w/w for a reason other than either of the 2 points above
    - assigned an EU limit value for exposure at the workplace (OELV).

A Safety Data Sheet must be:

- in an official language(s) of the Member State where the substance or mixture is being placed on the market;
- provided free of charge on paper or electronically;
- provided no later than at the time of first delivery;
- updated when new information on hazards or risk management measures of the substance or mixture becomes available or when an authorisation is granted or refused or a restriction is imposed under REACH Regulation;
- provided upon update or revision to everyone who has received the substance or mixture during the previous 12 months;
- prepared by a competent person;
- in the required 16 heading format and shall not contain blank subsections;
- specific to the substance or mixture;
- clear and understandable;

- dated and the pages numbered.

4.2 What information should be taken account of in a Safety Data Sheet?

There is an obligation under REACH on users of substance or mixture to take measures to protect both humans and the environment from any hazards associated with the substance or mixture. Therefore, it is important that the information provided in the safety data sheet is taken into account and used to prepare a chemical risk assessment for the workplace. Under CAD/CMD the obligation is to protect humans therefore information on substances and mixtures in the workplace must be provided to all employees and the SDS is a useful tool in communicating the hazards of these substances and mixture and the measures of protection to be taken when using them.

Each section of the SDS contains specific information relating to the substance or mixture for which the SDS is prepared. (Sections 1,2,4,7,8, 13 and ES Annex most important for OSH regulation)

- **Section 1** contains the substance identity and the Registration number, identified uses and uses advised against, contact details of the person/company responsible for supplying the chemical, as well as the telephone number to contact in case of an emergency

- **Section 2** gives details on the classification and labelling of the substance or mixture and the potential effects and symptoms resulting from use. This will help to assess the risk to health and safety, the health of workers and the environment. The information in this section must be consistent with the information on the label.

- **Section 3** gives information on the hazards of each of the individual substances in a mixture

- **Section 4** describes the necessary first aid measures to be taken in case of an accident

- **Section 5** gives specific information on fighting a fire caused by the substance or mixture, including the most suitable extinguishing media and protective equipment

- **Section 6** describes what actions need to be taken if there is an accidental release of the substance or mixture
- **Section 7** contains details on how to handle and store the substance or mixture safely. The process parameters and risk management measures form the ES shall be consolidated into sections 7 and 8.
- **Section 8** gives details of the steps needed to reduce exposure, e.g. ventilation and the personal protective equipment (PPE) necessary to protect health.
- **Sections 9, 11 and 12** provide detailed information on the physical/chemical, toxicological and ecological properties of the chemical

- **Section 10** contains details of any hazardous reactions that may occur if the chemical is used under certain conditions.
- **Section 13** explains how the chemical should be disposed of correctly
- **Section 14** contains information relating to the transportation of the chemical
- **Section 15** contains details on relevant EU/national legislation
- **Section 16** gives any other information relevant to the chemical e.g. training advice, full text of hazard statements etc.

In addition, SDSs for substances or voluntarily for mixtures containing substances that have been registered under REACH require inclusion of exposure Scenarios including any risk management measures required, in an Annex to the SDS for hazardous substances registered at >10 tonnes/year.

4.3 What should an inspector check when looking at a Safety Data Sheet?

- Inspectors should check that information from SDS has been evaluated for carrying out a work place risk assessment.
- Ensure that employees are informed of any risk management measures relevant to their use of the substance or mixture.
- Check that the SDS are accessible to all who use or are exposed to the chemical.
- Ensure that the SDS is in compliance with Annex II (as updated by Reg. (EU) No. 453/2010) of the REACH Regulation and ensure that the details on the label of the substance or mixture are as given in section 2 of the SDS.
- Ensure that the SDS is specific to the substance or mixture being supplied and not generic – though one SDS for a group of chemicals (e.g. paints with different colours) is possible where the hazards are the same.
- Check that the SDS is dated and any revision date and details of revisions are provided in section 16 or elsewhere
- Inspectors who check SDS for mixtures should also check whether eSDS for components have been evaluated and taken into account for compiling the SDS for the mixture .
- The SDS should also be checked against Annex IV of CLP

4.4 What do the different symbols mean?

Classification and labelling details for substances or mixtures are provided in section 2 of SDSs. Since 1st Dec 2012, all substances must be classified and labelled according to the EU CLP Regulation (EC) No. 1272/2008, and therefore, new pictograms, signal words, hazard statements and precautionary statements must appear in section 2. Until 1st June 2015, the classification according to Directive 67/548/EEC must also be given in section 2.

Mixtures remain classified and labelled according to the EU Dangerous Preparations Directive (1999/45/EC) until 1st June 2015 (unless CLP is applied voluntarily early) and thereafter according to CLP.

Since the 1st Dec 2012 all SDSs must be in accordance with Annex I of Regulation (EU) No. 453/2010. From 1st June 2015, all SDSs must be prepared in accordance with Annex II of Reg. No. 453/2010 with a derogation to 1st June 2017 for mixtures already placed on the market in the Annex I format on 1st June 2015.

Existing Indication of Danger & corresponding symbols (CPL)	**New** Signal words & corresponding pictograms (CLP) From Regulation EC 1272/2008
 ***Explosive E***	 ***Danger or Warning***
 ***Extremely or Highly Flammable***	 ***Danger or Warning***
 ***Oxidising***	 ***Danger or Warning***
 ***Corrosive***	 ***Danger or Warning***
 ***Very Toxic or Toxic***	 ***Danger***

 ***Harmful or Irritant***	 ***Warning***
  ***Harmful or Toxic***	 ***Danger***
 ***Dangerous to the Environment***	 ***Warning***

5. Exposure scenario

5.1 What does the SDS cover

An exposure scenario is the series of conditions (both operational conditions and risk control measures) describing how the substance is manufactured or used during its life cycle, and how the manufacturer or importer manages the exposure of people and the environment or recommends that downstream users manage this.
The exposure scenario also contains an estimate of the levels of exposure of both people (employees and consumers if relevant) and the environment, and users can get guidance on this in the Guidelines for downstream users http://echa.europa.eu/.

An exposure scenario is not a compulsory requirement for mixtures.

The SDS and the exposure scenario together provide information that is useful for carrying out a risk assessment for the workplace, particularly for:

- identifying the risks;
- determining the risk control measures;
- checking the effectiveness of the risk control measures.

Section 8 and the exposure scenario that is supplied as an appendix to the SDS provide more information, e.g. about the expected effectiveness of protective measures. This information must be taken into account in drawing up or revising risk control measures in the risk assessment (RA), including action plan.

In Section 7 "Use and storage" and Section 8 "Measures for the control of exposure / personal protection", the SDS describes risk control measures. Threshold values and DNELs (derived no-effect level or the dose derived by the manufacturer at which no damage to health occurs) can be found under Section 8.1 . Users should apply these to their operational conditions and review their existing risk management measures against the identified uses in the SDS. Information can be found in “How downstream users can handle exposure scenarios” – practical Guide 13,
http://echa.europa.eu/documents/10162/13655/du_practical_guide_13_en.pdf
The user should check on the basis of the information from Section 1.2 of the SDS, "Use of the substance/mixture", and the information in the exposure scenario, whether his own use is covered by the exposure scenario and whether he can make use of the risk control measures from the SDS or the exposure scenario for his own workplace risk assessment.

Even when his own use is not explicitly mentioned in the exposure scenario, it may still be covered by it. The user should check in any case whether his use conditions are identical or comparable with the use conditions referred to in an exposure scenario. In the case of doubt, users should contact the registrant and then if necessary further research should be done along the lines of the ECHA ‘Guideline for downstream users’.
http://echa.europa.eu/documents/10162/13643/du_en.pdf

The use conditions in the exposure scenario are described by a number of variables that determine the exposure (e.g. quantity of a substance used, concentration, temperature, frequency). The variables used to determine exposure vary according the model used fro exposure assessment. The risk control measures are also included. In the simplest situation all the use conditions, in the described exposure scenario are equal to those of the user’s own use.

If some of the user’s circumstances differ from those in the exposure scenario the use can possibly still remain within the conditions of the exposure scenario. Sometimes different variables can be compensated by other variables. The possibility of changing the individual parameters is called "scaling" which will be partly included in the ES and is described in the ECHA guideline for downstream users.

5.2 Risk management measures

If any REACH risk management measures are found to be inappropriate by users, the reasons should be recorded in their workplace risk assessment and users should have informed their supplier. Inspectors should check this has been done with the user and supplier.

5.3 Compliance when use is not covered

If the use is not covered by the exposure scenario there are a number of options:

- Bring the use into conformity with the exposure scenario, e.g. by applying the control measures referred to there; in doing so the downstream user must review the risk assessment required by CAD/CMD and ensure that adequate control of exposure is maintained during use
- The downstream user can provide the supplier with the relevant information needed to prepare the ES and ask the supplier to make their use an 'identified use' and to draw up an exposure scenario for it. In the interim the downstream should select measures on the basis of their own CAD/CMD risk assessment. Art. 39 foresees a timeframe of 6 or 12 months for fulfilling their duties according to Art. 37 und 38. In the meantime they may continue their activities. The supplier has to identifiy the use within 1 month (Art. 37(3)) ;

- Choose another supplier who has included the users use in his exposure scenarios;
- Draw up their own chemical safety assessment (Article 37 paragraph 4 of REACH states when DU-CSR is required or whether exemptions apply) and use it to determine the control measures. When a chemical safety assessment is not required under REACH, they are nevertheless obliged under the Health and Safety legislation (CAD/CMD) to adopt control measures based on their own RA;
- Stop using the substance or the mixture.

It is possible that there is no exposure scenario for a substance or mixture, e.g. because it was not yet registered, because a CSA was not necessary or because this is nog obligatory for mixtures. In those cases, the user of the substance or mixture should take measures based on their own risk assessment. It is important to incorporate the information from the SDS in the risk assessment, and to take the information in sections 7 and 8 into account when selecting RMMs.

5.4 Action by Inspectors if use not covered by downstream user

Management of deadlines for ES compliance are 12 months to implement per substance/per supplier upon receipt of the extended SDS incl. registration number and ES. Use should always be safe based on control measures identified by the users risk assessment.

6. Risk assessment

CAD and CMD require employers to make a suitable and sufficient assessment of the risks to employees' safety and health created by work with hazardous substances. Preventing exposure to substances hazardous to health is a fundamental requirement of CAD /CMD. When substitution is being considered, one of the factors that need to be taken into account is

the harmful properties of the proposed replacement. In the context of REACH, this should also include considering any risks to the environment created by the proposed replacement.

