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Evaluation of the Machinery Directive

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Glossary

Term or acronym	*Meaning or definition*
A&I	Accidents and injuries
AdCo	Administrative Cooperation (Group)
AI	Artificial Intelligence
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
DG GROW	Directorate-General for Growth - Internal Market, Industry, Entrepreneurship and SMEs
Directive	Machinery Directive 2006/42/EC
EEA	European Economic Area
EHSR	Essential Health and Safety Requirements
EMCD	Electromagnetic Compatibility Directive
ENs	European Standards
FTE	Full-Time Equivalent
hENs	Harmonised European Standards
IoT	Internet of Things
ISO	International Organisation for Standardization
MD	Machinery Directive 2006/42/EC
MME	Manufacture of Machinery and Equipment
MSA	Member States Authorities
NA	New Approach
NACE	(European) Classification of Economic Activities
NLF	New Legislative Framework
RAPEX	Rapid Alert System
RED	Radio Equipment Directive
REFIT	(Commission's) Regulatory Fitness and Performance
RfUs	Recommendation for Use sheets

1. INTRODUCTION

The Directive of the European Parliament and of the Council of 17 May 2006 on machinery[1], commonly known as the Machinery Directive, is the core European legislation regulating products of the mechanical engineering industries. It has the objectives to (i) ensure a high level of safety and protection for machinery users and other exposed persons and (ii) to secure the free movement of machinery in the internal market. An additional objective for the protection of the environment is limited to the machinery used in pesticide applications[2].

In 2015, after six years of implementation, it was necessary to assess in the context of regular evaluation of the acquis, if the Directive has achieved its objectives in an efficient, coherent and relevant way and still has EU added value. Therefore in line with the Commission's Regulatory Fitness and Performance (REFIT) programme[3], the Machinery Directive[4] was subject to an evaluation[5].

1.1. Purpose of the evaluation

The Machinery Directive ('the Directive') was adopted in 2006, and became applicable as of December 2009. It was further amended in 2009 to include environment protection requirements for machinery used in pesticide applications.

The purpose of this evaluation is to analyse the performance of the Machinery Directive since it has entered into force. In this respect, given the hype of emerging digital technologies wave, the evaluation analyses also the Directive's suitability to such technologies, particularly Artificial Intelligence and Internet of Things.

This evaluation assesses the extent to which the Machinery Directive is fit for purpose, hence continues to deliver effectively, efficiently and at minimum cost the intended benefits for consumers and business. It also assesses whether the Directive is coherent with other EU legislation and policies, relevant to stakeholders needs, considering in particular new evolving technological development and has EU added value.

The evaluation provides evidence and conclusions that will form the basis for possible future improvements in order to keep it up to date so that it can achieve its objectives and produce the desired results.

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[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) (OJ L 154, 9.6.2006, p. 24). As amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 (OJ L 188, 18.7.2009, p. 14); Directive 2009/127/EC of the European Parliament and of the Council of 21 October 2009 (OJ L 310, 25.11.2009, p. 29); Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 (OJ L 60, 2.3.2013, p. 1); and Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 (OJ L 96, 29.3.2014, p. 251). Corrected by Corrigendum (OJ L 76, 16.3.2007, p. 35).

[2] Directive 2009/127/EC.

[3] COM(2013)685

[4] The latest revision to a much earlier Directive (89/392/EEC) adopted in 1989.

[5] http://ec.europa.eu/smart-regulation/roadmaps/docs/2015_grow_051_evaluation_machinery_directive_en.pdf)

1.2. Scope of the evaluation

The evaluation covers all relevant product categories in the scope of the Directive and 33 countries (EU28, EFTA and Turkey). It focuses on the period from 2010 (i.e. subsequent to the deadline for application of the Directive across Europe at the end of 2009) to 2016, seeking to understand trends over this period wherever possible.

The evaluation covers the functioning of the Directive, including the processes involved in transposing, implementing and enforcing it, as well as associated assessment and monitoring procedures. The evaluation assesses the performance of the Directive according to five criteria: relevance, effectiveness, efficiency, coherence and EU added value.

2. BACKGROUND TO THE INTERVENTION

2.1. Description of the Machinery Directive and its objectives:

The scope of the Machinery Directive covers a wide range of products for both consumer and industrial use. Machinery is defined as *"an assembly … of linked parts or components, at least one of which moves…".* As such, the definition encompasses machinery ranging from, for example, lawnmowers to 3D printers, from powered hand-tools to construction machinery, from personal care robots or collaborative robots to complete automated industrial production lines. In addition to machinery in strict sense, the scope covers other related products, such as, for example, safety components or partly completed machinery.

There are various exclusions for machinery already covered by other more specific legislation. However, the Directive may apply alongside other legislation for hazards that the more specific legislation does not cover.

The Machinery Directive is a New Approach harmonised legislation[6] meaning that it provides a framework and establishes the mandatory essential health and safety requirements, but does not translate them into detailed requirements or processes.

The use of European harmonised standards is voluntary, but machinery manufactured in conformity with a European harmonised standards published in the Official Journal of the EU is presumed to comply with the essential health and safety requirements (EHSR) of the Directive that are covered by that standard.

The Directive places obligations on manufacturers to employ safety through design by means of EHSR and providing different choices of conformity assessment procedures.

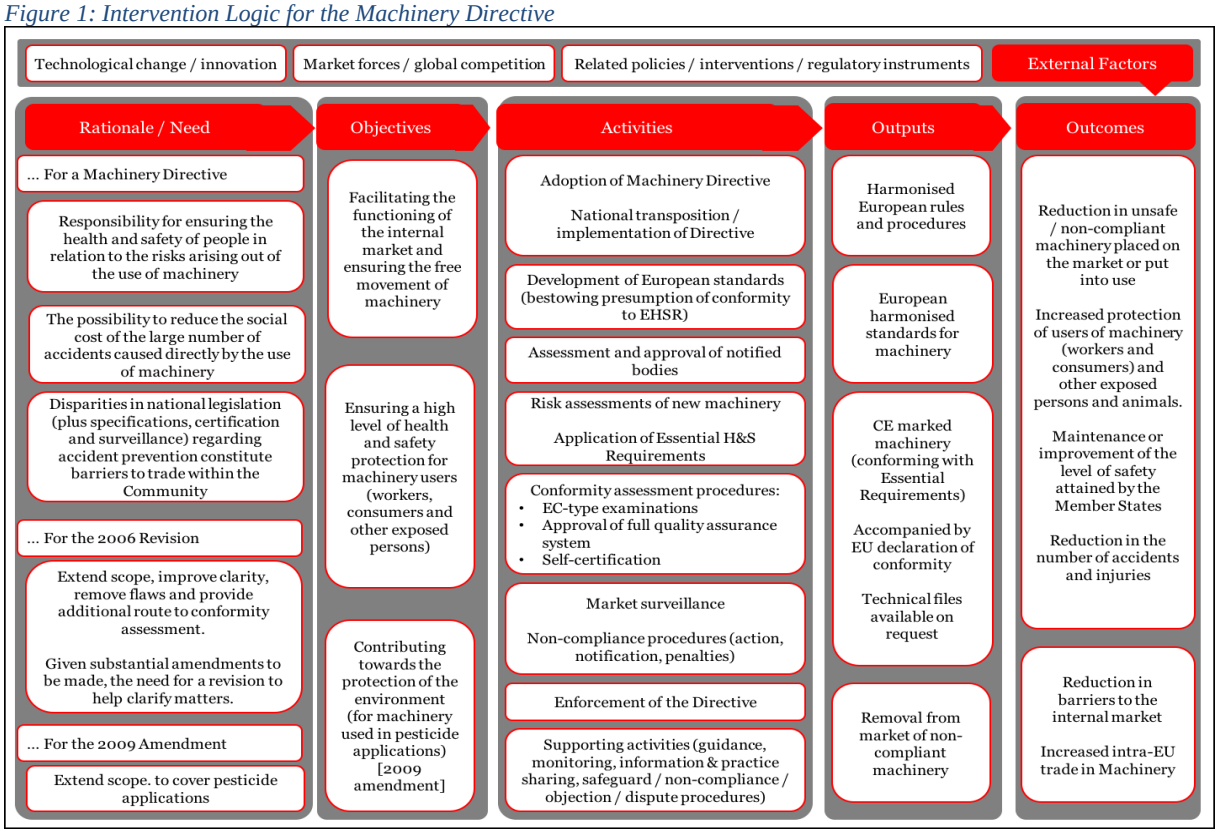
Manufacturers must ensure that the applicable EHSR of the Directive are met. Demonstrating compliance with the EHSR can be done through application of European harmonized standards or any other solution that allows demonstrating a similar level of safety. The administrative provisions of the Directive require manufacturers to produce a technical file, sign a Declaration of Conformity and affix the CE marking.

[6] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM%3Al21001a

The vast majority of machinery may be self-assessed by the manufacturer. This is also the case for the 23 categories of machinery in Annex IV of the Directive with the precondition that European harmonised standards covering all the essential health and safety requirements (EHSR) of those products are available and have been used by the manufacturer. Contrary, the manufacturer is required to involve a Notified Body.

The Machinery Directive has been revised several times since the adoption of the original version in 1989 (89/392/EEC). Building on the content of each successive versions of the Directive, an intervention logic was developed (see Figure 1). It shows the logical sequence and causal relationships between the Directive's rationale, based on identified needs, its objectives, the activities undertaken, the intended results (outputs) and outcomes. The figure also shows other external factors (beyond the Directive's control) that may influence outcomes.

Figure 1: Intervention Logic for the Machinery Directive



Source: Technopolis

2.2. Baseline scenario and points of comparison

The first Machinery 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[7], improve clarity, remove acknowledged flaws, and provide an additional route to conformity assessment for some products. This was then amended slightly

[7] COM/1987/564/FINAL

in 2009 (2009/127/EC) to include machinery with pesticide applications (applicable from 2011).

The original 1987 proposal for a Machinery Directive[8] 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 dual objectives of (i) free movement of machinery within the internal market; (ii) and a high level of protection for users (workers/consumers) and other exposed persons.

