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Evaluation of Directive 2006/42/EC on Machinery

Final Report

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Abbreviations

A&I	Accident and Injury
AdCo	Administrative Cooperation (Group)
CAs	Competent Authorities
CCMC	CEN-CENELEC Management Centre
CE	European Conformity
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CEOC	International Confederation of Inspection and Certification Organisations
CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
CN	Combined Nomenclature
CPSC	Consumer Product Safety Commission
DGUV	German Statutory Accident Insurance
EC	European Commission
EEA	European Economic Area
EN	European Standard
EPO	European Patent Office
EHSR	Essential Health and Safety Requirements
ESAW	European Statistics on Accidents at Work
ESO	European Standardisation Organisation
EU-LFS	European Union Labour Force Survey
ETSI	European Telecommunications Standards Institute
FTE	Full-Time Equivalent
HAS	Harmonised Standards (database)
HASS/LASS	Home and Leisure Accident Surveillance System
HS	Harmonised Standard
ICSMS	Information and Communication System for Market Surveillance
IDB	Injury Database
IFIA/	International Federation of Inspection Agencies
IEC	International Electrotechnical Commission
ISO	International Organisation for Standardization
JA	Joint Action
MD	Machinery Directive
MS	Member State
MSA	Market Surveillance Authorities / Agencies
NACE	(European) Classification of Economic Activities
NANDO	New Approach Notified and Designated Organisations (Database)
NB	Notified Body
NB-M	European Coordination of Notified Bodies for Machinery
NIM	National Implementing Measures
NSB	National Standards Body
OJ	Official Journal
PRODCOM	Community Production (database)
RAPEX	Rapid Alert System for Dangerous Non-Food Products
RIDDOR	Reporting Injuries, Diseases and Dangerous Occurrences Regulation (database)
TC	Technical Committee
WG	Working Group

Country Codes: Austria (AT), Belgium (BE), Bulgaria (BG), Cyprus (CY), Czech Republic (CZ), Germany (DE), Denmark (DK), Estonia (EE), Spain (ES), France (FR), Finland (FI), Greece (GR), Croatia (HR), Hungary (HU), Italy (IT), Ireland (IE), Luxembourg (LU), Lithuania (LT), Latvia (LV), Malta (MT), Netherlands (NL), Portugal (PT), Poland (PL), Romania (RO), Sweden (SE), Slovakia (SK), Slovenia (SI), United Kingdom (UK), Iceland (IS), Liechtenstein (LI), Norway (NO), Switzerland (CH), Turkey (TK).

Executive Summary

This report

This report presents the Evaluation of Directive 2006/42/EC on Machinery. It was commissioned by EC Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW), and undertaken by a consortium led by Technopolis Group over an 18-month period during 2016-2017. The findings and conclusions are based on a programme of research and analyses, which included a public consultation, a series of targeted consultation surveys, a programme of interviews, a review of relevant documentation and an analysis of statistical databases and reports.

Scope of the evaluation

The focus of the evaluation is the 2006 Machinery Directive (MD), which is concerned with the free movement of machinery within the EU internal market, and with ensuring health safety of users of machinery. It is in fact the latest revision to a much earlier Directive (89/392/EEC) adopted in 1989.

The purpose of the evaluation is to review the performance of the Directive and to determine the extent to which it is fit for purpose, providing evidence and conclusions that might form the basis for possible future legislative initiatives. In particular, the study is asked to assess the extent to which the Directive has met its twin objectives of (i) guaranteeing the free movement of relevant machinery within the Single Market, and (ii) ensuring a high level of safety and protection for machinery users (workers and consumers). To this end, the aims were to assess the relevance, effectiveness, coherence, efficiency and EU added value of the Directive, by addressing 18 specific evaluation questions. The evaluation covers the functioning of the Directive, including the processes involved in transposing, implementing and enforcing it. It covers all relevant product categories and 33 countries (EU28, EFTA and Turkey) and focuses on the period from 2010 (after the deadline for application of the MD).

Relevance of the Directive

The two objectives of the Directive – facilitating free movement of machinery and ensuring health and safety – **remain entirely relevant to market needs** (manufacturers and users).

The machinery sector continues to be an important part of the EU economy 30 years after the adoption of the original Directive, accounting for 4% of all manufacturing businesses, 9% of all manufacturing production (value) and 10% of employment in the manufacturing sector. Its importance in terms of trade is also significant, with machinery accounting for nearly one-quarter of the value of all EU exports in 2015, and 60% of this trade occurring between Member States. Facilitating the free movement of machinery is therefore a significant EU-wide concern. The great majority of stakeholders consulted for the study also agree that ensuring free movement of machinery is a very important objective, providing a strong indication that this is of high relevance to the needs and concerns of EU stakeholders, with widespread relevance both to the machinery market and amongst users. The vast majority also agreed that the Directive (at least in its concept and intentions) is an entirely appropriate response to the aim of ensuring free movement of machinery.

In relation to ensuring health and safety, despite a downward trend in the number of accidents at work (both in terms of absolute numbers and per 100,000 employees), there were still over 3 million non-fatal accidents and nearly 3,700 fatal accidents in EU workplaces in 2013 (all sectors). This implies that *on average* most people will have an accident at work during their lifetime causing more than three days of absence, or death, making this a significant and widespread issue. There are sizeable financial and other (social) costs of these accidents (e.g. productivity loss, healthcare, reduced quality of life, administration), which have been calculated in different countries as equating to 1-5% of GDP annually. Importantly, those sectors and occupations that are most relevant to machinery (and the Directive) tend to have some of the highest rates of injuries (e.g. the Manufacturing, Construction and Agriculture sectors combined accounted for 51% and 38% of all fatal and non-fatal accidents respectively in 2013), making this an even more pressing issue for this sector. Nearly all stakeholders consulted through the study placed great importance on ensuring a high level of health and safety for users of machinery, providing a strong indication that this objective is of high relevance to the needs

and concerns of EU stakeholders. The majority also felt that the Directive (its scope and provisions) was an 'entirely appropriate' response to addressing this aim.

The Directive has maintained its relevance, despite changes in technology and the business environment. It has undergone several iterations since 1989, adding or revising elements, including in its scope and requirements. However, these changes have been to improve clarity, adjust coverage of pre-existing machinery (and address associated risks), or reflect changes in the perceived relevance / importance of certain aspects of health and safety. They have not come about as a reaction to shifts in technology or the market. This is unsurprising, given that New Approach Directives (including the MD) are limited to essential requirements ("principles"), while the state of technology (state of the art) is then determined by stakeholders through technical specifications. As such, the majority view of stakeholders is that the MD copes well with change. Having said this, a significant minority of those consulted have highlighted that specific **new innovations may test the suitability of the Directive** and reduce its effectiveness going forward. This includes innovations in the areas of digitisation, robotics, software and autonomous control, as well as the increasing prevalence of e-trade, fulfilment houses and (un-checked) non-compliance of products from third countries.

Most stakeholders believe the rate and extent of innovation in the machinery sector has increased over the past decade, but the link between this and the Machinery Directive (specifically) is less clear. This is because **the Directive has acted as both an enabler and barrier to innovation** in the sector: positively influencing innovation through the facilitation of trade, support for technology transfer and encouragement of innovative safety features, tools and techniques; while at the same time reducing the rate of innovation by adding to the cost or complexity of introducing new technology.

Effectiveness of the Directive

The 2006 Directive has now been **fully and consistently transposed** across Member States. The Commission monitors and enforces the proper transposition of Directives and has opened a number of infringement procedures against Members States in relation to the Machinery Directive. However, these were all resolved at the first stage (letter of formal notice), suggesting that they were either invalid or had been rectified, and no further infringement procedures have since been instigated.

There are, however, concerns that **discrepancies have arisen in the subsequent application and interpretation of requirements** through some of the supporting actions and procedures. There are certain aspects of the "system" that are generally considered consistent across Europe (the initial transposition into law, the appointment of Notified Bodies, the conformity assessment options available, and the fulfilment of requirements not to impede the movement of compliant machinery). However, at the same time, there are other areas generally considered not to have been fully or consistently applied, **all of which relate to the monitoring and enforcement of the Directive** (the number of surveillance activities, the approach taken to determining compliance, the measures to withdraw or prohibit machinery, and the establishment of effective and proportionate penalties for infringements). Inadequacies here may reduce incentives to comply with the Directive, and risk undermining the wider intentions of the Directive in terms of protecting users and consumers.

The Directive has **successfully contributed towards its overarching objectives** by achieving a basic level of harmonisation in safety legislation and certification across Europe (facilitating trade) and by requiring conformity to essential health and safety (EHSR) requirements (encouraging safe design and construction of machinery). However, any impact on headline indicators (value / volume of intra-EU trade and machinery-related accidents) is hard to determine, both because of difficulties in aligning the Directive with specific sectors and occupations, and because of significant external factors (particularly the economic crisis) accompanying the application of the revised Directive (which had to be applied in Member States from the end of 2009). Perhaps more importantly, the Directive (in broadly the same form) had already been in force for two decades, and any step change in terms of reduced barriers to trade or increased health and safety protection will have already taken effect prior to the 2006 revision. The role of the current Directive is rather to maintain these benefits through **continuing to facilitate trade and ensure high levels of safety**.

However, a majority of respondents to the study consultations believed that the MD generally (not just the current revision) has had a positive impact on market efficiency and the effective operation of the internal market (the range of products available, turnover / profitability, competitiveness, volume / value of trade), and overall, three-quarters of stakeholders believe it has largely or entirely achieved its objective of ensuring an effectively operating internal market for machinery. Similarly, a majority of respondents believed the MD (generally) has had a positive impact on a range of areas relating to health and safety protection for consumers and users. For instance, most believe it has had a positive impact on the quality of machinery, information on safe operation, user confidence, the number and severity of accidents and injuries, the number of un-safe machines and more generally on the level of safety and protection for users. As such, nearly three-quarters suggested that the Directive had largely or entirely achieved its objective of protecting the health and safety of consumers and users.

Feeding this analysis of the achievement of overall objectives, the study assessed the effectiveness of specific procedures and activities that are integral to the Directive achieving its ambitions.

It is not possible (or even appropriate) to compare the effectiveness of conformity options through assessing differences in resulting non-compliance or accident and injury data. The general stakeholder view, however, is that **all conformity assessment options offered through the MD are effective** at both protecting health and safety and facilitating the internal market – **but there are drawbacks and barriers** to use in each case. Third-party involvement is seen as more effective in terms of ensuring protection for users, but also adds substantially to the costs and / or effort involved, when compared with self-certification options. There were also concerns raised about inconsistencies between Notified Bodies in undertaking assessments and in interpreting requirements, as well as a perceived decline in the knowledge and experience of particular machinery within these organisations, with possible implications for the effectiveness of the assessments undertaken. By comparison, the main drawbacks to self-assessment routes were seen to be the lack of reassurance and protection that might otherwise be provided by third-party involvement (which customers might expect/demand), the effort and expertise required internally to undertake the process, and the lack of relevant harmonised standards to support self-certification. There were also real concerns amongst stakeholders as to the extent of incorrect application of requirements during self-certification (intentional or not), reinforced by ineffective market surveillance that provides little incentive to do more than the bare minimum.

Standards are an important component in 'translating' the EHSR set out in the MD and - if given legal status as a European Harmonised Standard (EN) - can confer a presumption of conformity with one or more of these requirements. In effect, this means that by following the requirements of a transposed harmonised standard, a designer knows that their product will comply with the parts of the MD applying to the product, while also saving time in assessing risks and adopting strategies for safety. **Stakeholders held largely positive opinions as to the effectiveness of European Harmonised Standards** in relation to the MD (their quality and usability, how well they explain rules, guidelines and definitions, and in relation to the clarity over which ENs can be used in particular cases). These standards are also seen as being readily available, officially / widely recognised and well-perceived (by NBs, customers and other markets), well-aligned with requirements and reviewed regularly for possible update, as well as generally being an efficient means to comply with the MD. Therefore, European standards generally will be used to comply with the Directive, unless there are strong reasons not to (e.g. the specific requirements of customers / target markets, or a lack of coverage of existing ENs in the relevant area). On the latter point, it is recognised that **there are some gaps in the Type-C standards available** for machinery (these provide specifications for a given category of machinery), particularly for some smaller volume products, as well as those covered by Annex IV of the Directive. Most commonly, stakeholders suggested that there were missing standards relating to automated machines and vehicles; collaborative robots/systems; assembly machines and systems; additive manufacturing; interchangeable equipment; partly completed machines; wind turbines; food machines; metal working/bending; and risk assessment procedures.

Market surveillance is carried out through inspections by the responsible authorities/agencies (MSAs) in each Member State, and is essential in identifying non-compliant products and enforcing appropriate corrective measures (removing products from the market, applying penalties). MSA

reports suggest the **number of inspections related to machinery varies significantly** between countries (ranging from 50 to 500+) and from year to year. There is also significant variation across Member States in the extent to which inspections lead to a determination of non-compliance – for example 6% in Austria, compared with 79% in Denmark. Countries also differ in their approaches to rectifying measures, with some focusing mainly on voluntary measures, and others employing only restrictive measures and sanctions or penalties in the case of non-compliance.

In any case, **market surveillance and enforcement for the MD is generally seen as insufficient and ineffective**. When asked about the overall effectiveness of national authorities in monitoring manufacturers' adherence to the requirements of the MD, nearly three-quarters of stakeholders consulted rated these as having limited or no effectiveness. In addition, the vast majority believe that the number and frequency of inspections, as well as the likelihood of being inspected, were all currently too low. Tellingly, even a majority of national authorities believe that the likelihood of a company being inspected is too low, while the number of products never assessed is too large. To back this up, around three-quarters of businesses consulted for this study had not been subject to a machinery-related inspection in the past five years, while around half reported that none of their relevant products had ever been inspected. The main problems and barriers to the effective identification and removal of non-compliant machinery put forward by stakeholders included a lack of resources and funding, as well as a lack of cross-border cooperation, poor targeting of efforts, a lack of staff knowledge/competence and an imbalanced focus on consumer products.

Data from the RAPEX system (notification system for non-compliant products posing a serious risk) suggest that the **incidence of non-compliant products in the machinery sector is relatively low** (1.2% of all notifications 2005-15). However, since a 'professional product' option was added in 2013, the machinery sector has accounted for up to one-quarter of all new notifications. In addition, the notification system is somewhat dependent on the level of market surveillance and inspection. Therefore, given the apparent 'underperformance' of the surveillance system, **the statistics currently reported are likely to under-represent the true extent of non-compliance**.

In the analysis of the Directive's effectiveness, a number of **issues and barriers to the effective application** of the Directive have been identified. These include:

- Incomplete or inconsistent application of monitoring and enforcement procedures by Member States, including in the number of market surveillance activities undertaken, the approach taken to determining compliance, the measures taken to withdraw or prohibit machinery, and the establishment of effective, proportionate and dissuasive penalties for infringements.
- Inconsistencies in the interpretation of requirements and the assessments undertaken by Notified Bodies, as well as an apparent decline in their knowledge and experience of specific products.
- Incorrect application of self-certification requirements, combined with a lack of incentive to do more than the bare minimum (caused by an ineffective market surveillance system).
- Under-representation of various actor groups (users, regulators, national authorities) in standards development processes, which are often dominated by a small number of larger multi-nationals.
- Gaps in the portfolio of Type-C standards available, particularly for some smaller volume products, as well as for products covered by Annex IV of the Directive.
- Insufficient number and frequency of machinery-related inspections by market surveillance authorities, as well as a lack of cross-border cooperation between these bodies, poor targeting of efforts, a lack of staff knowledge/competence and an imbalanced focus on consumer products.

Efficiency of the Directive

The study explored the various processes triggered by the Machinery Directive, including the main specific actions involved in its implementation and application, that would incur **costs to stakeholders**. This showed that nearly all of the costs relate to the time and effort involved in different processes, and that these are spread across several key actors. The majority of data necessary for assessing these costs were not readily available, and so the study had to rely predominantly on

assessments from the actors involved. So as to not overburden stakeholders, we took a pragmatic approach: identifying a handful of broad and significant activities for each group and asking them to provide estimated averages. Nevertheless, few respondents were willing or able to provide the quantitative data requested and we have had to draw conclusions from a small number of data points in many cases. Using this base data, we have extrapolated to the full population of actors in each group and arrived at an approximate estimation of **the global cost incurred by all actors from the Machinery Directive each year: €136m** (with 90%+ incurred by industry).

On the other side of the coin, the main categories of **direct benefits** to flow from the Directive relate to improved well-being and market efficiency. The benefits to well-being (i.e. improved health and safety) have already been introduced above. For the Manufacturing, Construction and Agriculture sectors combined (those of highest relevance to machinery), 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 (figures adjusted for changes in employment in these sectors during the period). Combining this information with UK Health and Safety Executive estimates of the financial and non-financial costs incurred allowed the study to monetise the value (savings) from the reduction in relevant accidents during the period. This results in **total cost savings from a reduction in accidents in machinery-related sectors during the period of €401m per year** (€2.01b for the full five-year period, split between €1.53b for fatal and €0.47b for non-fatal accidents avoided).

Benefits in terms of market efficiency require a comparison between the costs incurred under the Directive, and the likely costs that would be incurred without it (i.e. the cost savings triggered by the Directive – for example through reduced requirements to enter other EU markets). Given the length of time that *a* Machinery Directive has been in place, it is difficult to make such a direct comparison, or expect others to do so, not least because the 28 national regimes would have evolved somewhat over the past 30 years, even if the Directive had not existed. We did ask businesses about the additional costs involved in supplying third countries – but the situation was complicated by the current MD (and associated ENs) often providing a good basis for meeting requirements in other countries with minimal cost and effort (perhaps ~2% of total costs to meet differing requirements and show conformity). The US provides an interesting example, because there is little compatibility with the European regime, and as a result several individuals quoted **additional costs of 5-10% for complying with this second system**. We estimated that EU industry currently incurs costs of around €128 million per year as a result of conformity assessments and inspections relating to the (single) European Directive. Therefore, even a 2% increase (for all businesses to operate in a second market) would add €2-3 million to overall costs. The implications (at least for some businesses) of additional requirements to enter many European markets would therefore be significant.

The main categories of **indirect benefits** expected to flow from the Directive include the wider macroeconomic benefits of a single internal market for machinery. However, while the sector has seen increases in production values, employment and volume/value of trade since the application of the Directive, a dip in statistics in 2009 (brought on by the economic crisis) creates a misleading picture. Using the more 'typical' base year of 2008 reveals a more stagnant situation, with the number of enterprises and levels of employment, production value and intra-EU exports broadly similar in 2013 or 2014 to before the application of the Directive. That is not to say that there have not been macroeconomic benefits from the Directive, just that the **available data does not provide clear evidence of a significant change in relevant indicators** at the time of the Directive's revision. There will be other indirect benefits triggered by the MD, which the evaluation has sought to identify. Indeed, we found that nearly all industry representatives claim that the MD has brought other benefits to companies, including through international recognition of the CE mark, the introduction of standardised procedures (saving time and money), and the reduced cost of self-certification options.

These various results suggest that the **global costs incurred** as a result of the Directive (estimated at some €136m per annum) **are far outweighed by the costs savings achieved** from improved health and safety (estimated at around €401m per year as a result of declining numbers of accidents and injuries). 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 consultation for the study did reveal that a majority of respondents felt that there had been an increase in the costs and burdens on businesses, users and authorities as a result of the Directive. However, these additional costs were generally not felt to be substantial, and the majority view across most groups was that, overall, any additional costs were outweighed by the benefits of the Directive. Only companies were more mixed in their assessment of costs and benefits to themselves specifically, and this appears to be mainly caused by the perceived reduction in benefits from having to compete against significant levels of non-compliance (caused by insufficient market surveillance and enforcement).

Some respondents to our consultations did highlight **disproportionate costs** arising from time and resources spent on documentation – and in particular the need to translate documentation into the language of destination, or the obligation to provide the declaration of conformity and the operating instructions in paper form with the product. But otherwise, few inefficiencies could be identified. Beyond this, a number of other **suggestions were put forward for simplifying or otherwise improving the Directive more generally moving forwards** (possibly as part of any future revision). Key areas mentioned included: adapting the Directive to fit with the New Legislative Framework (especially to provide a common framework for market surveillance); considering further the suitability of the current Directive (and EHSR) for new areas of development in machinery (particularly around digitisation and robots, as well as cyber security and the risk of hacking in relation to product safety); simplifying the risk assessment process; improving definitions of / demarcations between particular types of machinery; improving convergence with other similar Directives (at least in terms of terminology and definitions); and – most commonly – taking additional action to increase and improve inspection regimes, so as to better ensure widespread compliance with the Directive and the realisation of benefits for those that comply.

Coherence of the Directive

One intention of the 2006 revision was that the borderline between the scope of the Machinery Directive and other Directives, in particular the Low Voltage and Lifts 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 Machinery Directive. Indeed, while the study found that stakeholders were generally of the view that **the Directive fits well with other national, EU and international 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, including most commonly 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 the overlaps or inconsistencies were between the MD and the other legislation that they pointed to.

European added value of the Directive

As has been mentioned, the Directive provides a framework and establishes the 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 Machinery Directive 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 Directive reduced costs overall, compared to what might be the case otherwise (national legislation).

1 Introduction

This Final Report represents the final deliverable (D5) of the Evaluation of Directive 2006/42/EC on Machinery, which was commissioned by the European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW), and undertaken by Technopolis Group and VVA on behalf of a Framework Contract consortium.

It is intended to present a clear and sound analysis of findings, as well as factually based conclusions to the evaluation, drawing on a range of primary and secondary data sources. These include:

- A public consultation survey of 342 respondents from all relevant stakeholder groups
- A series of targeted consultation surveys with 98 respondents from national authorities, notified bodies, industry and industry associations, with questions that were tailored to the specific experiences and perspective of the group concerned
- A programme of 44 in-depth interviews with individuals from selected organisations in each of the main stakeholder groups, focusing on key areas of interest in greater detail
- A review of relevant documentation, including Regulations, Directives, Communications, Notices and Working Documents, as well as internal notes and minutes, reports from other studies, reviews and monitoring activities
- Analysis of relevant statistical databases, including Eurostat Business Statistics, ComExt, RAPEX, ESAW, EU LFS, NANDO and TRIS
- Other sources, including various websites and web-based portals

In line with schema set out in the original task specifications, this report is structured as follows:

- **Section 1** provides an **introduction**
- **Section 2** provides a **background to the intervention** (the Machinery Directive) that is the focus of the evaluation, including details of its origins, rationale and objectives, as well as its main provisions. This section concludes with a diagrammatic presentation of the intervention logic.
- **Section 3** provides a brief overview of the evaluation requirements, including the context for the study, its scope, purpose and objectives, and the specific **evaluation questions** to be addressed
- **Section 4** outlines the **research methodology** employed in undertaking the study
- **Section 5** presents **answers to the evaluation questions**, organised by evaluation criteria (context, relevance, effectiveness, efficiency, coherence and European added value)
- **Section 6** presents the main findings and **conclusions** against each criteria

Other supporting information is presented as **appendices** and referenced in the main body of the report. This includes:

- **Appendix A** – On the methods used in preparing the evaluation, including information on the main data sources used
- **Appendix B** – Providing details of the stakeholder consultation activities, including the strategy and process employed, the number and type of participants responding and the results obtained
- **Appendix C** – Other supporting information (tables and text referenced in the report)

2 Background to the Machinery Directive

A first step in any evaluation is to understand the background, context and current situation of the intervention under examination. This section therefore briefly introduces the Machinery Directive (MD), setting out its origins and objectives, its key provisions and details of its implementation and application. This introduction is intended to provide an overview of the main features of the intervention, which are then referred to later in the report in answering the evaluation questions.

2.1 Origins, rationale and objectives of the Directive

The **Directive 2006/42/EC on Machinery** was adopted on 17 May 2006. It is concerned with the free movement of machinery in the EU internal market and ensuring safety for users of machinery.

The 2006 Directive (henceforth "Machinery Directive" or "MD") was in fact the latest revision to a much earlier Directive. The first Directive (89/392/EEC) was adopted in 1989, before being amended in 1991 (91/368/EEC) and in 1993 (93/44/EEC). A second version (98/37/EC) consolidated these amendments. A third revision in 2006 (2006/42/EC) represented a comprehensive amendment and recasting, intended to extend the scope, improve clarity, remove acknowledged flaws, and provide an additional route to conformity assessment for some products. This was then amended slightly in 2009 (2009/127/EC) to include machinery with pesticide applications (applicable from 2011).

The original 1987 proposal for a Machinery Directive (COM/1987/564/FINAL) provides insight into the **rationale for the Directive**. This covers four main points relating to safety and trade, namely:

- That EU Member States have a responsibility to ensure the health and safety of machinery users

  "...Member States have the responsibility of ensuring the health and safety on their territory of their people ... in particular workers, notably in relation to hazards arising out of the use of machinery..."

- That accidents from using machinery have a social cost, which could be reduced through safer design, construction, installation and maintenance

  "...the social cost of the large number of accidents caused directly by the use of machinery can be reduced by inherently safe design and construction... and by proper installation and maintenance..."

- That the machinery sector is an important component of the EU economy

  "...the machinery sector is an important part of the engineering industry and is one of the industrial mainstays of the Community economy..."

- That a lack of harmonisation in machinery safety legislation and certification is a barrier to trade

  "...in Member States, the legislative systems regarding accident prevention are very different... the relevant compulsory provisions, frequently supplemented by de facto mandatory technical specifications and/or voluntary standards, do not necessarily lead to different levels of health and safety, but nevertheless, owing to their disparities, constitute barriers to trade... Conformity certification and national certification systems for machinery differ considerably"

Consequently, the resulting Directive aimed to guarantee a high level of confidence and ensure the twin **objectives** of: free movement of machinery within the internal market; and a high level of protection for users (workers/consumers) and other exposed persons. The 2009 amendment added a 'protection of the environment' objective (though limited to machinery used in pesticide applications).

No specific or quantified estimates were published of the **potential impact** (i.e. the expected costs and benefits) of the original Directive, or of subsequent revisions. Indeed, the proposal for the 2006 revision (COM/2000/899/final) was clear in stating that carrying out a proper cost-benefit analysis of the revision for every specific situation is virtually impossible, given the variety of possible situations.

Nevertheless, based on feedback from stakeholders, as well as the findings from an external study, the proposal for the 2006 revision concluded that opinions on the proposed revision were positive; that the revision improved upon a number of points whose interpretation had caused uncertainty; that it

represented significant progress in terms of safety at work; and that savings resulting from the additional level of detail in the new text would offset any expenditures required by a few points of detail.

Regarding the specific impact on enterprises specifically, the proposal only considered the implications of the *revision*, rather than the resulting Directive more generally: "Enterprises manufacturing products referred to by this proposal already have to apply Directive 98/37/EC; consequently, they will not have to take any specific measures in order to conform to the new text. The proposal will have no major economic impact on employment, investment or the creation of new enterprises. The competitiveness of firms is likely to be slightly increased by the application of a simpler text which allows fewer diverging interpretations by the parties concerned" (COM/2000/899/Final – Impact assessment).

2.2 Summary of the main provisions of the Directive

This sub-section presents a summary overview of the key provisions of the Directive, including basic information on its scope, implementation, application and associated processes and procedures. It is not intended to be exhaustive, but rather to introduce the most important aspects of the Directive.

2.2.1 Scope and exclusions (Articles 1-3)

The Directive applies to various machinery and equipment, covering machinery with both consumer and professional / industrial applications. This includes: machinery; interchangeable equipment; safety components; lifting accessories; chains, ropes and webbing; removable mechanical transmission devices; and partly completed machinery. As mentioned above, the 2009 amendment meant that the Directive now also covers machinery used for pesticide / herbicide applications. Certain types of machinery (listed in Annex IV to the Directive) are considered to present higher risks, and therefore must be subject to more stringent conformity assessment procedures, usually involving a third party. Annex IV products include many types of woodworking machinery, chainsaws, presses for the working of cold metal, manually loaded and unloaded compression moulding machines for plastics and rubber, certain types of lifting equipment, as well as various safety components, among others.

There are **various exclusions** for machinery already covered by other more specific Directives. For example, machinery that is exempted includes weapons (e.g. firearms); transport vehicles (e.g. tractors and motor vehicles); machinery designed for use in fairgrounds and amusement parks; nuclear machinery; machinery designed for the military and / or police; mine-winding gear; seagoing vessels and mobile offshore units (including machinery installed on board). However, the MD may apply alongside other Directives where there are hazards that the more specific Directive does not cover. Products that fall under both the Machinery and Low Voltage Directives are excluded from the former, on the grounds that the risks are mainly electrical (e.g. for electric / electronic products). There are also certain exclusions for older machinery (first used in the EEA <1995), unless its original specification is changed. However, old machinery brought into the EU after 1995 must comply.

2.2.2 Essential health and safety requirements (Annex I)

Annex I to the Directive sets out essential health and safety requirements (EHSR) relating to the design and construction of machinery. It is organised into several sections, with the first being general in scope and applicable to all kinds of machinery, and further sections referring to certain kinds of more specific hazards. These EHSR should be satisfied in order to ensure that machinery is safe.

In line with the New Approach and New Legislative Framework[1], the Directive only defines mandatory EHSR (including appropriate conformity assessment procedures) to protect public goals of health and safety. It does not translate these requirements into detailed criteria for specific products. Instead, more detailed technical specifications are determined and agreed by stakeholders.

[1] http://ec.europa.eu/growth/single-market/goods/new-legislative-framework/

2.2.3 Standardisation and Harmonised Standards (Article 7)

To prove conformity to the EHSR of the Directive, manufacturers can make use of technical specifications (standards). Harmonised standards at the European level (EN) can support the application of the Directive by translating the EHSR into detailed requirements for certain types of products. These EN are then used to assess conformity and demonstrate compliance.

European Harmonised Standards are developed by European Standardisation Organisations (CEN-CENELEC or ETSI) in partnership with other stakeholders. Certain standards are also developed within the framework of the Vienna and Frankfurt (former Dresden) Agreements, whereby the development of international standards is given priority when these will meet European requirements (preventing duplication of effort); these are subsequently transposed/referred as EN. Harmonised standards are published in the Official Journal. Their use is voluntary, but machinery manufactured in conformity with an EN published in the Official Journal of the EU is presumed to comply with the EHSR of the Directive that are covered by that standard.

2.2.4 Conformity assessment, technical files and Notified Bodies (Articles 12 - 14)

The MD requires that manufacturers carry out a risk assessment for machinery they wish to place on the market / put into service, and to determine which EHSR of the Directive are applicable, and therefore which measures must be taken to certify compliance. The MD offers the choice of up to three different conformity assessment procedures, depending on the machinery in question and the availability of relevant harmonised standards (see Figure 1):

- Where a product is *not* covered by Annex IV of the Directive (i.e. considered to present lower risk), manufacturers should self-certify and employ the procedure for **assessment of conformity with internal checks** as per Annex VIII. This involves compiling a Technical File (see below)
- For higher risk machinery (listed in Annex IV of the Directive), the manufacturer can choose:
  - An **EC-type examination** by a Notified Body of the technical file and a representative product, as per the procedure set out in Annex IX of the Directive. The Notified Body examines the technical file and carries out other tests and inspections to ensure that the EHSR of the Directive have been satisfied, before issuing an EC-type examination certificate.
  - Approval by a Notified Body of a **full quality assurance** system (procedures in Annex X). This was a new option in the 2006 MD, and involves a Notified Body assessing / approving the quality assurance system (rather than a sample product) and monitoring its application.
  - In addition, if the manufacturer applies an EN (type C) that covers all applicable requirements of the Directive, the manufacturer can self-certify **conformity with internal checks** without recourse to a Notified Body (as per the option for non-Annex IV products, above).

Machinery manufacturers are therefore required to involve Notified Bodies in the assessment of higher-risk machines, with the Notified Body conducting conformity assessment against the relevant sections of the Directive. The EC-type conformity assessment involves a review of the relevant Technical File provided by the manufacturer and the inspection, measurement and testing of the device to determine whether the solutions adopted satisfy the EHSR. Under this procedure, there is also an obligation on the manufacturer to confirm (self-certify) that is design, manufacturing and inspection processes are appropriate. For the full QA procedure, the Notified Body will attend the manufacturer's premises to assess and approve the full quality assurance system - on paper and in operation - from design through to manufacture, testing and final inspection.[2]

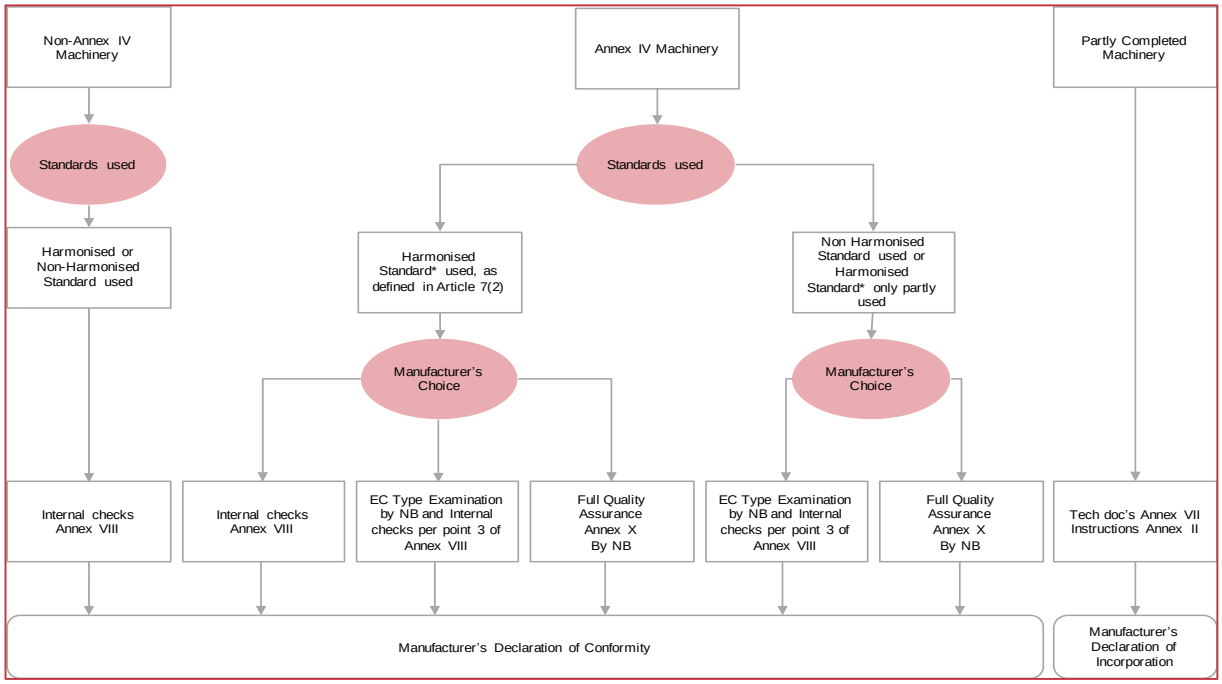
Member States should assess and appoint the Notified Bodies to carry out assessment of conformity, and notify other MS and the EC of these bodies and their scope (which procedures, which categories of machinery) for publication in the Official Journal. Member States shall also ensure that Notified

[2] There is a well-referenced explanation of the role of Notified Bodies in the conformity assessment process available on the web site of the UK Health and Safety Executive (http://www.hse.gov.uk/work-equipment-machinery/machinery-directive-conformity-assessment.htm).

Bodies are monitored regularly and comply with the necessary criteria (as set out in Annex XI of the Directive). In circumstances where manufacturers no longer meet the requirements of the Directive, Notified Bodies can suspend, withdraw or place restrictions on certificates that they have issued.

Technical Files are compiled by the manufacturer to demonstrate that machinery complies with the requirements of the MD. They should include (inter alia) descriptions / drawings of the machinery, proofs of conformity to EHSR, details of risk assessments undertaken, standards used, results of tests and instructions for use. These files have to be made available for inspection upon request (and as an integral part of the EC-type examination) to allow authorities to ascertain conformity with the EHSR.

Figure 1 Routes to conformity assessment



Source: Technopolis. *The Harmonised Standards referred to are those that give presumption of conformity (i.e. are published in the OJEU), and not other 'harmonised standards', so-called because they have been developed following a standardisation request (mandate) from the European Commission.

2.2.5 *Placing on the market / putting into service (Articles 5, 6, 16)*

Before placing machinery on the market / into service, a manufacturer should: carry out a risk assessment, ensure that it satisfies the EHSR of the Directive; carry out appropriate procedures for assessing conformity; ensure that the technical file is available; provide necessary information (instructions); draw up an EC declaration of conformity to accompany machinery; affix a CE marking. Member States should not prohibit, restrict or impede the placing on the market / putting into service of machinery which complies with the Directive (except in certain cases – see Article 11 below).

2.2.6 *Enforcement and penalties (Article 4)*

Market surveillance is considered essential for ensuring the proper and uniform application of the MD. Member States are required to take all appropriate measures to ensure that machinery may be placed on the market/put into service only if it satisfies the relevant provisions of the Directive, and should establish an authority to monitor the conformity of machinery with the provisions. They should also establish effective, proportionate and dissuasive penalties for infringements of MD provisions.

Market surveillance authorities (MSAs) are public bodies that monitor and, where appropriate, enforce the requirements of European product safety law, using their powers and enforcement tools to ensure that products likely to compromise health and / or safety are withdrawn from the market or have their availability restricted. Where non-compliance is found, the MSA will verify that corrective action

has been taken Different authorities enforce different aspects of product safety legislation. The MSAs will run a combination of reactive and pro-active investigations, with the former being triggered by complaints or accidents, while the latter may reflect concerns about the current status of knowledge with new technologies (e.g. lifts in tall wind turbine towers) or products that sit in the grey area between professional and consumer applications (e.g. chainsaws being used privately by consumers). An individual market surveillance activity may look quite similar to the work of a Notified Body, involved with the conformity assessment of specific product types, with the authority's experts reviewing the technical documentation on the one hand and organising testing of specific products on the other. The MSA also has a responsibility to alert users about any hazards identified to reduce the risk of injury or other damage. They are also required to notify the Commission where measures are taken to deal with products presenting serious risk, and communicate market surveillance findings to other member states through the RAPEX and ICSMS databases of market surveillance information and defective products.

2.2.7 Disputes, hazards and safeguards (Articles 9 - 11)

When an MS or the EC believes that a harmonised standard does not entirely satisfy the EHSR that it covers, it should bring this matter (formal objection) before the Standardisation Committee[3], which will deliver an opinion. The EC will then decide on the appropriate action to take (publish, not publish, publish with restriction, maintain, maintain with restriction, withdraw OJ reference). It may then take measures requiring MS to prohibit or restrict machinery presenting risks due to shortcomings of the standard.

Where an MS ascertains that relevant machinery bearing the CE marking is liable to compromise health and safety, it will take measures to withdraw such machinery from the market, prohibit it from being placed on the market, or restrict its movement. It will inform the EC and other MS of these measures and the type of non-conformity. The EC will then determine whether the measures were justified, and if necessary take action in relation to an EN (as set out above).

2.3 Transposition and implementation of the Directive

The Directive was published and entered into force in 2006. It was then to be adopted and published by all Member States by June 2008, and applied from December 2009. Member States are responsible for ensuring that the Directive is effectively enforced within their territories, and as such, are also responsible for market surveillance and penalties. They appoint competent authorities to monitor the implementation of the Directive and Notified Bodies to assess and certify compliance with the MD.

Member State transposition and implementation is explored further in the sections on effectiveness.

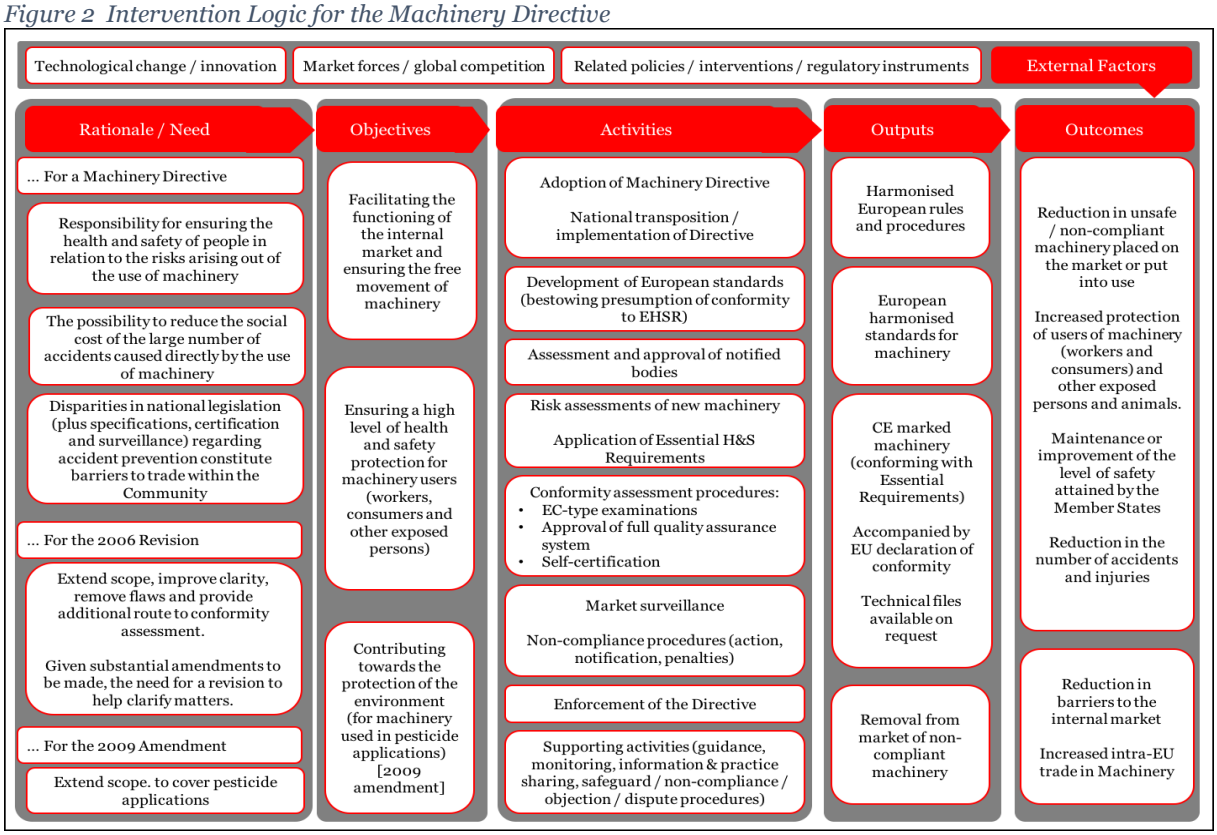
2.4 Defining the intervention logic for the Machinery Directive

The starting point for evaluating the Machinery Directive was an intervention logic model. This is a model of causality that presents the links between needs and objectives on the one hand, and the *intended* activities, outputs, and outcomes of the Directive on the other. Through this, it provides a visualised description that summarises how the intervention (the Directive) is expected to work, and forms a framework in which the achievements of the Directive can be assessed by the evaluation.

Building on the information contained within successive Machinery Directives (and their proposals), the study team developed an intervention logic for the Directive (see Figure 2). This shows the logical sequence and causal relationships between the Directive's rationale; its objectives; the activities undertaken; and the intended results (outputs) and changes (outcomes and impacts) that it was to realise. These achievements should in turn contribute towards addressing initial needs. The figure also shows other external factors (beyond the Directive's control) that may influence outcomes.

[3] Set up by the Regulation (EU) 1025/2012 on European standardisation

Figure 2 Intervention Logic for the Machinery Directive



Source: Technopolis

3 Evaluation requirements and questions

In September 2015, DG GROW Unit C.3 issued a request for services (and task specifications) for an evaluation of Directive 2006/42/EC on Machinery. The study would assess the performance of the Directive and its fitness for purpose, providing evidence and conclusions that might form the basis for possible future legislative initiatives from the Commission. In this section we outline the requirements for this evaluation, in terms of its objectives, its scope, and the specific questions it was to address.

Context

The Commission's 'vision for the internal market for industrial products'[4] noted that "stakeholders seem to be satisfied with the current Union rules on machinery… the Commission will however launch an evaluation of the Machinery Directive in 2015." On announcing the launch of the evaluation, the Commission stated further that the study could be considered as the very first step towards a possible revision of the Directive. The evaluation has also been linked to the REFIT (Regulatory Fitness and Performance) programme, which seeks to ensure that EU legislation remains fit for purpose and delivers intended results at lowest cost, and with minimum administrative burden.

Scope

The focus of the evaluation is the Directive 2006/42/EC on Machinery. It covers the functioning of the Directive, including the processes involved in proposing, adopting, transposing, implementing and enforcing it, as well as associated conformity assessment and monitoring procedures. It assesses performance in all relevant product categories, covering 33 countries (EU28, EFTA and Turkey) and focusing on the period from 2010 (i.e. subsequent to the deadline for application of the MD across Europe at the end of 2009), seeking to understand trends over this period wherever possible.

Purpose and objectives of the evaluation

The main purpose of the evaluation is to review the performance of the Machinery Directive and to determine the extent to which it is fit for purpose. In particular, it assesses the extent to which it has met its objectives of (i) guaranteeing the free movement of relevant machinery products within the Single Market, and (ii) ensuring a high level of safety and protection for machinery users (workers and consumers) and other exposed persons. To this end, the objectives of the evaluation were to assess:

- Relevance – the extent to which the Directive's objectives correspond to market and user needs
- Effectiveness – the extent to which the two objectives were achieved (and factors preventing this)
- Coherence – the extent to which the Directive is coherent with other legislation (i.e. whether it sets requirements that contradict other legislation), including other product Directives
- Efficiency – the extent to which the two objectives of the Directive were achieved at a reasonable cost (including compliance costs for manufacturers).
- EU added value – the extent to which the European Directive adds value compared to what could have been achieved at Member State level

In addition, as a REFIT evaluation, the study was expected to examine costs and benefits with a view to simplifying EU laws and reducing regulatory burdens. This placed an increased emphasis on the question of efficiency, as well as an additional focus on assessing (quantitatively) the regulatory and administrative costs and benefits, as well as aspects for simplification. Where appropriate, it is expected that REFIT evaluation findings will point to areas where there is potential to reduce inefficiencies, particularly in relation to regulatory burden, and to simplifying the intervention.

[4] COM(2014) 25 final

Evaluation questions

Shown below are the 18 evaluation questions (plus sub-questions) that were to be addressed by the evaluation, arranged under the main evaluation criteria introduced above[5]. Findings and conclusions presented later in this document are reported against these evaluation criteria and questions.

Context

1. What is the current size and structure of the machinery market in Europe, and how is it evolving?
    a. What is the size and structure of the machinery market in terms of producers and products, and how has this evolved?
    b. What is the size and structure of the machinery market in terms of consumption and intra- and extra- EU trade, and how has this evolved?
    c. What have been the extent, type and distribution of machinery-related health and safety incidents?
    d. What innovations have taken place during the time of the Directive's application?

Relevance of the Directive

2. To what extent do the two initial objectives of the Machinery Directive correspond to the current needs of the market, manufacturers and users?
    a. To what extent does the initial objective of 'facilitating the functioning of the internal market and the free circulation of products' correspond to current needs?
    b. To what extent does the initial objective of 'ensuring a high level of safety of machinery' correspond to current needs?
3. How (and to what extent) is the Directive (and the tools and mechanisms that it provides for) able to deal with innovations, new technologies and the changing business environment?
    a. How (and to what extent) is the Machinery Directive (including the essential Health and Safety requirements in Annex I) able to deal with innovation and new technologies?
    b. How (and to what extent) is the Machinery Directive able to deal with changes in the business environment (e.g. anticipated increases in extra-EU imports)?
    c. How is technological innovation influenced (positively/negatively) by the Directive?

Effectiveness of the Directive

4. What are the discrepancies between Member States in the interpretations of the requirements of the Directive, and what are the reasons for – and implications of – these discrepancies?
    a. Where are there discrepancies between Member States in the implementation of the Directive (e.g. in the rules for self-certification, inspections, scope and concepts, requirements for particular products, etc.)?
    b. What are the reasons for these discrepancies?
    c. What are the implications of these discrepancies (e.g. on costs, or on market behaviour)?
5. To what extent has the Machinery Directive been effective in contributing towards the achievement of its main objectives?
    a. To what extent has the Machinery Directive been effective in contributing towards 'an effectively operating internal market' for the products in its scope?
    b. To what extent has the Machinery Directive been effective in contributing towards 'protecting the health and safety of consumers and users (and where appropriate domestic animals or properties)' for the products in its scope?
    c. Have there been any particular barriers to the achievement of these objectives?
6. To what extent have the options of third party conformity assessment for Annex IV categories of machinery been effective?
    a. What are the reasons for choosing each of these options?
7. To what extent has the procedure for assessment of conformity with internal checks been effective in providing the highest degree of health and safety for consumers and users?

[5] The initial list of evaluation questions set out within the task specifications were developed slightly during the inception phase in order to better capture and express the full requirements (e.g. to cover additional questions and issues raised within the specifications). The amendments were set out and approved as part of the evaluation's Inception Report.

8. How effective was the development and use of European harmonised standards for the Directive?
    a. How effective was the development of European harmonised standards for the Directive?
    b. How effective was the take-up and use of European harmonised standards in relation to the Directive (giving particular attention to take up to pursue conformity assessment with internal checks for Annex IV products)
    c. What is the position of European harmonised standards for the Directive versus other technical specifications, national and international?
9. How effective are current mechanisms for identification of non-compliant products and their removal from market, and what are the barriers to effective enforcement?
    a. How effective are MS authorities in identifying non-compliant products?
    b. How effective are MS authorities in removing non-compliant products from the market?
    c. What are the barriers to effective market surveillance and enforcement?
    d. What are examples of good and bad practice in identifying and taking non-compliant products off the market (efficiently)?
10. What are the enablers and barriers to the effective / optimal application of the Directive?
    a. What has enabled effective application of the Machinery Directive?
    b. What examples are there of good practice in the application of the Machinery Directive?
    c. What have been the barriers to effective / optimal application of the Machinery Directive?
    d. What examples are there of bad practice in the application of the Machinery Directive?
11. Are there any aspects, means and / or actors that render certain aspects of the Machinery Directive more or less effective than others – and if so, what lessons can be drawn from this?

Efficiency of the Directive

12. What are the costs involved for different stakeholders and actors as a result of the Directive?
    a. What are the different costs (time and money) that result from the Directive (including for conformity assessment, self-certification, inspections, compliance, following/ participating in standardisation), and to whom do they apply? [identification & mapping]
    b. What is the scale and range of costs involved? [quantification]
13. What are the benefits (including costs saved) that have been realised by different stakeholders and actors as a result of the Machinery Directive?
    a. What are the different benefits that are realised as a result of the Machinery Directive, and to whom do they apply? [identification and mapping]
    b. What is the scale and range of benefits involved? [quantification]
14. To what extent are costs reasonable, affordable and proportionate to the benefits achieved (for different stakeholders and actors)?
15. Is there a need and what is the potential to reduce inefficiencies, burdens and costs, or to simplify the intervention?
16. What good and bad practices can be identified, in terms of increasing efficiency and minimising costs, when applying the Directive (including in the identification and removal of non-compliant products, and in the cost of controls for authorities and companies)?

Coherence of the Directive

17. To what extent is the Machinery Directive coherent with and / or complementary to other community, national or international legislation – are there overlaps, complementarities, contradictions or conflicting requirements?
    a. To what extent are there issues of coherence or overlap?
    b. What are the implications of this (e.g. for administrative burden)?

EU added value of the Directive

18. What is the added value (to stakeholders) of the Machinery Directive (and total harmonisation), compared to what could have been achieved by Member States at the national level?

4 Overview of research approach and methodology

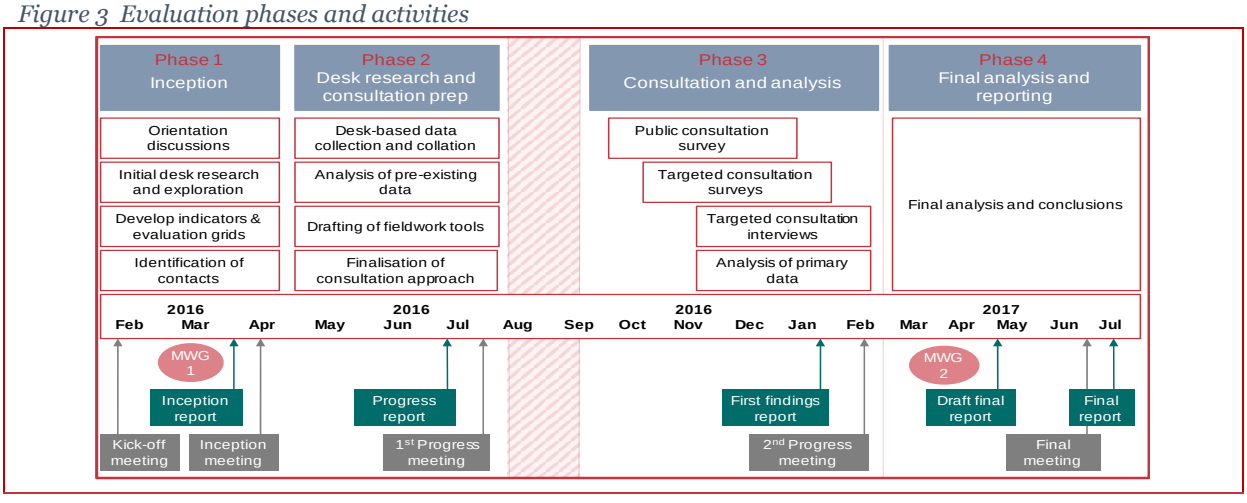
This section outlines the approach taken in conducting the evaluation and the principle evaluation methods deployed. Further details of each principle method and data source, as well as limitations to the approach and evidence, are provided in Appendix A.

4.1 Main phases of the evaluation

The study was undertaken over a period of 18 months and conducted in **four main phases** (see below). Each phase concluded with a (draft) deliverable, which was presented and discussed with the inter-service steering group for the study, before being finalised and approved.

- Inception phase (February – April 2016). The first phase included initial stakeholder discussions, background research and exploration of data sources. Activities also included the development of the intervention logic; a preliminary mapping of the types of costs and benefits triggered by the MD; identification of stakeholder groups; the development of evidence tables; and the revision of the approach and work plan for the study. The phase concluded with the delivery of an inception report, which was presented and discussed at an inception meeting.
- Desk research and consultation-preparation phase (April – July 2016). The second phase focused on extracting, collating and analysing relevant pre-existing data and information from databases, reports and other sources. The study team also drafted a series of tools for use in the stakeholder consultation activities planned for the next phase. Relevant groups and individuals to consult were identified, while the study team maintained contact with representatives of different stakeholder groups in order to make preparations for the consultations. The second phase concluded with the delivery of a progress report, which was discussed at a first progress meeting.
- Consultation and initial analysis phase (September 2016 – February 2017). The third phase of the study focused on undertaking targeted and public consultations with a range of stakeholder groups, analysing the results of these, and integrating this evidence with the earlier results from analysis of pre-existing information. This phase concluded with the delivery of a first-findings report and a second progress meeting between the study team and steering group.
- Final analysis and reporting phase (March – July 2017). The final phase of the study involved additional stakeholder interviews, as well as further analysis of the evidence collected. In particular, the study team sought to address a small number of issues/gaps identified in the initial analysis, before developing answers and conclusions to each of the study objectives and questions, and setting out possible considerations for the future. During this period, the evaluators also attended another meeting with the Machinery Working Group to present progress and findings. This phase concludes with the submission of this final report.

Figure 3 Evaluation phases and activities



4.2 Principle research methods and sources of evidence

The study deployed a combination of qualitative and quantitative research methods to undertake the evaluation, and the analysis presented in this report draws on several principle research methods and sources of evidence. An overview of each is presented below, with additional detail appended.

- Desk research and document review: An initial review of literature, reports, websites and databases during the inception phase identified a number of pre-existing evidence sources of potential relevance to the study. The study team returned to these in the second phase to extract, collate and analyse the available evidence, and to provide preliminary findings. The main documentary resources identified and drawn upon included: policy documents (Regulations, Directives, Communications, Notices and Working Documents); reports (other studies, reviews and monitoring activities); and other sources (various websites and web-based portals). Most are referenced directly in the body of this report, while a full list is provided in Appendix A.3.1 .
- Analysis of secondary data: The study was tasked with using pre-existing quantitative evidence wherever possible to reach conclusions. Thus, a focus of early work was the exploration and identification of available sources of relevant quantitative information. This included trade data and sectoral statistics (Eurostat SBS and COMEXT), accident and injury data (ESAW and LFS), market surveillance activity and non-compliance statistics (RAPEX notifications and Member State reports on market surveillance) and national implementation data (TRIS). Further information on each of these sources, including their limitations, is presented in Appendix A.3.2 .
- Stakeholder consultation: The analysis of available secondary sources identified various data and information that would help address the evaluation questions. However, in most cases such evidence was limited, and often not directly (or solely) related to the Directive. As such, the study needed to rely on consultation activities to build on this existing evidence base – both filling the large number of gaps in available information, and in relating this evidence more directly to the MD. The study therefore undertook public and targeted consultations, employing both surveys and semi-structured interviews to collect evidence from a range of different stakeholders.

  An open public consultation questionnaire was designed in collaboration with the Commission and made available online for 12 weeks at the end of 2016. During the same period the study team ran a series of four targeted surveys that sought more detailed and technical knowledge from key stakeholder groups. The public consultation was designed to address evaluation questions in a reasonably high-level manner (to be applicable to all groups), while the targeted questionnaires were designed to address the same types of questions in more depth, but with more / less focus in certain areas, depending on the interests, expertise and perspective of the group concerned. Follow up interviews were also undertaken with stakeholders from different groups. These were intended to fill gaps in understanding that emerged from the responses to the consultation questionnaires and other evidence sources, as well as to explore particular aspects further.

4.3 Summary of consultation numbers

For the evaluation consultation activities, the task specifications for the study required that at least 286 responses were received (through both questionnaires and at least 40 interviews), including replies from competent authorities, standardisation bodies, Notified Bodies, companies and other relevant representative organisations. These target numbers were surpassed, with 440 responses across all questionnaires (405 unique individuals), interviews undertaken with 44 stakeholders, and each of the required stakeholder groups consulted. The distribution of contributors to the evaluation across the main stakeholder groups and consultation methods is shown in Table 1.

It should be noted that consultation results represent the views of those that chose to respond. The consultation strategy (approved as part of the first progress report for the study) sought to ensure that anyone that wished to contribute to the evaluation could do so (through the public consultation questionnaire), while efforts could also be taken to achieve a significant number of contributions from particular stakeholder groups (through the targeted consultation questionnaires and interviews).

Table 1 Number of responses to consultations, by stakeholder group and consultation route

	Number of responses to...			Total responses
Stakeholder Group	**Public consultation questionnaire**	**Targeted consultation questionnaires**	**Interviews**	
National authority (implementing body / market surveillance)	19	10	10	**39**
Notified Body	16	12	4	**32**
Industry Association	42	41	10	**93**
Industry	159	35	17	**211**
Workers / consumers and their representatives	68	n/a	1	**69**
Consultancy / service provider relating to Machinery safety	31	n/a	0	**31**
Standardisation body	1	n/a	2	**3**
Unknown	6	n/a	n/a	**6**
Total	**342**	**98**	**44**	**484**

Respondents to the public and targeted questionnaires were based in 23 EU Member States (with no responses from HU, LT, LU, SK, SI) and three EFTA countries (no responses from IS). One respondent each from Canada, the US and Japan contributed to the consultation. The greatest numbers of survey respondents were based in Germany (123), Switzerland (41), the UK (39), Italy (30) and France (28). These countries (if we exclude Switzerland) have the largest machinery sectors in Europe (in terms of numbers of businesses), and together accounted for 58% of enterprises in the manufacture of machinery and equipment sector in 2014. In addition, 30 respondents were based in Belgium, but this total includes mostly European Industry Associations based in Brussels. All other countries had 20 or fewer respondents to the surveys. The smaller number of interviewees were spread across ten Member States and one EFTA country.

While a significant number of SMEs (<250 employees) responded to the surveys (they accounted for nearly half - 46% - of all industry respondents to the public and targeted consultations), this is still substantially lower than the proportion of enterprises in the 'manufacture of machinery and equipment' sector that are SMEs (98%). SMEs may therefore be under-represented in responses. However, it should be noted that ~100 industry associations have also been consulted, most of whom represent a wide range of businesses of different sizes, from SMEs to large multi nationals.

Further details on the consultation method, including a list of interviewees, the full breakdown of respondents by country and by stakeholder group, the targeted consultation questionnaires themselves, and the main results obtained through consultation are all provided in Appendix B.

4.4 Limitations for the analysis

The **coverage of the Directive** (and the evaluation) is broad, while the exact scope of the Directive is not clearly defined – at least in terms of standard classifications of sectors and products that are used by other organisations or key datasets. This lack of a clear and exact scope made it difficult to delineate data collection and consultation activities or to align pre-existing categorisations with the scope of the Directive. Several broad approximations for the 'Machinery Directive sector' are used in the report, depending on the systems employed by the data sources available. In particular, we have made use of NACE Code C28 (Manufacture of machinery and equipment n.e.c.) and Combined Nomenclature Section 16 (Machinery and mechanical appliances) as approximations of the Machinery Directive's scope. In both cases, most machinery within the scope of the Directive will fall within these classifications. However, they are also likely to include some products that are outside of scope.

The evaluation was expected to identify and assemble **quantitative secondary evidence** in order to answer most evaluation questions. However, the availability of such quantitative or quantifiable secondary data of relevance to the study objectives and questions has proved limited. It was already known that relevant information would often be difficult to identify and obtain (if at all), and so the first phases of the study were mainly focused on exploring potential data sources, to better understand

availability, applicability, limitations and gaps. This involved an extensive and creative approach, which went beyond basic data sources such as Eurostat or Rapex. It also recognised that incomplete data, as well as estimations, ranges and indicative examples may be the best available sources of evidence, and should not be discounted. Nevertheless, available sources of relevant information were found to be very limited. In particular, there were significant gaps in information relating to:

- Accidents and injury data linked to material agent, i.e. type of Machinery inflicting the injury
- Uptake / purchase of harmonised European standards to pursue conformity assessment
- Costs triggered by the Directive
- Take up of different conformity assessment options
- Non-compliant products
- Market surveillance activity for some Member States

There are also issues regarding the timeframe of data, or its comparability over time. Often there is only one data point available, while elsewhere there are multiple data points, but the nature of the data collected has changed over time. There can also be differences in reporting between Member States. Other issues and caveats with individual data sources are noted in Appendix A.3.2 .

Given the significant gaps in the pre-existing evidence base, the evaluation needed to draw heavily on **stakeholder consultation** activities. There was a risk, though, that certain data would not be readily available (too difficult for stakeholders to collate) or easily obtainable (it is distributed, or confidential). The consultation strategy and tools developed considered the needs of the study (i.e. gaps in the pre-existing evidence) and the full range of relevant stakeholders that might be approached. However, this had to be balanced with the resources available to the study, as well as the time and effort that could be requested of the individuals concerned. Alongside this, the study took efforts to encourage a good response through ensuring that requests were simple, straightforward and appropriate to those being consulted. The study team also undertook efforts to introduce and explain the study and consultation to various stakeholder groups, in order to encourage buy in and support.

The requirement for a public consultation questionnaire introduced additional challenges. Many of the individuals/organisations that might respond would be from stakeholder groups that would also be contacted by other means. There was therefore a risk of survey fatigue, in that stakeholders might be less inclined to contribute to a subsequent (more in-depth) targeted consultation. There was also a risk that some confusion might be caused by multiple consultation methods for the same evaluation. The study team adapted the approach email for the targeted consultations to reduce confusion caused by a second request while the public consultation was still live. We also offered shorter versions of the targeted questionnaires for those who had already completed the public consultation (removing duplicate questions), and explained that this second request would not cover the same ground.

While the 400+ responses received through the different consultation routes exceeded expectations for the study and provided a good overall number of inputs for the analysis, the number of responses within some individual sub-groups is relatively small. There are likely to be significant variations across the breadth of the Machinery sector (e.g. in the costs, benefits or experiences) that can therefore not be fully captured within the scope of this study. In addition, not all respondents felt able to respond to every question, meaning that some analysis – particularly around quantitative estimates – relies on a very small number of inputs, which may not well represent the broader population in some cases. Throughout the analysis, we indicate the number of responses upon which results are based.

There are several limitations that relate to issues of **attribution and causality**. The evaluation was asked to focus on the 2006 Directive and not its previous incarnations, and (mainly) on the period since 2010, after the deadline for application of the Directive across Europe. However, there were challenges in maintaining this scope in the practical implementation of the evaluation. While the 2006 Directive represented a comprehensive amendment to the previous version of the Directive, it was still very much building on the system and infrastructures established over decades through previous incarnations of the Directive. There are many aspects of the Directive which are the same as, or

similar to, previous versions. As a consequence, observable outputs and outcomes flow not just from the 2006 revision, but from the more general existence of a Machinery Directive over the past 30 years. Also, in line with the New Approach, the Directive only provides a framework, and establishes the mandatory essential health and safety requirements. It does not translate this into detailed requirements or processes. As such, the potential impact of the Directive is more directly a result of 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. These are not the specific subject of the evaluation, but are enabling activities that are in some way directed, encouraged or created by the Directive (and are therefore also addressed within the evaluation questions). These systems of standardisation, conformity assessment and market surveillance would, however, be likely to exist in some form regardless of the existence of the Directive.

While we can make clear that we are focused on the 2006 Directive, it is nearly impossible to separate the effects of this version from previous versions of the Directive (e.g. in terms of impacts on trade). There was a particular problem here with regard to the counterfactual, or 'business as usual' analysis. Many interlocutors will not have known (or will remember) a pre-Machinery Directive world. Even when they can, we cannot assume that this would have remained static over the intervening 30 years. The world in 2016 without the Directive, would not look like 1988 without such legislation. Similarly, the absence of the Machinery Directive would not necessarily remove all elements related to it (for example, similar national legislation might exist instead, or the market may drive similar activities around health and safety), but such scenarios are not likely to be well understood and could vary by country or sub-sector. These issues make assessing the added cost/benefit of the Directive, or its European Added Value very difficult. Nevertheless, it is something that we have sought to explore.

5 Answers to the evaluation questions

This main section of the report presents the analyses and findings regarding each of the *evaluation questions*, which are restated at the start of each sub-section. Questions are also organised by *evaluation criteria*.

Findings in relation to the Context of the Directive

The context criterion concerns the situation in the Machinery sector, and how this has evolved over time. Alongside the introduction to the Machinery Directive (Section 2), this section therefore provides a background and context for the analyses addressing the remaining evaluation questions.

5.1 Evaluation Question 1: the current size and structure of the market / sector

1. What is the current size and structure of the machinery market in Europe, and how is it evolving?
    a. What is the size and structure of the machinery market in terms of producers and products, and how has this evolved?
    b. What is the size and structure of the machinery market in terms of consumption and intra- and extra-EU trade, and how has this evolved?
    c. What have been the extent, type and distribution of machinery-related health and safety incidents?
    d. What innovations have taken place during the time of the Directive's application?

Evaluation Question 1 concerns the size and structure of the machinery market in Europe, and how this has evolved. The purpose is to provide background and context for the Directive and its evaluation. Causality (i.e. the impact of the MD on the sector) will be addressed in later questions.

The four sub-questions listed above focus on different aspects of the machinery market: producers and production; consumption and trade; machinery-related health and safety incidents; and innovations. Each is addressed separately below. A significant amount of information has been obtained, analysed and presented in this section, which sets out the size, structure and evolution of the machinery market, trade and related accidents and injury statistics in Europe. Appendix A.3.2 details key data sources.

The scope of the Directive (and therefore the evaluation) is broad, while the exact scope of the Directive is not clearly defined – at least in terms of the standard classifications of sectors and products. There are also certain exclusions and overlaps with other Directives for certain products, further complicating matters of scope. The lack of a clear and exact scope makes it difficult to delineate the parameters of data collection. In relation to production, consumption and trade we therefore used different approximations of the 'MD sector', depending on the data source used. The different categorisations used for different data sources are explained further in Appendix A.3.2 .

The years for which data is available vary by source. We have sought to at least include within each part of the analysis: (i) a figure for the latest available year; and (ii) a figure for the year (2009) from which the Directive first applied. Where the data allows it, we have also attempted to show trends over a longer period (i.e. also including the years preceding the application of the Directive), for a better overview of the context.

5.1.1 Producers and production of machinery

The manufacture of machinery and equipment n.e.c. sector (MME) (NACE Rev. 2, division 28) covers industries producing all types of machinery and tools, both those for general use and those specific to a particular manufacturing process. Many of the products are intermediate goods which enter into the manufacture of other goods or are capital equipment used by other industries.

There were **92,863 enterprises in the EU28** operating in the MME sector in 2014 (latest year available). This represents around one in 25 (4.1%) of all enterprises in the manufacturing sector as a whole (Section C). Despite a slight increase (+1%) in the number of businesses recorded in recent years (2013-2014), the general trend over the past decade has been downward (see Table 2). In 2005 there were over 105,000 enterprises in the sector (EU27 only), while by 2014 there were 12,823 fewer (-12%) (EU28), despite having added one more Member State.

Table 2 Number of enterprises, Manufacture of machinery and equipment, 2005-2014

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
EU28							96,619	93,000	91,979	92,863
EU27	105,686	105,145	106,248	102,523	96,566	98,059	95,829			

Source: Eurostat. Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) [sbs_na_ind_r2]

MME enterprises are not distributed evenly **across Member States**, with more than half (52%) of the 2014 total located in just three countries: Italy (25%), Germany (18%) and the United Kingdom (9%). There are a further seven countries (FR, CZ, ES, PL, NL, SE and HU) with over 2,000 relevant enterprises each (see full list of countries, in descending order in Table 3). The final column shows that the overall downward trend in the number of MME enterprises in Europe in the period since the Directive applied (-5% between 2009 and 2014) does not reflect the experiences within all Member States. In particular, some (MT, EE, DE, NL, LT, LV, SK) have seen significant (5%+) growth during the period, while others (GR, ES, HU, BE, HR) have seen the number decline by 15% or more.