As part of the risk assessment, CAD/CMD requires dutyholders to consider information on health effects provided by their supplier, including information contained in any relevant SDS. Article 37(5) of REACH builds on this duty, stating that downstream users must identify and apply appropriate measures to adequately control risks identified in any of the following:

- the SDS they are supplied with (or for substances that do not require an SDS, any other information on risk management measures supplied with the substance); or
- their own chemical safety assessment, if they are required to prepare one.

This duty extends only insofar as the risk management measures are 'appropriate', which implies a level of assessment. If the downstream user decides that certain risk management measures are inappropriate, they will need to be able to demonstrate and justify their reasoning, with reference to their risk assessment. Downstream users should document any decision not to apply REACH risk management measures detailed in the SDS in their risk assessment, along with the reasons for it. Downstream users are also required by Article 34 of REACH to report any information to their supplier on the SDS that might call into question the appropriateness of the risk management measures.

7. Control measures (REACH Vs CAD/CMD)

Downstream users should not only apply REACH risk management measures, but should also ensure that the measures are effective. In applying / implementing the measures identified by the dutyholders own risk assessment, downstream users will need to show they have taken account of the following:

- Article 60(10) of REACH which requires the holder of an authorisation to ensure that, notwithstanding any conditions of authorisation, exposure is "reduced to as low a level as is technically and practically possible".
- Any relevant workplace exposure limits (OELVs) set in relation to CAD /CMD will still need to be observed. In practice, application of the full suite of REACH risk management measures in an exposure scenario may result in achievement of an OELV. As the process for deriving DNELs may be more conservative than for some national OELVs, the DNEL may impose the more stringent level of protection. However, exposure scenarios may not always be provided for mixtures, and, downstream users may not necessarily have implemented all REACH risk management measures.
- There are additional requirements in CAD/CMD relating to the use of carcinogenic or mutagenic substance. In such cases, exposure must be reduced to a level as low as possible, even when this is stricter than the exposure scenario, However carcinogens

and mutagens may also be subject to authorisation under REACH, in which case the conditions of authorisation may be even more stringent.

- There are also additional requirements in CAD/CMD relating to the use of asthmagens, in which case exposure must be reduced to the lowest level possible.

7.1 Substitution

The registration under REACH does not contain an analysis of the possibilities of substitution. This means that the employer/downstream user himself must analyse and pursue the possibilities of substitution by a non-harmful or less harmful substance within the meaning of the CAD/CMD. When it is possible to replace a hazardous substance, the employer is obliged to do so under CAD/CMD with the goal to reduce the overall risk.

7.2 Different Control measures

Just because the downstream user has achieved adequate control under CAD/CMD, it does not mean that the REACH requirements can be ignored. However, the downstream user might be able to demonstrate that their existing control measures achieve an equivalent level of protection, and that the REACH controls are not appropriate for them. Downstream users will need to justify any such position with reference to their risk assessment.

Downstream users may need to be reminded that there may still be circumstances in which they must nevertheless prepare a CSR (for uses outside the conditions described in an exposure scenario, or uses that are against the advice of the supplier).

7.3 Engineering controls

CAD/CMD has the overriding duty for employers to prevent exposure or where this is not possible to adequately control any exposure. This requires that employers first look to see if they can avoid using the hazardous substance by substituting for less hazardous substances.

Where substitution is not possible then adequate control has to be achieved using engineering measures and this will require users to consider the hierarchy of engineering controls starting with full enclosure down to providing adequate ventilation measures. The assessment of where in the hierarchy the acceptable level of control will be achieved will depend on the ES in the SDS, and their own risk assessment.

7.4 PPE where appropriate

As part of the CSA, if risk management measures (RMM) are required to control risk these need to be specifically identified and communicated to downstream users in the SDS and ES.

SDS contain information only about the suitability of the PPE for a substance- and mixture-specific risks, as required in Section 8, e.g. of the type of material of which the PPE is made and the maximum period of use. Information about the cleaning, maintenance and storage of

the PPE comes from the PPE supplier and from the requirements of CAD/ CMD that require control measures including PPE to be maintained. Employers must also take into account the specific circumstances of use in their own business (such as the suitability with mixtures specific to the business) and the personal preferences and suitability of employees. It should be emphasised that PPE is the last resort in the hierarchy of control under CAD/CMD and where the SDS indicates the level of protection as PPE the employer should still assess whether control measures further up the hierarchy can be used.

8. OELVs vs. DNELs

In general, the exposure scenario is prepared ensuring that the estimated human exposure is lower than the relevant DNEL. Employers who have received an ES must first check whether or not this differs from the OELV. Secondly, the effectiveness of the risk control measures also depends on the plant conditions and on the technical condition (such as of an extraction system). The exposure must be determined, where necessary (by means of measurements or a suitable quantitative estimate), in order to establish the effectiveness of the risk control measures. In any case, the national occupational exposure limit value may not be exceeded.

Measures proposed in the ES will be sufficient to comply with the DNEL. Conditions described in the ES suppose that the (technical) measures are efficient. At plant level this must be controlled/assured.

According to REACH the risk control measures from the eSDS must guarantee that the DNEL has not been exceeded. This does not, however, relieve the employer of the obligation to check the effectiveness of the risk control measures in the manner required under CAD/CMD. The effectiveness of the ventilation, for example, depends on the specific industrial conditions.

9. REACH Compliance issues

See appendix 1 Flowchart for comparison of REACH and CAD/CMD duties

9.1 Examples of compliance issues typically found in relation to registration include:

- manufacture / import of substances at or above 1 tonne per year without a valid registration or pre-registration, e.g. because the dutyholder had not heard about REACH previously or had not taken action in time;
- pre-registrations that are not valid, e.g. mistakes were made during the pre-registration process (such as incorrect spelling of the substance name), or due to a pre-registered substance not being eligible for pre-registration;
- manufacture / import of substances which were pre-registered but which have not been registered by the relevant registration deadline;
- registrations submitted but which contain incorrect or insufficient data;

- importers who are supposedly covered by an only representative (OR) but do not have the necessary proof of this;
- 'reduced' registrations submitted for intermediates but where the substance does not qualify, e.g. because the substance does not meet the definition of intermediate or because it is not being handled and used under strictly controlled conditions;
- registrations submitted but not kept up-to-date, e.g. with new information on hazards, or following an increase in the amount manufactured or imported.

9.2 Information in the supply chain related duties

Information provision both down and back up supply chains is again critical to the successful operation of REACH. Inspection of safety data sheets has been carried out for many years, so this is not a new task for NLIs. What is new are the requirements concerning exposure scenarios that have to be annexed to safety data sheets, information requirements when a safety data sheet is not needed, information about substances of very high concern in articles, and requirements to pass information back up the supply chain in certain circumstances.
Examples of compliance issues typically found in relation to SDSs include:

- risk management measures that do not go into sufficient detail (especially in section 7 or 8 of the SDS);
- suppliers passing off another person's SDS as their own;
- failing to provide SDSs routinely to all customers, i.e. only providing them on request or only making them available on a website etc;
- incorrect hazard classifications, either of the substance / mixture overall, or of constituent substances in a mixture. Note that many substances have EU-wide harmonised classifications in AnnexVI to CLP regulation which you can check by visiting C&L Inventory on ECHA's website
- providing SDSs prepared for a different country, which often leads to incorrect regulatory and other information such as occupational exposure limits, emergency contact details etc;
- missing or incomplete sections;
- format errors, e.g. sections not ordered correctly, omission of revision numbers or dates etc; and
- for mixtures, failing to identify constituent substances correctly, e.g. not providing the proper chemical name or its EC / CAS number etc.

9.3 Use related duties

REACH places the main responsibilities on manufacturers and importers, for instance to gather and assess data and, through safety data sheets and exposure scenarios, inform downstream users about uses. However, unlike earlier legislation on chemicals control, REACH requires downstream users to either stick to these risk management measures, or to themselves take over the responsibility. This is primarily to ensure that the information gained through registration and evaluation, and passed down the supply chain, is effectively used to control risks, i.e. that the system created by REACH is more than a mere paper exercise.

9.4 Evaluation related duties

Registration dossiers can be subject to evaluation under REACH. 'Evaluation' refers to various different processes by which the accuracy and quality of registration information can be verified. These processes are largely the concern of ECHA and the Member States Competent Authorities (CAs), so no further details are provided here. However, there are some enforceable duties arising from the evaluation processes, the requirement to:

- submit of further information to ECHA by registrants or downstream users following examination of testing proposals during dossier evaluation (**Article 40(4)**);
- provide adequate or missing information to ECHA upon request following a compliance check of a registration dossier (**Article 41(4)**);
- provide further information to ECHA in support of substance evaluation being undertaken by Member States CAs (**Article 46(2)**);
- information to Member States CAs requested by them in relation to risks identified for on-site isolated intermediates (**Article 49(a)**); and
- further information to ECHA in relation to a substance no longer manufactured or imported by a registrant but for which there remain serious concerns relating to the protection of human health or the environment (Article 50(4)).

9.5 Authorisation related duties

See section 3.1 for detail of Authorisation

The enforceable duties relating to authorisation are as follows:

- Manufacturers, importers or downstream users must obtain an authorisation prior to placing on the market or using a substance listed in Annex XIV, unless an exemption from authorisation applies (**Article 56(1)**). There will not be any sort of 'blanket' authorisation for a substance to be used generally. Instead, companies that market or use the substance will have to apply for authorisation for specific uses. For the authorisation to remain valid, dutyholders will need to comply with any conditions of authorisation.
- A downstream user will not need an authorisation where a dutyholder further up his supply chain has already obtained one that covers his use, provided that the use of the substance is in accordance with any conditions of that authorisation (**Article 56(2)**) and he has notified ECHA of his use (**Article 66(1)**).
- Any holder of an authorisation must ensure that, notwithstanding any conditions of authorisation, exposure is reduced to as low a level as is technically and practically possible (**Article 60(10)**).
- Holders of an authorisation, as well as any downstream users including the substance in a mixture, must include the authorisation number on the product label before placing the substance (or mixture containing the substance) on the market for an authorised use (**Article 65**).

9.6 Restriction

Article 67(1) of REACH prohibits the use of a substance (on its own, in a mixture or in an article) outside the conditions of a restriction given in **Annex XVII**. The scope of a restriction

can vary from either an outright (or near outright) ban, to setting conditions on certain activities, processes or applications. Restrictions can be applied to any substance, including those that do not require registration.

Annex XVII is updated from time to time to include new or amended restrictions, and so Inspectors should refer to the latest version of Annex XVII for full details of current restrictions. Some examples of restricted substances include:

- asbestos;
- benzene;
- lead carbonates and lead sulphates in paint;
- mercury and arsenic compounds used in certain products or applications;
- substances that are carcinogenic, mutagenic or toxic to reproduction (category 1 or 2) in substances or mixtures supplied to the general public;
- creosote intended for the treatment of wood (and wood treated with creosote);
- chromium VI compounds in cement;
- polyaromatic hydrocarbons (PAHs) in extender oils used for the production of tyres (and tyres containing extender oils with such substances present).