There are no specific or quantified estimates published of the potential impact (i.e. the expected costs and benefits) of the original Directive, or of subsequent revisions. The proposal for the 2006 revision[9] 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, it was concluded 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

[8] COM/2000/899/final

[9] COM/2000/899/final.

that savings resulting from the additional level of detail in the new text would offset costs.

Regarding the specific impact on enterprises, 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*"[10].

3. IMPLEMENTATION / STATE OF PLAY

After some initial delays, the 2006 Directive has been fully and consistently transposed across Member States. Following the failure by several Member States to notify the Commission in time about national transposition measures within the June 2008 deadline, the Commission opened 12 non-communication cases.[11] Additionally, 15 formal infringements procedures were open against Member States for other reasons than the 'non-communication". By the end of 2010, all infringement proceedings concerning national measures implementing Directive 2006/42/EC were closed.

The evaluation showed that with the exception of one example[12], there have not been any problems in the transposition of the Directive into national legislation.

Member States are responsible for appointing competent authorities responsible for the implementation of the Directive at national level and for ensuring that the Directive is effectively enforced within their territories. As such, they are also responsible for market surveillance, including penalties. Also, they appoint and monitor Notified Bodies to assess and certify compliance with the Machinery Directive in the relevant cases.

At EU level, a network of fora (4) has 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 could arise. The **Machinery Committee** is responsible for assisting the Commission in the implementation of the Directive, notably in the adoption of implementing measures. The possibility to adopt such measures provided for the update of the indicative list of safety components and for restrictions of the placing on the market of potentially hazardous machinery. The Commission has made use of the latter

[10] COM/2000/899/Final – Impact assessment.

[11] 26th Report on monitoring the application of Community law [COM(2009) 675] – Situation in the different sectors [SEC(2009)1684/2]

[12] The issue has been reported in the Evaluation of Internal Market Legislation for Industrial Products. It concerned the misapplication of the Directive due to translation issues during the transposition process in a Member State. This issue led to a change in the original intended meaning of the legislation.. Although the problem was resolved at national level without the trigger of an infringement procedure, there was a high cost associated with the prolonged uncertainty. Table 6.1: Regulatory divergence in national transposition of EU Directives - Tunnelling machinery

empowerment on one occasion, restricting the placing on the market of certain dangerous cutting attachments for brush cutters.

The **Machinery Working Group** is the most frequently used forum to discuss the practical application of the Directive at EU level. It is composed of representatives of all relevant stakeholders (national authorities, standardisation bodies, notified bodies, industry associations, trade unions and consumer associations).

The **Administrative Cooperation (AdCo)** Group brings together the national market surveillance authorities responsible for enforcing the Machinery Directive and enables the cooperation and exchange of information on market surveillance issues. The **European Coordination of Notified Bodies for Machinery** is a forum for the exchange of experience between Notified Bodies, to harmonise their practices through the adoption of guidance documents, also known as Recommendations for Use (RfUs).

Additionally to these groups, the Guide to application of the Machinery Directive[13] developed in cooperation with all stakeholders represented in the Machinery Working Group is a widely used tool that is highly appreciated by the machinery community facilitating the effective and efficient application of the Directive.

Another highly important mechanism supporting the implementation of the Directive is European standardisation. Industry representatives active in the European standardisation organisations (CEN, CENELEC or ETSI), together with consumer and employees interest organisations have developed an impressive set of over 700 harmonised European standards (hENs) which gives presumption of conformity and facilitate the implementation of the Directive. Harmonised standard translate the essential health and safety requirements (EHSR) into detailed technical specifications for certain types of products. There are currently 50 technical committees within CEN and 3 technical committees within CENELEC active under the Machinery Directive.

4. METHOD

4.1. Short description of methodology

The Commission evaluation is based on two main building blocks and deployed a combination of qualitative and quantitative research methods.

[13] The Guide to application of the Machinery Directive 2006/42/EC - Edition 2.1 (July 2017).

1) A study[14] by an external contractor commissioned by EC Directorate-General for Growth - Internal Market, Industry, Entrepreneurship and SMEs (DG GROW), over an 18-month period during 2016-2017. The findings of the study are based on a programme of research and analyses, which included:
   - 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, which included trade data and sectoral statistics (Eurostat SBS and COMEXT), accident and injury data (ESAW and LFS), market surveillance activity and statistics on dangerous products (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 Annex 2;
   - An open online public consultation survey designed to address evaluation questions in a reasonably high-level manner (to be applicable to all groups) gathering 342 respondents from all relevant stakeholder groups;
   - A series of targeted consultation surveys designed to address the same types of questions as in the public consultation in more depth, and with more focus in certain areas, depending on the interests, expertise and perspective of the group concerned. The targeted consultation gathered 98 responses 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, 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. Further information on the stakeholder consultation respondents is presented in Annex 2.
2) Complementary research on aspects related to digitisation by the Commission services. The evaluation study addressed in a succinct manner the Directive's suitability to digitisation during stakeholders' consultations based on past and current experience. Further research was carried out, with a focus on industrial dimension, based on review of existing studies and inputs from various targeted stakeholders.

4.2. Limitations and robustness of findings

As already mentioned the scope of the Machinery Directive is wide. The evaluation study assessed the performance of the Directive in all relevant product categories, however to facilitate data gathering and impact measuring nine broad categories

[14] http://ec.europa.eu/docsroom/documents/25661

were defined and set out in task specifications[15] allowing to better target the evaluation.

Some limitations exist with a view to the concrete time frame under consideration. The evaluation focuses on the currently applicable 2006 version of the Directive. However, many of the elements assessed were already present in previous versions of the Directive. Therefore, many observable outputs and outcomes cannot be attributed exclusively to the 2006 version of the Directive, but may rather be the overall result of the existence of the Machinery Directive over the past 30 years.

Furthermore, the evaluation was expected to identify and assemble quantitative secondary (pre-existing) evidence in order to answer most evaluation questions. However, the availability of such secondary data turned out to be limited in several areas.

One example is the information on accidents and injury (A&I). A&I related to product use is collected to different degrees by national health and safety agencies, workers insurances, and some hospital emergency departments. Data collection focuses 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, however, do not capture the cause of the accident, notably if and what type of a machine was involved, nor 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. Therefore, none of the public data sources examined was sufficiently detailed to allow a robust analysis of A&I caused by a machinery product group, or individual machines.

The problem also occurred with data related to the uptake and use of harmonised European standards, the uptake of the two conformity options involving a Notified Body, the number of non-compliant products and market surveillance activities. Furthermore, there was also lack of readily available data on costs. In result, in some cases, conclusions were drawn from a small number of data points by extrapolation to arrive at very general approximate estimation.

As a mitigating measure, these aspects were addressed in the consultations activities. Questions regarding safety and the internal market were asked in the survey and interviews.

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. Nonetheless, these responses cannot be seen as representative in from a statistical viewpoint. They represent opinions of those who decided to participate. Also, the robustness of the consultations that targeted industry and economic operators is possibly influenced by the fact that economic operators generally favour

[15] Engines and turbines; Machinery for textile, paper, rubber and food; Machines for metalworking; Non-road mobile machinery; Woodworking machinery; Lifts for lifting persons and loads; Lifting accessories; Electric power tools; Robotics and automation.

the status quo as changes in legislation generally lead to additional costs for industry.

Respondents to the public and targeted questionnaires were based in 23 EU Member, as well as 3 EFTA countries (excludes Iceland) and the greatest numbers of respondents were based in countries with the largest machinery sectors. While a large number of SMEs responded (46% of all industry respondents), this is lower than the proportion in the sector as a whole (98%). However, many of the industry associations consulted represent businesses of all sizes.

Table 1 Unique respondents to consultations, by stakeholder group and consultation route

Stakeholder Group	Respondents	%
National authority	27	7%
Notified Body	25	6%
Industry Association	66	16%
Industry / companies	181	45%
Workers / consumers and their representatives	68	17%
Consultancy/service provider for Machinery safety	31	8%
Standardisation body	1	0.2%
Unknown	6	1.5%
Total	**405**	

Information related emerging digital technologies, i.e. Internet of Things (IoT) and Artificial Intelligence (AI), is scarce and often not sufficiently mature since these technologies are still under evolution. The conclusions are based on existing information collected from stakeholders and based on various studies, media sources and forecasts.

Notwithstanding the specific limitations mentioned above which could at least partially be compensated by the answers obtained during the several the consultation activities, the overall availability and reliability of data and the approach taken is generally considered satisfactory.

5. ANALYSIS AND ANSWERS TO THE EVALUATION QUESTIONS

5.1. Findings in relation to the Context of the Machinery Directive

The machinery sector continues to be an important part of the EU economy almost 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. Information about the size and structure of the machinery market in Europe, and how this has evolved, had been collected through the questionnaire.

5.1.1. *Producers and production of machinery*

The ongoing importance of the machinery sector within the EU was analysed.

The total EU28 production of the machinery and equipment (MME) sector[16] was valued at €599b in 2014 (9.4% of the total for the wider EU manufacturing industry)[17] and the sector has grown steadily since its low point in 2009 (during the economic crisis).

The annual turnover in 2015 for the European mechanical engineering was valued at €650b[18]. Employment is estimated at more than 2.9 million people.

In 2016 output grew at average by 1%. In 2017 it appears to grow again above average (2.1%), making it the strongest sector in the engineering industry.

Although the production value had still not returned to pre-crisis (2008) levels by 2016 in real terms, the mechanical engineering is profiting of the small recovery of the European industry since the beginning of 2013.

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 consultation activities believed that the competitiveness of the European sector had increased, compared with those that felt it had worsened.

There were 90,046 enterprises in the EU28 operating in the MME sector in 2015, with concentrations in certain Member States (Italy, Germany and the UK in particular – which together account for more than half (52%) of these businesses).

As shown in Table 2, nearly two-thirds (64%) of enterprises in the sector are micro-businesses, while just 2% (1,900) 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).