Table 3 Number of enterprises, Manufacture of machinery and equipment, by country

	Number of enterprises, 2009	Number of enterprises, 2014	% of 2014 total	% change 2009-14
Italy (IT)	24,072	23,617*	25%	-2%
Germany (DE)	15,107	16,315	18%	8%
United Kingdom (UK)	9,209	7,920	9%	-14%
France (FR)	6,134	5,641	6%	-8%
Czech Republic (CZ)	6,278	5,389	6%	-14%
Spain (ES)	6,509	5,276	6%	-19%
Poland (PL)	4,762	4,599	5%	-3%
Netherlands (NL)	2,850	3,117	3%	9%
Sweden (SE)	3,226	3,069	3%	-5%
Hungary (HU)	2,960	2,472	3%	-16%
Greece (GR)	2,647	1,782	2%	-33%
Denmark (DK)	1,672	1,670	2%	0%
Portugal (PT)	1,827	1,565	2%	-14%
Slovakia (SK)	678	1,450	2%	114%
Belgium (BE)	1,708	1,433	2%	-16%
Finland (FI)	1,575	1,429	2%	-9%
Austria (AT)	1,341	1,331	1%	-1%
Romania (RO)	1,435	1,265	1%	-12%
Bulgaria (BG)	918	906	1%	-1%
Croatia (HR)	878	743	1%	-15%
Slovenia (SI)	817	743	1%	-9%
Ireland (IE)	313	279*	0%	-11%
Lithuania (LT)	158	186	0%	18%
Latvia (LV)	117	182	0%	56%
Estonia (EE)	143	150	0%	5%
Cyprus (CY)	63	59	0%	-6%
Luxembourg (LU)	26	25	0%	-4%
Malta (MT)	22	23	0%	5%
Total	**97,445**	**92,636**	**100%**	**-5%**

Source: Eurostat. Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) [sbs_na_ind_r2]. *2013 data used.

Table 4 provides a breakdown of enterprise statistics by **sub-sectors** of MME –using 3-digit NACE codes ("groups") and then 4-digit NACE codes ("classes"). As indicated (shading), the main classes of activity (based on number of enterprises) include the manufacture of: lifting and handling equipment; non-domestic cooling and ventilation equipment; agricultural and forestry machinery; machinery for food, beverage and tobacco processing; and other general or special purpose machinery.

Table 4 Number of enterprises (EU28, 2013), Manufacture of machinery and equipment, by sub-sector

3-digit NACE Code ("Group")	% of enterprises	4-digit NACE Code ("Class")	% of enterprises
C281 - Manufacture of general-purpose machinery	13%	C2811 - Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	2%
		C2812 - Manufacture of fluid power equipment	2%
		C2813 - Manufacture of other pumps and compressors	3%
		C2814 - Manufacture of other taps and valves	3%
		C2815 - Manufacture of bearings, gears, gearing and driving elements	3%
C282 - Manufacture of other general-purpose machinery	39%	C2821 - Manufacture of ovens, furnaces and furnace burners	2%
		C2822 - Manufacture of lifting and handling equipment	10%
		C2823 - Manufacture of office machinery and equipment (except computers and peripheral equipment)	1%
		C2824 - Manufacture of power-driven hand tools	1%*
		C2825 - Manufacture of non-domestic cooling and ventilation equipment	9%
		C2829 - Manufacture of other general-purpose machinery n.e.c.	16%
C283 - Manufacture of agricultural and forestry machinery	8%	C2830 - Manufacture of agricultural and forestry machinery	8%
C284 - Manufacture of metal forming machinery and machine tools	9%	C2841 - Manufacture of metal forming machinery	5%
		C2849 - Manufacture of other machine tools	4%
C289 - Manufacture of other special-purpose machinery	31%	C2891 - Manufacture of machinery for metallurgy	3%
		C2892 - Manufacture of machinery for mining, quarrying and construction	4%
		C2893 - Manufacture of machinery for food, beverage and tobacco processing	7%
		C2894 - Manufacture of machinery for textile, apparel and leather production	2%
		C2895 - Manufacture of machinery for paper and paperboard production	1%
		C2896 - Manufacture of plastic and rubber machinery	3%
		C2899 - Manufacture of other special-purpose machinery n.e.c.	12%
C28 - Manufacture of machinery and equipment n.e.c.	**91,979**	**C28 - Manufacture of machinery and equipment n.e.c.**	**91,979**

Source: Eurostat. Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) [sbs_na_ind_r2]. *2012 data used.

Table 5 shows the distribution of MME enterprises across different **sizes of business**. Nearly two-thirds (64%) of enterprises in the sector are micro-businesses (<10 persons employed), while just 2% (1,870) are large businesses (employing 250+). These larger manufacturers are even more geographically concentrated than the sector as a whole, with 42% located within Germany. In contrast, Italy accounts for only 10% of large companies in the sector.

In the final columns, the table also shows the distribution of the nearly three million **persons employed** in the MME sector in 2013 across different sizes of companies. On average, each firm in the sector employs around 32 people (roughly double the average for manufacturing overall). However, the distribution of employees is heavily skewed across the size-classes. Despite the relatively small number of large firms, these businesses account for nearly half (47%) of all persons employed in

the sector (with 727 employees each on average). At the other end of the scale, the 58,000+ micro businesses (often handicraft companies) account for just 6% of the sector's workforce (averaging three employees each).

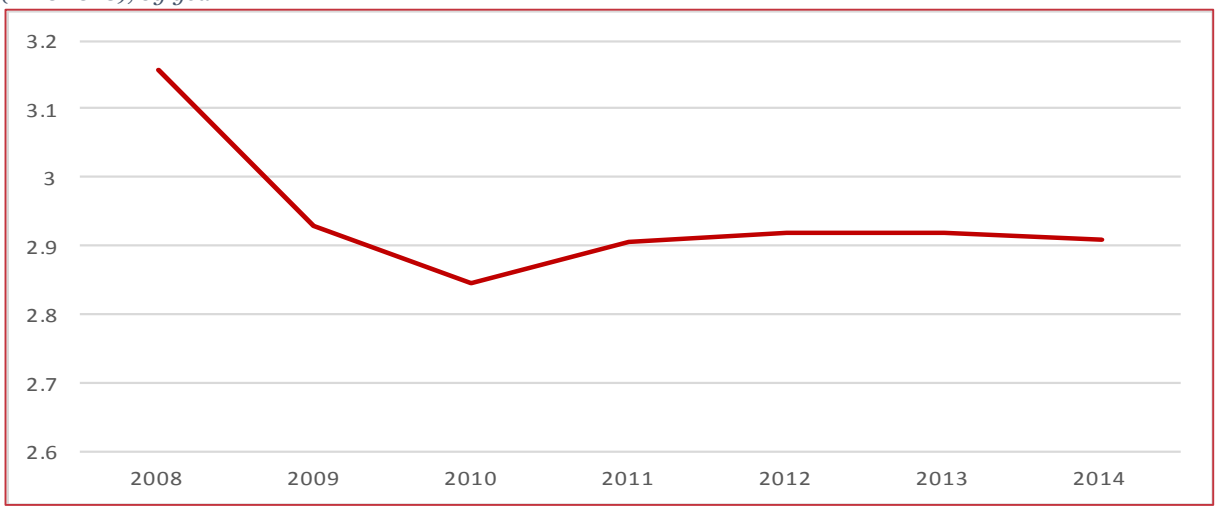
Table 5 Number of enterprises and persons employed (EU28, 2013), Manufacture of machinery and equipment (NACE C28), by size-class

	Number of enterprises	%	Number of persons employed	%
From 0 to 9 persons employed	58,600	64%	183,100	6%
From 10 to 19 persons employed	13,700	15%	192,000	7%
From 20 to 49 persons employed	9,774	11%	318,300	11%
From 50 to 249 persons employed	7,966	9%	860,600	29%
250 persons employed or more	1,870	2%	1,360,000	47%
Total	**91,979**		**2,920,000**	

Source: Eurostat. Industry by employment size class (NACE Rev. 2, B-E) [sbs_sc_ind_r2]

The total number of persons employed across the MME sector (~2.9 million) represents around 10% of the employees throughout the manufacturing sector in the EU. This number has not changed significantly since the Directive first applied (i.e. between 2009 and 2013), nor has its distribution across the five different size-classes of businesses. However, there was 7% decline in the number of persons employed in the sector between 2008 and 2009. An above average proportion of manufacturing employment (as of 2013) is concentrated within MME industries in DK (19%), DE (15%), FI (14%), AT (13%), SE (12%), IT (12%), NL (12%) and LU (12%).

Figure 4 Number of persons employed (EU28, millions), Manufacture of machinery and equipment (NACEC28), by year



Source: Eurostat. Industry by employment size class (NACE Rev. 2, B-E) [sbs_sc_ind_r2]

Total EU28 **production** of the MME sector was valued at €599b in 2014. This equates to 9% of the total production value for the EU manufacturing industry as a whole. Production value is not distributed evenly, with a majority (72%) of the 2014 total located in just four countries: Germany (39%), Italy (19%), the UK (7%) and France (7%). There are a further eight countries (NL, AT, SE, ES, DK, FI, CZ and BE) in which national production value exceeded €10b.

The sector has grown since its low point in 2009, when production value dropped to €499b (in 2014 prices) as a result of the financial and economic crisis. However, by 2014 it had still not returned to pre-crisis (2008) levels (see table below).

Table 6 Production value (€ million), Manufacture of machinery and equipment (NACE C28), 2008-14. 2014 prices

Value (€m)	2008	2009	2010	2011	2012	2013	2014
EU28				608,973	599,407	578,376	599,000
EU27 + Croatia	659,537	498,866	542,966	609,095			

Source: Eurostat. Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) [sbs_na_ind_r2]

A 2012 report on the competitiveness of EU mechanical engineering[6] notes that the mechanical engineering sector (which it also defines based on NACE C28), as one of the prime supplying industries of capital goods, is highly dependent on investment activities of its purchasing companies, which in turn are highly sensitive to developments in the wider economy. This dependency on investment activity has repeatedly subjected the industry to pronounced fluctuations in demand.

The key role of MME in supplying a range of other industries becomes evident in the data from the **World Input-Output Database** (WIOD) (2014). This shows a total output from the EU28 MME sector in 2014 of $801.6b (~€702.6b). This was consumed (globally) through:

- Intermediate consumption by all sectors ($397.8b)
- Final consumption by Government, Households and NGOs ($36.9b)
- Gross fixed capital formation ($357.8b)

Intermediate consumption is largely accounted for by the manufacturing sector itself (which consumes two-thirds), but most other broad sectors also consume multiple billion-dollars' worth of EU28 MME output each year.

Table 7 Intermediate consumption by sector of EU28 MME output, 2014 ($b)

Sector	Intermediate Consumption ($b / % of total)	
C - Manufacturing	263.7	66.3%
F - Construction	36.5	9.2%
B - Mining and quarrying	15.8	4.0%
G - Wholesale and retail trade; repair of motor vehicles and motorcycles	15.0	3.8%
H - Transporting and storage	10.9	2.7%
D - Electricity, gas, steam and air conditioning supply	7.5	1.9%
A - Agriculture, forestry and fishing	6.4	1.6%
M - Professional, scientific and technical activities	6.3	1.6%
J - Information and communication	5.5	1.4%
O - Public administration and defence; compulsory social security	5.4	1.4%
Q - Human health and social work activities	5.0	1.3%
N - Administrative and support service activities	5.0	1.3%
E - Water supply; sewerage; waste management and remediation activities	4.0	1.0%
R - Arts, entertainment and recreation	3.0	0.8%
L - Real estate activities	2.2	0.6%
K - Financial and insurance activities	2.2	0.5%
I - Accommodation and food service activities	2.1	0.5%
P - Education	1.3	0.3%
T - Activities of households as employers	0.0	0.0%
U - Activities of extraterritorial organisations and bodies	0.0	0.0%
Total	**397.8**	**100%**

Source: WIOD, 2014

[6] An introduction to Mechanical Engineering: Study on the Competitiveness of the EU Mechanical Engineering Industry, 2012

Through consultation activities, the study asked stakeholders about trends in the **turnover and profitability** of the European machinery sector and businesses over the past decade. As the following table shows, there were quite mixed impressions, with around half of respondents (48%) suggesting an improvement and around one-third (33%) indicating a decrease in turnover / profitability in the sector. However, on balance, the responses suggest a slight increase.

Table 8 Over the past 10 years, what has happened to…. Machinery sector turnover / profitability

	Decreased significantly	Decreased slightly	No change	Increased slightly	Increased significantly	n
Turnover and profitability of the European machinery sector/businesses	7%	26%	19%	39%	9%	227

Source: Machinery Directive Public Consultation

The 2012 report on the competitiveness of mechanical engineering points to the United States, Japan and China as the most important **competitor economies** for the EU in this sector. Key indicators presented on each of these countries have been collated in the table below, and compared with those from the EU27. This highlights the relative importance of the EU manufacturing sector globally.

Table 9 Key indicators for the mechanical engineering sector (NACE C28) across major competitor countries, 2010

Indicator	Value	EU27	USA	Japan	China
Output*	€b	502.1	221.6	151.9	480.6
Value added	€b	157.5	103	66.2	161.4
Employees	million	2.9	1.1	0.7	6.1
Labour productivity (value added per capita)	€	54,290	91,125	96,700	26,399
Labour costs (per employee)	€	33,243	39,815	32,400	3,700
Domestic demand (production+imports-exports)	€b	374.2	207.8	86.8	485.8
Mechanical engineering imports (total)**	€b	81.2	80	18.9	75.30
Mechanical engineering exports (total) **	€b	200.4	93.7	84	70.1
ME imports from EU27	€b		27.3	4.2	28
ME exports to EU27	€b		17.7	14.1	18.9

Source: Technopolis, extracted and collated from 'An introduction to Mechanical Engineering: Study on the Competitiveness of the EU Mechanical Engineering Industry', Ifo Institute (2012). 2010 prices and exchange rates. *Output equates to production (EU) and turnover (US, CN, JP). ** Imports to / exports from EU27 includes extra-EU trade only (and not transfers between Member States)

5.1.2 Innovation in the machinery sector

The 2012 competitiveness of mechanical engineering report[7] states that the sector belongs to the industries with medium-high **R&D intensity** – a group characterised by a ratio of R&D expenditure to sales between 2% and 5%. It noted that since 1995, R&D intensity of European mechanical engineering producing firms (NACE C28, EU27) has grown, while R&D intensity across all sectors combined has decreased.

The Community Innovation Survey (CIS) 2012[8] found that two-thirds (66%) of businesses in the MME sector (NACE C28) were 'innovative'. This compares favourably with 52% of all manufacturing businesses. More specifically, the survey found that 45% of machinery businesses were engaged in product innovation, compared with 28% of manufacturing businesses as a whole. Also, in 2012, there were 10,561 patent applications to the European Patent Office (EPO) by the manufacture of machinery sector (NACE C28) in the EU28[9].

In 2013, €13.1b was spent by EU businesses in the manufacture of machinery and equipment n.e.c. sector (MME) (NACE C28) on R&D (Business Enterprise Research and Development – BERD). This represents 12% of all BERD in the wider manufacturing sector, and 8% of BERD across all sectors of the economy. A large proportion (41% or €5.4b) of the total MME BERD is accounted for by Germany,

[7] An introduction to Mechanical Engineering: Study on the Competitiveness of the EU Mechanical Engineering Industry, 2012

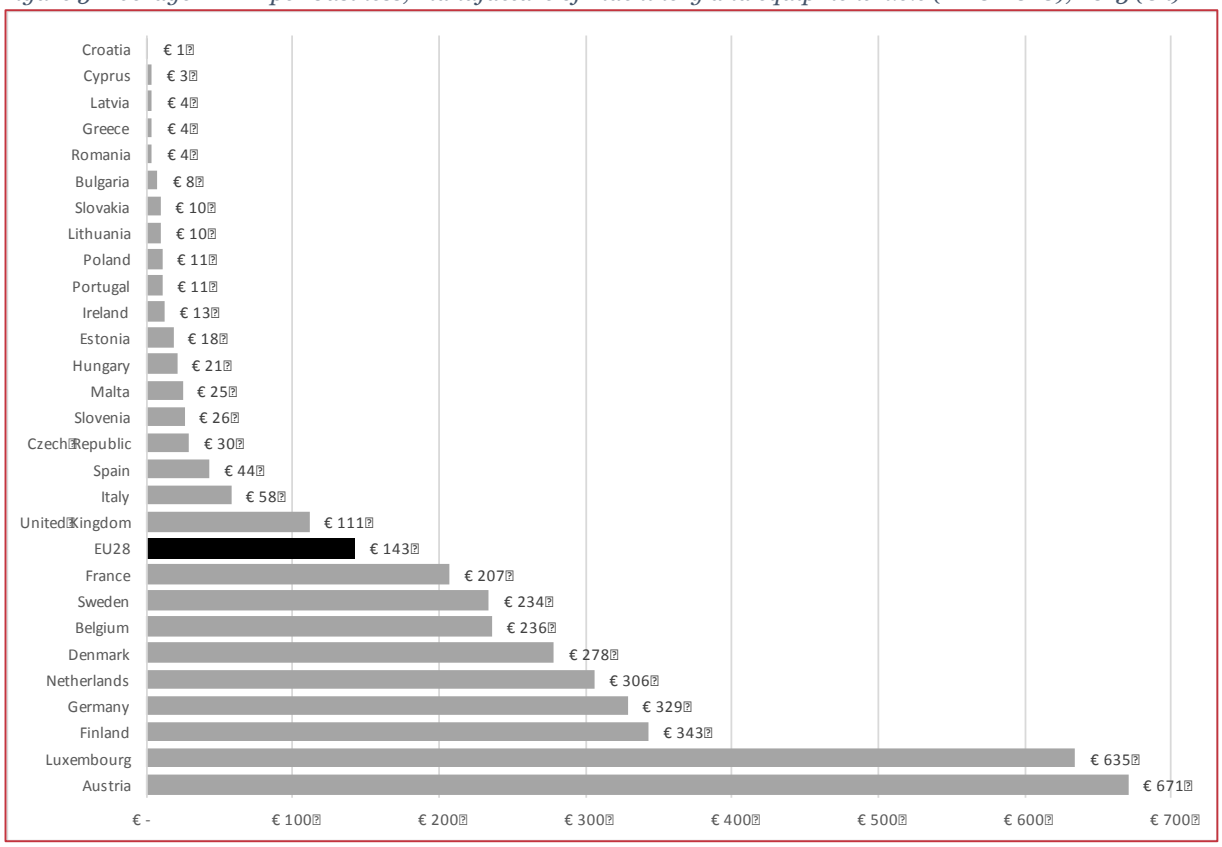
[8] Eurostat. Basic economic information on the enterprises by NACE Rev. 2 activity and size class [inn_cis8_bas]

[9] Eurostat. Patent applications to the EPO by priority year by NACE Rev. 2 activity [pat_ep_nnac2]

followed by Italy (€1.4b) and France (€1.0b). In Figure 5, total BERD is divided by the number of businesses in the sector. This shows the average MME BERD spend per business for the EU28 is €143,000, with businesses in FR, SE, BE, DK, NL, DE, FI, LU and AT spending more on average.

Historical data is missing for a number of countries, but for 23 Member States (where sufficient data is available) BERD in the MME sector has increased from €10.4b in 2010 to €11.5b in 2013 (2013 prices), an increase of 11% over three years.

Figure 5 Average BERD per business, manufacture of machinery and equipment n.e.c (NACE C28), 2013 (€k)



Source: Technopolis, based on Eurostat: Business enterprise R&D expenditure (BERD) by economic activity (NACE Rev. 2) [rd_e_berdindr2], & Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) [sbs_na_ind_r2]

Through the public consultation, stakeholders were asked for their views on trends in **innovation within the machinery sector** over the past decade. As the following table shows, the vast majority (80%) felt that the rate and extent of innovation in the sector had increased slightly or increased significantly over the period, while few felt that the pace and scale of innovation had decreased.

Table 10 Over the past 10 years, what has happened to…. Machinery innovation

	Decreased significantly	Decreased slightly	No change	Increased slightly	Increased significantly	n
The rate and extent of innovation in the machinery sector	1%	4%	16%	44%	36%	314

Source: Machinery Directive Public Consultation

The Orgalime annual report (2014-15)[10] notes more specifically that the sector is seeing a rapid evolution through the integration of Information and Communications Technology (ICT) into

[10] http://www.orgalime.org/sites/default/files/AR15%20web.pdf

manufacturing processes, products, value chains and service offerings. "Automated production systems using advanced robotics increasingly communicate with each other on detailed aspects of production, joining up a hitherto fragmented manufacturing processes and allowing the development of new products and service offerings… This evolution, commonly known as 'Industry 4.0' or 'Smart industry', is leading to better, greener and more customised products and to productivity gains."

5.1.3 Consumption and trade in machinery

Eurostat COMEXT Data is not available by NACE code. Following the approach used in the proposal for the Machinery Directive, consumption and trade statistics presented below are therefore based on 'Combined Nomenclature Section 16 – Machinery and Mechanical Appliances' (MMA)[11]. This is not directly comparable with the 'NACE C28 – Manufacture of Machinery and Equipment' (MME) used above for business statistics.

According to Eurostat COMEXT Data, the total value of EU28 Member State **exports** during 2015 was €4,862b (this includes movement of goods and services between EU countries). Nearly one-quarter (23%, €1,139b) of this was accounted for by the Machinery and Mechanical Appliances (MMA) sector.

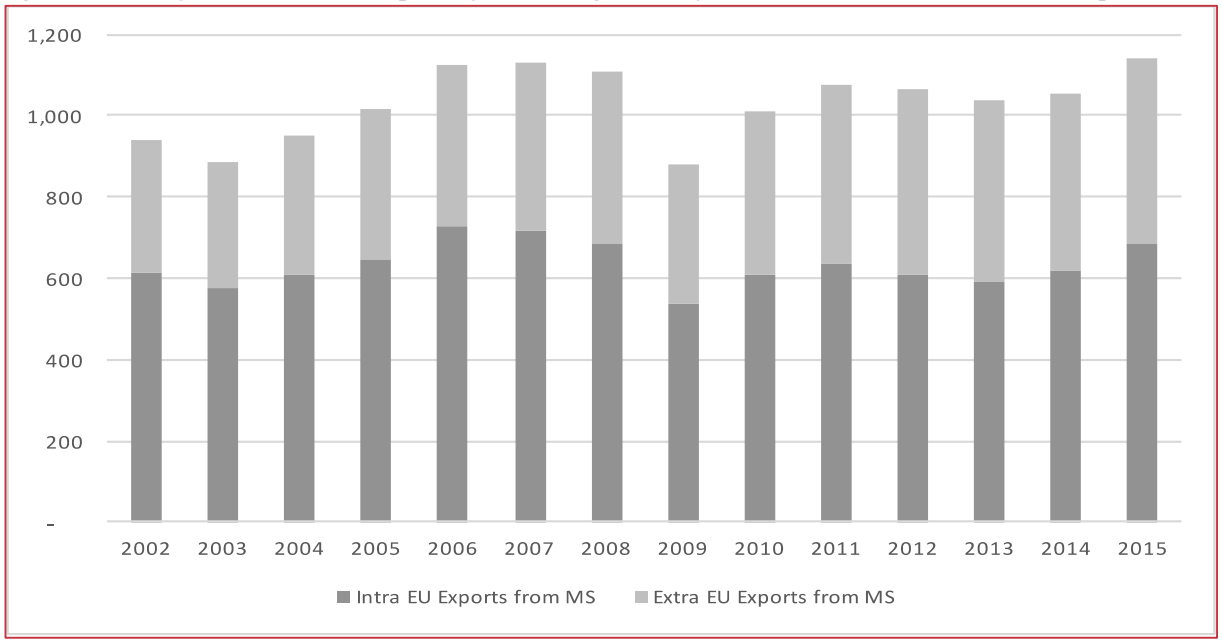
The majority (60%) of EU28 MMA exports in 2015 stayed within the EU (intra-EU28 trade), but the value of exports to other countries was still substantial (some €456b). Top non-EU **destinations** for MMA exports (in terms of value) included the United States (€90b), China (€51b), Russia (€24b), Switzerland (€22b), Turkey (€21b), the UAE (€14b), and South Korea (€14b) – which together accounted for over half (52%) of all extra-EU exports.

The value of EU28 MMA exports (2015 prices) increased each year from 2003 to 2007 (see Figure 6), before falling sharply (by -21%) between 2008 and 2009. Annual export totals have then steadily increased again, to slightly above 2008 levels. Intra- and extra-EU exports followed a similar trend.

Intra-EU MMA exports specifically have increased in value (using 2015 prices) from €536b in 2009 (the year the Directive was to be applied) to €683b in 2015 (the latest for which data is available), representing a 27% increase in the value of trade over the six years that the MD has applied. However, this period of growth followed a significant (-22%) fall in the value of intra-EU exports of machinery the previous year (2008-2009), while prior to this the value of intra-EU exports had also risen (by 11% over the six-years 2002-2008). If we take 2008 as a more 'typical' reference year, then intra-EU export values of machinery are almost exactly the same in 2015 as they were the year before the Directive applied (€683b and €685b respectively).

[11] CN Section 16: Machinery and mechanical appliances; electrical equipment; parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles.

Figure 6 Value of intra-/extra-EU exports of Machinery (CN 16) from EU28 Member States (€b, 2015 prices),



Source: COMEXT. EU trade since 1988 by CN Sections (DS-058342)

Table 11 presents data on the value of exports of MMA from **a selection of EU28 Member States** (largest exporters). The last two columns show the shares in each country's MMA exports, between intra- and extra- EU trade. Amongst the 'top' export countries, the Netherlands stands out as having a particularly high share of its exports staying within the EU.

Table 11 Value of intra-/extra-EU exports of Machinery (CN Section 16) from EU28 Member States, 2015

Total exports from…	Total (€b)	to outside EU28	to inside EU28
Germany (DE)	322.4	47%	53%
Netherlands (NL)	138.8	26%	74%
Italy (IT)	107.7	51%	49%
France (FR)	87.5	45%	55%
United Kingdom (UK)	83.8	60%	40%
Czech Republic (CZ)	51.0	20%	80%
Poland (PL)	44.8	22%	78%
Austria (AT)	41.9	34%	66%
Belgium (BE)	38.7	31%	69%
Hungary (HU)	35.6	20%	80%
Sweden (SE)	35.0	51%	49%
Spain (ES)	34.5	43%	57%
EU28	**1,139.0**	**40%**	**60%**

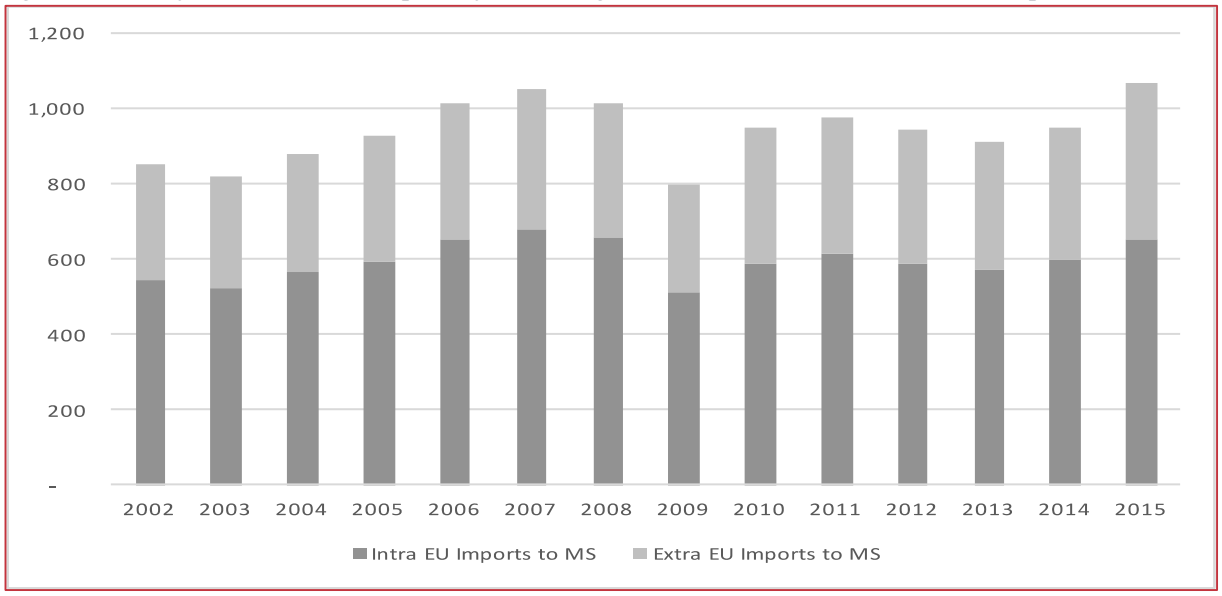
Source: COMEXT. EU trade since 1988 by CN Sections (DS-058342)

The total value of EU28 Member State **imports** during 2015 was €4,708b. Nearly one-quarter (23% or €1,067b) of this total was accounted for by the MMA sector.

The majority (61%) of MMA imports in 2015 were from within the EU (intra-EU28 trade), while some €416b of MMA imports came from other (non-EU) countries. The top **external origin** of machinery imports to the EU (in terms of value) was China (€170b or 41%). Other important countries of origin include the United States (€66b), Japan (€26b), Switzerland (€17b) and Vietnam (€15b).

The value of MMA imports to the EU (in 2015 prices) increased each year from 2003 to 2007 (see Figure 7), before falling slightly in 2008 and even more significantly (by -21%) the following year. Annual import totals have then tended to increase again since, exceeding their 2007 peak by 2015. Both intra- and extra-EU imports of MMA followed a similar trend.

Figure 7 Value of intra-/extra-EU imports of Machinery (CN Section 16) to EU28 MS (€b, 2015 prices)



Source: COMEXT. EU trade since 1988 by CN Sections (DS-058342)

Table 12 presents data on the value of MMA imports to selected EU28 Member State during 2015 (largest importers). The last two columns show the split in each country's MMA imports, between intra- and extra- EU trade. All of the 'top' importing countries (Germany, the UK, France and the Netherlands) import at least one-third from outside the EU, as do several other 'smaller' importers.

Table 12 Value of intra-/extra-EU imports of Machinery (CN Section 16) to EU28 Member States, 2015 (€b)

Total imports to...	Total	from outside EU28	from inside EU28
Germany (DE)	232.2	40%	60%
United Kingdom (UK)	130.5	52%	48%
Netherlands (NL)	124.7	68%	32%
France (FR)	106.8	33%	67%
Italy (IT)	63.2	34%	66%
Spain (ES)	49.2	28%	72%
Poland (PL)	45.5	30%	70%
Czech Republic (CZ)	45.2	34%	66%
Belgium (BE)	41.8	32%	68%
Austria (AT)	34.7	25%	75%
Sweden (SE)	33.7	23%	77%
Hungary (HU)	31.6	32%	68%
EU28	**1,067.2**	**39%**	**61%**

Source: COMEXT. EU trade since 1988 by CN Sections (DS-058342)

The public consultation also asked stakeholders about trends in the **trade in the machinery sector** over the past decade. As the following table shows, respondents generally held quite positive views. Half felt that the volume and / or value of intra-EU trade in machinery had increased, compared to only 21% who felt that it had decreased. Similarly, half (48%) believed that the international competitiveness of the European machinery sector and its businesses had increased over the past decade, compared with just 24% who thought that the situation had worsened.

Table 13 Over the past 10 years, what has happened to.... Machinery sector trade

	Decreased significantly	Decreased slightly	No change	Increased slightly	Increased significantly	n
The volume/value of intra-EU trade in Machinery	8%	13%	30%	38%	12%	216
The international competitiveness of the European machinery sector/businesses	5%	19%	29%	33%	15%	262

Source: Machinery Directive Public Consultation

5.1.4 Machinery-related accidents and injuries

Information on accidents and injuries (A&I) related to product use is collected to different extents by national health and safety agencies, workers' insurances, and some hospital emergency departments. Data collection focusses on aspects such as type of injury (e.g. fracture, dislocation, puncture wound), nature of the incident (e.g. moving part, fall from height), geographic distribution (by region), industry sector (by NACE, SIC code), and/or occupation of the injured (ISCO). The data do not capture the causative agent of the accident, e.g. if a machine was involved, the type of machine, or the circumstances under which the injury occurred, e.g. if the accident was caused by a fault with the machine or due to human error. Hence, none of the public data sources examined was sufficiently detailed to allow a robust analysis of A&I caused by machinery product group, or individual machines.

We were able to examine general trends in A&I by analysing aggregated accident and injury data from across Europe, both pre- and post-Directive[12], and to identify (potential) machinery-related occurrences within this. This provides evidence on general trends in A&I over time, allowing the study to address the evaluation questions on context (the extent, type and distribution of machinery-related health and safety incidents), as well as (in the next section) to draw on this to answer questions on relevance (the extent to which the objective of ensuring a high level of safety of machinery correspondents to needs).

Accidents and injuries at work – ESAW data

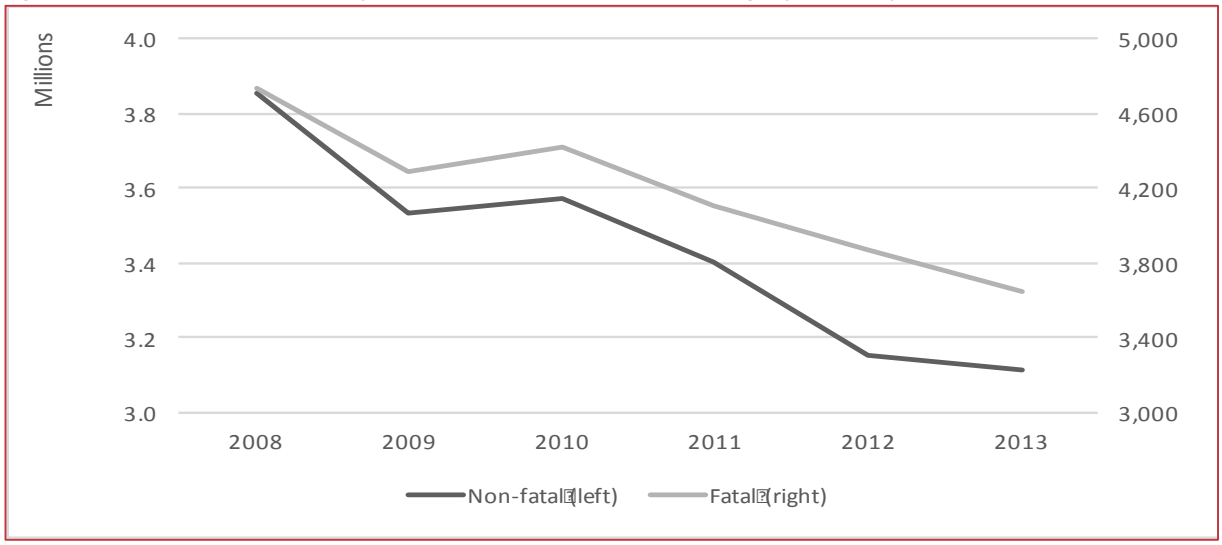
Due to mandatory reporting requirements, more data is collected on A&Is at work, compared to A&Is sustained at home or during leisure activities. The main collection of data relating to health and safety at work at the European level is the European Statistics on Accidents at Work (ESAW) data set.

An analysis of ESAW data shows that the **total number of accidents at work** has seen a downwards trend since the time of application of the Machinery Directive. Between 2009 and 2013, non-fatal accidents with more than three days of absence from work decreased from 3.53 million to 3.12 million (a reduction of 414,109, or 12%). Over the same period, the number of fatal accidents decreased from nearly 4,300 to less than 3,700 (a reduction of 649 accidents, or 15%).

The number of accidents in a particular year is likely to be affected by the overall level of economic activity, and there was a significant 'dip' in accident figures in 2009 – which is likely to be related to the onset of the economic crisis. If we take 2008 as a more 'typical' base year, the recent reductions in accident figures are even more pronounced. Between 2008 and 2013, non-fatal accidents decreased by 735,861 (19%) and fatal accidents dropped by 1,091 (23%).

[12] However, ESAW data used an earlier revision of the NACE classification system up until 2007. The statistics presented in this section therefore start in 2008, when ESAW data was classified according to NACE Rev 2.

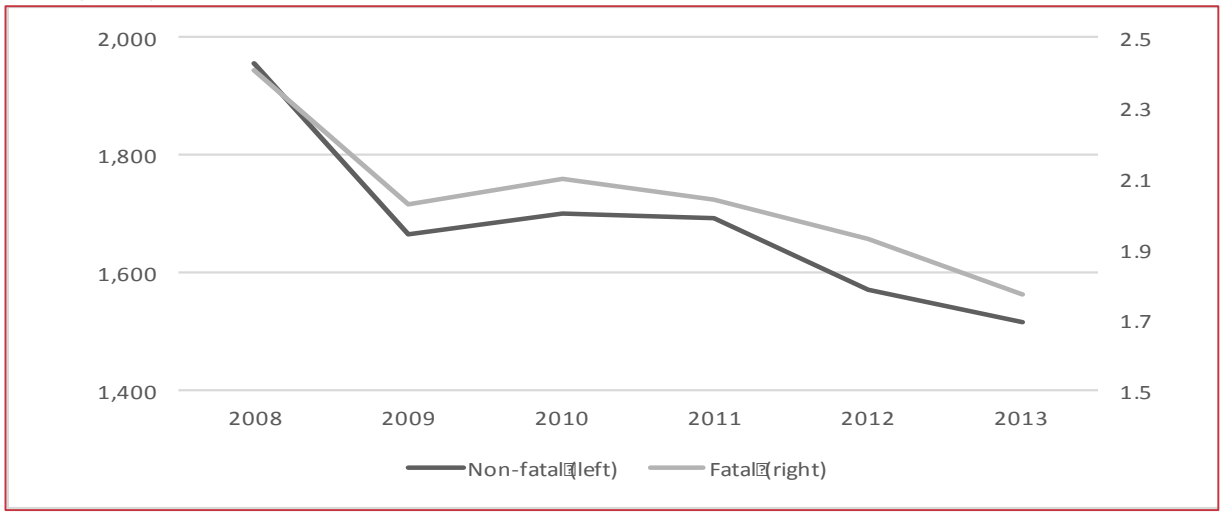
Figure 8 Fatal accidents and non-fatal accidents with more than 3 days of absence from work, 2008-13, EU27



Source: ESAW

The following figure shows the same data, but per 100,000 employees. This shows a similar decline in the incidence rates of non-fatal (-9%) and fatal accidents (-13%) between 2009 and 2013 (or -23% and -27% if 2008 is taken as the base year).

Figure 9 Incidence rates of fatal accidents and non-fatal accidents with more than 3 days of absence from work, 2008-13, EU27

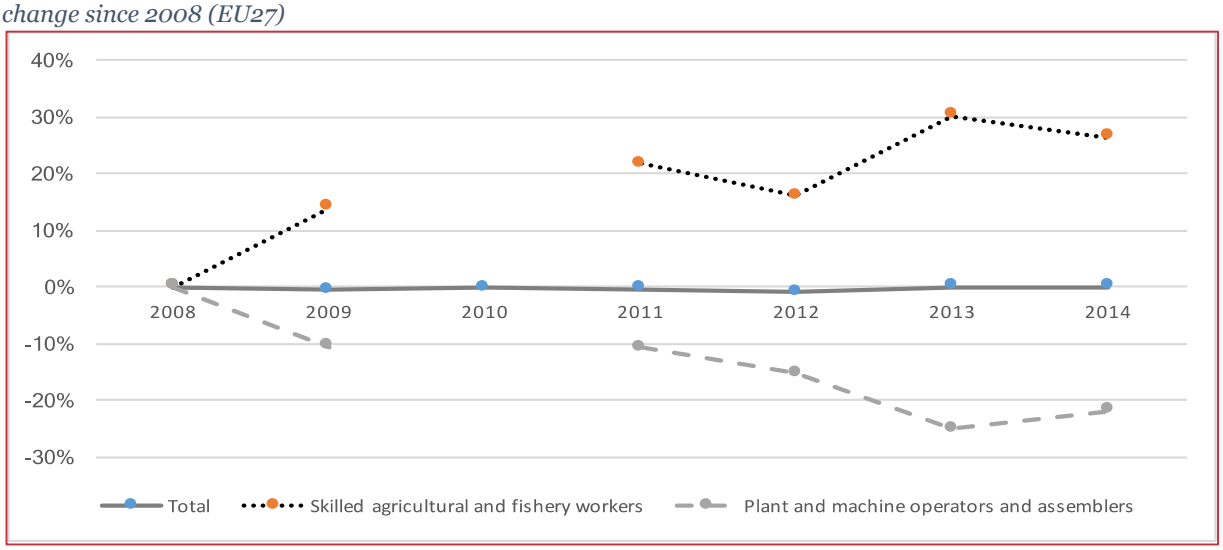


Source: ESAW. Incidence rates are calculated as the ratio between (i) the number of accidents for a given year, and sector and (ii) the corresponding number of employed persons (reference population) multiplied by 100,000.

We examined data from 18 of the **EU Member States** in more detail, with countries selected on the basis of the availability of yearly figures for the entire 2008-2013 period. These data showed that the number of fatal accidents and accidents with more than three days of absence from work (combined) for this selection of countries decreased respectively by 12% between 2009 and 2013, and by 25% between 2008 and 2013. However, the trends in the numbers of accidents differ between Member States. For example, Spain and Slovenia have seen a reduction of more than 50% and 40%, respectively, between 2008 and 2013. At the other end of the scale, after an initial drop in 2009 (potentially due to the impact of the economic crisis), Latvia and Lithuania saw their accident figures return to near 2008 levels by 2013.

When broken down by **category of occupation**, the incidence rates of accidents by workers most likely to operate machinery ('Plant machine operators and assemblers', ISCO_8) shows a pronounced decrease of 25% between 2008 and 2013 (Figure 10). However, for workers in occupations related to agriculture and fisheries (where there may also be a high proportion of accidents relating to machinery), the rate increased by 30% over the same period.

Figure 10 Incidence rates of fatal accidents and accidents with more than 3 days of absence from work, % change since 2008 (EU27)



Source: ESAW

The ESAW data can also be broken down **by economic activity** of the employer (NACE code), and is provided both as the total number of accidents and as the incidence rate, i.e. the number of accidents in a sector per 100,000 individuals employed in this sector.

Among the sectors most likely relevant to the use of machinery (Manufacturing, Construction, and Agriculture, Forestry and Fishing), there was a 31% decrease in the absolute number of fatal accidents (Table 14) and a 30% decrease in non-fatal accidents (Table 15) during the 2008-13 period.

Table 14 Fatal accidents, by economic activity of employer (NACE). EU27

Fatal	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2008-2013 change**
Manufacturing	837	704	710	684	651	609	-27%
Construction	1,258	1,156	1,049	958	869	787	-37%
Agriculture, forestry & fishing	591	484	583	552	527	467	-21%
Total (3 sectors)	**2,686**	**2,344**	**2,342**	**2,194**	**2,047**	**1,863**	**-31%**

Source: ESAW.

Table 15 Accidents resulting in more than 3 days of absence from work, by economic activity of employer (NACE). EU27

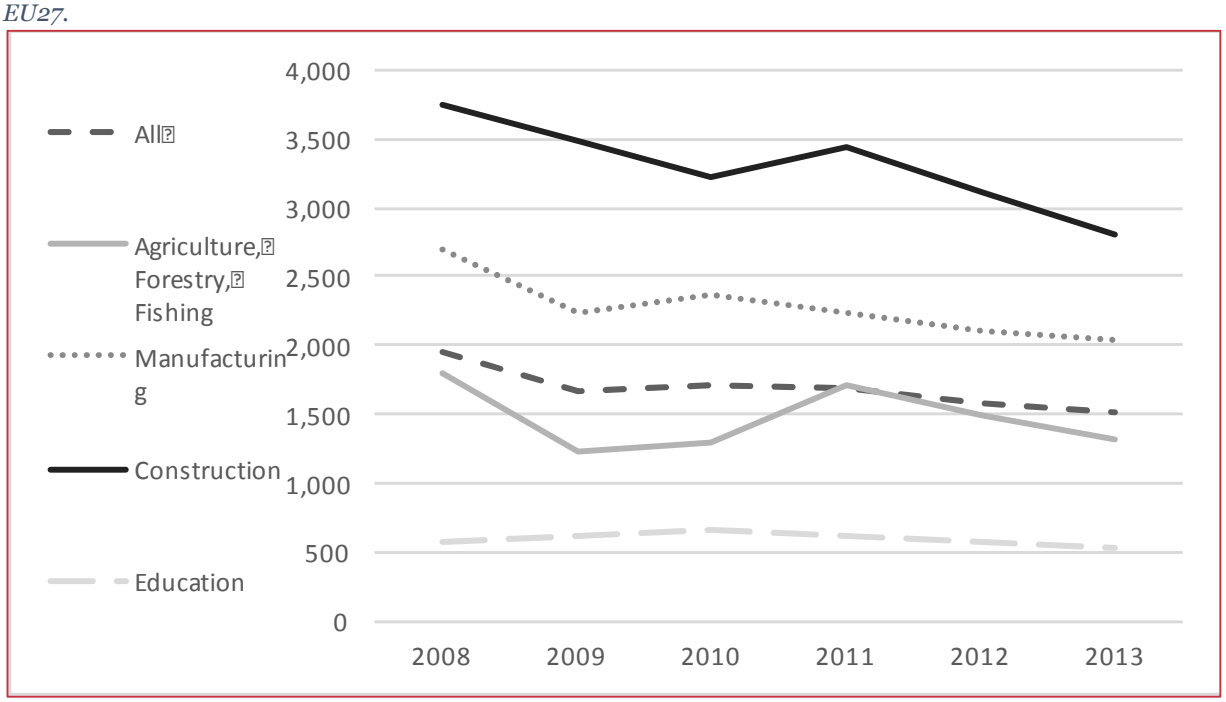
Non-fatal (>3 days absence)	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2008-2013 change**
Manufacturing	939,818	760,427	770,658	723,826	673,639	652,606	-31%
Construction	626,313	548,657	504,532	479,869	418,414	378,246	-40%
Agriculture, forestry & fishing	127,649	168,869	163,496	164,892	150,918	154,884	21%
Total (3 sectors)	1,693,780	1,477,953	1,438,686	1,368,587	1,242,971	1,185,736	-30%

Source: ESAW.

Among these sectors, the construction sector has the highest *incidence rate* of non-fatal accidents (2,797 per 100,000 in 2013), followed by the manufacturing sector (2,033 per 100,000). Both show well above the average incidence rates for all sectors (1,516 per 100,000), with construction workers 85% more likely to have an accident, while manufacturing workers are 34% more likely to have an accident than the overall average. The agriculture, forestry and fishing sector (which may also be relevant for machinery use), by comparison, has a relatively low incidence of accidents (86% of the overall rate in 2013). These sectors are presented in Figure 11. We have also included the education sector, as a non-manual, low machinery-use sector, for comparison. Here, the incidence rate (529 per 100,000 in 2013) is just one-third of the average rate.

Over the 2008 to 2013 period, the non-fatal accident incidence rate for all NACE codes combined fell by 23%. The reductions were comparable for the 'machinery-relevant' sectors, with declines of 27% for agriculture, forestry and fishing, 25% for construction, and 24% for manufacturing. The rate fell by only 6% in the education sector by comparison.

Figure 11 Incidence rate of accidents resulting in more than 3 days of absence from work, excluding fatal accidents, by economic activity of employer (NACE). Indicates number of incidents per 100,000 employees. EU27.



Source: ESAW. Incidence rates are calculated as the ratio between (i) the number of accidents for a given year, and sector and (ii) the corresponding number of employed persons (reference population) multiplied by 100,000.

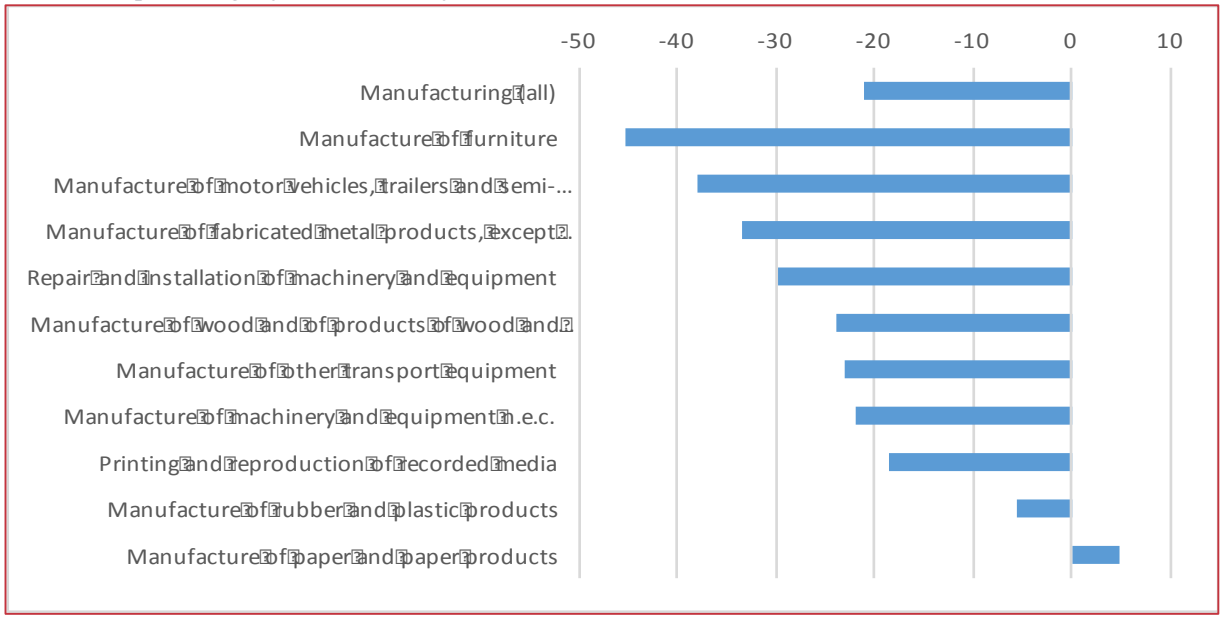
It is worth noting that within the overall agriculture, forestry, and fishing sector, the more specific forestry and logging sub-sector (which is particularly relevant to the Machinery Directive) showed very high accident incidence rates, at over two and a half times the overall rate. In addition, the incidence rate in this sector in 2013 (~4,000 per 100,000 employees) was higher than in 2008 (3,000), in contrast to the decline in rates over the period for the wider agriculture sector.

Similarly, within the machinery sector (NACE C), the sub-categories of "Manufacture of wood and of products of wood and cork, except furniture" and "Manufacture of fabricated metal products, except machinery and equipment" show particularly high accident incidence rates. By comparison, the lowest accident incidence rate is recorded for the manufacture of motor vehicles, trailers, and semi-trailers, with a rate 21% below the combined NACE rate in 2013.

A decreasing trend in accident incidence rates is visible for almost all sub-sectors of manufacturing (Figure 12). The strongest decrease was recorded for the manufacture of furniture, with a 45% drop

from 2008 to 2013. Two sub-sectors saw a marked increase from 2012 to 2013, the manufacture of wood and products of wood except furniture, and the manufacture of paper and paper products, masking or reducing a falling trend from 2008 to 2012. Of the two sub-sectors with the highest incidence rates, manufacturing of fabricated metal products saw a decrease of 22% from 2008 to 2013, while the incidence rate for manufacturing of wood increased by 5%, following an increase from 2012 to 2013.

Figure 12 Incidence rates of accidents with more than 3 days of absence from work in 2013, excluding fatal accidents as percentage of incidence rate for 2008



Source: ESAW.

Accidents and injuries at work – LFS data

The EU Labour Force Survey (EU LFS) is a large household survey providing data on labour participation of people aged 15 and over. In 2007 and 2013, it included ad-hoc modules which captured information on the number of employed persons who had one or more accidents at work resulting in injuries in the preceding 12 months. While accidents with less than four days' absence from work are included, fatal accidents at work are not included (unlike in the ESAW data above).

In both 2007 and 2013, 3% of the surveyed population (15-64 years in age, all 28 MS) reported that they had been involved in an accident at work. However, there were differences between occupations: with for example, higher rates in the groups 'skilled agricultural, forestry and fishery workers, craft and related trades workers' (OC6_7) and 'plant and machine operators and assemblers, elementary occupations' (OC8_9); and lower rates in the groups 'Managers, professionals, technicians and associate professionals' (OC1-3), and 'Clerical support workers, service and sales workers' (OC4_5).

However, the proportion reporting accidents in the first two groups (OC6_7 and OC8_9) fell between 2007 and 2013 (from 5.4% to 4.8% and from 4.3% to 3.9%), while the proportion reporting accidents in the second two groups rose (from 1.7% to 2.1% for OC1_3 and from 2.5% to 2.7% for OC4_5).

This trend is also visible when the data is broken down by economic activity of the employer: fewer individuals employed in the agriculture, forestry and fishing sector, as well as the construction sector reported accidents in 2013 (decrease from 3.7% and 3.2%, and 5.5% to 4.8%, respectively), while some sectors that are not based on manual labour (e.g. financial intermediation, real estate, renting and business activities, etc.) saw an increase from 2.2% to 2.6%.

Accidents and injuries relating to consumers

Data regarding consumer accidents are more difficult to find. One noteworthy example from Europe that covers consumer injuries (though not exclusively) is from the German Federal Institute for Occupational Safety and Health (BAuA), which publishes a yearly report on dangerous products that were identified. This includes an analysis of media articles on A&Is and of fatal accident statistics.

Media reports related to machinery accounted for 44.5% (265) of all reports on A&Is in 2013, and 41% (429) of all reports in 2014 (429). The two largest product groups were: machinery for transport and lifting - accounting for 23% of the reports in 2013 and 15% in 2014; and industrial machinery - accounting for 19% in 2013 and 18% in 2014. In 2014, other product groups mentioned with relevance to the MD include 'printers and printing accessories' (36, 4.4%), 'machinery for gardening, agriculture and forestry' (21, 3.5%), and electric tools (17, 2.9%). Individual products most frequently named were saws (electric tools), mowers and milling machines (gardening, agriculture and forestry), and fork lifts / lifting platforms (lifting). Products within the remit of the MD also accounted for the largest number of fatal accidents identified in the BAuA analysis (97, or 70%). Most of these were attributed to accidents involving earth-moving machinery (33%) such as excavators, cranes, and construction vehicles, while 26% were caused by "special purpose machinery".

Stakeholder views

The study consultation asked stakeholders about trends in **machinery-related health and safety** over the past decade. As the following table shows, respondents held very positive views about the changes they had seen. A majority reported increased levels of safety and protection for users of machinery (83%), improved information provided with machinery when purchased (71%) and increased user confidence in machinery safety (67%). A majority of respondents also suggested that the number (70%) and severity (70%) of machinery-related accidents and injuries had been reduced.

On a less positive note, around half of the respondents felt that the costs of ensuring that machinery is safe had increased significantly. Also, there were mixed views as to the number of unsafe or non-compliant machinery on the market or in use. While 45% felt the number of these products had decreased over the decade, almost as many (36%) felt that the number had increased.

Table 16 Over the past 10 years, what has happened to…. Machinery-related health and safety

	Decreased significantly	Decreased slightly	No change	Increased slightly	Increased significantly	n
The cost of ensuring that machinery is safe	2%	5%	8%	36%	49%	321
The level of safety/protection for users of machinery (workers/consumers)	2%	5%	10%	51%	32%	327
Usefulness of information provided with machinery when purchased	2%	6%	21%	41%	30%	328
User confidence in machinery safety	2%	5%	26%	44%	23%	318
The number of unsafe/non-compliant machinery on the market/in use	11%	34%	19%	28%	8%	285
The number of machinery-related accidents and injuries	16%	54%	22%	8%	1%	270
The severity of machinery-related accidents and injuries	23%	47%	20%	8%	2%	261

Source: Machinery Directive Public Consultation

Findings in relation to the Relevance of the Directive

The relevance criterion concerns the relationship between socio-economic needs and problems and the objectives of the intervention. More specifically, it relates to how well the original objectives of the intervention (still) match current needs and are appropriate to addressing current issues and problems.

5.2 Evaluation Question 2: correspondence between objectives and current needs

2. To what extent do the two initial objectives of the Machinery Directive correspond to the current needs of the market, manufacturers and users?
    a. To what extent does the initial objective of 'facilitating the functioning of the internal market and the free circulation of products' correspond to the current needs of the market, manufacturers and users?
    b. To what extent does the initial objective of 'ensuring a high level of safety of machinery' correspond to the current needs of the market, manufacturers and users?

Evaluation Question 2 concerns the extent to which the original objectives of the Machinery Directive are still relevant to the needs of the machinery market, including manufacturers and users. The two main objectives of the Directive relate to facilitating the functioning of the internal market for machinery, and ensuring a high level of safety of machinery. Each is addressed separately below.

This section presents economic data that show the continued importance of the MME sector within the EU and the significant level of MME trade within the Single Market. It provides evidence on the scale of A&I in relevant sectors (where rates tend to be above average) and estimates of the socio-economic cost of these incidents. The consultation exercises build on these secondary data, by seeking feedback from the different stakeholder groups as to their views on the relevance and appropriateness of the Directive and its main objectives from their perspective.

5.2.1 Relevance of objective to facilitate the functioning of the internal market

The original 1987 proposal for a Machinery Directive (COM/1987/564/FINAL) explained that the machinery sector was an important component of the EU economy, but that a lack of harmonisation in machinery safety legislation and certification created barriers to trade. One of the main objectives of the subsequent Directive was therefore to facilitate the functioning of the internal market and ensure the free movement of machinery within its scope.

In its proposal for the 2006 revision to the Directive (COM/2000/899/FINAL), the Commission highlighted the **significance of the sector**. It detailed that in 1998 the engineering sector (a proxy for machinery) in the EU15 had a production value of €300b (8% of total industry production), that it produced capital goods needed in a range of other sectors (giving it a key role in the competitiveness of the economy as a whole), that it led the world in terms of production volume, and that it employed 2.2 million engineers, technicians and workers. It also claimed the EU was by far the largest exporter of machinery and mechanical equipment at the time (€113b), and that the engineering sector generated the EU's largest trade surplus of all industrial sectors.

As was seen in the previous section, despite recent reductions in the number of MME enterprises, the machinery sector continues to be an important part of the EU economy 30 years after the adoption of the original Directive. It now accounts for 4% of all manufacturing businesses, 9% of all manufacturing production (value) and 10% of all persons employed in the wider manufacturing sector. Within certain Member States, the importance of machinery within the wider manufacturing sector is even more significant. In particular, in Denmark it accounts for 11% of manufacturing enterprises, 17% of manufacturing production and 19% of manufacturing employment, while in Germany it accounts for 8% of enterprises, 14% of production and 15% of employment in the wider manufacturing sector.

Its **importance in terms of trade** is even more significant (and growing). Nearly one-quarter (23%) of the value of all exports of EU MS in 2015 was accounted for by machinery. Around 60% of these exports went to other countries within the EU, meaning that €683b worth of machinery and equipment was traded between MS in a single year. Another €456b worth of machinery was exported from the EU to other countries around the world (particularly to the US and China), while €416b worth of machinery was imported to the EU from outside (predominantly from China, but also from another 200+ countries) – meaning the EU is a net exporter of machinery. The total value of both imports and exports of machinery to/from EU28 countries have also generally grown over the last decade, such that exports of machinery from the EU28 in 2015 (to the EU or elsewhere) were 12% higher (in real terms) than they were a decade earlier.

Table 17 attempts to summarise the movement of machinery within the EU. Using export values for 2015, the table shows for each EU28 country the total value of transfers to each other EU28 country, as well as the value of exports to other countries. It also uses import values to show imports to each country from outside of the EU. To take one example, the value of transfers from Spain to Italy in 2015 was €1,409m, while the value of transfers from Italy to Spain was €4,904m.

Shading is used to indicate the greatest concentrations of value (darker shading equals higher values of transfer between two countries). Countries that are the main origin/destination for transfers (in terms of value) appear towards the top left. These include, in particular, Germany and the Netherlands, which are the origin of ~40% of all transfers to other EU28 countries, and the destination for ~27%.

What this table demonstrates is not only the significant value of machinery being traded across the EU in a given year, but also the extent to which all MS are involved in the internal market for machinery. Trade is certainly concentrated – of the 756 combinations of countries, 18% account for 85% of the total value of trade – but this in part reflects significant differences in the sizes of MS economies. Also, the table shows that there is some level of intra-EU trade in machinery occurring between nearly every EU country and nearly every other one (just 3 cells are blank). Facilitating the functioning of the internal market and ensuring the free movement of machinery is therefore of EU-wide concern.

It is also worth noting the final row in the table, which shows the value of machinery entering each country from outside the EU. Three entry points stand out (Germany, the Netherlands and the UK), which account for nearly one-quarter of the value of all non-EU imports to the EU28. This partly reflects the size of the economies, but the Netherlands actually imports more than twice as much machinery (in terms of value) from non-EU sources than it does from EU sources. By comparison, the average EU28 country has non-EU imports of machinery that have half of the value of its EU imports.

Table 17 Value of intra-EU28 machinery trade (CN Section 16), 2015 (€m)

To / From	DE	NL	IT	FR	CZ	PL	UK	HU	AT	BE	ES	SK	SE	RO	DK	IE	FI	PT	SI	LU	BG	EE	LT	EL	HR	LV	MT	CY	**EU28**	**Non-EU**
DE		14,659	14,221	22,284	12,768	14,041	18,111	9,335	14,445	7,413	10,863	3,869	7,347	4,339	4,218	1,645	2,692	2,126	1,126	782	1,082	522	750	933	579	391	242	113	**170,906**	**151,512**
NL	27,811		6,678	13,124	4,447	4,249	15,454	1,706	1,426	8,047	4,827	754	5,380	798	2,095	1,198	1,566	1,025	183	386	341	418	364	427	191	169	57	95	**103,387**	**35,415**
IT	11,756	2,170		9,066	1,560	3,704	4,954	1,285	1,845	2,008	4,904	819	1,367	1,582	669	304	524	798	564	102	463	111	187	631	391	128	373	74	**52,339**	**55,381**
FR	14,348	3,328	4,512		938	1,784	5,574	1,000	670	3,631	6,110	850	1,161	1,150	541	378	384	622	121	209	198	52	83	181	53	85	131	26	**48,121**	**39,374**
CZ	17,643	2,004	1,640	3,019		1,950	3,052	1,435	1,628	905	1,533	2,500	817	660	410	252	305	167	107	42	197	67	146	105	85	72	20	52	**40,838**	**10,152**
PL	11,631	2,332	2,092	3,068	2,486		3,465	1,295	629	771	1,384	589	1,476	578	578	160	307	218	92	40	183	359	356	202	61	430	14	79	**34,877**	**9,935**
UK	8,791	3,006	2,409	4,106	1,022	1,261		516	528	1,600	1,987	200	1,243	372	738	4,136	436	264	64	55	148	73	96	197	45	63	82	56	**33,550**	**50,235**
HU	10,739	1,335	1,295	1,747	1,237	1,137	1,713		1,297	547	1,957	1,862	646	1,371	268	49	87	120	209	9	294	168	25	120	212	53	6	17	**28,519**	**7,130**
AT	11,768	536	1,081	1,232	1,078	1,225	1,324	1,257		336	784	3,569	527	631	195	73	173	73	404	44	158	34	37	94	308	44	12	17	**27,620**	**14,327**
BE	5,438	3,849	1,747	5,803	506	1,034	2,615	379	534		1,107	199	815	243	473	279	282	237	71	433	135	51	75	148	59	81	11	23	**26,628**	**12,102**
ES	3,587	496	1,409	4,425	331	1,044	2,718	272	187	484		140	485	657	250	87	260	2,141	41	55	66	19	103	147	53	22	23	21	**19,531**	**14,957**
SK	5,292	904	1,094	1,047	2,561	2,154	1,077	816	927	228	689		470	668	111	22	60	70	189	35	234	17	45	78	170	110	4	28	**19,099**	**3,189**
SE	2,215	1,136	660	1,724	229	708	1,032	106	255	1,924	524	62		84	2,731	82	2,183	101	45	42	46	262	204	56	27	92	10	4	**17,066**	**17,983**
RO	4,834	364	1,272	1,160	521	389	684	871	454	289	317	397	130		42	47	85	30	151	4	190	39	9	82	11	9	4	4	**12,389**	**2,812**
DK	4,341	718	383	682	162	553	1,117	152	163	222	371	53	1,696	45		85	454	40	20	8	17	40	124	38	20	48	5	7	**11,584**	**7,937**
IE	1,246	456	246	519	160	432	1,842	154	66	207	213	30	214	46	73		72	23	6	48	29	8	10	13	4	3	2	24	**6,149**	**5,262**
FI	868	549	285	337	86	315	310	57	172	132	210	23	890	69	181	49		27	12	6	22	304	62	21	11	75	1	1	**5,090**	**7,134**
PT	1,671	142	215	609	59	136	634	66	63	156	931	42	67	104	12	37	27		4	6	18	3	11	15	3	3	8	6	**5,050**	**2,224**
SI	1,576	95	372	237	154	167	163	232	453	38	129	650	85	145	82	8	22	13		2	27	6	6	18	269	12	4	8	**4,976**	**1,521**
LU	608	62	372	1,111	346	44	100	20	58	167	230	11	22	51	22	13	12	8	8		18	1	2	73	1	14	0.2	5	**3,582**	**986**
BG	744	170	356	304	105	93	85	116	137	67	90	63	54	302	23	4	18	16	57	1		10	12	111	10	7	3	7	**2,965**	**1,141**
EE	101	44	29	43	12	97	82	21	10	22	65	1	1,221	17	36	9	512	2	1	0.02	6		114	1	0.3	151	0.1	1	**2,600**	**716**
LT	199	40	43	46	42	241	45	22	10	27	24	22	87	14	61	3	49	8	3	1	12	201		7	2	358	1	3	**1,571**	**1,836**
EL	195	31	247	39	25	48	145	7	18	16	145	5	15	80	6	4	6	20	3	1	125	1	2		4	2	19	220	**1,429**	**826**
HR	316	41	143	80	32	35	55	30	234	33	22	22	24	21	35	14	13	2	158	1	9	2	6	5		8	1	2	**1,341**	**684**
LV	71	23	48	34	67	115	31	17	19	3	35	18	35	16	49	2	12	2	2	1	23	210	409	8	1		2	23	**1,276**	**747**
MT	74	9	23	78	1	0.3	21	1	1	2	4	1	1	0.5	0.3	0.3	0.1	1	0.2	0.2	0.1	-	-	0.1	0.02	0.1		0.1	**218**	**571**
CY	8	2	1	0.3	9	9	4	0.1	1	0.2	0.4	32	2	1	0.1	0.01	0.3	0.1	0.02	-	1	0.2	0.2	31	0.1	0.4	0.4		**105**	**75**
EU28	**147,870**	**38,501**	**42,872**	**75,923**	**30,945**	**36,968**	**66,408**	**21,168**	**26,230**	**29,274**	**39,456**	**16,784**	**26,279**	**14,043**	**13,901**	**8,939**	**10,542**	**8,156**	**3,643**	**2,315**	**4,045**	**2,979**	**3,240**	**3,740**	**2,572**	**2,431**	**1,033**	**919**	**682,806**	**456,165**
Non-EU	**92,130**	**84,917**	**21,287**	**35,305**	**15,224**	**13,537**	**68,142**	**10,116**	**8,664**	**13,476**	**13,822**	**5,123**	**7,920**	**3,634**	**3,417**	**5,465**	**2,060**	**1,522**	**1,603**	**3,001**	**1,147**	**655**	**486**	**1,737**	**503**	**541**	**368**	**142**	**415,941**	

Source: Technopolis, based on COMEXT. EU trade since 1988 by CN Sections (DS-058342)

Through consultation we asked various types of stakeholder to assess the **level of importance** they attached to the objective of ensuring free movement of machinery within the European Single Market. As the results below show, 99% of respondents regarded this aim as in some way important, with the majority (78%) suggesting it was 'very important'. This is a strong indication that the objective is of high relevance to the needs and concerns of EU stakeholders. Inevitably different stakeholder groups place different weights on the objective. Nevertheless, even a majority (57%) of users and consumers (and their representatives) regard it as very important. The proportion of public authorities, notified bodies and businesses seeing it as very important is 75%+ in each case. The objective can therefore be seen as having wide-spread support and relevance, both to the machinery market and amongst users.

Table 18 How important is the objective of ensuring the free movement of machinery

	Not at all important	Slightly important	Moderately important	Very important	n
Ensuring the free movement of machinery within the European single market	1%	4%	17%	78%	398

Source: Machinery Directive Public and Targeted Consultation. Excludes 'don't knows' and non-respondents.

In order to further assess relevance, stakeholders were also consulted on the **appropriateness** of the Machinery Directive, in terms of its scope and provisions, as a means to contribute towards the fulfilment of the objective of ensuring free movement of machinery. Again (see below), the responses were strongly positive, with the vast majority of stakeholders (88%) stating that the Directive (at least its concept and intentions) was 'entirely appropriate' as a response to this aim.

Table 19 Is the Machinery Directive an appropriate means to contribute to its objectives

	Not all appropriate	Somewhat appropriate	Entirely appropriate	n
Ensuring the free movement of machinery within the Single Market	1%	10%	88%	86

Source: Machinery Directive Targeted Consultation. Excludes 'don't knows' and non-respondents.

5.2.2 Relevance of objective to ensure a high level of safety of machinery

The original 1987 proposal for a Machinery Directive (COM/1987/564/FINAL) explained that EU Member States have a responsibility to ensure the health and safety of machinery users, and that accidents from using machinery have a social cost that could be reduced through safer design, construction, installation and maintenance. One of the main objectives of the subsequent Directive was therefore to ensure a high level of health and safety protection for machinery users.

As was seen in the previous section (ESAW data), despite a downward trend in the total **number and incidence rates of accidents at work** (all sectors) between 2008 and 2013 (-19% for total non-fatal and -23% for total fatal accidents), in 2013 there were still over three million non-fatal (more than three days of absence) and around 3,700 fatal accidents in the workplace across the EU in total (equivalent to one or two accidents each year per 100 people in employment). This implies that (at least *on average*) most people will have an accident at work during their lifetime that will cause more than three days of absence from work or fatality.