9.7 Other REACH related duties

The following are REACH requirements of general application to all dutyholders.

- **Access to information**: **Article 35** states that workers and their representatives shall be granted access by their employer to the information provided in accordance with Articles 31 and 32 (i.e. safety data sheets and any other information provided by the supplier) in relation to substances or mixtures that they use or may be exposed to in the course of their work.
- **Keeping information**: Under **Article 36**, each manufacturer, importer, downstream user and distributor must assemble and keep available all the information he requires to carry out his duties under REACH for a period of at least 10 years after he last manufactured, imported, supplied or used the substance or mixture.

10. Identifying REACH Compliance issues

10.1 Identifying and addressing REACH compliance issues

The following are questions that National Labour Inspectors can ask in order to identify whether there are likely to be REACH compliance issues:

- *Do you know what chemicals come into and go out of your business?*

  Particularly for companies that are new to REACH, it is important to build an inventory of every chemical that comes into, is part of, or goes out of the business - what feedstocks, intermediates or products are used or created? Once this inventory has been established, the dutyholder can identify where in the supply chain they sit for each, and therefore what aspects of REACH they need to observe. They can also use this information to identify the substances they particularly rely on, and consider the impact on their business should REACH influence the supply (or for registrants, the production or import) of a substance. It will also enable the business to consider contingencies, for example alternative supply routes, chemicals or processes.

- *What communication have you had with your suppliers / customers in relation to REACH?*

  Businesses will need to know how REACH is going to impact on their supply chain before they can decide what to do. For instance, have downstream users checked with the suppliers whether the substances they supply will be registered? Will the registrations cover their current uses of the chemicals? Or for registrants, have their customers confirmed their uses which then should be included in the registration?

- *Do you produce or import any chemicals at or above 1 tonne per year?*

  Even those companies that are predominantly regarded as downstream users under REACH may still import chemicals into the EU at sufficient levels to trigger registration duties.

- *Do you supply any chemicals (on their own or in mixtures)?*

  Even if a company is not a registrant, if they supply substances or mixtures they will have to ensure the substances are registered (where registration is required) as well as provide a SDS if classified.

- *What action do you take on receipt of new information on chemicals?*

  Under REACH, downstream users must identify and apply appropriate measures to adequately control risks, identified in information provided by the supplier such as SDSs. So called 'extended' SDSs (those that contain exposure scenarios as a result of registration) may contain important new risk management information that needs to be implemented. Additionally, the effect of the CLP Regulation may mean that the classification of certain chemicals used by the dutyholder has changed – what impact will this have on existing controls?

- *Do you have any unusual uses for chemicals?*

  If these are outside the conditions of an exposure scenario, or otherwise against the advice of the supplier, then the downstream user may have to take action to comply with REACH.

  If the use is not covered by the exposure scenario see section 5.3

  More information about the different options can be found in the document drawn up by the European umbrella organisation of traders in chemical products. ECHA has also drawn up a fact sheet on this with a step-by-step plan.

  See section 9.3 above for more details.

Market surveillance REACH duties are generally "administrative" in nature, i.e. registrations must be compiled and submitted, safety data sheets must be drawn up etc. This has advantages for inspection as compliance with such duties can often be verified without actually having to visit the dutyholder. It is possible to use **"desk-based" inspection** to confirm, for example, whether a (pre-)registration has actually been submitted by a dutyholder, or whether a safety data sheet meets the requirements of Annex II of REACH. Many NLI interventions can therefore be by correspondence, at least in the first instance.

If compliance issues are identified or suspected, Labour Inspectors should also bear in mind that it is normally more effective and proportionate to **target enforcement action at the top of the supply chain**, i.e. at the "source" of the offence. For example, where a distributor is supplying substances that have not been registered, then the manufacturer or importer should

be identified so that appropriate action can be taken against them (their compliance directly influences the compliance of everyone beneath them in that supply chain).

10.2 When to enforce under REACH rather than CAD/CMD

In terms of the duties relating to the **use** of chemicals in the workplace, CAD/CMD remain very relevant and in many cases will probably be chosen over REACH. Nevertheless, it is normally more appropriate to enforce under REACH rather than more general occupational health and safety legislation in the following situations:

- where the contravention consists of using a substance 'outside' the registration, i.e. outside the conditions of an exposure scenario, or otherwise against the advice of the supplier. This is because such situations are specifically provided for by REACH, but not by CAD/CMD;
- where the downstream user has not communicated information back up the supply chain where required, e.g. where they consider risk management information to be inappropriate or have information on new hazards;
- where the downstream user is using substances subject to authorisation but does not have an authorisation themselves for that use, or the use is not covered by an authorisation obtained by an actor further up the supply chain;
- where the downstream user is using a substance that has been authorised but is not complying with the conditions of the authorisation; or
- where the downstream user is using substances subject to restriction but in a manner which does not comply with the conditions of the restriction.
- Where the user must provide information (as supplied in the SDS) to his employees and others exposed to the hazardous substances or mixtures but does not do so
- where a formulator is required to prepare and provide a SDS but does not or provides one that is not suitable and sufficient
- where a re-filler or re-importer is required to provide a SDS but does not do so.

10.3 Evidence to support enforcement action under REACH

The following lists evidence that may need to be collected in order to demonstrate a contravention under REACH. As the decision to take enforcement action is always made on a case-by-case basis, the items in this list are not considered necessary to collect in every case, nor is this list considered to be exhaustive.

The following lists a number of general areas where evidence may need to be collected, i.e. to demonstrate:

(i) the dutyholder's position in the supply chain, i.e. whether they constitute a manufacturer, importer, supplier, downstream user, distributor etc (as defined). Supply chains can vary dramatically in terms of length and complexity, and it is vital to understand the roles and responsibilities of the various actors in the supply chain in order to establish their legal obligations;

(ii) whether the product in question constitutes a substance, mixture or article (as defined);

(iii) the hazards - these will often be given on a safety data sheet but alternatively may be available from REACH registration information, supply labelling, or from the EU-wide classification and labelling inventory established under the CLP Regulation. In particular, consider evidence of:

- whether a substance or mixture meets the criteria for classification as 'dangerous' under Dangerous Preparations Directive or hazardous under CLP Regulation; and
- whether a substance is subject to authorisation or restriction;

(iv) the risks – for many REACH duties this is not actually required to demonstrate a contravention, but it is likely to add weight to the case for enforcement action;

(v) the quantities manufactured, imported, supplied or used, and the numbers of users involved. This information is not always essential, but may be useful to highlight the extent of the problem;

(vi) Substance identity - where practicable and where necessary (e.g. when considering legal proceedings), a sample of the substance, mixture or article should be obtained. Any proposed enforcement may fail if the identity of the substance in question cannot be proven. National rules for taking samples should be followed.

(vii) the date(s) of the manufacture, importation, supply or use of the substance, and any documentary evidence to support this, e.g. delivery notes, invoices, production records etc.;

(viii) if applicable, the decisions, requirements or conditions placed on dutyholders by ECHA, the CA Competent Authority, or other bodies (e.g. following evaluation);

(ix) where an exemption applies proof of why it applies e.g. it is a substance listed on Annex V.

For potential breaches of **use** related duties, in addition to the general matters outlined above, evidence may need to be collected to demonstrate:

- that the dutyholder has identified and applied the risk management measures from the information available to them, in particular the SDS, and if they have not, can they demonstrate that the control measure(s) in question is not appropriate;
- that they provided information on the hazards and measures to be taken to protect those exposed.
- what more may need to be done to prevent harm;
- the way in which the product is actually being used - in particular, any use outside of the conditions described in an exposure scenario or otherwise against the advice of the supplier (these will be identifiable from the information provided in the safety data sheet);
- what action has (or has not) been taken in the circumstances described above, i.e. has the supplier been informed of the use, or has the downstream user prepared their own chemical safety assessment;
- the health risks created by the use;
- where appropriate, any failure to pass information back up the supply chain, e.g. on new hazards, or where the user considers information in the SDS inappropriate.

For potential breaches of **restrictions**, in addition to the general matters outlined above, evidence may need to be collected to demonstrate:

- that the substance is actually subject to restriction. Has the identity of the restricted substance been confirmed, e.g. by analytical testing? Or does the situation under consideration correspond to the conditions of the restriction? For instance, phthalates are restricted for use in toys and childcare articles, so is the product in question actually a toy or childcare article? Some restrictions also provide for exemptions within the conditions of the restriction itself, so checks will need to be made as to whether the exemption applies;
- the presence of the restricted substance at or above the relevant minimum concentration limit, where relevant. For example, some restrictions specify that a substance must be present in a mixture at 0.1% weight by weight or more for the restriction to apply. Not all restrictions have concentration limits (e.g. asbestos) so each case must be treated separately;
- whether the recipients are consumers or industrial / professional users, as a number of restrictions specify that supply to the former is prohibited, but not the latter.

For potential breaches of **supply** related duties, in addition to the general matters outlined above, evidence may need to be collected to demonstrate:

- that the supplier is required to provide a SDS for a substance or mixture, i.e. that it is classified as hazardous under CLP or for mixtures dangerous under DPD;
- whether the supplier routinely provides SDS to their customers, as opposed to simply making them available on a website or in response to requests etc;
- whether the SDS meets the requirements of Article 31 and Annex II of REACH. Inspectors should obtain a copy of the SDS in question, although checks will need to be made that any SDS produced by a user is still relevant. For example, an out of date SDS may be produced by a user due to in-house failures to update information kept on substances. Inspectors will also need to examine the supplier's procedures for ensuring the current SDS accompanies orders and that updated SDSs are sent to relevant customers when changes are made.

  Inspectors with responsibility for the market surveillance aspects of REACH should consider in particular:

  - whether the SDS is in the correct language;
  - whether the SDS contains accurate and sufficient information, in particular in relation to those sections dealing with risk management;
  - whether the SDS is relevant to the market and that it does not contain inappropriate or irrelevant information (e.g. occupational exposure limits for other countries);
  - how recently the SDS was last revised (at the very least, it should have been updated since REACH came into force in June 2007);
  - whether the SDS has the required 16 headings;
  - whether the SDS has been prepared by a competent person.

(See section 4 above for further details)

As the requirements of Annex II are prescriptive, inspectors will often be able to establish for themselves whether a SDS meets REACH requirements. However, in some cases e.g. when considering the adequacy of risk management information, specialist advice may be necessary;

- where appropriate, any failure to pass information back up the supply chain, e.g. on new hazards, risks or uses;
- the substance's intended / actual movement in the supply chain; and
- who the recipients are, and in particular whether they are industrial / professional users or consumers. Consumers do not have to be provided with a SDS, and will only receive information on SVHCs in articles on request.