Table 2 Number of enterprises and persons employed (EU28, 2015), Manufacture of machinery and equipment (NACE C28), by size-class

SIZE_EMP/INDIC_SB	Enterprises - number	Share of total	Persons employed - number	Share of total
From 0 to 9 persons employed	57,395	63%	175.228	6%
From 10 to 19 persons employed	13,129	15%	189.238	6%
From 20 to 49 persons employed	10,000	11%	321.203	11%
From 50 to 249 persons employed	7,923	9%	875.760	30%
250 persons employed or more	1,900	2%	1.382.763	47%
Total	90,347		2.944.192	

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

[16] NACE Rev. 2 sector C28 – Manufacture of Machinery and Equipment

[17] 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.

[18] ORGALIME resources - *"Resilience under pressure: EU engineering industry continues to grow at a moderate pace"*

Through the consultation activities, stakeholders were asked about the trends in the turnover and profitability of the European machinery sector and businesses over the past decade. 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.

The 2012 report on the competitiveness of mechanical engineering points to the USA, 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 Table 3, and compared with those from the EU27. This highlights the relative importance of the EU manufacturing sector globally.

Table 3 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. Consumption and trade in machinery

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[19]. 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 USA, China and Russia) is also substantial (€465b in 2015). The value of total EU exports of Machinery to third countries 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 account together for nearly one-quarter of the value of all non-EU imports of machinery to the EU28. Indeed, the Netherlands actually imports more than twice as much machinery (in terms of value) from non-

[19] Combined Nomenclature Section 16 – Machinery and Mechanical Appliances.

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.

Table 4 Value of intra-/extra-EU exports/imports of Machinery (CN Section 16) from EU28 Member States, 2015

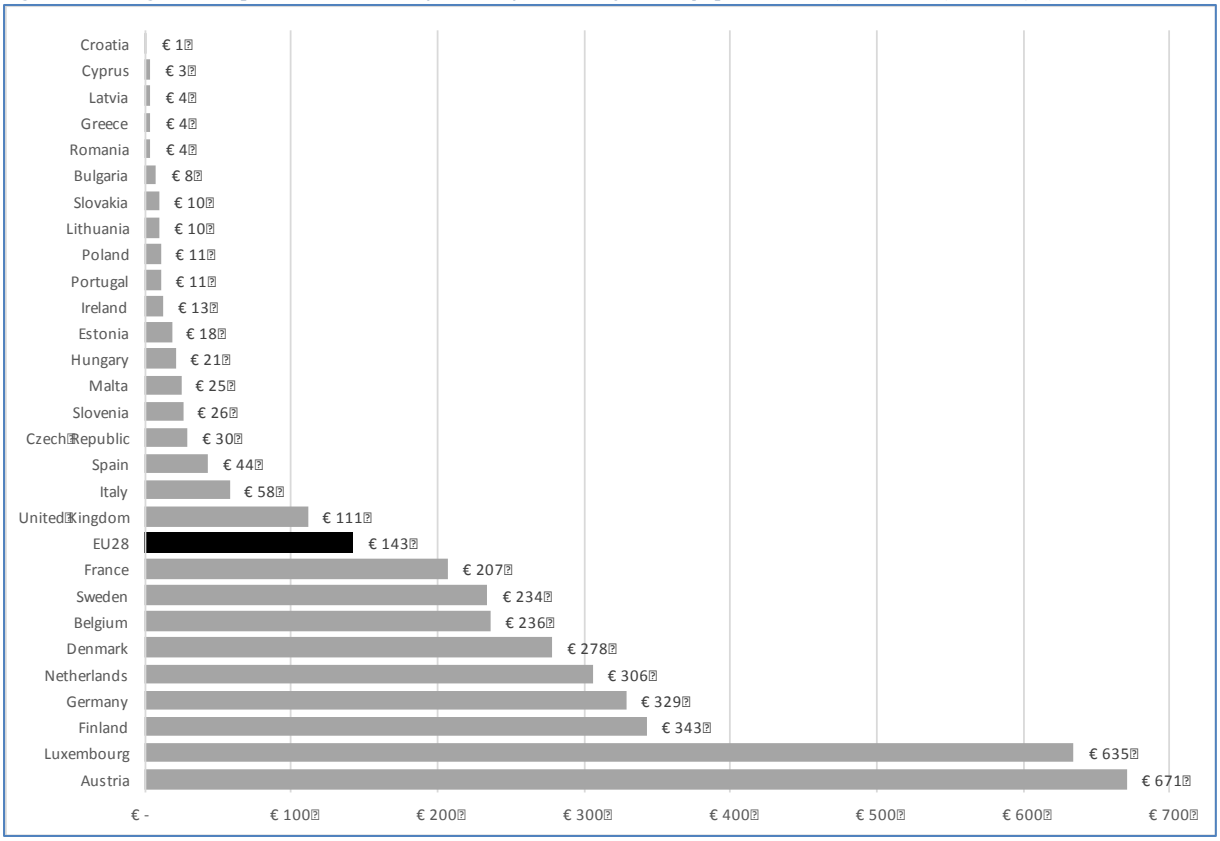
	Exports			Imports		
Member state	**Total (€b)**	**to outside EU28**	**to inside EU28**	**Total (€b)**	**from outside EU28**	**from inside EU28**
Austria (AT)	41.9	34%	66%	34.7	25%	75%
Belgium (BE)	38.7	31%	69%	41.8	32%	68%
Czech Republic (CZ)	51.0	20%	80%	45.2	34%	66%
France (FR)	87.5	45%	55%	106.8	33%	67%
Germany (DE)	322.4	47%	53%	232.2	40%	60%
Hungary (HU)	35.6	20%	80%	31.6	32%	68%
Italy (IT)	107.7	51%	49%	63.2	34%	66%
Netherlands (NL)	138.8	26%	74%	124.7	68%	32%
Poland (PL)	44.8	22%	78%	45.5	30%	70%
Spain (ES)	34.5	43%	57%	49.2	28%	72%
Sweden (SE)	35.0	51%	49%	33.7	23%	77%
United Kingdom (UK)	83.8	60%	40%	130.5	52%	48%
EU28	**1,139.0**	**40%**	**60%**	**1,067.2**	**39%**	**61%**

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

5.1.3. Innovation in the machinery sector

The machinery sector is R&D intensive compared with other areas of manufacturing or the economy more generally. In 2013 there were €13.1b spent on R&D by EU MME businesses (having increased by around 11% in real terms in just three years). A large proportion (41% or €5.4b) of the total MME BERD (Business enterprise R&D expenditure) is accounted for by Germany, followed by Italy (€1.4b) and France (€1.0b). The average MME BERD spent per business for the EU28 is €143,000, with businesses in France, Sweden, Belgium, Denmark, the Netherlands, Germany, Finland, Luxembourg and Austria spending more on average.

Figure 2 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]

The overriding view from stakeholders consulted was that the rate and extent of innovation in the sector had increased over the past decade (80% felt that the rate and extent of innovation in the sector had increased slightly or increased significantly over the period). One of the factors is the rising of the Internet of Things (IoT) through the integration of ICT into manufacturing processes, products, value chains and service offerings. The manufacturing industry is leading in the Industrial IoT, heralded as the new, fourth industrial revolution[20], which will play a pivotal role in Europe's global competitiveness[21]. As pointed out by the Commission Communication on a renewed EU Industrial Policy Strategy[22], the distinctive feature of this new industrial age are the technological breakthroughs in areas like robotics, Internet of Things, Artificial Intelligence (AI), which is transforming traditional manufacturing processes.

The industrial uptake of IoT or AI is increasing as it enables businesses to benefit from the way product design and manufacturing processes are monitored, analysed and improved to tracking and tracing products across global supply chains. In the same vain, consumers will benefit of a greater product choice, cost savings, convenience and personalisation.

[20] The first industrial revolution involved cast iron and the steam engine, the second steel, electricity, turbines, and the combustion engine, and the third, computers, communications, and globalization.

[21] https://ec.europa.eu/digital-single-market/en/fourth-industrial-revolution.

[22] COM/2017/0479 final

Moreover, with the emergence of the IoT, sensor technology and radio frequency identification (RFID) tags[23] are improving, enabling Machine-to-Machine (M2M) communication and making it possible for machines to share detailed information about their use.[24] The number of M2M connections worldwide increased from 0.5billions in 2014 to 0.8billions in 2016 and is expected to reach 2.6billions in 2020.[25]

According to a European Commission study[26] the market value of the IoT in the EU is expected to exceed one trillion euros in 2020, while digitalisation of products and services can add more than 110 billion euros of annual revenue in Europe in the next five years[27].

5.2. Findings in relation to the Relevance of the Machinery Directive

5.2.1. Relevance of the two initial objectives

The Directive has a dual objective. On the one hand, it aims to guarantee the safety of machinery through inherently design measures. On the other hand, it intends to ensure the free movement of machinery throughout the EU.

In relation to ensuring health and safety, nearly all stakeholders consulted during the consultation activities[28] carried out 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. Responses collected from the consultation activities reported increased levels of safety and protection for users of machinery (84%), improved information provided with machinery when purchased (71%) and increased user confidence in machinery safety (67%), over the past decade. A majority of respondents also suggested that the number (70%) and severity (70%) of machinery-related accidents and injuries had been reduced.

In respect to ensuring the free movement of machinery within the internal market, trade in machinery is 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. Therefore, the Directive has an importance in terms of facilitating the free movement of machinery as this is a significant EU-wide concern. The great majority of stakeholders consulted during the execution of the study also agreed 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

[23] Radio-frequency identification (RFID) is a technology to record the presence of an object using radio signals and is used for automatically identifying a person, a package or an item.

[24] https://www.pwc.com/gx/en/industrial-manufacturing/publications/pdf/pwc-rethinking-innovation-in-industrial-manufacturing-are-you-up-for-the-challenge.pdf.

[25] https://www.statista.com/statistics/487280/global-m2m-connections/.

[26] https://ec.europa.eu/digital-single-market/en/news/definition-research-and-innovation-policy-leveraging-cloud-computing-and-iot-combination.

[27] https://ec.europa.eu/digital-single-market/en/policies/digitising-european-industry.

