Executive Summary

This report presents the Evaluation of Directive 2006/42/EC on Machinery, which was undertaken by Technopolis during 2016-2017. The focus is the 2006 Machinery Directive (MD), which is concerned with the free movement of machinery within the EU, and ensuring health safety of machinery users. The purpose was to review the performance of the MD and determine the extent to which it is fit for purpose, providing evidence and conclusions that might form the basis for future legislative initiatives. The study was asked to assess the relevance, effectiveness, coherence, efficiency and EU added value of the MD and to address 18 specific evaluation questions. The findings and conclusions presented are based on a programme of research and analyses that included a public consultation, targeted surveys, a programme of interviews, a literature review and an analysis of statistical databases and reports.

Relevance of the Directive - The study concluded that the objectives of the MD – facilitating free movement of machinery and ensuring health and safety – remain entirely relevant to market needs. The machinery sector continues to be an important part of the EU economy 30 years after the adoption of the original Directive, accounting for a significant proportion of production, employment and trade. Facilitating the free movement of machinery is a significant EU-wide concern and the great majority of stakeholders consulted for the study agreed that this was a very important objective. Most also agreed that the MD (in its concept and intentions) is an entirely appropriate response to this aim. However, there were over 3 million non-fatal and 3,700 fatal accidents in EU workplaces in 2013 (all sectors), with associated financial and social costs equating to 1-5% of GDP. Importantly, sectors and occupations of most relevance to machinery tend to have among the highest rates of injuries, making this an even more pressing issue. Nearly all stakeholders placed great importance on ensuring health and safety of machinery users, and a majority felt that the MD was an 'entirely appropriate' response.

The MD has also maintained its relevance over time, despite changes in technology and the business environment. New Approach Directives are limited to essential requirements, while the state of technology is determined by stakeholders through technical specifications. As such, the majority view of stakeholders is that the MD has coped well with change. Having said this, a significant minority believe new innovations may test the suitability of the MD and reduce its effectiveness going forward. This includes innovations in digitisation, robotics, software and autonomous control, as well as the increasing prevalence of e-trade, fulfilment houses and non-compliance from third countries.

Effectiveness of the Directive - The MD has successfully contributed towards its objectives by achieving a basic level of harmonisation in safety legislation and certification across Europe (facilitating trade) and by requiring conformity to EHSR (encouraging safe design and construction). A majority of respondents believed that the MD has had a positive impact on market efficiency, the effective operation of the market and a range of areas relating to health and safety. However, any impact on headline indicators (trade and accidents) is hard to determine, both because of difficulties in aligning the MD with specific sectors/occupations, and because of external factors (e.g. economic crisis) accompanying the application of the revised Directive. Perhaps more importantly, the MD (in broadly the same form) had already been in force for two decades, and any step change will have taken effect prior to the 2006 revision. The role of the *current* MD is rather to maintain these benefits.

The 2006 MD has now been fully and consistently transposed across Member States. However, there are concerns that discrepancies have arisen in the subsequent application and interpretation of requirements, and particularly in relation to monitoring and enforcement, where inadequacies may reduce incentives to comply and risk undermining wider intentions of protecting users and consumers.

The general stakeholder view is that all conformity assessment options offered through the MD are effective at protecting health and safety and facilitating the internal market – but there are drawbacks and barriers in each case. Third-party involvement is seen as more effective in ensuring protection for users, but also adds substantially to the costs and effort compared with self-certification options. There were also concerns about inconsistencies between Notified Bodies in undertaking assessments and in interpreting requirements. By comparison, the main drawbacks to self-assessment routes were seen to be the lack of reassurance that might otherwise be provided by third-party involvement, the effort and expertise required, and the lack of relevant standards to support self-certification. There were also real concerns about incorrect application of requirements during self-certification, reinforced by ineffective market surveillance providing little incentive to do more than the minimum.

Standards are an important component in translating the EHSR in the MD and - if given legal status as a European Harmonised Standard (EN) - can confer a presumption of conformity with requirements. Stakeholders held positive opinions as to the effectiveness of ENs in relation to the MD and would use these to comply unless there were strong reasons not to (e.g. there are gaps in the Type-C standards available, particularly for smaller volume products and those covered by Annex IV of the MD)

Market surveillance is carried out through inspections by the responsible authorities/agencies (MSAs) in each country, and is essential in identifying non-compliant products and enforcing appropriate corrective measures (removing from the market, applying penalties). MSA reports suggest the number of inspections related to machinery varies significantly between countries and from year to year. There is also significant variation in the extent to which these lead to a determination of non-compliance. In any case, market surveillance and enforcement for the MD is generally seen by all stakeholder groups as insufficient and ineffective and the vast majority believe that the number and frequency of inspections, as well as the likelihood of being inspected, are all currently too low. Suggested reasons for ineffective market surveillance included a lack of resources, a lack of cross-border cooperation, poor targeting of efforts, a lack of staff competence and an imbalanced focus on consumer products.