For potential breaches of **registration** related duties, in addition to the general matters outlined above, evidence may need to be collected to demonstrate:

- for importers, whether a non-EU manufacturer or formulator has appointed an only representative (OR) and, if so:
    - the identity of the OR; and
    - the letter of appointment, which will need to state which substance(s) the OR is assuming responsibility for, and which EU-based importers are covered by the appointment;
- the quantity (in tonnes per year) of the substance that has been manufactured or imported. Inspectors should note the following when determining the quantity of a substance manufactured or imported:
    - registration related duties will only apply if the substance is being manufactured or imported at or above 1 tonne per year, and as tonnage levels increase, so too does the amount of information required for the registration;
    - "per year" means per calendar year, and for phase-in substances that have been manufactured or imported for three or more consecutive years, the average quantities for the 3 preceding calendar years should be used. So if a substance has been manufactured at 0.5 tonnes for two years, and then 1.5 tonnes in the third year, then the average quantity manufactured over the three year period does not exceed 1 tonne per year and so there is no registration duty;
    - calculating the quantity of a substance manufactured / imported on its own is relatively straightforward, though bear in mind that 1 litre may not necessarily mean 1 kg;
    - calculating the quantity of a substance in a mixture is more complicated. The dutyholder will first need to determine the proportion of each substance in the mixture. They can then use this to calculate the total amount of each substance imported each year. If the information suggests a range of possible concentrations (e.g. 5%-15%), the higher number should be used for calculations.
    - it is not the quantity of 'product' manufactured / imported that matters, rather the quantity of the substances that make it up
    - the same substances may be present across a range of different products

- where it is believed a registration or pre-registration has not been submitted, confirmation that this is the case;
- where a registration or pre-registration has been submitted but is deficient, evidence concerning the deficiencies with the information submitted.

For potential breaches of **restrictions**, in addition to the general matters outlined above, evidence may need to be collected to demonstrate:

- that the substance is actually subject to restriction. Has the identity of the restricted substance been confirmed, e.g. by analytical testing? Or does the situation under consideration correspond to the conditions of the restriction? For instance, phthalates are restricted for use in toys and childcare articles, so is the product in question actually a toy or childcare article? Some restrictions also provide for exemptions within the conditions of the restriction itself, so checks will need to be made as to whether the exemption applies;
- the presence of the restricted substance at or above the relevant minimum concentration limit, where relevant. For example, some restrictions specify that a substance must be present in a mixture at 0.1% weight by weight or more for the restriction to apply. Not all restrictions have concentration limits (e.g. asbestos) so each case must be treated separately;
- whether the recipients are consumers or industrial / professional users, as a number of restrictions specify that supply to the former is prohibited, but not the latter.

10.4 Documents that a dutyholder may use to demonstrate compliance

Inspectors are likely to need a number of documents in the course of a typical REACH inspection, to assist them in checking whether the dutyholder is compliant or not. It is not possible to list these exhaustively because it will depend on the particular circumstances of the case. However, the following documentation is likely to be useful:

- safety data sheets
- invoices
- receipts
- delivery notes
- production records
- certificates (or other results) of analysis, which meet relevant testing standards
- confirmatory letters / emails from suppliers or customers

Dutyholders should also be prepared to demonstrate whether (and how) appropriate communication has been taking place within their supply chain. Evidence that REACH compliance is considered as part of a wider management system would also be helpful, e.g. a purchasing policy that incorporates REACH conformity as a criterion.

Under Article 36 of REACH, dutyholders must **assemble and keep available** all the information they require to carry out their duties under REACH for a period of at least 10 years after they last manufactured, imported, supplied or used the relevant substance(s) or mixture(s). Inspectors could remind dutyholders of this provision if they are unable to produce information requested. It may sometimes be the case that the information requested is in

existence but not available during the visit, e.g. because it is held at another site. In such cases, Inspectors are encouraged to allow the dutyholder a reasonable period of time to gather and forward the information.

11. Questions and answers section

What if a downstream user can demonstrate compliance with CAD/CMD but not REACH?

REACH and CAD/CMD requirements apply 'without prejudice' to each other and so compliance with one regime cannot be used as a justification for failure to comply with the other.

What if the downstream user has achieved adequate control under CAD/CMD but has not followed the REACH risk management measures?

Just because the downstream user has achieved adequate control under CAD/CMD, it does not mean that the REACH requirements can be ignored. However, the downstream users might be able to demonstrate that their existing control measures achieve an equivalent level of protection, and that the REACH controls are not appropriate for them. Downstream users will need to justify any such position with reference to their risk assessment.

Downstream users should remember that there may still be circumstances in which they must nevertheless prepare a CSR (for uses outside the conditions described in an exposure scenario, or uses that are against the advice of the supplier).

What if a downstream user has not been provided with a safety data sheet?

Suppliers of substances or mixtures classified as 'hazardous' must provide recipients with a safety data sheet (SDS) compiled in accordance with REACH requirements. There are also some other circumstances under REACH where a supplier will need to provide a SDS. However, a SDS will not always be required, e.g. for substances or mixtures that are not classified. This means the downstream users may not receive a SDS for every substance or mixture they use.

Where a SDS is required, the obligation falls on the supplier to ensure one is provided to the downstream user. Simply making them available (e.g. on a website, or only in response to requests from customers etc) is not enough. However, this does not mean that the SDS must be provided to the same customer every time they order the same substance or mixture; in such circumstances, it is enough to provide the SDS either before or at the time of first delivery of the substance or mixture, providing the SDS is re-sent following any revisions. The SDS can be provided electronically or in writing but must be free of charge.

The downstream user has the obligation to assemble and keep available for a minimum of 10 years all the necessary information to perform his duties. If he does not receive an SDS for a

hazardous substance or mixture (which may become clear from labelling), he should actively look for the information himself. The easiest way may be to approach his supplier and ask to send a recent SDS.

What if there are no exposure scenarios appended to a safety data sheet?

There may be valid reasons why there is no ES appended to a SDS. While a safety data sheet (SDS) must be provided for all substances or mixtures classified as hazardous irrespective of the tonnage supplied, exposure scenarios are only required to be developed for those substances registered in quantities of 10 or more tonnes per year per registrant and classified as hazardous. SDSs for substances registered in quantities less than 10 tonnes per year (or not requiring registration at all) would not be expected to have exposure scenarios attached. There are several other cases where a CSA (and thus exposure scenario) is not required, e.g. for the substances in appendices IV and V. For mixtures, the appendage of exposure scenario's is a possibility, but the formulator may also decide to include the relevant information in the body of the SDS.

What should the user do when they receive a revised safety data sheet?

This should trigger a review of their existing risk assessment under CAD/CMD.

What if the downstream user purchases the same substance from two or more suppliers and the risk management information in their safety data sheets is different?

REACH states that 'appropriate' risk management measures must be identified and applied, and so it is for the downstream user to decide, when performing their CAD/CMD assessment, which risk management measures are 'appropriate' in the circumstances. However, in such situations it is possible that some of the risk management measures in the safety data sheets are inappropriate. If this is the case, the downstream user will need to inform the relevant supplier(s), who must then take action.

What should the downstream users do if they do not understand the risk management measures in the safety data sheet?

It is possible that certain terms or phrases used in one industry sector will not be understood in another, or that the downstream user is not sure how to apply the risk management measures to their situation. Inspectors should recommend downstream users contact their supplier for clarification.

What if it is not possible or impractical to apply the risk management measures in a safety data sheet?

This will need to be considered as part of the CAD/CMD assessment. There is a clear expectation in REACH that downstream users should apply the full range of control measures identified in the SDS. But if there are clear and justifiable reasons for not doing so (i.e. the risk management measures are not 'appropriate'), then it is not a contravention of REACH to

take other measures. In such circumstances, the downstream user should be able to demonstrate how the other measures taken provide for an equally effective level of protection, and should document in their risk assessment the reasons for not applying the REACH controls. Downstream users should also report any inappropriate risk management measures to their supplier.

Will measures from an ES suffice if OEL and DNEL are different?

The DNEL under REACH is used to determine the appropriate risk management measures, and so full implementation of them should ensure the DNEL is met. Clearly, if this level of protection meets or exceeds the OELV then no further action is required. If it does not, then the user will need to consider further controls to ensure the OELV is also met. For risk assessment under CAD employers should also be aware that measures under REACH apply to the use of the ONE registered substance. Different or additional measures may be necessary if several substances are used in a workplace.

What if the information on the safety data sheet is missing / inaccurate?

The safety data sheet (SDS), including any annexes, remains a vital communication tool between suppliers and downstream users of chemicals. Accurate, complete and correct information on the safety data sheet (SDS) is essential when considering workplace controls. If inspectors have concerns over the quality or reliability of information provided on a SDS, they should refer the matter either to the relevant regional product safety team, or to the National REACH Competent Authority (CA).

Inspectors should also remind downstream users that they also have a specific obligation under REACH to report any information on the SDS that might call into question the appropriateness of the risk management measures.

12. Case Studies

The following case studies set out hypothetical scenarios which involve contraventions of REACH, and / or potential contraventions of CAD / CMD. The case studies have been designed to address most aspects of REACH, i.e. registration, supply and use-related obligations, as well as authorisation / restriction provisions. They have also been designed to highlight the sheer range of dutyholders to which REACH could potentially apply.

For each case study, Labour Inspectors can consider:

- who the dutyholder(s) is/are;
- the relevant legal requirements that are probably being contravened;
- what enforcement action they would take; and
- whether there are any practical enforcement issues that come to light.

After each case study, "model answers" are provided, though clearly the case studies are illustrative only and all situations should be judged on a case by case basis.

12.1 Tyre recycling

You are inspecting a tyre crumbing plant where waste tyres are taken in, shredded and then separated into the following four materials:

- rubber crumb
- wire / metal
- fibres
- dust

Following this process, three of the four materials are sold on to industry for use in a variety of applications (with the exception being the metal, which is sold to smelters as scrap).

The company has not pre-registered anything under REACH as it does not think REACH applies to its business.
CAD / CMD will apply to the processes and the generation of dusts and fibres which if not properly controlled would expose workers to potentially hazardous substances

Purpose of the case study

- To focus on exemptions from registration, in particular the exemptions for waste and for recovered substances
- To consider the definition of 'article' in REACH and its application here
- To look at when inspectors should prioritise CAD / CMD

Identification of the dutyholder(s):

- The tyre recovery operator

Contraventions of REACH:

Potentially Article 5, with reference to Article 6(1) for failure to register or pre-register the substances it manufactures and places on the market, if they are not exempt.

Waste is exempt from REACH as it is covered by other legislation. However, when waste is re-introduced into the supply chain it ceases to be waste and therefore becomes subject to REACH - the company are effectively manufacturing substances from the waste, so they potentially have registration duties. In this instance the dutyholder is recovering waste and placing it back on the market, apart from the metal which remains waste as it is sold as scrap.