In addition, ESAW data suggest that the sectors and occupations that are most relevant to the Machinery Directive tend to have higher rates of accidents, compared to the economy as a whole. For instance, the incidence rate of accidents in manufacturing (2.0 non-fatal accidents per 100 employees) and construction (2.8 non-fatal accidents per 100 employees) in 2013, were both well above the average for all sectors (1.5 non-fatal accidents per 100 employees). Certain sub-sectors experience even higher rates, e.g. 4/100 for forestry and logging, 4/100 for manufacture of wood products, and 3/100 for manufacture of fabricated metal products. Similarly, in 18 EU countries with data, the number of accidents in 2013 for plant machine operators and assemblers totalled over 270,000, accounting for 14% of accidents across all occupations.

Data on accidents at work collected within the 2013 EU LFS also suggest higher rates amongst groups such as skilled agricultural workers (4.8%) and plant/machine operators (3.9%) which are likely to be more relevant to the Machinery Directive than others, e.g. managers and professionals (2.1%).

It is also well documented that there are significant financial and other (social) **costs of accidents and injuries in the workplace**. The European Agency for Safety and Health at Work (EU-OSHA) recently commissioned a review of past studies evaluating the costs of Occupational Safety and Health[13]. This identified over 400 relevant studies, of which a small number were looked at in more depth. Within these studies, the main categories of financial and non-financial costs considered were:

- Productivity costs - costs related to the loss of output or production
- Healthcare costs - direct (e.g. pharmaceuticals) and indirect (e.g. care time) medical costs
- Quality-of-life losses - monetary valuation of e.g. pain and suffering
- Administration costs - e.g. applying for support or reporting on an accident
- Insurance costs - such as compensation and insurance premiums

The review found variation in the overall cost estimates for different cases, but provided examples to indicate the general size and scale of costs related to OSH. These included:

- Costs to the UK economy of €16b in 2010/11 (~1% of GDP)
- Costs to the Australian economy of AU$37b in 2008/9 (4.8% of GDP)
- Costs to the Netherlands economy of €12.7b in 2001 (3% of GDP)

The Health and Safety Executive[14] also recently estimated the financial and non-financial costs of *individual* fatal and non-fatal accidents at work in the UK. The results (see extract in Table 20 below) suggest that the total costs of a fatal injury at work are around €2m, while the total cost of non-fatal injuries can be between €1,000 and €35,000, depending on the severity of the injury.

These figures are used to monetise the benefits of the MD (in terms of cost savings) in Section 5.11.

Table 20 Estimated cost of accidents at work in the UK (per injury)

Type	Non-financial human cost	Financial cost	Total cost
Fatal injuries	€ 1,423,457	€ 520,494	€ 1,944,444
Non-fatal injuries: 7+ days absence	€ 21,728	€ 12,469	€ 34,198
Non-fatal injuries: <7 days absence	€ 407	€ 679	€ 1,086

Source: Costs to Britain of workplace fatalities and self-reported injuries and ill health, 2013/14 (HSE, 2014). Figures converted by Technopolis based on exchange rate of £1: €1.23

There are fewer studies on the **costs of accidents and injuries in the home**, **or involving consumers**. However, one example is an Australian study conducted in 2006[15] which looked at the direct financial costs (only) of consumer product-related injuries. This concluded that the direct treatment of all non-intentional consumer product-*related* injuries in Australia cost at least AU$1,364m annually, while treatment for non-intentional consumer product-*caused* injuries cost at least AU$253m. The methodology does not allow a cost per injury to be calculated.

These various statistics confirm that machinery can and does threaten health and safety, and that accidents and injuries, at work and in the home, have significant economic and social costs.

Through consultation we also asked various types of stakeholder to assess the **level of importance** that they attached to the objective of ensuring a high level of health and safety for users of machinery. As the results below show, 99% of respondents regarded this aim as in some way important, with the vast majority (91%) suggesting it was 'very important'. This is a strong indication that this objective is of high relevance to the needs and concerns of EU stakeholders.

[13] Estimating the cost of accidents and ill health at work (EU-OSHA, 2013)

[14] Costs to Britain of workplace fatalities and self-reported injuries and ill health, 2013/14 (HSE, 2014), available at: http://www.hse.gov.uk/statistics/pdf/cost-to-britain.pdf

[15] Consumer product-related injury in Australia: direct hospital and medical costs to Government (2006). Available at: http://www.monash.edu/__data/assets/pdf_file/0004/217399/muarc083.pdf

Different stakeholder groups place slightly different weight on this objective. Even so, at least 91% (in the cases of businesses and their representatives) of each of the stakeholder groups consulted rated the objective as 'very important'. It can therefore be seen as having widespread support and relevance, both to the machinery market and amongst users, as well as amongst other interested bodies.

Table 21 How important is the objective of ensuring a high level of health and safety for users of machinery

	Not at all important	Slightly important	Moderately important	Very important	n
Ensuring a high level of health and safety for users of machinery (workers/consumers)	1%	1%	8%	91%	400

Source: Machinery Directive Public and Targeted Consultation. Excludes 'don't knows' and non-respondents.

Stakeholders were also consulted on the **appropriateness** of the Machinery Directive, in terms of its scope and provisions, as a means to contribute towards the fulfilment of the objective of ensuring the health and safety of machinery users. Again (see below), the responses were strongly positive, with the vast majority of stakeholders (84%) stating that the Directive (at least its concept and intentions) was 'entirely appropriate' as a response to this aim.

Table 22 Is the Machinery Directive an appropriate means to contribute to its objectives

	Not all appropriate	Somewhat appropriate	Entirely appropriate	n
Ensuring a high level of health and safety for users of machinery (workers and consumers)	0%	16%	84%	86

Source: Machinery Directive Targeted Consultation. Excludes 'don't knows' and non-respondents.

5.3 Evaluation Question 3: The extent to which the Directive deals with innovation

3. How (and to what extent) is the Machinery Directive (and the tools and mechanisms it provides for) able to deal with innovations, new technologies and the changing business environment?
    a. How (and to what extent) is the Machinery Directive (including the essential Health and Safety requirements in Annex I) able to deal with innovation and new technologies?
    b. How (and to what extent) is the Machinery Directive able to deal with changes in the business environment (e.g. anticipated increases in extra-EU imports)?
    c. How is technological innovation influenced (positively or negatively) by the Directive?

Evaluation Question 3 concerns changes in machinery technology or the wider sector/market, and the relationship of these to the Directive. This first requires an assessment of the ability of the Directive (through revision or in its existing form) to accommodate or deal with the changing business and technological environment (e.g. to ensure safety for new types of machinery, or to address rising imports from third countries). Secondly, the question requires an assessment of the influence of the Directive *on* technological innovation – to ensure that this is positive (i.e. the Directive acts as an enabler of innovation), or that it at least does not have a negative influence (i.e. acting as a barrier).

5.3.1 Whether the Directive can accommodate changes in technology or the business environment

As already noted, the Machinery Directive has actually undergone several iterations since the adoption of the original version in 1989 (89/392/EEC). Below, we examine these changes in more detail, and in particular the main changes to the scope and requirements of the Directive over time.

The **first version** of the Directive (89/392/EEC) was amended by Directive 91/368/EEC and Directive 93/44/EEC. The main changes introduced by these two amendments are summarised in Table 23 below. Both amendments widened and at the same time narrowed the scope of the

Machinery Directive (in terms of the machinery covered by the requirements). Both amendments also added new essential health and safety requirements, mostly to reflect changes to scope.

Table 23 Significant amendments to the Machinery Directive (1991, 1993)

Directive	Main changes to scope	Main changes to EHSR	Other
91/368/EEC	**Widened scope** to include • mobile equipment (assembled with machines by operator) • machinery for lifting/lowering loads **Narrowed scope** to exclude • means of transport • seagoing vessels and mobile offshore units • cableways for transportation of persons • agricultural and forestry tractors • machines specially designed and constructed for military or police purposes	**Chapters added:** • 3 EHSR to Offset the Particular Hazards Due to the Mobility of Machinery • 4 EHSR to Offset the Particular Hazards Due to A Lifting Operation • 5 EHSR for Machinery Intended Solely for Underground Work Small number of changes to wording in existing EHSR.	
93/44/EEC	**Widened scope** to include • safety components placed on the market separately **Narrowed scope** to exclude • funicular railways • lifts that permanently serve specific levels • means of transport of persons using rack and pinion rail mounted vehicles, • mine winding gear, • theatre elevators, • construction site hoists intended for lifting persons	**Chapters added**: • 6 EHSR to Offset the Particular Hazards Due to the Lifting or Moving of Persons Small number of changes to wording within existing EHSR.	Minor additions/ changes to wording of several articles

Source: Technopolis, based on review of Directives and associated proposals

A **second version** of the Directive was then adopted in 1998 (98/37/EC), which updated the original version of the Directive to consolidate the subsequent amendments that had been introduced. This Directive was amended once by Directive 98/79/EC on in vitro diagnostic medical devices (which excluded such products from the scope of the Machinery Directive).

A **third version**, which is the focus of this evaluation, was adopted in 2006 (2006/42/EC). This was a comprehensive amendment and recasting, intended (inter alia) to extend the scope and improve the clarity of the Directive, remove acknowledged flaws, and provide an additional route to conformity assessment for some products. The main changes introduced by this revision are summarised in Table 24. This Directive was then amended in 2009 to cover pesticide applications.

Table 24 Significant amendments to the Machinery Directive (2006, 2009)

Directive	Main changes to scope	Main changes to EHSR	Other changes
2006/42/EC	**Widened scope** to explicitly include • Partly completed machinery • Certain lifts (Construction site hoists intended for lifting persons or persons and goods; lifts with a travel speed no greater than 0.15m/s) and lifting accessories • Chains, ropes and webbings • Portable cartridge-operated fixing and other cartridge-operated impact machinery (Reintroduction from 89/392/EEC)	Broadly same structure as Directive 98/37/EC, though wording changed in many instances, with text consolidated into new sub-sections. **Subsections added:** • 1.1.6. Ergonomics • 1.1.7. Operating positions • 1.1.8. Seating (Under section 1.1) **Additional requirements** to include more languages for instructions, and pictograms for information and warnings • 1.7.1 Information and warnings on machinery • 1.7.4. Instructions	Introduction of new 'full quality assurance' system option for conformity assessment.

Directive	Main changes to scope	Main changes to EHSR	Other changes
2009/127/EC	Machinery on pesticide application had been included in scope in Directive 2006/42/EC, but no specific requirements were mentioned for this type of machinery at that time.	**Section added**: 2.4. Machinery for Pesticide Application	

Source: Technopolis, based on review of Directives and associated proposals

Each iteration to the Directive outlined above contained additional / revised elements, including changes to the scope and/or to the EHSR set out in its annex. However, none of these changes obviously came about as a reaction to changes in technology or the market (and there is nothing within the Commission proposals for these amendments to suggest this). Instead, the scope has been widened to cover (or more explicitly cover) a wider range of pre-existing machinery, or narrowed to reflect the introduction of other more specific Directives, while the main changes to the EHSR have then been additions / subtractions to reflect this changing scope. Other changes to the wording of the Directive / EHSR tend to reflect an effort to improve clarity, rather than changes in technology.

The 2009 amendment to include pesticide applications within the scope of the Machinery Directive was in response to external policy changes (i.e. to support wider efforts to reduce the impact of pesticides on human health and the environment), rather than changing technology. Similarly, new requirements on ergonomics and operating positions are likely to reflect changes in the perceived relevance / importance of these aspects of health and safety, rather than technological change.

This apparent lack of adjustment of the Directive to reflect changes in technology or the business environment is unsurprising, given the intentions of the New Approach. The fundamental principle is that legislative harmonisation is limited to essential requirements, while the task of drawing up technical specifications is entrusted to organisations competent in standardisation which take the current stage of technology into account. Indeed, the Directive itself states that "the Directive must be based on a general definition of the term 'machinery', so as to allow the technical development of products…" and that "requirements must be applied with discernment to take account of the state of the art at the time of construction, and technical and economic requirements". In this way the Directive itself should stand the test of time, except in those cases where its scope expands and the particular types of machinery in question are associated with new and different risks to health and safety (e.g. particular hazards due to mobility of machinery), or indeed where the understanding or perception of risks changes (e.g. in the case of ergonomics, seating, operating positions).

The question is whether this works in practice (i.e. are the EHSR set out in the Annex to the Directive appropriate / sufficient when applied to new technologies?). There are indications that it does - the 2012 competitiveness of mechanical engineering report[16] found that the Machinery Directive had been "appreciated by industry", and that "sufficient leeway is given for the design of innovative products". We have consulted stakeholders further on this issue through the current study.

Specifically, respondents to the public consultation were first asked for their **views on the extent to which the Directive takes sufficient account of new innovations** and new technologies. The overall response was positive, in the sense that only 4% reported that the Directive *did not* sufficiently take account of innovation at all. However, the opinions of the remainder of respondents were divided as to whether it took sufficient account of innovation only to a small (26%), moderate (33%) or large extent / entirely (36%), suggesting that for a majority of stakeholders the Directive is not entirely adequate in the face of ongoing technological change in the machinery sector.

Through targeted consultation, we explored the issue in more detail. Respondents were asked to think specifically about the 2006 revision to the Directive, which applied from the end of 2009 (and is the particular focus of this evaluation). They were asked to consider the situation for three different

[16] An introduction to Mechanical Engineering: Study on the Competitiveness of the EU Mechanical Engineering Industry' (2012)

periods (at the time of publication, in the period since, and over the next decade), and to assess the extent to which the Directive has / will be sufficiently able to cope with technological change.

Stakeholders generally had very positive opinions, with half or more reporting that the Directive largely or entirely took account of and was able to cope with innovations across the three periods concerned (i.e. taking account of innovation at the time of its introduction, able to deal with innovations since, and likely to be able to deal with innovations emerging over the coming decade). As might be expected, there is some evidence of a downward trend in expectations over time (i.e. the Directive is less widely perceived as being able to deal with coming innovations than it was able to deal with recent innovations at the time of its first publication). However, the shift in views across the time periods is relatively minor, suggesting that the Directive is generally seen as being able to "cope" with changing technology over a very long time period (some 20+ years are considered in the table overall).

Table 25 To what extend does the current Directive sufficiently allow for innovation – three perspectives

	Not at all	To a small extent	To a moderate extent	To a large extent	Entirely	n
Took account sufficiently of new innovations and new technologies at the time?	1%	11%	26%	45%	16%	87
Has been able to deal with new innovations and new technologies since?	0%	12%	32%	29%	27%	85
Is likely to be able to deal with new innovations and technologies over the next 10 years?	0%	20%	32%	23%	26%	82

Source: Machinery Directive Targeted Consultation. Excludes 'don't knows' and non-respondents.

Stakeholders were asked further whether they could point to **particular areas** where the Machinery Directive (its provisions and requirements) is not / will not be fit for purpose in relation to innovations and new technologies. Most comments supported the idea that there was no real issue because of the way in which the Directive works. They pointed to the fact that the Directive sets out in general terms the essential health and safety requirements, which are principles and not devised to apply to specific technologies or to prescribe the type of technical solutions to be used. As a result, manufacturers can utilise the state of the art (as described in standards), whilst having the freedom for further technological development and innovation. As such, these stakeholders explained, no change to the Directive is necessary in order to address changes in technologies and their application. Rather, as one respondent put it, "the concept is a successful basis for the integration of future technologies." Related to this point, one interlocutor did raise a concern that the 2006 revision to the Directive had introduced certain content from existing standards into the EHSR themselves (in relation to the requirements for guards), with the risk that these requirements may consequently become less flexible in adapting to future changes. The stakeholder explained that the success of the Directive relied on not blurring the lines between the essential requirements and technical specifications.

A number of individuals did point to specific new products, innovations or requirements that they felt may not be well addressed by the Directive currently. These tended to relate to the areas of digitisation and robotics. For example, the respondents mentioned autonomous machines/systems, artificial intelligence, collaborative robotics, mobile robotics, electrified machines, hybrid engines, smart appliances, wireless applications, and issues around cyber security (the risk of hacking and implications for product safety), digitisation, online control of functions and remote management. A selection of more detailed observations is presented below.

Figure 13 Examples of innovations and new technologies where the Directive is thought to be insufficient

"Today, machine "intelligence" is in electronics and especially in software. The MD covers mechanics and especially hardware very well, but it does not provide much for complex embedded software systems, especially with increasingly autonomous function."

"The MD needs a clear position on the use of assistance systems. The safety of machines is increasingly dependent on software; knowledge and consideration by the manufacturers is sometimes very low."

"Use of modern media for machine control is not considered. Particularly dangerous are, in my view, the

possibilities of remote control, data collection and security in installations (in the sense of Industry 4.0)."

"Software is not considered at all in the Directive, but it is a very important part of many products in industrial automation and plays a large role regarding machinery safety."

Source: Machinery Directive Public Consultation. Selected quotes.

Respondents to the public consultation were also asked for their **views on the extent to which the Directive takes sufficient account of wider changes in the business environment** (beyond innovation and technological change, covered above). The response again was broadly positive, in that that only 9% of stakeholders reported that the Directive was not at all sufficient to take account of recent changes. However, there was a range of opinions amongst the remainder of respondents as to the extent to which it was able to deal with the evolving business environment - to a small (32%), moderate (35%) or large extent / entirely (25%) – suggesting that for a majority of stakeholders the Directive is not entirely adequate in the face of changes in the business environment.

Through the targeted consultation, we explored this issue in more detail. Respondents were again asked to think specifically about the 2006 revision, and to assess the extent to which it sufficiently allowed/allows for the changes in the business environment that were seen or expected.

Stakeholders were generally positive, with 59% reporting that the Directive largely or entirely took into account recent changes in the business environment at the time of its publication, 48% reporting it had been able to deal with changes since this time, and 45% reporting that it was likely to be able to deal with further changes emerging over the coming decade. There is some evidence of a downward trend in expectations over time. For instance, while nearly a quarter of respondents (23%) felt that the Directive had entirely taken into account the changes seen in the business environment at its time of publication, only 8% believed that it would be entirely appropriate to cope with future changes. This shift in the perception of the relevance or appropriateness of the Directive for the evolving business environment appears somewhat more significant than the opinions related to its ability to cope with technological change.

Table 26 To what extent does the current Directive sufficiently allow for a changing business environment – three perspectives

	Not at all	To a small extent	To a moderate extent	To a large extent	Entirely	n
Sufficiently took account of recent changes in the business environment (i.e. in the machinery sector / market / trade) at the time?	3%	12%	27%	36%	23%	78
Has been able to deal with changes in the business environment since?	1%	16%	34%	34%	14%	79
Is likely to be able to deal with changes to the business environment over the next 10 years?	3%	19%	33%	37%	8%	73

Source: Machinery Directive Targeted Consultation. Excludes 'don't knows' and non-respondents.

Stakeholders were further asked whether they could point to **particular areas** where the MD (i.e. its provisions and requirements) is not (or will not be) fit for purpose in relation to changes in the business environment. Frequent responses concerned the rise of Internet sales/ e-trade and fulfilment houses[17] (where products are not owned by the operator of the fulfilment house). Many respondents also mentioned an apparent rise in non-compliant machinery (particularly from outside of the EU) and inadequate action to address this (be that awareness and understanding of requirements, more or better targeted market surveillance, or other enforcement measures). Other individual respondents highlighted a need to better address the innovative market of machine modification, and a desire for better alignment with legislation on workers (which implies additional requirements on equipment

[17] Third-party firms that take another company's products from the supplier, stock the inventory on their own premises, then package and ship off the products when an order is received.

when it is put into service). Several commentators also suggested that the provision of instructions in electronic format (not prohibited by the Directive, but not explicitly allowed) should be considered.

5.3.2 How technological innovation is influenced by the Directive

As was noted above, a majority of respondents to the public consultation felt that the rate and extent of innovation in the machinery sector overall has increased over the past decade. Indeed, over one-third felt that it had increased *significantly* over the period. We asked further whether a link could be made between the MD (specifically) and any increase in the rate and extent of innovation. Views were mixed. Around half of the respondents to the targeted consultation (49%) reported that the Directive had had a positive impact on the rate and extent of innovation in the machinery sector, while 44% believed there had been little or no impact. A further 8% felt that it had in fact had a negative effect.

Similarly, in the public consultation (see Table 27) 44% of respondents claimed there had been an increase in the rate and extent of innovation as a result of the Machinery Directive (though mostly to a limited extent), while 47% felt there had been no change as a result of the Directive. A further 9% felt it had actually led to a decrease in innovation activity in the sector.

Table 27 Impact of the Directive on rate and extent of innovation

	Substantial decrease	Some decrease	No change	Some increase	Substantial increase	n
The rate and extent of innovation in the sector	1%	8%	47%	31%	13%	209

Source: Machinery Directive Public Consultation. Excludes 'don't knows' and non-respondents.

It is likely that the Directive is acting both as an enabler and barrier to innovation, and that the perception of the balance between these different influences is different for different stakeholders.

There are a couple of key means by which the Directive might **positively influence or enable technological innovation**. First, the Directive seeks – as one of its core objectives – to facilitate trade within the Single Market through the reduction of barriers to trade. This implies that businesses can trade throughout the EU more easily and efficiently as a result of the legislation, and therefore (potentially) generate greater returns to investments in innovation because of improved access to a large marketplace. Second, the Directive relies on the development of a large portfolio of standards. It is well documented[18] that such standards can be beneficial for innovation (e.g. as a technology transfer channel for the state of the art). Stakeholders also mentioned innovative safety features being introduced as a direct result of the Directive, as well as innovative measurement and detection tools / techniques that had been established as part of related conformity assessment activities.

At the same time, the Directive could have a **negative influence on, or act as a barrier to, innovation**. In particular, the need to adhere to the relevant requirements of the Directive may add to the costs and / or complexity of introducing new technology, and therefore discourage or hinder innovation. This could have negative impacts on the overall rate and extent of innovation, or at least balance out to some extent the positive influences suggested above. The Community Innovation Survey 2012[19] lends some support to this conjecture (though its focus is broader than just Machinery). It found that that 26% of innovative enterprises across 18 EU countries (for which data is available) considered the 'high costs of meeting regulations' to have been a highly important obstacle to innovation in recent years. This compares to 23% that felt that the costs of regulations had not been at all important. (The costs of the Machinery Directive are looked at in more detail within Section 5.10 of this report). Stakeholders also mentioned that with more advanced and innovative manufacturing technologies, it may (at least in the short term) be more difficult to demonstrate compliance with the Machinery Directive. Examples associated with robotics and digitisation were again mentioned.

[18] See, e.g. 'Encouraging innovation and growth with standards': http://www.bsigroup.com/en-GB/standards/benefits-of-using-standards/standards-for-innovation-and-growth/ or 'Standards for innovation-benefits': http://www.cencenelec.eu/research/innovation/Pages/default.aspx

[19] [inn_cis8_obst] 'Obstacles of innovative and non-innovative enterprises - as highly important and not relevant'

Findings in relation to the Effectiveness of the Directive

This criterion concerns how successful an intervention has been in achieving or making progress towards its aims and objectives. This includes an assessment of the extent of progress made as a result of the intervention, as well as of the factors driving or hindering this progress.

5.4 Evaluation Question 4: discrepancies in interpretation of requirements

4. What are the discrepancies between Member States in the interpretations of the requirements of the Machinery Directive, and what are the reasons for – and implications of – these discrepancies?
    a. Where are there discrepancies between Member States in the implementation of the Directive (e.g. in the rules for self-certification, inspections, scope and concepts, requirements for particular products, etc.)?
    b. What are the reasons for these discrepancies?
    c. What are the implications of these discrepancies (e.g. on costs, or on market behaviour)?

EU Directives set out results that all EU Member States must achieve, as well as some broad requirements for activities and procedures that must be put in place, but national authorities then have the choice of form and method to meet these results and requirements through the adoption of their own national transposition measures (which incorporate obligations of a Directive into national law). They must do so by a set deadline (June 2008 for the 2006 revision to the Machinery Directive).

Evaluation Question 4 concerns the extent to which the requirements of the Directive have been interpreted and implemented differently across Member States as part of this process. It requires the study to identify discrepancies that exist, and to explore the reasons for, and implications of, these differences. While such a question touches on the 'coherence' of the Directive's implementation, it is included under the criteria of 'effectiveness' at the request of the Steering Group, because discrepancies can be considered as a potential barrier to the effectiveness of the Directive.

Initial reviews of national legislation highlighted that it would prove difficult within this study to make wide-ranging comparisons between all national legislation, because of the complexity of the relevant set of transposing documents in some Member States. Instead, the evaluation has focused on identifying areas of potential incoherence by exploring the infringement procedures initiated against Member States and by asking stakeholders to highlight potential problematic areas.

5.4.1 Member State transposition and implementation

All Member States must provide the Commission with the texts of **transposition measures** adopting Directives. These are examined to verify what measures have been taken to incorporate EU Directives into national law and to ensure that they achieve the results required by the Directive. When Member States fail to notify the Commission in time regarding national transposition measures, or if after assessment the Commission finds that the national measures are incomplete, it opens an infringement procedure against the Member State for 'non-communication'.

The Commission's annual reports monitoring the application of Union law[20] provide details of these non-communication infringements, including those relating specifically to the Machinery Directive. The 2008 report[21] notes that 12 non-communication cases were opened (letter of formal notice) following the June 2008 deadline. These concerned BE, IE, GR, ES, FR, IT, CY, LU, HU, PL, RO, and

[20] http://ec.europa.eu/atwork/applying-eu-law/infringements-proceedings/annual-reports/index_en.htm

[21] 26th Report on monitoring the application of Community law [COM(2009) 675] – Situation in the different sectors [SEC(2009)1684/2]

SI. The 2009 report[22] confirms that all but three (GR, IT, LU) of these infringement proceedings for non-communication were closed following receipt of measures, and that reasoned opinions had been addressed to the three remaining countries. The 2010 report[23] then shows: that the Italian case was closed on 18/3/2010 following reasoned opinion; that the case of Luxembourg received a referral to Court, which was subsequently withdrawn; and that the case of Greece was referred to Court and closed during 2010. Therefore, by the end of 2010, all infringement proceedings concerning national measures implementing Directive 2006/42/EC were closed.

Possible infringements of EU law can also be identified by the Commission or reported in a complaint after this initial transposition period. These also result in infringement procedures against countries. The EU infringement process is generally divided into two phases:

- Early settlement: where the relevant Member State is informed of a possible infringement via the EU Pilot system, and has two months to respond with further information. Ideally, a quick solution can be found, without the need to instigate a formal infringement procedure.
- Formal procedures: if the Commission is not satisfied with the Member State's reply, a formal infringement procedure is opened consisting of up to five steps[24], from a letter of formal notice through to judgement by the Court of Justice and possible penalty payments.

Early settlements are usually resolved through the EU Pilot system. Between April 2008 and September 2011, 1,410 files were opened in this system (concerning *any* Directive), and in the vast majority (79%) of these cases the response by the national government was satisfactory to the Commission, and no formal infringement procedure was launched[25]. However, a minority of cases do proceed to formal measures. Details of all formal infringement procedures from 2002 onwards are published in a dedicated EU website[26]. There are 27 infringement procedures relating to "2006/42" (the Machinery Directive), of which 12 can be accounted for by the non-communication infringements mentioned above, meaning that 15 concerned other formal infringements procedures (involving AT, BE, CY, CZ, FI, FR, DE, GR, HU, IT, LU, NL, SI, ES and UK). We do not have details of the specifics of these cases, but all were resolved after the first stage (letter of formal notice), suggesting that the possible infringements were either found to be invalid, or have now been rectified within national legislation.

5.4.2 Views on discrepancies and differences of interpretation

Stakeholders also were asked for their views as to the extent to which various aspects of the Machinery Directive have been fully and consistently interpreted and applied across Europe. This went beyond the initial transposition of legislation to also ask about the establishment of bodies and procedures, and the fulfilment of conformity assessment, market surveillance and enforcement activities.

The table below shows the extent to which stakeholders believed that each of these areas had been fully and consistently interpreted and applied in Europe. It suggests that there is considerable variability between the experiences and views of individual stakeholders (i.e. on a given aspect some rate consistency very poorly, while others rate it very highly), as well as significant differences in the seeming consistency with which different parts of the Directive 'system' are generally considered to have been interpreted and applied (i.e. the majority view of some areas is very positive, while the majority view of others is not).

Broadly, there appear to be five areas (appearing at the top of the table) where implementation and application of the Directive are generally considered to be **largely consistent across Europe**. These are: the initial transposition of the Directive into law, the appointment of Notified Bodies and

[22] 27th Report on monitoring the application of EU law [COM(2010) 538]

[23] 28th Report on monitoring the application of EU law [COM(2011) 588]

[24] http://ec.europa.eu/atwork/applying-eu-law/infringements-proceedings/index_en.htm

[25] Commission Staff Working Paper accompanying the document 'Second Evaluation Report On EU Pilot' SEC(2011) 1626 final (http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52011SC1626&from=EN)

[26] http://ec.europa.eu/atwork/applying-eu-law/infringements-proceedings/infringement_decisions/?lang_code=en

the assessments they undertake, the conformity assessment procedures available to companies, and the fulfilment of the requirement of not prohibiting, restricting or impeding machinery that has demonstrated compliance with the requirements of the Directive. However, even in these areas it should be noted that there are several respondents who believe that the procedures have not been very consistently applied.

As a related aside, a separate question on the clarity of the Directive itself found that the vast majority (80%+) of stakeholders were largely or entirely clear about the products covered by the Directives, the essential health and safety requirements specified, and the requirements and obligations placed upon their organisation by the Directive. This suggests overall levels of knowledge and understanding of the Directive and its core parameters are very good (at least from each individual's own perspective).

The four areas at the bottom of the table are of greater concern, in that a majority of respondents believe that these have **not been applied fully or consistently** at all, or only to a small extent. These all relate to the monitoring and enforcement of the Directive and include: the number of market surveillance activities, the approach taken during market surveillance to determining compliance, the measures taken to withdraw or prohibit machinery that may compromise health and safety, and the establishment of effective, proportionate and dissuasive penalties for infringements.

Table 28 Extent to which the Directive has been fully and consistently interpreted and applied

	Not at all	To a small extent	To a moderate extent	To a large extent	Entirely	n
The transposition of the Directive into national legislation	0%	2%	14%	49%	35%	88
The appointment of Notified Bodies to carry out conformity assessment	1%	4%	18%	34%	43%	74
The conformity assessment procedures available to companies	0%	6%	17%	36%	41%	87
Not prohibiting, restricting or impeding machinery that complies with the Directive	1%	9%	24%	52%	14%	79
The assessments undertaken by Notified Bodies	1%	8%	41%	42%	8%	76
The suspension, withdrawal or placement of restrictions on certificates issued	0%	25%	50%	20%	5%	40
The approach of Market Surveillance Authorities to determining compliance	6%	46%	21%	24%	3%	80
Taking measures to withdraw / prohibit machinery that may compromise health and safety	5%	60%	21%	10%	4%	78
The establishment of effective, proportionate and dissuasive penalties for infringements	22%	53%	9%	16%	0%	68
The number of market surveillance activities	23%	53%	15%	8%	1%	75

Source: Machinery Directive Targeted Consultation. Excludes 'don't knows' and non-respondents.

When stakeholders were specifically asked whether in the last five years the approval of their product in one EU country had not been recognised in another, only 14 of 146 respondents (9%) claimed that this had been the case. These individuals identified the following countries where they experienced issues: Germany (4), France (4), Turkey (4), Spain (2), Poland, Belgium, Sweden, Italy and Austria (1 each).

However, in their comments, most stakeholders highlighted differences in the interpretation / application of the requirements of the Directive between countries. Some commented broadly, for example: "The interpretation of the MD from one body to another, and one country to another, is completely different." Others provided more specific examples.

For example, one stated: "As a manufacturing company, we often relocate machines and plants between our European plants. If we were to bring machines built in the Czech Republic which were originally intended for our Czech factory to Germany, retrofits are the order of the day, since they bear the CE mark completely wrongly." Another respondent gave an example of where machinery had been categorised differently, based on national guidelines: "German authorities refer to the document 'Substantial modification of machinery (Wesentliche Veränderung von Maschinen)' (BMAS, 9.4.2015-

IIIb5-39607-3). As a result, Germany concluded that the machine in question had not been substantially modified, whereas the Netherlands concluded that there were substantial modifications."

Several stakeholders also highlighted that countries often required national standards to be applied, e.g. "National standards still take precedence in the Netherlands, Belgium, France, Germany and Poland." Other countries were also mentioned in this respect, e.g. Italy and France. Similar issues were raised in relation to customer requirements: examples were given for requests from users in Germany to have the «GS» mark (which takes priority over the CE marking), and customers in France demanding that machines fulfil Apave standards, on top of European standards.

France was highlighted multiple times as a country where respondents had encountered issues. This concerned compliance with additional national directives and requirements going beyond those of the Machinery Directive, stricter interpretation of the Directive and standards, and "very dogmatic enforcement action by French enforcement authorities", e.g. "unreasonable assessment of hazards and, as a result, the demand for adaptations, thus limiting the ability to compete." One respondent commented: "France appears to have its own agenda, even when standards and Directives are agreed by all European parties, as its Customs do not seem to allow products into the country at times despite containing all the relevant documentation." Another respondent had encountered the situation that French authorities required translation of the technical documentation (manufacturer's documentation) and did not accept documentation in English.

5.5 Evaluation Question 5: the extent to which the Directive has contributed to objectives

5. To what extent has the Machinery Directive been effective in contributing towards the achievement of its main objectives?
    a. To what extent has the Machinery Directive been effective in contributing towards 'an effectively operating internal market' for the products in its scope?
    b. To what extent has the Machinery Directive been effective in contributing towards 'protecting the health and safety of consumers and users (and where appropriate domestic animals or properties)' for the products in its scope?
    c. Have there been any particular barriers to the achievement of these objectives?

Evaluation Question 5 concerns the extent to which the Machinery Directive has contributed towards its overarching objectives of facilitating the functioning of the internal market for machinery and ensuring a high level of safety of machinery (plus protecting the environment in relation to machinery for pesticide application). It requires the study to identify and assess positive impacts in these areas, and to examine whether (and to what extent) these can be attributed to the Directive. The final sub-question also asks whether there are any significant factors that may have reduced, delayed, or in some other way hampered the contributions and achievements of the Directive.

5.5.1 Contribution to facilitating trade and an effectively operating internal market

The first of the two overarching objectives is the facilitation of an effectively operating internal market for the products in its scope. The Directive seeks to contribute to this through the harmonisation of machinery safety legislation and certification, where historically the disparities between different Member States are considered to have constituted barriers to trade.

A first key indicator of the success of the Directive is, therefore, the extent to which **legislative harmonisation** has been achieved. As discussed in the previous section (Q4), all Member States had notified the Commission of national measures implementing the 2006 Directive by the end of 2010, and while possible infringements have subsequently been identified in relation to most countries, these have all now been found to be invalid, or have been rectified. We can therefore infer that a basic level of harmonisation has been achieved. In the previous section we also saw that 94% of

stakeholders believed that the Directive had been fully and consistently transposed into national legislation (to a 'large extent' or 'entirely'), and that a majority (77%) also believed that the conformity assessment procedures available to companies were largely or entirely consistent.

Where there is more concern is around the harmonisation of the process of certification. We saw in relation to Question 4 (above) that there were mixed opinions regarding the consistency of assessment undertaken by Notified Bodies. Only 8% of stakeholders felt that these assessments fully and consistently interpreted and applied the requirements of the Directive. There have also been concerns raised by many stakeholders (as is discussed later in this report) about the consistency with which the self-certification process is applied. These concerns might put into question the true effectiveness of the Directive's contribution to the internal market, though this has more to do with the extent to which it is effectively protecting health and safety, rather than the extent to which it is facilitating the free movement of machinery.

Another important indicator of the success of the Directive is the level (value and / or volume) of **intra-EU trade in machinery**. Section 5.1.3 presented data on the value of intra-EU exports of machinery from EU28 Member States over time. This showed that intra-EU exports had increased in value (using 2015 prices) from €536b in 2009 (the year the Directive was to be applied) to €683b in 2015 (the latest for which data is available). This represents a 27% increase in the value of trade over the six years that Directive 2006/42/EC has been applied.

However, this period of growth followed a significant (-22%) fall in the value of intra-EU exports of machinery in the previous year (2008-2009), while before this the value of intra-EU exports had also risen (by 11% over the six-years 2002-2008). If we take 2008 as a more 'typical' reference year, then intra-EU export values of machinery were almost exactly the same in 2015 as they were the year before the Directive applied (€683b and €685b respectively).

There has therefore been an upward trend in intra-EU trade in machinery over a longer period (10+ years), punctuated by a significant dip at the time of the economic and financial crisis. It is difficult to discern any impact of the 2006 Directive within this period from the data, particularly given the significant external factors influencing trade at the same time as the Directive was introduced.

This said, even if external shocks were removed from such trend data, one would not necessarily expect to see any significant impact on trade from the application of the Directive at the end of 2009. Despite a number of significant changes in the 2006 revision, the Directive (in broadly the same form) had already been in force for two decades, with the same aim of facilitating trade and the Single Market for machinery. As such, one might expect that much of the impact of harmonisation efforts in relation to machinery, in terms of reduced barriers to trade, will have already taken effect previously.

As the Commission has previously noted, the impact of the Single Market and the new approach to product regulation on intra-EU trade was evident before the 2006 revision to the Machinery Directive.

> *"Since the Single Market became a reality in 1993, intra-EU trade in goods has grown as a share of GDP by around 5 percentage points (from 17% in 1999 to 22% in 2011).... While there are significant differences between the sectors covered by Union harmonisation legislation on industrial products, most have experienced an increase in the level of intra-EU trade, particularly between 2003 and 2008...."*[27]

The Communication goes on to state that "the so-called 'new approach' to product regulation... has brought about a single, borderless market for harmonised industrial products. It lowered market access barriers for industry and made it easier for business to operate in pan-European markets. The internal market in industrial products has brought about economic and employment benefits through its contribution to increased EU-trade." The current Directive is therefore *continuing* an already well established process that facilitates trade and ensures the effective operation of this market.

[27] COM(2014) 25 final

Despite (or rather because of) issues of attribution, the targeted consultations were used to ask for **stakeholder views** as to the impact of the Directive (specifically) on a range of areas relating to market efficiency and the effective operating of the internal market for machinery. As the table below indicates, opinion was largely positive, with a majority of respondents believing that the Directive has had a positive or very positive impact on the range of products available, turnover and profitability in the sector, international competitiveness and the volume and value of machinery trade within the EU. There was particularly widespread belief that the Directive had had a very positive impact on the free movement of machinery and (reducing) barriers to trade within the internal market.

Table 29 Impact of the Directive on market efficiency and the effective operating of the internal market

	Very negative	Negative	None	Positive	Very positive	n
The range of machinery products available	0%	5%	41%	49%	5%	39
Turnover and profitability of the European machinery sector / businesses	3%	3%	36%	50%	8%	36
The international competitiveness of the European machinery sector / businesses	0%	0%	22%	67%	11%	36
The volume / value of intra-EU trade in Machinery	0%	0%	19%	68%	13%	31
Barriers to the internal market / free movement of machinery	0%	0%	21%	37%	42%	38

Source: Machinery Directive Targeted Consultation. Excludes 'don't knows' and non-respondents.

Similar issues were addressed in the public consultation, though from a slightly different angle. Here, we asked respondents to assess whether the Directive had led to an increase or decrease in a range of areas relating to the machinery sector and trade in Europe. The results (below) show that most respondents believe that the Directive has led to an increase in the range and quality of machinery products available and an increase in the international competitiveness of the European machinery sector / business. The views on the impact of the Directive on turnover and profitability in the sector and on the volume and value of intra-EU trade are more mixed, but are on balance positive.

Table 30 Impact of the Directive on the machinery sector and trade in Europe

	Substantial decrease	Some decrease	No change	Some increase	Substantial increase	n
The range and quality of machinery products available	1%	4%	25%	55%	15%	231
The international competitiveness of the European machinery sector/businesses	6%	12%	29%	42%	12%	194
Turnover and profitability of the European machinery sector/businesses	4%	19%	38%	34%	5%	154
The volume/value of intra-EU trade in Machinery	3%	10%	50%	32%	5%	146
Barriers to the internal market/free movement of machinery	28%	20%	29%	18%	4%	213

Source: Machinery Directive Public Consultation. Excludes 'don't knows' and non-respondents.

There is also a widely held view that there has been some decrease in barriers to the internal market and free movement of machinery in Europe. However, views here were somewhat mixed. When respondents were further asked to explain why they felt that barriers had increased or decreased, those that responded tended to focus on the (negative) reduction in barriers to machinery *entering* the Single Market. A selection of these additional comments is presented in the figure below.

Figure 14 Further explanation as to decreased barriers to the internal market / free movement of machinery

> *"Uncontrolled foreign imports claiming compliance but not actually being compliant."*
>
> *"Mainly related to the lack of effective market surveillance."*
>
> *"Market surveillance in France on machines is non-existent, particularly in BtoB… Many machines imported into our domain present nonconformities which can be considered as minor but leads to the decline of the CE marking and all our efforts in France and Europe to meet them and leaves the door wide open to abuses and importers without ex. Confoomité declaration without any proof of conformity!"*
>
> *"Imports from the Far East are cheaper and less safe."*
>
> *"Inner European market has improved, although even (small) European manufacturers do not all understand the Directive(s). Imported products are increasingly suspect, whether from China or developed countries like the USA."*
>
> *"Too many cheap and unsafe tools can enter the EU-market."*

Source: Machinery Directive Public Consultation. Selected quotes.

More broadly, stakeholders also were asked to assess overall the extent to which they believed the Machinery Directive specifically had contributed towards its objective of ensuring an effectively operating internal market for the products in its scope. The feedback was generally very positive, with nearly three-quarters (74%) of respondents reporting that the Directive had achieved this objective to a large extent, and a further 21% believing it had achieved this to a moderate extent. Only 5% reported that it had contributed to a small extent or not at all.

Table 31 The contribution of the Machinery Directive towards an effectively operating internal market

	Not at all	To a small extent	To a moderate extent	To a large extent / entirely	n
An effectively operating internal market for the products in its scope?	1%	4%	21%	74%	308

Source: Machinery Directive Public and Targeted Consultation. Excludes 'don't knows' and non-respondents.

5.5.2 Contribution to ensuring health and safety

The second of the two overarching **objectives** is to ensure a high level of protection for users of machinery. The Directive seeks to contribute to this through requiring conformity to relevant safety requirements and therefore encouraging inherently safe design and construction of machinery. Its impact in this regard relies on a number of different processes and procedures operating effectively under the overarching framework of the Directive itself (e.g. in terms of standardisation, conformity assessment and market surveillance systems, as well as compliance with the requirements of the Directive), each of which is assessed separately in the following sections. Here, we limit our focus on investigating contributions to the ultimate goal of minimising/reducing the extent (i.e. the number, rate and / or socio-economic cost) of machinery-related accidents and injuries in Europe, as well as the related levels of safety and protection regarding machinery and its use.

ESAW data (in Section 5.1.4) showed a downward trend in the total number and incidence rates of **accidents at work** between 2009 (the year from which the Directive applied) and 2013 (the latest year for which data is available). Over this period the absolute number of non-fatal accidents decreased by 12%, and the number of fatal accidents decreased by 15%. If we take 2008 as a more 'typical' base year (there was a significant dip in accidents in 2009, likely influenced by a drop in economic activity), the recent reductions in accident figures are even more pronounced. Between 2008 and 2013, non-fatal accidents declined by 19%, while fatal accidents dropped by 23%. This downward trend is evident across nearly all EU countries. Similar declines are seen in incidence rates.

There is some evidence to suggest that sectors and occupations most closely related with the use of machinery covered have seen more significant declines in A&I numbers/rates during this period – although this is not necessarily directly linked to the application of the 2006 revision to the Directive.

For example, accidents relating to plant machine operators and assemblers fell by 30% between 2009 and 2013 (for 18 countries with sufficient data). But accidents also had declined by 22% in the previous year (2008-2009). Similarly, the incidence rate of accidents (accidents per 1,000 employees) in manufacturing, construction and agriculture, forestry and fishing sectors all fell (by 9%, 20% and 7% respectively) between 2009 and 2013. However, a similar downward trend is seen for all sectors (9%) during this period, and continues a decline seen the previous year (e.g. -17% between 2008 and 2009 for manufacturing). Separate data from the 2007 and 2013 EU LFS (the only years for which relevant data were collected) suggest that the rate of accidents at work for some machinery-related occupations (skilled agriculture and plant/machine operators) fell during the period between the two surveys, while they increased for some non-manual professions (managers, clerical support).

As with trade, the overall trends in the number or rate of machinery-related accidents seem largely undisturbed by the application of the 2006 revision to the Machinery Directive from the end of 2009. Accident and injury rates were already declining in the period preceding the introduction of the Directive, while trends in A&I data for machinery and non-machinery related sectors and occupations do not obviously diverge at the date of application of the Directive. Again, the lack of obvious impact on headline data is unsurprising. Without a significant expansion of the scope or requirements of the Directive (at the time of revision) to cover new types of machinery or new aspects of safety, one wouldn't expect to see a step-change in terms of reduced machinery-related A&I. Nevertheless, the MD is likely to be playing a significant role in supporting the ongoing trend of reduced accidents and injuries in machinery-relevant sectors over time.

Again, despite / because of the issues of attribution, the targeted consultations were used to ask for **stakeholder views** as to the impact of the Directive (specifically) on a range of areas relating to protecting the health and safety of consumers and users of machinery and improving well-being. As the table below indicates, opinions were largely positive, with nearly all respondents believing that the Directive had had a positive or very positive impact on the quality of machinery, information as to safe operation, user confidence, the number and severity of accidents and injuries, the number of unsafe machines and more generally on the level of safety and protection for machinery users.

Table 32 What has been the impact of the Directive in areas relating to health and safety

	Very negative	Negative	None	Positive	Very positive	Total n
The quality of machinery products available	0%	5%	7%	69%	19%	42
Information and instructions relating to the safe operation of machinery	4%	2%	2%	64%	27%	45
The level of user confidence in machinery safety	3%	0%	10%	64%	23%	39
The number of machinery-related accidents and injuries	0%	0%	3%	65%	32%	37
The severity of machinery-related accidents and injuries	0%	0%	0%	74%	26%	38
The number of unsafe / non-compliant machines on the market / in use	3%	8%	13%	72%	5%	39
The level of safety / protection for users of machinery (workers / consumers)	2%	2%	0%	73%	22%	41

Source: Machinery Directive Targeted Consultation. Excludes 'don't knows' and non-respondents.

Similar issues were addressed in the public consultation, though from a slightly different angle. This asked respondents to assess whether the Directive had led to an increase or decrease in a range of areas relating to health and safety. The results (below) show that most respondents believe that the Directive has led to an increase in the level of user confidence in machinery safety and in the level of safety and protection for users of machinery. Most also believe that the number of non-compliant machines on the market has decreased, as has the number of machinery-related accidents and injuries, as a result of the Directive. Respondents also generally felt that there has been an even more

significant reduction in the *severity* of machinery-related accidents and injuries as a result of the Directive.

Table 33 Impact of the Directive on levels of health and safety

	Substantial decrease	Some decrease	No change	Some increase	Substantial increase	n
The level of user confidence in machinery safety	2%	2%	17%	57%	23%	242
The level of safety/protection for users of machinery (workers/consumers)	3%	4%	7%	53%	33%	249
The number of unsafe/non-compliant machines on the market/in use	18%	46%	17%	12%	7%	209
The number of machinery-related accidents and injuries	27%	55%	14%	5%	0%	200
The severity of machinery-related accidents and injuries	41%	35%	18%	6%	1%	198

Source: Machinery Directive Public Consultation. Excludes 'don't knows' and non-respondents.

More broadly, stakeholders also were asked to assess overall the extent to which they believed the Machinery Directive specifically had contributed towards its objective of protecting the health and safety of consumers and users of the products in its scope. The feedback (shown below) was generally very positive, with nearly three-quarters (71%) of respondents reporting that the Directive had achieved this objective to a large extent, and a further quarter (25%) believing it had achieved it to a moderate extent. Only 4% said it had made little or no contribution to protecting health and safety.

Table 34 Contribution of the Directive to protecting the health and safety of consumers / users of products

	Not at all	To a small extent	To a moderate extent	To a large extent / entirely	n
Protecting the health and safety of consumers and users of the products in its scope?	1%	3%	25%	71%	311

Source: Machinery Directive Public and Targeted Consultation. Excludes 'don't knows' and non-respondents.

5.5.3 Contribution to protecting the environment

The 2009 revision to the Directive introduced the additional objective of ensuring environmental protection – though limiting this objective to the machinery used in pesticide application. The Directive already applied to such types of machinery with respect to the protection of health and safety of the users (and other exposed persons), but did not cover environmental protection requirements.

As the amendment to the Directive explained, well-designed, constructed and maintained machinery for pesticide applications plays a significant role in reducing the adverse impacts of pesticides on the environment. To this end, it introduced supplementary essential environmental protection requirements to be fulfilled by new machinery for pesticide application before it is placed on the market and/or put into service in the Community.

The impact assessment[28] of the wider thematic strategy on sustainable pesticide use (which the amendment to the Directive was intended to support) looked to assess the potential impacts of reduced pesticide use. However, it concluded "it is recognised to be extremely difficult to quantify many of the actual adverse effects resulting from the use of pesticides and even more difficult to attribute monetary values to them… Nevertheless, it is justified to assume that reduced input of pesticides – and in particular excessive use – will in general lead to a reduction of adverse effects in the environment." The proposal for the Directive[29] subsequently concluded that "in the long run, it is expected that introducing environmental protection requirements for new machinery for pesticide application will have positive impacts on human health and the environment via the expected decrease in exposure to pesticides."

[28] SEC(2006) 894

[29] COM(2008) 535 final

We tested this view with stakeholders through consultation. The targeted consultation asked stakeholders about the overall impact of the Machinery Directive on the environment, and nearly three-quarters of respondents (72%) though it had a positive or very positive impact, while the remainder saw no impact in this area. Through the wider public consultation, stakeholders were also asked whether the Directive had led to an increase or decrease in the level of environmental protection in pesticide applications. While the majority of respondents did not have a view, the results (below) show that most of those who felt able to respond believe there has been some increase in the level of environmental protection as a result of the Directive.

Table 35 Impact of the Directive on levels of environmental protection

	Substantial decrease	Some decrease	No change	Some increase	Substantial increase	n
The level of environment protection in pesticide applications	5%	7%	33%	45%	9%	75

Source: Machinery Directive Public Consultation. Excludes 'don't knows' and non-respondents.

More broadly, stakeholders were asked to assess overall the extent to which the Directive had contributed towards its objective of protecting the environment in relation to machinery for pesticide and herbicide applications. Only half of the respondents had a view on this issue, but those who did generally expressed positive views. More than three-quarters (78%) thought the Directive had contributed to a moderate or large extent towards this objective. Others thought it had contributed little (17%) or not at all (6%).

Table 36 Machinery Directive contribution to protecting the environment for the products in its scope

	Not at all	To a small extent	To a moderate extent	To a large extent / entirely	n
Protecting the environment in relation to machinery for pesticide/herbicide application	6%	17%	34%	44%	156

Source: Machinery Directive Public and Targeted Consultation. Excludes 'don't knows' and non-respondents.

5.6 Evaluation Question 6/7: the effectiveness of conformity assessment options

6. To what extent have the options of third-party conformity assessment for Annex IV categories of machinery been effective?
    a. What are the reasons for choosing each of these options?
7. To what extent has the procedure for assessment of conformity with internal checks (self-certification) been effective in providing the highest degree of health and safety for consumers and users?

Evaluation Questions 6 and 7 both relate to the effectiveness of conformity assessment options in supporting the Directive's contribution towards its objectives:

The first question focuses on the effectiveness of two of the routes for conformity assessment available to Annex IV categories of machinery – both of which require **third-party assessment** and approval. Unless designed to harmonised standards that cover all applicable EHSRs (in which case self-certification is allowed), machinery within Annex IV of the Directive must undergo third-party conformity assessment by a Notified Body. There are two options: an EC-type examination of the technical file and a representative product; or an examination and approval of a full quality assurance system (an option that was introduced with the 2006 Directive). According to this new procedure, a Notified Body assesses not an individual product, but the manufacturer's quality assurance system for design, manufacture, final inspection and testing of one or more categories of machinery listed in Annex IV of the Directive. This additional conformity assessment option had already been used within

the Lifts Directive, and is thought to have the potential to be a more cost-effective route to compliance than EC-type examination in some cases (e.g. for prototype and bespoke machinery).

The evaluation question seeks to explore the effectiveness of these two options (to prove conformity and to ensure the protection of health and safety), as well as the reasons why businesses might choose each option (i.e. the pros and cons).

The second question concerns a third conformity assessment route – the **assessment of conformity with internal checks** - which is available to most manufacturers, and does not require the services of a third-party organisation. Where machinery is not referred to in Annex IV, the manufacturer should apply the procedure (also referred to as 'self-certification'). Machinery that is referred to within Annex IV, but is designed to harmonised standards covering all applicable EHSRs, may also use the same procedure. As the name suggests, self-certification does not require the services of a third-party organisation. Instead, the manufacturer makes its own declaration of conformity that its product satisfies the relevant provisions of the Directive. A technical file must be drawn up, and must be retained and made available on request to market surveillance authorities for at least 10 years.

Again, the evaluation question here asks for an assessment of the effectiveness of the self-certification option, and particularly in relation to the Directive's objective of ensuring health and safety.

5.6.1 Take-up of conformity assessment options

Data on uptake of different conformity assessment options are not readily available. Indications have therefore been sought as part of the study consultation activities as to the level of take-up of different conformity assessment options in relation to the Machinery Directive.

Specifically, **industry respondents** to the targeted consultation survey and interviews were asked whether (and how many times) they had employed each conformity assessment option in the past five years. Of the 36 companies that answered, four indicated that they had not undergone conformity assessment at all the last five years at all in relation to the Machinery Directive. Of the remainder, 15 had only used one method (always self-assessment), while 17 had experience of two or more options. Overall, responding companies had undergone conformity assessment (by any route) 23 times each in the past five years (i.e. 4-5 times per year on average). The following table summarises their responses.

As an example of the data presented, 13 of the 36 companies had undertaken at least one EC-type examination in the past five years. In fact, between them, they had used this method 241 times, or 19 times each on average. Applying these rates to all companies in the sample implies that 'on average' a given company will undertake seven EC-type examinations over the course of five years. Following the same method in calculating an average for the other three options would suggest that the total number of conformity assessments undertaken might be split approximately into 80% self-assessment (non-Annex IV), 10% self-assessment (Annex IV), 8% EC-type examination and 2% approval of full quality assurance system. This suggests that in most cases manufacturers are using the self-certification route to conformity - particularly outside of the main areas covered by Annex IV (saws and woodworking machinery, presses, lifting equipment, etc.).

Table 37 Number of times companies have employed each conformity assessment option over 5 years

Conformity Assessment Option	Companies (out of 36) undertaking this option	No. times undertaken (total)	Avg. times undertaken per 'user' Co.	Avg. times undertaken per Co. (all)
Assessment of conformity with internal checks (non-Annex IV products)	30	2605	87	72
Assessment of conformity with internal checks (Annex IV products) using EN	6	328	55	9
EC-type examination (Annex IV products)	13	241	19	7
Approval by a Notified Body of a full quality assurance system (Annex IV products)	2	70	35	2

Source: Machinery Directive Targeted Consultation.

This overall estimation is broadly supported by a separate question to industry on the most recent assessment option they had used. A somewhat smaller sample of companies (26) responded here, with 69% reporting self-assessment (non-Annex IV), 15% self-assessment (Annex IV), 8% EC-type examination and 8% full quality assurance.

Similar patterns were suggested by **industry associations**, which were also asked to estimate the proportion of their members' products that are certified through the different options. Estimates were provided by 21 organisations, and on average they suggested that 77% of products were self-assessed (non-Annex IV), 8% were self-assessed (Annex IV), 12% were certified through EC-type examination and just 2% through approval of a full quality assurance system.

Notified Bodies were also asked about the number of times that their organisation had undertaken EC-type examinations and approvals of full quality assurance systems in the past five years. Of the 11 organisations providing data, only one reported having undertaken an approval of a full quality assurance system (one time) in this period. The remainder had only undertaken EC-type examinations (ranging from 1 to over 700 times in the past five years, or 167 each on average).

Notified Bodies responding to the consultation also suggested that there had been no significant trends in the number or type of assessment being undertaken in recent years. They did however point out that many manufacturers would try to avoid using Notified Bodies because of the additional cost involved in paying an external party for conformity assessment, and when they did use a Notified Body they would tend to choose an EC-type examination.

It is also interesting to note here that Notified Bodies were also asked how many times in the past five years they had **suspended, withdrawn or placed restrictions on certificates** that they had issued in relation to the Machinery Directive. Of the 12 bodies responding, only three reported having taken such action in the last five years, in one, 10 and 30 cases. These 41 cases, equate to around 2% of the total number of assessments that these same organisations have undertaken over the five-year period.

5.6.2 Effectiveness of conformity assessment options

We have not identified any recorded data or opinion on the positives and negatives of the different conformity options, or of their relative effectiveness as routes to conformity, or as a means to protect health and safety. Even if it were possible to segment the machinery sector into sub-parts that self-certify and sub-parts that use third-party conformity assessment, comparing A&I data between the two would be of little value. Self-certification is designed to be used in those cases where machinery is considered to present lower risks, and so (we would assume) will naturally have a different (i.e. lower) A&I profile. As such, consultation has been used to collect informed opinions from across stakeholder groups as to the effectiveness of the different conformity assessment options.

Specifically, we consulted on the effectiveness of each conformity assessment option, both in facilitating the internal market for machinery (e.g. ability to export to other countries) and in protecting the health and safety of machinery users. The responses (shown below) suggest that all conformity assessment options are generally seen as effective in facilitating the internal market for machinery as well as protecting the health and safety of machinery users. There is a tendency in each case for respondents to be slightly more positive as to the effectiveness in facilitating trade, rather than protecting health and safety, but the difference is minimal.

There are more evident differences *between* the different options in their perceived effectiveness in protecting user health and safety. For example, EC-type examination is seen as very effective in this regard by nearly half of all respondents (49%), while assessment of conformity with internal checks is seen as very effective by only 32% (for non-Annex IV products) and 41% (for Annex IV products using a harmonised standard) of respondents. The approval of a full quality assurance system is only rated as very effective in protecting health and safety by less than one-third of respondents (29%) – though additional comments provided suggest that ratings may reflect low use of this option (and therefore low contribution to objectives), rather than a criticism of the effectiveness of the option itself.

Table 38 Effectiveness of conformity assessment options for facilitating trade and protecting health and safety

Conformity assessment option	Effectiveness at...	Not effective	Slightly ineffective	Moderately effective	Very effective	n
Assessment of conformity with internal checks for products not covered by Annex IV	...facilitating the internal market for machinery?	3%	6%	40%	51%	235
	...protecting the health and safety of machinery users?	4%	18%	46%	32%	252
Assessment of conformity with internal checks for products covered by Annex IV, where a Harmonised Standard is applied that covers all applicable requirements	...facilitating the internal market for machinery?	3%	8%	38%	51%	186
	...protecting the health and safety of machinery users?	4%	13%	42%	41%	201
EC-type examination for Annex IV products	...facilitating the internal market for machinery?	2%	8%	44%	46%	180
	...protecting the health and safety of machinery users?	1%	6%	45%	49%	199
Approval by a Notified Body of a full quality assurance system for Annex IV products (which was introduced with the latest version of the Directive)	...facilitating the internal market for machinery?	7%	9%	49%	35%	136
	...protecting the health and safety of machinery users?	6%	14%	51%	29%	148

Source: Machinery Directive Public and Targeted Consultation. Excludes 'don't knows' and non-respondents.

5.6.3 Barriers to take-up and effectiveness

Stakeholders with experience of conformity assessment were asked whether they had encountered any problems with each of the assessment options. Only 13% had experienced problems with full quality assurance approval, compared with 20-26% that had experienced problems with other methods. However, this variation could (at least in part) reflect differences in levels of use of these different options (i.e. previous answers suggest that many stakeholders may not have any experience of approval of a full quality assurance system). Indeed, one respondent commented that there were likely to be major differences in the level of knowledge of different assessment processes between machine manufacturers. The respondent suggested that manufacturers of serial machines, for example, were likely to be more well informed than manufacturers of special machines.

Stakeholders were asked whether they could point to any particular issues or problems specifically with the **third-party options** that might reduce levels of take up and/ or their effectiveness.

For both EC-type examination and NB approval of full quality assurance, stakeholders believe the cost of assessment may reduce take-up. For the full quality assurance system, it was also pointed out that this option may be too complicated for some, and also that many SMEs were unlikely to have in place the necessary quality systems. Potential take up of this option is therefore lower. Indeed, several stakeholders pointed out that they thought the approval of full quality systems option had had very little take up, was not well established, and should perhaps be removed as an option.

Stakeholders also questioned the effectiveness of third-party options, given a lack of consistency between Notified Bodies in undertaking assessments and interpreting requirements. Although efforts to increase alignment (horizontal and vertical NB groups at EU level and Recommendations for Use) were noted, there were questions over low participation levels in these efforts. In relation to EC-type examination specifically, one stakeholder suggested that because few machines were now sent to Notified Bodies, the levels of knowledge and experience within these organisations (of particular machinery) is reduced, with possible implications for the effectiveness of assessment. In relation to approval of full quality assurance, several stakeholders suggested it was inconsistent with module H of Decision 769/2008 on a common framework for the product marketing (the CE Mark Decision).

Similarly, stakeholders were asked whether they could point to any particular issues or problems with the **self-certification options** that might either reduce levels of take up or their effectiveness.

Several respondents suggested that some manufacturers and (even more so) some customers are uncomfortable with the concept of self-certification and want to have (or sometimes demand) the reassurance and protection of third-party involvement / certification. This need for reassurance can dissuade companies from taking the self-certification route. One respondent also pointed out that the effort and expertise required internally for self-certification might prove too great for some businesses. Specifically referring to assessment of conformity with internal checks for products covered by Annex IV, a number of respondents highlighted that harmonised standards are not available for all Annex IV machinery, or that they do not cover all essential requirements / risks relevant to the machinery in question. For example, one stakeholder commented that "The theory of using harmonised standards for Annex IV equipment is good, but is let down by the lack of good harmonised standards in some areas." These issues with standards may also be reducing take-up of self-assessment options.

A significant number of respondents also raised concerns about the effectiveness of the assessment of conformity with internal checks in ensuring the protection of health and safety. Some were concerned about (unintentional) incorrect application of the process by manufacturers and the lack of involvement / checks from a third party. Others suggested that the option of self-certification (combined with poor market surveillance) actually encouraged businesses not to comply fully with the Directive, or to do the bare minimum to "just to meet the bureaucratic aspect of the Directive, rather than as a tool for risk reduction." For instance, some stakeholders pointed out that manufacturers may just look to one harmonised standard, when in fact more than one has to be applied to properly assess a product. These concerns are heightened by a lack of an effective market surveillance system.

Several respondents also questioned the current scope of Annex IV, suggesting that it should be broadened to cover a greater range of products. One also suggested that EC-type examination should be mandatory for such products, even where a harmonised standard existed covering all requirements.

5.7 Evaluation Question 8: the effectiveness of European harmonised standards

8. How effective was the development and use of European harmonised standards for the Machinery Directive?
    a. How effective was the development of European harmonised standards for the Machinery Directive?
    b. How effective was the take-up and use of European harmonised standards in relation to the Machinery Directive (giving particular attention to take up to pursue conformity assessment with internal checks for Annex IV products)
    c. What is the position of European harmonised standards for the Machinery Directive versus other technical specifications, national and international?

Evaluation Question 8 concerns the effectiveness of the development and use of European harmonised standards in relation to the application of the Machinery Directive and the achievement of its objectives.

5.7.1 European Harmonised Standards and the Machinery Directive

Standards contain technical information to guide or define practice in a consistent way, and are used by designers and manufacturers of products, or by authorities when checking product compliance (particularly where the use of a standard is listed in the declaration of conformity or technical file). Standards exist at different levels – international (e.g. ISO), European (e.g. EN), national (e.g. BS, DIN), industrial, sectoral and in-house – and may deal with broad general principles ("A" standards), aspects of safety common to many products ("B" standards), or be product specific ("C" standards).

Standards are an important component in 'translating' the EHSR set out within the Machinery Directive under the so-called New Approach. The use of standards in complying with the Directive is not compulsory, however standards often define the state of the art for a product or safety feature.

Some European standards (**harmonised standards**, or "EN") have a special legal status (confirmed by their listing in the Official Journal of the European Union) and define minimum acceptable levels for health and safety by supporting the essential requirements of the Directive.

If a transposed harmonised standard (the national publication of a European standard) is followed in full, it can confer **presumption of conformity** with one or more EHSR, provided that the product is within the scope of the standard and the standard supports the Directive. In effect, this means that by following the requirements of a transposed harmonised standard, a designer knows that his product will comply with the parts of the Directive applying to his product. The use of such standards can save designers time in assessing risks and adopting strategies for safety, particularly where the standard deals with all essential requirements relating to a particular product.

Standards may be used for each of the routes for **conformity assessment** under the Machinery Directive, but the assessment of conformity with internal checks is only available for Annex IV products when they are manufactured fully in accordance with EN that cover all relevant EHSRs.

5.7.2 Effectiveness of the development of European harmonised standards

Standardisation requests (previously 'Mandates') are the instrument through which the Commission requests the European Standardisation Organisations (ESOs) to develop and adopt European Standards in support of policies and legislation, including the Machinery Directive[30]. A new mandate (M/396) for standardisation in the field of machinery was issued in December 2006, following the adoption of the revised Machinery Directive earlier that year. This requested that CEN-CENELEC verify the effectiveness of existing harmonised standards that support the Machinery Directive, and undertake any necessary modifications (drawing up new standards, or amending / revising existing standards) in order to make certain that harmonised standards for machinery are available that cover the scope of the revised Directive 2006/42/EC and provide specifications enabling manufacturers to comply with the revised EHSR of the revised Directive. Theoretically, this request is open-ended, meaning it is the basis for the ESOs to continue to ensure that harmonised standards are adapted / introduced to meet the ongoing needs of the Directive. A small number of more specific standardisation requests relating to the Directive have also been issued. These include M/440 (amendment of standard EN 12312-9:2005 – aircraft ground support equipment – specific requirements – part 9: container/pallet loaders) and M/471 (machinery used in pesticide application).

Relevant technical committees (TCs) within the ESOs are assigned the task of undertaking required **standardisation work** – and they may then convene Working Groups (WG) to prepare a draft standard. In the process of writing a standard, both the TCs and WGs are often reliant upon the expertise of manufacturers, regulators and subject matter experts, who are proposed by the National Standards Bodies (NSB) of individual Member States. CEN/CENELEC technical consultants may also supervise the process of drafting, providing advice on its quality where necessary, and assessing the standard for compliance with the essential health and safety requirements of the Directive.

Upon completion of a draft standard, it is publicised and available for public enquiry for a period of typically six months, during which NSBs may submit comments to be taken into account in re-drafting. Upon the completion of this process, the standard is submitted to formal vote by qualified majority. It is then submitted to the Commission, ratified, and published in the three official languages of the EU[31]. A deadline of six months is currently set for the Member State bodies to then publish the unaltered standard in their territory before it comes into effect. If Member States have any comments on the new standard, then these should be made during this initial six-month period.

[30] Regulation (EU) No. 1025/21012 sets the framework for these requests.

[31] English, French and German.

European standards are subject to **regular reviews**, and these represent opportunities to revise standards, whether defective or not, taking into account technological and other developments. Under CEN-CENELEC rules, standards are reviewed by the relevant TC at least every five years after their adoption (although it often occurs before this time). This includes asking national mirror committees for their opinion. This process may or may not result in a revision of the standard.

Through consultation, the study asked stakeholders to **rate the development of European Harmonised Standards supporting the Machinery Directive**, in terms of the level of involvement of industry and the length of time taken to develop a European Harmonised Standard.

As can be seen in the table below, a majority (82%) of respondents believe that the **involvement of industry** in the development of these standards is good or very good. However, additional comments suggest that participation does vary between sectors and between different types of businesses. In particular, it was highlighted by some that standards development is dominated by a small number of larger multi-national businesses, which have the time, resources and expertise to dedicate to what can be a rather lengthy, complicated and involved process. Some stakeholders also highlighted underrepresentation / absence of other types of organisation involved in standards development, including users, regulators and national authorities, where time and resource requirements were also cited as a reason. Broad involvement of stakeholders in standards development was seen as important for the creation of more rounded and widely-applicable standards, for avoiding problems at a later stage, and for more general awareness-raising reasons.

There was a more mixed assessment of the **length of time** required in the harmonised standard development process. This was reflected in follow on remarks, in which some stakeholders complained about the slow pace at which standards could be produced (discussed further below), while at the same time other stakeholders highlighted that they were content that the time taken was necessary to find consensus and ensure sufficient quality. In addition, one respondent pointed out that if the process were too fast, then new and revised standards would be produced at a rate that would be hard to follow (or indeed afford).

Table 39 Rating aspects of the European Harmonised Standard development process

	Very poor	Poor	Good	Very good	n
The involvement of industry in the development of European Harmonised Standards	2%	15%	38%	44%	82
The length of the European Harmonised Standards development process	16%	44%	36%	4%	283

Source: Machinery Directive Public and Targeted Consultation. Excludes 'don't knows' and non-respondents.

Finally, it is worth considering **formal objections** as an indicator of the effectiveness of standards development. A formal objection can be raised by a Member State or the Commission against a harmonised standard under the Machinery Directive, as set out under Article 10 / 11 (the "safeguard clause"). This can happen at (or after) the point at which standards are ratified by the Member States, but not before. We understand from CEN-CENELEC that many formal objections are triggered by one or more accidents that bring into question the appropriateness or sufficiency of standardisation in the area. The matter is discussed in the Machinery Committee Working Group after consulting with the CEN Working Group that had been convened to create the standard, and if the grounds of the objection are found to be valid, the formal objection is brought before the Committee on Standards. Discussions over formal objections can take years, during which time publication of a standard may be delayed.

Current pending formal objections that have been raised by national authorities against EU harmonised standards (as well as decisions taken by the Commission) are available on the EC website[32]. Details of the standard to which the objection is raised are noted within the objection title, and a pdf document is attached to each file containing details of the objection and argumentation for

[32] http://ec.europa.eu/growth/single-market/european-standards/notification-system/index_en.htm#objections

either the removal or the adaptation of the standard. However, as of the start of 2017, none of the formal objections listed (which date back to June 2013) relate to standards under the Machinery Directive.