[28] See Annex 4 on the Synopsis report

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.

5.2.2. Relevance in light of technological developments, particularly emerging digital technologies

The Machinery Directive has maintained its relevance, despite changes in technology and the business environment. It has undergone several modifications since 1989, adding or revising elements, including in its scope and requirements. These changes aimed at improving 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, however, not come about as a reaction to shifts in technology or the market. This is not surprising, given that New Approach Directives (including the Machinery Directive) are limited to setting out 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 who contributed to the consultations activities is that the Machinery Directive copes well with change.

Table 5 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	**Total responses**
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

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

Having said this, only 4% out of 254 respondents to the questionnaire of the public consultation have highlighted that specific new innovation in digital technologies, such as Internet of Things (IoT)[29], robotics, software and autonomous control, may test the suitability of the Directive and reduce its effectiveness going forward. However, the respondents to the questionnaires did not elaborate further on which are the aspects making the Directive potentially ineffective as regards these emerging digital technologies. The Commission services have followed up on these questions and present its findings in section 5.3.2.6 on the effectiveness of the Directive moving forward in a digital era.

[29] There is no universal agreed definition on IoT, but IoT could be seen as being enabled by the confluence of network connectivity, machine to machine ("M2M") interconnection, machine-embedded software, data collection and analysis ("big data"), as well as technology, such as artificial intelligence, blockchain, and cloud computing.

5.3. Findings in relation to the Effectiveness of the Machinery Directive

5.3.1. Effectiveness of the Directive's contribution to its objectives

The Directive (in broadly the same form) had already been in force for three decades. Therefore, its impacts in terms of reduced barriers to trade or increased health and safety protection have already started taking effect prior to the 2006 revision. That revision extended the scope and improved clarity while removing acknowledged flaws. It also provided an additional route to conformity assessment for some products. The main role of the current Directive is hence to maintain the benefits through continuing to facilitate trade and ensuring high levels of safety.

5.3.1.1 Contribution to product safety

A majority of respondents to the consultation activities[30] believed that the Directive (generally) has had a positive impact on a range of areas relating to health and safety protection for consumers and users, as shown in Table 7. For instance, most believe it has had a positive impact on the quality of machinery, information on safe operation, user confidence, reduction in the number and severity of accidents and injuries, reduction in the number of unsafe 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.

Table 7 What has happened to machinery-related health and safety over the past 10 years?

	Decreased significantly	Decreased slightly	No change	Increased slightly	Increased significantly	Total responses
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.

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, the aggregated data was analysed 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 (1,516 per 100,000). Within the Manufacturing, Construction, and Agriculture, Forestry and Fishing

[30] See Annex IV on the Synopsis report

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) totalled 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). In lack of granular data with respect to the exact causes of the accidents (e.g. non-compliant machinery or users' errors) these accidents cannot be attributed clearly to unsafe machinery. Consequently it is not possible to establish a clear link between the Directive and the decrease in accidents.

Additionally, 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, out of which more than three-quarters (78%) thought the Directive had contributed to a moderate or large extent towards this objective.

5.3.1.2 Contribution to the internal market

Based on the data available on the value of intra-EU28 machinery trade[31], the study on the evaluation of the Directive shows that nearly one-quarter (23%) of the value of all exports of EU Member States 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 Member States in a single year and intra-EU trade in machinery occurring between nearly every EU country. It demonstrates not only the significant value of machinery being traded across the EU in a given year, but also the extent to which all Member States are involved in the internal market for machinery. Such dynamics cannot be attributed to the current Directive only, given that it is maintaining an already well-established process that facilitates trade and ensures the effective operation of the internal market, inherited from the first version of the Directive.

Through the targeted consultations stakeholders were asked for their views as to the impact of the Directive (specifically) on the effective operation of the internal market for machinery. Stakeholder's 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 trades within the EU. There was particularly widespread belief that the Directive has had a very positive impact overall on the free movement of machinery by reducing barriers to trade within the internal market. Indeed, the Directive appears successful in harmonising rules and requirements in the Member States and thus facilitating the free movement of machinery across the Union. However, there are reports from economic operators and standardization bodies about national requirements, which

[31] COMEXT

(may) result in a barrier to trade, e.g. certain countries that often required national standards to be applied, as indicated in the section below.

5.3.2. Factors influencing the effectiveness of the Machinery Directive:

5.3.2.1 Role of provisions and requirements set out in the Directive

Certain aspects of the Machinery Directive are generally considered to have been consistently applied across Europe such as the initial transposition into national law, the appointment of Notified Bodies, the conformity assessment options available, and the fulfilment of requirements ensuring the free movement of compliant machinery.

At the same time, other aspects of the Directive are considered as not having been fully or consistently applied and that risk to reduce the effectiveness of the Directive. They are related to the enforcement of the Directive (the number and the extent of market surveillance activities, the approach taken to determining compliance, the measures to withdraw or prohibit non-compliant or unsafe machinery, and the establishment of effective and proportionate penalties for infringements)[32] .

5.3.2.2 Consistency in application of requirements

Most stakeholders consulted highlighted differences in the interpretation/ application of the requirements of the Directive between countries.

Some stakeholders also highlighted that some countries required national standards to be applied. For example, respondents have indicated that 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[33], which takes priority over the CE marking and customers in France demanding that machines fulfil Apave[34] standards, on top of European standards.

It should be clearly noted that Member States are not allowed to impose requirements from national standards. This is incompatible with the provisions of the Machinery Directive. Such practices undermine the effectiveness of the directive with a view to achieving the objective of free movement.

However, while such instances occur, they are not a systematic problem and only affect the effectiveness of the Directive to a limited extent. This is also confirmed by the fact that only 9% of stakeholders reported that in the last five years the approval of their product in one EU country had not been recognised in another country. Furthermore, there are also mechanisms for in place addressing such problems, in particular the Machinery Working Group. Different interpretations are usually

[32] This is explained in more detail in Section 5.3.2.50 *5.3.2.5 Role of mechanisms relating to non-compliance.*

[33] Geprüfte Sicherheit

[34] http://www.apave-certification.com/en/

brought to the attention of this group, where they are discussed with all stakeholders. In the last years no major issues have been observed. The few concrete cases that were actually reported by stakeholders in the consultation would need to be analysed more deeply in order to understand the underlying issues and the extent of the problem.

Table 6 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	Total responses
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.

5.3.2.3 Role of conformity assessment options

The evaluation focused on the extent to which the three routes for conformity assessment provided by the Directive are affecting its functioning:

- Assessment of conformity through manufacturer's internal checks (also known as self-assessment) which is available for:
  - Machinery not covered by Annex IV of the Machinery Directive;
  - Machinery that is referred to within Annex IV of the Directive, but is designed according to harmonised European standards covering all applicable EHSRs;
- EC-type examination for Annex IV products;
- 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).

Through the consultations activities, the evaluation explored the effectiveness of these three 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).

During the targeted consultation survey and interviews, industry respondents were asked whether (and how many times) they had employed each conformity assessment option in the past five years. The answers indicated that 'on average' the total number of conformity assessments undertaken might be split approximately into 80% assessment of conformity with internal checks (self-assessment) for products which are not part of the Annex IV, 10% self-assessment for Annex IV products, 8% EC-type examination and 2% approval of full quality assurance system. Similar patterns were suggested by industry associations and Notified Bodies. This indicates that in most cases manufacturers are using the self-assessment route to conformity – particularly outside of the main areas covered by Annex IV; and the procedure for full quality assurance systems for Annex IV products is very seldom used. For both procedures involving Notified Bodies, 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 and also that many SMEs were unlikely to have in place the necessary quality systems, hence the potential take up of this option is lower.

Stakeholders were also 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. There were differences between the different options in their perceived effectiveness in protecting user health and safety. These can be seen in the table below.

Table 8 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**	Total responses
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 European 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%	5%	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.

Third-party involvement is perceived by the economic operators 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-assessment option. By comparison, the main drawbacks to self-assessment routes were deemed 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 European standards to support self-assessment choice. Specifically, some stakeholders were concerned about (unintentional) incorrect application of the process by manufacturers and the lack of involvement / checks from a third party. For instance, manufacturers may just look to one harmonized standard, when in fact more than one has to be applied to properly assess a product.

However, the results of a joint market surveillance action involving 13 Member States on two categories of Annex IV products (chain saws and vehicle servicing lifts)[35] indicate that third party involvement does not always guarantee the reassurance, which the manufacturers are seeking and that it is not more effective in terms of ensuring safety protection than internal production control. The number of technical non-conformities detected was significantly higher for products subject to EC type-examination than for products subject to self-assessment. An interesting observation was that the number of products for which no technical non-conformities were detected were all subject to self-assessment.

While the economic operators perceive that third party conformity assessment option provided by the Directive is effective in achieving the dual objectives of the Directive for Annex IV products, they also perceived drawbacks. Concerns were raised about inconsistencies between Notified Bodies in undertaking assessments and in interpreting requirements, as well as a about perceived decline in the knowledge and experience of particular machinery. However, these concerns were not further substantiated in the consultation. Also, the lack of harmonised standards for various products in the scope of the Directive influences the effectiveness of the Directive (see next section).

5.3.2.4 Role of European harmonized standards

Standards are an important component in 'translating' the essential health and safety requirements (EHSR) set out in the Machinery Directive and – if given legal status as a Harmonised European Standard (hEN) when published in the Official Journal of the EU – confer a presumption of conformity with one or more of these EHSR. In effect, this means that by following the technical specifications of a harmonised standard, the manufacturer can show that his product complied with the EHSR covered by that standard, thus saving time in adopting strategies for ensuring safety.

Certain hENs are developed within the framework of the agreements between CEN and the International Standardisation Organisation (ISO) or between CENELEC and the International Electrotechnical Commission (IEC)[36]. Around 30% out of

[35] http://www.prosafe.org/jamach2014.

[36] The agreement between CEN and ISO is known as the Vienna Agreement. The agreement between CENELEC and IEC is known as the Frankfurt Agreement (former Dresden Agreement).

approximately 800 hEN providing presumption of conformity to the Machinery Directive are derived from international standards.