There are, however, further exemptions that could apply:

- some of the rubber crumb that is placed on the market could be considered to be an "article" (as defined) if it is recycled to meet certain size and shape requirements. If the company can provide an acceptable argument that they are producing an article then this would not require registration. This is a decision for the dutyholder to make and justify.
- there is an exemption in REACH which means that those recovering substances do not have to register them if the substances are already registered. Technically this

exemption does not apply if the recovered substances have only been pre-registered (as opposed to registered in full)

- Annex V exemptions may also apply, e.g. the exemption for substances that occur in nature and are not chemically modified or classified as hazardous.

Contraventions under CAD/CMD

The processing of the waste at the site would attract duties under CAD/CMD for the employer whether or not REACH applies to the incoming waste products.

When processing the employer should have assessed the risks from exposure using either national exposure limits or DNEL if available for the products

What action should be taken?

If no exemptions apply, enforcement may be needed relating to the failure to register or pre-register. The employer will also need to comply with duties under CAD/CMD.

If exemptions apply the employer should still be able to demonstrate they are controlling exposure to the hazardous substances. If they cannot then enforcement may be needed in accordance with national guidelines.

Practical enforcement issues:

- To highlight the difficulties with the definition of articles – is rubber crumb an article or mixture under REACH?
- To highlight the difficulties with the operation of certain exemptions under REACH:
    - when does waste start and stop being waste for REACH purposes?
    - the fact that the "recovered substances" exemption in REACH only operates to exempt substances already registered, not substances that are pre-registered. Assuming that such substances are eventually registered in full, allowing the exemption to operate, what action should Inspectors take in the meantime?
    - do any other exemptions apply, e.g. from Annex V, and if so, which?
- Tyre recovery is specifically considered in the ECHA guidance document on waste and recovered substances. Ref.
- To highlight that there will be circumstances where it is possible that enforcement issues can be identified be under REACH and CAD/CMD simultaneously.

12.2 Hospital (estates department)

You are in the process of inspecting the estates department of a hospital and find some tins of drain cleaner in a storage cupboard. On closer examination, you notice that the labels state that the drain cleaner contains sodium hydroxide (a hazardous substance which is classified as a corrosive).

The maintenance manager says that he was completely unaware that the drain cleaner contained sodium hydroxide, and is very concerned when you explain its hazardous effects.

He states that the product is not used regularly, but when it is, staff will not use any control measures such as personal or respiratory protective equipment.

You ask the maintenance manager for a copy of the relevant risk assessment but all he can provide you with is a copy of the safety data sheet.

Looking at the safety data sheet, you note that sodium hydroxide is listed as a hazardous ingredient in section 3 of the safety data sheet, but it has not been classified correctly as a corrosive (merely as a substance that is 'harmful by inhalation and if swallowed'). In addition, the safety data sheet states, in section 8, that exposure controls to be used are "appropriate respiratory protective equipment and/or gloves", and no further details are provided.

Purpose of the case study

- To focus on REACH downstream use issues and consider the overlap with other chemicals legislation e.g. CAD / CMD
- To highlight the failure to identify and apply relevant risk management measures
- To demonstrate issues concerning poor quality safety data sheets, and REACH provisions on passing information back up the supply chain

Identification of the dutyholder(s):

- The hospital (as downstream user)
- The supplier of the drain cleaner

Contraventions:

- Article 37(5) of REACH in relation to the hospital's failure to identify and apply appropriate risk management measures to adequately control risks
- Linked to above, contraventions of Articles 4−6 CAD for failure to adequately assess the health risks to employees, and prevent or adequately control exposure
- Article 34(b) of REACH in relation to the hospital's failure to inform their supplier about the inappropriateness of the risk management measures identified in a SDS supplied to him
- Article 31(1) of REACH in relation to the supplier's duty to provide a SDS compiled in accordance with Annex II (poor risk management information, and incorrect classification of sodium hydroxide)
- Likely breach of the CLP Regulation too – as incorrect classification and labelling information is given on the SDS

What action should be taken?

Inspectors should consider whether there is a risk of serious personal injury. If they consider this to be the case this would suggest enforcement under CAD / CMD as a priority. This could be followed by action to resolve the REACH and DPD/CLP breaches.

Practical enforcement issues:

- Inspectors will want to consider whether to use REACH or CAD /CMD to pursue enforcement action in such circumstances. The issue at hand, for instance, probably

lends itself better to CAD/CMD enforcement, other than the Article 34(b) contravention for failing to communicate up the supply chain, which is a provision that is not mirrored in CAD/CMD.

- While it is clearly the supplier's duty to provide a SDS that meets REACH requirements, downstream users now have a duty under REACH to communicate with their suppliers in the event that the risk management information in the SDS is considered inappropriate.
- The case study highlights some common problems with SDSs, such as lack of detail in risk management information, or incorrect classifications etc.

12.3 Turbine manufacturer

A turbine manufacturer you are inspecting has found a novel use for an aerosol furniture polish which it uses in the production of its turbines. It uses several tonnes of the polish each year for this purpose. Their use is not specifically advised against on the supplier's safety data sheet, but the use is outside the conditions described in the exposure scenario that is annexed to the safety data sheet.

The company wants to keep this use hidden from its competitors as it believes it gains a significant commercial advantage from the use. The company believes their use is safe and any risks have been controlled, but the controls implemented differ significantly from those on the exposure scenario and you are doubtful that they are as effective. The company has taken no further action under REACH so far.

Purpose of the case study

- To focus on downstream use issues, in particular use outside the conditions described in an exposure scenario
- To demonstrate the actions a company in this situation should take under REACH, in order to protect their business interests

Identification of the dutyholder(s):

- The turbine manufacturer

Contraventions:

- Article 37(5) of REACH in relation to the failure to identify and apply appropriate risk management measures to adequately control risks
- Potentially more general obligations under CAD/CMD relating to safe use of hazardous substances at work (e.g. risk assessment, prevention and control of exposure)
- Article 37(4) of REACH in relation to the failure to prepare a chemical safety report for a use outside the conditions described in an exposure scenario
- Article 38(1) of REACH in relation to the failure to report to ECHA the information required by Article 38(2) prior to commencing or continuing their particular use

What action should be taken?

As with the preceding case study priority may be given to the CAD / CMD issues relating to the safe use of the hazardous substances to ensure risks to work health are controlled. This will then be followed by resolving the contraventions for failing to prepare a substance or mixture chemical safety report etc. that will require enforcement action.

Practical enforcement issues:

- In this case study, there are concerns that the existing risk management measures are not sufficient. But what happens when a downstream user finds a way to control risks arising from the use of a substance adequately, but in a way which is different to the measures contained in the exposure scenario? Inspectors will want to consider whether to use REACH or CAD/CMD to pursue enforcement action in this case. Unlike the preceding case study, REACH is probably more relevant, as it contains specific provisions which regulate use outside the conditions of an exposure scenario. CAD/CMD would still be relevant in addressing the concerns over the effectiveness of the existing control measures.

12.4 Paint supplier (restrictions)

You receive information in relation to the supply of paint by a small builder's merchant from a member of the public after purchasing some paint from the builder's merchant, only to discover that the label carried a warning that the paint contains lead.

You are provided with the name of the importer who supplies the paint wholesale to the builder's merchant. You visit the importer, and they show you the product in question in their warehouse. You note that the tins of paint do indeed carry a warning on the label about the paint containing lead, although there is little other information on the label, in particular, no hazard statements or pictograms. You ask the importer for a copy of the safety data sheet for this product to find out more, but they are unable to produce one for it.

The importer states that they only supply this product to retailers (and not direct to the public). The builder's merchant would have supplied the paint both to trade and consumers, although they have now prohibited further supply and are working with the company on a product recall.

Purpose of the case study

- To focus on restrictions (in this case, the restriction relating to the supply of leaded paint)
- To consider related issues around the provision of safety data sheets, and also classification and labelling issues under the CLP Regulation

Identification of the dutyholder(s):

- The builders merchant
- The importer
- Other recipients of the leaded paint (identities not yet known)

Contraventions of REACH:

- Article 67(1) in relation to the failure to observe the relevant restriction on the marketing and use of leaded paint – this contravention is on the part of both the builder's merchant, the importer, and other customers of the importer.

- Article 31(1) in relation to the failure to provide a SDS to recipients that is compiled in accordance with Annex II – this contravention is on the part of both the importer and the builder's merchant.
- Article 31(4) in relation to the failure to provide sufficient information to enable members of the general public to take necessary measures to protect human health or the environment
- Article 34(b) may also apply to the builder's merchant, as they have not raised the issue of lack of provision of a SDS with their supplier.
- There are likely to be further contraventions under the CLP Regulation in relation to the failure to label the paint properly – again, this contravention is on the part of both the builder's merchant and the importer.

What action should be taken?

In terms of the contravention of Article 67 (restrictions) consideration should be given to enforcement notice to prohibit all further supply of the paint unless the conditions of the restriction were observed. While both dutyholders have contravened Article 67 enforcement action against the importer should be considered first, because it is usually more effective to target enforcement action at the top of the supply chain.

In terms of the contravention of Article 31 (the failure to provide any SDS) Enforcement notice should be considered but inspectors should also consider the risk of serious personal injury due to recipients not being provided with SDS, information on the label being insufficient and the paint is very hazardous.

Practical enforcement issues:

- There are potentially three restrictions in Annex XVII of REACH that apply here - nos 16 and 17 which concern lead carbonates and lead sulphates in paint, and no. 30 on substances that are toxic to reproduction. Inspectors will need to identify what lead compound is actually present in the paint to determine which of the REACH restrictions applies. If the importer does not know, analytical testing may be required.
- Restrictions nos 16 and 17 only apply to substances or mixtures intended for use as paint. Could a dutyholder avoid being caught by the restriction by claiming that they do not intend the substance or mixture to be used as a paint? How would you go about disproving this?
- The Enforcement Notice (EN) can be used to prohibit all further importation and supply, though it can be used to achieve other outcomes as well (recall, disposal, destruction etc).
- Restrictions nos 16 and 17 (the lead in paint restrictions) state that Member States may permit the use on their territory of the substance or mixture for the restoration and maintenance of works of art and historic buildings and their interiors.

12.5 Manufacturer of plastic cabling (authorisation)

You are inspecting a manufacturer of plastic cabling. In the production of the finished material you notice that the company uses a plasticiser to ensure the final product is flexible. You ask them what this plasticiser is. They inform you that it is benzyl butyl phthalate (BBP). You establish that they obtain the BBP from a company within the EU that manufactures it. You ask to see the safety data sheet for the substance.