However, the Commission have provided internal documents[33] that detail formal objections pending at various points in time during the period 2010 to 2015. This includes formal objections relating to the harmonised standards under the Machinery Directive, and provides details of the 'state of play' in relation to each objection. From these documents, 21 formal objections have been identified over the course of nine years (see Table 40). This is a relatively small number, equivalent to ~3% of the overall portfolio of relevant ENs. These objections relate to just eight different CEN Technical Committees, as shown in the final column (however, it should be noted that these eight TCs together are responsible for a third of all European Harmonised Standards under the Machinery Directive).

In most cases, the formal objection has resulted in the standard being amended, or published in the OJ with a warning. In only one case was a standard withdrawn, with no revision planned.

Table 40 Formal objections to European Harmonised Standards relating to the Machinery Directive (2006/42)

EN Number	EN Title	FO Received	Outcome	Relevant TC
EN 12635:2002 +A1:2008	Industrial, commercial and garage doors and gates. Installation and use	01/12/2010	Standard reference expected to be published with a warning	CEN/TC 33 - Doors, windows, shutters, building hardware and curtain walling
EN 13241-1:2003 +A1:2011	Industrial, commercial and garage doors and gates. Product standard. Products without fire resistance or smoke control characteristics'	01/11/2012	Standard reference expected to be published with a warning	
EN 1870-17 +A2:2009	Safety of woodworking machines - Circular sawing machines - Part 17: Manual horizontal cutting cross-cut sawing machines with one saw unit (manual radial arm saws)'	01/05/2013	Standard reference expected to be published with a warning	CEN/TC 142 - Woodworking machines - Safety
EN ISO 4254-1	Agriculture machinery - Safety - Part 1: general requirements	16/05/2006	Standard being revised	CEN/TC 144 - Tractors and machinery for agriculture and forestry
EN ISO 11681-2:2004 /A1:2007	Machinery for forestry – Portable chain-saw safety requirements and testing – Part 1: Chain saws for forest service – Amendment 1: Balance (ISO 11681-1:2004/Amd 1/2007)	13/10/2008	Concerns addressed through revision to part 1 of the standard.	
EN 13525:2005 +A2:2009	Forestry machinery. Wood chippers. Safety	01/07/2012	Standard withdrawn	
EN 13001-2	Cranes – General design – Load actions	15/01/2008	Standard amended	CEN/TC 147 - Cranes - Safety
EN 14985	Cranes – Slewing jib cranes	15/01/2008	Standard being revised	
EN 13135:2013	Cranes. Safety. Design. Requirements for equipment'	01/07/2014	Ongoing	
EN 1459:1998	Safety of industrial trucks - Self-propelled variable reach trucks	20/10/2006	Standard revised and reference published with warning	CEN/TC 150 - Industrial Trucks - Safety
EN 474-4	Earth-moving machinery - Safety - Part 4: Requirements for backhoe loaders	28/12/2006	Standard amended	CEN/TC 151 - Construction equipment and building material machines - Safety
EN 474-5	Earth-moving machinery - Safety - Part 5: Requirements for hydraulic excavators	28/12/2006	Standard amended	
EN 474-1:2006	Earth-moving machinery	03/04/2008	Standard reference expected to be published with a warning	
EN 12151:2007	Machinery and plants for the preparation of concrete and mortar	01/08/2008	Standard being revised (and divided into two parts)	
EN 12649:2008	Concrete compactors and smoothing machines	13/10/2008	Standard revised	
EN 500-4:2006	Mobile road construction machinery - Safety - Part 4: Specific requirements for	01/03/2008	Standard revised	

[33] Note to members and observers of the Committee on Standards: formal objections against harmonised standards- state of play (various dates).

EN Number	EN Title	FO Received	Outcome	Relevant TC
	compaction machines			
EN 1501-1:2011	Refuse collection vehicles and their associated lifting devices. General requirements and safety requirements. Part 1: rear-end loaded refuse collection vehicles	01/06/2012	Standard being amended	CEN/TC 183 - Waste management
EN 1501-1:1998 +A2:2009	Refuse collection vehicles and their associated lifting devices. General requirements and safety requirements. Part 1: Rear-end loaded refuse collection vehicles'	01/12/2011	Standard being amended	
EN 12215:2004	Coating plants - Spray booths for application of organic liquid coating materials - Safety requirements	19/10/2005	Standard being amended	CEN/TC 271 - Surface treatment equipment - Safety
EN 13355:2004	Coating plants - Combined booths - Safety requirements	19/10/2005	Standard being amended	

Source: Technopolis, from notes to members and observers of the Committee on Standards

5.7.3 Effectiveness of the take-up and use of European Harmonised Standards for the Directive

There are three types of European standards available in relation to the Machinery Directive. These are different in their scope, with implications for their use in relation to conformity assessment:

- Type-A standards specify basic concepts, terminology and design principles applicable to all categories of machinery. Application of such standards alone, although providing an essential framework for the correct application of the Directive, is not sufficient to ensure conformity with the relevant EHSR and therefore does not give a full presumption of conformity.
- Type-B standards address specific aspects of machinery safety or specific safeguards that can be used across a wide range of machinery. Application of Type-B standards confers a presumption of conformity with the EHSR of the Directive when a Type-C standard or the manufacturer's risk assessment shows that a technical solution specified by the Type-B standard is adequate.
- Type-C standards provide specifications for a given category of machinery. The different types of machinery belonging to the category covered by a Type-C standard have a similar intended use and present similar hazards. Application of the specifications of a Type-C standard on the basis of the manufacturer's risk assessment confers a presumption of conformity with the essential health and safety requirements of the Machinery Directive covered by the standard.

European Harmonised Standards that have been published in relation to the 2006 Machinery Directive are published in the OJ (13.5.16)[34]. This shows that, as of May 2016, there were 761 European Harmonised Standards relating to the 2006 Directive published in the OJ. This included one Type-A, 105 Type-B and 655 Type-C standards. The majority (90%) were CEN standards.

In line with the signing of the Vienna Agreement (ISO-CEN) and the Frankfurt Agreement (IEC-CENELEC), CEN and CENELEC cooperate closely with ISO and IEC, respectively, in the creation of standards and new standards projects are always jointly planned in order to avoid replication of results. According to the current list of standards issued under the 2006/42/EC Directive, it would appear (based on classifications) that around 31% of all HS are derived from international standards.

Based on the reference numbers of EN standards listed within the OJ, we have matched each to the relevant technical committee within CEN/CLC (see C.1). This gives a sense of the distribution of standards across machinery sub-sectors, although some of the technical bodies are cross-cutting (e.g. ergonomics, or safety of machinery). So, for example, at the top of the list are the technical committees for safety in construction equipment and building material machines (83 ENs) and for tractors and machinery for agriculture and forestry (63 ENs). Such analysis does not however, allow for the identification of gaps in coverage, as there is no defined list of Machinery Directive sectors, and we can also not assume the need for standards will be the same in different areas.

[34] Available here: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2016.173.01.0001.01.ENG&toc=OJ:C:2016:173:TOC

The CEN sector rapporteur for Machinery presents a brief report on standardisation at the Machinery Working Group twice a year, summarising recent and ongoing standardisation activity in relation to machinery. This report provides some additional details which are of interest. For instance, a recent report (15 January 2016) states that of the 666 Type-C machinery standards listed in the OJ[35], 37 were for Annex IV machinery. Also, of the 763 CEN Harmonised EN standards (of all types), 66 were amendments. This report also claims (for CEN standards) that every three months around 20 new EN for the Machinery Directive (including revisions) are ready for citation. The update also notes new standardisation activity on human interaction with machinery in cooperation with ISO/TC299 "Robotics" (although CCMC report that new standards may take a long time to emerge).

The consultations asked stakeholders to rate various aspects of the **coverage and relevance of the current portfolio** of European Harmonised Standards supporting the Machinery Directive.

As can be seen in Table 41, respondents generally expressed positive views about most aspects. In particular, 89% regarded the **scope and coverage** of the current portfolio to be good/very good. Respondents did however acknowledge gaps in the portfolio. (Specific gaps in the standards portfolio are explored in more detail below.). One stakeholder commented that "The coverage of harmonised standards is reasonably good for some products and sectors, because of a high level of interest in the creation of such standards from both safety authorities and large manufacturers. However, coverage of some smaller volume or lower value products is low, meaning that manufacturers must revert to the EHSRs and interpret them themselves. While understandable, this can lead to greater variety of interpretation of the state of the art and the appropriate level of safety provision." Another respondent, however, cautioned against increasing coverage by expanding the scope of individual standards. This interlocutor claimed that "there are many excellent B-Type standards available that apply to most types of machinery. Grouping too many different machine types in one C-Type standard removes the added value of this standard, as it makes it difficult to develop scientific requirements."

Positive appraisals were also generally given for the extent to which standards were **up-to-date** with technological developments (83% rated this as good / very good) and, to a lesser extent, the frequency with which standards are reviewed and **revised** (66%). The availability of standards for new **innovative products** was in general rated poorly. There were several concerns raised in comments about the mismatch between the time needed for the development and revision of standards, and the speed of technological development and advancement in the state of the art. However, at the same time, there was acceptance that standards will necessarily lag behind technological development, and several commentators argued that trying to increase the speed of development / revision might reduce overall quality or usability or (with more regular revision) create a less stable framework for industry.

Stakeholders had overall more negative views about the **cost** of European Harmonised Standards. Additional comments revealed that the costs are particularly problematic for SMEs, especially when one standard makes a number of references to other norms. One commentator highlighted that "the cost of acquisition is prohibitive… most are €50-€200 each, and you usually need a suite of A and B standards to fully understand a C (product specific) standard." Several also argued that, given their support to protecting human safety, standards should be made freely available.

Table 41 Rating aspects of the European Harmonised Standard portfolio

	Very poor	Poor	Good	Very good	n
The scope and coverage of the current portfolio of European Harmonised Standards	1%	6%	67%	26%	82
The extent to which European Harmonised Standards are up-to-date with technological developments	0%	17%	63%	20%	81
The frequency with which existing European Harmonised Standards are reviewed / revised	5%	29%	59%	7%	296
The availability of European Harmonised Standards for new innovative products	11%	52%	32%	5%	257
The cost of European harmonised standards	28%	42%	29%	2%	249

Source: Machinery Directive Public and Targeted Consultation. Excludes 'don't knows' and non-respondents.

[35] This is higher than the total number of C-Type standards quoted previously, as the figures reported by CEN also include standards published during the period which have subsequently been amended / revised.

As was discussed in relation to conformity assessment, a number of respondents highlighted that harmonised standards are not available for all Annex IV machinery, or that they do not cover all essential requirements/risks relevant to the machinery in question. This may be reducing take-up of the self-assessment option for Annex IV products, or (more seriously) may be reducing the effectiveness of self-certification in ensuring the protection of health and safety.

Respondents were invited to identify areas where European Harmonised Standards were currently not available (but should be), or in some other way insufficient. Around three-quarters of stakeholders said that there were **gaps** and went on to provide further (brief) details. A wide range of often very specific products/types of products were identified as having gaps in standards. These include (mentioned more than once) Automated machines and vehicles; Additive manufacturing/3D-printing; Collaborative robots/systems; Assembly machines and systems; Interchangeable equipment; Partly completed machinery; Wind turbines; Food machines; Metal working/bending machines; Risk assessment procedures. Other areas mentioned by single respondents are shown below. A full list of over 100 suggestions is presented in C.2 for reference.

Table 42 Other identified gaps in available European Harmonised Standards

Agricultural machinery	Entertainment industry	Industrial trucks	Pressure equipment
Anchor points	Ergonomics	Internet of Things	Pumps
Building equipment	Fans	Laser lights	Software / systems
Computer hacking	Forestry shredders	Loading wagons	Steam turbine
Construction machinery	Gas turbines	Medical devices	Surface coating machines
Cordless leaf blowers	Gear boxes	Melting furnaces	Turbo-expander
Electric brush cutters	Generators	Mixers	Tyre changers
Industrial measuring machines	Hoisting gear	Non-enclosed lifting platforms	Wireless technologies
Electric hand-held cutting tools	Industrial ovens	Passenger bridge to ships	Electric generators

Source: Machinery Directive Public and Targeted Consultation. Excludes 'don't knows' and non-respondents.

Several respondents however pointed out that the development and availability of standards is driven by economic operators. There is a robust process to identify and establish standards where required and if there is sufficient interest new standards will be developed. Also, one respondent pointed out that even if there is no C-Type standard, the B-Type and A-Type standards are helpful.

Stakeholders were also asked to rate the overall **usability** of European Harmonised Standards in relation to the Machinery Directive. A majority (90%) had positive views as to clarity over which standards could be used. However, several respondents noted that it was at times difficult to find the right standard to apply based on the summaries that were freely available, or to be sure of using the correct and up-to-date standard. Some were also more generally concerned about a lack of awareness and knowledge amongst SMEs. Most stakeholders (93%) also expressed positive opinions about the quality and usability of existing standards in relation to the Machinery Directive. However, there was less agreement that these standards did a good job of explaining rules, guidelines and definitions. Additional comments provided suggested that standards could often be hard to read and understand, or difficult to implement (because of the methods chosen). One stakeholder commented that "there are typically too few descriptive worked examples that can be used as a reference, which means you have to rely on experience and a knowledge of what might be 20-30 cross-referenced standards."

Table 43 Rating the quality and usability of European Harmonised Standards

	Very poor	Poor	Good	Very good	n
The quality / usability of existing European Harmonised Standards	0%	7%	60%	33%	85
How well European Harmonised Standards explain rules, guidelines and definitions	5%	24%	58%	13%	244
The clarity over which European Harmonised Standards can be used	0%	10%	59%	31%	80

Source: Machinery Directive Targeted Consultation. Excludes 'don't knows' and non-respondents.

5.7.4 The position of European Harmonised Standards vs others

Stakeholders were asked what types of standards industry tended to use in applying the Machinery Directive. Just over half (54%) reported the use of both European Harmonised Standards and other standards, while a further 42% reported the use of mainly European Harmonised Standards. Only 4% claimed that other types of standards were mainly used, or no standards at all were applied.

The **main benefits of using European Harmonised Standards** in applying the Machinery Directive, as mentioned by respondents, include:

- They provide presumption of conformity with the essential requirements
- They are readily available
- They are officially recognised across the EU (and beyond)
- The content, validity and scope of these standards is well /widely known
- They form part of contractual requirements of customers
- They are preferred by Notified Bodies
- The European Commission has verified their integrity
- They are well aligned with the specific requirements of the Machinery Directive
- Their use reverse burden of proof
- They simplify the demonstration of conformity and have well-defined evaluation procedures
- Through the Vienna Agreement harmonised EN ISO standards have a positive influence on non-EU requirements.
- When identical to a corresponding international standard (i.e. where an international standard has been transposed), then advantages increase, as this facilitates market access at a global level
- They are evaluated regularly for possible updating
- Different stakeholders participate in their development
- They provide an efficient (cost/effort) way to comply with the Directive

Many respondents explained that European Harmonised Standards are used, unless there are specific reasons not to (e.g. due to specific requirements of their customers or target market, or a lack of coverage of existing harmonised standards in the relevant area). Therefore, the **main benefits of using other** (non-harmonised) standards or specifications (at least in specific circumstances) that were mentioned included: the fact that no relevant harmonised standard exists; that other specific standards are more globally applicable / acceptable; that they form part of contractual requirements of customers; that they are more up to date; and that they are referred to by harmonised standards.

5.8 Evaluation Question 9: the effectiveness of mechanisms relating to non-compliance

9. How effective are current mechanisms for identification of non-compliant products and their removal from market, and what are the barriers to effective enforcement?
    a. How effective are MS authorities in identifying non-compliant products?
    b. How effective are MS authorities in removing non-compliant products from the market?
    c. What are the barriers to effective market surveillance and enforcement?
    d. What are examples of good and bad practice in identifying and taking non-compliant products off the market (efficiently)?

Evaluation Question 9 concerns market surveillance and penalties in relation to non-compliance with the Machinery Directive. It asks about the effectiveness of national authorities' activities in identifying and removing non-compliant products from the market, whether there are any barriers to the effectiveness of these mechanisms, and whether good or bad practice examples can be identified.

The number and proportion of non-compliant product identifications will be highly dependent on market surveillance activities carried out within the Member States. Unfortunately, there are few publicly available data on the level of inspections and the findings of non-compliance specifically related to products falling under the Machinery Directive and across Member States. The Report on the Member States reviews and assessment of the functioning of market surveillance activities for the 2010-2013 period – Sector 9 Machinery[36] (henceforth referred to as the "MSA report") does give an indication of the number and types of inspections carried out in different Member States with relevance to the machinery sector, and the numbers and types of findings. However, for most countries, the data are not complete, and some data are internally inconsistent (e.g. sub-categories add up to more than the total number indicated). Also, some countries used a different reporting format (e.g. Malta, Estonia) and several do not provide any data at all (e.g. Germany, Spain, the Netherlands).

Despite these caveats, we have made use of the data contained within this report in our analysis - although we focus only on the 19 countries with complete datasets for the examined parameters. We also draw on various feedback and information collected from stakeholders through consultation, as well as other data sources to provide additional insights into market surveillance and enforcement.

In this section we look first at the activities of market surveillance authorities (drivers, numbers of inspections), then at resulting findings of non-compliance and the measures taken. We consider the extent of non-compliant products that are present in the market before ending with a discussion as to the barriers to more effective market surveillance and enforcement and examples of good practice.

5.8.1 Market surveillance activities

Market surveillance is essential in identifying non-compliant products and enforcing appropriate corrective measures. It is carried out through inspections by the responsible market surveillance authorities/agencies (MSAs) within each Member State, and may include documentary checks (e.g. conformity assessment, technical files) or technical checks (e.g. physical checks of machinery, laboratory test of the product).

Drivers for inspections (proactive / reactive)

Member States draw up an annual action plan for the surveillance of products in the national market These plans and the resulting surveillance regimen are generally based on risk assessment, e.g. efforts are targeted at products or economic operators suspected of not meeting the requirements. The basis

[36] Report on the Member States reviews and assessment of the functioning of market surveillance activities for the 2010-2013 period pursuant to Article 18(6) of Regulation (EC) No 765/2008 (Sector 9 Machinery)

for this risk assessment and subsequent action plan might originate from previous inspections, complaints, accident reports, or information from RAPEX[37] and ICSMS[38].

Most countries that provided data for the MSA Report indicated that they performed mainly self-initiated inspections, e.g. explicitly targeting product categories and economic operators, based on knowledge built and priorities set by authorities. Such proactive inspections generally accounted for more than 75% of all inspections in these countries. Only Belgium, Austria and Denmark indicated that they carried out mostly reactive inspections (>80% in each case), i.e. as a response to complaints, accidents, or RAPEX notifications.

Through the targeted consultation we also asked MSAs about the extent to which their Machinery-related inspections tended to be proactive (i.e. targeting of particular product categories) or reactive (i.e. in response to a complaint or accident). The ratio of the type of approach to inspections (proactive: reactive) ranged widely among these organisations[39] from 0:100% (i.e. entirely reactive) to 90:10% (mostly proactive). However overall (i.e. average of organisations) the distribution of proactive and reactive inspections is relatively balanced (47:53%).

Through the consultation we also asked more about the extent to which different drivers influence their market surveillance activity. As can be seen from the results below, most organisations cited a range of minor and major influences. However, accident reports were a major influence on all MSAs, while complaints and RAPEX were also cited by most as a major influence. 'Other' important influences mentioned by respondents included AdCo (Administration Cooperation) meetings between MSAs dealing with the Machinery Directive, and specific pro-active projects and campaigns launched by the specific market surveillance authority.

Table 44 Drivers of market surveillance activity

	Not at all	Minor influence	Major influence	n
Government policy	14%	43%	43%	7
Previous inspections	0%	43%	57%	7
Complaints	0%	14%	86%	7
Accident reports	0%	0%	100%	7
RAPEX (Rapid Alert System for non-food dangerous products)	0%	29%	71%	7
ICSMS (Information and Communication System for Market Surveillance) systems	0%	43%	57%	7
Joint market surveillance programmes (e.g. PROSAFE Joint Actions)	14%	29%	57%	7
Other (please specify)	25%	0%	75%	4

Source: Machinery Directive Targeted Consultation. Excludes 'don't knows' and non-respondents.

As an aside, national authorities were asked to rate the adequacy of the RAPEX system on a number of different dimensions. The results (below) suggest that it is generally well regarded, particularly in relation to its completeness (i.e. non-compliant findings recorded), and in terms of the action taken as a result of notifications on the system. Authorities tended to be less positive about its ease of use, both in providing notifications and in monitoring the notifications of others.

[37] Rapid Alert System for non-food dangerous products (RAPEX) - a publicly accessible notification system for non-compliant products posing a serious risk. It has been operating across the EU since 2004. Member States use the system to notify the Commission of measures taken against products posing serious risks (which the Commission then disseminates to other Member States). Following a RAPEX notification, Member States are expected to take action and remove products from market.

[38] Information and Communication System for Market Surveillance (ICSMS) - an information support system that enables sharing of a wider range of information about market surveillance activities performed by Member States, including on products found to be non-compliant that do not pose a serious risk.

[39] Which covered the following member states: Cyprus, Denmark, Greece, Malta, Sweden and the UK.

Table 45 National authority assessment of RAPEX

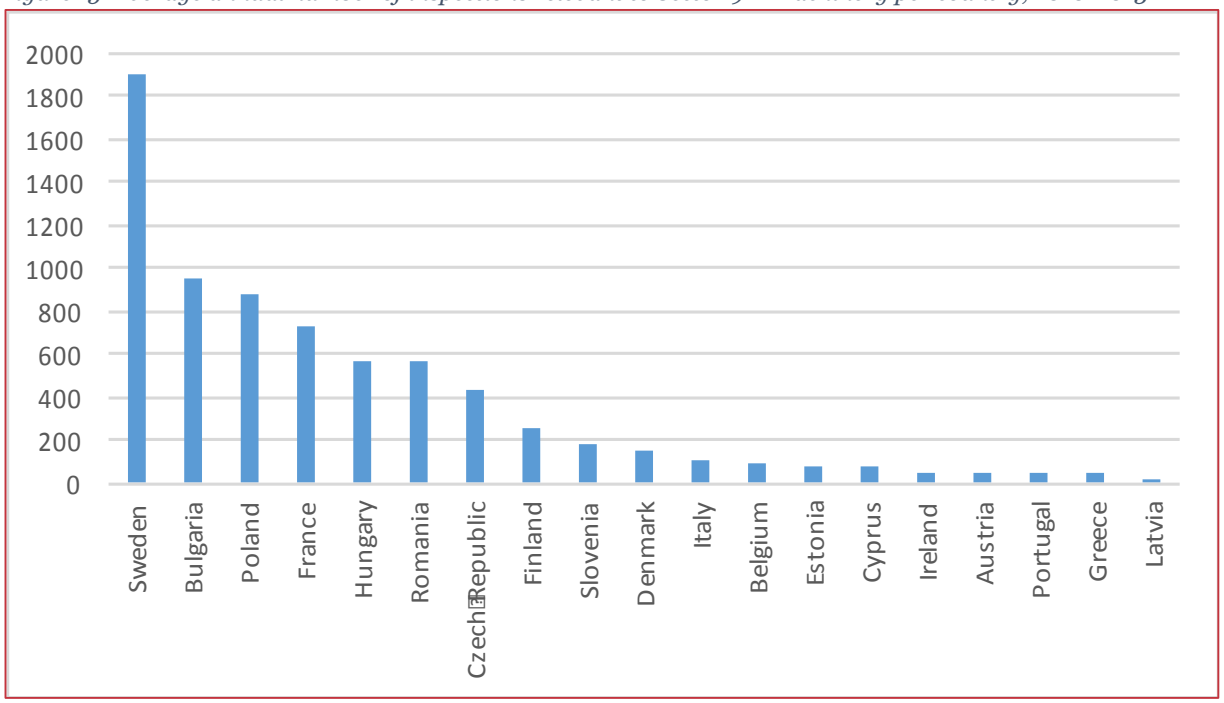
	Very / Poor	Adequate	Very / Good	n
Action taken as a result of notifications	0%	57%	43%	7
Its completeness (in terms of non-compliant findings recorded)	14%	29%	57%	7
Its ease of use (in monitoring others' notifications)	29%	29%	43%	7
Its ease of use (in notifying)	29%	43%	29%	7

Source: Machinery Directive Targeted Consultation. Excludes 'don't knows' and non-respondents.

Number of inspections undertaken

According to the MSA Report, the number of inspections per year varies significantly between different Member States (Figure 15) –as well as from year to year. Sweden indicated by far the largest number of inspections, with an average of 1,900 inspections per year, including a total of 5,003 inspections in 2012. Bulgaria, Poland, France, Hungary, and Romania carried out an average of between 500 and 1,000 inspections per year, and the Czech Republic, Finland, Slovenia, Denmark, and Italy between 100 and 500.

Figure 15 Average annual number of inspections relevant to Sector 9 – Machinery per country, 2010-2013



Source: Report on the Member States reviews and assessment of the functioning of market surveillance activities for the 2010-2013 period pursuant to Article 18(6) of Regulation (EC) No 765/2008 (Sector 9 Machinery)

The following table weights these average number of inspections according to several different sectoral indicators (number of enterprises, production value, total import and export value). Sweden, Bulgaria, Poland, Hungary and Romania still tend to perform well on these measures, though France and the Czech Republic fall below average. Slovenia, Estonia and Cyprus also tend to have above average rates of inspections based on this selection of indicators.

Table 46 Average annual number of inspections (2010-13) relevant to Sector 9 – Machinery, as a proportion of production value, imports and exports, by country

Machinery	Number of Inspections…	…Per 100 enterprises (2013)	…Per €1bn of production value (2013)	…Per €1bn of import value (2013)	…Per €1bn of export value (2013)
Sweden	1,904	60	91	61	56
Bulgaria	951	109	785	200	263
Poland	884	19	101	22	22
France	727	15	19	7	9
Hungary	570	23	81	20	17
Romania	559	44	206	35	41
Czech Republic	434	8	38	11	9
Finland	248	17	18	20	20
Slovenia	178	24	130	38	29
Denmark	152	9	9	10	8
Italy	103	0	1	2	1
Belgium	93	7	9	2	3
Estonia	76	51	239	19	21
Cyprus	71	120	1661	133	349
Ireland	52	19	27	5	5
Austria	52	4	3	2	1
Portugal	52	3	23	6	7
Greece	42	2	47	8	21
Latvia	22	13	116	8	11
EU (19 countries)	**7,168**	**13**	**27**	**16**	**14**

Sources: Inspections (Report on the Member States – Sector 9 Machinery), Number of enterprises and Production values (Eurostat [sbs_na_ind_r2]), Import / export values (COMEXT EU trade data).

Through the targeted consultation we also asked **market surveillance authorities** to provide data on the number of inspections carried out within the scope of the Machinery Directive over the course of the last 12 months. Just five authorities (CY, SE, MT, GR, DK) were able to provide such an estimate, and these ranged from 30 to 80 inspections per year (52 inspections per country on average). This is significantly below the average reported by 15 countries in MSA reports (an average of 455 inspections per country, per year, 2010-13). Only three countries can be matched between the two sources, but in these cases the average number of inspections for the country in the MSA report are 1.4, 1.9 and 29 times greater than the rates quoted for the same countries in the survey responses. There may of course be other market surveillance authorities in a country, beyond the respondent to the survey, but these results do add to the concerns raised in Section 0 about the quality of the MSA reports as a reliable / consistent data source.

The consultation also asked about recent trends in the number of inspections they carried out in relation to the Machinery Directive. There was a reasonably even split between MSAs reporting an increase in inspections over the past five years (three reported a slight increase, one reported a significant increase) and those reporting a decrease in the number of inspections during this period (two reported a slight decrease, one indicated a significant decrease). Reasons given for increased activity included the participation in Joint Actions, an increase in available resources, and the introduction of a web-based complaint-reporting system, whilst all of the authorities reporting a decrease in activity blamed a lack of / reduced resources available for market surveillance.

For a different perspective, we also asked **industry respondents** about their experience of market surveillance activities. We first asked whether they had been the subject of a machinery-related inspection in the past five years, and just under one-third (29%) reported that they had been, while the remainder had not. Respondents were then asked to indicate the number of times that their organisation had been subject to a machinery-related inspection over the past five years. Twenty-one companies provided data, with the number of inspections varying between none (in half of these cases) and 10 (in two cases). The average number of machinery-related inspections for these respondents was around two each over a five-year period.

The public consultation also asked industry to estimate the average number of inspections to which they had been subjected. Of 99 respondents who provided an answer to this question, 80% reported that they had never been inspected by the authorities, or that they had seen very few inspections (less

than one in five years) – including one respondent from Germany, who noted that he was unaware of any controls of his approximately 500 customer companies. Nine respondents (9%) indicated annual inspections, nine respondents (9%) were inspected 2-4 times per year, and one respondent mentioned that inspections took place 10 times per year.

In addition, of the respondents that did undergo inspection regularly, three mentioned (though this was not specifically asked) that they underwent voluntary inspections (requested by company); six noted that they undertook internal inspections or inspections by Notified Bodies; and one indicated that the company was regularly inspected by customer-appointed third parties.

They were also asked what percentage of their product types have *never* been inspected during the past five years. There was significant variation in the responses. Of the 114 responses, 54% (61) indicated that none of their products had been inspected, 14% (16) that 75-99% had not been inspected, 7% (7) that between 25% and 75% of product types had not been inspected, 7% (8) that less than 25% had not been inspected, and 19% (22) that all product types had been inspected. Of those who indicated that all product types had been inspected, several mentioned internal checks; it is hence unclear if the answer refers to inspections by MSAs.

On a related topic, businesses were asked how much time typically passes from market entry to inspection. Information was provided by only 45 respondents; of these, three respondents (7%) indicated less than six months as a typical time elapsed from market entry to inspection, eight (18%) indicated six months to one year, six (13%) indicated two years, and three (7%) indicated three-to-four years. A fairly large number of respondents (24%) stated that the time elapsed tended to be highly variable, and depended on the product and national legislation, and on the level of advertising and popularity (with new strongly selling products being inspected within 2-4 weeks). Two respondents (4%) explained that inspections took place on request only, and 12 (27%) indicated that their products were inspected before market entry; however, for the latter it was unclear if respondents were referring to inspections by the MSA or internal checks.

All stakeholders were also asked whether there were countries / products where the number of inspections is thought to be particularly high. The countries perceived to have the highest number of inspections were France (17 responses) and Germany (13 responses), followed by the USA (6), Italy (5), England (4) and Turkey (4). However, the (concentration) of locations in which respondents operate is likely to be a strong influence on these perceptions – and the survey questionnaire did not collect such details. Nevertheless, it is still interesting to note some of the product categories that were mentioned in terms of the high number of inspections in certain countries, which were:

- For France - construction machinery, machine tools, concrete plant installations, power tools
- For Germany - chainsaws, robotic lawn mowers, power-operated doors and gates
- For Italy - tractors, cranes and excavators, machine tools, agricultural machines.

With respect to Turkey, two respondents pointed to issues with 'unreasonable' inspections, e.g. "Turkey seems to have a rigorous, if in some cases misguided, application of their implementation of Machinery Directive for customs inspection on entry to the country."

Stakeholders were similarly asked whether there were any countries / products where the number of inspections is thought to be particularly low. There were 38 responses that specified a country, region, or machinery category: Countries specified as having a particularly low number of inspections were Italy (11 responses), Germany (7 responses), and Spain (5 responses). Eastern Europe and Asia were also mentioned (3 responses each). Machinery categories highlighted as being subject to relatively few inspections included large moving machinery (e.g. bridges, lock gates, Roll-on roll-offs), small generators, power-operated doors and gates, power tools, concrete plant installations, and pumps and pumping systems.

Stakeholders were further asked about the **overall effectiveness of national authorities** in Europe in relation to monitoring manufacturers' adherence to the requirements of the Directive. As

shown below, nearly three-quarters (74%) of respondents rated national efforts as having limited or no effectiveness.

Table 47 Effectiveness of national authorities in monitoring adherence to the Machinery Directive

	Not at all	To a limited extent	To a large extent	Entirely	n
Monitoring machinery manufacturers on their adherence to health and safety requirements for their products	11%	63%	23%	3%	328

Source: Machinery Directive Public Consultation

The consultation also asked stakeholders in more detail about their **views on current levels of market surveillance undertaken** in relation to the Machinery Directive across Europe. The response was very negative (see table below). Most respondents (80%+) believed that the number and frequency of inspections, as well as the likelihood of being inspected, were all currently too low. A majority also believed that the typical time from market entry to inspection was currently also too short. As a result, it is unsurprising that over three-quarters of respondents (77%) also believe that the number of products on the market that have never been assessed is currently too large.

Table 48 Views on current levels of market surveillance undertaken

	Too low	About right	Too large	n
The number and frequency of inspections carried out	83%	16%	2%	64
The likelihood of an individual company being inspected	80%	19%	1%	261
The typical time from market entry to inspection / assessment	57%	27%	16%	37
The number of products on the market that have never been assessed	13%	11%	77%	47

Source: Machinery Directive Public and Targeted Consultation. Excludes 'don't knows' and non-respondents.

Even national authorities (competent authorities and / or market surveillance authorities), when asked specifically about the level of market surveillance activity within their own country, were generally critical. For instance:

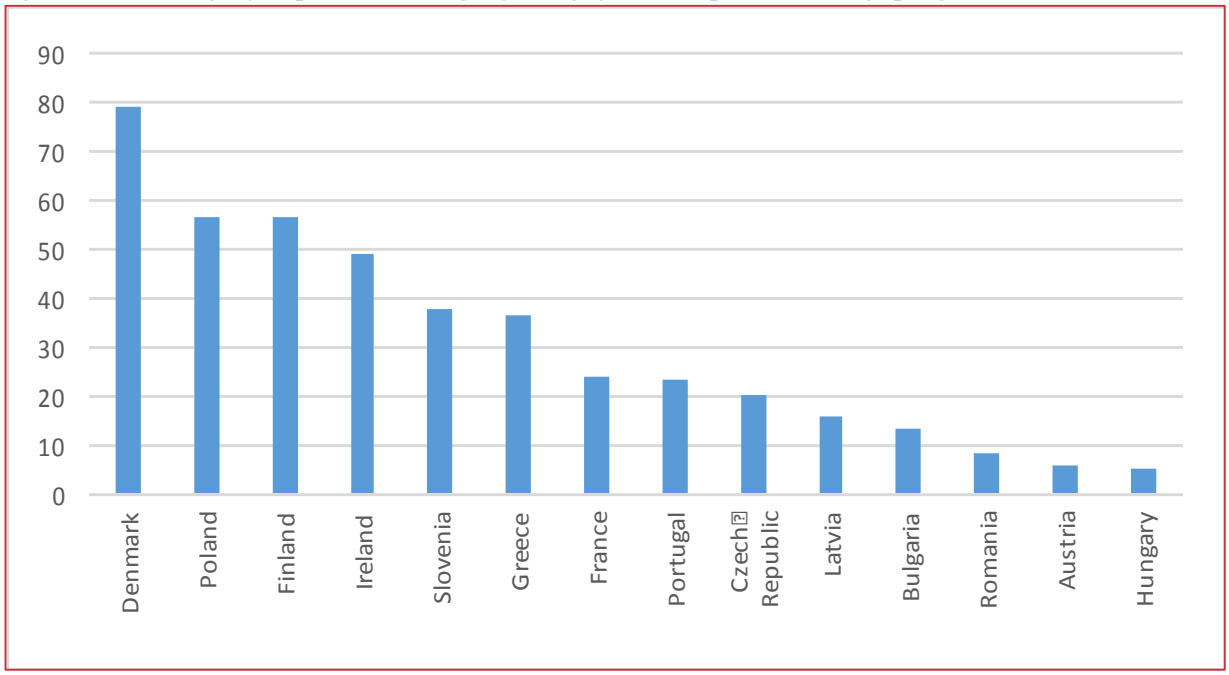
- Half (50%) considered the number/frequency of inspections to be too low, while the other half thought the current rate was about right
- A majority (83%) believed the likelihood of a company being inspected was too low, while just 17% thought it was currently about right
- A majority (71%) felt that the number of products on the market that had never been assessed was too large, while a third (29%) thought it was about right.

5.8.2 Findings of non-compliance

Fifteen Member States provided data to the MSA Report both on the number of inspections and the findings and actions resulting from inspections. The data are difficult to interpret. For example, the 'measures taken' categories should be a sub-set of the 'finding of non-compliance' category; however, some countries (Hungary, Poland, and Bulgaria) indicate a larger number of restrictive measures than the number of findings of non-compliance. This may be the result of multiple counts for cases were a finding of non-compliance led to several restrictive measures, or Member States may differ in their interpretation of the requested data parameters.

Within these data analysis constraints, it still remains evident that there is significant variation across the MS in terms of the level of inspections that lead to determination of non-compliance. Denmark has the highest level of inspections leading to findings of non-compliance at 79%, followed by Poland, Finland, and Ireland (57%, 56%, and 49%, respectively) (Figure 16). Austria has a very low level of findings of non-compliance at 6% (3 cases of non-compliance per year, resulting from an average of 50 inspections per year). As mentioned above, the data for Hungary, Romania, and Bulgaria may not represent the actual level of findings of non-compliance.

Figure 16 Percentage of inspections leading to finding of non-compliance, average per year (2010-2013)



Source: Report on the Member States reviews and assessment of the functioning of market surveillance activities for the 2010-2013 period pursuant to Article 18(6) of Regulation (EC) No 765/2008 (Sector 9 Machinery). Notes: Finding of non-compliance: any non-compliance (formal or substantial, minor as well as serious) of a product, Restrictive measure: compulsory measures to restrict the product being made available, to withdraw it, or to recall it. Sweden: no entry for 'finding of non-compliance'.

Through the targeted consultation we also asked market surveillance authorities about the results of their Machinery Directive-related inspection activities, in terms of the proportion of inspected machinery products (in the previous 12 months) that had been found to be non-compliant. Just four authorities (DK, GR, MT, SE) provided an estimate, and these ranged from 10% to 90% (46% non-compliance on average across these authorities). These authorities also suggested that non-compliance was particularly common (i.e. over-represented) in relation to Chinese-manufactured goods (indicated by 2 authorities), consumer goods, lawnmowers and fulfilment houses (indicated by 1 authority each).

The estimated share of these non-compliance findings that was due to issues with documentation, technical issues, or issues with CE marking varies by country (see below). However, on average, across the five authorities concerned[40] (CY, GR, MT, SE, UK), non-compliance was most often related to issues with CE marking (43%), followed by issues with documentation (35%) and then technical issues (23%).

Table 49 Reasons for non-compliance findings

	Minimum	Maximum	Average
Issues with documentation	10%	50%	35%
Technical issues	10%	35%	23%
Issues with CE marketing	25%	80%	43%

Source: Machinery Directive Targeted Consultation. Excludes 'don't knows' and non-respondents.

[40] The selection of responding authorities is different to the preceding paragraph because some were able to provide estimates as to the rate of non-compliance, while some could provide estimates of the rates of different types of non-compliance, though not necessarily both.

The Report shows that Member States differ in their approaches to rectifying measures (Table 50). While the vast majority of measures taken by Sweden were voluntary (95% average over 2010-2013), Romania, the Czech Republic and Hungary applied only restrictive measures and sanctions/penalties.

Table 50 Number of inspections, non-compliance, and measures taken per year by country (2010-13)

Country	Inspections	Finding of non-compliance	Voluntary measures	Restrictive measures	Sanctions / penalties
Bulgaria	951	94	148	1	10
Czech Republic	434	87	0	0	65
Denmark	152	116	109	8	0
Ireland	52	18	15	3	0
Greece	42	14	11	3	12
France	727	187	n/a	70	14
Latvia	22	4	4	0	1
Hungary	570	32	1	38	23
Austria	52	3	2	0	1
Poland	884	500	668	12	0
Portugal	52	10	n/a	0	7
Romania	559	35	0	35	35
Slovenia	178	67	57	10	9
Finland	248	143	14	7	0
Sweden	1904		1171	8	4

Source: Report on the Member States reviews and assessment of the functioning of market surveillance activities for the 2010-2013 period pursuant to Article 18(6) of Regulation (EC) No 765/2008 (Sector 9 Machinery)

All stakeholders were asked about the **overall effectiveness of national authorities** in Europe with regard to identifying unsafe machinery and removing it from the market. As shown below, 80% of respondents rated national efforts as having limited or no effectiveness in identifying and removing unsafe machinery.

Table 51 Effectiveness of authorities in monitoring adherence, and identifying & removing unsafe machinery

	Not at all	To a limited extent	To a large extent	Entirely	n
Identifying unsafe machinery and removing it from the market	16%	64%	18%	2%	314

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5.8.3 RAPEX

The RAPEX system is the single best source for analysing the incidence rates and origins of non-compliant products over time. However, caution needs to be exercised regarding the interpretation of data, as the RAPEX database has several well-documented limitations (see Appendix A.3.2). In addition, as RAPEX notifications are only issued in response to products posing a serious risk to users, the type of non-compliance identified is limited to serious safety concerns (e.g. risk of injury, electric shock etc.). Products for which other types of non-compliance have been identified, such as issues with documentation (technical file, declaration of conformity, instructions for installation and use) or incorrect CE marking, are not reported through RAPEX.

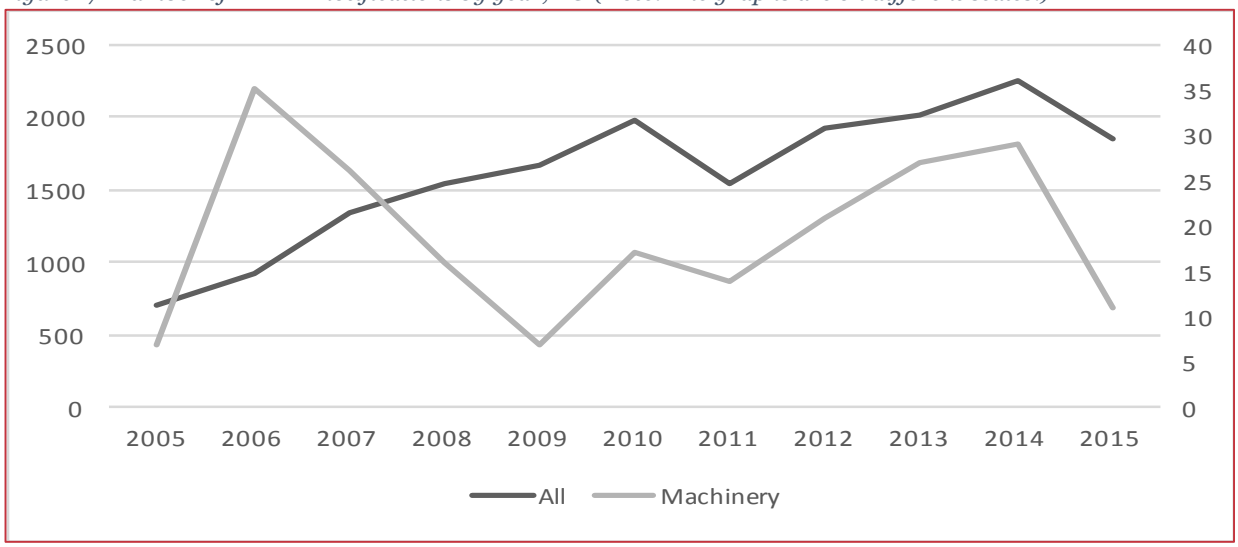
The percentage of **RAPEX entries in the 'machinery' category** is low. Out of 17,724 notifications registered between 2005 and 2015, only 210 were classified within the product category 'machinery'[41]. This equates to an average of 19 notifications per year, or around 1.2% of all alerts – although there have been significant annual fluctuations during the 2005-2015 period (see Figure 17).

The highest 'relative' levels of notifications related to machinery were reached in 2006 and 2007, at 3.8% and 2.0% of all notifications. For these years, the number of alerts from Hungary (2006 and 2007) and the UK (2006) are very high, dropping to much lower levels in all other years. The reasons

[41] We filtered out 10 notifications, as the products they referred to did not fall under the Machinery Directive, e.g. soldering irons, a drill bit set and four electric bicycles (where the issues related to the battery only)

are not clear, and this trend may represent a change in the inspection regime. In 2011 there was a dip in the number of notifications (for Machinery and overall), possibly owing to reduced surveillance budgets as an effect of the financial crisis.

Figure 17 Number of RAPEX notifications by year, EU (Note: The graphs are on different scales.)

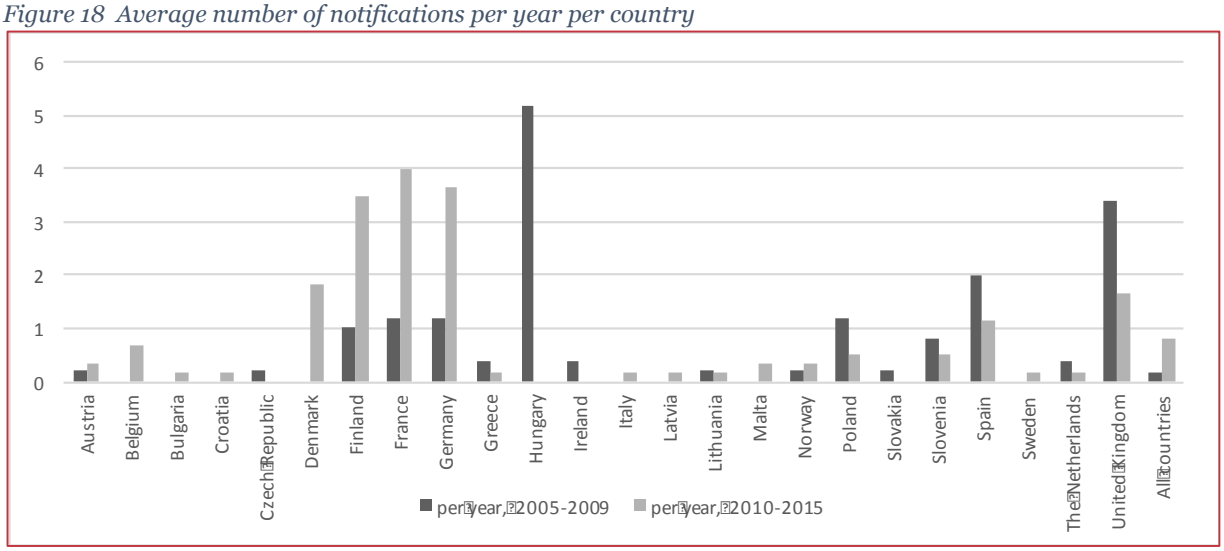


Source: RAPEX

The vast majority of RAPEX notifications in the machinery category relate to consumer products. A 'professional product' option was added to the RAPEX database in 2013. Since then, 3-5 notifications per year have fallen into this category, accounting for between 17- 25% of notifications.

The number of notifications in the machinery category is uneven **across countries** (see Figure 18). The number of notifications relevant to the MD across countries equates to 3.25 per country over the 2005-2009 period, and 4.25 per country over the 2010-2015 period[42]. For the 2005-2009 period, Hungary, the United Kingdom, and Spain accounted for the largest numbers of notifications (with averages of 5.2, 3.4, and 2 notifications per year, respectively). For 2010-2015, the highest numbers of notifications came from France, Germany, and Finland (with averages of 4, 3.7 and 3.5).

Figure 18 Average number of notifications per year per country



Source: RAPEX. EE, CY, LU and RO did report any relevant notifications during the period.

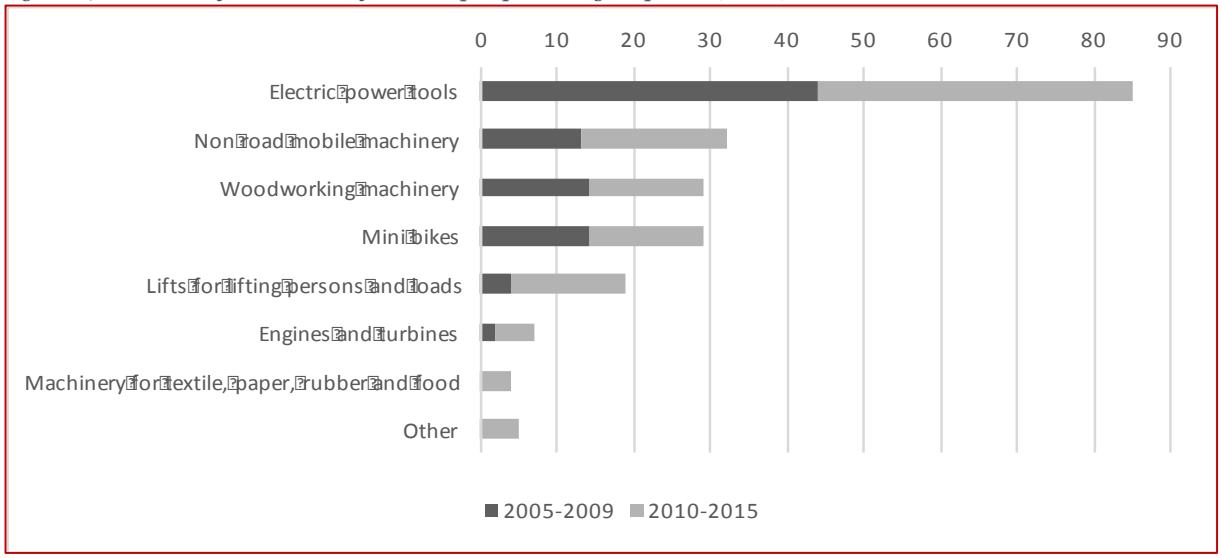
[42] Only 24 EU countries made relevant notifications during the period, but we have calculated these averages based on all EU28.

China is the **country of product origin** involved in most RAPEX notifications overall, but only a small share of these notifications is related to the Machinery Directive. Of 10,472 RAPEX notifications for products originating in China, just 125 (or 1.4%) were categorised as machinery.

Nevertheless, notifications for products originating in China still dominate the machinery alerts (both overall, and for sub-categories of machinery). Of all RAPEX notifications categorised as machinery, 69% were for products from China (145 of 210 notifications). This figure has increased slightly over time, from 66% for the 2005-2009 period (60 of 91), to 71% for the 2010-2015 period (85 of 119). Following China, Italy and Germany were the most common countries of origin, accounting for 5% and 3% of machinery notifications, respectively (10 and 7).

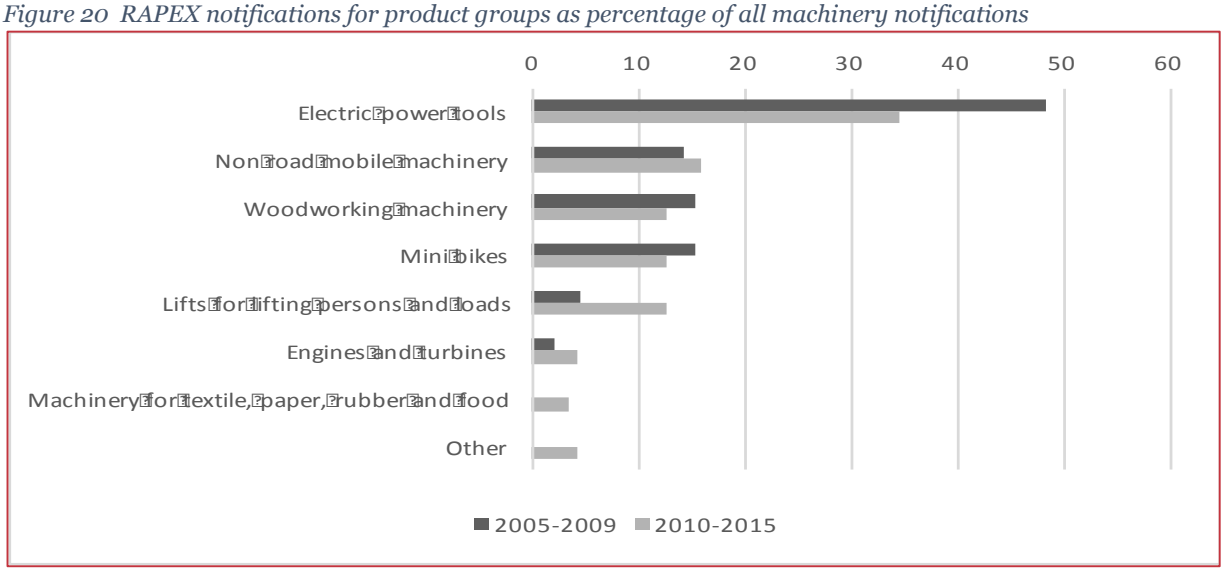
Figure 19 provides an overview of the number of RAPEX notifications by broad product group over the 2005-2015 period (and split between the periods before and after the application of the 2006 Machinery Directive at the end of 2009). Figure 20 shows the same notification data, but as a percentage of all machinery notifications in each period.

Figure 19 Number of RAPEX notifications per product group (2005-2015)



Source: RAPEX

Figure 20 RAPEX notifications for product groups as percentage of all machinery notifications



Source: RAPEX

These two figures show that:

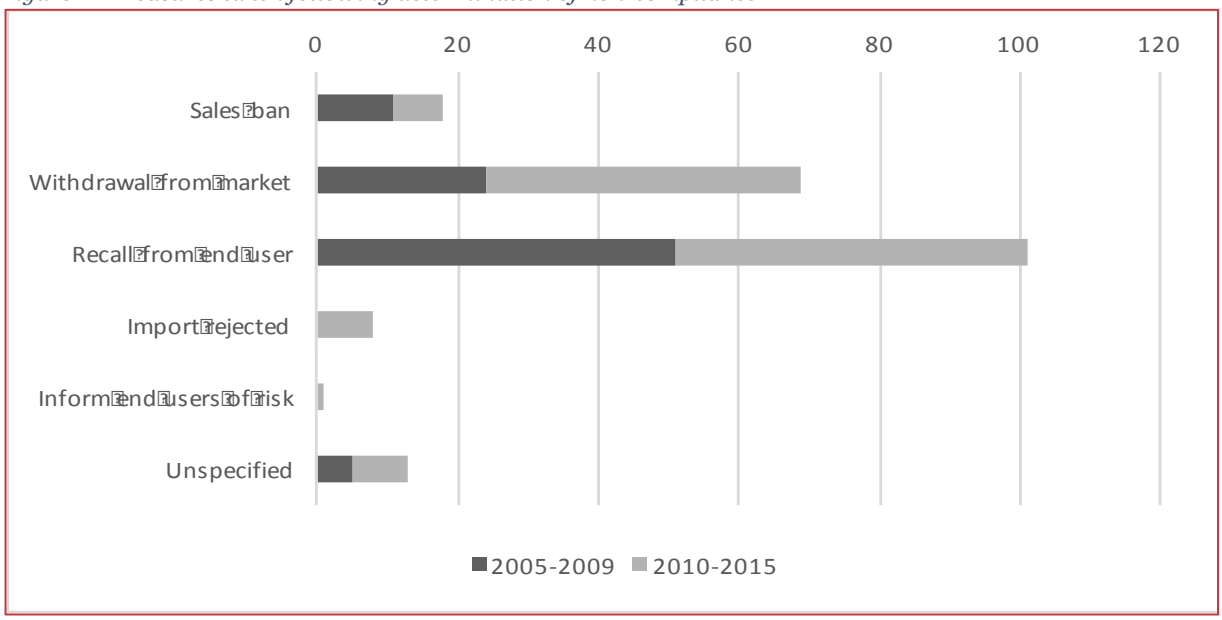
- The largest number of RAPEX notifications related to hand-held power tools (chainsaws, mitre saws, angle grinders, hand-guided circular saws, etc.), accounting for 40% of notifications (85 of 210). The majority (76%) of these products originated in China (65 of 85). Over the 2005-2009 period, this group made up 48% of machinery alerts (44 of 91), with an average of 8.8 notifications filed per year. This dropped to 34% for the 2010-2015 period (41 of 119), with an average of 6.8 notifications per year. The number of notifications were the highest in 2007 (19) and 2006 (17). Most of the notifications originated in Hungary (26 of 44 over the 2005-2009 period). For 2010-2015, Germany, France, and Denmark submitted the largest numbers of alerts (10, 7 and 7 of 41, respectively). Within this group, the largest number of alerts were in relation to angle grinders (22), drills (20), and chainsaws (15).
- The non-road mobile machinery group accounted for 15% of notifications (32 of 210), with an average of 2.9 alerts per year. The majority of notifications in this group (66%) relates to mowers (21 of 32). Over the 2005-2009 period, 14% of notifications related to this group (13 of 91), remaining fairly steady at 16% for 2010-2015 (19 of 119). A relatively low proportion of products in this category originated in China (41%, or 13 of 32), with the USA accounting for 16% (5 of 32, e.g. ride-on mowers). No single notifying country stands out in terms of number of notifications. The largest numbers of notifications were made in 2008 and 2014 (7), followed by 2013 (6).
- Woodworking machinery accounted for 14% of notifications (29 of 210), with an average of 2.6 alerts per year. The number of notifications stayed fairly constant over the 2005-2009 and 2010-2015 periods. Of products associated with the notifications in this category, 62% originated in China (18 of 29), with Finland making the highest number of notifications (11 of 29). Mitre saws accounted for most of these alerts (41%, or 12 of 29), followed by (stationary) circular saws (4 of 29).
- 'Mini bikes' (which we have separated out from other non-road mobile machinery because of their significance within the RAPEX notifications) also accounted for 14% of notifications (29 of 210), with 15% of alerts in 2004-2009 (14), and 13% in 2010-2015 (15). Mini motorbikes accounted for most of these alerts (69%, or 20 of 29). An overwhelming 86% (25 of 29) originated in China. The numbers of alerts were highest in 2006 (14) and 2011 (7). The average number of notifications per year has remained constant over the 2005-2015 period, at three notifications per year. Most notifications were made by the UK (10 of 16) for 2005-2009, and by France and Finland (6 and 4 of 17, respectively) for 2010-2015.
- The lifts for lifting persons and loads group accounted for 9% of notifications (19 of 210), with a marked increase in alerts between the 2005-2009 period (4%, or 4 of 91) and the 2010-2015 period (13%, or 15 of 119). Most of these alerts related to jacks (74%, or 14 of 19). Finland and France registered the most notifications (6 and 4, respectively), and 47% of notifications were made in 2014 alone (9 of 19). Of the products notified, 68% originated in China.
- Only very few notifications related to the product groups engines and turbines (3%, or 7 of 210) and machinery for textiles, paper, rubber, and food (2%, or 4 of 210).
- There were no notifications regarding two products groups set out in the task specifications, machines for metal working and lifting accessories.

Half of the **measures taken** as a result of non-compliance in the machinery category of RAPEX were voluntary (50%), 44% led to compulsory measures, and 5% resulted in both compulsory and voluntary measures. The data show a trend from compulsory towards voluntary measures over time: during the 2005-2009 period, 62% of notifications led to compulsory measures, 35% to voluntary measures, and 5% to both. This compares to 33%, 62%, and 5%, respectively, for the 2010-2015 period (i.e. a switch in the proportion of voluntary and compulsory measures).

We classified a range of descriptive terms for measures taken under five categories, and assigned each notification to the most extensive measure taken. Overall, nearly half (48%) of the measures led to a recall of the product from end users (101 of 210), with a downward trend from 56% over the 2005-

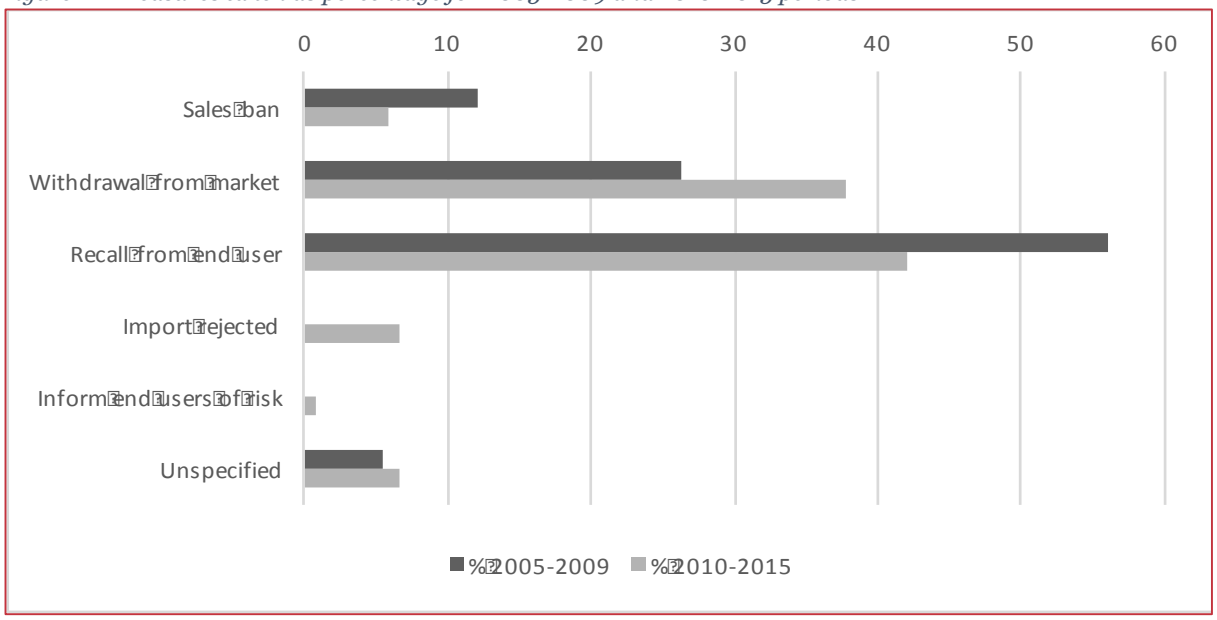
2009 period (51 of 91) to 42% over the 2010-2015 period (50 of 119). A third of the measures (33%) led to the products' withdrawal from market (69 of 210)[43], with an increase from 26% in 2005-2009 (24 of 91) to 38% in 2010-2015 (45 of 119). Figure 21 and Figure 22 summarise these data.

Figure 21 Measures taken following determination of non-compliance



Source: RAPEX

Figure 22 Measures taken as percentage for 2005-2009 and 2010-2015 periods



Source: RAPEX

The RAPEX database also includes information on whether **responses were taken in other MS** ("Products were found and measures were taken also in:" – though not what these responses were). In the machinery category, entries relevant to this question started in 2009, with 26% of products (33 of

[43] It is unclear what, if any, difference there is between a recall from end users and withdrawal from the market. Sometimes one or other measure is stated, sometimes both.

126) triggering a response in other countries over the 2009-2015 period. This is in line with the response rate for all RAPEX notifications during this time (24%, or 3,158 of 13,221). Of the 33 machinery product alerts triggering measures elsewhere, the majority triggered responses by one or two countries only (67%, or 22 of 33). Another 24% triggered responses by three or four countries (8 of 33), and just 9% triggered responses by five, six or seven countries (3 of 33). The highest share of responses was for alerts regarding products in the non-road mobile machinery category (45%, or 9 of 20), followed by the woodworking machinery category (39% or 7 of 18). This compares to 20% (10 of 43) in the hand-held power tools category. Notably, none of the 10 alerts relating to angle grinders and only 17% of alerts relating to chain saws and jacks (2 of 12, each) led to responses by others, whereas 67% of notifications regarding brush cutters (4 of 6) and 45% of those regarding mowers (5 of 11) were followed up. This may be due to the type of non-compliance.

5.8.4 Non-compliant products on the market

It is difficult to draw conclusions on the share of non-compliant machinery products currently on the market. An estimation of this level can be made by examining the share of inspections that led to a finding of non-compliance. However, this share is highly variable between different Member States, ranging from nearly 80% for Denmark to 6% for Austria. The sharp variations may be due to different approaches in targeting inspections; however, both Denmark and Austria indicated that more than 80% of inspections are 'reactive' rather than 'pro-active'.

Targeted actions by product group can also provide an indication of the share of non-compliant products on the market. For example:

- The regional authorities in Baden-Württemberg tested 20 drills with rechargeable batteries in 2011/12[44]. The tests showed that 17 of the 20 drills had issues involving the required markings and three did not include the required safety instructions – but all 20 were found to be compliant in technical checks.
- The same authorities also tested 23 sit-on mowers (non-road mobile machinery) for compliance. One mower was found to be dangerous as it allowed access to drive elements while a person was sitting on the mower, and the relevant MSA was informed.
- An inspection of 57 products exhibited at the International Exhibition for Metal Working (AMB) in 2012 found that 34 products (60%) did not comply with safety-related requirements, and 42 products (74%) had insufficient documentation (e.g. instructions or declarations of conformity). However, the proportion of non-compliant machines may be higher at trade fairs, where novel products or products from overseas / new manufacturers with insufficient knowledge of MD requirements are exhibited.
- Inspections by Italian Customs authorities in collaboration with the Italian Plastics and Rubber Industry Association indicate that 95% of imported machinery in Annex IV of the MD "do not meet the requirements of CE marking"[45] (it is not made clear whether this includes intra-EU trade). As a result, the point of import has been diverted from Italian ports to other countries (presumably with lower surveillance activity).
- The 2011 Joint Action on Lawn Mowers tested seven robotic mowers, four electric cordless mowers, seven electric corded mowers and seven petrol mowers[46]. It was found that 68% (17 of 25) of the tested mowers were non-compliant, with 28% (7 of 25) found to have major non-compliances. Visual inspections of 17 ride-on lawn mowers revealed that 29% (5 of 17) did not comply.

Across these examples of targeted actions, the average non-compliance rate was around 55%.

[44] Jahresbilanz 2012 Marktüberwachung für die Bereiche Produktsicherheitsgesetz und Energieverbrauchsrelevante-Produkte-Gesetz in Baden-Württemberg

[45] EUROPMAP (2011) Market Surveillance: an example of cooperation with customs authorities. Presentation at Conference for Market Surveillance and Machinery, Nov 24, 2011.

[46] PROSAFE (2014) Joint Action 2011 GPSD - Final Technical Implementation Report

The study consultation also asked stakeholders about the current number of products on the market that are non-compliant with the Machinery Directive. The response was very negative (see below), with most respondents (77%) believing the number to be too large.

Table 52 Views on current levels of market surveillance undertaken

	Too low	About right	Too large	n
The number of products on the market that are non-compliant	13%	10%	77%	52

Source: Machinery Directive Public and Targeted Consultation. Excludes 'don't knows' and non-respondents.

5.8.5 Problems and barriers

Unsafe and non-compliant products can lead to unfair competition. Operators that do not adhere to the rules can achieve significant savings on compliance costs, and consequently offer products at lower prices than their competitors. A 2006 public consultation on the New Legislative Framework (NLF) found that 87% of operators believed that there was unfair competition due to the presence of non-compliant products on the internal market. A major reason for the relatively high levels of non-compliant products on the market was felt to be that market surveillance did not operate effectively in the European Union (Impact Assessment, accompanying the Product Safety and Market Surveillance Package, 2013). This was attributed to: "(i) weak coordination between product safety market surveillance authorities in different Member States, (ii) sub-optimal functioning of EU procedures for exchange of information on product risks and (iii) inconsistent enforcement of EU-wide product safety action." Other reasons for inefficiencies put forward were the difficulty to trace economic operators in a globalised market, the limitation of resources of MSAs, and the growing number of imports of non-food products from third countries.

Through the study consultation stakeholders were asked to assess the main problems or barriers to the effective identification of non-compliant products in relation to the Machinery Directive, and to their removal from the market. Three issues were suggested in the question: the lack of cooperation between customs, a lack of staff, and wrong targeting of inspections and actions. Alternatively, respondents could suggest a different issue. As shown in the table below, of the three suggested options, most respondents claimed that insufficient staffing levels were the key problem or barrier to both the identification and removal of non-compliant products. Incorrect targeting and a lack of cooperation were less frequently cited.

Table 53 Main problem / barrier to identification of non-compliant products and removal from market (n=264)

	The effective identification of non-compliant products:	The removal of non-compliant products from the market:
Lack of cooperation between customs	9%	7%
Not enough staff	40%	35%
Wrong targeting of inspections/actions	16%	17%
Others	35%	41%

Source: Machinery Directive Public Consultation. Excludes 'don't knows' and non-respondents.

The large number of respondents indicating another problem or barrier were asked to explain further. Some additional issues were pointed out, but most commentators used the opportunity to return to the same issues already suggested in the questions.

Of the 123 further explanations given in relation to this question, around half pointed to a shortage of staff and resources, leading to low number of controls. Specifically mentioned were budgetary constraints due to the low political priority of market surveillance. As risks of detection and prosecution are perceived to be low, an example was given for the construction industry, where some operators are willing to 'risk' using non-compliant machinery.

A further 32 respondents highlighted a lack in staff knowledge and competence. This was due to the broad remit of the MD and the complex nature of many of the machines falling under it; for example, one respondent observed that "low skilled people in occupational health and safety give very bad advice to companies". Another respondent highlighted difficulties with determining responsibilities: “Machinery imported from China, listed in UK and placed on the market in Germany had considerable shortcomings. There was no market supervisory authority which wanted to be responsible for this.” One respondent felt that adequate understanding of the machinery could only be achieved if national authorities and producers cooperated closely; this was mirrored by another's experience that the company's safety specialists were taking over part of the work of the supervisory authorities when testing their new equipment.

A lack of clarity regarding harmonised standards and Directives was seen by one respondent to lead to inconsistencies in inspections and resulting actions.

Furthermore, some respondents felt that removal of non-compliant products was not prioritised, that there was a lack of consistent implementation of penalties for non-compliance across EU MS, or a lack of reaction altogether, even after determination of non-compliance. Seven respondents commented on a lack of coordination between the MSA and customs staff, or of lack of communication between various national bodies and across borders. Five respondents remarked on cases of inaction of national authorities to remove non-compliant machinery from the market. After alerting authorities to non-compliant products, their complaints were not followed up on (or, in one case, the answer from the authority stated that “the gaps found were correct but [the complaint] would not be prioritised”).