Stakeholders contributing to the consultation activities held largely positive opinions as to the effectiveness of hENs in relation to the Machinery Directive (their quality and usability, how well they explain rules, guidelines and definitions, and well-aligned with EHSR)[37]. Positive appraisals were also generally given for the extent to which standards were up-to-date with technological developments (83% of respondents 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.

The costs of the European Harmonised Standards (finding and purchase of relevant standards) have been indicated by the respondents of the consultation activities (42% out of 249 answers) as being 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*[38] *to fully understand a C (product specific) standard*."

The respondents to the consultation activities have pointed to 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.

Harmonised standards are generally 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 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. The use of harmonised standards is facultative under the Directive, but their availability for Annex IV products influences the effectiveness of the Directive on the uptake of conformity assessment procedures, given that the involvement of a Notified Body for Annex IV products is obligatory in the lack of harmonised standard available.

Most commonly, stakeholders suggested that there were missing standards in specific areas, such as 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.

[37] Summary report - Public consultation on the Evaluation of the Machinery Directive 2006/42/EC

[38] A-type standards specify basic concepts, terminology and design principles applicable to all categories of machinery; B-type standards deal with specific aspects of machinery safety or specific types of safeguard that can be used across a wide range of categories of machinery; C-type standards provide specifications for a given category of machinery.

However, given that there is already a set of standards available for some of the machinery/areas indicated by the respondents, and in lack of further specific explanations given on those gaps, it is less clear what specific standardization developments should be pursued and if the Commission should intervene by means of standardization requests. However, through the practical application of the Directive, the need was identified for ensuring availability of harmonised standards for additive manufacturing machinery, e.g. 3D printers, for which there is no harmonised European standard currently available to provide exhaustive technical specifications for conformity with the EHSR of the Machinery Directive.

5.3.2.5 Role of mechanisms relating to non-compliance

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 that the number of inspections related to machinery varies significantly between countries (ranging from 50 to 500+) and from year to year.

Table 9 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).

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 differed not only in the number of inspections carried out and products targeted, but also in their approaches to

rectifying measures. Some focus mainly on voluntary measures, while others resort to restrictive measures and sanctions or application of penalties in the case of non-compliance.

Measures such as suspending or prohibiting the placing on the market of the CE-marked[39] machinery and/or their putting into service must be notified to the Commission, in line with the safeguard clause procedure set by the Directive. This procedure obliges the Commission, after consulting the concerned parties, to adopt Decisions stating that national measure was justified or was not justified. The form and content of the measures is a matter for the Member State concerned, but the measures must be both sufficient to protect the health and safety of persons and proportionate to the risk involved.

45 safeguard notifications from the Member States concerning national measures taken for unsafe CE-marked machinery have been received by the Commission from 2010 to 2016. In 18 cases the Commission has issued a decision. All of these decisions considered the national measures justified. Three of the Commission Decisions have been challenged by the manufacturers at the European Court of Justice (ECJ). In one case, the General Court dismissed the manufacturer's action[40], in the second case the General Court annulled the Commission Decision on grounds which were not related to safety[41] and a third case is still pending[42]. According to the safeguard clause procedure, the market surveillance authorities shall follow up the Decisions made by the Commission and take the measures necessary to ensure the protection of the health and safety of persons with respect to the non-compliant machinery.

The market surveillance authorities shall also follow up information on unsafe products notified under the Rapid Alert System for dangerous non-food products (RAPEX) set up under the General Product Safety Directive[43].

Data from the RAPEX indicates that 1.2% of all notifications from 2005-2015 refer to non-compliant products under the scope of the Machinery Directive. After the 'professional product' option was added in 2013, the machinery sector has accounted for up to one-quarter of all new notifications. The notification system is dependent on the level of market surveillance and inspection and as such, it does not represent the true extent of unsafe products on the market.

Market surveillance and enforcement for the Directive are generally seen as insufficient and ineffective. When asked about the overall effectiveness of national authorities in monitoring manufacturers' adherence to the requirements of the Directive, nearly three-quarters of stakeholders consulted rated these as having limited or no effectiveness. In addition, the vast majority believed that the number

[39] CE marking is affixed by the manufacturer and guarantees that machinery conforms to the requirements of this Directive

[40] Case T-337/13 - CSF v Commission

[41] Case T-474/15 - GGP Italy v Commission

[42] Case T-168/16 - Grizzly Tools v Commission

[43] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety. OJ L 11, 15.1.2002, p. 4.

and frequency of inspections, as well as the likelihood of being inspected, were all currently too low. 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. During the evaluation of the Directive, the Commission has adopted a proposal for a Regulation on compliance and enforcement[44] with the objective to enhance compliance and practical functioning of the EU Single Market, through fostering more cooperation among national market surveillance authorities. This will include sharing information about illegal products and ongoing investigations so that authorities can take effective action against non-compliant products. The Regulation is also expected to help national authorities to improve checks on products entering the EU market.

5.3.2.6 Role of Directive's requirements to emerging digital technologies such as AI and IoT

While the Directive has maintained its relevance over time and overall is conceptually well suited to cope with innovation given that its foundation lays on the principles of the New Approach, there are questions raised with respect to its effectiveness with the advent of emerging digital technologies.

Since the number of responses to the consultation activities was insufficient and also given the fact that those who responded did not elaborate on their answers, the Commission services have followed up on questions together with the machinery community e.g. industry representatives, Member States via the Machinery Working Group. The answers received varied from (i) suggestions from industry representatives to not opt for legislative changes but rather to ensure legal clarity via non-legislative instruments, e.g standards, to (ii) improve the current Directive by incorporating Asimov's laws[45] into the EHSR of the Directive or (iii) making the EHSR more explicit to deal with the emerging digital technologies, for example 'mental' ergonomic issues that may exist with people working (in conjunction with or just incidentally) alongside Artificial Intelligent controlled robots. The latter two suggestions were brought forward by Member States.

The Commission Communication on Digitising European Industry[46] underlines that the integration of ICT in all types of products and artefacts offers a wide range of

[44] COM(2017)795 - Proposal for a Regulation laying down rules and procedures for compliance with and enforcement of Union harmonisation legislation on products and amending Regulations and Directives

[45] *1) A robot may not injure a human being or, through inaction, allow a human being to come to harm; 2)A robot must obey the orders given it by human beings except where such orders would conflict with the First Law; 3) A robot must protect its own existence as long as such protection does not conflict with the First or Second Laws*

[46] SWD(2016) 110 final - http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52016DC0180.

opportunities for the growth of new industries and is transforming all sectors of the economy.

The potential of emerging digital technologies brought by the ubiquitous connectivity trespassing the main production environment and intelligence of digital processing in manufacturing sector is giving rise to new safety concerns[47].

The European Parliaments' resolution on civil law rules on robotics[48] highlights that robots, while continuing to be products, may display an increasingly autonomous and self-learning behaviour.
In contrast to purely software based AI systems that depend on software designed for a specific problem to guide its response, robots enabled by AI have increased capabilities to interpret the environment, interact with humans, learn new behaviours and execute actions autonomously without human intervention. Such systems are increasingly penetrating all aspects of our lives. In human-machine collaboration, AI robots are posing much higher risks than purely software AI systems, due to their mechanical moving parts.
This gives a new safety edge to the interaction between humans and technology.

These emerging digital technologies may not be inherently less safe than more traditional products whose risks are well addressed by the Machinery Directive, but their evolutionary and self-learning capabilities require attention in terms of safety.

AI-powered advanced robots and autonomous self-learning systems[49] alike must meet the essential health and safety requirements (EHSR) laid down in the Machinery Directive, additional to any other applicable legislation[50]. Manufacturers must ensure that products meet the applicable EHSR identified through the risk assessment. In choosing the most appropriate methods for ensuring compliance with the EHSR, the manufacturer must apply the so called 'principles of safety integration' by eliminating or reducing risks as far as possible at the design phase. The manufacturer should also take the necessary protective measures in relation to risks that cannot be eliminated and inform users of the residual risks by means of warnings or manual of instruction. Manufacturers should keep the technical documentation about the products that they place on the market.

A number of harmonised European standards (hENs) for robots intended for industrial and consumer applications are already available. Additionally, ongoing

[47] Commission SWD on Advancing IoT in Europe.

[48] European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL)).

[49] Within the scope of the Machinery Directive.

[50] Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC OJ L 153, 22.5.2014, p. 62.

work at international level may form the basis for more European standards deliverables for the safety of robots and systems in a digital era[51].

Questions are emerging, for example, to which extent the existing EHSR for the safety and reliability of control systems are exhaustively reflecting the potential risks related to control systems in an IoT ecosystem. In the same vein, it can be questioned to which degree the Directive approach to measures for risk reduction, specifically protective measures (e.g. guards, protective devices), accommodates collaboration of humans and machines in shared workspaces, such as, for example, fulfilment centres. Should 'injuries' be limited to physical ailments, or does safety also encompass emotional damage?

In a digital market driven by the Internet of Things and AI powered systems, vulnerability to cyberattacks of factories and critical infrastructures is a de facto concern and a growing threat. For example, some industrial processes nowadays are conveniently managed through mobile apps. While such remote controls might increase production's efficiency, they also create targets for cyber-attacks[52]. This means that cybersecurity has a direct impact on workplace safety, and that the cybersecurity of industrial control systems and networks has therefore become a prerequisite.

Consideration to the threats and vulnerabilities described above needs to be given as early as the design stage by employing "security by design" solutions. In the *Communication for Resilience, Deterrence and Defence: Building strong cybersecurity for the EU*[53] this is considered a priority area for stakeholders.

While the evaluation indicates that the Directive largely or entirely took account of and was able to cope with innovations since it became applicable, it is quite possible that some characteristics of the emerging digital technologies may come to test the limits of the existing product safety framework. This stance was echoed by the respondents to the consultation activities carried out during the execution of the study, as indicated in Table 10. There are expectations that over time and in view of emerging technologies the Directive will no longer be able to deal with innovations in the same way as it did in the past.