You are aware this substance appears on Annex XIV for REACH and is subject to authorisation. While the safety data sheet appears to contain all the necessary information to

ensure safe use, you notice that it does not contain an indication that an authorisation exists for this substance. Neither is there any indication on the product label. On further questioning it becomes apparent that the company you are inspecting is unaware of the need for an authorisation. (You do not yet know whether the EU manufacturer of BBP has obtained an authorisation.)

Purpose of the case study

- To focus on authorisation and consider the roles of the various actors in the supply chain as regards authorisation requirements
- To highlight the supplier's duties to pass on information on authorisation in the supply chain

Identification of the dutyholder(s):

- The plastics manufacturer (downstream user)
- The manufacturer of the BBP (in the other EU state)

Contraventions of REACH:

- Article 56(1) in relation to the failure by the manufacturer of the cabling to obtain an authorisation for the substance before using it. If the EU manufacturer of the BBP has also failed to obtain an authorisation then their supply would also contravene Article 56(1).
- Note that if the EU manufacturer had obtained an authorisation, the national manufacturer of the plastic cabling would not need a separate authorisation, but would need to ensure they stick to the conditions of use (Article 56(2)) and notify ECHA of their use (Article 66(1))
- The EU manufacturer has probably also contravened:
    - Article 65 for failing to put the authorisation number on the product label
    - Article 31(9) for failing to update the SDS with details of the authorisation
    - Potentially Article 60(10) in that the holder of an authorisation must ensure that, notwithstanding any conditions of use, exposure is reduced to as low a level as technically and practically possible

What action should be taken?

An Enforcement Notice should be used where it is appropriate to require an immediate halt to the importation, supply or use of authorisable substances without authorisation. Such decisions should be made on a case-by-case basis, although it is likely that an Enforcement Notice will be appropriate in many circumstances as substances that require authorisation will all have very hazardous properties.

As there are compliance issues with the EU manufacturer, details should be referred as soon as practicable to the national CA, who will then refer the matter on to the relevant EU member states authorities.

12.6 Chemicals manufacturer

You visit the site of a global chemicals manufacturer who produces polychloroethene (polyvinyl chloride or PVC) by the following process:

- reacting ethene (ethylene) and chlorine to produce 1,2-dichloroethane (ethylene dichloride)
- converting 1,2-dichloroethane to chloroethene (vinyl chloride monomer) by thermal cracking
- converting chloroethene to polychloroethene (polyvinyl chloride, PVC)

The company imports ethene from its plant in the USA, but sources its chlorine from a different company based in the EU. Occasionally the company will also import 1,2-dichloroethane from its plant in the USA to supplement existing stocks.

The company states that it has submitted pre-registrations to ECHA, although it has not yet submitted any full registrations. On checking further into this you discover that the company has pre-registered three substances: ethene, chlorine and 1,1-dichloroethane (rather than 1,2-dichloroethane), which appears to be an error on the part of the company.

Purpose of the case study

- To focus on registration and pre-registration and consider a number of registerable substances
- To consider issues surrounding pre-registration and registration:
    - one substance not (pre-)registered at all (chloroethene)
    - one substance pre-registered correctly (ethene) but not yet registered in full
    - one substance pre-registered incorrectly (1,2-dichloroethane) and also not yet registered in full
    - one substance pre-registered unnecessarily (chlorine)
    - one substance not requiring pre-registration as it is a polymer
- To consider issues surrounding registration of intermediates
- To consider enforcement of 'no data, no market'

Identification of the dutyholder(s):

- The chemicals manufacturer – with roles under REACH as a manufacturer, an importer and a downstream user (of chlorine, though there is no evidence that there are any contraventions relating to downstream use)
- Potentially also the EU based supplier of chlorine (though again there is no evidence of contravention on their part)

Contraventions of REACH:

- Article 5 (no data, no market) with reference to Article 6(1) as a result of a failure to pre-register 1,2-dichloroethane correctly and subsequently continuing to manufacture and import it despite not having (properly) registered this substance. Initially this could be seen as a "technical" breach although 1,2-dichloroethane is classified as a category 1B carcinogen and so should have been registered in full by 1 December 2010. The company may be able to show that their manufacture of this substance on-site qualifies

as being an intermediate, but a "full" registration would still be required in respect of the quantities imported, provided this is over 1 tonne per year.

- Article 5 (no data, no market) with reference to Article 6(1) as a result of a failure to pre-register chloroethene and continuing its manufacture without having registered this substance in full. Chloroethene is a category 1A carcinogen and again should have been registered in full by 1 December 2010 even had the company pre-registered it. However, it is possible that the substance is an intermediate; see further below.
- Potentially a further breach of Article 5 (no data, no market) with reference to Article 6(1) for failure to register ethene. Although the company have pre-registered the substance, it is possible that the quantities imported from the USA exceed 1,000 tonnes per year and should have been registered in full by 1 December 2010.

What action should be taken?

Inspectors should consider whether it would be proportionate to enforce the "no data, no market" requirements of REACH with immediate effect, i.e. requiring manufacture and importation of the substances in question to cease until registrations are fully completed. Factors in favour of such action are that two are carcinogenic and therefore very hazardous, and all three are likely to be manufactured / imported in significant quantities. Factors against would be the potential for such action to cause a disproportionate effect (effectively a plant shutdown for the time it takes to register the substances, which could be some months) as well as the fact that at least the company has taken some, albeit limited, action to comply with REACH.

In cases where an incorrect pre-registration has been submitted, e.g. due to a spelling mistake, there is a technical breach of REACH Article 5 if the substance continues to be manufactured or imported.

Practical enforcement issues:

- Enforcement of Article 5 and the effect this could have on this company's business (see section above).
- Would the 1,2-dichloroethane, chloroethene and ethene be intermediates under REACH? An intermediate is defined by REACH as "a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance" so it is likely. Non-isolated intermediates are exempt from REACH. Isolated intermediates are not exempt but registrants can submit reduced registration information if they can demonstrate that the intermediates are only handled and used under strictly controlled conditions.
- There may be other ways in which the company could comply, e.g. contracting a toll manufacturer who can pre-register 'late', sourcing from a compliant EU-based supplier etc, though other solutions are often not practical for the company.
- The company have pre-registered one substance unnecessarily (chlorine) as they are not the manufacturer or importer of it. This is not a contravention under REACH, as pre-registration is voluntary. However, the company may want to check that their supplier has complied with their duties under REACH; if they have not, it puts their supply of chlorine at risk.

12.7 Chemicals manufacturer supplying substances

The chemicals manufacturer in case study 1 above supplies some of the 1,2-dichloroethane it manufactures directly to the European market. You ask to see a copy of the company's safety data sheet (SDS) for this substance to verify its compliance with REACH requirements.

You are presented with the safety data sheet. The company confirms it will supply the SDS on request to its customers and the SDS is on the company's website, but it does not routinely provide the SDS to customers otherwise.

On inspection, the SDS contains the required 16 headings but appears to have been prepared for the US market (there are occupational exposure limits for the US and not the EU, and references to US legislation). The classification of the substance (section 2) is incorrect in that it does not reflect the fact that the substance is carcinogenic. You are also concerned about the risk management information in section 8 which specifies that users should wear "gloves" and "appropriate RPE" but with no further details.

Purpose of the case study

- To focus on supply (SDS provisions) and consider the format and content of the SDS against REACH Annex II requirements
- To consider when a SDS should be 'provided' to recipients

Identification of the dutyholder(s):

- The chemicals manufacturer (as supplier)

Contraventions:

- Article 31(1) of REACH as the SDS is not compiled in accordance with Annex II, for example:
    - Not providing occupational exposure limits and other information (e.g. regulatory information) relevant to the EU market (with US standards / information which are unlikely to be helpful to downstream users who must comply with domestic legislation)
    - incorrect or insufficient information in the SDS, e.g. incorrect classification of the substance, insufficient risk management information (which should specify the type of PPE required, for instance, with references to the appropriate standards)
- Article 31(1) of REACH for the failure to provide the SDS to recipients (it is merely being made available on request or on the company's website). The SDS must be provided to the recipient (electronically or in writing) at or before the time of first delivery.
- If incorrect classification information is given in section 2 of the SDS, then it is reasonable to assume that the classification and labelling requirements of CLP Regulation are also not being met.

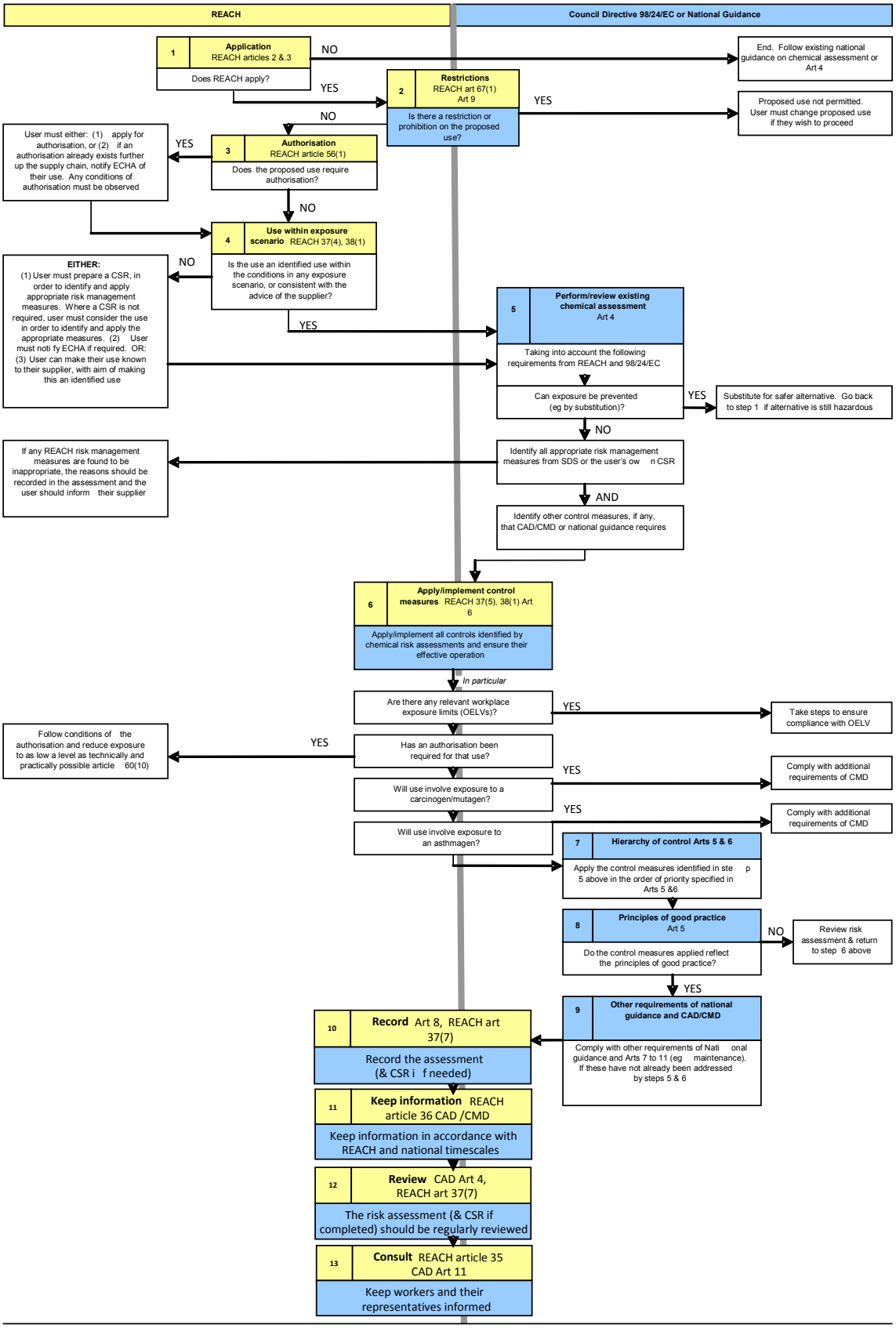
What action should be taken?