Respondents also noted that market surveillance authorities were mainly concerned with consumer products**,** with insufficient focus on industrial machinery. One respondent explained further: “Market surveillance authorities mainly work on protecting consumer interests and check machinery products in retail. But retail is not a problem compared with investment projects, where manufacturers often try to save costs and purchase used machinery and work equipment from third countries (also from EU) which do not comply with today’s safety requirements.” Regarding controls, respondents mentioned that the focus should be redirected from users to machinery manufacturers, target machinery imported from outside the EU more strongly, particularly from China, and from smaller producers rather than well-known brands. An example of how the system can be manipulated was also provided: “The product in the exhibition centre of the dealer is in order; however, the actual products sold can have considerable deficiencies. Products are simply made at other points of sale, and the authority is not able to control the entire territory.”

5.8.6 Good practice

The study consultation also asked stakeholders whether they would highlight **countries that are particularly effective at identifying and removing non-compliant products**, and that might serve as good practice examples. The following table summarises the countries that were mentioned (in parenthesis we show the totals when the respondent’s ‘home’ country is excluded).

Germany was highlighted most frequently as a good example of market surveillance (42 of 118 responses), even when we exclude the respondents’ home country (31 of 94 responses). The country's market surveillance system was described as “well organised”, “competent” and “experienced”, “actively monitoring compliance” with “stringent minimum requirements”. Two respondents pointed to product-specific checks, such as on chain saws and brush cutters, carried out; other respondents pointed to Germany's facilities for in-house testing. Respondents also stated that German operators had the greatest awareness of regulatory standards (4 responses), with a "real interest in good products" and with large technology vendors driving product compliance. Six respondents felt that German authorities and industry had adopted a collaborative approach, with MSAs working as "consultants for specified requirements of very complex machine systems to cover all requirements". Two respondents pointed out that there were differences between the MSAs of different German Länder, but did not elaborate further.

Table 54 Countries cited as good practice examples in effectively identifying/removing non-compliant products

Country	Responses		Country	Responses
DE	42 (31)		SE	5 (6)
UK	21 (13)		AT	4 (0)
FR	16 (15)		FI	3 (3)
IT	7 (5)		PL	3 (3)
CH	6 (3)		Scandinavian/Nordic	3 (3)
DK	6 (5)		USA	3 (3)
NL	5 (4)			

Source: Machinery Directive Public Consultation. Numbers in parenthesis exclude the respondents' home country

Elsewhere, specific explanations given for rating a country as especially effective at identifying and removing non-compliant products included the following (see Figure 23).

Figure 23 Explanations for countries being cited as effective at identifying / removing non-compliant products

- Minimal bureaucracy (CH)
- Centralised system (CH)
- Well established / embedded systems (DE, FR, UK, IT)
- Well organised system (DE)
- Proactive targeting (DE, AT, UK)
- Scale of activity / resource (DE, DK, FR)
- Strictness / thoroughness (DE, NL, UK, FR)
- Collaboration / dialogue with industry (AT, DE, PL, UK, SE, IT, DK)
- Experience with relevant machinery (DE)
- High level of competence and experience of staff (DE)
- Clarity over compliance / non-compliance of product (DE)
- Well represented within European working groups / ADCO (FR, DE, IT, UK, SE, PL)
- Involvement in standardisation (DE, DK)
- Good use of ICSMS database (DE)
- Good use of RAPEX system (UK)
- Use of customs to effectively enforce market surveillance (FR)
- Strong, independent bodies responsible (UK, DE, FR, CH)
- Well-equipped for in-house testing of products (UK, IT, DE)
- Reactiveness to non-compliance alerts (UK)
- Information and advice provided (UK)

Source: Summary of open responses to Machinery Directive Public Consultation.

5.9 Evaluation Questions 10/11: enablers and barriers to effectiveness

10. What are the enablers and barriers to the effective / optimal application of the Machinery Directive? a. What has enabled effective application of the Machinery Directive? b. What examples are there of good practice in the application of the Machinery Directive? c. What have been the barriers to effective / optimal application of the Machinery Directive? d. What examples are there of bad practice in the application of the Machinery Directive?
11. Are there any aspects, means and / or actors that render certain aspects of the Machinery Directive more or less effective than others – and if so, what lessons can be drawn from this?

Evaluation Questions 10 and 11 both relate to enablers and barriers to the effectiveness of the Directive and its application, including examples of good and bad practices, and lessons that might be drawn.

5.9.1 Barriers to the effective application of the Machinery Directive

A number of issues and barriers have already been identified above in relation to specific aspects of the effective application of the Directive. These include:

- Incomplete or inconsistent application of monitoring and enforcement procedures by Member States, including in the number of market surveillance activities undertaken, the approach taken to determining compliance, the measures taken to withdraw or prohibit machinery, and the establishment of effective, proportionate and dissuasive penalties for infringements.
- Inconsistencies in the interpretation of requirements and the assessments undertaken by Notified Bodies, as well as an apparent decline in their knowledge and experience of specific products.
- Incorrect application of self-certification requirements, combined with a lack of incentive to do more than the bare minimum (caused by an ineffective market surveillance system).
- Under-representation of various actor groups (users, regulators, national authorities) in standards development processes, which are often dominated by a small number of larger multi-nationals.
- Gaps in the portfolio of type-C standards available, particularly for some smaller volume products, as well as for products covered by Annex IV of the Directive.
- Insufficient number and frequency of machinery-related inspections by market surveillance authorities, as well as a lack of cross-border cooperation between these bodies, poor targeting of efforts, a lack of staff knowledge/competence and an imbalanced focus on consumer products.

5.9.2 Enablers to the effective application of the Machinery Directive

Comprehensive **guidance** on the implementation of EU product rules (generally) can be found in the so-called 'Blue Guide'. This was originally published in 2000, but has been recently updated[47] to reflect changes to the legal framework. It primarily relates to European Union legislation in ~30 areas, including Machinery, and provides various information on harmonisation legislation, the actors involved, product requirements, conformity assessment, accreditation and market surveillance. The Guide is intended to contribute to a better understanding of EU product rules and to their more uniform and coherent application across different sectors and throughout the Single Market, and it therefore serves as a key reference document for the implementation of harmonisation legislation.

A guidance document that focuses more specifically on the application of the Machinery Directive is also available. The second edition of the Guide to the application of the Machinery Directive 2006/42/EC[48] was published in June 2010, updated to reflect the 2006 revision to the Directive. The

[47] The 'Blue Guide' on the implementation of EU product rules 2016. C(2016) 1958 final

[48] http://ec.europa.eu/growth/sectors/mechanical-engineering/machinery_en

Guide is a comprehensive 400+ page document that follows the Directive almost sentence by sentence and provides accompanying discussion, comments and explanations on the concepts and requirements. It is aimed at all parties involved in applying the Directive and is intended to ensure the uniform interpretation and application of the Directive throughout the EU.

Stakeholders were asked through the consultations to rate the European Commission's 'Guide to Application of the Machinery Directive' as an aid to understanding the Directive. Only a very small proportion of respondents (5%) were not aware of, or had never used this Guide. Of the remainder that had, the view was generally positive. Most (91%) rated it as good or very good, compared with just 8% that said it was a poor aid to understanding the Directive and 1% that claimed it was very poor.

In addition to these two core Commission guidance documents, a number of other supporting references are available. For instance, the Commission has published a number of guidance documents approved by the Machinery Working Group that deal with specific machinery (equipment used for lifting persons, safety fences, filtration systems, etc.) and that provide further information or clarification[49]. A number of other organisations have also produced additional guidance to the Directive and its application (e.g. the HSE[50], KAN[51], Procter Machine Guarding[52], and Rockwell Automation[53]) or on machinery safety and compliance more generally (e.g. TÜV SÜD[54]).

A number of centralised bodies have also been established to support the effective and optimal implementation and application of the Directive through e.g. sharing of information and best practices, or addressing potential issues and barriers that may arise. These **supporting mechanisms** include:

- *Machinery Committee*: The Machinery Committee assists the Commission in an *advisory role*, by providing suggestions and recommendations on any appropriate measure connected with the practical application of the Machinery Directive, as well as in a *regulatory role*, giving its opinion on measures proposed which amend or supplement the provisions of the Directive.
- *Machinery Working Group*: The Machinery Working Group is set up by the Machinery Committee and allows observers from industry, standardisation and the Notified Bodies to take part in the discussion of problems relating to the practical application of the Machinery Directive. The Machinery Working Group usually meets twice a year in Brussels.
- *Administrative Cooperation (AdCo) Group*[55]: The Administrative Cooperation (AdCo) Group for Machinery is made up of representatives of Member States who meet to exchange information and discuss issues regarding the implementation of the Directive. The meetings, which take place twice a year, are restricted to the representatives of the Member States and the Commission, and the proceedings and documents of the AdCo Group are confidential, since they frequently refer to specific cases under investigation.
- *European Coordination of Notified Bodies for Machinery (NB-M)*: The exchange of experience between the Notified Bodies takes place within the framework of a European Coordination of Notified Bodies for Machinery (NB-M) framework which meets twice a year to discuss problems arising in the course of the conformity assessment procedures and to harmonise the practice of the Notified Bodies (adopting common positions called 'Recommendations for Use').

[49] Available from http://ec.europa.eu/growth/sectors/mechanical-engineering/machinery/index_en.htm

[50] http://www.hse.gov.uk/pubns/indg270.pdf

[51] https://www.kan.de/fileadmin/Redaktion/Dokumente/KAN-Studie/en/2008_KAN-Study_New_Machinery_Directive.pdf

[52] http://www.machinesafety.co.uk/free-downloads/directive-guide

[53] http://literature.rockwellautomation.com/idc/groups/literature/documents/rm/shb900-rm001_-en-p.pdf

[54] http://www.ppma.co.uk/technical/pdf/A-Practical-Guide-to-Machinery-Safety-Edition-4.pdf

[55] http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/administrative-cooperation-groups_en

All of the Notified Bodies responding to the targeted consultation were aware of the European Coordination of Notified Bodies for the Machinery Directive (NB-M) platform. Half (50%) reported that they participated in this forum and a further third (33%) reported to follow its activities and discussions. The remainder (17%) did not actively follow the platform. Those Notified Bodies that followed the activities of the platform were asked to rate its effectiveness in several regards. As the table below shows, most expressed broadly positive views across all aspects.

Table 55 Effectiveness of European Coordination of Notified Bodies for the Machinery Directive (NB-M)

	Not at all effective	Not very effective	Effective	Very effective	n
Harmonising practice	0%	11%	44%	44%	9
Discussing issues and problems arising	0%	10%	50%	40%	10
Exchanging and sharing practices	0%	20%	30%	50%	10
Reaching common positions (Recommendations for Use)	0%	0%	40%	60%	10

Source: Machinery Directive Targeted Consultation. Excludes 'don't knows' and non-respondents.

The targeted consultation also asked national authorities and industry representatives to identify any activities that they undertake in order to support knowledge and understanding of the Machinery Directive and its implications, and therefore help to enable its effective and efficient application. Respondents described a wide range of activities, which are summarised in the table below.

Table 56 Types of activities undertaken to support knowledge and understanding of the Machinery Directive

National Authorities	Industry Associations
• Translated version of Directive and Guide • Development of guidelines and information • Information dissemination • Workshops / presentations • Consultations • Help / Question Answer service • Dedicated website • Liaison with industry associations • Liaison with Notified Bodies	• Analysis of the Directive • Guidelines / Explanatory notes / Fact sheets • Articles / Newsletters / Position papers • Website information • Training / seminars / presentations / workshops / meetings / discussions / forums / information sessions • Help / Question Answer service • Participation in Machinery Working Group • Exchange with other associations • Discussion with Notified Bodies • Participation in standards development

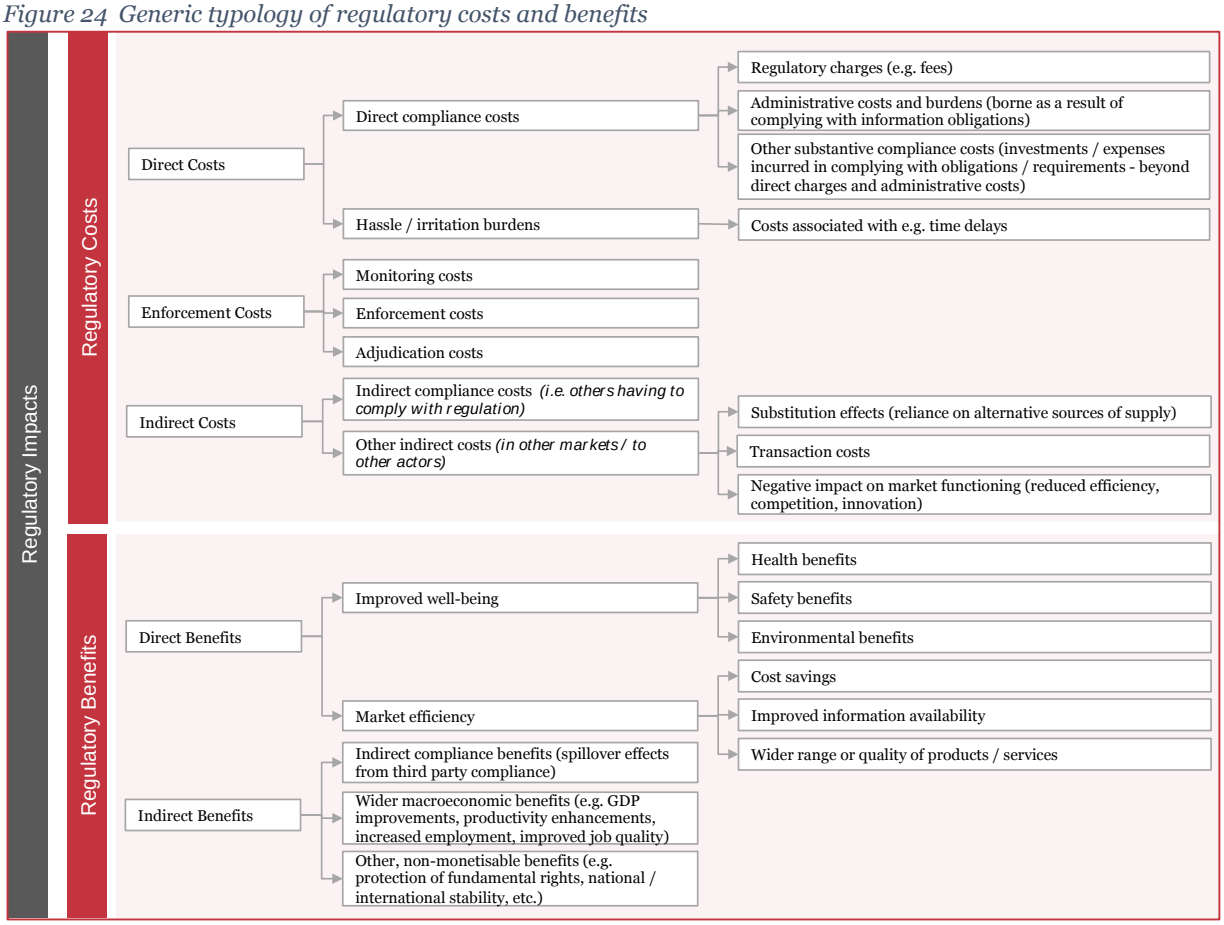
Source: Machinery Directive Targeted Consultation.

Findings in relation to the Efficiency of the Directive

This criterion concerns an assessment of – and comparison between - the costs and benefits of the intervention to different stakeholders. The evaluation study is required to assess the efficiency of the Directive, with a "reinforced focus" on the analysis of costs and benefits.

The study was to first map the different costs and benefits triggered by the Directive, before trying to obtain data (quantified wherever possible) on these aspects from existing sources and primary data collection (consultation). A generic typology of regulatory costs and benefits was elaborated for the Better Regulation Toolbox (European Commission, 2015), and has been adapted slightly for this study and presented in Figure 24 below. This, and the supporting discussion in the toolbox, served as a basis for the study team in identifying the main areas of costs and benefits triggered by the Machinery Directive. These are discussed separately below, with reference to Evaluation Questions 12 and 13.

Figure 24 Generic typology of regulatory costs and benefits



Source: Technopolis, adapted from European Commission Better Regulation Toolbox

5.10 Evaluation Question 12: the costs involved as a result of the Directive

12. What are the costs involved for different stakeholders and actors as a result of the Machinery Directive?
    a. What are the different costs (time and money) that result from the Machinery Directive (including for conformity assessment, self-certification, inspections, compliance, following /participating in standardisation), and to whom do they apply?
    b. What is the scale and range of costs involved? [quantification]

5.10.1 Identification of costs

Using the typology above for guidance, the study team explored the various processes triggered by the Directive, including the main specific actions involved in its implementation and application, that would incur costs to stakeholders (see Appendix C.3). This analysis showed that nearly all of the different costs incurred relate to the time and effort involved in different processes (and the associated cost of these). In a small number of cases, costs would be monetised already – e.g. where a fee is paid for a third party to undertake conformity assessment - but in most cases it would be necessary to apply a financial value (a 'tariff') to figures for FTE hours/days expended in order to determine a financial cost. This assessment is backed up by the evaluation of the Internal Market Legislation for Industrial Products[56], which – when investigating the costs and benefits of conformity assessment – found that fees to third parties represented less than 5% of total compliance costs of firms.

Costs are also borne at different times and with varying frequency. For example, Member State authorities incur one-off up-front costs in transposing the Directive, but also incur ongoing costs of approving Notified Bodies when new applications are made by such organisations during the lifetime of the Directive. At the same time, businesses will incur costs associated with undergoing conformity assessment, but with a regularity determined by their rate of introduction of new/amended products, and a cost that will be specific to their individual circumstances. An evaluation should try to take account of these variations over time and between actors, but it also has to employ an approach that is capable of aggregating costs to some overall set of figures. For example, pro-rating one-off costs over the lifetime of the Directive, taking averages of particular costs across different cases, and multiplying costs of particular activities by the number of times such an activity occurs in an average year.

From exploratory work undertaken during earlier phases of the study, it became clear that the majority of data necessary for assessing the identified categories of costs were unlikely to have been collected / aggregated already, or to be readily accessible. While some sub-components for the assessment of particular costs were available (e.g. the number of standards developed), these limited inputs would need to be complemented by the collection of additional (new) information. The study has therefore had to rely predominantly on assessments from the actors involved (through consultation) in order to determine the costs incurred (e.g. staff effort expended) in undertaking particular activities.

However, this also needs to be balanced against the burden being placed on a community – particularly given that the assessment of costs is only one part of a wider evaluation that requires consultation with the same actors on a larger range of topics and issues than just the regulatory costs and burdens. In addition, we knew that individual actors might be unable or unwilling to provide cost information. They also could not be expected to spend any significant time on finding or calculating precise costs, or to provide information that is commercially sensitive. Similarly, if an actor has incurred a particular cost multiple times (e.g. self-certifying a number of different products), this interlocutor could not reasonably be expected to provide an assessment of these costs for each individual occurrence.

The results of the 2014 Internal Market Legislation study[57] support these concerns. This evaluation undertook several in-depth case studies on products that fall within the scope of the Machinery

[56] CSES for DG Enterprise, 2014

[57] CSES for DG Enterprise, 2014

Directive, highlighting a number of issues concerning the availability of data (e.g. companies did not capture all costs relating to conformity assessment, or did not want to share these due to commercial sensitivity). There were also problems with the disaggregation of data (i.e. the cost of conformity assessment pertaining to a single piece of legislation) – especially where products fell under several Directives. Importantly, the study also found that many activities addressing safety testing would have taken place even in the absence of specific legislation. Testing is considered largely as being part of business as usual, which firms would perform regardless of whether European legislation was in place or not.

The study therefore had to frame requests in such a way that actors felt able and comfortable to (immediately) provide broad estimates of the cost information being sought. We proposed a pragmatic approach: for each group of actors, we identified a limited number of broad activities, and asking them to provide estimated averages of these costs where information is not easily available and / or where the costs of a particular action vary for an individual actor.

We suggested that the following categories of cost (Table 57) form the basis for our enquiries to different groups. The first column indicates the actor(s), while the second column indicates the activity for which they have been asked to provide estimates of average costs. In addition, stakeholders were asked to identify any additional costs not identified above (e.g. if there are costs borne because of overlaps / duplication of requirements with other legislation).

Table 57 Categories of cost to be assessed through consultation with different actors

Actor	Estimate the average cost of:
All National Authorities	• The FTE effort involved in the assessment, appointment and monitoring of Notified Bodies • The FTE effort involved in participation in AdCo Group activities and other MD committees • The FTE effort involved in participation in standardisation relating to the MD
All Market surveillance authorities	• The FTE effort involved in undertaking market surveillance and inspection activities (including follow-up actions) per year
All Notified Bodies	• The FTE effort involved in initial appointment as a Notified Body for the Machinery Directive, and in maintaining status • The FTE effort involved in undertaking an EC-type examination • The FTE effort involved in undertaking approval of a quality assurance system • The FTE effort involved in participation in NB-M activities
All Industry Representatives	• The FTE effort devoted to the Machinery Directive (participation in meetings, informing/advising members, etc.) • The FTE effort involved in participation in standardisation relating to the MD
All Machinery Manufacturers	• The FTE effort involved in ensuring and certifying that a product conforms to the essential health and safety requirements (for each of the 3 conformity assessment options) • The (other) financial costs involved in this process (and to identify significant items) (for each of the 3 conformity assessment options) • The FTE effort involved in meeting market surveillance / inspection requirements per year • The FTE effort involved in participation in standardisation relating to the MD

Source: Technopolis

5.10.2 Evidence on costs

Below we outline various data provided through the consultations that offer insight into the effort and costs involved for the various stakeholders that relate to the Machinery Directive.

National authorities

The targeted consultation asked national authorities to estimate the number of days of effort (FTE) that their organisation devoted each year to the MD (excluding market surveillance activities, which might also be undertaken by the same organisation). It was suggested that this might include monitoring or participating in committees and informing or advising businesses, among other activities. Amongst the ten authorities providing data, estimates ranged from 3 FTE to 400 FTE days per annum, with an average across these organisations of 80 days each. One authority also indicated that the cost of travel and subsistence for Member State Authorities to attend ~10 meetings per year in Brussels would be in the range of €10,000 for each organisation. If these figures were applied to all EU28 countries, it is estimated that around 2,240 FTE days per year would be dedicated to these MD-related activities overall by national implementing authorities, with associated costs of €280,000.

These same organisations were asked separately to estimate the time and effort incurred each year in relation to the development of European Harmonised Standards for the MD (contributing to the development and monitoring / following developments). On average, the seven organisations responding estimated 84 days of effort and €6,429 in other costs per annum. Applied to all EU28 countries, this equates to around 2,348 days and €180,000 in other costs per year.

Market surveillance authorities

Market surveillance authorities were asked through our survey to estimate the total staff time (FTE effort) and other costs (€) that their organisation has incurred in the past year in relation to machinery-related inspections it had carried out. None of the authorities were willing/able to provide cost information, but seven organisations indicated the staff effort involved, which ranged from 0.5 to 15 days per inspection (3 days per inspection on average across these organisations). These specific authorities also estimated that on average they undertook 60 inspections per year – from which we can calculate 180 days of effort in total per organisation (i.e. 3 days per inspection, multiplied by 60 inspections each year). This would equate to 5,040 days of effort if applied to all 28 Member States.

The 'Report on the Member States reviews and assessment of the functioning of market surveillance activities for the 2010-2013 period – Sector 9 Machinery' also provides some information on MSA budgets / staffing for a small number of Member States. This information has been extracted and presented in the three tables below. Based on a small sub-set of Member States, the 'average' annual resources available to each market surveillance authority in relation to Machinery are comprised of around €400,000 in terms of budget and 6 FTE staff (~1,200 days). If applied to all EU28 countries, this would equate to around 33,600 FTE days and €11.2m per year. This is clearly much (over 6 times) higher than the average figures emerging from the targeted survey. This may be caused by the MSA reports use of the phrase 'staff available to MSAs in relation to machinery' – which does not necessarily imply that all their time is used in this sector.

For the summary presented at the end of this section, we have taken the initial 180 day estimate above (from the targeted survey), and an equivalent proportion (15%) of the MSA Report cost figures.

Table 58 Budget available to market surveillance authorities in relation to Machinery

Country	2010	2011	2012	2013
Denmark	€ 1,300,000	€ 1,300,000	€ 1,200,000	€ 1,000,000
France*	€ 400,000	€ 400,000	€ 400,000	€ 400,000
Hungary	€ 74,035	€ 154,736	€ 159,649	€ 169,122
Slovenia	€ 12,300	€ 19,590	€ 13,680	€ 10,680
Finland	€ 260,000	€ 205,000	€ 235,000	€ 250,000
Sweden	€ 388,000	€ 583,200	€ 654,400	€ 309,600
Average (6 MS)	**€ 405,723**	**€ 443,754**	**€ 443,788**	**€ 356,567**

Table 59 Staff available to market surveillance authorities in relation to Machinery (FTE)

Country	2010	2011	2012	2013
Denmark	11.3	11.4	10.6	8.8
Greece	1	1	0.5	0.5
France*	6	6	6	6
Italy	5	6	5	5
Hungary	7	8	9	9
Finland	6.5	5	6	6.5
Sweden	8.33	8.33	8.33	5.33
Average (7 MS)	**6.4**	**6.5**	**6.5**	**5.9**

Table 60 Number of inspectors available to market surveillance authorities in relation to Machinery (FTE)

Country	2010	2011	2012	2013
Denmark	9.2	9.3	8.5	6.7
Greece	2	2	1	1
France*	5	5	5	5
Italy	2	2	1	1
Hungary	4	5	6	6
Finland	4	2.5	4	3.5
Average (6 MS)	**4.4**	**4.3**	**4.3**	**3.9**

Source: Report on the Member States reviews and assessment of the functioning of market surveillance activities for the 2010-2013 period pursuant to Article 18(6) of Regulation (EC) No 765/2008 Sector 9 Machinery. * Machinery for consumers only.

Industry associations

The targeted consultation asked European industry associations to estimate the number of days of effort (FTE) that their organisation (internally) devoted each year to the MD. It was suggested that this might include monitoring or participating in committees and informing or advising businesses, among other activities (though should exclude standardisation). Amongst the 36 associations providing data, estimates ranged widely from 1 FTE day to 1,500 FTE days per annum, with an average across these organisations of 102 FTE days each. Only one organisation provided information on additional costs, which equated to €670 for every FTE day of effort. Applied to the 102 FTE day average, we might estimate average additional costs to these organisations of €68,340 each. Based on searches undertaken to identify stakeholders to consult during the study, we estimate that there are around 50 European industry associations responsible for sectors of relevance to the Machinery Directive. Based on the average of the amounts indicated in the responses to the consultation, we therefore estimate that industry associations may dedicate around 5,100 FTE days per year to the Machinery Directive in total, with additional costs totalling €3.4m.

Industry Associations were also asked to estimate the time and effort incurred each year in relation to the development of European Harmonised Standards for the MD (contributing to development and monitoring / following developments). On average, the 33 organisations responding estimated 93 days of effort and €13,074 in other costs per annum. Applied to 50 associations, this equates to 4,650 days and €653,700 in other costs per year.

Industry

The targeted consultation asked industry to estimate the total staff time (FTE effort) and other costs (€) that their organisation incurred in relation to their last conformity assessment exercise relating to the Machinery Directive (which might relate to any of the four options for conformity assessment). They were asked to provide input data for various stages in the process of conformity assessment. The averages of the responses are shown in the table below. No one provided data in relation to self-certification for Annex IV products, so this option is not included.

Table 61 Average industry estimate of effort and cost of undertaking each conformity assessment option

Average response per company	i) Assessment of conformity with internal checks (non-Annex IV)	iii) EC-type examination (Annex IV)	iv) Approval by NB of a full quality assurance system (Annex IV)
FTE Effort (days)			
Undertaking risk assessment (to determine applicability of the Directive's requirements)	115	3	1
Conformity assessment work internally	350	12	1
Conformity assessment work by third party	370	4	-
Development of technical file	484	13	1
Declaration of conformity/affixing of CE mark	73	2	1
Total FTE effort	**1,393**	**33**	**4**
Other costs (€)			
Undertaking risk assessment (to determine applicability of the Directive's requirements)	€17,758	€ 100,000	No data
Conformity assessment work internally	€63,800	€ -	No data
Conformity assessment work by third party	€9,167	€ 150,000	No data
Development of technical file	€11,856	€ 25,000	No data
Declaration of conformity/affixing of CE mark	€2,478	€ -	No data
Total other Costs (€)	**€ 105,059**	**€ 275,000**	No data
n	25	2	2

Source: Machinery Directive Targeted Consultation. Excludes 'don't knows' and non-respondents.

We reported earlier that, amongst those responding to our survey from industry, the average number of times each conformity assessment option was used over the course of five years were: 72 (option i above), 9 (option ii), 7 (option iii) and 2 (option iv). Using annualised versions of these figures in the following table, we have applied these averages to the average FTE and cost figures from above.

Table 62 Calculating average cost per company of annual conformity assessment activities

Per individual (respondent) company	i) Assessment of conformity with internal checks (non-Annex IV)	iii) EC-type examination (Annex IV)	iv) Approval by NB of a full quality assurance system (Annex IV)
Average no. times undertaken in year	14.5	1.3	0.4
Average FTE effort per assessment	1,393	33	4
Average other Costs per assessment	€ 105,059	€ 275,000	No data
Average FTE effort per year (days)	20,199	43	2
Average other costs per year	€ 1,523,356	€ 357,500	No data

Machinery Directive Targeted Consultation. Excludes 'don't knows' and non-respondents.

However, there is a significant caveat to these figures. The average company providing data on the number of assessments and the costs involved employees over 10,000 people – well above the average number of employees per company in the sector as a whole (~32 people). The estimates are therefore likely to significantly overestimate the costs incurred by many (smaller) businesses.

If we were to assume that costs were entirely proportionate to the size of business, then the above estimates for self-assessment (based on responses from companies with an average staff of 13,500) could be scaled down to the size of the average business in the machinery sector (with 32 employees). This would provide an estimate of annual costs to a business of self-assessment of around 48 FTE days and €3,600 in additional costs. This broadly aligns with the figures provided by the one business in our sample with ~32 employees, which reported that self-assessment required 37 days of effort and €4,500 in other costs in a given year. While less than ideal, we have used these conservative figures in our summary below (and applied them to the 92,863 enterprises in the MME sector[58]).

[58] Eurostat, number of enterprises in EU28 operating in the MME sector in 2014.

The most informative and relevant analysis on costs of conformity assessment that we have identified elsewhere was carried out as part of the evaluation of the Internal Market Legislation for Industrial Products[59]. The authors gathered most of the information through a survey of Notified Bodies (128 responses) and a programme of interviews (201 in total, including with 40 industry associations and 62 companies). The study included case studies on a number of specific products / product groups.

It determined an average cost of conformity assessment with third-party involvement to be in the range of €30- 50k/firm/annum or €3-4k on a per product basis, and found that the fees to third parties did not represent more than 5% of the total compliance costs incurred by firms. These excluded testing costs that would have to take place even in the absence of third-party certification. Particularly SMEs, but also larger companies, indicated that they may outsource parts of the conformity assessment to a third party voluntarily, either due to limited in-house resources to undertake the assessment, or because they valued the credibility offered by independent assessment as a result of a risk-averse approach. Some industry stakeholders highlighted that the main concern related to potential delays and negative effects on time-to-market, rather than the costs of fees associated with conformity assessment. It is also interesting to note that many firms indicated that activities addressing safety testing would take place even in the absence of legislation, e.g. in the case of the MD, testing was seen largely as part of business-as-usual costs, which firms would incur irrespective of whether European harmonised product legislation was in place.

The study also included several case studies on products that fall within the Machinery Directive. These cases highlighted a number of issues with *availability of data*, e.g. companies did not capture all costs relating to conformity assessment, or did not want to share information on costs due to commercial sensitivity. Another problem was the *disaggregation of data*, i.e. determining the cost of conformity assessment pertaining to a single directive (e.g. the MD). For example, electric motors may fall under seven different directives (including the MD) – however, generally not all directives are applicable to all electric motors. Where they apply, the most important directives in terms of impacts are considered to be the Ecodesign and ATEX Directives. In this product category, the average costs for conformity assessment procedures and relevant documentation of the companies made up approximately 0.3% of turnover (consisting of 57% human resource costs, 32% third-party costs, and 11% testing equipment costs). In the garden equipment category, products may fall under different combinations of 10 directives, with the MD representing the main legislation. A large firm indicated that of the €50-60m annual R&D budget it invested in a new product, around 3% (€4m) was directly related to ensuring compliance with internal market legislation. A small firm indicated investments for product design of €200-300k. Gardening equipment was the category with the highest percentage spent on compliance (3.9% of annual turnover), e.g. compared to air conditioners at 1%.

Through our surveys, industry was also asked to estimate the total staff time and other costs (€) that their organisation had incurred in the past year in relation to machinery-related inspections. Estimates ranged between one and five days of effort per inspection (3 on average) and other costs of up to €3,000 (average of €1,000). These companies also estimated that they were subject to 1.5 inspections every five years (equivalent to 0.3 times per year) on average. As such, we estimate an average yearly cost per business of 0.9 days of FTE effort and €300 in other costs.

[59] CSES for DG Enterprise, 2014

Summary

The following table summarises the various estimates arrived at above for annual average costs (FTE and other financial costs) from the Machinery Directive for individual actors in each main stakeholder group. The second table extrapolates to the wider sector, by multiplying by the number of actors in each group. Average wages in the EU (of €135.20 per day)[60] are used to monetise the FTE days.

This results in an annual cost from the Directive of 510,000 days (equating to €69m in staff costs), plus €68m in other financial costs. Total annual costs incurred across actors are therefore estimated to total €136m.

Table 63 Estimated total costs incurred by relevant actors each year, as a result of the MD

Actor	Number of actors	Total FTE days	Total cost of FTE days	Total other financial costs	Total costs
Market surveillance authority	28	5,040	€ 681,408	€1,680,000	€ 2,361,408
Implementing authority	28	4,592	€ 620,838	€460,012	€ 1,080,850
European Industry Association	50	9,750	€ 1,318,200	€4,070,700	€ 5,388,900
Industry	12,863	487,508	€ 65,911,082	€61,742,400	€ 127,653,482
Total for all actors		**510,246**	**€ 68,531,528**	**€67,953,112**	**€ 136,484,640**

Source: Technopolis

5.11 Evaluation Question 13: the benefits realised as a result of the Directive

13. What are the benefits (including costs saved) that have been realised by different stakeholders and actors as a result of the Machinery Directive?
    a. What are the different benefits that are realised as a result of the Machinery Directive, and to whom do they apply?
    b. What is the scale and range of benefits involved?

The typology of regulatory impacts presented at the start of the efficiency section suggests that the main categories of regulatory benefits will include direct benefits (in terms of improved well-being and market efficiency) and indirect benefits (from compliance; in terms of wider macroeconomic improvements; and in other non-monetisable areas). In line with this, the objectives of the Directive (as set out earlier in the intervention logic) suggest that the main benefits that should be triggered by the Directive relate to enhanced well-being (improvements to health, safety and the environment) and to an effectively / efficiently operating internal market and free movement for the products in scope.

The **direct benefits** of the Directive in terms of **improved well-being** have been assessed by the evaluation through exploring changes in the number of machinery-related accidents and injuries in Europe over time.

ESAW data (in Section 5.1.4) showed that between 2008 and 2013 there was a reduction in non-fatal accidents in EU workplaces of 735,861 (or 19%), and reduction in fatal accidents (causing more than three days of absence) in EU workplaces of 1,091 (or 23%).

It is difficult to determine the role of machinery within these overall estimates, let alone the impact of the Machinery Directive. However, it is clear from the data presented in that section that machinery-relevant sectors and occupations experience high numbers and rates of accidents compared to other sectors, and that it is therefore likely that machinery-related accidents represent a significant proportion of all accidents occurring in the workplace. For example, the Manufacturing, Construction

[60] Average EU hourly wage, plus non-wage labour costs and 25% overhead calculated to be €16.90. Commission figures, based on ESTAT: Structure of Earnings Survey. 8 hour working day assumed (€16.90 x 8 = €135.20).

and Agriculture, forestry and fishing sectors combined (those assumed to have high relevance to machinery use) accounted for 1,863 fatal and 1,185,736 non-fatal accidents in 2013 – equivalent to 51% and 38% (respectively) of accidents across all sectors in this year.

Machinery-related sectors (and occupations) have also tended to see greater reductions in accidents, compared with the all sector average. So, for the three sectors mentioned, between 2008 and 2013 the number of fatal accidents decreased by 823 (a reduction of 31%) and the number of non-fatal accidents declined by 508,044 (a reduction of 30%).

In the table below we have adjusted these figures for changes in employment in the three sectors (-1.2 million employees during the period)[61] in order to estimate the change in the number of accidents due to other factors (i.e. excluding changing employment levels). This results in an (adjusted) reduction of 767 in fatal accidents and a reduction of 472,718 non-fatal accidents during the period.

Table 64 Changes in number of accidents 2008-13, adjusted for changes in employment, 3 relevant sectors

Three machinery-relevant sectors	2008	2013	2008-2013 change	2008-2013 change (adjusted)	2008-2013 % change (adjusted)
Number of fatal accidents	2,686	1,863	-823	-767	-29%
Number of non-fatal accidents	1,693,780	1,185,736	-508,044	-472,718	-28%
Employees (estimated from incidence rates)	58.9	57.6	-1.2		

Source: ESAW. Manufacturing, Construction and Agriculture, forestry and fishing sectors combined.

Section 5.2.2 introduced available data on the costs of accidents and injuries in the workplace. This included recent (2014) work from the UK Health and Safety Executive (HSE), which estimated the financial and non-financial cost of a fatal injury at work to be €2m and the cost of a non-fatal injury to be around €1,000. Eurostat data on total labour costs[62] suggest that in 2013 UK costs were aligned with the EU28 average, and so we have not adjusted the HSE cost estimates for differential labour costs across Europe.

It should be noted that the non-fatal cost was calculated for absences of <7 days, while accident data (above) refers to non-fatal accidents involving more than three days of absence. The two are therefore not exactly aligned, and the non-fatal accident cost estimate taken from the HSE is likely to represent a lower-bound of true costs when applied to the non-fatal accident numbers from ESAW.

Combining these estimated financial and non-financial costs of injuries, with adjusted ESAW accident reduction data for 2008-2013 (for the three most machinery-relevant sectors), we can attempt to monetise the value (savings) from the reduction in fatal and non-fatal accidents during the period. As the following table lays out, total cost savings from a reduction in accidents in machinery-related sectors during the period are estimated be €2.01b (€1.53b for fatal and €0.47b for non-fatal accidents avoided) during the period. This is the equivalent to €401m in savings per year during the five-year period.

Table 65 Estimated cost of fatal and non-fatal accident reduction in machinery-related sectors, 2008-13

Type	Reduction in number of accidents 2008-13	Financial and non-financial cost per accident	Total cost saved from accident reductions
Fatal injuries	767	€ 2 million	€ 1,534,000,000
Non-fatal injuries	472,718	€ 1,000	€ 472,718,000
Total			**€ 2,006,718,000**

Source: Technopolis calculations based on ESAW data and HSE cost estimates.

[61] Adjusted change in Accidents 2008-13 = Accidents 2013 – [(Employees 2013 / Employees 2008) x Accidents 2008]

[62] Eurostat. Labour cost levels by NACE Rev. 2 activity [lc_lci_lev]

The direct benefits of the MD in terms of **market efficiency** need to be assessed by comparing the costs incurred under the Directive, with the likely costs that would be incurred without it (i.e. the cost savings triggered by the MD). Given the length of time that *a* Machinery Directive has been in place, it is difficult to make such a direct comparison, or expect others to do so, not least because the 28 national regimes would have evolved somewhat over the past 30 years, even if the Directive had not existed. However, we did ask businesses to assess the extent that the MD achieves more than would be achieved otherwise (i.e. in its absence) in terms of reducing costs. As can be seen below, nearly all businesses (92%) believed it had reduced costs, including 21% that believed it had to a large extent.

Table 66 Extent to which the Machinery Directive has added value in terms of reducing costs to industry

	Not at all	To a small extent	To a moderate extent	To a large extent	n
Reducing costs	8%	28%	43%	21%	72

Source: Machinery Directive Targeted Consultation. Excludes 'don't knows' and non-respondents.

Through follow-up interviews with businesses we tried to take this assessment further. Specifically, taking compliance with the Directive as a baseline, we asked companies to estimate the additional cost of complying with the regime in a second European market where the Directive did not apply. We then intended to multiply this additional cost by the number European markets that this company serves (or rather would serve under such conditions), in order to estimate the likely additional cost of complying with multiple European regimes, rather than just one.

However, most of the interviewees highlighted that because they meet the requirements of the European Directive (and associated European Harmonised Standards), often the additional costs of selling to other markets is minimal (i.e. meeting MD requirements serves as a good basis for meeting requirements elsewhere and demonstrating conformity to these). As such, there might be an additional 1-2% (of total cost) to meet slightly different health and safety requirements, and another 1-2% (of total costs) to undergo compliance to these requirements. Several interviewees mentioned that requirements and compliance processes in the US were very different from those in Europe, and that there was little comparability between the respective regulations or standards. In these cases, the additional costs were estimated as being between 5% and 10%. This is a clear indication of the additional effort and cost that would be involved if the MD were replaced with multiple national regimes – even if they were not as different as from Europe to the US.

We estimated above that EU industry currently incurs costs of around €128 million per year as a result of conformity assessment and inspection relating to the (single) European Directive. Even a 2% addition (for all businesses to operate in a second market) would add €2-3 million to overall costs, and it is likely that many businesses will be exporting to more than one (and perhaps many) EU country. As such, the true additional cost to the machinery sector in Europe of multiple conformity assessment and inspection regimes is more likely to be several times higher than this conservative €2-3m estimate. The implications (at least for some businesses) of additional requirements would be significant.

The **indirect benefits** in terms of the **wider macroeconomic benefits** of a single internal market for machinery have been assessed (Section 5.1) by examining data on the machinery sector over time, including production and employment statistics, and the volume / value of intra-EU trade (and its origin and destination), relying on pre-existing statistical data and studies. This analysis has shown:

- That despite a slight increase (+1%) in the number of businesses operating in the MME[63] sector in recent years (2013-2014), the general trend over the past decade has been downward. IN 2005 there were over 105,000 enterprises in the sector (EU27 only), which was 12,800 (+14%) more than in 2014 (EU28).
- That the total number of persons employed across the MME sector was ~2.9 million in 2013, and that this number had not changed significantly since the Directive was first applied (i.e. since

[63] Manufacture of machinery and equipment – NACE code C28

2009), when there were just 18,000 more people employed in the sector. There has however been a 7% decline in the number of persons employed in the sector between 2008 and 2009.

- That the MME sector has grown since its low point in 2009, when production value dropped to €499b (in 2014 prices) as a result of the financial and economic crisis. However, by 2014 MME production value (€601b) had still not returned to pre-crisis levels (€599b in 2014 prices).
- That the value of intra-EU exports of machinery (MMA[64]) was almost exactly the same in 2015 (€683b) as it was the year before the Directive applied (€685b in 2015 prices).

There also will be **other indirect benefits** triggered by the Directive which the evaluation has sought to identify and assess through consultation. Specifically, the targeted consultation asked industry and its representatives about some specific potential benefits of the Machinery Directive for business. Nearly all respondents agreed that the Directive brought strong benefits in all four areas suggested (see below), and in particular that having one standardisation procedure (instead of 28 individual standards) saved time and money for industry.

Table 67 Benefits of the Machinery Directive for industry

	Not at all	To a small extent	To a large extent	n
The CE mark is a recognised quality certificate also outside of the EU	6%	21%	73%	33
One standardisation procedure instead of 28 individual standards saves time and money	0%	6%	94%	35
The existence of European Harmonised Standards saves time in finding appropriate technical specifications	0%	13%	88%	32
Self-certification cuts certification costs significantly	0%	16%	84%	32

Source: Machinery Directive Targeted Consultation. Excludes 'don't knows' and non-respondents.

Several respondents provided further comments on **self-certification**. Many considered this important for cutting costs. One respondent stated that "self-certification is a must for small volume production and one-off products. In these cases, third-party certification would not work." However, one respondent pointed out that "if self-certification is done correctly, it is not that much cheaper for companies who do not have ready access to the expertise needed. But I think in many cases, it is not done fully and so would save costs. For larger companies who do have in-house expertise then it is a big saving." Others respondents were generally more critical of self-certification, with views including that "self-certification reduces costs but allows impunity to bring non-compliant machines to market."

With reference to the **CE Mark**, respondents commented that "CE marking is accepted as a reputable mark in Africa, Russia, Middle East, and other non-EU countries", and that "the CE marking is a welcome and accepted symbol in the world." One respondent remarked that "customers from non-EEA countries often demand CE marking. It brings a competitive advantage." However, another respondent flagged issues for international trade: "The CE Mark is not a quality mark or a Safety Mark, so to enter international markets, re-certification to different schemes may be required (such as IECEx, GOST). If CE marking were related to ISO standards and returned to a quality Safety Mark, maybe other nations would accept them instead of requiring re-certification. This would help in removing trade barriers and reduce costs." The issue of incorrect application of CE marks was raised, e.g. "even at international major trade fairs, conveyors and hoists are issued without CE-compliant safety devices but with CE marks."

Regarding **harmonised standards**, one respondent commented that "by applying the harmonised European standards, conformity can be systematically developed 'into' the product", rather than leaving assessment to the end of the process. If conformity is only assessed at the end, considerable costs for necessary changes are incurred. Another explained that "the availability of harmonised standards greatly facilitates work for economic operators as they can refer to the standard rather than having to assess the compliance of their product with the essential safety requirements without the guidance of harmonised standards."

[64] Machinery and mechanical appliances – Combined Nomenclature Section 16

5.12 Evaluation Question 14: the extent to which costs are reasonable and proportionate

14. To what extent are costs reasonable, affordable and proportionate to the benefits achieved (for different stakeholders and actors)?

The consultation asked all stakeholders about their views on the impact of the Machinery Directive on the costs and burdens placed on business, users/consumers and authorities. As shown in the table below, the majority of respondents felt that there had been an increase in the costs and burdens on each group as a result of the Directive – though these were generally not felt to be substantial.

Table 68 Impact of the Machinery Directive on costs and burdens

	Substantial decrease	Some decrease	No change	Some increase	Substantial increase	n
The costs and burdens on businesses	3%	4%	10%	54%	29%	235
The prices for users (workers/consumers)	2%	5%	22%	57%	14%	221
The costs and burdens on authorities	6%	4%	35%	40%	14%	119

Source: Machinery Directive Public Consultation. Excludes 'don't knows' and non-respondents.

As part of the targeted consultation, stakeholders were asked to weigh the costs and benefits of the Machinery Directive for industry. Both industry itself and its representatives on balance held positive views, with a majority of both groups claiming that the benefits to industry outweighed the costs. The associations had a slightly more positive opinion overall than industry itself, in that a quarter of the respondents believed that benefits significantly outweighed costs.

Table 69 How do the costs and benefits of the Machinery Directive for industry compare

	Costs significantly outweigh benefits	Costs slightly outweigh benefits	Benefits and costs are equal	Benefits slightly outweigh costs	Benefits significantly outweigh costs	n
Industry view	0%	27%	18%	45%	9%	11
Industry association view	0%	17%	17%	42%	25%	12

Source: Machinery Directive Targeted Consultation. Excludes 'don't knows' and non-respondents.

Authorities were also asked to assess the costs and benefits for them. All reported that benefits outweighed the costs (57% stated that benefits outweighed costs significantly) or that they were broadly equal.

Each stakeholder group was also asked to assess more generally how the various costs triggered by the Directive compared to the benefits that it brought (for the internal market, for health and safety and in other areas). Across all groups, the balance of opinion was significantly positive. Overall, two thirds of respondents (69%) believed that the benefits outweighed the costs either slightly or significantly, while only 18% believed that costs outweighed benefits. The response from industry was the most mixed, and indeed this was the only group where the same proportion of respondents thought the benefits outweighed the costs compared to the costs outweighing the benefits.

Table 70 How do the costs and benefits of the Machinery Directive compare overall

	Costs significantly outweigh benefits	Costs slightly outweigh benefits	Benefits and costs are equal	Benefits slightly outweigh costs	Benefits significantly outweigh costs	n
National authority view	0%	13%	0%	25%	63%	8
Notified Body view	0%	0%	20%	40%	40%	5
Industry association view	0%	10%	10%	40%	40%	10
Industry view	0%	40%	20%	30%	10%	10
View across all groups	0%	18%	12%	33%	36%	33

Source: Machinery Directive Targeted Consultation. Excludes 'don't knows' and non-respondents.

In their comments, stakeholders from industry justified their negative assessment because of the scale of costs and efforts companies incur in complying with the Directive which then get passed on to customers. One gave the example that 10-20% of their R&D project budget was related to compliance topics. What can make this worse is decreased competitiveness due to insufficient surveillance and enforcement to prevent other manufacturers (often from outside the EU) from placing cheaper non-compliant products on the market.

Some respondents had a more positive view, mentioning lower costs of compliance with the MD compared to national regulations, increased competitiveness due to high acceptance of EU regulations and standards outside Europe, and an appreciation of the MD's creation of a common approach to safe design of products and free movement of products on the EU market. For example, one respondent pointed out that "The CE marking is recognised in international trade. Customers in the USA and also China would like machines with CE marking. Thus, by slightly increasing costs, the balance of machinery sales has also been offset by the recognition of the CE marking on the international market." Another respondent saw clear impact on the safety of machinery available: "Over the past 20 years, I have seen a massive improvement in the safety of machinery and I think this is at least in part due to the EU New Approach Directives as I see machinery not subject to this (for example agricultural and construction machinery from outside the EU) not having the safety features such as better vision, access and guarding."

We have not identified any other sources that address the questions of affordability or proportionality of the costs given the benefits, at least none that specifically relate to the Machinery Directive. However, the internal market study[65], which looked more generally at internal market legislation, did conclude that the administrative burdens of compliance with EU harmonisation legislation were sometimes seen as disproportionate for micro enterprises. It gave the example of manufacturers that wished only to place their product on the domestic market, but who must still comply with internal market legislation if their product falls within the harmonised sectors. The report also discussed how some SMEs could not afford to set up internal testing facilities (especially where production volumes are small), and often have no choice but to use external laboratories.

5.13 Evaluation Questions 15 & 16: potential for simplification and reduced inefficiency

15. Is there a need and what is the potential to reduce inefficiencies, burdens and costs, or to simplify the intervention?

16. What good and bad practice can be identified, in terms of increasing efficiency and minimising costs, when applying the Directive (including in the identification and removal of non-compliant products, and in the cost of controls for authorities and companies)?

[65] Evaluation of the Internal Market Legislation for Industrial Products, CSES, 2014

Evaluation Questions 15 and 16 require the study to assess whether there is the potential to simplify the Directive and its application and / or reduce inefficiencies, burdens and costs.

5.13.1 Areas where costs are disproportionate

Most respondents to the consultations highlighted disproportionate costs arising from time and resources spent on documentation. In particular, the need to translate documentation into the language of the destination country was seen as an undue burden by a number of respondents. One respondent suggested "some more flexibility for the requirements for language (of instructions) be added. For example, professional users often require instructions in a language which is different from the language(s) determined by the Member State concerned. It would be possible to reduce the unnecessary burden of translation if the intended could agree to machine instructions in English, or another language, by means of a contract." The obligation to provide the declaration of conformity and the operating instructions in paper form with the product was also seen as a disproportionate cost, as were the requirements for documentation of maintenance and spare parts for unique specialised machinery. Fifteen respondents suggested that the burden could be reduced by allowing documentation in electronic format, with a paper copy to be sent upon request. Other areas of disproportionate cost highlighted included:

- Testing of products / quality assurance systems by third parties (6 respondents)
- Finding and purchase of relevant standards (6 respondents), especially for SMEs
- Risk assessment procedure (5 respondents)

Costs were seen to be particularly/disproportionately high for:

- Small businesses (4 respondents)
- Low volume production (3 respondents). One respondent commented that "the requirements are on the same level for every machine, if small series or large series production. It is obvious that the cost/effort for machines in low-volume production is high, since all regulations have to be equally fulfilled." This includes documentation: "For the production of the documentation (especially for risk assessment) for a smaller plant / machine which is built only once, the cost share is very high." Another remarked that "the type-examination for a single product does not make sense economically so either it is not carried out, or the product will not be produced at all. There should be a simpler/cheaper alternative."
- Machines built for internal use, for which it was suggested that "it should be possible to confirm conformity without driving the extensive documentation effort."

Three respondents referred to a specific example of cost: the "overload tests" for lifting machinery according to EHSR 4.1.3 MD which requires each hoisting machine to be tested, even if manufactured in series. This was considered to generate disproportionate costs without additional improvement to the safety of the product. Two respondents pointed to high costs of noise measurement, e.g. "Even if a loud machine or process is known, it has to be measured quite exactly to know that you have to wear ear protection anyway."

5.13.2 Areas where the Directive's burden on organisations could be reduced

The issue of "sprawling operating instructions overfilled with safety instructions" was repeatedly highlighted as an area of excessive burden on businesses. One respondent explained: "Due to the protection against legal issues, the quality of the documentation has declined considerably in recent years, which is no longer legible. Product [manuals] have now exceeded 1,000 pages due to warnings and the like." Several respondents were of the opinion that "user documentation in all member languages is too costly." Another set out a list of shortcomings: "The documentation tends to be unintelligible because it is too often written in "conformity checkbox" style rather than as clear instructions of what to do. Examples include:

- Massive fold-out sheet with instructions in all EU languages - yours are somewhere and written very tiny, often abridged to fit.
- Manuals where the first 10 pages are just a list of warnings, many of which are irrelevant - as a result, they do not get read by most users. The later instructions do not explain the risks for each step so you have to find them in the 10 pages of warnings at the front.
- The tendency to use pictograms not words to avoid translation - often completely meaningless.

A lot of this is driven by over-specification of requirements for warnings both in Directives and in Harmonised Standards."

Several respondents pointed to options for reducing the burden of certification of Annex IV machines. One respondent felt that "Annex I and (harmonised) standards may also provide a sufficient level of protection for machines listed in Annex IV. The high costs involved in the procedure set out in Annex IV are not (always) justified." Another mentioned that "there are plenty of high risk categories of machinery which are not in Annex IV. The Annex IV list could be abandoned, but with the option of a notified body opinion on conformity, similar to the provision in Electromagnetic Compatibility Directive."

High costs are a particular problem for SMEs, and may limit the development of new products. As one respondent noted: "The costs for an EC-type examination or comprehensive quality assurance are too high for SMEs in special-purpose machine construction. This precludes the manufacture of Annex IV machines if there are no harmonised C standards available, even though the residual risk would be acceptable. It would be useful to restrict Annex IV to consumer products."

Two respondents highlighted the requirement to include the product serial number in the declaration of conformity as a high burden, even if the machinery is produced at a relatively high volume per year. This was considered a significant administrative cost with little apparent benefit for most machines.

Another respondent described the identification of suitable standards as "complex and expensive, since there are hardly any ways to look into a standard without procuring it, which is at a relatively high cost." A simplified, improved search option for relevant standards was suggested.

5.13.3 Areas for improvement

The public consultation asked stakeholders what areas a **future revision** of the Directive should aim to address (and why). Over 150 comments were received, covering the following areas / issues:

- Adapting the Directive to fit / integrate with the New Legislative Framework - Since the Machinery Directive was not drafted under the NLF, it should now be adapted to the framework, which will help to increase the quality of machinery and the confidence in products in the European market, as well as ensure good levels of safety and create a common framework for market surveillance
- Adapting the Directive to ensure suitability for new developments – e.g. in relation to "quasi-machines", Industry 4.0, digitisation, increased use of ICT, robotics and Internet of Things, as well as cyber security and the risk of hacking in relation to product safety
- Simplification of risk assessment process – to make it less subjective and generally easier
- Various improvements to the definitions of, and demarcations between, particular types of machinery – e.g. interlinked machines / set of machines, sports equipment, process plants
- Improved convergence / harmonisation with other similar legislation – e.g. Low Voltage, Medical Devices, Pressure Equipment, Lifts and ATEX Directives, for example using the same definitions where possible
- Ensuring compliance to the Directive – through increased / improved inspection

Findings in relation to the Coherence of the Directive

This criterion concerns how the intervention works with other interventions and actions, both inside and outside the EU. This includes analysis of where and how interventions work well together (i.e. are complementary) and identifies where there are tensions (i.e. overlaps, contradictions, inefficiencies).

5.14 Evaluation Question 17: coherence and complementarity of the Directive

17. To what extent is the Machinery Directive coherent with and / or complementary to other community, national or international legislation – are there overlaps, complementarities, contradictions or conflicting requirements?
    a. To what extent are there issues of coherence or overlap?
    b. What are the implications of this (e.g. for administrative burden)?

Evaluation Question 17 concerns the 'fit' of the Machinery Directive with other legislation, and whether there is evidence of incoherence, overlaps or inconsistencies (or indeed whether there are complementarities).

At the **European level**, the original proposal for the 2006 Directive (COM/2000/899/FINAL) stated that there did not appear to be any inconsistency between the Directive and other Community policies. In addition, one intention of the 2006 revision to the Directive was that the borderline between the scope of the Machinery Directive and other Directives, in particular the Low Voltage (73/23/EEC) and Lifts Directives (95/16/EC), 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 Machinery Directive. For example, the Low Voltage Directive, the Medical Device Directive, the Tractor Regulation, the General Product Safety Directive, the Directive on use of work equipment, etc. cover products that are similar to those in the Machinery Directive.

At the **national level**, the Technical Regulation Information System (TRIS)[66] enables Member States to notify of their legislative projects regarding products and Information Society services, allowing others to issue their opinions on the notified draft. It was thought that exploration of this database could provide evidence of Member States introducing specific national laws relating to Machinery that go beyond the Directive, and which may imply additional burdens on firms. The study team have searched the database for legislation mentioning the term 'machinery' during the period since June 2008 (i.e. since the deadline for transposition of the Machinery Directive). In total 155 items were found, which were then interrogated further. Specifically, we coded each piece of legislation as to whether it (i) set out health and safety requirements for products, *and* (ii) included machinery within its scope. Both criteria appear to be true for 73 pieces of draft legislation identified through the database. These include, most commonly, legislation relating to lifts (n=17), marine vehicles (13), agricultural machinery (7) and other vehicles (12), but also machinery related to construction, dry-cleaning, fairgrounds, fire-fighting, wind-power generation, and other areas.

The targeted consultation asked stakeholders about the extent to which the Machinery Directive fitted with other national, EU or international legislation. A majority reported that the Directive was both coherent and complementary to both national and other EU legislation to a large extent. By comparison, the fit with other international legislation was generally considered 'moderate'.

Table 71 Extent to which the Machinery Directive fits with other legislation

	Not at all	To a small extent	To a moderate extent	To a large extent	n
With national legislation	0%	1%	22%	77%	79
With other EU legislation	0%	5%	34%	61%	79
With international (non-EU) legislation	2%	20%	72%	6%	64

Source: Machinery Directive Targeted Consultation. Excludes 'don't knows' and non-respondents.

[66] http://ec.europa.eu/growth/tools-databases/tris/en/

The consultation asked more specifically what kinds of overlaps or inconsistencies with other EU legislation may exist. The main issue (reported by 51%) was that the same product is regulated by two or more directives (causing additional burden). Smaller numbers pointed to issues with different definitions causing divergent interpretations (31%), the potential for regulatory arbitrage (i.e. choosing less stringent rules) (22%) and the potential for multiple inspection for the same / similar issues (17%).

Table 72 gives on overview of the directives and regulations most mentioned by respondents as having overlaps or inconsistencies with the Machinery Directive. In total, 99 respondents mentioned specific directives and/or regulations, with 70 respondents mentioning more than one directive or regulation.

The two pieces of legislation most often cited as overlapping and/or having inconsistencies with the Machinery Directive are the Low Voltage Directive (LVD) 2014/35/EU and the Electromagnetic Compatibility Directive (EMC) 2014/30/EU. These were considered to be closely linked to the Machinery Directive by respectively 35% (35) and 30% (30) of the respondents. The two directives which were mentioned by 22% (22) of the respondents each are the Pressure Equipment Directive (PED) 2014/68/EU and the Radio Equipment Directive (RED) 2014/53/EU, making them the third and fourth most mentioned. The Outdoor Noise Directive (OND) 2000/14/EC and the Directive on equipment for use in explosive atmospheres (ATEX) 2014/34/EU are the fifth and sixth most mentioned, with 14% (14 respondents) mentioning each. Lastly, the Directive on the Restriction of Hazardous Substances (RoSH) 2011/65/EU was mentioned by 9% (9) of respondents, and the Waste Electrical and Electronic Equipment Directive (WEEE) 2012/19/EU was mentioned by 8% (8) of the respondents. All other directives and regulations were mentioned by less than 8% (8) of respondents.

Table 72 Overlaps or inconsistencies with other EU legislation

Directive / Regulation which is seen to overlap with the Machinery Directive	**%[67] of respondents who gave answer (Total)**
Low Voltage Directive (LVD) 2014/35/EU	35% (35)
Electromagnetic Compatibility Directive (EMC) (EMV) 2014/30/EU	30% (30)
Pressure Equipment Directive (PED) 2014/68/EU	22% (22)
Radio Equipment Directive (RED) 2014/53/EU	22% (22)
Outdoor Noise Directive (OND) 2000/14/EC	14% (14)
Directive on equipment for use in explosive atmospheres (ATEX) 2014/34/EU	14% (14)
Restriction of Hazardous Substances (RoSH) 2011/65/EU	9% (9)
Waste Electrical and Electronic Equipment Directive (WEEE) 2012/19/EU	8% (8)
Medical Devices Directive [93/42/EC] IVD Directive	6 1
Minimum safety and health requirements for the use of work equipment Occupational Health & Safety Directives Personal protective equipment. Directive 89/686/EEC	4 3 1
Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	3
Lifts Directive Elevator guidelines	3 1
Construction Product Directive (CPD) / CPR	3
Other European Directives / Regulations: Eco Design; Agricultural machinery; Combustion engines emissions [Regulation (EU) 2016/1628]; General Product Safety (GPSD) [2001/95/EC]; Roadworthiness tests [Directive 2014/45/EU]; Gas Appliances Regulation (GAR) [2016/426]; F-Gas Regulation; Regulation on materials and articles intended to come into contact with food - provisions on food contact materials [No 1935/2004]; Tractor Directive; Toy Directive	Mentioned by just 1 respondent in each case.

Source: Machinery Directive Public Consultation. Excludes 'don't knows' and non-respondents.

[67] As noted above, 70% of respondents mentioned more than one directive or regulation, therefore the percentages do not add up to 100%.

Unfortunately, most respondents did not take up the opportunity to explain more specifically the nature of the overlaps or inconsistencies were between the MD and the other legislation that they had indicated. Several comments were provided in relation to overlaps with the LVD (which was the most frequently cited Directive), which went a little beyond just naming the Directive. These are listed (verbatim) below.

- *There is an overlap between the MD and LVD that is still very much misunderstood, with several phrases ("office equipment", "domestic appliance") not defined.*
- *Confusing jurisdictional disputes by the applicability of several directives, in particular on the declaration of conformity. Is the Low Voltage Directive or the Machinery Directive or both? What has priority?*
- *A lot of the ESHR's are the same across the Directives. So Risk Assessments and compliance requirements are repeated. It would be easier if Product Design directives were laid out in a similar way to the EMC Directive so that Industrial and commercial equipment is separated. In that way the Machinery Directive 2006/42/EC could cover other directives and then transpose any applicable harmonised standards across. Then Notified Bodies could assess under 1 directive, for either Commercial or industrial use and certification could be improved, reduced or simplified, rather than several different Notified Bodies looking at the same product.*
- *The Machinery Directive is less stringent when the machine can be used by non-professional end users in the domestic (or Household) insufficient risk analysis. The Low Voltage Directive with its harmonized standards and more rigorous and precise for domestic appliance applications (Household). Reducing the application of the Low Voltage Directive to "housekeeping" for certain appliances that may fall within the definition of the Machinery Directive is a challenge. Devices used in "housekeeping" are identical to a use outside the dwelling (household) with identical risks. The Machinery Directive should be reserved for machines intended for professional users and in the field of industry or collective applications ("commercial").*
- *Question how to differentiate between Machinery and Low Voltage Directive. Electric motors are quite often an issue. Still there are products certified to both directives, which should not be at all.*
- *Where several directives (e.g. MD including LVD) are applicable to the same product there is potential for multiple inspections by different market surveillance authorities.*
- *Simultaneous application of MD and the other directives needs good and unambiguous demarcation. Today this is not the case with the LVD and MD. This leads to lack of legal certainty and increasing cost of additional conformity assessment procedures. Also, the structure of MS authorities in MS is different. Products are checked by different authorities for different directives in a different way in every country.*
- *The biggest problem is definitions that are very different from normal usage; between LVD and MD where the product is in the grey area between them; and poor coordination of MSA addressing the same product at different times.*
- *Unclear definitions / exceptions result in unclear areas of application. The interfaces between policies are unclear. This relates to e.g. The interface to the LVD (see "household appliances", "ordinary office machines").*

Findings in relation to the European Added Value of the Directive

This criterion concerns the value resulting from an EU intervention that is *additional* to the value that would have resulted from interventions initiated at regional or national levels (i.e. in the absence of the EU intervention).

5.15 Evaluation Question 18: added value of a European directive

18. What is the added value (to stakeholders) of the Machinery Directive (and total harmonisation), compared to what could have been achieved by Member States at national level?

In line with the New Approach, the Directive only provides a framework, and establishes the mandatory essential health and safety requirements. It does not translate this into detailed requirements or processes. As such, the impact of the Directive is more directly a result of 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. These are not the specific subject of the evaluation, but are enabling activities that are in some way directed, encouraged or created by the Directive (and are therefore also addressed within the evaluation questions). These systems of standardisation, conformity assessment and market surveillance would, however, be likely to exist in some form regardless of the existence of the Directive. There are also issues in trying to disentangle the implications of the Machinery Directive from those incurred as a result of other pieces of legislation, or that would be incurred in any case without the Directive. There may also be other significant factors, such as economic downturn that have an impact (e.g. these seem to have had implications for the number of inspections).

Nevertheless, we asked stakeholders through the targeted consultation about the extent to which the Machinery Directive achieves more in relation to its objectives than would be achieved otherwise (i.e. in its absence). All respondents agreed that it added value in terms of facilitating the internal market and ensuring the health and safety requirements of machinery, and a majority reported that it did so to a large extent. Respondents were only slightly less positive about the added value of the Directive in ensuring environmental protection in relation to pesticide applications.

Table 73 Extent to which the Machinery Directive has added value in the achievement of objectives

	Not at all	To a small extent	To a moderate extent	To a large extent	n
Facilitating the free circulation of machinery within the internal market	0%	4%	14%	83%	80
Ensuring a high degree of health and safety of machinery	0%	1%	20%	79%	80
Ensuring environmental protection in relation to machinery used in pesticide applications	6%	14%	53%	28%	36

Source: Machinery Directive Targeted Consultation. Excludes 'don't knows' and non-respondents.

In addition, 92% of respondents believed that the Directive reduced costs overall, compared to what might be the case otherwise (e.g. with national legislation in place instead). The internal market study[68] also suggested that the cost of complying with EU legislation (for internal market legislation more generally) is likely to be much less than the cost of complying with the requirements of 28 different national legislative regimes. It also noted that in some cases, this might be of disproportionate benefit to SMEs compared to large enterprises (which might be better-placed to meet different national requirements).

[68] Evaluation of the Internal Market Legislation for Industrial Products, CSES, 2014

6 Conclusions

In this section we draw on the analysis presented in the main body of the report to present conclusions in relation to each of the questions posed for the evaluation. The section is organised by the main evaluation criteria (relevance, effectiveness, etc.) and then by the relevant evaluation questions posed under each.

6.1 Context of the Directive

The study was asked to assess **the size and structure of the machinery sector and market, as well as the extent, type and distribution of machinery-related health and safety incidents (EQ1)**, so as to provide context for the remainder of the study. Our analysis draws on various statistics and stakeholder views in order to examine four main aspects: producers and production; consumption and trade; machinery-related accidents and injuries (A&I); and innovations.

This analysis highlights the ongoing importance of the machinery sector within the EU. For instance, total EU28 production of the manufacture of machinery and equipment (MME) sector[69] was valued at €599b in 2014 (9.4% of the total for the wider EU manufacturing industry) and the sector has grown steadily since its low point in 2009 (during the economic crisis). However, production value had still not returned to pre-crisis (2008) levels by 2014 in real terms. Across various indicators (output, value added, exports) the EU sector compares favourably with key competitor economies (USA, Japan and China). Supporting this view, twice as many respondents to our consultation believed that the competitiveness of the European sector had increased, compared with those that felt it had worsened.

There were 92,863 enterprises in the EU28 operating in the MME sector in 2014, with concentrations in certain Member States (Italy, Germany and the UK in particular – which together account for more than half of these businesses). Key sub-sectors include lifting and handling equipment; non-domestic cooling and ventilation equipment; agricultural and forestry machinery; machinery for food, beverage and tobacco processing; and other general or special-purpose machinery. Nearly two-thirds (64%) of enterprises in the sector are micro-businesses, while just 2% (1,870) are large companies. Yet despite the predominance of small firms, the sector employs some three million people in total (~10% of all EU28 manufacturing employment).

The sector is highly R&D intensive compared with other areas of manufacturing or the economy more generally, and in 2013 €13.1b was spent on R&D by EU MME businesses on R&D (having increased by around 11% in real terms in just three years). Indeed, the overriding view from stakeholders consulted was that the rate and extent of innovation in the sector had increased over the past decade – partly driven by the integration of ICT into manufacturing processes, products, value chains and service offerings.

The machinery sector is one of the prime suppliers of capital goods to a wide variety of sectors – particularly the manufacturing sector itself - and the value of EU machinery trade is significant. Around one-quarter of the total value of exports from EU28 Member States (€1,139b of €4,862b in 2015) is accounted for by the Machinery and Mechanical Appliances (MMA) sector[70]. Much of this trade (60% of total value) is between Member States (i.e. intra-EU), but the value of exports to third countries (especially the US, China and Russia) is also substantial (€465b in 2015). The value of total EU exports of Machinery has also now recovered above pre-economic crisis levels.