[51] e.g. https://ec.europa.eu/digital-single-market/en/news/reporting-main-outcome-workshop-standardisation-support-digitising-european-industry.

[52] https://www.technologyreview.com/s/609946/hackers-could-blow-up-factories-using-smartphone-apps/.

[53] JOIN/2017/0450 final

1. *Table 10 To what extent does the current Directive sufficiently allow for innovation and a changing business environment*

	Not at all	To a small extent	To a moderate extent	To a large extent	Entirely	**Total responses**
Took account sufficiently of new innovations and new technologies at the time?	1%	11%	26%	46%	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%	31%	23%	26%	82
Sufficiently took account of recent changes in the business environment (i.e. in the machinery sector / market / trade) at the time?	3%	12%	27%	35%	23%	78
Has been able to deal with changes in the business environment since?	1%	17%	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.

5.4 Findings in relation to the Efficiency of the Machinery Directive

5.4.1 Costs involved as a result of the Machinery Directive

The supporting study analysis (based on typology of regulatory costs and benefits Fig.26 p.91) showed that nearly all of the costs relate to the time and effort involved in different processes, which are spread across several key actors. The majority of data necessary for assessing these costs were not readily available, and so the evaluation relied predominantly on assessments from the actors involved.

The first column in the following table summarises the various estimates for annual average costs (FTE and other financial costs) from the Machinery Directive for individual actors in each main stakeholder group. Average wages in the EU (of €135.20 per day)[54] are used to monetise the FTE days. This results in an annual cost of 510,000 days (equating to €69m in staff costs) from the Directive, plus €68m in other financial costs. This arrives 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 11: Estimated total costs incurred by relevant actors each year, as a result of the Directive

Actor	**Number of actors**	**Total FTE days**	**Total cost of FTE days**	**Total other financial costs**	**Total costs**	**Average cost per actor**
Market surveillance authority	28	5,040	€ 681,408	€1,680,000	€ 2,361,408	€ 84,336
Implementing authority	28	4,592	€ 620,838	€460,012	€ 1,080,850	€ 38,602
European Industry Association	50	9,750	€ 1,318,200	€4,070,700	€ 5,388,900	€ 107,778

[54] 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).

Actor	Number of actors	Total FTE days	Total cost of FTE days	Total other financial costs	Total costs	Average cost per actor
Industry	12,863	487,508	€ 65,911,082	€61,742,400	€ 127,653,482	€ 9,924
Total for all actors		**510,246**	**€ 68,531,528**	**€67,953,112**	**€ 136,484,640**	

Source: Technopolis

Administrative burden was investigated (section 5.13.3 of the report). Most respondents to the consultation activities highlighted disproportionate administrative costs arising from time and resources spent on documentation. In particular, on one hand, the requirement to translate the manual of instructions into the language of the destination country and on the other hand, the requirement to supply the instruction in paper format were seen as an undue burden. Another requirement perceived to bring a significant administrative cost with apparent little benefit for most machines is to include the product serial number in the Declaration of Conformity even if the machinery is produced in high volume per year. Such costs are particularly disproportionate for SME, low volume producers and manufacturers producing machines built for internal use. The report, in the part related to simplification potential, highlighted areas where there is still room for action like translation requirements or form of documentation (electronic versus paper). However taken into account all costs (approximately 136m EUR) compared to value to intra EU trade (approximately 700b EUR) this issue has limited relevance for the overall efficiency of the Directive.

In the case study research for the *Evaluation of Internal Market Legislation for Industrial Products*, economic operators indicated that even if a requirement for mandatory third party conformity assessment has been removed from the current version of the Directive (as was the case for the categories of machinery in Annex IV that formerly required mandatory third party conformity assessment), this did not necessarily lead to a sudden reduction in demand for Notified Bodies services. Many manufacturers have continued to use the services of third parties "voluntarily" for reputational reasons and to reassure their customers that their products are safe, despite the feedback received during the revision of the Directive mandatory third party assessment would create additional costs for industry and would also potentially lead to delays in time-to-market.

5.4.2 Benefits realised as a result of the Machinery Directive

The benefits to well-being (i.e. improved health and safety) have already been introduced above.[55] 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

[55] Section 5.3 - the effectiveness of the Machinery Directive to achieve its main objectives.

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)[56].

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 revised 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 Directive, which the evaluation has sought to identify. Nearly all respondents agreed that the Directive has brought strong benefits to the four areas suggested in Table 12. They agreed in particular that having one standardisation procedure (instead of 28 individual standards) saved time and money for industry.

Table 12 Benefits of the Machinery Directive for industry

	Not at all	To a small extent	To a large extent	**Total responses**
The CE marking 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 Harmonised European Standards saves time in finding appropriate technical specifications	0%	12%	88%	32
Self-certification cuts certification costs significantly	0%	16%	84%	32

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

5.4.3 Extent to which the costs are reasonable and proportionate

Benefits in terms of market efficiency (the extent to which the objective of free movement of machinery within the internal market was achieved at reasonable costs) 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, not least because the 28 national regimes would have evolved somewhat over the past 30 years, if the Directive had not existed.

The majority of the economic operators consulted (92%) were of the opinion that the Directive has reduced costs overall, compared to what might be the case

[56] Other factors could have contributed such as work culture and environment or better health care.

otherwise (national legislation). However, some respondents also highlighted that countries often required national standards to be applied. This still bears additional costs of compliance with national directives and requirements going beyond those of the Machinery Directive, stricter interpretation of the Directive and 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.

With regards to additional costs involved in supplying third countries, the economic operators suggested that due to the fact that they meet the requirements of the Directive and associated standards, the additional cost is often minimal (i.e. Machinery Directive's requirements serve as a good basis for meeting requirements / demonstrating conformity elsewhere).

The comments of the economic operators suggest an additional 1-2% of the total cost to meet slightly different requirements, and another 1-2% (of total costs) to undergo compliance therewith. The USA 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. On the other hand, regulatory synergies are seen with certain countries in Asia. For example, most of the machine safety standards published in China are derived from European and international standards. As a consequence, it should save on the costs for supplying machinery in China.

The evaluation 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 such as the USA) 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.

These 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.

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).

Table 13 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	**Total responses**
National authority view	0%	12%	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%	13%	33%	36%	33

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

5.5 Findings in relation to the Coherence of the Machinery Directive

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 various Directives and Regulations with perceived overlaps with the Machinery Directive. Indeed, while the study[57] found that stakeholders were generally of the view that the Directive fits well with other national, EU and international legislation, large numbers of contributors to the consultations pointed 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 Machinery Directive, including most commonly the Low Voltage, Pressure Equipment, Electromagnetic Compatibility and Radio Equipment Directives. Respondents of the consultation activities did not take up the opportunity to explain more specifically the nature of the overlaps or inconsistencies that they pointed to. However, through issues stemming from the practical application of the Directive, the Commission services have been able to identify the pieces of legislation that may be the sources for such perception.

For example, the interpretation of 'household appliance for domestic use' with respect to products excluded by the Machinery Directive and which are covered by the Low Voltage Directive is causing uncertainty.

As for the interplay with the Pressure Equipment Directive, the need has been identified to examine whether the risks due to pressure for certain category of equipment, excluded from the scope of the Pressure Equipment Directive, are sufficiently addressed by the EHSRs of the Machinery Directive.

An inconsistency with the Radio Equipment Directive and the Electromagnetic Compatibility Directive has also been perceived. However, the Radio Equipment Directive and the Electromagnetic Compatibility Directive regulate different aspects

[57] Technopolis study on the Evaluation of the Machinery Directive - September 2017

not related to safety and may hence apply in addition to the Machinery Directive[58]. Issues raised by stakeholders in that context relate to the simultaneous application of different pieces of legislation and not to the overlapping with the scope of the Machinery Directive as such. In particular, there are certain inconsistencies in the administrative requirements pointing to potential for alignment.

It also needs to be pointed out that Article 2 of the Directive lists some specific products covered by other EU legislation that are excluded from the Directive. However, since it would be impossible to continuously update this list, Article 3 of the Directive stipulates that if a specific legislation covers particular risks, the Machinery Directive does not apply for those risks but continues to apply for the other risks. In that case, both legal acts apply to the product concerned. For specific Directives that cover all the risks associated with the products that are in their scope, the Machinery Directive does not apply at all, such as, for example, the Medical Devices Directives.

With respect to the scope and definitions set by the Directive, the new definition of 'partly completed machinery' has raised a number of concerns particularly centred at the borderline with the definition of 'machinery' or 'interchangeable equipment'.

There are certain areas of the Directive, such as definitions, which could have been addressed by a full alignment of the Directive to the New Legislative Framework (NLF)59. NLF consists of two legal acts related to the marketing of products, the Regulation 765/2008 on accreditation and market surveillance and the Decision 768/2008/EC on a common framework for the marketing of products.

However, the Machinery Directive was adopted in 2006, two years before the NLF package. While the process of revision of certain other New Approach Directives, such as the Lifts Directive was put on hold while awaiting the outcome of the NLF process in order to avoid the need for two revisions in quick succession, in the case of the Machinery Directive, the revision was launched before the start of the NLF process. The Commission services have decided at the time to pursue the revision of the Machinery Directive while anticipating the reforms being prepared, with the same objective of avoiding the need for two revisions of the Directive in quick succession. For example, the definition of ‘importer’, ‘distributor’ and ‘economic operator’ in Regulation (EC) No 765/2008 was not inserted in the Directive since new definition of ‘manufacturer’ in Article 2 of the Directive covers any person responsible for placing machinery on the market, hence it is broader than the definition provide by the NLF.

[58] The Guide on the Machinery Directive describes the scope of those Directives. While the Machinery Directive covers the health and safety aspects of the machines, the requirements of the RED with respect to the use of the radio frequency spectrum apply to radio equipment within its scope that is incorporated into machinery, such as, for example, certain remote control devices. The EMCD applies to machinery that contains electrical or electronic parts that may generate or be affected by electromagnetic disturbance. However, the MD covers the immunity of machinery with respect to safety-related electromagnetic disturbance, whether transmitted by radiation or by wire.

[59] https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en.