Efficiency of the Directive - The study explored the various processes triggered by the MD that would incur costs to stakeholders. Nearly all of these relate to the time and effort involved in different processes and are spread across several key actors. From the data available we have estimated the global cost incurred by all actors from the MD each year at €136m (with 90%+ incurred by industry).

The main category of direct benefits to flow from the Directive relates to improved well-being. For the manufacturing, construction and agriculture sectors combined, the number of fatal accidents decreased by 767 (-29%) and the number of non-fatal accidents dropped by 472,718 (-28%) between 2008 and 2013. Combining this with UK estimates of the costs, the study estimated the value (savings) from the reduction in accidents in machinery-related sectors at €401m per year.

Benefits in terms of market efficiency require a comparison between the costs incurred under the MD, and the likely costs without it. We asked businesses about the additional costs involved in supplying third countries, but the situation was complicated by the current MD providing a good basis for meeting other requirements with minimal cost and effort (perhaps ~2% of total costs to meet differing requirements and show conformity). We estimated that EU industry incurs costs of around €128 million per year from conformity assessments and inspections relating to the MD. Therefore, even a 2% increase for all businesses to operate in a second market would add €2-3 million to overall costs. The implications (for some) to enter *many* European markets would therefore be significant.

The main indirect benefits expected to flow from the MD include the wider macroeconomic benefits of a single internal market for machinery. However, the available data does not provide clear evidence of a significant change in relevant indicators at the time of the MD's revision. The number of enterprises and levels of employment, production value and intra-EU exports are broadly similar in 2013 or 2014 as they were in 2008. There will be other indirect benefits triggered by the MD. For instance, industry representatives pointed to the benefits from international recognition of the CE mark, the introduction of standardised procedures (saving time and money), and the reduced cost of self-certification options.

These results suggest that the global costs incurred as a result of the Directive (~€136m per annum) are far outweighed by the costs savings achieved from improved health and safety (~€401m per year). In addition, there are likely to be multi-million Euro savings being realised as a result of a single European market for machinery (e.g. through reduced costs relating to multiple conformity assessment and inspection requirements), even though this pre-dates the specific 2006 revision. The majority of respondents to the study felt that there had been an increase in the costs and burdens on businesses, users and authorities as a result of the MD. However, these were generally not felt to be substantial, and the majority view across most groups was that any additional costs were outweighed by the benefits. Only companies were more mixed in their assessment, which appears to be caused by a perceived reduction in benefits from having to compete against significant levels of non-compliance.

Few inefficiencies could be identified, but suggestions were put forward for simplifying or improving the MD more generally. Areas mentioned included: adapting the MD to fit with the New Legislative Framework; considering the suitability of the MD (and EHSR) for new areas; simplifying the risk assessment process; improving demarcations between types of machinery; improving convergence with other similar Directives; and taking additional action to increase and improve inspections.

Coherence of the Directive - One intention of the 2006 revision was that the borderline between the scope of the MD and other Directives would be redefined in order to provide greater legal certainty. Nevertheless, there are numerous similar Directives and Regulations with the potential for some (at least perceived) overlap with the MD. Indeed, while the study found that stakeholders were generally of the view that the MD fits well with other legislation, large numbers of contributors could point to overlaps or inconsistencies with other specific Directives or Regulations – particularly where the same product is covered in the scope of both. Over 30 other Directives and Regulations were mentioned as overlapping and/or having inconsistencies with the MD, the Low Voltage, Electromagnetic Compatibility, Pressure Equipment and Radio Equipment Directives. Unfortunately, respondents did not take up the opportunity to explain more specifically the nature of these overlaps or inconsistencies.

EU added value of the Directive – The MD provides a framework and establishes mandatory EHSR, but does not translate these into detailed requirements or processes. As such, the impact of the MD is more directly attributable to the activities of the standardisation bodies, Notified Bodies, market surveillance authorities and businesses that interpret and apply systems and processes that support and enable the Directive. While they currently support the MD, these systems of standardisation, conformity assessment and market surveillance would likely exist in some form anyway, regardless of the existence of the Directive – though not necessarily coordinated in the same way. There are also issues in trying to disentangle the implications of the MD from those incurred as a result of other pieces of legislation, or that would be incurred in any case without the Directive. Nevertheless, all stakeholders consulted through the study agreed that the MD added value (compared to what would be achieved in its absence) in terms of facilitating the internal market and ensuring the health and safety requirements of machinery. Importantly, 92% of respondents also believed that the MD reduced costs overall, compared to what might be the case otherwise (national legislation).