The proportion of machinery imports to Member States coming from within the EU (61% of value) is similar to exports – though much of the remainder originates from just one country (China). The biggest importers of machinery (Germany, the UK, France and the Netherlands) all import at least one-third from third countries. Germany, the Netherlands and the UK together account for nearly one-quarter of the value of all non-EU imports of machinery to the EU28. Indeed, the Netherlands

[69] NACE Rev. 2 sector C28 – Manufacture of Machinery and Equipment

[70] Combined Nomenclature Section 16 – Machinery and Mechanical Appliances

actually imports more than twice as much machinery (in terms of value) from non-EU sources than it does from EU sources (whereas the average EU28 country imports just one-third from outside the EU). The Netherlands is therefore a particularly important point of entry to the Single Market.

Public data sources on accidents and injuries (A&I) are not sufficiently detailed to allow a robust analysis of A&I caused by individual product groups. However, we have analysed aggregated data to identify (potential) machinery-related occurrences and provide evidence on general trends over time.

For instance, data is available on accidents per 100,000 individuals employed per sector, which shows that among sectors most relevant to the use of machinery, incidence rates are well above the average for all sectors. Within the Manufacturing, Construction, and Agriculture, Forestry and Fishing sectors (combined), the number of fatal accidents across the EU28 in 2013 was 1,863, while non-fatal accidents (resulting in more than three days of absence from work) totaled nearly 1.2 million.

However, there has been a significant decrease in the number of fatal and non-fatal accidents at work over the past decade – both overall and in relation to sectors and occupations of particular relevance to machinery (e.g. plant machine operators and assemblers, where the number of accidents dropped by 46% between 2008 and 2013). This finding is supported by stakeholder opinion, with a majority reporting increased levels of safety and protection for users and increased user confidence in machinery safety, as well as a reduction in the number and severity of machinery-related A&I over the past decade.

6.2 Relevance of the Directive

The study was asked to assess **the extent to which the original objectives of the MD are still relevant (EQ2)** to the needs of the machinery market (manufacturers and users). The starting point for addressing this question was therefore understanding the original rationale and aims of the Directive.

The original 1987 proposal for a Machinery Directive explained that the machinery sector was an important component of the EU economy, but that a lack of harmonisation in safety legislation and certification created barriers to trade. One of the two main objectives of the Directive is therefore to facilitate the functioning of the internal market and ensure the free movement of machinery.

Despite recent reductions in the number of MME enterprises, the machinery sector continues to be an important part of the EU economy 30 years after the adoption of the original Directive. It now accounts for 4% of all manufacturing businesses, 9% of all manufacturing production (value) and 10% of all persons employed in the manufacturing sector. Its importance in terms of trade is also significant. Nearly one-quarter (23%) of the value of all exports of EU MS in 2015 was accounted for by machinery and equipment, with significant levels of both intra (€683b) and extra-EU (€456b) export trade. Trade is certainly concentrated between particular Member States – but this partly reflects differences in the sizes of economies – and in fact there is some level of intra-EU trade in machinery between nearly every EU country and every other one. Facilitating the functioning of the internal market and ensuring the free movement of machinery is therefore of EU-wide concern.

The great majority of stakeholders consulted for the study believe that ensuring free movement of machinery is a very important objective, providing a strong indication that this is of high relevance to the needs and concerns of EU stakeholders, with widespread support and relevance, both to the machinery market and amongst users. Also important in assessing relevance, is the fact that stakeholders were consulted on the *appropriateness* of the Machinery Directive itself (its scope and provisions) as a means to contribute towards the fulfilment of the objective of ensuring free movement of machinery. Again, responses were strongly positive, with the vast majority of stakeholders stating that the Directive (at least its concept and intentions) was an 'entirely appropriate' response to this aim.

The original proposal for the MD also explained that Member States have a responsibility to ensure the health and safety of machinery users, and that accidents from machinery have a social cost that could

be reduced through safer design, construction, installation and maintenance. The other main objective of the MD is therefore to ensure a high level of health and safety protection for machinery users.

Despite a downward trend in the number of accidents at work between 2008 and 2013, there were still over 3 million non-fatal accidents and around 3,700 fatal accidents in EU workplaces in 2013 (all sectors). This implies that *on average* most people will have an accident at work during their lifetime that will cause more than 3 days of absence or death, making this a significant and widespread issue.

Sectors and occupations that are most relevant to machinery tend to have higher rates of accidents. For instance, the incidence rate in manufacturing in 2013 (2.0 non-fatal accidents per 100 employees) and construction (2.8 non-fatal accidents per 100 employees) were both well above the all sector average (1.5). Certain sub-sectors experience even higher rates (e.g. the number of accidents for plant machine operators and assemblers accounted for 14% of accidents across all occupations in 2013).

It is also well documented that there are significant financial and other (social) costs of accidents and injuries in the workplace (productivity loss, healthcare, reduced quality of life, administration, etc.) which have been calculated as equating to some 1-5% of GDP (overall, not just from machinery). A recent UK study put the total financial and non-financial cost of a fatal injury at nearly €2m.

These various statistics confirm that machinery can and does threaten health and safety, and that accidents and injuries, at work and in the home, have significant economic and social costs.

Nearly all stakeholders consulted through the study placed great importance on ensuring a high level of health and safety for users of machinery, providing a strong indication that this objective is of high relevance to the needs and concerns of EU stakeholders, both in the machinery market and amongst users and other interested bodies. The vast majority also stated that the Directive was 'entirely appropriate' as a response to this aim.

The study was also asked to assess **the relationship between the MD and innovation (EQ3)**, including the ability of the Directive to accommodate changes in the business and technological environment, as well as its influence on technological innovation (i.e. as an enabler or barrier).

The MD has undergone several iterations since the adoption of its original version in 1989, each time adding or revising certain elements, including changes to the scope or requirements. However, our review suggests that none of these changes came about as a reaction to shifts in technology or the market – but rather to improve clarity, to change the coverage of pre-existing machinery (and address any associated risks), or to reflect changes in the perceived relevance / importance of certain aspects of health and safety (ergonomics, operating positions). This apparent lack of adjustment to reflect changes in technology or the business environment is unsurprising. The New Approach is intended to stand the test of time, with the MD limited to essential requirements ("principles"), with the state of technology (state of the art) left to be determined by stakeholders through technical specifications.

As to whether this works in practice (i.e. whether the EHSR in the Directive are appropriate and sufficient when applied to new technologies), there are strong indications that it does. Other studies have found the MD to be "appreciated by industry", with "sufficient leeway given for the design of innovative products", while respondents to our targeted consultations were also generally positive. For instance, a majority reported that the Directive largely or entirely took account of innovation at the time of its introduction, has been able to deal with innovations since, and is likely to be able to deal with innovations emerging over the coming decade. A similar response was given in relation to changes in the business environment. Any shift in views across the time periods is relatively minor, suggesting that the Directive is generally seen as being able to "cope" with changing technology over a very long time period (some 20+ years are considered in questions that were put to stakeholders).

However, whilst the majority view was that the MD is adequate to cope with change, a significant minority of the individuals consulted did point to specific new products, innovations or requirements that they felt might not be well addressed by the Directive currently. Most pointed to innovations in

the areas of digitisation, robotics, software and autonomous / remote control, or to the increasing prevalence of e-trade, fulfilment houses and (un-checked) non-compliance (from non-EU origins).

Most stakeholders believe the rate and extent of innovation in the machinery sector has increased over the past decade. However, when asked whether a link could be made between the MD (specifically) and any increase in innovation, views were mixed. Indeed, the available evidence suggests that the Directive is acting both as an enabler and as a barrier to innovation, and that the experience and the perception of the balance between these different influences vary between stakeholders.

The MD will have had some positive influence on innovation through facilitating trade (allowing easier access to a larger market), by encouraging standardisation (encouraging technology transfer), and through the encouragement of new innovative safety features (or indeed detection/measurement tools and techniques). At the same time, it will have had a negative influence by adding to the cost or complexity of introducing new technology (through the need to demonstrate compliance), particularly given the (inevitable) lack of precedent in ensuring/demonstrating compliance in 'innovative' cases.

6.3 Effectiveness of the Directive

The first effectiveness question concerns the implementation of the Directive, and specifically **the extent to which requirements have been interpreted and implemented differently across Member States (EQ4)**. This was explored by examining infringement procedures initiated against Member States and by consulting stakeholders as to their views on problematic areas and issues.

The Commission has a clear role in monitoring and enforcing the proper transposition of Directives and when Member States fail to notify the Commission of national transposition measures (incorporating the obligations of the Directive into domestic law), or where the Commission finds that the national measures are incomplete, it opens an infringement procedure for 'non-communication'. Twelve such cases were opened against Member States following the initial deadline for transposition of the MD, but these had all been resolved and closed by the end of 2010. Further infringement procedures can also be instigated after the initial transposition period and we are aware of 15 such cases being opened in relation to the MD. However, all were resolved at the first stage (letter of formal notice), suggesting that these infringements were either found to be invalid, or were subsequently rectified.

The study also asked stakeholders more specifically whether a range of implementation actions and procedures had been fully and consistently applied across Europe, which revealed considerable variability between the experiences and views of individual stakeholders (i.e. on any given aspect, some rated consistency very poorly, while others rated it very highly). However, there were clearly certain aspects of the "system" that were generally considered to be largely consistent across Europe (the initial transposition into law, the appointment of Notified Bodies, the conformity assessment options available, and the fulfilment of requirements not to impede the movement of compliant machinery). At the same time, there were other areas that most stakeholders believed had not been applied fully or consistently, including the number of market surveillance activities, the approach taken during market surveillance to determining compliance, the measures taken to withdraw or prohibit machinery, and the establishment of effective, proportionate and dissuasive penalties for infringements. These areas all relate to the monitoring and enforcement of the MD, which is addressed specifically in EQ9 below.

The study was then asked to assess the **extent to which the Machinery Directive has contributed towards its overarching objectives (EQ5)** (introduced above) of facilitating the functioning of the internal market for machinery and ensuring a high level of safety of machinery.

The Directive seeks to contribute to an effectively operating internal market for machinery through the harmonisation of safety legislation and certification, where historically disparities between different Member States have constituted barriers to trade. A first key indicator of success is therefore the extent to which legislative harmonisation has been achieved. From the fact that all national

infringements have been found to be invalid or rectified, we infer that a basic level of harmonisation has been completed. Most stakeholders also confirm that the MD has been fully and consistently transposed and that conformity assessment procedures available are also consistent. There are, however, concerns amongst many about the consistency with which conformity assessment is then applied – both by Notified Bodies and (more so) by individual businesses through self-certification.

Another important indicator of success is the level (value/volume) of intra-EU trade in machinery. However, the picture here is a little unclear. While there has been a significant (27%) increase in the value of intra-EU exports in the six years (2009-2015) since the Directive was applied, the value of exports had also risen considerably over the seven-years from 2001-2008. There has therefore been an upward trend in intra-EU trade in machinery over a longer (10+ year) period, punctuated by a significant dip at the time of the economic crisis, and it is difficult to discern any impact of the 2006 Directive itself. This said, even if external shocks were removed, one would not necessarily expect to see any significant impact on trade from the application of the Directive at the end of 2009. Despite a number of significant changes in the 2006 revision, the Directive (in broadly the same form) had already been in force for two decades, and one might expect that much of the impact of harmonisation efforts, in terms of reduced barriers to trade, will have already taken effect. The 2006 Directive should instead be seen as *continuing* the process of facilitating the functioning of the internal market.

A majority of respondents to the study believed that the MD generally (not just the current revision) has had a positive impact on a range of areas relating to market efficiency and the effective operation of the internal market (the range of products available, turnover/profitability, competitiveness, volume and value of trade), and overall, three-quarters of stakeholders suggested that it had largely or entirely achieved its objective of ensuring an effectively operating internal market for the products in its scope.

The MD also seeks to protect the health and safety of consumers and users of machinery by requiring conformity to safety requirements and thereby encouraging inherently safe design and construction. Its contribution in this regard relies on a number of different processes and procedures (such as standardisation, conformity assessment, market surveillance and business compliance) all operating effectively under the overarching framework of the Directive itself. Each of these aspects of the system are assessed separately in the evaluation questions that follow, and here we have limited our focus to the contribution of the Directive to its ultimate goal of increasing safety and minimising or reducing the extent and socio-economic cost of machinery-related accidents and injuries in Europe.

There is some evidence to suggest that sectors and occupations most closely associated with the use of machinery have seen above average reductions in accident and injury numbers and rates since the application of the MD in 2009. However, as with trade, the longer term trends in machinery-related accidents seem largely undisturbed by the 2006 revision to the MD. Accident rates were already declining before the revision to the Directive, while trends in accident data for machinery and non-machinery related sectors and occupations do not obviously diverge at the date of application at the end of 2009. Again, the lack of obvious impact on headline data is unsurprising. Without a significant expansion of the scope or requirements of the Machinery Directive (at the time of revision) to cover new types of machinery or new aspects of safety, one would not expect to see a step-change in terms of reduced machinery-related accidents and injuries.

Nevertheless, a majority of respondents contributing to the study believed the MD (generally) has had a positive impact on a range of areas relating to health and safety protection for consumers and users. For instance, most believe the MD has had a positive impact on the quality of machinery, information on safe operation, user confidence, the number and severity of A&I, the number of unsafe machines and more generally on the level of safety and protection for machinery users. As such, nearly three-quarters of stakeholders suggested that the Directive had largely or entirely achieved its objective of protecting the health and safety of consumers and users of machinery products.

Feeding this analysis of the achievement of overall objectives, the next evaluation questions concern the effectiveness of specific procedures and activities (conformity assessment, standardisation and market surveillance) that are integral in supporting the Directive in achieving its ambitions.

The study was first asked to assess **the effectiveness of conformity assessment options (EQ6/7)**, including the third-party options and the procedures for assessment of conformity with internal checks (self-certification), in supporting the Directive's contribution towards its objectives.

Data on the uptake of different conformity assessment options for the MD are not readily available, and so indications were sought as part of the study consultation activities. The results from industry suggest that companies undergo some form of conformity assessment four or five times per year on average. In most of these cases (90%) conformity assessment is undertaken by self-certification, while third-party assessment through an EC-type examination (8%) and approval by a Notified Body of a full quality assurance system (2%) were much less common amongst this sample of companies. Notified Bodies themselves reported that there had been no significant trends in the numbers or types of assessments being undertaken in relation to the MD in recent years. They did however suggest that most manufacturers would try to avoid using third parties where possible, because of the extra costs.

Stakeholders were asked further about any barriers to the take-up of different conformity assessment options. The main drawbacks to third-party options were said to be the greater costs involved, while for the approval of full quality assurance, the complexity of this option and the requirements for extensive quality systems were regarded as off-putting. Indeed, several stakeholders mentioned that the quality assurance option has so far had very little take-up and so was still not seen as an established option for Machinery. By comparison, the main drawbacks to self-assessment routes were the lack of reassurance and protection that might otherwise be provided by third-party involvement (which customers might expect/demand), the effort and expertise required internally to undertake the process, and the lack of relevant harmonised standards (especially for Annex IV products).

It is not possible to use available A&I data to reach conclusions on the effectiveness of different routes to conformity in protecting health and safety. Even if it were possible to segment the machinery sector into parts that self-certify and parts that use third-party assessment, comparing A&I data between the two would be of little value. Self-certification is designed for cases where machinery is considered to present lower risks, and so (we would assume) will naturally have a different (i.e. lower) A&I profile. Instead, the consultations were used to collect informed opinions from across stakeholder groups as to the effectiveness of the different conformity assessment options. The feedback suggests that all four options are generally seen as effective at both protecting health and safety and (even more so) facilitating the internal market. There are more evident differences between the different options in their perceived effectiveness in protecting user health and safety, with half of respondents believing EC-type examination is 'very effective', compared with one-third for self-certification for non-Annex IV products, suggesting third-party involvement is more effective in ensuring protection of users.

Stakeholders were asked further about whether there were any specific issues that might reduce the effectiveness of the different conformity assessment options. For third-party options, the main concern was around inconsistencies between Notified Bodies in undertaking assessments and in interpreting requirements. A related concern was that declining use of third-party assessment might be reducing knowledge and experience of particular machinery within Notified Bodies, with possible implications for the effectiveness of the assessments undertaken. For self-assessment routes, stakeholders were most commonly concerned about the extent of incorrect application of requirements (be that intentional or not), as well as the incentive given by an ineffective market surveillance system for manufacturers to do no more than the bare minimum to meet requirements.

The study was similarly asked to assess **the effectiveness of the development and use of European Harmonised Standards (EQ8)** in relation to the application of the MD.

Standards are an important component in 'translating' the EHSR set out in the MD and - if given legal status as a European Harmonised Standard (EN) - can confer a presumption of conformity with one or more of these requirements. In effect, this means that by following the requirements of a transposed harmonised standard, designers know that their products will comply with the parts of the MD applying to their products, while also saving time in assessing risks and adopting strategies for safety.

Relevant technical committees (TCs) within the European Standardisation Organisations (ESOs) are assigned the task of undertaking standards development work, and they are reliant upon the expertise of manufacturers, regulators and other stakeholders contributing to the writing or revision of a standard. The great majority of stakeholders consulted for this study are content with the current level of involvement of industry in the development of harmonised standards for the MD. However, additional comments suggest that participation does vary between sectors and between different types of businesses, and some standards development is thought to be dominated by a small number of larger multi-nationals (with the time, resources and expertise to dedicate to a lengthy, complicated and involved process). Some also highlighted an underrepresentation or absence of other types of organisations in standards development, including users, regulators and national authorities (again, time and resource requirements were cited as a reason). Broad involvement of stakeholders in standards development was seen as important for the creation of more rounded and widely-applicable standards, for avoiding problems at a later stage, and for more general awareness-raising reasons.

Another indicator of the effectiveness of EN development for the MD is formal objections raised against published standards. We have identified only 21 such objections relating to MD standards over nine years, which is a very small number when one considers that it equates to just 3% of the overall portfolio of relevant ENs. In most of these cases the formal objection resulted in an amendment to the standard, or the addition of a warning note. In only one case was the standard withdrawn.

There are now ~800 ENs relating to the 2006 MD, with 5-10 new / revised standards each month. This portfolio of machinery ENs includes one Type-A standard (specifying basic concepts, terminology and design principles applicable to all machinery categories), ~100 Type-B standards (addressing specific aspects of machinery safety or safeguards across a wide range of machinery) and nearly 700 Type-C standards (providing specifications for a specific machinery category). Around 40 of the ENs available relate to Annex IV machinery, thereby allowing the possibility of self-certification.

Through consultation we asked stakeholders to rate various aspects of the coverage and relevance of the current portfolio. The responses were generally positive, with most reporting the scope and coverage to be good or very good overall. However, it is generally recognised that there are gaps in the Type-C standards available, particularly for some smaller volume products, as well as for products covered by Annex IV of the Directive. When invited to identify gaps in the standards portfolio, respondents indicated that these existed for a wide range of specific products. Most commonly, these included missing standards for automated machines and vehicles; collaborative robots/systems; assembly machines and systems; additive manufacturing and 3D-printing; interchangeable equipment; partly completed machines; wind turbines; food machines; metal working/bending machines; and risk assessment procedures.

Positive appraisals were also generally given for the extent to which standards were up-to-date with technological developments and, to a lesser extent, the frequency with which standards are reviewed and revised. There were concerns raised about the mismatch between the time needed for the development of standards and the speed of technological development and advancement in the state of the art. However there was also an acceptance that standards will necessarily lag behind technological development, and several commentators argued that trying to increase the speed of standard development and application might reduce overall quality or usability or (with more regular revision) create a less stable framework for industry.

When asked about the use of ENs in relation to the MD, stakeholders mostly held positive views as to their quality and usability, how well they explain rules, guidelines and definitions, and in relation to the clarity over which ENs can be used in particular cases. European Harmonised Standards are also seen as having many benefits when applying the Machinery Directive. This includes the fact that they are readily available, officially / widely recognised and well-perceived (by NBs, customers and other markets), well-aligned with requirements and reviewed regularly for possible update, as well as generally being an efficient means to comply with the MD. Many stakeholders therefore highlighted that ENs are used to comply with the MD, unless there are strong reasons not to (for instance, the

specific requirements of customers / target markets, or a lack of coverage of existing ENs in the relevant area).

Next, the study was asked to assess **the effectiveness of market surveillance and enforcement activities in relation to non-compliance with the MD (EQ9)**. Specifically, the study was required to assess the effectiveness of national authorities' activities in identifying and removing non-compliant products from the market, and to consider whether there are any barriers to the effectiveness of these mechanisms (or indeed examples of good or bad practice).

Unfortunately, there is little publicly available data on the level of inspections and the findings of non-compliance specifically related to products falling under the Machinery Directive, and what does exist ("MSA reports") is incomplete and internally inconsistent (within and across countries). Nevertheless, we have made use of data reported by 19 countries (in areas where these were more complete), combined with feedback from stakeholders (including authorities), to gain insight into activities related to the MD.

Market surveillance is carried out through inspections by the responsible authorities/agencies (MSAs) in each Member State, and is essential in identifying non-compliant products and enforcing appropriate corrective measures. Member States often draw up an annual action plan for the surveillance of products on the national market, generally based on previous inspections, complaints, accident reports, or information from RAPEX and ICSMS European notification systems. The MSAs consulted through the study suggest a mix (50:50 overall) of proactive (e.g. explicitly targeting product categories and economic operators, based on knowledge built and priorities set by authorities) and reactive (i.e. as a response to complaints, accidents, or RAPEX notifications) approaches.

MSA reports suggest that the numbers of inspections undertaken each year in relation to machinery varies significantly between countries (ranging from 50 to 500+) and from year to year (an average of 455 inspections per country, per year, 2010-2013). Through the targeted consultation a small number of market surveillance authorities directly provided data on the number of inspections carried out within the scope of the Machinery Directive over the course of the last 12 months. Their estimates ranged from 30 to 80 inspections per year (52 on average). This is significantly below the average reported by 15 countries in MSA reports, and below the figures given for the specific countries in question (further adding to concerns about the reliability / consistency of MSA reports as a data source).

Amongst those consulted, there was a reasonably even split between MSAs reporting an increase in inspections over the past five years (due to joint actions and additional funding) and those reporting a decrease (mainly due to a reduction in resources). From a different perspective, around three-quarters of businesses consulted had not been subject to a machinery-related inspection in the past five years, while around half reported that none of their relevant products had ever been inspected. In a number of cases, where inspections did occur, these were self-initiated by the company itself.

When asked about the overall effectiveness of national authorities in monitoring manufacturers' adherence to the requirements of the MD, nearly three-quarters of respondents rated these authorities as having limited or no effectiveness. In addition, the vast majority of consulted stakeholders believe that the number and frequency of inspections, as well as the likelihood of being inspected, were currently too low. Tellingly, even a majority of national authorities believes the likelihood of a company being inspected is too low, while the number of products never assessed is too large.

MSA reports suggest there is also significant variation across Member States in the extent to which inspections lead to a determination of non-compliance – for example 6% in Austria, compared with 79% in Denmark. There is some evidence to suggest that specific targeted actions tend to achieve higher 'hit rates', which may go some way to explaining the differences. Countries also appear to differ in their approaches to rectifying measures, with some focusing mainly on voluntary measures, and others employing only restrictive measures and sanctions or penalties in the case of non-compliance.

The RAPEX system is the single best source for analysing the incidence rates and origins of non-compliant products over time. However, it is not without its limitations, and importantly it only covers products posing a serious risk to users, rather than other types of non-compliance (e.g. issues with documentation or CE marking). Nevertheless, this source suggests that the incidence of non-compliant products in the machinery sector is relatively low. Out of 17,724 notifications registered between 2005 and 2015, only 210 (1.2%) were classified within the product category 'machinery'. However, the vast majority of RAPEX notifications relate to consumer products, and since a 'professional product' option was added in 2013, the machinery sector has accounted for up to one-quarter of all new notifications. Notifications for products originating in China dominate the machinery alerts (both overall, and for sub-categories), as they do the RAPEX system of notifications more generally (products originating in China account for 59% of all notifications registered between 2005 and 2015). Nevertheless, of all RAPEX notifications categorised as machinery, two-thirds were for products from China, with some indication of an increase over time.

Unsafe and non-compliant products can lead to unfair competition, and operators that do not adhere to the rules can achieve significant savings on compliance costs, and consequently offer products at lower prices than competitors. A 2006 public consultation on the New Legislative Framework (NLF) found that most operators (not just in the machinery sector) believed there to be unfair competition due to the presence of non-compliant products on the internal market, with the main reason felt to be that market surveillance did not operate effectively. This was attributed to weak coordination between authorities, sub-optimal functioning of EU procedures for exchange of information on product risks and inconsistent enforcement of EU-wide product safety action. Other reasons for inefficiencies put forward were the difficulty to trace economic operators in a globalised market, the limitation of resources of MSAs, and the growing number of imports of non-food products from third countries.

Similar issues arose in the consultation for the current study. The main problems and barriers to the effective identification and removal of non-compliant machinery put forward by stakeholders here included a lack of resources and funding, as well as a lack of cross-border cooperation, poor targeting of efforts, a lack of staff knowledge/competence and an imbalanced focus on consumer products.

Finally, on effectiveness, the study was asked about **enablers and barriers to the effectiveness of the Directive and its application (EQ10/11).**

A number of issues and barriers have already been identified above in relation to specific aspects of the effective application of the Directive, which include:

- Incomplete or inconsistent application of monitoring and enforcement procedures by Member States, including in the number of market surveillance activities undertaken, the approach taken to determining compliance, the measures taken to withdraw or prohibit machinery, and the establishment of effective, proportionate and dissuasive penalties for infringements.
- Inconsistencies in the interpretation of requirements and the assessments undertaken by Notified Bodies, as well as an apparent decline in their knowledge and experience of specific products.
- Incorrect application of self-certification requirements, combined with a lack of incentive to do more than the bare minimum (caused by an ineffective market surveillance system).
- Under-representation of various actor groups (users, regulators, national authorities) in standards development processes, which are often dominated by a small number of larger multi-nationals.
- Gaps in the portfolio of type-C standards available, particularly for some smaller volume products, as well as for products covered by Annex IV of the Directive.
- Insufficient number and frequency of machinery-related inspections by market surveillance authorities, as well as a lack of cross-border cooperation between these bodies, poor targeting of efforts, a lack of staff knowledge/competence and an imbalanced focus on consumer products.

Here we focus on noting several resources, mechanisms and activities that have been mentioned by stakeholders during the course of the evaluation as acting as enablers to the MD's effectiveness.

In terms of supporting literature, this includes the comprehensive 'Blue Guide' to the implementation of EU product rules and the Guide to the application of the Machinery Directive. The latter is a comprehensive 400+ page document that follows the Directive almost sentence by sentence, providing accompanying discussion, comments and explanations on the concepts and requirements to help ensure uniform interpretation and application of the Directive throughout the EU. The Commission has also published a number of guidance documents approved by the Machinery Working Group that deal with specific machinery and provide further information or clarification. A number of other organisations have similarly produced guidance to the Directive and its application.

Several centralised bodies have also been established to support the effective and optimal implementation and application of the Directive through e.g. sharing of information and best practices, or addressing potential issues and barriers that may arise. These supporting mechanisms include the Machinery Committee (giving advice to the Commission on appropriate measures connected with the practical application of the MD, as well as opinions on measures proposed), the Machinery Working Group (allowing a wider group of stakeholders to take part in discussion of problems relating to the practical application of the MD), the Administrative Cooperation (AdCo) Group (to exchange information and discuss issues between Member States), and the European Coordination of Notified Bodies for Machinery (NB-M) (for the exchange of experience between Notified Bodies and to harmonise their practices through the adoption of Recommendations for Use).

Beyond these, most national authorities and industry associations also regularly undertake various activities to support knowledge and understanding of the MD and its implications across wider groups of stakeholders, thereby helping to enable its effective and efficient application. These activities include dissemination of information, the provision of help services, by hosting workshops, and offering guidelines, fact sheets, explanatory notes and translations of key documents.

While not specifically addressed by one of the evaluation questions, the study was asked to also consider **the effects of the Machinery Directive on competitiveness**. There might be a risk that such Directives could damage the economic performance of relevant industries by increasing administrative and even production costs without a commensurate improvement in product value, leading to higher prices and possibly lower sales and lower margins. Moreover, where there are differences in the requirements applied to firms competing in the same global market, higher costs may negatively affect market share. In the short term, uneven requirements (internationally) could lead to reduced global exports by regions with relatively stringent rules. Other commentators argue that this view is insufficiently dynamic, and that Directives can cause firms to innovate and develop products that perform rather better than the machines manufactured by their competitors in regions with fewer or more lenient Directives.[71] The evaluation has considered the international competitiveness of Europe's machinery sector from a number of perspectives, on the assumption that the machinery directive may have had a material effect on the sector over time, positive or negative.

Effects of the Directive on competitiveness: We began by looking for studies that had considered the relationship between the directive and the sector's competitiveness, and were not able to identify any that had looked at these questions specifically and exhaustively. The issue was touched on briefly in the previous evaluation of the machinery directive, and we also identified two studies that had looked at the competitiveness of Europe's machinery sector. The latter studies provided helpful contextual data, but ultimately did not formally review the effect of the directive on sector performance. There are more generic studies as well as more focused work exploring the effect of current environmental regulations, which suggest that legislation is rather less critical than other factors such as market conditions and the quality of the local workforce in determining where trade and investment take place.[72] It is unclear to what extent this conclusion of regulation as important but not critical to

[71] For a good overview of the issues, see The Impact of Regulation on Innovation, by Professor Knut Blind, for NESTA, 2012. Or more recently, 'Does EU regulation hinder or stimulate innovation? Jacques Pelkmans and Andrea Renda, CEPS Special Report No. 96 / November 2014.

[72] 'The impacts of environmental regulations on competitiveness,' Antoine Dechezleprêtre and Misato Sato, Policy brief November 2014, The Grantham Research Institute on Climate Change and the Environment.

competitiveness would hold equally well for the machinery sector. This is a gap in the evidence base that the European Commission might usefully help to fill in the near future.

Exports and trade statistics: Our next step was to use studies and trade statistics to explore the changing fortunes of the machinery sector; has it become more or less competitive over the last 10-20 years. Competitiveness at the sector level may be measured or judged in terms of performance in international trade (net exports, investment flows). This is based on the assumption, that a more competitive sector will tend to show stronger export performance when compared with the same sector in less competitive countries. Our analysis of Eurostat trade statistics is broadly positive, albeit we have had to use a slightly larger sector, the Machinery and Mechanical Appliances (MMA), as our proxy for the machinery sector more narrowly. Eurostat statistics show that Europe's MMA sector has continued to expand its exports over the past 15 years, with the exception of a 2008 and 2009. Notwithstanding the reversal during the economic crisis, the total volume of MMA exports was around 20% higher in 2015, when compared with 2002. The importance of the sector to Europe's economy is also underlined by these trade data. In 2015, the Machinery and Mechanical Appliances (MMA) sector accounted for nearly one quarter (23%, €1,139bn) of all EU28 exports, intra and extra EU. Our analysis also shows that the EU28 was a net exporter of machinery over the period.

We struggled to find statistics that would allow us to place these figures in an international context: in a period of rapid globalisation and double-digit annual growth rates in several, large emerging markets, it is entirely possible that Europe's exports may be growing in absolute terms while our global market share is in decline relatively. We did however find a number of one-off studies, which do provide a window onto these issues. A 2012 report on the competitiveness of EU mechanical engineering[73] is strongly positive and notes that the sector (which it defines based on NACE C28) is a major employer, even bigger exporter and one of the keys to Europe's wider competitiveness, as one of the prime suppliers of its capital goods. The report presents statistics for 2010 showing the EU was one of the world's leading manufacturing regions, alongside China, Japan and the United States. In 2010, the EU outperformed Japan and the US on output, value added and employment. It had a similar output and value added to China, albeit the latter had more than double the employment (so around half the labour productivity). While Europe's output exceeded that of Japan and the US, Europe's machinery sector had much lower labour productivity levels than was the case for these two other advanced manufacturing regions. Lastly, the 2012 report makes no suggestion that the industry is being hampered in any way by specific European regulations.

A more recent analysis carried out for The European Association of the Machine Tool Industries (CECIMO) shows a similarly positive view, in terms of the rising value of Europe's machinery exports over time. However, the CECIMO study also shows that Europe's share of global machine tool sales fell substantially between 1999 (44%) and 2014 (25%), with Asia's share increasing strongly in the same period, from 24% to 59% of global sales.[74] The trade body's analysis suggests these changing fortunes affected Japan and the US too, and are driven primarily by the dramatic growth in demand for machine tools in Asia, combined with the 20-30 percentage point difference in cost-competitiveness between Asia and Europe. The issue of regulation does get picked up in the report's discussion of the statistics, however, the challenge is seen as being one of complex and unclear local regulations that make it that little bit harder for Europe's firms to access potential customers in emerging markets. There is no specific mention of Europe's machinery directive, nor any more general remark about EU regulations having had a deleterious effect on the industry's global competitiveness. Instead, the CECIMO report exhorts Europe's machine tool firms to focus on combining forces, moving their products further up the value chain and giving more weight to innovation and in particular the opportunities promised by Industry 4.0. The message for policy makers emphasises the need for continued support for relevant public research, industry led-standardisation and improved physical and digital infrastructure.

[73] An introduction to Mechanical Engineering: Study on the Competitiveness of the EU Mechanical Engineering Industry, 2012

[74] http://www.ims.org/wp-content/uploads/2017/01/6.03_Luigi-Galdabini_WMF2016.pdf

Industry opinion: Turning to our own consultations, a majority of respondents believe that the MD – across successive editions – has been positive for the competitiveness of Europe's machinery sector:

- More than 80% of the respondents to our targeted survey judged the Directive to have had a positive impact on the sector, including through the range of products available, turnover and profitability in the sector, international competitiveness and the volume of trade within the EU and internationally.
- The public consultation was also broadly positive about the effects of legislation on the machinery sector, with around 50% reporting that exports had increased in the past decade, especially intra-EU trade, with a similar proportion reporting that the sector had improved its international competitiveness in that time

The feedback is not universally positive, with a small minority of respondents arguing that the directive had had a slightly negative effect, as a result of their having to increase costs unilaterally in what is a global market place. In their written comments, stakeholders stated that the costs incurred in complying with the Directive are substantial, and inevitably will be passed on to customers. This reduces competitiveness internationally, however, it can also impact negatively within the EU, whereby other manufacturers (from outside the EU) continue to sell cheaper, non-compliant products to EU customers safe in the knowledge that market surveillance is under-resourced and unlikely to identify and remove such goods from the market. Other respondents suggested the MD compliance costs are lower than for analogous national regulations, and that those additional administrative costs are also offset by the positive reputational impact of the machinery directive. Several contributors suggested the Directive had increased the competitiveness of the EU machinery sector as a result of the high regard for EU regulations and standards outside Europe, and in particular the positive appreciation of machines with CE marking.

6.4 Efficiency of the Directive

The first efficiency question concerns **the costs resulting from the MD for different actors (EQ12)**, which the study was asked to identify and (as far as possible) quantify.

Using a typology presented in the Better Regulation Toolbox for guidance, the study team explored various processes triggered by the Machinery Directive, including the main specific actions involved in its implementation and application, that would incur costs to stakeholders. This analysis showed that nearly all of the costs relate to the time and effort involved in different processes. It also highlighted that costs from the MD are borne at different times and with varying frequency. For example, national authorities incur one-off up-front costs in transposing the Directive, but also incur ongoing costs of approving Notified Bodies during the lifetime of the Directive. At the same time, businesses will incur costs associated with undergoing conformity assessment, but with a regularity determined by their rate of introduction of new products, and a cost that will be specific to their circumstances.

From exploratory work undertaken during early phases of the study, it became clear that the majority of data necessary for assessing the costs were unlikely to have been collected already, or be readily accessible. The study had therefore to rely predominantly on assessments from the actors involved (through consultation) in order to determine the costs incurred in undertaking particular activities. We took a pragmatic approach: identifying a handful of broad activities for each group and asking them to provide estimated averages where information is not easily available. Nevertheless, few respondents were willing or able to provide the quantitative data requested and we have had to draw conclusions from a small number of data points in many cases.

The following table provides a summary of the estimates regarding the average annual cost (FTE days plus other financial outlays) to the average actor in each of the four main stakeholder groups.

Table 74 Average costs incurred by relevant actors each year, as a result of the MD

Actor	Action	FTE days	Other financial costs
Market surveillance authority	Inspection	180	€60,000
Implementing authority	Standardisation	84	€6,429
	Other activities	80	€10,000
European Industry Association	Standardisation	93	€13,074
	Other	102	€68,340
Industry	Conformity assessment	37	€4,500
	Inspections	0.9	€300

Source: Technopolis

Using these data as a basis, we also extrapolated the figures to the full population of actors in each group (see below) and arrived at an approximate estimation of the global cost incurred by all actors from the Machinery Directive each year: €136m (with 90%+ incurred by industry).

Table 75 Estimated total costs incurred by relevant actors each year, as a result of the MD

Actor	Number of actors	Total FTE days	Total cost of FTE days	Total other financial costs	Total costs
Market surveillance authority	28	5,040	€ 681,408	€1,680,000	€ 2,361,408
Implementing authority	28	4,592	€ 620,838	€460,012	€ 1,080,850
European Industry Association	50	9,750	€ 1,318,200	€4,070,700	€ 5,388,900
Industry	12,863	487,508	€ 65,911,082	€61,742,400	€ 127,653,482
Total for all actors		**510,246**	**€ 68,531,528**	**€67,953,112**	**€ 136,484,640**

Source: Technopolis

Similarly, the study was asked to identify the range and scale of **the benefits realised by different stakeholders as a result of the Machinery Directive (EQ13)**.

The typology of regulatory impacts suggests that the main categories of direct benefits to flow from the Directive will relate to improved well-being and market efficiency.

The benefits to well-being (i.e. improved health and safety) have already been introduced under EQ5, where we considered changes in machinery-related A&I in Europe over time. For the Manufacturing, Construction and Agriculture, forestry and fishing sectors combined (those assumed to have highest relevance to machinery use), the number of fatal accidents decreased by 767 (a reduction of 29%) between 2008 and 2013, while the number of non-fatal accidents dropped by 472,718 (a reduction of 28%) (figures adjusted for changes in employment in these sectors over the period).

Combining this information with UK Health and Safety Executive estimates of the financial and non-financial costs incurred because of fatal and non-fatal accidents has allowed the study to monetise the value (savings) from the reduction in relevant accidents during the period. As the following table lays out, total cost savings from a reduction in accidents in machinery-related sectors during the period are estimated be €2.01b (€1.53b for fatal and €0.047b for non-fatal accidents avoided). This is the equivalent to €401m in savings per year during the period.

Table 76 Estimated cost of fatal and non-fatal accident reduction in machinery-related sectors, 2008-13

Type	Reduction in number of accidents 2008-13	Financial and non-financial cost per accident	Total cost saved from accident reductions
Fatal injuries	767	€ 2 million	€ 1,534,000,000
Non-fatal injuries	472,718	€ 1,000	€ 472,718,000
Total			**€ 2,006,718,000**

Source: Technopolis calculations based on ESAW data and HSE cost estimates.

The benefits in terms of market efficiency require a comparison between the costs incurred under the Directive, and the likely costs that would be incurred without it (i.e. the cost savings triggered by the Directive – for example through reduced requirements to enter other EU markets). Given the length

of time that *a* Machinery Directive has been in place, it is difficult to make such a direct comparison, or expect others to do so, not least because the 28 national regimes would have evolved somewhat over the past 30 years, even if the Directive had not existed. We did however ask businesses during interviews about the additional costs involved in supplying third countries – but the situation was complicated by the fact that the current MD (and associated ENs) often providing a good basis for meeting requirements in other countries with minimal cost and effort (perhaps ~2% of total costs to meet differing requirements and show conformity). The US provides an interesting example, because there is little compatibility with the European regime, and as a result additional costs were quoted by several individuals as being closer to 5-10% for complying with this second system. We estimated above that EU industry currently incurs costs of around €128 million per year as a result of conformity assessments and inspections relating to the (single) European Directive. Even a 2% addition (for all businesses to operate in a second market) would add €2-3 million to overall costs. The implications (at least for some businesses) of additional requirements to enter each European market would therefore be significant.

Businesses were also asked more generally whether the Machinery Directive achieves more than would be achieved otherwise (i.e. in its absence) in terms of reducing costs, and nearly all businesses believed it had (mostly to a "moderate extent").

The main categories of indirect benefits expected to flow from the Directive include the wider macroeconomic benefits of a single internal market for machinery. Under EQ5 above we discussed the fact that the sector has seen increases in production values, employment and volume/value of trade since the application of the Directive. However, a dip in statistics in 2009 (brought on by the economic crisis) creates a misleading picture. Using the more 'typical' base year of 2008 reveals a more stagnant picture, with the number of enterprises and the levels of employment, production value and intra-EU exports broadly similar in 2013 or 2014 (depending on data availability) to the situation prior to the application of the Directive. That is not to say that there have not been macroeconomic benefits from the existence of the Directive. Just that the available data does not provide clear evidence of a significant change in relevant indicators at the time of the Directive's revision.

There will be other indirect benefits triggered by the MD, which the evaluation has sought to identify. Indeed, we found that nearly all industry representatives claim that the MD has provided other benefits to companies, including through international recognition of the CE mark, the introduction of standardised procedures (saving time and money), and the reduced cost of self-certification options.

The study was also asked to assess **whether the costs incurred as a result of the MD are reasonable, affordable and proportionate (EQ14)** given the benefits for different stakeholders.

The results above suggest that the global costs incurred as a result of the Directive (estimated at some €136m per annum) are far outweighed by the kinds of cost savings achieved from improved health and safety (estimated at around €401m per year as a result of declining numbers of accidents and injuries). 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 consultation for the study did reveal that the majority of respondents felt there had been an increase in the costs and burdens on businesses, users and authorities as a result of the Directive. However, these additional costs were generally not felt to be substantial, and the majority view across most groups was that, overall, any additional costs were outweighed by the benefits of the Directive. Only companies expressed more mixed views in their assessment of costs and benefits, and this appears to be mainly caused by the perceived reduction in benefits from having to compete against significant levels of non-compliance (caused by insufficient market surveillance and enforcement).

Finally, on efficiency, the study was asked to consider the **potential to simplify the Directive and its application and / or reduce inefficiencies, burdens and costs (EQ15/16).**

Some respondents to our consultations did highlight disproportionate costs arising from time and resources spent on documentation – and in particular the need to translate documentation into the language of destination, or the obligation to provide the declaration of conformity and the operating instructions in paper form with the product. But otherwise, few inefficiencies could be identified.

Beyond this, a number of other suggestions were put forward for simplifying or otherwise improving the Directive moving forwards (possibly as part of any future revision). Key areas mentioned included: adapting the Directive to fit with the New Legislative Framework (especially to provide a common framework for market surveillance); considering further the suitability of the current Directive (and EHSR) for new areas of development in machinery (particularly around digitisation and robots, as well as cyber security and the risk of hacking in relation to product safety); simplifying the risk assessment process; improving definitions of (and demarcations between) particular types of machinery; improving convergence with other similar Directives and Regulations (at least in terms of terminology and definitions); and – most commonly – taking additional action to increase and improve inspection regimes, so as to better ensure widespread compliance with the Directive and the realisation of benefits for those that comply.

6.5 Coherence of the Directive

On coherence, the evaluation was asked to consider **the 'fit' of the Machinery Directive with other legislation (EQ17)**, and whether there is evidence of incoherence, overlaps or inconsistencies.

The original proposal for the 2006 Directive itself stated that there did not appear to be any inconsistency between the Directive and other Community policies. In addition, one intention of the 2006 revision was that the borderline between the scope of the Machinery Directive and other Directives, in particular the Low Voltage and Lifts 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 Machinery Directive.

Indeed, while the study found that stakeholders were generally of the view that the Directive fits well with other national, EU and international 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, including most commonly 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 the indicated overlaps or inconsistencies between the MD and the other legislation that they pointed to.

6.6 European Added Value of the Directive

The study was finally asked about **the added value to stakeholders of the MD (EQ18)** (and total harmonisation), compared to what could have been achieved by Member States alone.

As has been mentioned, the Directive provides a framework and establishes the mandatory EHSR, but does not translate these into detailed requirements or processes. As such, the impact of the Directive 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 Machinery Directive from those incurred as a result of other pieces of legislation, or that would be incurred in any case without the Directive. There may also be other significant factors, such as economic downturn that have an impact.

Nevertheless, we asked stakeholders through the targeted consultation about the extent to which the MD achieves more in relation to its objectives than would be achieved otherwise (i.e. in its absence). All respondents agreed that it added value in terms of facilitating the internal market and ensuring the health and safety requirements of machinery, and a majority reported that it did so to a large extent. In addition, 92% of respondents believed that the Directive reduced costs overall, compared to what might be the case otherwise (e.g. with national legislation in place instead). This is backed up by the recent internal market study[75] which also suggested that the cost of complying with EU legislation (for internal market legislation generally) is likely to be much less than the cost of complying with the requirements of 28 different regimes. It also noted that this might be of disproportionate benefit to SMEs compared to large enterprises (with the latter better-placed to meet different national requirements).

[75] Evaluation of the Internal Market Legislation for Industrial Products, CSES, 2014

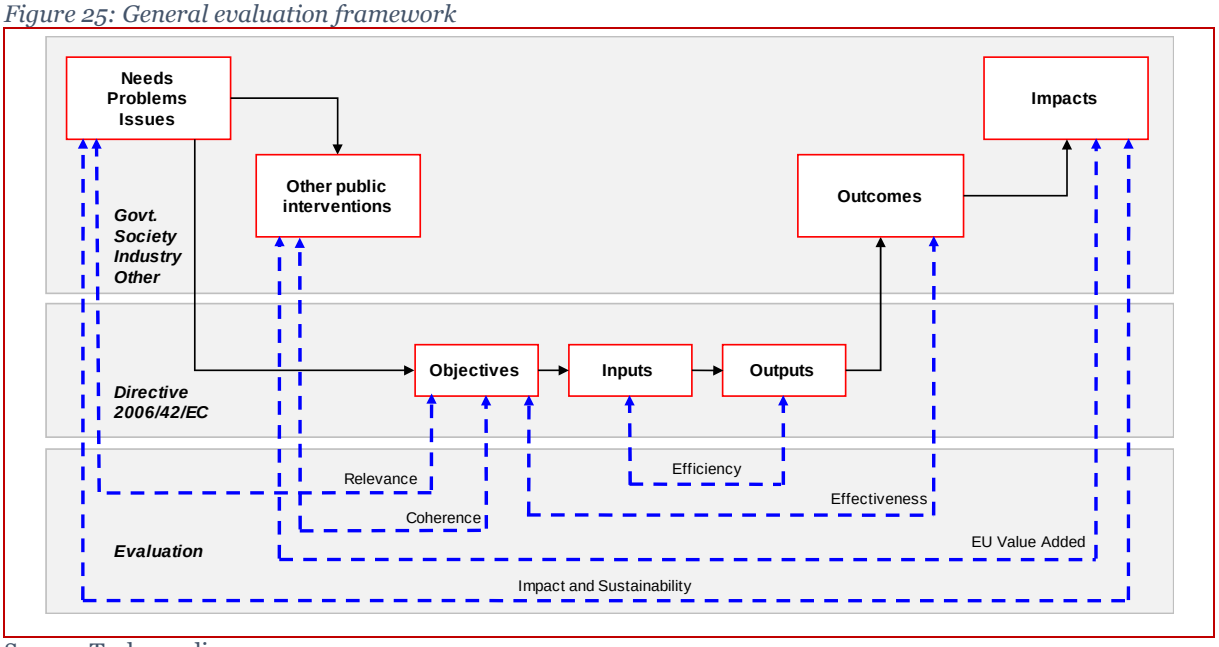
Appendices

Appendix A Methodology

A.1 Evaluation approach

The overall methodological approach used for the study follows a theory-based **evaluation framework** that is suited to the evaluation of complex policy interventions. As the name suggests, the framework is concerned with the theory and the assumptions of policy makers (and others) about the preconditions, context and challenges that justified a particular policy intervention, in this case the adoption of the Machinery Directive. Figure 25 shows a generic framework that is commonly used in policy evaluation. It serves to explain how each of the five broad evaluation criteria (e.g. relevance or efficiency) are linked to the specific intervention logic for the adoption of Directive 2006/42/EC.

Figure 25: General evaluation framework



Source: Technopolis

Based on this generic model the team developed an **intervention logic** for the Machinery Directive. This is presented in Section 2.4 of the main report and shows the logical sequence and causal relationships among: the Directive's rationale; the activities undertaken; and the results (outputs) and changes (outcomes and ultimately impacts) that it is intended will be realised as a result. These achievements should in turn contribute towards addressing the initial challenges and needs identified, which were the original basis for the Directive. Defining the intervention logic was an essential first step in the evaluation. Not only did it demonstrate the logic of the Directive; the elements presented then also served as a basis for undertaking the evaluation.

A.2 Conduct of the evaluation

Based on initial discussions and inception work, as well as a better understanding of the requirements of the study that resulted, the study team proposed a slight change in the phases and timing of the evaluation compared to that presented in the proposal. This was to better take account of: the delayed start to the study; the need to fully interrogate and analyse existing evidence before launching consultations; the Commission's intention to begin the public consultation in late summer; and the need to allow time to iterate tools before launching consultation activities. These revisions - which were set out and approved in the inception report – resulted in four-phase study. Each of these phases is summarised below, and presented graphically in Figure 26. The following sub-section goes on to provide further detail on each of the key research methods deployed during these phases, including the main sources of evidence drawn on during the course of the evaluation.

Phase 1 (February - April 2016) – Inception

The first phase of the study began with a kick-off meeting between the study team and members of an inter-service steering group established to oversee the study. Inception work then included initial discussions with stakeholders, background research, and exploration of potential data sources. Activities during this phase also included the development of the MD intervention logic; a preliminary mapping and assessment of the types of costs and benefits triggered by the Directive; identification of stakeholder groups; the development of evidence tables (cross-referencing questions, indicators and evidence sources); the identification of risks / challenges and mitigation strategies, and the revision of the approach and work plan for the study. Introductory presentations on the proposed study were also given to the Machinery Working Group and to the Orgalime Machinery Core Group. The first phase concluded with the delivery of an inception report, which set out the activities and results of the inception period. These were presented and discussed with the steering group at an inception meeting.

Phase 2 (April - July 2016) – Desk research and consultation preparation

The second phase of the study focused on extracting, collating and analysing relevant pre-existing data and information from databases, reports and other sources, including by seeking access to information held by certain stakeholders. During this period the study team also drafted a series of tools (survey questionnaires and interview guides) for use in the various stakeholder consultation activities planned for the next phase of the study. Relevant groups and individuals to consult were also identified. The study team also continued to be in contact with representatives of different stakeholder groups in order to initiate interactions regarding the evaluation and make preparations for the consultations. Specifically, the study team participated in events and discussions with Orgalime, SEMI, ETUI, CEN-CENELEC and others, and had contact with various other industry representatives who were interested in hearing more about the study, and wanted to ensure that they and their members were kept informed of opportunities to contribute to consultation activities. The second phase concluded with the delivery of a progress report, which was discussed at a first progress meeting.

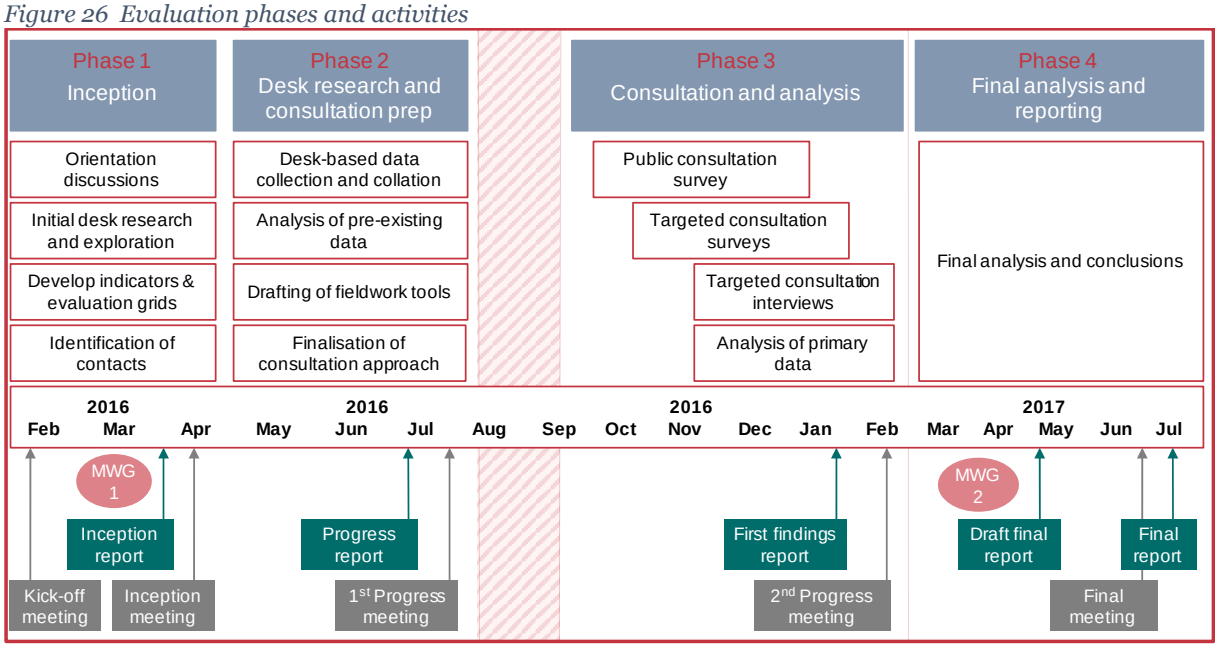
Phase 3 (September 2016 – February 2017) – Consultation and initial analysis

The third phase of the study focused on undertaking targeted and public consultations with a range of stakeholder groups, analysing the results of these, and integrating this evidence with the earlier results from analysis of pre-existing information. This phase concluded with the delivery of a first-findings report and a second progress meeting between the study team and steering group.

Phase 4 (March – July 2017) – Final analysis and reporting

The final phase of the study involved additional stakeholder interviews, as well as further analysis of the evidence collected. In particular, the study team sought to address a small number of issues/gaps identified in the initial analysis, before developing answers and conclusions to each of the study objectives and questions, and setting out possible considerations for the future. During this period, the evaluators also attended another meeting with the Machinery Working Group to present progress and emerging findings. The phase concludes with the submission of this final report.

Figure 26 Evaluation phases and activities



A.3 Principle evaluation methods and sources

A.3.1 Desk research and document review

An initial review of literature, reports, websites and databases during the inception phase of the study identified a number of potential pre-existing evidence sources and provided basic information on their scope, relevance and limitations. This fed into the development of indicators and then evaluation grids, which set out the evaluation criteria, questions and sub-questions, and cross-referenced these with potential indicators and likely sources of evidence to address these. During phase 2, the study team returned to the identified sources to extract, collate and analyse the available secondary evidence, and to provide preliminary findings in relation to many of the evaluation questions.

The main secondary resources identified and drawn upon included: policy documents (Regulations, Directives, Communications, Notices and Working Documents); reports (from other studies, reviews and monitoring activities); and other sources (including various websites and web-based portals). The following three figures list the main documentary references identified, obtained and reviewed by the study in each of these areas. Most are referenced directly within the main body of this report. Details of pre-existing databases are set out separately in the next section on secondary data.

Figure 27 Key references – policy documents

- Regulation (EU) No 1025/2012 Of The European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (2012) OJ L316/12
- Council Directive of 14 June 1989 on the approximation of the laws of the Member States relating to machinery (89/392/EEC) (1989) OJ L183/9
- Council Directive of 20 June 1991 amending Directive 89/392/EEC on the approximation of the laws of the Member States relating to machinery (91/368/EEC) (1991) OJ L198/16
- Council Directive 93/68/EEC of 22 July 1993 amending Directives 87/404/EEC (simple pressure vessels), 88/378/EEC (safety of toys), 89/106/EEC (construction products), 89/336/EEC (electromagnetic compatibility), 89/392/EEC (machinery), 89/ 686/ EEC (personal protective equipment), 90/ 384 / EEC (non-automatic weighing instruments), 90/ 385 / EEC (active implantable medicinal devices), 90/ 396/ EEC (appliances burning gaseous fuels), 91/263/EEC (telecommunications terminal equipment), 92/42/EEC (new hot-water boilers fired with liquid or gaseous fuels) and 73/23/EEC (electrical equipment designed for use within certain voltage limits) (1993) OJ L220/1

- Council Directive 93/44/EEC of 14 June 1993 amending Directive 89/392/EEC on the approximation of the laws of the Member States relating to machinery (1993) OJ L175/12
- Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery (1998) OJ L207/1
- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (1998) OJ L331/1
- DIRECTIVE 2006/42/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast) (2006) OJ L157/24
- Directive 2009/127/EC of the European Parliament and of the Council of 21 October 2009 amending Directive 2006/42/EC with regard to machinery for pesticide application (2009) OJ L310/29
- Proposal for a Council Directive on the approximation of the laws of the Member States relating to machinery COM(87) 564 final (1987) OJ C29/1
- Proposal for a Directive of the European Parliament and of the Council on machinery and amending Directive 95/16/EC (2001/C 154 E/15) COM(2000) 899 final (2001) OJ C154E/164
- COM(2008) 535 final Proposal for a Directive of the European Parliament and of the Council on machinery for pesticide application, amending Directive 2006/42/EC of 17 May 2006 on machinery (2008)
- COM(2013) 685 final Annex to the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Regulatory Fitness and Performance (REFIT): Results and Next Steps (2013)
- COM(2014) 25 final Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee A vision for the internal market for industrial products
- C(2016) 1958 final Commission Notice of 5.4.2016 The 'Blue Guide' on the implementation of EU product rules 2016
- SEC(2006) 894 Commission Staff Working Paper Accompanying the Proposal for a Directive of the European Parliament and of the Council establishing a framework for Community action to achieve a sustainable use of pesticides {COM(2006) 373 final} The Impact Assessment of the Thematic Strategy on the Sustainable Use of Pesticides
- SEC(2011) 1626 final Commission Staff Working Paper Functioning of the system Accompanying the document Report from the Commission Second Evaluation Report on EU Pilot {COM(2011) 930 final}
- Minutes of the meeting of the Consumer Safety Network (CSN) and the Expert Group on the Internal Market for Products – Market Surveillance Group (IMP-MSG), Brussels, Friday 30 January 2015
- Note to members and observers of the committee on standards: formal objections against harmonised standards - state of play (European Commission, various dates) (internal document)

Figure 28 Key references – existing studies

- An introduction to Mechanical Engineering: Study on the Competitiveness of the EU Mechanical Engineering Industry (ECORYS, Ifo Institute, Cambridge Econometrics and Danish Technological Institute for DG Enterprise, 2012), available at: http://ec.europa.eu/DocsRoom/documents/12329
- Evaluation of the Internal Market Legislation for Industrial Products (CSES for DG Enterprise, 2014), available at: http://ec.europa.eu/DocsRoom/documents/4223
- Costs to Britain of workplace fatalities and self-reported injuries and ill health, 2013/14 (HSE, 2014), available at: http://www.hse.gov.uk/statistics/pdf/cost-to-britain.pdf
- Consumer product-related injury in Australia: direct hospital and medical costs to Government (Monash University, 2006), Available at: http://www.monash.edu/__data/assets/pdf_file/0004/217399/muarc083.pdf
- Independent Review of the European Standardisation System (EY for DG Growth, 2015), available at: http://ec.europa.eu/DocsRoom/documents/10444
- Jahresbilanz 2012 Marktüberwachung für die Bereiche Produktsicherheitsgesetz und Energieverbrauchsrelevante-Produkte-Gesetz in Baden-Württemberg, (Ministerium für Umwelt, Klima und Energiewirtschaft Baden-Württemberg 2012)
- Report on the Member States reviews and assessment of the functioning of market surveillance activities for the 2010-2013 period pursuant to Article 18(6) of Regulation (EC) No 765/2008 (Sector 9 Machinery) (European Commission, 2015), available at: http://ec.europa.eu/DocsRoom/documents/13909
- Commission's annual reports monitoring the application of Union law (European Commission, multiple years), available at: http://ec.europa.eu/atwork/applying-eu-law/infringements-proceedings/annual-reports/index_en.htm, For example: 26th Report on monitoring the application of Community law [COM(2009) 675] – Situation in the different sectors [SEC(2009)1684/2]
- Commission communication in the framework of the implementation of Directive 2006/42/EC of the European Parliament and of the Council on machinery, and amending Directive 95/16/EC (recast) (Publication of titles and references of

harmonised standards under Union harmonisation legislation) OJ C173/1 (European Commission, 2016), available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2016.173.01.0001.01.ENG&toc=OJ:C:2016:173:TOC

Figure 29 Key references – other sources

- CIRCABC portal. Available at: https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp
- Encouraging innovation and growth with standards'. Available at: http://www.bsigroup.com/en-GB/standards/benefits-of-using-standards/standards-for-innovation-and-growth/
- Standards for innovation-benefits'. Available at: http://www.cencenelec.eu/research/innovation/Pages/default.aspx
- European Commission at work: Details of EU infringement process. Available at: http://ec.europa.eu/atwork/applying-eu-law/infringements-proceedings/index_en.htm
- European Commission at work: Details of formal infringement procedures taken. Available at: http://ec.europa.eu/atwork/applying-eu-law/infringements-proceedings/infringement_decisions/?lang_code=en
- CEN policy for the transposition of International Standards into European Standards. Available at: http://boss.cen.eu/reference%20material/Guidancedoc/Pages/TranspoPolicy.aspx
- Details of pending formal objections. Available at: http://ec.europa.eu/growth/single-market/european-standards/notification-system/index_en.htm#objections
- Economic consequences of the revision of the Machinery Directive: costs in terms of man days. Orgalime. 5 July 2004. Available at: http://www.orgalime.org/position/economic-consequences-revision-machinery-directive-costs-terms-man
- Orgalime letter to Mr Brinkhorst. 7 July 2004. Available at: http://www.orgalime.org/position/competitiveness-eu-industry-revision-machinery-directive

A.3.2 Analysis of secondary data

The Steering Group made clear at the kick-off meeting that it expected the evaluation team to work hard to identify and assemble relevant pre-existing *quantitative* evidence, and to use 'hard data' wherever possible to reach conclusions regarding evaluation questions. Thus, a focus of early work was the exploration and identification of available sources of such quantitative information. The logic for such an approach was that any stakeholder consultations to be conducted by the evaluation could then be designed to fill gaps in information and enhance the pre-existing evidence base.

To provide some structure and guidance to a very open exploratory exercise, the study team turned first to the large number of indicators that the task specifications had suggested might be used as a basis for answering the evaluation questions. These covered the following broad areas:

- Economic / sectoral statistics and trade data
- Accident and injury data
- Market surveillance activities and non-compliance data
- National implementation (including infringement) data

Focusing on each of these areas separately, and using the suggestions in the terms of reference as guidance, the study team then undertook a desk-based review of literature, reports, websites and databases to look for relevant (quantitative) data.

It is not practicable here to set out in detail the full extent of the (sometimes laborious and often unproductive) search processes undertaken, or indeed to comprehensively report on all information identified and recorded for later reference. Instead, we focus on detailing the core sources of relevant secondary data that have provided useful and relevant evidence for the evaluation.

Data on production, consumption and trade

As was noted in the Commission's proposal for the 2006 revision to the Directive[76], there are no statistics available specifically relating to the sector(s) covered by the Machinery Directive. Instead, that report made use of statistics on the 'engineering industry', as a broad approximation of the relevant parts of the economy. Similar broad approximations are used for this evaluation.

The scope of the Directive (and therefore the evaluation) is broad, while the exact scope of the Directive is not clearly defined – at least in terms of the standard classifications of sectors and products. There are also certain exclusions and overlaps with other Directives for certain products, further complicating matters of scope. The lack of a clear and exact scope makes it difficult to delineate the parameters of data collection. In relation to production, consumption and trade we therefore used different approximations of the 'MD sector', depending on the data source used:

- The Eurostat structural business statistics (SBS) database[77] uses 2- and 4-digit NACE (Rev. 2) Codes for its annual enterprise statistics, and annual detailed enterprise statistics for industry, respectively. We have taken the NACE Code division C28 (Manufacture of machinery and equipment n.e.c.) and its sub-sectors, as an approximation of the Machinery Directive's scope.
- COMEXT data (trade statistics) uses various nomenclatures. We have used the Combined Nomenclature (CN) classification, and specifically CN Section 16, which covers 'Machinery and mechanical appliances; electrical equipment; parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles'.

In both cases, most machinery within the scope of the Directive will fall within these classifications. However, they are also likely to include some products that are outside of the scope of the Directive. The sub-section below provides more details on these classifications. The context section of this report (Section 5.1) also draws on evidence presented in the recent study on the competitiveness of the EU Mechanical Engineering Industry[78], which also uses the NACE Code division C28 (Manufacture of machinery and equipment n.e.c.) as the basis for its assessment of that sector.

Eurostat Structural Business Statistics (SBS) – NACE (Rev. 2).[79] Structural business statistics (SBS) and global business activities cover industry, construction, trade and services. Presented according to the NACE activity classification, they describe the structure, conduct and performance of businesses across the European Union (EU) – data are available for the EU28/EU27 and for the Member States.

Division 28 - the manufacture of machinery and equipment n.e.c. – most closely aligns with the scope of the Machinery Directive. This division includes the manufacture of machinery and equipment that act independently on materials either mechanically or thermally, or perform operations on materials (such as handling, spraying, weighing or packing), including their mechanical components that produce and apply force, and any specially manufactured primary parts. This includes the manufacture of fixed and mobile or hand-held devices, regardless of whether they are designed for industrial, building and civil engineering, agricultural or home use. The manufacture of special equipment for passenger or freight transport within demarcated premises also belongs within this division. The sub-groups of division 28 distinguishes between the manufacture of special-purpose machinery, i.e. machinery for exclusive use in a NACE industry or a small cluster of NACE industries, and general-purpose machinery, i.e. machinery that is being used in a wide range of NACE industries. This division also includes the manufacture of other special-purpose machinery, not covered elsewhere in the classification, whether or not used in a manufacturing process, such as fairground amusement equipment, automatic bowling alley equipment, etc. This division excludes the manufacture of metal products for general use, associated control devices, computer equipment, measurement and testing equipment, electricity distribution and control apparatus, and general-purpose motor vehicles.

[76] COM/2000/899/Final

[77] http://ec.europa.eu/eurostat/web/structural-business-statistics/overview

[78] An introduction to Mechanical Engineering: Study on the Competitiveness of the EU Mechanical Engineering Industry, 2012

[79] http://ec.europa.eu/eurostat/web/structural-business-statistics/overview

The following table lists the sub-sectors within NACE Code 28 (i.e. 4-digit sub-classification). All of these sub-sectors may include activities within the scope of the Machinery Directive. At the same time, some (if not all) of these sub-sectors will also include activities that fall outside of the scope of the Machinery Directive. One clear example is NACE Code 28.22 (Manufacture of lifting and handling equipment), which covers both lifting equipment considered as machinery (under the MD), as well as lifts for people (which are covered under the Lifts Directive).

Table 77 Eurostat 4-digit NACE Codes within the 'manufacture of machinery and equipment' sector (NC 28)

NACE Code	NACE Description
28.11	Manufacture of engines and turbines, except aircraft, vehicle and cycle engines
28.12	Manufacture of fluid power equipment
28.13	Manufacture of other pumps and compressors
28.14	Manufacture of other taps and valves
28.15	Manufacture of bearings, gears, gearing and driving elements
28.21	Manufacture of ovens, furnaces and furnace burners
28.22	Manufacture of lifting and handling equipment
28.23	Manufacture of office machinery and equipment (except computers and peripheral equipment)
28.24	Manufacture of power-driven hand tools
28.25	Manufacture of non-domestic cooling and ventilation equipment
28.29	Manufacture of other general-purpose machinery n.e.c.
28.3	Manufacture of agricultural and forestry machinery
28.92	Manufacture of machinery for mining, quarrying and construction
28.41	Manufacture of metal forming machinery
28.91	Manufacture of machinery for metallurgy
28.49	Manufacture of other machine tools
28.93	Manufacture of machinery for food, beverage and tobacco processing
28.94	Manufacture of machinery for textile, apparel and leather production
28.95	Manufacture of machinery for paper and paperboard production
28.96	Manufacture of plastics and rubber machinery
28.99	Manufacture of other special-purpose machinery n.e.c.

COMEXT data (trade statistics)[80]. COMEXT data are available according to a number of different nomenclature. We have focused on the Combined Nomenclature (CN) classification system, as this is used by EU Customs authorities and is also based on the international Harmonised System nomenclature. CN Section 16 covers 'Machinery and mechanical appliances' etc. (as above) and has been used as the basis for trade data analysis in this report.

Data on machinery-related accidents and injuries (A&Is)

For evidence on machinery-related accidents and injuries, we draw on two key data sources:

- European Statistics on Accidents at Work (ESAW) – the main collection of data relating to health and safety at work at the European level, which offers data on occupational accidents that result in more than three calendar days of absence from work, including fatal accidents.
- EU Labour Force Survey (LFS) - a large household survey providing data on labour participation, which included ad-hoc modules in 2007 and 2013 on accidents at work resulting in injury.

In both cases, the data are classified by occupation (International Standard Classification of Occupations – ISCO) and by economic activity of the employer (NACE code). In the analysis we have highlighted particular sub-categories that are most relevant to machinery, namely: ISCO categories of 'Plant machine operators and assemblers' and 'Occupations in agriculture and fisheries'; and NACE sectors of 'Agriculture, forestry, fishing', 'Construction' and 'Manufacturing' (and its sub-sectors).

ESAW data (accidents at work)[81]. Due to mandatory reporting requirements, more data are collected on A&Is sustained at work, compared to A&Is sustained at home or during leisure activities. The main

[80] http://epp.eurostat.ec.europa.eu/newxtweb/

[81] http://www.edac.eu/indicators_desc.cfm?v_id=142

collection of data relating to health and safety at work at the European level is the European Statistics on Accidents at Work (ESAW) data set. This offers data on occupational accidents that result in more than three calendar days of absence from work, including fatal accidents. The data are compiled by Eurostat, and can be broken down by categories of occupation (by ISCO - International Standard Classification of Occupations of the International Labour Organisation). The ESAW data publically available on the Eurostat website do not include information on the causative agent of the accident. The statistics refer to declarations made to either public (social security administrations) or private insurance schemes, or to other relevant national authorities. ESAW data generally include cases of road traffic accidents in the course of work, but exclude those during the journey between home and the workplace[82]. It is thought that these accidents may account for about half of all fatal accidents at work. This report draws on data from 2008 onwards. A separate dataset covering the period before 2007 is available, but this is based on NACE Rev. 1.1 classifications, rather than NACE Rev 2 – and so is not directly comparable.