5.6 Findings in relation to the EU Added Value of the Machinery Directive

Given the fact that the Machinery Directive does not translate the EHSR into detailed requirements or processes, the impact of the Directive is more directly attributable to the activities of the market surveillance authorities, businesses that interpret and apply systems and processes that support and enable the Directive, the Notified Bodies or the harmonised European standards when chosen to prove presumption of conformity. While they currently support the Directive, these systems of standardisation, conformity assessment and market surveillance would likely exist in some form anyway, regardless of the existence of the Directive.

For instance, the report on *Evaluation of Internal Market Legislation for Industrial Products* indicates that until the adoption of the Machinery Directive in 1989, many national legal frameworks did not sufficiently regulate the safety and usage of machinery, despite the high level of risk involved for those operating such machinery. It further indicates that different national regulations would have led to higher administrative burdens for regulatory compliance for economic operators.

All respondents to the consultation activities agreed that Directive 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[60] 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.

Table 14 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	Total responses
Facilitating the free circulation of machinery within the internal market	0%	4%	13%	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%	13%	53%	28%	36

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

6. CONCLUSIONS

There is a consensus among all stakeholders that overall the Directive has successfully contributed towards its overarching objectives by facilitating the free movement of machinery across the Union and protecting the health and safety of consumers and users.

The evaluation indicated that the Directive has maintained its **relevance** related to both its objectives, despite changes in technology and the business environment. The value of machinery being traded across the EU in a given year (€684b in 2015) and the extent to

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

which all Member States are involved in the internal market for machinery (intra-EU trade in machinery is occurring between nearly every EU country and every other one, with 756 combinations of countries) is of great significance. In terms of Directive's importance related to the objective of ensuring a high level of health and safety for users of machinery, 99% of respondents to the consultation activities regarded it as important, with the vast majority (91%) suggesting it was 'very important'. This is a strong indication that both objectives are of high relevance to the needs and concerns of EU stakeholders.

As regards the influence of the Directive on innovation, the consultation activities indicated that stakeholders have generally positive opinions; the Directive took account of innovation at the time of its introduction and was able to deal with innovations since. However, there is a downward trend in expectations over time and the Directive is widely perceived as being less able to deal with coming emerging digital innovations than it was so far. In particular, doubts have been raised on the relevance of the Directive to cover future digital innovation. While the majority of stakeholders (mainly manufacturers) are of the opinion that the Directive is still a suitable framework, the analysis carried out in the context of the evaluation indicates that some characteristics of the emerging digital technologies, such as Artificial Intelligence and Internet of Things, may test the suitability of the Directive. This may reduce its **effectiveness** going forward.

The evaluation indicates that Directive's essential health and safety requirements combined with the quality and usability of harmonised standards as well as all conformity assessment options offered are both protecting health and safety and facilitating the internal market, considering however the methodological difficulties linked to the absence of database tracking the injuries related to machinery. In contrast, market surveillance and enforcement in relation to non-compliance with the Directive, and the mechanism of accreditation and monitoring the performance of Notified Bodies are seen insufficient and not effective. The Commission has adopted in the meantime a proposal for a Regulation on compliance and enforcement aiming to tackle some of the issues identified by the evaluation.

Furthermore, several economic operators have also indicated that in certain cases Member States insist on technical specifications from national standards. However, while such instances occur, they are not a systematic problem and only affect the effectiveness of the Directive to a limited extent.

As regards **efficiency**, the global costs incurred as result of the Directive (estimated at approximately €136m per annum) are far outweighed by the costs savings achieved from improved health and safety (estimated at approximately €401m per annum). However, stakeholders indicated disproportionate administrative costs arising from certain administrative requirements, such as documentation, so there is potential for some simplification.The evaluation shows that overall the Directive is **coherent** with other national, EU and international legislation. Yet, a number of overlaps or inconsistencies with other EU specific legislation, such as for example the Low Voltage Directive or the Pressure Equipment Directive, have been identified. The evaluation indicates also the need for greater legal clarity in its scope and definitions.

In terms of **EU added value**, the vast majority of respondents to the consultation activities are of the opinion that the Directive reduced costs overall compared to what

might have been achieved without a Single Market for machinery in force; hence the EU value added is seen positive.

The overall conclusion is that the Directive is generally *relevant, effective, efficient, coherent and has EU added value*. However, a need for greater legal clarity of some of its provisions and better coherence with other legislation has been identified. In addition, the evaluation indicated that shortcomings in monitoring and enforcement of the Directive have affected its effectiveness. It further detected some administrative requirements that affect the efficiency of the directive and could be simplified. The evaluation shows that the Directive, underpinned by the New Approach principles, is sufficiently flexible to allow technological developments in a digital era. Yet, new innovations in digitisation may test Directive's effectiveness and fitness for purpose going forward.

ANNEX 1 PROCEDURAL INFORMATION

1. Lead DG, Decide Planning/CWP references

Lead DG: Directorate-General for Growth - Internal Market, Industry, Entrepreneurship and SMEs (DG GROW); Unit C3: Advanced Engineering and Manufacturing Systems.

Agenda planning/work programme reference: 2015/GROW/051

2. Organisation and timing

Organisation and timing: the inter-service Steering Group consisted of SG, DG JUST, DG EMPL and DG CNECT. After the kick-off meeting on 5 February 2016, it met two times in 2016, two times in 2017 and once in 2018.

3. Exceptions to the better regulation guidelines

Not applicable.

4. Consultation of the RSB (if applicable)

Not applicable.

5. Evidence, sources and quality

The evaluation study was outsourced to a consultant.

Literature, open on-line sources and publicly available reports have been used. The main source of information was the stakeholder consultations and the Machinery Working Group. During the consultation phase, the information was collected via interviews (economic operators and national authorities in charge of policy or market surveillance), targeted consultations of economic operators and market surveillance authorities and an online public consultation reaching out to a wider audience in particular SMEs and consumers.

General market information was collected from the European and national industry associations' publications such as annual reports. More detailed cost related information was collected via a specific consultation of a limited number of economic operators which agreed on a voluntary basis to provide elementary data.

The robustness of the consultations:

- During the preparatory phase, the external consultant used existing studies and meeting documents of the Machinery Working Group to prepare the next steps in the study. The work resulted in questionnaires for the interviews, targeted and public consultation.
- A steering group composed of representatives of several Commission departments monitored the development of the consultation both with regard the process and the analysis of the information collected by the contractor. The steering group paid particular attention to the independence of the evaluation team considering that information sources were limited and replies were potentially driven by commercial interests of the economic operators.

- The external consultant team included highly qualified technical experts to assist the evaluation team in analysing the more technical and/or safety related issues. This approach results in good quality consultation and analysis of the replies and reduced the risk of errors in the interpretation of the results.
- The public consultation was widely publicised via indirect channels (DG GROW Enterprise Europe Network to reach also SMEs and consumer associations) to unlock the potential of stakeholders who initially did not engage in the evaluation process.
- Contributions by industry appear to be coherent and representative for the sector. Through targeted interviews of national authorities information could be collected from the majority of the Member States. The open consultation resulted in 342 replies and confirmed the information already obtained from economic operators and national authorities.
- By triangulating data from survey, interviews and online public consultation, it has been possible to identify divergences between the data collected through the different tools.
- Compliance cost appears to be limited but it was difficult to obtain this kind of information as economic operators do not have a record of the break-down of costs for this purpose.

Whereas the number of replies and the level of coherence are high, the qualitative assessment can be considered as reliable. However, information related to market size and compliance costs need to be interpreted with care and should be seen as indications of an order of magnitude rather than as precise estimates.

ANNEX 2 METHODS AND ANALYTICAL MODELS

1. Analysis of secondary data

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)
- national implementation data (TRIS)

Further information on each of these sources, including their limitations, is presented below.

The **Eurostat 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. The database[61] uses 2- and 4-digit NACE (Rev. 2) codes for its annual enterprise statistics, and annual detailed enterprise statistics for industry, respectively. This evaluation has 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 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 Machinery Directive), as well as lifts for people (which are covered under the Lifts Directive).

Table 15 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

[61] http://ec.europa.eu/eurostat/web/structural-business-statistics/overview

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) uses various nomenclatures. This evaluation has 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. The CN Section 16 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".

European Statistics on Accidents at Work (ESAW) is 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. 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 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[62]. 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.

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).

[62] 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

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 (**Member State reporting on market surveillance activities**[63]). The Report on the Member States reviews 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, the data contained within this report has been made use of in the analysis – although the focus lies only on the 19 countries with complete datasets for the examined parameters.

The Rapid Alert System for dangerous non-food products (**RAPEX)** is a publicly accessible notification system for dangerous 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 has fallen into this group so far.

RAPEX is the single best source for analysing the incidence rates and origins of products presenting serious risks 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.

[63] 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)

- 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 notification 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". This being true, the European Commission have adopted, as part of the guidelines for the management of RAPEX[64], specific risk assessment guidelines for consumer products. These guidelines have the purpose of providing a transparent and practicable method for Member States' authorities when they assess the risks of non-food consumer products, contributing this way to the reduction of diverging results between Member States and leading to widely acceptable consensus on the risks that the many non-food consumer products may present.

At the national level, the **Technical Regulation Information System (TRIS)**[65] 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.

2. Stakeholder Consultation

The stakeholder consultation consisted of three main data collection tools, namely:

- **Open public consultation questionnaire**, made available online for 12 weeks at the end of 2016. It was available in 6 official EU languages (EN, FR, DE, ES, IT, PL). The public consultation was designed to address evaluation questions in a reasonably high-level manner (to be applicable to all groups).
- A series of four **targeted questionnaires** that sought more detailed and technical knowledge from key stakeholder groups. The survey was designed to address the same types of questions a in the open public consultation but in more depth with more / less focus in certain areas, depending on the interests, expertise and perspective of the group concerned.
- **Follow up interviews** were 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.

[64] Commission Decision of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System RAPEX established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive). C(2009) 9843

[65] http://ec.europa.eu/growth/tools-databases/tris/en/

The distribution of contributors to the evaluation across the main stakeholder groups and consultation methods is shown in the table below.