Inspectors could also consider using enforcement powers, e.g. recipients are not being provided with the SDS routinely, and even if they do receive it (or find it on the company's website) it does not contain appropriate risk management information and, in particular, does not mention the carcinogenic properties of the substance.

Practical enforcement issues:

- Taking enforcement action due to 'format' errors, such as the order of headings in a SDS, is considered less important than taking enforcement action due to substantive errors, such as deficiencies in the quality of information.
- The case study also intends to highlight some common errors in SDSs – such as a lack of detail in the risk management information, incorrect classifications, or SDSs that are prepared for different markets being provided in the EU without modification.
- It is a common misperception that it is acceptable to bring SDSs to the attention of others merely by putting them on a website or providing them only on request. The requirement in REACH is to 'provide' a SDS to a recipient, which is a proactive duty to ensure that essential safety, health and environmental information actually reaches actors further down the supply chain.
- Each supplier in a supply chain is responsible for complying with Article 31 and Annex II requirements. While the information provided by their own supplier is clearly a useful and relevant source of information for them to use when compiling their SDSs, each supplier remains responsible for the accuracy of the information on the SDSs they provide.

Appendix 1 - Reach v CAD Flowchart



Appendix 2 - Glossary

There are a number of acronyms, terms and phrases used in this guide which have specific meanings in the context of REACH. The definitions of some of these terms are based in law and given in Article 3 of REACH.

Actor in the supply chain: means any manufacturer, importer, supplier or downstream user in a supply chain.

Agency, The: European Chemicals Agency (see ECHA).

Annex II: Annex II of REACH sets out the requirements for the format and content of safety data sheets.

Annex XIV: Annex XIV of REACH lists all substances which are subject to authorisation. The use and placing on the market for a use of substances listed on Annex XIV is prohibited from the "sunset" date unless an authorisation has been granted for that use or unless an exemption applies.

Annex XVII: Annex XVII of REACH lists all restricted substances and the conditions of their restrictions under REACH.

Article (1): A legal requirement of REACH, e.g. Article 31 which requires suppliers of substances or mixtures classified as hazardous to provide recipients with a safety data sheet.

Article (2): An article is an object which during production is given a special shape, surface or design, which determines its function to a greater degree that does its chemical composition. Examples of articles range from simple articles such as cups, clothes or furniture, to more complex articles such as computers or cars. Some products are difficult to define, such as a candle –there are arguments either way. Articles may also act as carriers or containers for substances or mixtures, for instance, a tin of paint. Again there are some products which are borderline, a good example of which is a wet-wipe type product.

Authorisation: REACH sets up a system under which the use of substances with properties of very high concern and their placing on the market can be made subject to an authorisation requirement. Such substances are included in Annex XIV of REACH, and may not be placed on the market or used without an authorisation. This authorisation requirement ensures that risks from the use of such substances are either adequately controlled or outweighed by socio-economic benefits. An analysis of alternative substances or technologies will be a fundamental component of the authorisation process

CA: Competent Authority. The authority or authorities or bodies established by the Member States to carry out the obligations arising from REACH.

Candidate list: The candidate list refers to the list of substances of very high concern (SVHCs) from which the substances to be included in Annex XIV (list of substances subject to authorisation) are selected. The candidate list is established in accordance with Article 59 and maintained by ECHA on its website.

CAS: Chemical Abstracts Service, a division of the American Chemical Society. CAS maintains a comprehensive list of chemical substances. Each substance registered in the CAS Registry is assigned a CAS Registry Number (see CAS Number).

CAS Number: Chemical Abstracts Service index number. This is a unique numeric identifier for a chemical. It includes up to 9 digits which are separated into 3 groups by hyphens. The first part of the number, starting from the left, has up to 6 digits, the second part has 2 digits and the final part consists of a single check digit.

Classification: Classification is the process by which a given substance or mixture is assigned one or more categories of danger depending on its hazardous properties, in accordance with the criteria for classification specified in the CLP Regulation. If the substance is not found to be hazardous, according to these criteria, then it is not classified.

CLP Regulation: Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures.

CMR: carcinogenic, mutagenic or toxic to reproduction.

Conditions of use: Conditions of use refer to the operational conditions and risk management measures as described in an exposure scenario.

CSA: Chemical Safety Assessment. This is carried out for all registered substances manufactured or imported at 10 tonnes per year or greater. It should address all the identified uses of a substance on its own (including any major impurities and additives), in a mixture and in an article. The assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses. The chemical safety assessment shall be based on a comparison of the potential adverse effects of a substance with the known or reasonably foreseeable exposure of man and/or the environment to that substance taking into account implemented and recommended risk management measures and operational conditions.

CSR: Chemical Safety Report. A CSR should be completed for all substances subject to registration in quantities of 10 tonnes or more per year per registrant and is a documentation of the chemical safety assessment (see CSA).

Distributor: Any natural or legal person established within the Community who only stores and places on the market a substance (whether on its own or in a mixture) for third parties. This definition includes retailers, for instance.

DMEL: Derived Minimal Effect Level. This is a type of exposure limit and is established during the chemical safety assessment. It is used where a DNEL cannot be established (e.g. where a 'safe' level of exposure cannot be determined), to expresses an exposure level corresponding to a low, possibly theoretical, risk to human health, which should be seen as a tolerable risk.

DNEL: Derived No-Effect Level. This is a type of exposure limit and is established during the chemical safety assessment. A DNEL is the level of exposure to a substance below which no adverse effects to human health are expected to occur. It is therefore the level of exposure to the substance above which humans should not be exposed.

Downstream user: Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance (either on its own or in a mixture) in the course of their industrial or professional activities, i.e. work activities. Although not specified in the legislation, there are three main types of downstream user:

- those who continue the supply chain, e.g. formulators or re-fillers (and so will also be suppliers under REACH). Re-importers who are able to rely on the exemption from registration for re-imported substances (see above) may also be considered downstream users under REACH;
- those that use and/or consume the substance during their activities, e.g. article producers (end-users); and
- importers covered by an only representative.

The definition in REACH specifically excludes distributors and consumers from being downstream users.

Dutyholder: Any natural or legal person who has a duty placed on them by virtue of their role under the legal provisions from REACH, CAD or CMD or any other enacted European or National legislation

EC number: A numeric identifier for a chemical. The three European lists of substances from the previous EU chemicals regulatory framework (EINECS, ELINCS and the no-longer-polymers list) in combination are called the EC Inventory. The EC Inventory is the source for the EC Number as an identifier of substances. EC numbers can be found using the ESIS website.

ECHA: European Chemicals Agency. ECHA is a new EU Agency based in Helsinki, Finland. It was established by REACH for the purposes of managing and carrying out the technical, scientific and administrative aspects of the Regulation. This represents a significant change from previous chemicals legislation (e.g. on biocides, pesticides and legislation on the notification of new chemical substances prior to REACH), in that substance registrations are now sent to an EU Agency rather than a national authority. For more information on ECHA, please visit their website.

EIES: Electronic Information Exchange System. Generic term referring to any system by which information on REACH and REACH enforcement can be exchanged electronically between public authorities. Existing examples include RAPEX and ICSMS.

ESIS: European chemical Substances Information System. ESIS is an IT System developed by the European Chemicals Bureau which provides a wide variety of information on chemicals, related to:

- EINECS (European Inventory of Existing Commercial chemical Substances)
- ELINCS (European List of Notified Chemical Substances)
- NLP (No-Longer Polymers)
- HPVCs (High Production Volume Chemicals) and LPVCs (Low Production Volume Chemicals), including EU producers / importers lists
- C&L (Classification and Labelling), Risk and Safety Phrases, Danger etc...

ESR: Existing Substances Regulation. This refers to Council Regulation (EEC) No. 793/93 on the evaluation and control of the risks of existing substances, which was one of the pieces of EU legislation replaced by REACH.

Evaluation: This refers to various different processes by which the accuracy and quality of registration information can be verified by ECHA or Competent Authorities. There are a number of different kinds of evaluation under REACH:

- All registration dossiers undergo an automated *completeness check* to ensure that all the relevant pieces of information are present. This completeness check will not assess the quality or suitability of the information.
- *Compliance checking*: This is a check of the quality of the information submitted by industry. It is undertaken by ECHA on a sample (minimum of 5%) of dossiers submitted at each tonnage level.
- *Testing Proposal Evaluation (Dossier Evaluation)*: For substances registered at the higher tonnage levels (≥100 tonnes/year) a proposal is made by the registrant detailing those animal tests they consider are required from the list of standard tests. ECHA evaluates these testing proposals to prevent unnecessary animal testing.
- *Substance evaluation*: This is undertaken by national Competent Authorities on substances that have been prioritised for potential regulatory action due to a risk based concern relating to their hazardous properties. A key regulatory outcome of evaluation could be the imposition of restrictions on the manufacture, supply or use of a substance. Substance evaluation may also lead to a substance being added to the priority list for authorisation or a proposal to change the classification and labelling.

Exposure scenario: An exposure scenario describes the conditions under which a substance (on its own or in a mixture) can be used safely. They are normally developed by manufacturers and importers as part of their registration dossier for substances which are hazardous and produced/imported in amounts of 10 tonnes per year or more. The exposure scenario covers all life cycle stages of a substance, from production to disposal. Exposure scenarios are forwarded along the supply chain as Annexes to safety data sheets. SDSs for mixtures may have exposure scenarios attached that refer to the mixture, or to the individual hazardous substances contained in the mixture, or both.