LFS data (accidents at work)[83]. The EU Labour Force Survey (EU LFS) is a large household sample survey providing data on labour participation of people aged 15 and over. The surveys are conducted by the national statistical institutes across Europe and are centrally processed by Eurostat. In 2007 and 2013, the EU LFS included ad-hoc modules which captured information on the number of employed persons who had one or more accidents at work resulting in injuries in the preceding 12 months. The data compiled include broad categories of occupation (by ISCO) and the area of economic activity of the employer (by NACE code). While accidents with less than four days' absence from work are included, fatal accidents at work are not included (unlike in the ESAW data above).

Other accident and injury data. Data on consumer accidents are more difficult to find. An online survey launched by the European Commission in 2014 found that in Europe there are "few significant examples of data collection systems which can establish causal relations between accidents and their consequent injuries, and detect whether such causes are related to faulty or dangerous products or to other circumstances (misuse by users, external causes, etc.)"[84], and there have been various calls for a comprehensive database at the European level. The situation is better addressed in other countries; for example, the Consumer Product Safety Commission (CPSC) in the United States operates the National Electronic Injury Surveillance System (NEISS), described as "a probability sample of about 100 hospitals with 24-hour emergency rooms." NEISS collects data on consumer product related injuries treated in hospital emergency departments and can be used to generate national estimates. The CPSC combine NEISS with other data sources including death records, Market Surveillance Authority intelligence and consumer complaints to develop a better understanding of product safety issues. The Public Health Agency in Canada funds a similar product-related injury surveillance and risk assessment system - Canadian Hospitals Injury Reporting and Prevention Program (CHIRPP). The one noteworthy example identified in Europe that covers consumer injuries (though not exclusively) is the German Federal Institute for Occupational Safety and Health (BAuA), which publishes a yearly report on dangerous products identified.

Market surveillance and Non-compliance information

Member State reporting on market surveillance activities.[85] There are few publicly available data on the level of inspections and the findings of non-compliance specifically related to products falling under the Machinery Directive and across Member States. The Report on the Member States reviews

[82] Note, however, that the UK does not report accidents at work occurring in road traffic during work. http://ec.europa.eu/eurostat/statistics-explained/index.php/Accidents_at_work_statistics

[83] http://ec.europa.eu/eurostat/web/lfs/data/database

[84] Minutes of the meeting of the Consumer Safety Network (CSN) and the Expert Group on the Internal Market for Products – Market Surveillance Group (IMP-MSG), Brussels, Friday 30 January 2015.

[85] Report on the Member States reviews and assessment of the functioning of market surveillance activities for the 2010-2013 period pursuant to Article 18(6) of Regulation (EC) No 765/2008 (Sector 9 Machinery)

and assessment of the functioning of market surveillance activities for the 2010-2013 period – Sector 9 Machinery (henceforth referred to as the "MSA report") does give an indication of the numbers and types of inspections carried out in different Member States with relevance to the machinery sector, and the numbers and types of findings. However, for most countries, the data are not complete, and some data are internally inconsistent (e.g. sub-categories add up to more than the total number indicated). Also, some countries used a different reporting format (e.g. Malta, Estonia) and several do not provide any data at all (e.g. Germany, Spain, the Netherlands). Despite these caveats, we have made use of the data contained within this report in our analysis - although we focus only on the 19 countries with complete datasets for the examined parameters.

RAPEX notifications data (non-compliance alerts)[86]. The RAPEX system is a publicly accessible notification system for non-compliant products posing a serious risk. It has been operating across the EU since 2004. Member States use the system to notify the Commission of measures taken against products posing serious risks (which the Commission then disseminates to other Member States). Following a RAPEX notification, Member States are expected to take action and remove products from market. RAPEX originally only communicated notifications on consumer products. This was widened to include health and safety of professional workers in 2010. RAPEX also covers products posing a risk to other public interests protected via relevant EU legislation, for example, relating to environmental risk; however, none of the 'machinery' notifications fall into this group.

The RAPEX system is the single best source for analysing the incidence rates and origins of non-compliant products over time. However, caution needs to be exercised regarding the interpretation of data, as the RAPEX database has several well-documented limitations. These include the following:

- It is limited in that it predominantly applies to products posing serious and immediate danger. While a section for products posing risks below the 'serious' category was added in 2013, this contains relatively few entries (only eight for the machinery category in 2013-2015 compared to a total of 202 products representing a serious risk). In addition, the database concerns predominantly consumer goods; products used by professional workers were added in 2013, with few entries to date (13 entries for machinery during 2013-2015).
- The data are highly dependent on market surveillance activity. For example, resource constraints linked to the effects of the economic recession are likely to have impacted surveillance activity; also, some Member States (e.g. Greece, Ireland, Slovenia) made significant changes to their market surveillance systems and programmes during the lifetime of RAPEX.
- Reporting may not be evenly applied in all MS, and awareness / use levels have been increasing after its establishment.

The assessment of severity may vary between different MSAs, leading to a RAPEX alert for a given product in some countries but not others. For example, the 2014 study on the internal market for products stated that: "One of the criticisms made by stakeholders is that there is no definition in the Regulation of what constitutes risk, and the criteria to assess it."

We attempted to categorise the RAPEX notifications in the machinery category into nine machinery product groups set out in the task specifications for this study. As the products did not clearly fall into these groups, we had to make some adjustments:

- We included petrol-powered hand tools in the 'electric power tools' group, as they deal with similar risks (cuts, injuries, burns), and renamed the group 'hand-held power tools'. We have also included brush cutters in this category. [Electric power tools carry the additional risk of electric shock, which features prominently in the risk type category (included for 43 of 85 products, but often multiple risk types are indicated).]

[86] http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/index_en.htm

- Some machines, e.g. circular saws, can be hand-guided (power tool group) or fixed to a bench (woodworking machinery group). We examined the image available on the RAPEX notification to determine the most likely fit.
- A large number of notifications related to mini motorbikes, small all-terrain vehicles, and electric bicycles, which we have grouped under 'Mini bike' in this analysis (rather than combining these with other products under 'non-road mobile machinery'). We understand that mini-motorbikes were included under the MD from July 2006 onwards. Since early 2010, "cycles with pedal assistance which are equipped with an auxiliary electric motor having a maximum continuous rated power of 0.25 kW, of which the output is progressively reduced and finally cut off as the vehicle reaches a speed of 25 km/h, or sooner, if the cyclist stops pedaling this is more complicated for electric bicycles" are also included. The different time-frames, along with insufficient description of the product parameters make an analysis of this group difficult. We have excluded four electric bicycles, as the product issues cited were related to the battery only, and the Machinery Directive was not mentioned in the descriptive text.
- A small number of RAPEX notifications (5) did not fit into any of the nine product categories ('Other'). This includes gate closers, an automotive refrigeration unit, and a compressor with pressure vessel and V-belt drive.
- It is not always clear which directive the product fails to comply with. In some cases, there is no statement, in other cases it refers to the Low Voltage Directive only (9). Unless the product was clearly outside the remit of the MD, we have included these cases in our analysis.

Other secondary data sources

Technical Regulation Information System (TRIS)[87]. At the national level, the Technical Regulation Information System (TRIS)[88] enables Member States to notify of their legislative projects regarding products and information society services, allowing others to issue their opinions on the notified draft. It was thought that exploration of this database could provide evidence of Member States introducing specific national laws relating to Machinery that go beyond the Directive, and which may imply additional burdens on firms. The results of this search are mentioned in the main body of the report.

A.3.3 Stakeholder consultation

During the second phase of the evaluation, the study team developed an approach and methodology for the consultation of stakeholders. In line with the task specifications, this involved both public and targeted consultation activities, and employed both questionnaire surveys and semi-structured interviews to collect evidence and input from a range of different stakeholder groups.

Earlier desk-based work had demonstrated that various data and information already existed that went some way to supporting the study's ability to address many of the evaluation questions. However, in most cases such evidence was limited, and often not directly (or solely) related to the Machinery Directive. Often it provided background or contextual evidence that would be useful, but which on its own would be insufficient to fully answer any of the evaluation questions.

As such, the study would need to rely heavily on consultation activities to build on this existing evidence base – both filling the large number of gaps in available information, and in relating this evidence more directly to the Directive. The consultation activities – collectively - therefore needed to address each and every one of the evaluation questions in some form, though with more / less focus in certain areas, depending on the interests, expertise and perspective of the particular stakeholder group concerned. This was to balance the wide-ranging needs of the evaluation, with the time and effort that

[87] http://ec.europa.eu/growth/tools-databases/tris/en/

[88] http://ec.europa.eu/growth/tools-databases/tris/en/

could be requested of any one group or individual. Given the 'reinforced focus' that the evaluation was asked to give to the regulatory (including administrative) costs and benefits triggered by the Directive, and the lack of existing evidence in this area, the study also needed to ensure particularly that relevant data on costs was collected through the different consultation routes.

The task specifications required that at least 286 responses be received through consultations for the evaluation (including both questionnaires and interviews), including replies from competent authorities, standardisation bodies, Notified Bodies, companies and other relevant representative organisations. This should include 40 interviews. These targets were surpassed. Overall there were 342 responses to the public consultation questionnaire and 98 responses to the targeted consultation questionnaires. A small number of respondents (35) replied to both, meaning that the overall number of unique respondents across the surveys was 405, while the total number of responses to questionnaires was 440.

Follow up interviews were also planned with at least 40 stakeholders, from across different groups. These were intended to fill gaps that emerged through the consultation questionnaires and other evidence sources, as well as to explore particular aspects in more depth. Interviews were undertaken with 44 individuals from different groups. These included: 10 individuals from competent authorities and / or market surveillance authorities; 10 individuals from industry associations; 17 individuals from companies that apply the Machinery Directive; 4 individuals from Notified Bodies; and 3 individuals from other organisations (standardisation bodies and a worker's representative).

Appendix B provides further details of the consultation strategy and process, the number and type of stakeholders participating, and the main results of the consultation exercise.

A.4 Limitations and mitigation measures

6.6.1 The scope of the Directive and evaluation

The scope of the Directive, and therefore the evaluation, is broad. It applies to both machinery with consumer and professional / industrial applications, as well as a large number and range of different products. In addition, the exact scope of the Directive is not clearly defined – at least in terms of the standard classifications of sectors and products that are used by other stakeholder organisations or key datasets. There are also various exclusions for machinery already covered by more specific directives, as well as areas where the Machinery Directive applies alongside other Directives – further complicating matters of scope. There are a couple of particular challenges that result. The lack of a clear and exact scope makes it difficult to delineate data collection and consultation activities (what to include / exclude?) – and there is a risk that pre-existing categorisations will not align with the scope of the Directive. There may also be significant variations across the breadth of the Machinery sector, e.g. in the costs, benefits or experiences, which cannot be fully captured within the scope of this study.

The difficulties in defining the exact scope of the Directive are well recognised, and the task specifications included a list of nine product categories in an attempt to summarise some of the main types of machinery covered by the evaluation. However, while this broad categorisation is a useful 'headline' guide, it is not an exhaustive or definitive list. It is also not based on the classification systems used within other data sources. As was noted in the Commission's proposal for the 2006 revision to the Directive[89], there are no statistics available specifically relating to the sector(s) covered by the Machinery Directive. Instead, that report made use of statistics on the 'engineering industry', as a broad approximation of the relevant parts of the economy. Similar broad approximations for the 'Machinery Directive sector' are used for this evaluation – and these vary depending on the data source available and the classification system it uses. The two main classification systems used are:

- NACE Codes: The Eurostat structural business statistics (SBS) database[90] uses 2- and 4-digit NACE (Rev. 2) Codes for its annual enterprise statistics, and annual detailed enterprise statistics

[89] COM/2000/899/Final

[90] http://ec.europa.eu/eurostat/web/structural-business-statistics/overview

for industry, respectively. We have taken the NACE Code division C28 (Manufacture of machinery and equipment n.e.c.) and its sub-sectors, as an approximation of the Machinery Directive's scope. The context section of this report also draws on evidence presented in the recent study on the competitiveness of the EU Mechanical Engineering Industry[91], which also uses the NACE Code division C28 as the basis for its assessment of that sector.

- Combined Nomenclature: COMEXT data (trade statistics) uses various nomenclatures. We have used the Combined Nomenclature (CN) classification, and specifically CN Section 16, which covers 'Machinery and mechanical appliances; electrical equipment; parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles'.

In both cases, most machinery within the scope of the Directive will fall within these classifications. However, they are also likely to include some products that are outside of the scope of the Directive. The section above on data sources provides more details on these classifications.

6.6.2 Secondary data availability and relevance

The evaluation was asked to make the best use of objective evidence, and – as far as possible - to identify and assemble relevant *quantitative* evidence in order to answer most (if not all) evaluation questions. However, the availability of pre-existing quantitative or quantifiable evidence of relevance to the study objectives and questions has proved limited. This was already highlighted by the Steering Group at the kick off meeting (when it was reported that past efforts to identify or obtain data on issues relating to the Machinery Directive had proved difficult and had shown that there is a lack of data readily available), and was further confirmed by preliminary investigations of potential data sources during the inception phase. In particular, the inception report highlighted significant gaps in availability of pre-existing information relating to:

- Accidents and injury data linked to material agent, i.e. type / class of Machinery inflicting the injury,
- Data on the uptake / purchase of harmonised European standards to pursue conformity assessment
- Information on costs triggered by the Directive
- Evidence of take up of different conformity assessment options
- Data on non-compliant products
- Data on market surveillance activity for some Member States (e.g. Germany)

There are also issues regarding the timeframe of data, or its comparability over time / between Member States. Often there is only one data point available, or multiple data points, but the nature of the data collected has changed over time. An example of this is the ESAW data, where until 2005, data collection included a 'material agent' category. There can also be differences in reporting between Member States (e.g. different agencies responsible for accidents at work / in the home; for example, Slovenia only reports cases that have been admitted to hospital in the IDB). The section above on data sources provides more details of the limitations and issues with individual datasets.

It was recognised at the beginning of the study that it would be necessary to make full use of secondary data as a key source of evidence for the evaluation, but also that relevant information would often be difficult to identify and obtain (if at all). With this in mind, the inception phase of the study was mainly focused on undertaking an initial exploration of potential data sources, to better understand availability, applicability, limitations and gaps. This involved an extensive and creative approach, which went beyond basic data sources such as Eurostat or Rapex. It also recognised that incomplete data, as well as estimations, ranges and indicative examples may be the best available sources of evidence, and should not be discounted. Nevertheless, available sources of relevant information were found to be very limited.

[91] An introduction to Mechanical Engineering: Study on the Competitiveness of the EU Mechanical Engineering Industry, 2012

A revision to the original timetable and phasing of the study was proposed, such that the second phase might be used to undertake further desk-based exploration, in order to assemble, interpret and combine the evidence that is available and set out a first analysis against specific evaluation questions. The revision also meant that consultation activities could be planned and undertaken in light of this better understanding of the pre-existing evidence base (or lack thereof). Where it was clear that there was no source of (quantitative) data available or where this is seen as insufficient – for example in the significant gaps listed above - then the evaluation attempted to design the stakeholder consultation activities to obtain relevant evidence, or to build on that already obtained.

6.6.3 Primary data collection

Given the significant gaps in the pre-existing evidence base, the evaluation needed to draw heavily on stakeholder consultation activities in order to address a number of areas of interest. There was still a risk, though, that certain data would neither be readily available (i.e. because of the excessive workload required for stakeholders to collate) nor easily obtainable (i.e. it is distributed, or confidential) through consultation. Flowing from this, were potential challenges in terms of the completeness, comparability or robustness of the information obtained through this route. There was also an associated risk that the various requests for data and information would be too great for the individuals concerned. The evaluation's requirements are extensive, with several objectives and large numbers of questions and sub-questions.

In addition, there was a particular interest in obtaining an in-depth (quantitative) understanding of the various costs and benefits triggered. However, individual actors might be unable or unwilling to provide cost information in any detail. They could also not be expected to spend any significant time finding or calculating precise costs, or providing information that is commercially sensitive. Similarly, if an actor has incurred a particular cost multiple times (e.g. self-certifying a number of different products), they could not reasonably be expected to provide an assessment of these costs for each individual occurrence.

The 2014 Internal Market Legislation study[92] backs up these concerns. This evaluation undertook several in-depth case studies on products that fall within the scope of the Machinery Directive, highlighting a number of issues concerning the availability of data (e.g. companies did not capture all costs relating to conformity assessment, or did not want to share these due to commercial sensitivity). There were also problems with the disaggregation of data (i.e. the cost of conformity assessment pertaining to a single piece of legislation) – especially where products fell under several Directives.

While the study attempted to draw on a wide range of sources, and to use existing evidence to the greatest extent possible, there was still a significant need for additional input through stakeholder consultation, and in particular with the business community. The consultation strategy and tools developed considered the needs of the study (bearing in mind pre-existing evidence) and the full range of relevant stakeholders that might be approached. However, this had to be balanced with the resources available to the study, as well as the time and effort that could be requested of others.

Alongside this, the study took efforts to encourage a good response through ensuring that requests were simple, straightforward and appropriate to those being consulted. The study sought to frame requests in a way that actors felt able and comfortable to (immediately) provide a response (for example broad estimates of costs using averages or ranges rather than exact data). It was also necessary to provide assurances as to how information would be used (i.e. to offer a certain level of anonymity and confidentiality to respondents and the responses they give, and to explain approaches to data collection and sharing). The study team also undertook efforts to introduce and explain the study to various stakeholder groups, in order to encourage buy in and support, as well as working with key representatives (e.g. Orgalime) to gather feedback on the appropriateness of fieldwork tools before any consultation activities were launched.

[92] CSES for DG Enterprise, 2014

6.6.4 The public consultation

The requirement for a public consultation questionnaire introduced additional challenges. Many of the individuals/organisations that might respond would be from stakeholder groups that would also be contacted by other means. There was therefore a risk of survey fatigue, in that stakeholders might be less inclined to contribute to a subsequent (more in-depth) targeted consultation. There was also a risk that some confusion might be caused by multiple consultation methods for the same evaluation. The study team adapted the approach email for the targeted consultations to reduce confusion caused by a second request while the public consultation was still live. We also offered shorter versions of the targeted questionnaires for those who had already completed the public consultation (removing duplicate questions), and explained that this second request would not cover the same ground.

6.6.5 Assessing attribution and causality

The evaluation was asked to focus on the 2006 Directive and not its previous incarnations, and (mainly) on the period since 2010, after the deadline for application of the Directive across Europe. However, there were challenges in maintaining this scope in the practical implementation of the evaluation. While the 2006 Directive represented a comprehensive amendment to the previous version of the Directive, it was still very much building on the system and infrastructures established over decades through previous incarnations of the Directive. There are many aspects of the Directive which are the same as, or similar to, previous versions. As a consequence, observable outputs and outcomes flow not just from the 2006 revision, but from the more general existence of a Machinery Directive over the past 30 years. Also, in line with the New Approach, the Directive only provides a framework, and establishes the mandatory essential health and safety requirements. It does not translate this into detailed requirements or processes. As such, the potential impact of the Directive is more directly a result of 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. These are not the specific subject of the evaluation, but are enabling activities that are in some way directed, encouraged or created by the Directive (and are therefore also addressed within the evaluation questions). These systems of standardisation, conformity assessment and market surveillance would, however, be likely to exist in some form regardless of the existence of the Directive.

There are also issues in trying to disentangle the implications of the Machinery Directive from those incurred as a result of other pieces of legislation, or that would be incurred in any case without he Directive. Similarly, the study needed to be cognisant of significant factors, such as economic downturn (and e.g. implications for the number of inspections).

While we can make clear that we are focused on the 2006 Directive, it is nearly impossible to separate the effects of this version from previous versions of the Directive (e.g. in terms of impacts on trade). There was a particular problem here with regard to the counterfactual, or 'business as usual' analysis. Many interlocutors will not have known (or will remember) a pre-Machinery Directive world. Even when they can, we cannot assume that this would have remained static over the intervening 30 years. The world in 2016 without the Directive, would not look like 1988 without such legislation. Similarly, the absence of the Machinery Directive would not necessarily remove all elements related to it (for example, similar national legislation might exist instead, or the market may drive similar activities around health and safety), but such scenarios are not likely to be well understood and could vary by country or sub-sector. These issues make assessing the added cost/benefit of the Directive, or its European Added Value very difficult. Nevertheless, it is something that we have sought to explore.

Appendix B Stakeholder consultation

B.1 Consultation strategy and process

In line with the task specifications, stakeholder consultation activities during the study involved both public and targeted consultations, and employed questionnaire surveys and semi-structured interviews to collect evidence and input from a range of different groups. Below we outline the methodology employed for the consultation surveys and interviews.

B.1.1 Public consultation

As part of its Better Regulation Agenda, the Commission intends to "listen more closely to citizens and stakeholders throughout the policy lifecycle" through more frequent and effective consultation. This includes providing an opportunity to express views on key elements of evaluations and fitness checks.

The task specifications for the evaluation therefore required the study team (in consultation with the EC) to prepare questionnaires for an online public consultation, which would form one element of the data collection activities employed during the study. The results would feed directly into the study, as well as provide an additional evidence base for the Commission's own reporting.

Based on the details provided in the task specifications for the study, and subsequent clarifications provided by the evaluation Steering Group, the intentions for the public consultation were as follows:

- Target: The intention with a public consultation is that the survey is open to anyone who wants to respond. This includes the 'public' (i.e. individual citizens / consumers / workers), but also businesses, public authorities and any other organisations who wish to contribute. It was agreed at the kick-off meeting for the study that the Commission would promote the consultation through different communication channels, including the EUROPA webpage and CIRCABC system.
- Format: While the public consultation is open to anyone, preliminary questions need to be used to differentiate between different types of respondents. The task specifications suggested that each respondent might be faced with 10 to 30 questions in total.
- Language: The questionnaire itself would be drafted in English, but then translated by the Commission Services into five additional EU languages. Similarly, the answers received would be translated into English (where necessary), before being forwarded to the contractor for analysis.
- Implementation: The consultation would be hosted online by the European Commission on the 'Your Voice in Europe' portal. The minimum time period for public consultations is 12 weeks (or more, if run during holiday periods).
- Scope and focus: The Steering Group made a number of suggestions in relation to the scope and focus of the public consultation questionnaire, which were taken into account in its drafting:
  - It should address stakeholder perceptions and appreciation in relation to the Directive
  - It should focus on experiences, rather than inviting general views (e.g. on relevance)
  - It should be as specific and precise as possible
  - It should employ mainly closed questions with possibility to explain
  - It should take account of the broad and (potentially) non-specialised nature of respondents
  - It should seek information that is not readily available elsewhere

A draft of the consultation questionnaire was provided by the study team within the first progress report of the study. This questionnaire was subsequently amended by the Commission before being uploaded to its survey platform and launched on 22nd September 2016. The public consultation was then closed at the end of December 2016 and results downloaded. The Commission provided translated versions of each response as individual pdfs in January 2017. Response numbers have been combined with the targeted consultations, and are reported later in this appendix.

B.1.2 Targeted survey consultations

The task specifications for the evaluation required the study team to undertake targeted consultations, which would provide more detailed and technical knowledge from certain stakeholders. These would be undertaken initially via survey, to be designed and conducted by the contractor, with input from the Commission. In addition, the contractor was asked to conduct interviews with at least 40 individuals, clarifying and building on answers provided through surveys (detailed separately below).

The public consultation was therefore complemented by a series of targeted consultations run by the study team. These would employ (initially) questionnaire surveys to consult in more detail with selected key stakeholders from all main groups. The study team's proposal was that the targeted consultation would include survey questionnaires addressed to:

- All 30+ Competent Authorities (responsible for implementation of the Directive and market surveillance activities in each country)
- All ~180 Notified Bodies approved to undertake conformity assessment under the MD
- All relevant international, European and national industry associations
- All relevant companies applying the Machinery Directive

Through these routes the study expected to be able to achieve the 250 responses required in the task specifications, as well as a good number of responses from each of the target groups outlined.

The public consultation questionnaire (see above) was designed to address most of the evaluation questions, but in a reasonably high-level manner (so as to be applicable to all groups, and achieve brevity in the questionnaire). The targeted consultation questionnaires were designed to address the same types of questions, but with more / less focus in certain areas, depending on the interests, expertise and perspective of the group concerned. Draft questionnaires were developed for the various target groups and presented as part of the first progress report for comment and approval. Final versions were then put online and tested internally. Copies are shown later in this appendix.

The targeted consultations were announced directly by the study team to known individuals and representatives within each stakeholder group during October 2016. We emailed directly 183 Notified Bodies, 33 national authorities - including those responsible for implementation of the Directive and / or for market surveillance activities (using a list of appropriate contacts provided by the Commission), and 41 European industry associations. The industry associations were also asked to pass our request on to their members – national associations and companies - so as to reach out to this broader group. A total of 257 stakeholders were contacted directly for the targeted consultations, with unknown numbers of others informed through industry associations.

The study team was on hand to deal with questions with regard to the survey and also created Word versions of each questionnaire following requests from stakeholders for copies that could be shared and answered collectively (e.g. at relevant working group within industry associations). Technopolis also attended a meeting of the Orgalime working group on machinery at the end of October 2016 in order to promote the surveys, encourage distribution of our request to other associations and companies, and to answer queries regarding both the public and targeted questionnaires.

Because of simultaneous requests for responses to quite substantial questionnaires, industry associations explained that a couple of months would be needed to provide input (allowing time for discussion at pre-arranged association meetings). The study team agreed with the Commission that both the public and targeted questionnaires would therefore run through to the end of December 2016.

B.1.3 Programme of interviews

Follow up interviews were also planned with at least 40 stakeholders, from across different groups. These were intended to fill gaps in understanding that emerged through the consultation questionnaires and other evidence sources, as well as to explore particular aspects in more depth. As such, no formal interview guide was used and each interview explored different aspects of interest.

B.2 Consultation responses

The total number of responses by stakeholder group, across the public and targeted consultations are shown in the table below. The task specifications required that at least 286 responses be received through consultations for the evaluation (including both questionnaires and interviews), including replies from competent authorities, standardisation bodies, Notified Bodies, companies and other relevant representative organisations. This should include 40 interviews.

These targets were surpassed. Overall there were 342 responses to the public consultation questionnaire and 98 responses to the targeted consultation questionnaires. A small number of respondents (35) replied to both, meaning that the overall number of unique respondents across the surveys was 405 (as shown in Table 78 below), while **the total number of responses to questionnaires was 440**. All identified stakeholder groups were reached through one or other consultation route.

Table 78 Respondents to consultations, by stakeholder group and consultation route

Stakeholder Group	PC	TC	Both	Total
National authority (implementing body / market surveillance)	17	8	2	27
Notified Body	13	9	3	25
Industry Association	25	24	17	66
Industry	146	22	13	181
Workers / consumers and their representatives	68	0	0	68
Consultancy / service provider relating to Machinery safety	31	0	0	31
Standardisation body	1	0	0	1
Unknown	6	0	0	6
Total	**307**	**63**	**35**	**405**

Machinery Directive Public Consultation and Targeted Consultations

Respondents to the questionnaires included:

- 27 national authorities, including 16 that were (also) responsible for undertaking market surveillance activities in relation to the Machinery Directive.
- 25 Notified Bodies.
- 66 industry associations. They each represented between one and over 30,000 members, with 1,600 each on average. Total membership of responding industry associations is calculated to be in excess of 93,000 organisations (mostly companies, and some national/sectoral associations).
- 181 industry respondents. The vast majority (162) *manufacture* machinery, while the remainder only purchase machinery. Two-thirds of industry respondents were single enterprises, with the remainder being part of a larger group. They were relatively evenly split between SMEs (44%) and larger companies (56%).
- 38 workers who use machinery and nine organisations representing workers
- 19 consumers / citizens and two organisations representing consumers.
- 38 Other individuals. These were mostly (31) consultancies and service providers working in the area of machinery safety, but also one national standardisation body and six individuals with unknown affiliation.

Respondents to the public and targeted questionnaires were based in 23 EU Member States (excluding HU, LT, LU, SK, SI), as well as three of the four EFTA countries (excludes IS). There was also 1 respondent from each of Canada, the US and Japan. The greatest numbers of survey respondents were based in Germany (123), Switzerland (41), the UK (39), Italy (30) and France (28). These countries (if we exclude Switzerland) have the largest machinery sectors in Europe (in terms of numbers of businesses), and together accounted for 58% of enterprises in the manufacture of machinery and equipment sector in 2014. In addition, 30 respondents were based in Belgium, but this total includes mostly European Industry Associations based in Brussels. All other countries had 20 or fewer respondents to the surveys. The much smaller number of interviewees were spread across 10 EU Member States and 1 EFTA country.

The full breakdown of respondents to the questionnaire surveys, by country and by stakeholder group, is shown in Table 79.

Table 79 Respondents to consultations, by stakeholder group and country

Country	Nat. Auth.	Ind. Assoc.	Ind.	NB	Worker/ Consumer	Consultant/ Service provider	Other / Unknown	Total	
Austria	0	2	7	1	5	2	1	**18**	4.4%
Belgium (incl. EU)	0	18	6	0	4	1	1	**30**	7.4%
Bulgaria	0	1	0	1	0	0	0	**2**	0.5%
Croatia	1	0	0	0	0	0	0	**1**	0.2%
Cyprus	1	0	0	0	0	0	0	**1**	0.2%
Czech Republic	1	0	0	2	0	0	0	**3**	0.7%
Denmark	1	2	6	0	4	0	0	**13**	3.2%
Estonia	1	0	2	1	0	0	0	**4**	1.0%
Finland	1	1	3	1	1	1	0	**8**	2.0%
France	0	6	14	1	5	1	1	**28**	6.9%
Germany	6	5	74	6	24	7	1	**123**	30.4%
Greece	1	0	0	1	0	0	0	**2**	0.5%
Hungary	0	0	0	0	0	0	0	**0**	0.0%
Ireland	0	0	1	0	1	0	0	**2**	0.5%
Italy	0	6	10	2	4	7	1	**30**	7.4%
Latvia	0	0	0	1	0	0	0	**1**	0.2%
Lithuania	0	0	0	0	0	0	0	**0**	0.0%
Luxembourg	0	0	0	0	0	0	0	**0**	0.0%
Malta	2	0	0	0	0	0	0	**2**	0.5%
Netherlands	0	2	8	0	5	4	1	**20**	4.9%
Poland	2	0	0	0	1	0	0	**3**	0.7%
Portugal	0	0	0	2	1	1	0	**4**	1.0%
Romania	1	0	0	0	1	0	0	**2**	0.5%
Slovakia	0	0	0	0	0	0	0	**0**	0.0%
Slovenia	0	0	0	0	0	0	0	**0**	0.0%
Spain	0	2	1	1	1	0	1	**6**	1.5%
Sweden	1	3	2	0	1	1	0	**8**	2.0%
United Kingdom	1	13	12	3	6	4	0	**39**	9.6%
Iceland	0	0	0	0	0	0	0	**0**	0.0%
Liechtenstein	0	1	1	0	0	0	0	**2**	0.5%
Norway	1	0	0	0	0	0	0	**1**	0.2%
Switzerland	5	1	28	2	4	1	0	**41**	10.1%
Turkey	0	0	0	0	0	0	0	**0**	0.0%
Other	0	0	3	0	0	0	0	**3**	0.7%
Unknown	1	3	3	0	0	1	0	**8**	2.0%
Total	**27**	**66**	**181**	**25**	**68**	**31**	**7**	**405**	
	6.7%	16.3%	44.7%	6.2%	16.8%	7.7%	1.7%		

Source: Machinery Directive Public Consultation and Targeted Consultations

While a significant number of SMEs (<250 employees) responded to the surveys (they accounted for nearly half (46%) of all industry respondents to the public and targeted consultations), this is still substantially lower than the proportion of enterprises in the 'manufacture of machinery and equipment' sector that are SMEs (98%). SMEs may therefore be under-represented in responses. However, a large number of industry associations have also been consulted, most of whom represent a wide range of businesses of different sizes, from SMEs to large multi nationals.

Interviews were undertaken with 44 individuals from different groups. These included:

- 10 individuals from competent authorities and / or market surveillance authorities
- 10 individuals from industry associations
- 17 individuals from companies that apply the Machinery Directive
- 4 individuals from Notified Bodies
- 3 individuals from other organisations (standardisation bodies and a worker's representative)

Lists of individual interviewees are provided in the tables below.

Table 80 Competent authorities / market surveillance authorities

Name	Job title / role	Organisation Name	Country
Michał GÓRNY	Technical inspection - Machinery and ATEX Directives	Urząd Dozoru Technicznego	Poland
Kevin LANE	Product safety team, regulatory delivery	Department for Business, Energy and Industrial Strategy BEIS	UK
Richard SAARMAN	Chief Specialist	Estonian Technical Regulatory Authority	Estonia
Fabian KRATZKE	Advisor	Regierungspräsidium Tübingen	Germany
Peter HAAS	Department of market Surveillance Authority	SUVA	Switzerland
Robert PLECHINGER	Deputy head of unit on technical market (Machinery Directive and horizontal market surveillance)	MSA for Bavaria	Germany
Marie Laurence GUILLAUME	Head of Sector for market surveillance. Lead for Machinery.	Directorate General of Work (technical directorate) within the Labour Ministry.	France
Isabelle MAILLARD			
Roger UPFOLD	HM Inspector of Health and Safety	UK Health and Safety Executive HSE	UK
Norman LYONS	Manufacturing Sector	Health and Safety Executive Northern Ireland HSENI	UK

Table 81 Industry associations

Name	Job title / role	Organisation Name	Country
Urs MEIER	Lawyer (EU Technical Law)	Swissmem	Switzerland
Bert NAGTEGAAL	Regulation and standardisation manager	FME- Federation of enterprises in the technological industrial sector	Netherlands
Shinya SASAKI	Policy manager	JBCE (Japan Business Council in Europe)	Belgium
Eleonore VAN HAUTE	Secretary General	EGEA Association	Italy
Neil PATTEMORE			
Fausto MANGANELLI			
John MORTELL	Technical and Regulatory Affairs Manager	EUROMOT	Belgium
Charles TOLLIT	Director General (outgoing)	EPTA - European Power Tool Association	Belgium
Josef ORTOLF	Director General (incoming)		
Gerhard STEIGER	Managing Director	VDMA	Germany

Table 82 Industry

Name	Job title / role	Organisation name	Country
Orio SARGENTI	Conformity & Standards Manager	GF Machining Solution - BU EDM	Switzerland
Vincent THEVENET	Technical & Innovations Director	ASCOREL (ASCOTRONICS)	France
John DE SMIT	Managing Director	BKL Engineering BV	Netherlands
Hannes HAUSBICHLEDR	team leader mechanical design	Dividella AG	Switzerland
Dina KOEPKE	Governmental Affairs	Emerson Climate Technologies GmbH	Belgium
Alfred LENNERTZ	Regulatory Adviser		
Wilco DE GROOT	Managing Director	IGT Testing Systems	The Netherlands
Esfandiar GHARIBAAN	Vice President for Codes and Standards	KONE Corporation	Finland
Lukas BALDAUF	Safety & Documentation	LTW Intralogistics GmbH	Austria
Johannes SCHWARTZE			
Annette SCHÖNBERNER	Documentation/CE Representative	Oerlikon Balzers	Germany
Thomas ZWATZ	CAD/PDM Administration	PÖTTINGER Landtechnik GmbH	Austria

Name	Job title / role	Organisation name	Country
Volker SCHABER	Standardization and Regulations	SICK AG	Germany
Otto GÖRNEMANN			
Falko FEURSTEIN	Head of electrical department	Starrag AG	Switzerland
Chris YOUNG	Senior Production Engineer	Calsonic Kansei - ISA	UK
Albert GRUENINGER	Product compliance (product safety)	Trumpf	Germany

Table 83 Notified Bodies

Name	Job title / role	Organisation Name	Country
Peter MCNICOL	Managing director	Safenet	UK
Daniele PAOLI	Machinery Manager	SGS	UK
Gregor STUPP	Certifier	TÜV Rheinland LGA Products GmbH	Germany
Pierre BELINGARD	Coordinator of Notified Bodies for Machinery in France.	Eurogip - Coordination des Organismes Notifiés français	France

Table 84 Other stakeholders

Name	Job title / role	Organisation Name	Country
Stefano BOY	Senior Research, Health and Safety, Working Conditions	ETUI - European Trade Union Institute	Brussels
Joanna FRANKOWSCA	Sector Manager, Machinery	CEN	Brussels
Geert MAES	Senior Manager, Standards (Industry and Infrastructure)	CEN/CLC	Brussels

It should be noted that consultation results represent the views of those that chose to respond. The consultation strategy (approved as part of the first progress report for the study) sought to ensure that anyone that wished to contribute to the evaluation could do so (through the public consultation questionnaire), while efforts could also be taken to achieve a significant number of contributions from particular stakeholder groups (through the targeted consultation questionnaires and interviews).

B.3 Targeted consultation questionnaires

Presented below are the questionnaires used for the online targeted surveys of different stakeholder groups (competent authorities, notified bodies, industry associations and industry). The longer versions are presented. Shorter alternatives were also available for individuals who had already participated in the public consultation (with certain duplicative questions removed).

B.3.1 Questionnaire for Competent Authorities and Market Surveillance Authorities

Welcome

19. Please confirm whether or not your organisation has submitted a response to the public consultation on the Machinery Directive.

	Yes – We have submitted a response to the Public Consultation	*Please refer to alternative version of survey*
	No – We have not submitted a response to the Public Consultation	
	Don't know	

About you and your organisation

All responses and associated personal information will be treated in the strictest confidence, in line with EU legislation on data protection. You are asked to provide your name and organisation name only so that we can provide a list of contributors to the evaluation within the final report. Please leave these fields blank if you do not wish to be identified. Other inputs provided through this survey will only be presented and shared in an aggregate and anonymised way.

20. Please provide the following information about yourself and your organisation:

Your name	
Your job title / role	
Your organisation's name	
Country	

The Aims of the Machinery Directive

21. In your opinion, how important are the following objectives of the Machinery Directive?

	Not at all important	Slightly important	Moderately important	Very important	Don't know
Ensuring the free movement of machinery within the European Single Market					
Ensuring a high level of heath safety for users of machinery (workers and consumers)?					
Protecting the environment in relation to machinery for pesticide / herbicide application?					

22. In your experience, to what extent is the Machinery Directive (i.e. its scope and provisions) an appropriate means to contribute towards the following objectives?

	Not at all appropriate	Somewhat appropriate	Entirely appropriate	Don't know
Ensuring the free movement of machinery within the European Single Market				
Ensuring a high level of heath safety for users of machinery (workers and consumers)?				
Protecting the environment in relation to machinery for pesticide / herbicide application?				

The relevance and appropriateness of the Machinery Directive

23. Thinking specifically about the 2006 revision to the Machinery Directive (which applied from the end of 2009)... To what extent do you feel that it:

	Not at all	To a small extent	To a moderate extent	To a large extent	Entirely	Don't know
Took account sufficiently of new **innovations and new technologies** at the time?						
Has been able to deal with new innovations and new technologies since?						
Is likely to be able to deal with new innovations and technologies over the next 10 years?						

24. Similarly, to what extent do you feel that this revision to the Directive:

	Not at all	To a small extent	To a moderate extent	To a large extent	Entirely	Don't know
Sufficiently took account of recent **changes in the business environment** (i.e. in the machinery sector / market / trade) at the time?						
Has been able to deal with changes in the business environment since?						
Is likely to be able to deal with changes to the business environment over the next 10 years?						

25. Can you point to particular areas where the Machinery Directive – its provisions and requirements - has / will not be fit for purpose, and explain why?

For innovations / new technologies (e.g. robotics, Industry 4.0, Internet of Things):	
For changes in the business environment:	

Clarity of the Directive

26. How would you rate the level of knowledge and understanding amongst stakeholders in your country of:

	Very poor	Poor	Good	Very Good	No opinion
The scope of the Directive (in terms of the machinery products covered)					
The essential health and safety requirements specified by the Directive in Annex I					
The requirements / obligations on organisations					
Obligations in case of modifications and refurbishment of machinery					

27. How would you rate the European Commission's 'Guide to Application of the Machinery Directive' as an aid to understanding the Directive?

No aware of it	Have never used it	Very poor	Poor	Good	Very good

28. Please briefly describe any activities that you undertake to support knowledge and understanding of the Machinery Directive and its implications:

29. Please estimate the effort (FTE days) that your organisation devotes each year to the Machinery Directive? This might include monitoring / participating in committees, informing or advising your members, or other activities.:

Interpretation of the Directive

30. To what extent do you believe that the following aspects of the Machinery Directive have been fully and consistently interpreted and applied across Europe?

	Not at all	To a small extent	To a moderate extent	To a large extent	Entirely	No opinion
The transposition of the Directive into national legislation						
The conformity assessment procedures available to companies						
The appointment of Notified Bodies to carry out conformity assessment						
The assessments undertaken by Notified Bodies						
The suspension, withdrawal or placement of restrictions on certificates issued						
The approach of Market Surveillance Authorities to determining compliance						
The number of market surveillance activities						
The establishment of effective, proportionate and dissuasive penalties for infringements						
Not prohibiting, restricting or impeding machinery that complies with the Directive						
Taking measures to withdraw / prohibit machinery that may compromise health and safety						

31. Please detail any particularly problematic areas that you are aware of in terms of different interpretations of the Directive, and explain what the implications of this have been:

Conformity Assessment

The Machinery Directive offers the choice of up to three different **conformity assessment** procedures, depending on the machinery in question (whether it appears in the Annex IV list of products considered to present higher risks) and on the use of harmonised standards.

32. If you are aware of these conformity assessment options, how would you rate the effectiveness of each, from the perspective of: (i) facilitating the internal market for machinery (e.g. ability to export to other countries); (ii) protecting the health and safety of machinery users?

In each case, select from: Very effective; Moderately effective; Slightly ineffective; Not effective; No opinion	Facilitating the internal market	Protecting health and safety
Assessment of conformity with internal checks (non-Annex IV products):		
Assessment of conformity with internal checks (Annex IV products) using harmonised standards		
EC-type examination (Annex IV products)		
Approval by a Notified Body of a full quality assurance system (Annex IV products)		

33. Can you point to particular problems with any of these options that might reduce overall levels of take up of the option, or its effectiveness:

Assessment of conformity with internal checks (non-Annex IV products):	
Assessment of conformity with internal checks (Annex IV products) using harmonised standards	
EC-type examination (Annex IV products)	
Approval by a Notified Body of a full quality assurance system (Annex IV products)	

Harmonised European Standards - Development

In order to prove conformity to the essential health and safety requirements of the Directive, manufacturers can make use of technical specifications (standards). **Harmonised standards** at the European level support the application of the directive by translating the essential health and safety requirements into detailed requirements for certain types of products.

34. Has your organisation **contributed to the development** of European harmonised standards in support of the Machinery Directive? *(tick all that apply)*

	Yes, through direct participation in European technical committees or working groups
	Yes, through national mirror committees or national standards body
	No, we have contributed to the development of such standards
	Don't know

35. Please estimate the total staff time (FTE effort) that your organisation has incurred in the past year in relation to the development of European harmonised standards for the machinery Directive:

	Total Staff time (FTE effort)
Contributing to the development of European harmonised standards	
Monitoring / following the development of European harmonised standards	

36. Please estimate other costs (€) that your organisation has incurred in the past year in relation to the development of European harmonised standards for the machinery Directive:

	Other Costs (€)
Contributing to the development of European harmonised standards	
Monitoring / following the development of European harmonised standards	

37. Can you point to any particular advantages and disadvantages of using European Harmonised Standards, compared with other technical specifications?

Advantages:	
Disadvantages:	

Harmonised European Standards – Your Assessment

38. How would you rate the following aspects relating to European Harmonised Standards supporting the Machinery Directive?

	Very poor	Poor	Good	Very Good	Don't know
The length of the European Harmonised Standards development process					
The involvement of industry in the development of European Harmonised Standards					
The scope and coverage of the current portfolio of European Harmonised Standards					
The frequency with which existing European Harmonised Standards are reviewed / revised					
The extent European Harmonised Standards are up-to-date with technological developments					
The quality / usability of existing European Harmonised Standards					
The clarity over which European Harmonised Standards can be used					
The availability of European Harmonised Standards for new innovative products					

39. Please provide further explanation of any areas you have rated as (very)poor:

40. Please highlight any particular gaps in the current coverage of Harmonised Standards in supporting the application of the Machinery Directive (i.e. missing or insufficient standards):

Market Surveillance and Penalties

The Directive requires Member States to take all appropriate measures to ensure that machinery may be placed on the market / put into service only if it satisfies the relevant provisions of the Directive, and should establish an authority for **monitoring** conformity of machinery, as well as effective, proportionate and dissuasive **penalties** for infringements.

41. What are your views on current levels of monitoring activity in relation to:

In each case, select from: Too low; About right; Too large; Don't know	In your country	Across Europe
The number and frequency of inspections carried out		
The likelihood of an individual company being inspected		
The typical time from market entry to inspection / assessment		
The number of products on the market that have never been assessed		
The number of products on the market that are non-compliant		

42. How effective do you believe national authorities are in relation to:

In each case, select from: Not at all; To a limited extent; To a moderate extent; To a large extent; Entirely; Don't know	In your country	Across Europe
Identifying non-compliant products		
Removing non-compliant products from the market		

43. Can you point to specific problems or barriers to:

The effective identification of non-compliant products:	
The removal of non-compliant products from the market:	

44. Can you highlight countries that are particularly effective / ineffective at identifying and removing non-compliant products, and explain your choice:

Very effective country	
Very ineffective country	

Benefits and impacts of the Machinery Directive

45. In your opinion, what has been the impact of the Directive in the following areas (which relate to **market efficiency**)?

	Very negative	Negative	None	Positive	Very positive	Don't know
The costs and burdens on businesses						
The costs and burdens on consumers						
The range of machinery products available						
The quality of machinery products available						
Information and instructions relating to the safe operation of machinery						
The rate and extent of innovation in the sector						
Turnover and profitability of the European machinery sector / businesses						
The international competitiveness of the European machinery sector / businesses						
The volume / value of intra-EU trade in Machinery						
Barriers to the internal market / free movement of machinery						

46. In your opinion, what has been the impact of the Directive in the following areas (which relate to **improved well-being**)?

	Very negative	Negative	None	Positive	Very positive	Don't know
The level of user confidence in machinery safety						
The number of machinery-related accidents and injuries						
The severity of machinery-related accidents and injuries						
The number of un-safe / non-compliant machines on the market / in use						
The level of safety / protection for users of machinery (workers / consumers)						
The environment						

47. Please provide any further explanation you would like to give in relation to the impact of the Directive.

Contributions of the Machinery Directive

48. Could you give a specific example of where the Machinery Directive has had:

A significant positive influence on innovation	
A significant negative influence on innovation	

49. Overall, to what extent do you believe the Machinery Directive has contributed towards:

	Not at all	To a small extent	To a moderate extent	To a large extent	Don't know
An effectively operating internal market for the products in its scope?					
Protecting the health and safety of consumers and users of the products in its scope?					
Protecting the environment, for the products in its scope					

50. Are there any negative impacts of the Directive on your organisation, beyond any direct compliance costs that it might trigger:

Comparing costs and benefits

51. To what extent are the costs triggered by the Directive proportionate, given the benefits for:

	Benefits significantly outweigh costs	Benefits slightly outweigh costs	Benefits and costs are equal	Costs slightly outweigh benefits	Costs significantly outweigh benefits	Don't know
Your organisation						
Your country						
Europe more generally						

52. Are there particular aspects / areas that you would highlight where the costs are disproportionate?

53. Are there areas of the Directive's application that could be made more efficient? Please explain

54. Are there areas of the Directive's application, where the burden on your organisation could be reduced?

Coherence of the Directive with other legislation

55. To what extent does the Machinery Directive fit with other legislation?

	Not at all	To a small extent	To a moderate extent	To a large extent	Don't know
With national legislation					
With other EU legislation (e.g. other product Directives)					
With international (non-EU) legislation					

56. If you are aware of any overlaps or inconsistencies with other legislation, please can you describe these briefly, and what the implications are:

European added value

57. To what extent does the Machinery Directive achieve more than would be achieved otherwise (i.e. in its absence), in terms of:

	Not at all	To a small extent	To a moderate extent	To a large extent	Don't know
Facilitating the free circulation of machinery within the internal market					
Ensuring a high degree of health and safety of machinery					
Ensuring environmental protection in relation to machinery used in pesticides					
Reducing costs					
Reducing disparities between Member States					
Other areas of added value (please specify)					

Future improvements

58. What one area of implementation / application of the current Directive do you believe could / should be improved? How and why?

59. What one area could / should a future revision to the Directive aim to address? Why?

Market Surveillance Authorities

60. Is your organisation responsible for undertaking market surveillance activities in relation to the Machinery Directive?

Yes	*Please continue*
No	*Please skip to the final question*
Don't know	*Please skip to the final question*

About your market surveillance authorities

61. Please indicate the coverage of your market surveillance remit in terms of:

Geographical scope	
Product scope	
Imports / exports / domestic	

62. Approximately, what proportion of your organisation's market surveillance activity relates to products that fall within the scope of the Machinery Directive?

63. What drives the pattern of your market surveillance activity in relation to machinery?

	Not at all	Minor influence	Major influence
Government policy			
Previous inspections			
Complaints			
Accident reports			
RAPEX (rapid alert system for non-food dangerous goods)			
ICSMS (Information and Communication System for Market Surveillance systems)			
Joint market surveillance programmes (e.g. PROSAFE Joint Actions)			
Other (please specify)			

Market surveillance activity in relation to the Machinery Directive

64. To the best of your ability, please estimate for the latest available year:

The total number of inspections carried out that fall within the scope of the Machinery Directive	
… Of which, proactive (e.g. targeting of particular product categories)	
… Of which, reactive (e.g. in response to a complaint / accident)	

65. Please estimate the total staff time (FTE effort) and other costs (€) that your organisation incurred in relation to these machinery-related inspections (i.e. the annual total)

FTE effort (days)	
Other costs (€)	

Trends in market surveillance activity

66. Over the past five years, has the number of inspections tended to:

Increase significantly	Increase slightly	Remain approximately the same	Decrease slightly	Decrease significantly

67. What are the reasons behind any trends?

68. What have been the implications of any decrease in activity?

Non-Compliance

69. To the best of your ability, please estimate for the latest available year the proportion of inspected machinery products that are found to be non-compliant:

70. Of these non-compliance findings, approximately what proportion are due to:

Issues with documentation	
Technical issues	
Issues with CE marking	
Other (please specify)	

71. Also, of these non-compliance findings, approximately what proportion resulted in:

Voluntary measures	
Compulsory measures	
Withdrawal from market	
Recall from market	
Recall from consumers	

72. Are there any particular types of product or business that are over-represented in terms of non-compliance? What is the possible reason for this?

73. Are there particular areas where (you suspect) greater levels of market inspection are needed?

RAPEX

74. Please rate the RAPEX system on the following aspects

	Very poor	Poor	Adequate	Good	Very good
Its ease of use (in notifying)					
Its ease of use (in monitoring others' notifications)					
Its completeness (in terms of non-compliant findings recorded)					
Action taken as a result of notifications					

Final questions

75. If you would be willing to have a follow up discussion to explore your answers in more detail, please provide your contact details below (these will not be used for any other purpose):

Telephone number	
Email address	

B.3.2 Questionnaire for Notified Bodies

Welcome

76. Please confirm whether or not your organisation has submitted a response to the public consultation on the Machinery Directive.

	Yes – We have submitted a response to the Public Consultation	*Please refer to alternative version of survey*
	No – We have not submitted a response to the Public Consultation	
	Don't know	

About you and your organisation

All responses and associated personal information will be treated in the strictest confidence, in line with EU legislation on data protection. You are asked to provide your name and organisation name only so that we can provide a list of contributors to the evaluation within the final report. Please leave these fields blank if you do not wish to be identified. Other inputs provided through this survey will only be presented and shared in an aggregate and anonymised way.

77. Please provide the following information about yourself and your organisation:

Your name	
Your job title / role	
Your country of residence / work	
Your organisation's name	

78. Is your organisation approved to undertake each of the following in relation to the Machinery Directive:

	EC-type examination (Annex IX)
	Approval of Full Quality Assurance System (Annex X)

79. Could you estimate the total staff time (FTE effort) that your organisation has incurred in the past five years in relation to:

Applying and being assessed to become a body notified under the Machinery Directive?	
Ongoing monitoring by the authorities of your organisation as a body notified under the Machinery Directive?	

80. Could you estimate the other costs (€) that your organisation has incurred in the past five years in relation to:

Applying and being assessed to become a body notified under the Machinery Directive?	
Ongoing monitoring by the authorities of your organisation as a body notified under the Machinery Directive?	

The Aims of the Machinery Directive

81. In your opinion, how important are the following objectives of the Machinery Directive?

	Not at all important	Slightly important	Moderately important	Very important	Don't know
Ensuring the free movement of machinery within the European Single Market					
Ensuring a high level of heath safety for users of machinery (workers and consumers)?					
Protecting the environment in relation to machinery for pesticide / herbicide application?					

82. In your experience, to what extent is the Machinery Directive (i.e. its scope and provisions) an appropriate means to contribute towards the following objectives?

	Not at all appropriate	Somewhat appropriate	Entirely appropriate	Don't know
Ensuring the free movement of machinery within the European Single Market				
Ensuring a high level of heath safety for users of machinery (workers and consumers)?				
Protecting the environment in relation to machinery for pesticide / herbicide application?				

The relevance and appropriateness of the Machinery Directive

83. Thinking specifically about the 2006 revision to the Machinery Directive (which applied from the end of 2009)… To what extent do you feel that it:

	Not at all	To a small extent	To a moderate extent	To a large extent	Entirely	Don't know
Took account sufficiently of new **innovations and new technologies** at the time?						
Has been able to deal with new innovations and new technologies since?						
Is likely to be able to deal with new innovations and technologies over the next 10 years?						

84. Similarly, to what extent do you feel that this revision to the Directive:

	Not at all	To a small extent	To a moderate extent	To a large extent	Entirely	Don't know
Sufficiently took account of recent **changes in the business environment** (i.e. in the machinery sector / market / trade) at the time?						
Has been able to deal with changes in the business environment since?						
Is likely to be able to deal with changes to the business environment over the next 10 years?						

85. Can you point to particular areas where the Machinery Directive – its provisions and requirements - has / will not be fit for purpose, and explain why?

For innovations / new technologies (e.g. robotics, Industry 4.0, Internet of Things):	
For changes in the business environment:	

Clarity of the Directive

86. To what extent is each of the following aspects of the Machinery Directive clear to you?

	Very poor	Poor	Good	Very Good	No opinion
The scope of the Directive (in terms of the machinery products covered)					
The essential health and safety requirements specified by the Directive in Annex I					
The requirements / obligations on organisations					
Obligations in case of modifications and refurbishment of machinery					

87. How would you rate the European Commission's 'Guide to Application of the Machinery Directive' as an aid to understanding the Directive?

Not aware of it	Have never used it	Very poor	Poor	Good	Very good

Interpretation of the Directive

88. To what extent do you believe that the following aspects of the Machinery Directive have been fully and consistently interpreted and applied across Europe?

	Not at all	To a small extent	To a moderate extent	To a large extent	Entirely	No opinion
The transposition of the Directive into national legislation						
The conformity assessment procedures available to companies						
The appointment of Notified Bodies to carry out conformity assessment						
The assessments undertaken by Notified Bodies						
The suspension, withdrawal or placement of restrictions on certificates issued						
The approach of Market Surveillance Authorities to determining compliance						
The number of market surveillance activities						
The establishment of effective, proportionate and dissuasive penalties for infringements						
Not prohibiting, restricting or impeding machinery that complies with the Directive						
Taking measures to withdraw / prohibit machinery that may compromise health and safety						

89. Please detail any particularly problematic areas that you are aware of in terms of different interpretations of the Directive, and explain what the implications of this have been:

Conformity Assessment

The Machinery Directive offers the choice of up to three different **conformity assessment** procedures, depending on the machinery in question (whether it appears in the Annex IV list of products considered to present higher risks) and on the use of harmonised standards.

90. If you are aware of these conformity assessment options, how would you rate the effectiveness of each, from the perspective of: (i) facilitating the internal market for machinery (e.g. ability to export to other countries); (ii) protecting the health and safety of machinery users?

In each case, select from: Very effective; Moderately effective; Slightly ineffective; Not effective; No opinion	Facilitating the internal market	Protecting health and safety
Assessment of conformity with internal checks (non-Annex IV products):		
Assessment of conformity with internal checks (Annex IV products) using harmonised standards		
EC-type examination (Annex IV products)		
Approval by a Notified Body of a full quality assurance system (Annex IV products)		

91. Can you point to particular problems with any of these options that might reduce overall levels of take up of the option, or its effectiveness:

92. Please estimate how many times in the past 5 years that you have undertaken each type of conformity assessment procedure in relation to the Machinery Directive

EC-type examination (Annex IV products)	
Approval of a full quality assurance system (Annex IV products)	

93. Are there certain types of organisation or product that tend to pursue conformity assessment through each of these options? Please explain:

94. Have there been any trends in recent years in the number of organisations choosing each of these options? Can you suggest any reasons for these changes?

95. Could you indicate the range of fees that you charge for an EC-type examination

Minimum fee charged (€)	
Maximum fee charged (€)	
Average fee charged (€)	

96. How many times in the past 5 years have you suspended, withdrawn or placed restrictions on certificates that you have issued in relation to the Machinery Directive?

97. Are you aware of the European Coordination of Notified Bodies for the Machinery Directive (NB-M) platform?

Not aware of it	Yes, aware of the platform	Yes, follow NB-M activities and discussions	Yes, participate in NB-M meetings

98. If you are aware of the NB_M platform, please rate its effectiveness, in terms of:

	Not at all effective	Not very effective	Effective	Very effective	No opinion
Discussing issues and problems arising					
Exchanging and sharing practices					
Harmonising practice					
Reaching common positions (Recommendations for Use)					

Harmonised European Standards - Development

In order to prove conformity to the essential health and safety requirements of the Directive, manufacturers can make use of technical specifications (standards). **Harmonised standards** at the European level support the application of the directive by translating the essential health and safety requirements into detailed requirements for certain types of products.

99. Has your organisation **contributed to the development** of European harmonised standards in support of the Machinery Directive? *(tick all that apply)*

	Yes, through direct participation in European technical committees or working groups
	Yes, through national mirror committees or national standards body
	Yes, through industry association or other representative body
	No, we have contributed to the development of such standards
	Don't know

100. Please estimate the total staff time (FTE effort) that your organisation has incurred in the past year in relation to the development of European harmonised standards for the machinery Directive:

	Total Staff time (FTE effort)
Contributing to the development of European harmonised standards	
Monitoring / following the development of European harmonised standards	

101. Please estimate other costs (€) that your organisation has incurred in the past year in relation to the development of European harmonised standards for the machinery Directive:

	Other Costs (€)
Contributing to the development of European harmonised standards	
Monitoring / following the development of European harmonised standards	

102. Within the organisations you assess, what types of standards do organisations tend to use in applying the Machinery Directive?

	Mainly Harmonised European standards
	Both harmonised and other standards
	Mainly other standards
	Most do not use standards
	Don't know

103. Can you point to any particular advantages and disadvantages of using European Harmonised Standards, compared with other technical specifications?

Advantages:	
Disadvantages:	

104. Can you estimate the number of European Harmonised Standards that your organisation has purchased in the past 5 years in relation to the Machinery Directive?

Harmonised European Standards – Your Assessment

105. How would you rate the following aspects relating to European Harmonised Standards supporting the Machinery Directive?

	Very poor	Poor	Good	Very Good	Don't know
The length of the European Harmonised Standards development process					
The involvement of industry in the development of European Harmonised Standards					
The scope and coverage of the current portfolio of European Harmonised Standards					
The frequency with which existing European Harmonised Standards are reviewed / revised					
The extent European Harmonised Standards are up-to-date with technological developments					
The quality / usability of existing European Harmonised Standards					
The clarity over which European Harmonised Standards can be used					
The availability of European Harmonised Standards for new innovative products					

106. Please provide further explanation of any areas you have rated as (very)poor:

107. Please highlight any particular gaps in the current coverage of Harmonised Standards in supporting the application of the Machinery Directive (i.e. missing or insufficient standards):

Market Surveillance and Penalties

The Directive requires Member States to take all appropriate measures to ensure that machinery may be placed on the market / put into service only if it satisfies the relevant provisions of the Directive, and should establish an authority for **monitoring** conformity of machinery, as well as effective, proportionate and dissuasive **penalties** for infringements.

108. What are your views on current levels of monitoring activity in relation to:

In each case, select from: Too low; About right; Too large; Don't know	In your country	Across Europe
The number and frequency of inspections carried out		
The likelihood of an individual company being inspected		
The typical time from market entry to inspection / assessment		
The number of products on the market that have never been assessed		
The number of products on the market that are non-compliant		

109. How effective do you believe national authorities are in relation to:

In each case, select from: Not at all; To a limited extent; To a moderate extent; To a large extent; Entirely; Don't know	In your country	Across Europe
Identifying non-compliant products		
Removing non-compliant products from the market		

110. Can you point to specific problems or barriers to:

The effective identification of non-compliant products:	
The removal of non-compliant products from the market:	

111. Can you highlight countries that are particularly effective / ineffective at identifying and removing non-compliant products, and explain your choice:

Very effective country	
Very ineffective country	

Benefits and impacts of the Machinery Directive

112. In your opinion, what has been the impact of the Directive in the following areas (which relate to **market efficiency**)?

	Very negative	Negative	None	Positive	Very positive	Don't know
The costs and burdens on businesses						
The costs and burdens on consumers						
The range of machinery products available						
The quality of machinery products available						
Information and instructions relating to the safe operation of machinery						
The rate and extent of innovation in the sector						
Turnover and profitability of the European machinery sector / businesses						
The international competitiveness of the European machinery sector / businesses						
The volume / value of intra-EU trade in Machinery						
Barriers to the internal market / free movement of machinery						

113. In your opinion, what has been the impact of the Directive in the following areas (which relate to **improved well-being**)?

	Very negative	Negative	None	Positive	Very positive	Don't know
The level of user confidence in machinery safety						
The number of machinery-related accidents and injuries						
The severity of machinery-related accidents and injuries						
The number of un-safe / non-compliant machines on the market / in use						
The level of safety / protection for users of machinery (workers / consumers)						
The environment						

114. Please provide any further explanation you would like to give in relation to the impact of the Directive.

Contributions of the Machinery Directive

115. Could you give a specific example of where the Machinery Directive has had:

A significant positive influence on innovation	
A significant negative influence on innovation	

116. Overall, to what extent do you believe the Machinery Directive has contributed towards:

	Not at all	To a small extent	To a moderate extent	To a large extent	Don't know
An effectively operating internal market for the products in its scope?					
Protecting the health and safety of consumers and users of the products in its scope?					
Protecting the environment, for the products in its scope					

Comparing costs and benefits

117. To what extent are the costs triggered by the Directive proportionate, given the benefits for:

	Benefits significantly outweigh costs	Benefits slightly outweigh costs	Benefits and costs are equal	Costs slightly outweigh benefits	Costs significantly outweigh benefits	Don't know
Your organisation						
The organisations you assess						
Europe more generally						

118. Are there particular aspects / areas that you would highlight where the costs are disproportionate?

119. Are there areas of the Directive's application that could be made more efficient? Please explain

120. Are there areas of the Directive's application, where the burden on your organisation could be reduced?

Coherence of the Directive with other legislation

121. To what extent does the Machinery Directive fit with other legislation?

	Not at all	To a small extent	To a moderate extent	To a large extent	Don't know
With national legislation					
With other EU legislation (e.g. other product Directives)					
With international (non-EU) legislation					

122. If you are aware of any overlaps or inconsistencies with other legislation, please can you describe these briefly, and what the implications are:

European added value

123. To what extent does the Machinery Directive achieve more than would be achieved otherwise (i.e. in its absence), in terms of:

	Not at all	To a small extent	To a moderate extent	To a large extent	Don't know
Facilitating the free circulation of machinery within the internal market					
Ensuring a high degree of health and safety of machinery					
Ensuring environmental protection in relation to machinery used in pesticides					
Reducing costs					
Reducing disparities between Member States					
Other areas of added value (please specify)					

Future improvements

124. What one area of implementation / application of the current Directive do you believe could / should be improved? How and why?

125. What one area could / should a future revision to the Directive aim to address? Why?

Final questions

126. If you would be willing to have a follow up discussion to explore your answers in more detail, please provide your contact details below (these will not be used for any other purpose):

Telephone number	
Email address	

B.3.3 Questionnaire for Industry associations

Introduction

Please confirm whether or not your organisation has submitted a response to the public consultation on the Machinery Directive.

	Yes – We have submitted a response to the Public Consultation *(continue)*
	No – We have not submitted a response to the Public Consultation *(see alternative questionnaire)*
	Don't know

About you, your organisation and those you represent

All responses and associated personal information will be treated in the strictest confidence, in line with EU legislation on data protection. You are asked to provide your name and company name only so that we can provide a list of contributors to the evaluation within the final report. Please leave these fields blank if you do not wish to be identified. Other inputs provided through this survey will only be presented and shared in an aggregate and anonymised way.

127. Please provide the following information about yourself and your organisation:

Your name	
Your job title / role	
Your country of residence / work	
Your organisation's name	
The area / sector you represent	
The number of businesses you represent	

128. Please briefly detail the type of products that fall within the scope of the Machinery Directive and that are of relevance to your membership:

The Aims of the Directive

129. In your experience, to what extent is the Machinery Directive (i.e. its scope and provisions) an appropriate means to contribute towards the following objectives?

	Not at all appropriate	Somewhat appropriate	Entirely appropriate	Don't know
Ensuring the free movement of machinery within the European Single Market				
Ensuring a high level of heath safety for users of machinery (workers and consumers)?				
Protecting the environment in relation to machinery for pesticide / herbicide application?				

The relevance and appropriateness of the Machinery Directive

130. Thinking specifically about the 2006 revision to the Machinery Directive (which applied from the end of 2009)… To what extent do you feel that it:

	Not at all	To a small extent	To a moderate extent	To a large extent	Entirely	Don't know
Took account sufficiently of new **innovations and new technologies** at the time?						
Has been able to deal with new innovations and new technologies since?						
Is likely to be able to deal with new innovations and technologies over the next 10 years?						

131. Similarly, to what extent do you feel that this revision to the Directive:

	Not at all	To a small extent	To a moderate extent	To a large extent	Entirely	Don't know
Sufficiently took account of recent **changes in the business environment** (i.e. in the machinery sector / market / trade) at the time?						
Has been able to deal with changes in the business environment since?						
Is likely to be able to deal with changes to the business environment over the next 10 years?						

132. Can you point to particular areas where the Machinery Directive – its provisions and requirements - has / will not be fit for purpose, and explain why?

For innovations / new technologies (e.g. robotics, Industry 4.0, Internet of Things):	
For changes in the business environment:	

Clarity of the Directive

133. How would you rate the level of knowledge and understanding amongst your membership of:

	Very poor	Poor	Good	Very Good	No opinion
The scope of the Directive (in terms of the machinery products covered)					
The essential health and safety requirements specified by the Directive in Annex I					
The requirements / obligations on organisations					
Obligations in case of modifications and refurbishment of machinery					

134. Please briefly describe any activities that you undertake to support your members' knowledge and understanding of the Machinery Directive and its implications:

135. Please estimate the effort (FTE days) that your organisation devotes each year to the Machinery Directive? This might include monitoring / participating in committees, informing or advising your members, or other activities.:

Interpretation of the Directive

136. To what extent do you believe that the following aspects of the Machinery Directive have been fully and consistently interpreted and applied across Europe?

	Not at all	To a small extent	To a moderate extent	To a large extent	Entirely	No opinion
The transposition of the Directive into national legislation						
The conformity assessment procedures available to companies						
The appointment of Notified Bodies to carry out conformity assessment						
The assessments undertaken by Notified Bodies						
The suspension, withdrawal or placement of restrictions on certificates issued						
The approach of Market Surveillance Authorities to determining compliance						
The number of market surveillance activities						
The establishment of effective, proportionate and dissuasive penalties for infringements						
Not prohibiting, restricting or impeding machinery that complies with the Directive						
Taking measures to withdraw / prohibit machinery that may compromise health and safety						

137. Please detail any particularly problematic areas that you are aware of in terms of different interpretations of the Directive, and explain what the implications of this have been:

Conformity Assessment

The Machinery Directive offers the choice of up to three different **conformity assessment** procedures, depending on the machinery in question (whether it appears in the Annex IV list of products considered to present higher risks) and on the use of harmonised standards.

138. Within your membership, can you estimate the proportion of products that are certified through each conformity assessment procedure:

Assessment of conformity with internal checks (non-Annex IV products):	%
Assessment of conformity with internal checks (Annex IV products) using harmonised standards	%
EC-type examination (Annex IV products)	%
Approval by a Notified Body of a full quality assurance system (Annex IV products)	%

139. Can you point to particular problems with any of these options that might reduce overall levels of take up of the option, or its effectiveness:

Assessment of conformity with internal checks (non-Annex IV products):	
Assessment of conformity with internal checks (Annex IV products) using harmonised standards	
EC-type examination (Annex IV products)	
Approval by a Notified Body of a full quality assurance system (Annex IV products)	

Harmonised European Standards - Development

In order to prove conformity to the essential health and safety requirements of the Directive, manufacturers can make use of technical specifications (standards). **Harmonised standards** at the European level support the application of the directive by translating the essential health and safety requirements into detailed requirements for certain types of products.