Forum, The: The Forum for Exchange of Information on Enforcement ('the Forum') is the principle mechanism for ensuring cooperation and information exchange across the European Union. The Forum is established by REACH, and Article 76(1) indicates that the Forum "shall coordinate the network of Member State authorities responsible for enforcement" of REACH. Article 77(4) allocates to the Forum the following specific tasks:

- spreading good practice and highlighting problems at Community level;
- proposing, co-ordinating and evaluating harmonised enforcement projects and joint inspections;
- co-ordinating exchange of inspectors;
- identifying enforcement strategies, as well as best practice in enforcement;
- developing working methods and tools of use to local inspectors;
- developing an electronic information exchange procedure;
- liaising with industry and other stakeholders, including relevant international organisations; and
- examining proposals for restrictions with a view to advising on enforceability.

The Forum is composed of representatives from all EU Member States and also the EEA-EFTA States (Iceland, Liechtenstein and Norway). More information is available on ECHA's website, including a list of Forum members and the documents adopted and published by the Forum. These include guidance on national enforcement strategies, and minimum criteria for REACH inspections

ICSMS: An electronic information exchange system used to exchange information between public authorities across the EU on various product safety issues. ICSMS consists of a closed and a public area. The closed area is for the use of market surveillance authorities, customs authorities and the EU Commission, and contains product information, test results, enforcement action taken, and so on. The

public area is for the use of consumers and manufacturers, and contains, for example, official information about hazardous products, as well as voluntary industry recalls.

Import: means the physical introduction into the customs territory of the Community.

Importer: An importer is any natural or legal person established within the Community who is responsible for import. This means that an importer under REACH is someone who imports from outside the EU. Goods obtained from another EU Member State, or an EEA-EFTA State (Iceland, Lichtenstein or Norway) are not considered to have been imported under REACH. The identification of the importer within a particular supply chain can be difficult, particularly when different freight handlers or customs agents are involved. It is the responsibility of industry to determine who in the supply chain should be designated as the importer in complex situations. This could be based on a range of factors, such as who is responsible for customs clearance or whether a company is simply employed by the actual importer to ship the goods.

Intermediate: REACH defines an intermediate as a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance(s). REACH recognises three types of intermediates:

- A 'non-isolated' intermediate means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place
- An 'on-site isolated' intermediate means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one or more legal entities
- A 'transported isolated' intermediate is an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites.

Joint registration: A group of companies formed together in a SIEF for the purpose of joint submission of their registrations.

Lead registrant: A company which submits registration information to ECHA on behalf of other members of a joint registration.

Manufacture: means production or extraction of substances in the natural state.

Manufacturer: A manufacturer is any natural or legal person established within the Community who manufactures a substance within the Community. Inspectors should note that this definition relates to the manufacture of a substance only, as opposed to the manufacture of a mixture or article. Consequently, formulators of mixtures or producers of articles are not regarded as manufacturers under REACH. See also Toll Manufacturer.

Mixture: A mixture or solution composed of two or more substances.

Monomer: means a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer forming reaction used for the particular process. See also Polymer.

Natural or legal person: A natural person is an individual person and includes self-employed people, sole traders or people in partnerships. A legal person is not a specific individual but something with a legal personality such as a limited company, trust, charity etc.

No data, no market: This refers to the core provision in REACH (Article 5) that substances (on their own, in mixtures or intentionally released from articles) must not be manufactured, imported or supplied if they have not been registered or pre-registered, where registration is required.

No longer polymers: are a group of substances that were once considered to be polymers (and so were not listed on EINECS) and were also not notified under the original NONS legislation. The introduction of a new polymer definition in 1993 in the new NONS legislation led to these substances losing their polymer status, however they remained exempt from notification under NONS. To qualify as a no-longer polymer (NLP) a substance must have been on the market between September 18th 1981 and October 31st 1993 (inclusive) and satisfy the requirement that they were considered polymers under the reporting rules for EINECS, but were no longer considered polymers under the 7th Amendment Directive (92/32/EEC).

Notification: The submission of specific information to ECHA in accordance with a REACH requirement. REACH requires actors in the supply chain to submit the following types of notifications, under certain circumstances:

- Notification of a substance in an article
- Notification of classification and labelling
- Notification of substances for the purposes of product and process orientated research and development
- Notification by downstream user of use within the conditions of authorisation granted to an actor up his supply chain
- Notification of restart of use by downstream user

Notification may also refer to substances notified under the NONS Regulation.

Only representative (OR): Companies outside the EU that manufacture substances, formulate mixtures or produce articles cannot register chemicals themselves. However, they can (by mutual agreement) appoint an EU-based agent to fulfil, as their only representative, the obligations on EU-based importers regarding the registration of substances. When appointed, all the EU-based importers from the non-EU manufacturer covered by the OR agreement become downstream users. The only representative must also comply with all other obligations of importers under REACH.

PBT: Persistent, Bio-accumulative and Toxic. Annex XIII of REACH defines criteria for the identification of substances that are PBT and therefore very hazardous to the environment. PBTs meet the criteria for being substances of very high concern (SVHC) and may therefore be included in the candidate list and Annex XIV of REACH.

Phase-in and non phase-in substances: A phase-in substance (often referred to as an "existing" substance) is a substance which meets at least one of the following criteria:

- it is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS); or
- it was manufactured in the EU (including the newer Member States) at least once in the 15 years before REACH became law, but was not placed on the market by the manufacturer (provided the manufacturer has documentary evidence of this). For example, it was only manufactured for export, or for the manufacturer's own use; or
- it is a so-called 'no longer polymer' (again provided there is documentary evidence of this).

Non phase-in substances (often referred to as "new substances") are all other substances that do not meet the above criteria and which are not otherwise exempt from registration under REACH. Non phase-in substances are not eligible for pre-registration, and must therefore be registered in full before they can be manufactured or imported at or above one tonne per year.

Placing on the market: This means supplying or making available to a third party, whether in return for payment or free of charge. Import is specifically included in the definition and so is deemed to be placing on the market. Inspectors should note that the definition of placing on the market in REACH is different to a number of other European Directives and Regulations. This is because placing on the market is not limited to the first time the product is supplied or made available. Under REACH, placing on the market can occur at each and every stage in the supply chain.

Pre-registration: This refers to the submission of certain information to ECHA by potential registrants of a substance. Pre-registration is not compulsory under REACH but if a valid pre-registration is submitted, then registrants can delay the submission of their full registration to one of three phased deadlines (2010, 2013 or 2018 depending on tonnages manufactured / imported and the hazardous properties of the substance in question). The pre-registration period ran from 1 June 2008 to 1 December 2008 and so is now closed, with the exception that those manufacturing or importing a substance at or above 1 tonne per year *for the first time after 1 December 2008* can still pre-register, assuming that the relevant registration deadline itself has not yet passed. Only phase-in substances can be pre-registered.

Preparation: the previous term for a mixture (see Mixture).

Polymer: means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:

- a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;
- less than a simple weight majority of molecules of the same molecular weight.

In the context of this definition a 'monomer unit' means the reacted form of a monomer substance in a polymer. See also Monomer.

PPORD: Product and process orientated research and development. This refers to any scientific development related to product development or the further development of a substance, on its own, in mixtures or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance

RAPEX: The EU rapid alert system for all dangerous consumer products, with the exception of food, pharmaceutical and medical devices. It allows for the rapid exchange of information between Member States via central contact points and the Commission of measures taken to prevent or restrict the marketing or use of products posing a serious risk to the health and safety of consumers.

REACH: Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals.

REACH-IT: The central IT system maintained by ECHA, which used by ECHA, Member States competent authorities and industry to manage REACH processes and is the main portal for industry to submit information (e.g. registration dossiers, authorisation applications etc.) to ECHA

Registration: Registration is the submission to ECHA of a technical dossier of information and, if required, a chemical safety report, for a substance being manufactured in, or imported into, the European Union in quantities of one or more tonnes per year.

Registrant: Registrant means the manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance.

Restriction: means any condition for, or prohibition of, the manufacture, importation, supply or use of a substance (whether on its own, in a mixture or in an article)

RIPE: REACH Information Portal for Enforcement. To bypass the need to contact national Competent Authorities every time information from REACH-IT is required, ECHA have designed a secondary system known as RIPE. This will allow enforcing authorities to get direct access to much data held in REACH-IT – an estimated 80% of information available for their Member State. RIPE is a web-based, token-accessed system.

RMM: Risk Management Measures. These are measures describing the control strategy for a substance that reduce the emission and exposure to a substance, thereby reducing the risk to human health or the environment.

SDS: Safety data sheet (sometimes referred to as a MSDS, manufacturer's safety data sheet). A SDS is a document used to convey safety, health and environmental information about a substance or a mixture down the supply chain. Under REACH, suppliers of a substance or mixture classified as dangerous under CHIP (or hazardous under the CLP Regulation) must provide a safety data sheet to recipients. The SDS will contain information on the dangerous properties (hazards) of the substance or mixture, as well as information on safe handling and use, and what to do in emergencies. The SDS must be compiled in accordance with Annex II of REACH, which lays down prescriptive requirements for their format and content.

SME: means small and medium-sized enterprises as defined in the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises.

Substance: A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

Supplier: any manufacturer, importer, distributor or downstream user who places on the market a substance, mixture or article.

SVHC: Substance of Very High Concern. In general terms, SVHCs are substances that have hazardous properties with serious consequences, such as persistence in the environment, or carcinogenic, mutagenic or reprotoxic properties, or substances that present an equivalent level of concern to CMRs and PBT/vPvBs. If a substance meets certain criteria and is prioritised by REACH national Competent Authorities then it may be added to the candidate list of substances for authorisation (and from there, it may be drawn for inclusion in Annex XIV of REACH).

Third party representative: Although similar in name to an only representative, a third party representative serves a completely different purpose. These can be appointed to act on behalf of a

registering company so that the identity of the company remains undisclosed within discussions with other companies, either for commercial reasons or because the registrant does not have the expertise in house to submit the registration. The third party, however, does not take over responsibility for the REACH duties

Toll manufacturer: This is a particular type of manufacturer, usually producing a substance on the request of a second company. In terms of responsibility for a substance registration, it is likely that this would fall on the EU-based toll manufacturer, as they are responsible for the physical introduction of the substance to the EU, despite not being the licence holder / substance owner. See Manufacturer.

Tonnage threshold: Volume based criteria for different requirements under REACH, formulated as "X tonnes/year per manufacturer/importer". In addition, the tonnage threshold will affect registration deadlines for phase-in substances.

Use: this means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation.

vPvB: Very persistent and very bio-accumulative. Annex XIII of REACH defines criteria for the identification of substances that are vPvB and therefore very hazardous to the environment. vPvBs meet the criteria for being substances of very high concern (SVHC) and may therefore be included in the candidate list and Annex XIV of REACH.