140. Has your organisation **contributed to the development** of European harmonised standards in support of the Machinery Directive? *(tick all that apply)*

	Yes, through direct participation in European technical committees or working groups
	Yes, through national mirror committees or national standards body
	No, we have contributed to the development of such standards
	Don't know

141. Please estimate the total staff time (FTE effort) and other costs (€) that your organisation has incurred in the past year in relation to the development of European harmonised standards for the machinery Directive:

	Total Staff time (FTE effort)	Other Costs (€)
Contributing to the development of European harmonised standards		
Monitoring / following the development of European harmonised standards		

Harmonised European Standards - Usage

142. Within your membership, what type of standards do organisations tend to use in applying the Machinery Directive? *(tick all that apply)*

	Mainly Harmonised European standards
	Both harmonised and other standards
	Mainly other standards
	Most do not use standards
	Don't know

143. Can you point to any particular advantages and disadvantages of using European Harmonised Standards, compared with other technical specifications?

Advantages:	
Disadvantages:	

Harmonised European Standards – Your Assessment

144. How would you rate the following aspects relating to European Harmonised Standards supporting the Machinery Directive?

	Very poor	Poor	Good	Very Good	Don't know
The involvement of industry in the development of European Harmonised Standards					
The scope and coverage of the current portfolio of European Harmonised Standards					
The extent European Harmonised Standards are up-to-date with technological developments					
The quality / usability of existing European Harmonised Standards					
The clarity over which European Harmonised Standards can be used					

145. Please provide further explanation of any areas you have rated as (very)poor: _____

Market Surveillance and Penalties

The Directive requires Member States to take all appropriate measures to ensure that machinery may be placed on the market / put into service only if it satisfies the relevant provisions of the Directive, and should establish an authority for **monitoring** conformity of machinery, as well as effective, proportionate and dissuasive **penalties** for infringements.

146. What are your views on current levels of monitoring activity across Europe in relation to:

	Too low	About right	Too large	Don't know
The number and frequency of inspections carried out				
The typical time from market entry to inspection / assessment				
The number of products on the market that have never been assessed				
The number of products on the market that are non-compliant				

147. Could you highlight countries that are particularly ineffective at identifying and removing non-compliant products, and explain your choice:

Costs and impacts of the Machinery Directive

148. Are there any negative impacts of the Directive on your members, beyond any direct compliance costs that it might trigger:

149. Are there areas of the Directive's application that could be made more efficient? Please explain: _

Coherence of the Directive with other legislation

150. To what extent does the Machinery Directive fit with other legislation?

	Not at all	To a small extent	To a moderate extent	To a large extent	Don't know
With national legislation					
With other EU legislation (e.g. other product Directives)					
With international (non-EU) legislation					

151. If you are aware of any overlaps or inconsistencies with other legislation, please can you describe these briefly, and what the implications are:

European added value

152. To what extent does the Machinery Directive achieve more than would be achieved otherwise (i.e. in its absence), in terms of:

	Not at all	To a small extent	To a moderate extent	To a large extent	Don't know
Facilitating the free circulation of machinery within the internal market					
Ensuring a high degree of health and safety of machinery					
Ensuring environmental protection in relation to machinery used in pesticide applications					
Reducing costs					
Reducing disparities between Member States					
Other areas of added value (please specify)					

Final questions

153. If you would be willing to have a follow up discussion to explore your answers in more detail, please provide your contact details below (these will not be used for any other purpose):

Telephone number	
Email address	

B.3.4 Questionnaire for Industry

Welcome

Please confirm whether or not your organisation has submitted a response to the public consultation on the Machinery Directive.

	Yes – We have submitted a response to the Public Consultation	*Please refer to alternative version of survey*
	No – We have not submitted a response to the Public Consultation	
	Don't know	

About you and your organisation

All responses and associated personal information will be treated in the strictest confidence, in line with EU legislation on data protection. You are asked to provide your name and company name only so that we can provide a list of contributors to the evaluation within the final report. Please leave these fields blank if you do not wish to be identified. Other inputs provided through this survey will only be presented and shared in an aggregate and anonymised way.

154. Please provide the following information about yourself and your organisation:

Your name	
Your job title / role	
Your country of residence / work	
Your organisation's name	
The name of your parent company (where relevant)	
The number of people your organisation employs	

155. Is your organisation:

	A business that manufactures machinery?
	A business that purchases machinery?

156. If you manufacture machinery, please estimate your annual turnover from these products:

157. Please estimate the proportion (%) of machinery sales from:

Your domestic market	
Other EU/EEA countries	
Non-EU/EEA countries	

About your products

158. How many different product types does your organisation currently produce that fall within the scope of the Machinery Directive?

Products listed within Annex IV of the Directive (those deemed to present higher risks)	
Products not listed within Annex IV of the Directive	
Total	

159. How many of these product types have been introduced to the market within the past 5 years:

160. Please briefly detail the type of products you produce that fall within the scope of the Machinery Directive:

The Aims of the Machinery Directive

161. In your opinion, how important are the following objectives of the Machinery Directive?

	Not at all important	Slightly important	Moderately important	Very important	Don't know
Ensuring the free movement of machinery within the European Single Market					
Ensuring a high level of heath safety for users of machinery (workers and consumers)?					
Protecting the environment in relation to machinery for pesticide / herbicide application?					

162. In your experience, to what extent is the Machinery Directive (i.e. its scope and provisions) an appropriate means to contribute towards the following objectives?

	Not at all appropriate	Somewhat appropriate	Entirely appropriate	Don't know
Ensuring the free movement of machinery within the European Single Market				
Ensuring a high level of heath safety for users of machinery (workers and consumers)?				
Protecting the environment in relation to machinery for pesticide / herbicide application?				

The relevance and appropriateness of the Machinery Directive

163. Thinking specifically about the 2006 revision to the Machinery Directive (which applied from the end of 2009)… To what extent do you feel that it:

	Not at all	To a small extent	To a moderate extent	To a large extent	Entirely	Don't know
Took account sufficiently of new **innovations and new technologies** at the time?						
Has been able to deal with new innovations and new technologies since?						
Is likely to be able to deal with new innovations and technologies over the next 10 years?						

164. Similarly, to what extent do you feel that this revision to the Directive:

	Not at all	To a small extent	To a moderate extent	To a large extent	Entirely	Don't know
Sufficiently took account of recent **changes in the business environment** (i.e. in the machinery sector / market / trade) at the time?						
Has been able to deal with changes in the business environment since?						
Is likely to be able to deal with changes to the business environment over the next 10 years?						

165. Can you point to particular areas where the Machinery Directive – its provisions and requirements - has / will not be fit for purpose, and explain why?

For innovations / new technologies (e.g. robotics, Industry 4.0, Internet of Things):	
For changes in the business environment:	

Clarity of the Directive

166. To what extent is each of the following aspects of the Machinery Directive clear to you?

	Not at all	To a small extent	To a moderate extent	To a large extent	Entirely	Not applicable
The scope of the Directive (in terms of the machinery products covered)						
The essential health and safety requirements specified by the Directive in Annex I						
The requirements / obligations on your organisations						
Obligations in case of modifications and refurbishment of machinery						

167. How would you rate the European Commission's 'Guide to Application of the Machinery Directive' as an aid to understanding the Directive?

No aware of it	Have never used it	Very poor	Poor	Good	Very good

Interpretation of the Directive

168. To what extent do you believe that the following aspects of the Machinery Directive have been fully and consistently interpreted and applied across Europe?

	Not at all	To a small extent	To a moderate extent	To a large extent	Entirely	No opinion
The transposition of the Directive into national legislation						
The conformity assessment procedures available to companies						
The appointment of Notified Bodies to carry out conformity assessment						
The assessments undertaken by Notified Bodies						
The suspension, withdrawal or placement of restrictions on certificates issued						
The approach of Market Surveillance Authorities to determining compliance						
The number of market surveillance activities						
The establishment of effective, proportionate and dissuasive penalties for infringements						
Not prohibiting, restricting or impeding machinery that complies with the Directive						
Taking measures to withdraw / prohibit machinery that may compromise health and safety						

169. Please detail any particularly problematic areas that you are aware of in terms of different interpretations of the Directive, and explain what the implications of this have been:

Conformity Assessment

The Machinery Directive offers the choice of up to three different **conformity assessment** procedures, depending on the machinery in question (whether it appears in the Annex IV list of products considered to present higher risks) and on the use of harmonised standards.

170. If you are aware of these conformity assessment options, how would you rate the effectiveness of each, from the perspective of: (i) facilitating the internal market for machinery (e.g. ability to export to other countries); (ii) protecting the health and safety of machinery users?

In each case, select from: Very effective; Moderately effective; Slightly ineffective; Not effective; No opinion	Facilitating the internal market	Protecting health and safety
Assessment of conformity with internal checks (non-Annex IV products):		
Assessment of conformity with internal checks (Annex IV products) using harmonised standards		
EC-type examination (Annex IV products)		
Approval by a Notified Body of a full quality assurance system (Annex IV products)		

171. Can you point to particular problems with any of these options that might reduce overall levels of take up of the option, or its effectiveness:

Conformity Assessment and Your Organisation

172. Please indicate how many times in the past 5 years that you have undergone each type of conformity assessment procedure in relation to the Machinery Directive:

Assessment of conformity with internal checks (non-Annex IV products):	
Assessment of conformity with internal checks (Annex IV products) using harmonised standards	
EC-type examination (Annex IV products)	
Approval by a Notified Body of a full quality assurance system (Annex IV products)	

173. Which of these conformity assessment options have you used most recently?

Assessment of conformity with internal checks (non-Annex IV products):	
Assessment of conformity with internal checks (Annex IV products) using harmonised standards	
EC-type examination (Annex IV products)	
Approval by a Notified Body of a full quality assurance system (Annex IV products)	

174. Thinking about this occasion… Please estimate the total staff time (FTE effort) involved in:

Undertaking risk assessment (to determine applicability of the Directive's requirements)	
Conformity assessment work undertaken internally	
Conformity assessment work undertaken by a third party	
Development of technical file	
Declaration of conformity / affixing of CE marking	

175. And please estimate any other costs involved (€)

Undertaking risk assessment (to determine applicability of the Directive's requirements)	
Conformity assessment work undertaken internally	
Conformity assessment work undertaken by a third party	
Development of technical file	
Declaration of conformity / affixing of CE marking	

Harmonised European Standards - Development

In order to prove conformity to the essential health and safety requirements of the Directive, manufacturers can make use of technical specifications (standards). **Harmonised standards** at the European level support the application of the directive by translating the essential health and safety requirements into detailed requirements for certain types of products.

176. Has your organisation **contributed to the development** of European harmonised standards in support of the Machinery Directive? *(tick all that apply)*

	Yes, through direct participation in European technical committees or working groups
	Yes, through national mirror committees or national standards body
	Yes, through industry association or other representative body
	No, we have contributed to the development of such standards
	Don't know

177. Please estimate the total staff time (FTE effort) that your organisation has incurred in the past year in relation to the development of European harmonised standards for the machinery Directive:

	Total Staff time (FTE effort)
Contributing to the development of European harmonised standards	
Monitoring / following the development of European harmonised standards	

178. Please estimate other costs (€) that your organisation has incurred in the past year in relation to the development of European harmonised standards for the machinery Directive:

	Other Costs (€)
Contributing to the development of European harmonised standards	
Monitoring / following the development of European harmonised standards	

Harmonised European Standards – Usage

179. Has your organisation **used standards** in applying the Machinery Directive?

	Yes, mainly Harmonised European standards
	Yes, both harmonised and other standards
	Yes, mainly other standards
	No, we have not been using any standards
	Don't know

180. Can you estimate the number of European Harmonised Standards that your organisation has purchased in the past 5 years?:

181. Can you point to any particular advantages and disadvantages of using European Harmonised Standards, compared with other technical specifications?

Advantages:	
Disadvantages:	

Harmonised European Standards – Your Assessment

182. How would you rate the following aspects relating to European Harmonised Standards supporting the Machinery Directive?

	Very poor	Poor	Good	Very Good	Don't know
The length of the European Harmonised Standards development process					
The involvement of industry in the development of European Harmonised Standards					
The scope and coverage of the current portfolio of European Harmonised Standards					
The frequency with which existing European Harmonised Standards are reviewed / revised					
The extent European Harmonised Standards are up-to-date with technological developments					
The quality / usability of existing European Harmonised Standards					
The clarity over which European Harmonised Standards can be used					
The availability of European Harmonised Standards for new innovative products					

183. Please provide further explanation of any areas you have rated as (very)poor:

184. Please highlight any particular gaps in the current coverage of Harmonised Standards in supporting the application of the Machinery Directive (i.e. missing or insufficient standards):

185. If the availability of Harmonised Standards has influenced your choice of conformity assessment option, please explain:

Market Surveillance and Penalties

The Directive requires Member States to take all appropriate measures to ensure that machinery may be placed on the market / put into service only if it satisfies the relevant provisions of the Directive, and should establish an authority for **monitoring** conformity of machinery, as well as effective, proportionate and dissuasive **penalties** for infringements.

186. What are your views on current levels of monitoring activity in relation to:

In each case, select from: Too low; About right; Too large; Don't know	In your country	Across Europe
The number and frequency of inspections carried out		
The likelihood of an individual company being inspected		
The typical time from market entry to inspection / assessment		
The number of products on the market that have never been assessed		
The number of products on the market that are non-compliant		

187. How effective do you believe national authorities are in relation to:

	Not at all	To a limited extent	To a moderate extent	To a large extent	Entirely	Don't know
Identifying non-compliant products						
Removing non-compliant products from the market						

188. Can you point to specific problems or barriers to:

The effective identification of non-compliant products:	
The removal of non-compliant products from the market:	

Market surveillance and your organisation

189. During the past 5 years:

How many times has your organisation been the subject of a machinery related inspection?	
What proportion of your relevant 'product types' have been inspected (%)?	
How many times has your organisation been found to be non-compliant?	

190. If in the last five years your organisation has been found to be non-compliant, please explain:

The reason for non-compliance:	
The measures taken by the authorities:	
The action taken by your organisation:	

191. Can you estimate the typical time from market entry to inspection for a product covered by the Machinery Directive?

192. Please estimate the total staff time (FTE effort) and other costs (€) that your organisation incurs in relation to a machinery-related inspection?

FTE effort (days)	
Other costs (€)	

Benefits of the Machinery Directive

193. Which of the following **benefits** does the Machinery Directive bring to your organisation:

	Not at all	To a small extent	To a large extent	Don't know
The CE mark is a recognised quality certificate also outside of the EU				
One standardisation procedure instead of 28 individual standards saves time and money				
The existence of European Harmonised Standards saves time in finding appropriate technical specifications				
Self-certification cuts certification costs significantly				

194. What other benefits does the Machinery Directive bring to your organisation:

195. Are there any negative impacts of the Directive on your organisation, beyond any direct compliance costs that it might trigger:

Impacts of the Machinery Directive

196. In your opinion, what has been the impact of the Directive in the following areas (which relate to **market efficiency**)?

	Very negative	Negative	None	Positive	Very positive	Don't know
The costs and burdens on businesses						
The costs and burdens on consumers						
The range of machinery products available						
The quality of machinery products available						
Information and instructions relating to the safe operation of machinery						
The rate and extent of innovation in the sector						
Turnover and profitability of the European machinery sector / businesses						
The international competitiveness of the European machinery sector / businesses						
The volume / value of intra-EU trade in Machinery						
Barriers to the internal market / free movement of machinery						

197. In your opinion, what has been the impact of the Directive in the following areas (which relate to **improved well-being**)?

	Very negative	Negative	None	Positive	Very positive	Don't know
The level of user confidence in machinery safety						
The number of machinery-related accidents and injuries						
The severity of machinery-related accidents and injuries						
The number of un-safe / non-compliant machines on the market / in use						
The level of safety / protection for users of machinery (workers / consumers)						
The environment						

198. Please provide any further explanation you would like to give in relation to the impact of the Directive.

Overall assessment

199. Could you give a specific example of where the Machinery Directive has had:

A significant positive influence on innovation	
A significant negative influence on innovation	

200. Overall, to what extent do you believe the Machinery Directive has contributed towards:

	Not at all	To a small extent	To a moderate extent	To a large extent	Don't know
An effectively operating internal market for the products in its scope?					
Protecting the health and safety of consumers /users of the products in its scope?					
Protecting the environment, for the products in its scope					

Comparing costs and benefits

201. To what extent are the costs triggered by the Directive proportionate, given the benefits for:

	Benefits significantly outweigh costs	Benefits slightly outweigh costs	Benefits and costs are equal	Costs slightly outweigh benefits	Costs significantly outweigh benefits	Don't know
Your organisation						
Your industry						
Europe more generally						

202. Are there particular aspects / areas that you would highlight where the costs are disproportionate?

203. Are there areas of the Directive's application that could be made more efficient? Please explain

204. Are there areas of the Directive's application, where the burden on your organisation could be reduced?

Coherence of the Directive with other legislation

205. To what extent does the Machinery Directive fit with other legislation?

	Not at all	To a small extent	To a moderate extent	To a large extent	Don't know
With national legislation					
With other EU legislation (e.g. other product Directives)					
With international (non-EU) legislation					

206. If you are aware of any overlaps or inconsistencies with other legislation, please can you describe these briefly, and what the implications are:

European added value

207. To what extent does the Machinery Directive achieve more than would be achieved otherwise (i.e. in its absence), in terms of:

	Not at all	To a small extent	To a moderate extent	To a large extent	Don't know
Facilitating the free circulation of machinery within the internal market					
Ensuring a high degree of health and safety of machinery					
Ensuring environmental protection in relation to machinery used in pesticides					
Reducing costs					
Reducing disparities between Member States					
Other areas of added value (please specify)					

Final questions

208. What one area of implementation / application of the current Directive do you believe could / should be improved? How and why?

209. What one area could / should a future revision to the Directive aim to address? Why?

If you would be willing to have a follow up discussion to explore your answers in more detail, please provide your contact details below (these will not be used for any other purpose):

Telephone number	
Email address	

B.4 Survey consultation results

This appendix provides summary tables of results for the main (closed) questions posed to stakeholders through the public and / or targeted consultation surveys. Where the same question was posed through both surveys, the results have been combined. The source underneath each table indicates whether the results come from one or other survey, or both.

B.4.1 Relevance of the Directive

Table 85 How important are the following objectives?

	Not at all important	Slightly important	Moderately important	Very important	n
Ensuring the free movement of machinery within the European single market	1%	4%	17%	78%	398
Ensuring a high level of health and safety for users of machinery (workers/consumers)	1%	1%	8%	91%	400
Protecting the environment in relation to machinery for pesticide/herbicide application	2%	4%	21%	73%	305

Source: Machinery Directive Public and Targeted Consultations. Excludes non-respondents

Table 86 To what extent is the machinery Directive (i.e. its scope and provisions) an appropriate means to contribute towards the following objectives?

	Not all appropriate	Somewhat appropriate	Entirely appropriate	n
Ensuring the free movement of machinery within the European single market	1%	10%	88%	86
Ensuring a high level of health and safety for users of machinery (workers/consumers)	0%	16%	84%	86

Source: Machinery Directive Targeted Consultations. Excludes non-respondents

Table 87 To what extent, in your experience, the Directive:

	Not at all	To a small extent	To a moderate extent	To a large extent	Entirely	n
takes account sufficiently of new innovations and new technologies (e.g. robotics, advanced manufacturing, etc.)?	4%	26%	33%	30%	6%	254
sufficiently takes into account the recent changes in business environment?	9%	32%	35%	17%	8%	218
is likely to be able to deal with new innovations and technologies over the next 10 years (e.g. digitalisation of the single market: Internet of Things, Industry 4.0)?	13%	29%	30%	23%	4%	245

Source: Machinery Directive Public Consultations. Excludes non-respondents.

Table 88 Thinking specifically about the 2006 revision to the Machinery Directive (which applied from the end of 2009) To what extent do you feel that it:

	Not at all	To a small extent	To a moderate extent	To a large extent	Entirely	n
Took account sufficiently of new innovations and new technologies at the time?	1%	11%	26%	45%	16%	87
Has been able to deal with new innovations and new technologies since?	0%	12%	32%	29%	27%	85
Is likely to be able to deal with new innovations and technologies over the next 10 years?	0%	20%	32%	23%	26%	82

Source: Machinery Directive Targeted Consultations. Excludes non-respondents.

Table 89 Similarly, to what extent do you feel that this revision to the Directive:

	Not at all	To a small extent	To a moderate extent	To a large extent	Entirely	n
Sufficiently took account of recent changes in the business environment (i.e. in the machinery sector / market / trade) at the time?	3%	12%	27%	36%	23%	78
Has been able to deal with changes in the business environment since?	1%	16%	34%	34%	14%	79
Is likely to be able to deal with changes to the business environment over the next 10 years?	3%	19%	33%	37%	8%	73

Source: Machinery Directive Targeted Consultations. Excludes non-respondents.

Table 90 On the contrary, can you point to particular areas where the Machinery Directive creates obstacles to:

	Innovations/new technologies	Changes in the business environment	Others	n
Areas where the Machinery Directive creates obstacles	35%	24%	57%	263

Source: Machinery Directive Public Consultations. Excludes non-respondents.

B.4.2 Knowledge and understanding of the Directive

Table 91 How would you rate the level of knowledge and understanding amongst stakeholders in your country / amongst your members of National Authorities and Industry Associations?

	Very poor	Poor	Good	Very good	n
The scope of the Directive (in terms of the machinery products covered)	2%	15%	33%	50%	48
The essential health and safety requirements specified by the Directive in Annex I	2%	9%	36%	53%	47
The requirements / obligations on organisations	2%	17%	40%	40%	47
Obligations in case of modifications and refurbishment of machinery	9%	39%	46%	7%	46

Source: Machinery Directive Targeted Consultation. Excludes non-respondents.

Table 92 How would you rate the level of knowledge and understanding amongst stakeholders in your country / amongst your members of Industry and NBs?

	Not at all	To a small extent	To a moderate extent	To a large extent	Entirely	n
The scope of the Directive (in terms of the machinery products covered)	0%	4%	4%	48%	44%	25
The essential health and safety requirements specified by the Directive in Annex I	0%	0%	4%	60%	36%	25
The requirements / obligations on your organisation	0%	0%	12%	56%	32%	25
Obligations in case of modifications and refurbishment of machinery	8%	21%	21%	38%	13%	24

Source: Machinery Directive Targeted Consultation. Excludes non-respondents.

Table 93 Are you aware that some products are labelled with a "CE marking"?

	Yes, and I understand its meaning	Yes, but I do not understand its meaning	No	n
Awareness that some products are labelled with a “CE” marking	89%	11%	0%	19

Source: Machinery Directive Public Consultation. Excludes non-respondents.

Table 94 Does the presence of CE marking affect your purchasing decision?

	Yes, positively	Yes, negatively	Not at all	n
Does the presence of CE marking affect your purchasing decision?	82%	0%	18%	17

Source: Machinery Directive Public Consultation. Excludes non-respondents.

Table 95 How would you rate the Guide to Application of the Machinery Directive?

	Very poor	Poor	Good	Very good	n
Guide to Application of the Machinery Directive rating	1%	8%	53%	38%	305

Source: Machinery Directive Public and Targeted Consultations. Excludes non-respondents.

Table 96 To what extent is each of the following aspects of the Machinery Directive clear to you?

	Not at all	To a small extent	To a moderate extent	To a large extent	Entirely	n
The scope of the Directive (in terms of the machinery products covered)	1%	2%	13%	49%	35%	289
The essential health and safety requirements specified by the Directive in Annex I	0%	1%	10%	51%	39%	289
The requirements/obligations on you/your organisation (where relevant)	0%	1%	10%	50%	38%	289

Source: Machinery Directive Public and Targeted Consultations. Excludes non-respondents.

B.4.3 Interpretation and application of the Directive

Table 97 To what extent do you believe that the following aspects of the Machinery Directive have been fully and consistently interpreted and applied across Europe?

	Not at all	To a small extent	To a moderate extent	To a large extent	Entirely	n
The transposition of the Directive into national legislation	0%	2%	14%	49%	35%	88
The conformity assessment procedures available to companies	0%	6%	17%	36%	41%	87
The appointment of Notified Bodies to carry out conformity assessment	1%	4%	18%	34%	43%	74
The assessments undertaken by Notified Bodies	1%	8%	41%	42%	8%	76
The suspension, withdrawal or placement of restrictions on certificates issued	0%	25%	50%	20%	5%	40
The approach of Market Surveillance Authorities to determining compliance	6%	46%	21%	24%	3%	80
The number of market surveillance activities	23%	53%	15%	8%	1%	75
The establishment of effective, proportionate and dissuasive penalties for infringements	22%	53%	9%	16%	0%	68
Not prohibiting, restricting or impeding machinery that complies with the Directive	1%	9%	24%	52%	14%	79
Taking measures to withdraw / prohibit machinery that may compromise health and safety	5%	60%	21%	10%	4%	78

Source: Machinery Directive Targeted Consultation. Excludes non-respondents.

Table 98 Have you encountered problems with the following?

	Yes	No	n
Implementation of the Directive in EU countries	38%	62%	235
The conformity assessment procedures available to companies	32%	68%	240
The appointment of notified bodies to carry out conformity assessment	14%	86%	201
The assessments undertaken by notified bodies	33%	67%	207
The suspension, withdrawal or placement of restrictions on certificates issued	16%	84%	178
The number of market surveillance activities	49%	51%	186
The approach of national market surveillance authorities to determining compliance	48%	52%	200
Inaction of national authorities to remove non complaint machinery from the market	57%	43%	186
Fairness, proportionality and discouraging effect of penalties for infringements	38%	63%	144
Others	31%	69%	105

Source: Machinery Directive Public Consultations. Excludes non-respondents.

B.4.4 Conformity Assessment and the Directive

Table 99 If you are aware of these conformity assessment options, how would you rate the effectiveness of each, from the perspective of:

	Very effective	Moderately effective	Slightly ineffective	Not effective	n
Assessment of conformity with internal checks for products not covered by Annex					
...facilitating the internal market for machinery (your ability to export to other countries)?	51%	40%	6%	3%	235
...protecting the health and safety of machinery users?	32%	46%	18%	4%	252
...protecting the environment in pesticide applications?	20%	46%	23%	11%	74
Assessment of conformity with internal checks for products covered by Annex IV, where a Harmonised Standard is applied that covers all applicable requirements					
...facilitating the internal market for machinery (your ability to export to other countries)?	51%	38%	8%	3%	186
...protecting the health and safety of machinery users?	41%	42%	13%	4%	201
...protecting the environment in pesticide applications?	23%	43%	17%	16%	69
Approval by a Notified Body of a full quality assurance system for Annex IV products (which was introduced with the latest version of the Directive)					
...facilitating the internal market for machinery (your ability to export to other countries)?	35%	49%	9%	7%	136
...protecting the health and safety of machinery users?	29%	51%	14%	6%	148
...protecting the environment in pesticide applications?	17%	56%	11%	17%	54

Source: Machinery Directive Public and Targeted Consultations. Excludes non-respondents.

Table 100 Which of these conformity assessment options have you used most recently?

	Conformity assessment options
Assessment of conformity with internal checks (non-Annex IV products)	69%
Assessment of conformity with internal checks (Annex IV products) using harmonised standard	15%
EC-type examination (Annex IV products)	8%
Approval by a Notified Body of a full quality assurance system (Annex IV products)	8%
n	26

Source: Machinery Directive Targeted Consultation. Excludes non-respondents.

Table 101 Have you encountered any problems with:

	Yes	No	n
Assessment of conformity with internal checks for products not covered by Annex IV	26%	74%	206
Assessment of conformity with internal checks for products covered by Annex IV, where a European harmonised standard is applied that covers all applicable requirements	21%	79%	147
EC-type examination for Annex IV products	20%	80%	145
Approval by a notified body of a full quality assurance system for Annex IV products which was introduced by the latest version of the Directive	13%	87%	97
Has it happened during the last 5 years that approval of your product in one EU country was not recognised in another?	9%	91%	160

Source: Machinery Directive Public Consultations. Excludes non-respondents.

Table 102 Are you aware of the European Coordination of Notified Bodies for the Machinery Directive (NB-M) platform?

	No, not aware	Yes, aware of the platform	Yes, follow NB-M activities and discussions	Yes, participate in NB-M meetings	n
Awareness of the European Coordination of NB-M platform	0%	17%	33%	50%	12

Source: Machinery Directive Targeted Consultation. Excludes non-respondents.

Table 103 If you are aware of the NB-M platform, please rate its effectiveness, in terms of:

	Not at all effective	Not very effective	Effective	Very effective	n
Discussing issues and problems arising	0%	10%	50%	40%	10
Exchanging and sharing practices	0%	20%	30%	50%	10
Harmonising practice	0%	11%	44%	44%	9
Reaching common positions (Recommendations for Use)	0%	0%	40%	60%	10

Source: Machinery Directive Targeted Consultation. Excludes non-respondents.

B.4.5 Standardisation and the Directive

Table 104 Has your organisation contributed to the development of European harmonised standards in support of the Machinery Directive?

	Contribution to the development of the standards
Yes, through direct participation in European technical committees or working groups	56%
Yes, through national mirror committees or national standards body	25%
Yes, through industry association or other representative body	3%
No, we have contributed to the development of such standards	15%
n	87

Source: Machinery Directive Targeted Consultation. Excludes non-respondents.

Table 105 Have you been using European harmonised standards?

	Mainly Harmonised European standards	Both harmonised and other standards	Mainly other standards	Tend not to use standards	n
Use of European harmonised standards	42%	54%	1%	3%	361

Source: Machinery Directive Public and Targeted Consultations. Excludes non-respondents.

Table 106 How would you rate the following aspects relating to European harmonised standards supporting the Machinery Directive?

	Very poor	Poor	Good	Very good	n
The length of the European harmonised standards development process	16%	44%	36%	4%	283
The cost and availability of European harmonised standards	28%	42%	29%	2%	249
The product coverage of European harmonised standards	0%	14%	64%	22%	245
The frequency with which existing European harmonised standards are revised	5%	29%	59%	7%	296
How well European harmonised standards explain the rules or guidelines or definitions?	5%	24%	58%	13%	244
The frequency of usage of European harmonised standards vs. other technical specifications	1%	7%	54%	38%	233
The availability of European harmonised standards for new innovative products	11%	52%	32%	5%	257

Source: Machinery Directive Public and Targeted Consultations. Excludes non-respondents.

Table 107 Are there areas where European harmonised standards are missing/not sufficient?

	Yes	No	n
Are there areas where European harmonised standards are missing/not sufficient	77%	23%	174

Source: Machinery Directive Public Consultations. Excludes non-respondents.

B.4.6 Market Surveillance and the Directive

Table 108 What are your views on current levels of monitoring activity in relation to:

	Too low	About right	Too large	n
In your country:				
The number and frequency of inspections carried out - In your country	50%	50%	0%	8
The likelihood of an individual company being inspected - In your country	83%	17%	0%	6
The typical time from market entry to inspection / assessment - In your country	14%	71%	14%	7
The number of products on the market that have never been assessed - In your country	0%	29%	71%	7
The number of products on the market that are non-compliant - In your country	17%	0%	83%	6
Across Europe				
The number and frequency of inspections carried out - Across Europe	83%	16%	2%	64
The likelihood of an individual company being inspected - Across Europe	79%	21%	0%	29
The typical time from market entry to inspection / assessment - Across Europe	57%	27%	16%	37
The number of products on the market that have never been assessed - Across Europe	13%	11%	77%	47
The number of products on the market that are non-compliant - Across Europe	13%	10%	77%	52

Source: Machinery Directive Targeted Consultations. Excludes non-respondents.

Table 109 How effective do you believe national authorities are in relation to:

	Not at all	To a limited extent	To a moderate extent	To a large extent	Entirely	n
Identifying non-compliant products	20%	56%	17%	7%	0%	296
Removing non-compliant products from the market	18%	56%	16%	10%	0%	282

Source: Machinery Directive Public and Targeted Consultations. Excludes non-respondents.

Table 110 Can you point to any specific problems or barriers to:

	Lack of cooperation between customs	Not enough staff	Wrong targeting of inspections / actions	Others	n
The effective identification of non-compliant products:	9%	40%	16%	35%	264
The removal of non-compliant products from the market:	7%	35%	17%	41%	264

Source: Machinery Directive Public Consultations. Excludes non-respondents.

Table 111 Is your organisation responsible for undertaking market surveillance activities in relation to the Machinery Directive?

	Yes	No	n
Is your organisation responsible for undertaking market surveillance activities in relation to the Machinery Directive?	70%	30%	10

Source: Machinery Directive Targeted Consultation. Excludes non-respondents.

Table 112 What drives the pattern of your market surveillance activity in relation to machinery:

	Not at all	Minor influence	Major influence	n
Government policy	14%	43%	43%	7
Previous inspections	0%	43%	57%	7
Complaints	0%	14%	86%	7
Accident reports	0%	0%	100%	7
RAPEX (Rapid Alert System for non-food dangerous products)	0%	29%	71%	7
ICSMS (Information and Communication System for Market Surveillance) systems	0%	43%	57%	7
Joint market surveillance programmes (e.g. PROSAFE Joint Actions)	14%	29%	57%	7
Other (please specify)	25%	0%	75%	4

Source: Machinery Directive Targeted Consultation. Excludes non-respondents.

Table 113 Over the past five years, has the number of inspections tended to:

	Increase significantly	Increase slightly	Remain approximately the same	Decrease slightly	Decrease significantly	n
Over the past five years, the number of inspections tended to:	14%	43%	0%	29%	14%	7

Source: Machinery Directive Targeted Consultations. Excludes non-respondents.

Table 114 How effective do you believe authorities are in relation to... Monitoring machinery manufacturers on their adherence to health and safety requirements for their products

	Entirely	To a large extent	To a limited extent	Not at all	n
Businesses and their representatives	4%	22%	63%	12%	190
Notified Bodies	0%	13%	63%	25%	16
Other	0%	8%	87%	5%	38
Public Authorities	11%	42%	42%	5%	19
Users and their representatives	2%	31%	57%	11%	65
All	3%	23%	63%	11%	328

Source: Machinery Directive Public Consultation. Excludes non-respondents.

Table 115 How effective do you believe authorities are in relation to... Identifying unsafe machinery and removing it from the market

	Entirely	To a large extent	To a limited extent	Not at all	n
Businesses and their representatives	2%	13%	65%	20%	178
Notified Bodies	0%	13%	80%	7%	15
Other	3%	13%	74%	11%	38
Public Authorities	11%	53%	26%	11%	19
Users and their representatives	0%	23%	64%	13%	64
All	2%	18%	64%	16%	314

Source: Machinery Directive Public Consultation. Excludes non-respondents.

Table 116 How effective do you believe authorities are in relation to... Assisting economic operators in manufacturing and selling machinery

	Entirely	To a large extent	To a limited extent	Not at all	n
Businesses and their representatives	2%	15%	52%	32%	171
Notified Bodies	0%	0%	71%	29%	14
Other	0%	22%	56%	22%	36
Public Authorities	6%	28%	56%	11%	18
Users and their representatives	4%	23%	55%	19%	53
All	2%	17%	54%	27%	292

Source: Machinery Directive Public Consultation. Excludes non-respondents.

Table 117 What is your view on the likelihood of an individual company being inspected?

	Too low	About right	Too large	n
Likelihood of an individual company being inspected	20%	56%	17%	261

Source: Machinery Directive Public and Targeted Consultations. Excludes non-respondents.

Table 118 Machinery related inspections in the last 5 years

	Yes	No	n
During past 5 years, have you been subject of a machinery related inspection?	29%	71%	272
During past 5 years, have you been subject of a machinery related inspection? [Only those that manufacture]	42%	58%	145
Has it ever happened that you have been subject to multiple inspections for the same product in different EU countries?	10%	90%	295

Source: Machinery Directive Public Consultations. Excludes non-respondents.

Table 119 Please rate the RAPEX system on the following aspects:

	Very / Poor	Adequate	Very / Good	n
Its ease of use (in notifying)	29%	43%	29%	7
Its ease of use (in monitoring others' notifications)	29%	29%	43%	7
Its completeness (in terms of non-compliant findings recorded)	14%	29%	57%	7
Action taken as a result of notifications	0%	57%	43%	7

Source: Machinery Directive Targeted Consultations. Excludes non-respondents.

B.4.7 Benefits of the Directive

Table 120 Which of the following benefits does the Machinery Directive bring to you / your members:

	Not at all	To a small extent	To a large extent	n
The CE mark is a recognised quality certificate also outside of the EU	6%	21%	73%	33
One standardisation procedure instead of 28 individual standards saves time and money	0%	6%	94%	35
The existence of European Harmonised Standards saves time in finding appropriate technical specifications	0%	13%	88%	32
Self-certification cuts certification costs significantly	0%	16%	84%	32

Source: Machinery Directive Targeted Consultations. Excludes non-respondents.

Table 121 What benefits does the Machinery Directive bring to you, your organisation or the wider machinery industry/economy/society?

	Benefits of the Machinery Directive
The CE marking is positively influencing sales outside EU	53%
One standardisation procedure instead of 28 national standards saves time and money	84%
The existence of European harmonised standards saves time in finding appropriate technical specifications	78%
Self-certification cuts certification costs significantly	66%
The Directive protects the internal market from hazardous products made abroad	54%
Others	8%
n	264

Source: Machinery Directive Public Consultation. Excludes non-respondents.

B.4.8 Impacts of the Directive

Table 122 Over the past 10 years, based on your experience what has happened to:

	Decreased significantly	Decreased slightly	No change	Increased slightly	Increased significantly	n
The cost of ensuring that machinery is safe	2%	5%	8%	36%	49%	321
Usefulness of information provided with machinery when purchased	2%	6%	21%	41%	30%	328
The range and quality of machinery products available	2%	5%	21%	43%	31%	308
The rate and extent of innovation in the machinery sector	1%	4%	16%	44%	36%	314
Turnover and profitability of the European machinery sector/businesses	7%	26%	19%	39%	9%	227
The international competitiveness of the European machinery sector/businesses	5%	19%	29%	33%	15%	262
The volume/value of intra-EU trade in Machinery	8%	13%	30%	38%	12%	216
Barriers to enter the EU internal market/free movement of machinery	8%	18%	42%	22%	11%	285
User confidence in machinery safety	2%	5%	26%	44%	23%	318
The number of machinery-related accidents and injuries	16%	54%	22%	8%	1%	270
The severity of machinery-related accidents and injuries	23%	47%	20%	8%	2%	261
The number of un-safe/non-compliant machinery on the market/in use	11%	34%	19%	28%	8%	285
The level of safety/protection for users of machinery (workers/consumers)	2%	5%	10%	51%	32%	327

Source: Machinery Directive Public Consultation. Excludes non-respondents.

Table 123 In your opinion, are there any negative impacts of the Directive?

	Negative impacts of the Machinery Directive
Costs of certification is high	37%
Random ex-post checks are not eliminating all non-compliant products	56%
Divergent strictness of checks by national authorities creates a room for circumventing the rules	49%
European harmonised standards are not up-to-date with technological developments	34%
There are areas where European harmonised standards are non-existent or insufficient	48%
Process of European harmonised standards setting does not consider views of industry	13%
Self-certification procedure is too complex	13%
Risk assessment is too complex	18%
Others	13%
n	295

Source: Machinery Directive Public Consultation. Excludes non-respondents.

Table 124 What has been the impact of the Machinery Directive on:

	Substantial increase	Some increase	No change	Some decrease	Substantial decrease	n
The costs and burdens on businesses	29%	54%	10%	4%	3%	235
The prices for users (workers/consumers)	14%	57%	22%	5%	2%	221
The costs and burdens on authorities	14%	40%	35%	4%	6%	119
The range and quality of machinery products available	15%	55%	25%	4%	1%	231
Quality of information and instructions relating to the safe operation of machinery	33%	49%	14%	2%	2%	249
The rate and extent of innovation in the sector	13%	31%	47%	8%	1%	209
Turnover and profitability of the European machinery sector/businesses	5%	34%	38%	19%	4%	154
The international competitiveness of the European machinery sector/businesses	12%	42%	29%	12%	6%	194
Barriers to the internal market/free movement of machinery	4%	18%	29%	20%	28%	213
The volume/value of intra-EU trade in Machinery	5%	32%	50%	10%	3%	146

Source: Machinery Directive Public Consultation. Excludes non-respondents.

Table 125 What has been the impact of the Machinery Directive on health, safety and environment:

	Substantial increase	Some increase	No change	Some decrease	Substantial decrease	n
The level of user confidence in machinery safety	23%	57%	17%	2%	2%	242
The number of machinery-related accidents and injuries	0%	5%	14%	55%	27%	200
The severity of machinery-related accidents and injuries	1%	6%	18%	35%	41%	198
The number of un-safe/non-compliant machines on the market/in use	7%	12%	17%	46%	18%	209
The level of safety/protection for users of machinery (workers/consumers)	33%	53%	7%	4%	3%	249
The level of environment protection in pesticide applications	9%	45%	33%	7%	5%	75

Source: Machinery Directive Public Consultation. Excludes non-respondents.

Table 126 What has been the impact of the Directive on market efficiency:

	Very negative	Negative	None	Positive	Very positive	n
The costs and burdens on businesses	3%	31%	26%	36%	5%	39
The costs and burdens on consumers	0%	21%	33%	38%	8%	39
The range of machinery products available	0%	5%	41%	49%	5%	39
The quality of machinery products available	0%	5%	7%	69%	19%	42
Information and instructions relating to the safe operation of machinery	4%	2%	2%	64%	27%	45
The rate and extent of innovation in the sector	0%	8%	44%	46%	3%	39
Turnover and profitability of the European machinery sector / businesses	3%	3%	36%	50%	8%	36
The international competitiveness of the European machinery sector / businesses	0%	0%	22%	67%	11%	36
The volume / value of intra-EU trade in Machinery	0%	0%	19%	68%	13%	31
Barriers to the internal market / free movement of machinery	0%	0%	21%	37%	42%	38

Source: Machinery Directive Targeted Consultations. Excludes non-respondents.

Table 127 What has been the impact of the Machinery Directive on wellbeing:

	Very negative	Negative	None	Positive	Very positive	n
The level of user confidence in machinery safety	3%	0%	10%	64%	23%	39
The number of machinery-related accidents and injuries	0%	0%	3%	65%	32%	37
The severity of machinery-related accidents and injuries	0%	0%	0%	74%	26%	38
The number of un-safe / non-compliant machines on the market / in use	3%	8%	13%	72%	5%	39
The level of safety / protection for users of machinery (workers / consumers)	2%	2%	0%	73%	22%	41
The environment	0%	0%	28%	69%	3%	32

Source: Machinery Directive Targeted Consultation. Excludes non-respondents.

Table 128 In your experience, does the Machinery Directive (i.e. its scope and provisions) contribute towards these objectives? (PC Question: Overall, to what extent do you believe the MD has contributed towards...?)

	Not at all	To a small extent	To a moderate extent	To a large extent / entirely	n
An effectively operating internal market for the products in its scope?	1%	4%	21%	74%	308
Protecting the health and safety of consumers and users of the products in its scope?	1%	3%	25%	71%	311
Protecting the environment in relation to machinery for pesticide/herbicide application	6%	17%	34%	44%	156

Source: Machinery Directive Public and Targeted Consultations. Excludes non-respondents.

B.4.9 Costs and benefits of the Directive

Table 129 To what extent are the costs triggered by the Directive proportionate, given the benefits for:

	Benefits significantly outweigh costs	Benefits slightly outweigh costs	Benefits and costs are equal	Costs slightly outweigh benefits	Costs significantly outweigh benefits	n
You / your organisation	25%	27%	21%	19%	8%	193
Businesses	21%	32%	19%	21%	6%	191
Member State authorities	33%	26%	20%	11%	10%	89
Users (workers / consumers)	36%	33%	10%	15%	5%	174
Overall	19%	34%	28%	14%	4%	173

Source: Machinery Directive Public Consultation. Excludes non-respondents.

Table 130 To what extent are the costs triggered by the Directive proportionate, given the benefits for:

	Benefits significantly outweigh costs	Benefits slightly outweigh costs	Benefits and costs are equal	Costs slightly outweigh benefits	Costs significantly outweigh benefits	n
Your organisation	22%	39%	22%	17%	0%	18
Your members / industry	21%	41%	17%	17%	3%	29
Your country	88%	0%	0%	13%	0%	8
Europe	36%	33%	10%	18%	0%	33

Source: Machinery Directive Targeted Consultation. Excludes non-respondents.

Table 131 Are there areas of the Directive's application where burden could be reduced?

	Areas of the Directive's application where burden could be reduced
Assessment of conformity with internal checks for products not covered by Annex IV	18%
Assessment of conformity with internal checks for products covered by Annex IV, where a European harmonised standard is applied that covers all applicable requirements	13%
EC-type examination for Annex IV products	15%
Approval by a notified body of a full quality assurance system for Annex IV products	10%
Content of EC declaration of conformity	13%
Others	60%
n	262

Source: Machinery Directive Public Consultation. Excludes non-respondents.

B.4.10 Coherence of the Directive

Table 132 To what extent, in your experience, the Directive:

	Not at all	To a small extent	To a moderate extent	To a large extent	n
With national legislation	0%	1%	22%	77%	79
With other EU legislation (e.g. other product Directives)	0%	5%	34%	61%	79
With international (non-EU) legislation	2%	20%	72%	6%	64

Source: Machinery Directive Targeted Consultations. Excludes non-respondents.

Table 133 To what extent does the Machinery Directive differentiate or fit with other EU legislation (e.g. Lifts Directive, Low Voltage Directive, Medical Devices Directive, Tractor Regulation, Directive on Use of Work Equipment at Work, Electromagnetic Compatibility Directive, Radio Equipment Directive, etc.)?

	Not at all	To a limited extent	To a moderate extent	To a large extent	Entirely	n
To what extent does the Machinery Directive differentiate or fit with other EU legislation	3%	31%	42%	24%	0%	207

Source: Machinery Directive Public Consultations. Excludes non-respondents.

Table 134 What kind of overlaps or inconsistencies with other EU legislation exist?

	Overlaps or inconsistencies with other EU legislation
Different definitions are used causing divergent interpretation	31%
Same product is regulated by two or more directives causing additional burden	51%
There is potential for regulatory arbitrage (choose less stringent rules)	22%
There is potential for multiple, repetitive inspection on same/similar issue	17%
Others	21%
n	286

Source: Machinery Directive Public Consultation. Excludes non-respondents.

B.4.11 European Added Value of the Directive

Table 135 To what extent does the Machinery Directive achieve more than would be achieved otherwise (i.e. in its absence), in terms of:

	Not at all	To a small extent	To a moderate extent	To a large extent	n
Facilitating the free circulation of machinery within the internal market	0%	4%	14%	83%	80
Ensuring a high degree of health and safety of machinery	0%	1%	20%	79%	80
Ensuring environmental protection in relation to machinery used in pesticide applications	6%	14%	53%	28%	36
Reducing costs	8%	28%	43%	21%	72
Reducing disparities between Member States	1%	1%	29%	68%	78
Other areas of added value	0%	15%	35%	50%	20

Source: Machinery Directive Targeted Consultations. Excludes non-respondents.

Appendix C Additional data

C.1 Distribution of published EN by technical body

Based on the reference numbers of EN standards listed within the OJ, we have matched each to the relevant technical committee within CEN/CLC, in order to give a sense of the distribution of standards across machinery sub-sectors.

Table 136 Distribution of published EN, by CEN-CENELEC technical body

TC Number	TC Name	Number of EN
CEN/TC 151	Construction equipment and building material machines - Safety	83
CEN/TC 144	Tractors and machinery for agriculture and forestry	65
CEN/TC 153	Machinery intended for use with foodstuffs and feed	44
CLC/TC 116	Safety of motor-operated electric tools	39
CEN/TC 114	Safety of machinery	36
CEN/TC 168	Chains, ropes, webbing, slings and accessories - Safety	34
CEN/TC 142	Woodworking machines - Safety	33
CEN/TC 147	Cranes - Safety	24
CEN/TC 211	Acoustics	23
CEN/TC 214	Textile machinery and accessories	23
CEN/TC 274	Aircraft ground support equipment	23
CLC/TC 61	Safety of household and similar electrical appliances	22
CEN/TC 198	Printing and paper machinery - Safety	21
CEN/TC 122	Ergonomics	20
CEN/TC 231	Mechanical vibration and shock	19
CEN/TC 150	Industrial Trucks - Safety	18
CEN/TC 145	Plastics and rubber machines	17
CEN/TC 255	Hand-held, non-electric power tools - Safety	15
CEN/TC 143	Machine tools - Safety	14
CEN/TC 192	Fire and Rescue Service Equipment	13
CEN/TC 271	Surface treatment equipment - Safety	13
CEN/TC 10	Lifts, escalators and moving walks	11
CEN/TC 322	Equipment's for making and shaping of metals - Safety requirements	10
CEN/TC 98	Lifting platforms	10
CLC/TC 44X	Safety of machinery: electrotechnical aspects	10
CEN/TC 201	Leather products machinery [extinct]	9
CEN/TC 146	Packaging machines - Safety	8
CEN/TC 196	Machines for underground mines - Safety	7
CEN/TC 33	Doors, windows, shutters, building hardware and curtain walling	7
CEN/TC 123	Lasers and photonics	6
CEN/TC 197	Pumps	6
CEN/TC 148	Continuous handling equipment and systems - Safety	5
CEN/TC 183	Waste management	5
CEN/TC 188	Conveyor belts	5
CEN/TC 202	Foundry machinery	5
CEN/TC 256	Railway applications	5
CEN/TC 270	Internal combustion engines	5
CEN/TC 186	Industrial thermoprocessing - Safety	4
CEN/TC 200	Tannery machines and plants [extinct]	4
CEN/TC 232	Compressors, vacuum pumps and their systems	4
CEN/TC 305	Potentially explosive atmospheres - Explosion prevention and protection	4
CEN/TC 310	Advanced automation technologies and their applications	3
CEN/TC 354	Non-type approved light motorized vehicles for transportation of persons, goods & related facilities	3
CEN/TC 397	Baling presses - Safety requirements	3
CEN/TC 149	Power-operated warehouse equipment	2

TC Number	TC Name	Number of EN
CEN/TC 182	Refrigerating systems, safety and environmental requirements	2
CEN/TC 393	Equipment for storage tanks and for filling stations	2
CLC/TC 121A	Low-voltage switchgear and controlgear	2
CEN/SS H10	Sewing machines	1
CEN/TC 109	Central heating boilers using gaseous fuels	1
CEN/TC 131	Gas burners using fans	1
CEN/TC 136	Sports, playground and other recreational facilities and equipment	1
CEN/TC 155	Plastics piping systems and ducting systems	1
CEN/TC 169	Light and lighting	1
CEN/TC 213	Cartridge operated hand-held tools - Safety	1
CEN/TC 242	Safety requirements for passenger transportation by rope	1
CEN/TC 313	Centrifuges - Safety requirements	1
CEN/TC 47	Atomizing oil burners and their components - Function - Safety - Testing	1
CEN/TC 85	Eye protective equipment	1
CLC/SC 31-8	Electrostatic painting and finishing equipment	1
CLC/SR 27	Industrial electroheating and electromagnetic processing	1
CLC/TC 204	Safety of electrostatic painting and finishing equipment	1
CLC/TC 22X	Power electronics	1
Grand Total		761

Source: Technopolis

C.2 Suggested gaps in the Harmonised Standards portfolio

Respondents to the public and targeted consultations were asked to highlight any particular gaps in the current coverage of Harmonised Standards in supporting the application of the Machinery Directive (i.e. missing or insufficient standards). A large number of (often very specific) suggestions were put forward, covering a wide range of areas. In section 5.7.3 we attempt to summarise the main areas mentioned, as well as the wider range of individual suggestions given. Nevertheless, a full list of suggestions given is presented verbatim below for reference.

- *A C standard as a real work aid is often missing. (E.g. In the field of electric motor-operated hand-held pressing tools / cutting tools*
- *A counterpart to EN ISO 82079-1 is urgently needed !!!*
- *A standard for assemblies and relevant risk assessment would be handy.*
- *A uniform definition of a risk assessment procedure across all standards 13849/62061/61508 / ...*
- *Added manufacturing (3D printing)*
- *Robots outside the industrial environment*
- *IOT*
- *Additive Manufacturing*
- *Almost all technical building equipment.*
- *There doesn't seems to be Harmonised standard for protection against computer hacking, both commercial and industrial. I am sure this topic is going to become a bigger issue in the future due to industrial connectivity improvements and 'SMART' systems being developed.*
- *Applications powered fuel not in the scope of EN 746. The EN 746 series of standards envisaged but never enacted (eg melting furnaces)*
- *Assembly machines should be framed by a standard.*
- *Assistance systems, collaborative systems / robots*
- *Autonomous functions, complex software systems*
- *C standards for assembly systems / assembly machines*
- *Collaborative robotic systems. Interaction between man and machine.*

- *Construction machinery, agriculture machinery, industrial trucks*
- *Coverage of some smaller volume or lower value products is low, meaning that manufacturers must revert to the EHSRs and interpret them themselves. While understandable this will lead to greater variety of interpretation of the state of the art and the appropriate level of safety provision*
- *Current harmonised standards are not always sufficiently technically robust for innovative products. Therefore, other means would be required to comply with the Machinery Directive, until industry and /or institutions are ready and willing to develop these standards. (and for niche products sometimes their are not enough parties/ stakeholders)*
- *Examples: electric pole pruner, electric brush cutters, cordless leaf blowers"*
- *Drones, autonomous vessels.*
- *EN ISO 12417 should be updated to meet today's needs at IB.*
- *EN1570-3*
- *EN61010 series is not harmonised under machinery directive but a large number of equipment types within the scope of 61010 also fall within the definition of machine.*
- *Entertainment Industry. Although TC433 has start producing working items intended to become EN standards, it would be important - at least for lifting equipment and automation machineries used in the Entertainment industry - that CEN receives a mandate to produce an harmonised standard. In this way presumption of conformity could be achieved by manufacturers - even using he Annex IV provisions - without grey areas."*
- *Ergonomics, access/egress related to emergency and rescue, anchor point and its anchorage (type A + its anchorage)for securing person working at heights on machinery - constructions,*
- *European standard for tube bending machines is needed.*
- *External Q standards must be used when creating performance indicators. Partially based on customer standards that deviate strongly from the EU standard.*
- *Food machines*
- *Food machines that cause high dust concentrations in the interior of the machine (process chamber).*
- *For certain products and innovative technologies, only technical reports exist which do not lead to presumption of conformity.*
- *For example an assembly machine. A general standard in the field would be desirable*
- *For example, for wire bending machines*
- *For many interchangeable equipment and equipment service machines.*
- *For some products to lift loads*
- *For some special types of machines with high potential for hazards*
- *FTS (driverless transport systems) - outdated content with few concrete statements on the general design of protective equipment.*
- *Fundamental requirements of optical safety sensors are covered in Standards EN 61496-2, -3, 4-2 etc. Those Standards are not listed by the machine directive. This prevents companies from self certification of this type of products.*
- *Gashock cooker in flat design*
- *Generate more standards for different types of product and not create a single generalizing standard for various types of machines*
- *Harmonised standard for Harbor Passenger Bridge to Ships*
- *Harmonised standards need to be developed to start addressing innovative products that are becoming increasingly common; such as collaborative robots, etc.*
- *Harmonized standards missing for cobots*
- *Hoisting gear / multi-axis gantries which are not subject to the standard for rack-mounted devices.*
- *How can C-standards be used when a machine consists of more than one machine in a combination, esp when a C-standard deviates from the B-standards and give specific measures etc, that are not accepted for other types of machinery. Missing standards: E.g. Permanent means of access to mobile machinery, standard for collaborative robots,*
- *I advise you to look at the recent Agendas of the MWG which are packed with topics concerning problems with harmonised standards.*
- *I have just now a job by helping af company to CE- mark a fire protection system. There are standards which advice in design and verification of the specific product which is part of a system but no standard which specify demands for a complete system*
- *If necessary, C standards for "exotic" machines, e.g. Hump welding machines*
- *In heat-treatment of products and in the corrosion protection of coating.*

- *In my experience, many machines for working metal (eg. Calandratrici, plasma cutting machines, laser and flame cutting etc.).*
- *In the definition area for an incomplete machine, cutting quantities / overlapping ranges result in the application frame for interchangeable equipment. In this respect, it is desirable to specify the relevant harmonized standards.*
- *In the field of machines, cableless, the electro-equipment in 3D whose work for the first edition legislation are still ongoing.*
- *Indeed, tyre changers are today not covered by harmonized Standard and should be.*
- *ISO 21789 would be a harmonized standard.*
- *ISO10218 part 1/ 2 does not provide clear guidance on the required safeguarding for low payload cobots and because of this unclarity suppliers are delivering COBOTS that are not conform the specification (Pl_d) ISO13849 - 1 there is after 10 years still no guidance based upon science on the definitions of S, F & P. This was the same for EN954-1. It would be of great value to the industry if there would be better guidance and direction on how to select the best values.*
- *Lack of harmonized regulations for specific areas of application for Turbines and Generators for Power Generation.*
- *Lack of presumption of conformity in EN 474- "Earth-moving machinery - Safety-Part 1" for the requirements of the visibility requirements laid down therein.*
- *Laserlight and protection. standards for using machines as hobby*
- *Lifting platform for disabled people without liftwell and maximum rise 1 m*
- *Machine Safety vs Plant Safety*
- *Machines for pyrolysis where explosive gases are produced.*
- *Many standards do not take into account the automated control of the machines by integrated software*
- *medical devices*
- *Missing: harmonized standards on classification of process equipment (pumps, fans, mixers, conveying equipment) in terms of machinery versus partly-completed machinery.*
- *Missing(unaware of) B type standards (harmonized) for EHSR: 1.1.7, 1.1.8, 1.3.1, 1.3.5, 1.3.6, 1.5.16, 1.6.4, 1.6.5, 1.7.2, 1.7.3, 1.7.4*
- *New products, or new state of the art for products already on the market are two of the reasons for continuous activity to develop new standards or revise existing ones.*
- *No C standard for Industrial measuring machines (but not legal metrology).*
- *No current harmonized standard for FTS (AGV).*
- *No EN for industrial ovens, floor ovens, tunnel ovens, ovens with thermal oil heating. Here exists only the EN 1673: 2010 rack ovens - safety and hygiene requirements*
- *No harmonized standards for assistance systems and driverless transport systems are available. Standards for the same machines in different fields of application*
- *Non-electrical EX range*
- *Off-shore sector.*
- *Collaborative robots and wind turbines"*
- *Oil and gas sector.*
- *Operating instructions for machines intended for commercial use.*
- *Particularly in the field of machine safety, there are a number of standards, which could also partly be summarized. Eg ISO 7010 and EN 4844-2 (could be summarized) or ISO 14119 and ISO 14120 (could also be summarized)*
- *Partly Completed Machinery and interchangeable equipment standards*
- *PCM and interchangeable equipment standards.*
- *Pickling plants (use of hydrofluoric acid in stainless steel pickling plants)*
- *Plasma treating surface coating machines*
- *Pressure equipment , casted aluminium*
- *Probably many, because machinery is such a wide topic covering 10s of thousands of machine types, so for many there will only ever be the A and B standards, but at least: Access to wind turbines (progress has been stalled for a long time), firewood processors (new work item now agreed) and boom saws (market probably too small to justify at present).*
- *Product standard for general production machinery is missing, EN ISO 12100 is not specific enough.*
- *Products in the field of functional safety (sensor, evaluation, actuator). (For example, shaft doors, buffers, catchers, electrical safety components-FuSi ....) There are too many general requirements in standards where clear measurable parameters are necessary.*

- *Quarry installations and machines for the production of concrete.*
- *Regarding instructions for use there is no harmonised standard. The by CENELC as European standard adopted "EN 82079-1 Preparation of instructions for use - structuring, conten and presenation - Part 1 General principles and detailed requirements" covers all relevant issues but is not harmonsed yet.The rules and regulations applying to instructions for use stipulated within the harmonised standards so far do not reflect properly the complex process of drafting instructions for use.*
- *Risk assessment*
- *Risk could be reduced by including development targets in a certain timeframe: e.g. Current methodes to fill water in tanks are not precise */+15% (technology exist to make this very precise), Residual volume standard is too high. Most sprayers fulfill the standard but best sprayers have only 50% of residual volume (this should be the target) , in future residual volume should be eleiminated ? Find high and very low technology on the same machine (consistency is often missing) (GPS does not help if you cannot adjust the sprayer correctly.*
- *Risk Management*
- *Safety factors (for example with regard to spring forces for closing pressure or bursting pressures) for the design of fluid-technical components (eg: hoses, valves, cylinders). These components are generally excluded from the pressure gauge line and the pressure vessel direc- tive.*
- *Safety of materials still insufficient in certain areas. Protection of the health of workers and persons in the machine environment (eg dusting) and taking into account the processes of implementation.*
- *Safety related control systems*
- *Safety std for complex machinery do not exist. (EN ISO 21789 is in progress)*
- *See the agenda of the Machinery Working Group. There is almost no area that has not been problematic in recent years.*
- *shortening hooks for sling chains, lifting eyes*
- *Smart appliances, appliances equipped with radio modules*
- *Software, Security, Automated Flotation Vehicles, Control Technology Automotive (ISO 26262),*
- *Some examples of products where there is a lack of European harmonisaed standards: electric pole pruner, electric brush cutters, cordless leaf blowers*
- *Some of the machines in the concrete products sector*
- *Some standards should be clarified on the aspects covered and the aspects which are not dealt with. Type C Harmonized standards shall have a clear scope including the link with other Type C standards that have a closed scope*
- *Some well known cases e.g. forestry shredders.*
- *Special machine construction*
- *Standard for road traffic approval for earth-moving machinery*
- *Standards for interchangeable equipment and some machines.*
- *Standards for plate bending machines and wind turbine access are needed.*
- *Standards for the road traffic permit of earth-moving machinery, or possibly as an alternative to the tractor regulation 167/2013 a type-approval ordinance as an alternative.*
- *Standards need to be clear and unambiguous. Standardisers need to understand that Market Surveillance are the final users of standards and hence the document they produce needs to stand the test of the market.*
- *Test standards for complex safety-relevant products.*
- *Test stands, special machine construction in connection with buildings / rooms*
- *The Standard on Concrete Plants pr EN 12151 was started in 1992, it is still in process ..... The color and the type of electric cables is different according to the European countries, the "local" disconnector is of different color Depending on the country and may be more or less close to the engine. In UK it must be next to the engine, in Germany it can cut an entire automatic installation and not just a motor.*
- *The whole standards in the field of laboratory equipment !! (Electrical safety, laser safety, etc.)*
- *There are 4 ENs dealing with gas burners (EN 676, EN 746, EN 12952-8, EN 12953-7), the control areas partly overlap, the regulations contain contradictions and the users are not clear where to apply which norm . There are EN 61508/61511 and EN 13849 which regulate similar areas*
- *There are no C type standards for many large machines manufactured in low volumes. The use of B-Type standards although perfectly possible can result in 20 or even 30 standards to consider which is very time consuming and costly. There are many cross over areas with other Directives and MD standards are frequently not listed in OJ lists for other Directives and vice versa. there can be no alignment of standards or requirements in these cross over areas*
- *There are no EN or NP standards for all types of machinery*

- *There are no European harmonised standards for non-enclosed lifting platforms (covered by BS 6440 in UK) and homelifts (covered by BS 5900 in UK) although there is work starting at CEN. There is no European harmonised standard for "slow speed lifts" although EN 81-42 is under preparation at CEN. All these standards are late as there have been products on the market in these areas for many years. This acts as a barrier to trade for SMEs since the cost of EC Type Examination discourages its use for low volumes.*
- *There are no standard values for physical conditions independent of C standards. (E.g. It is not comprehensible that there are different requirements from C standards, even though the threat situations are identical*
- *There is a gap for the rules on the safety of additive technology machines.*
- *There is a lack of standards covering additive manufacturing (3D printing) for metal powders in industrial applications and the laser machines.*
- *There is no harmonised available for example for roll-pending machines*
- *There is no harmonised standard specifically for Turbines and Electric Generators for Power Plants yet, but work within CEN is addressing this matter. A combination of both harmonised and other standards are used on the basis of contractual requirements and specific products Codes, supporting the conformity to EHSR of the Machinery Directive. The peculiarity of certain products may lead to the use of international standards.*
- *There is no harmonised standard specifically for Turbines and Electric Generators for Power Plants yet, but work within CEN is addressing this matter. A combination of both harmonised and other standards are used on the basis of contractual requirements and specific products Codes, supporting the conformity to EHSR of the Machinery Directive. The peculiarity of certain products may lead to the use of international standards.*
- *There is no harmonized standard for "loading wagons" (but is in progress).*
- *There is no valid C standard for AGV's*
- *There is only one category. There are many categories of harmonization still discoveries machines. Many special machines, for example, are to be supported in similar machinery standards. I can think of shippers (self-propelled unloader cranes, excavators type) which are not defined in the 474.*
- *Use of Fence or Light Screen. Reach/clean ability versus more down time.*
- *Water treatment: many dangerous machines not covered by standards (bar screens, agitators, carpets, ...)*
- *We build horizontal chopping machines for the production of pulp. Neither by their own research nor by inquiries with the BGRCI or the BGHM could a C-standard for such machines be found.*
- *We have no standard for platform lift without completely enclosed lift way*
- *Well, very wide field. In essence, harmonized standards are missing in "exotic" machines, such as a grinding jig, as a simple example.*
- *Wind energy*
- *Winding machines*
- *Wireless technologies are not very strong.*
- *Yes, many MRL standards are insufficient, in particular, the comprehensive risk assessment according to EN ISO 12100 is missing and thus the standards are generally incomplete.*

C.3 Mapping of actions (and costs) triggered by the Machinery Directive

Table 137 Main actions triggered by the Directive – identification of costs

Action conferring cost	Actor incurring cost	Cost type	Frequency incurred	Cost Category
Set-up costs				
Development and proposal of legislation	European Commission MS and other representatives	FTE effort	One-off for lifetime of Directive	n/a
Adoption of legislation	European Council and Parliament	FTE effort	One-off for lifetime of Directive	
Transposition of Directive into national legislation	Member States (x33)	FTE effort	One-off for lifetime of Directive	Direct compliance cost
Establishment of supporting legislation and procedures (e.g. relating to market surveillance)	Member States (x33)	FTE effort	One-off for lifetime of Directive	
Familiarisation with the Directive / national legislation	All	FTE effort	One-off for lifetime of Directive	
Assessment and appointment of Notified Bodies	Notified Bodies (x187) Member States (x33)	FTE effort	Determined by no. NBs applying during lifetime of Directive	
Monitoring of Notified Bodies	Notified Bodies (x187) Member States (x33)	FTE effort	Determined by no. NBs appointed	
Standardisation				
Mandating the development of harmonised standards	European Commission	FTE effort	Twice (to date)	Indirect costs
Managing standards development	European Commission ESO	FTE effort	Determined by number of relevant standards developed / revised	
Participation in European standards development	ESOs National Standards Bodies National authorities Manufacturers Users Others	FTE effort T&S	Determined by number of relevant standards developed / revised	
Following standardisation (e.g. through mirror committees)	National Standards Bodies Manufacturers Users Others	FTE effort	Determined by number of relevant standards developed / revised	
Compliance costs (conformity assessment)				
Undertaking risk assessment (relevance of Directive)	Businesses	FTE effort	Determined by number of new products	Direct compliance costs
Option 1: Conformity assessment for Annex IV products	Notified Bodies Businesses	FTE effort Fees (of NB) 3rd party costs (e.g. tests, standards)	Determined by number of products, where this option is taken.	
Option 2: Approval of quality assurance system	Notified Bodies Businesses	FTE effort Fees (of NB) 3rd party costs (e.g. tests, standards)	Determined by number of products, where this option is taken.	

Action conferring cost	Actor incurring cost	Cost type	Frequency incurred	Cost Category
Option 3: Self-certification – assessment of conformity with internal checks	Businesses	FTE effort 3rd party costs (e.g. tests, standards)	Determined by number of products, where this option is taken.	
Development of Technical file	Businesses	FTE effort	Determined by number of new products	
Declaration of conformity / Affixing CE mark	Businesses	FTE effort	Determined by number of new products	
Monitoring and Enforcement costs				
Market surveillance / inspection activities	Businesses (if involved in inspection) Market Surveillance Authorities	FTE effort T&S	Determined by number of surveillance activities / inspections entered in ICMS database	Monitoring costs
Follow-up action (penalties, notification, etc.)	Market Surveillance Authorities Businesses	FTE effort	Determined by number of non-compliant products identified	Enforcement and adjudication costs
Review / response to notification of non-compliance – complaints; court cases.	European Commission Member States ESOs Businesses	FTE effort	Determined by number of non-compliance notifications on RAPEX	
Supporting activities				
Ensuring correct implementation of the Directive	European Commission	FTE effort	Continuous	Indirect costs
Machinery Committee – meetings and associated activities to provide advice and opinions on measures connected to the Directive and its practical application	Member State representatives European Commission	FTE effort T&S	No. meetings	
Machinery Working Group – meetings and associated activities to take part in discussion relating the practical application of the Directive.	Industry ESOs Notified Bodies Member States European Commission	FTE effort T&S	No. meetings (2 per year)	
Administrative Cooperation (AdCo) Group. Meetings and associated activities to exchange information and discuss issues regarding implementation of the Directive.	Member States European Commission	FTE effort T&S	No. meetings (2 per year)	
European Coordination of Notified Bodies for Machinery (NB-M). Meetings and associated activities to exchange experience and harmonise practices (RfU), as well as discussion conformity assessment issues.	Notified Bodies	FTE effort T&S	No. meetings (2 per year)	

Source: Technopolis

C.4 Price deflation calculations

The following Eurozone-based inflation data were used to convert annual figures to constant prices.

Year	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**
Price (2015 = 100)	117.17	114.58	112.44	109.1	107.4	106.41	104.12	101.33	99.12	98.29	100	101.24
Deflator	1.172	1.146	1.124	1.091	1.074	1.064	1.041	1.013	0.991	0.983	1.000	1.012
Year	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**
Price (2014 = 100)	117.87	115.27	113.12	109.76	108.04	107.05	104.74	101.94	99.72	100	101.74	101.41
Deflator	1.179	1.153	1.131	1.098	1.080	1.071	1.047	1.019	0.997	1.000	1.017	1.014
Year	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**
Price (2013 = 100)	116.97	114.38	112.25	108.91	107.21	106.23	103.94	101.15	100	100.28	100.88	100.56
Deflator	1.170	1.144	1.123	1.089	1.072	1.062	1.039	1.012		1.003	1.009	1.006

Source: Stat Bureau (https://www.statbureau.org/)

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