Table 16 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**

The respondents to the questionnaires (public and targeted) 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 (with no responses from Hungary, Lithuania, Luxembourg, Slovakia and Slovenia) and three EFTA countries (no responses from Iceland). One respondent each from Canada, the USA 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 (excluding 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 was spread across ten Member States and one EFTA country.

The full breakdown of respondents to the questionnaire surveys, by country and by stakeholder group, is shown in Table 172.

Table 172 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, 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.

The follow up 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).

ANNEX 3 EVALUATION QUESTIONS

The evaluation assesses the relevance, effectiveness, efficiency, coherence, and EU added value of the Machinery Directive. To this end, a set of questions was defined to guide the data collection and analysis (see table below), as indicated in the evaluation roadmap.

Description of the market
1.
Relevance

Criteria	Evaluation questions
Context	What is the current situation and trends in the machinery market?
Relevance	To what extent do the initial objectives of facilitating the functioning of the internal market and ensuring a high level of safety for machinery correspond to current needs of the market, manufacturers and users? How are innovation and new technologies taken into account?
Effectiveness	4. To what extent has the Machinery Directive contributed to an effectively operating internal market for the products in its scope and to what extent has it achieved its aims with regard to the protection of health and safety of consumers and users, and where appropriate, domestic animals or properties for the products in its scope? 5. What are the positive factors and the negative factors (e.g. barriers) for an effective application and enforcement of the Directive, in particular through surveillance of machinery on the market? 6. Are there any aspects/means/actors that render certain aspects of the Directive more or less effective than others, and if there are, what lessons can be drawn from this? 7. How effective are MS authorities in identifying non-compliant products? 8. To what extent has the option of third party conformity assessment for Annex IV categories of machinery, been effective? 9. To what extent has the procedure for assessment of conformity with internal checks been effective in providing highest degree of health and safety for consumers and users? 10. How effective was the development and use of the European harmonised standards for the Machinery Directive?

Criteria	Evaluation questions
Efficiency	11. What are the regulatory (including administrative) costs and benefits for the different stakeholders and/or other actors, and to what extents are these costs proportionate to the benefits achieved? 12. What are the reasons for discrepancies between Member States? 13. How affordable were the costs borne by the different stakeholders (manufacturers, users, conformity assessment bodies, standardisers and public authorities) given the benefits they receive? What does this represents in terms of administrative and reporting burdens on stakeholders and/or other actors?
Coherence	14. Are there overlaps or complementarities between the Machinery Directive and any other Community or international legislation (General Product Safety Directive, Type approval legislation for agricultural and forestry tractors, and for two or three wheel motor vehicles, Medical Device Directive, etc.). To what extent are they coherent?
EU Added Value	15. What is the additional value resulting from the Machinery Directive, compared to what could be achieved at national level? What is the added value of the Machinery Directive for stakeholders?

ANNEX 4 SYNOPSYS REPORT

Stakeholder consultation activities included a **Public Consultation (PC)** questionnaire, **four Targeted Consultation (TC) surveys**, and a programme of **interviews**.

The PC questionnaire was open to anyone and was widely promoted through e.g. the EUROPA webpage and CIRCABC system. It covered most evaluation questions in a reasonably high-level manner, so as to be applicable to all groups. The TC questionnaires sought more detailed input from specific groups. Surveys took place from September to December 2016 (14 weeks).

Overall there were 342 responses to the PC and 98 responses to the TC. A small number of respondents (35) replied to both. There were **405 unique *respondents* to the surveys** (*Table 38*), with all identified stakeholder groups reached through one or other route.

Table 38 Respondents to consultations, by stakeholder group and consultation route

Stakeholder Group	**PC**	**TC**	**Both**		**Respondents**	**%**
National authority	17	8	2		27	7%
Notified Body	13	9	3		25	6%
Industry Association	25	24	17		66	16%
Industry / companies	146	22	13		181	45%
Workers / consumers and their representatives	68				68	17%
Consultancy/service provider for Machinery safety	31				31	8%
Standardisation body	1				1	0.2 %
Unknown	6				6	1.5 %
Total	**307**	**63**	**35**		**405**	

While the 400+ responses exceeded expectations, and provided a good overall number of inputs for analysis, the numbers for some individual sub-groups is small. There are likely to be significant variations across the breadth of the sector that can therefore not be fully captured. In addition, not all respondents felt able to respond to every question, meaning that some analysis relies on a small number of inputs. These responses cannot be seen as representative in statistical sense, just as opinions of those who decided to participate.

Respondents to the public and targeted questionnaires were based in 23 EU Member States (excluding Hungary, Lithuania, Luxembourg, Slovakia and Slovenia), as well as 3 EFTA countries (excludes Iceland). The greatest numbers of respondents were based in countries with the largest machinery sectors. In addition, 30 respondents were based in Belgium, but these are mostly European associations.

While a large number of SMEs responded (46% of all industry respondents), this is lower than the proportion in the sector as a whole (98%). They may therefore be under-represented. However, many of the industry associations consulted represent businesses of all sizes.

Interviews with 44 individuals from different stakeholder groups were also undertaken. These were used to fill gaps in understanding and explore certain aspects in more depth.

Main Results from Consultation Activities

This section presents the main evidence obtained through consultation. Where the same question was addressed by both the PC and TC questionnaires, the combined results are used.

Relevance

Relevance of objectives

Stakeholders were asked to assess the level of importance they attached to **the MD's objectives** of ensuring (1) free movement of machinery within the Single Market and (2) a high level of health and safety for users. Nearly all respondents (99% of 398) saw both aims as important (with 78% and 91% respectively saying 'very important').

For the first goal, even a majority (57%) of users and consumers (and their representatives) regard it as very important, while the proportion of public authorities, notified bodies and businesses seeing it as very important is 75%+ in each case. Support for the second goal was similar across all categories of stakeholders.

Changes in technology and business environment

One third of respondents agreed to a large extent/entirely that the MD takes sufficient account of **new innovations and technologies**, followed by one third who agreed to a moderate extent and a quarter to a small extent. Only 4% (of 254) disagreed. Around half of targeted stakeholders predicted that the MD will be able to also cope with future technologies.

Many individuals did point to specific new products, innovations or requirements that they felt might not be well addressed by the MD. These tended to relate to digitisation and robotics.

Respondents were also asked whether the MD took account of **wider changes in the business environment.** The response was again broadly positive, with only 9% (of 218) reporting it was not at all sufficient. However, the remainder were evenly split between those who felt the MD took sufficient account to a small, moderate or large extent / entirely.

Stakeholders pointed to changes where the MD may not be fit for purpose. Frequent responses concerned the rise of Internet sales/ e-trade and fulfilment houses (where products are not owned by the operator of the fulfilment house). Many also mentioned an apparent rise in non-compliant machinery (particularly from outside of the EU) and

inadequate action to address this (e.g. knowledge/understanding, market surveillance, enforcement measures).

Effectiveness

Discrepancies in interpretation

Stakeholders were asked for their views on the **full and consistent interpretation / application** of the MD across Europe, going beyond the initial transposition of legislation to also ask about the establishment of bodies and procedures.

Broadly, there are five areas where implementation and application are considered to be "largely or entirely consistent" across Europe (at least two-thirds agreeing in each case). These are: the initial transposition, the appointment of Notified Bodies and the assessments they undertake, the conformity assessment procedures available, and the fulfilment of requirements to not prohibit, restrict or impede machinery that has demonstrated compliance.

There are then four areas of greater concern, in that a majority (50%+) believe these are applied "not at all" fully or consistently, or only "to a small extent". These all relate to monitoring and enforcement and include: the number of market surveillance activities, the approach taken by market surveillance to determining compliance, the measures taken to withdraw or prohibit machinery, and the establishment of penalties for infringements.

Contribution to objectives

Nearly three-quarters of respondents to the consultations (74% of 308) reported that the MD had "to a large extent" **achieved its objective** of ensuring an effectively operating internal market for the products in its scope, while a further 21% believed it had to a moderate extent.

A majority of targeted respondents believed the MD has had a "very/ positive impact" on the range of products (54% of 39), turnover and profitability (58%), international competitiveness (78%), the volume and value of trade (81%) and the free movement of machinery (42%).

Nearly three-quarters of respondents (71% of 311) also reported that the MD had achieved "to a large extent" its objective of protecting the health and safety of consumers/ users, while a further quarter (25%) believed it had achieved it to a moderate extent.

Nearly all respondents to the targeted consultations believed the MD had had a "very/ positive" impact on machinery quality (88% of 42), information on safe operation (91%), user confidence (87%), the number and severity of injuries (100%), the number of unsafe machines (75%) and on the level of safety and protection for users (95%).

Conformity assessment options

Stakeholders were consulted on the **effectiveness of conformity assessment options**, both in facilitating the internal market and in protecting health and safety. The responses suggest that all options are seen as very/effective in both regards.

There are more evident differences between the options in their perceived effectiveness in protecting health and safety. 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). 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 suggest that ratings may reflect low use.

The main drawbacks to the take-up or effectiveness of third-party options were said to be the greater costs involved, while for the approval of full quality assurance, the complexity and the requirements for extensive quality systems were regarded as off-putting. Indeed, several stakeholders mentioned this was still not seen as an established option for Machinery.

By comparison, the main drawbacks to self-assessment were the lack of reassurance and protection that might otherwise be provided by a third-party (which customers might expect/demand), the effort and expertise required to undertake the process, and the lack of relevant standards.

European Harmonised Standards

Most (89%) regarded the scope and coverage of the current portfolio of **standards** to be good/very good. However, it is generally recognised that there are some gaps in the Type-C standards available, particularly for some smaller volume products and those covered by Annex IV of the MD. Positive appraisals were also generally given for the extent to which standards were up-to-date with technological developments and the frequency with which standards are revised. However, the availability of standards for new innovative products was often rated poorly – though there was acceptance that standards necessarily lag behind.

A majority (90%) was positive as to clarity over which standards to use. However, several noted that it was difficult to find the right standard to apply based on the summaries, or to be sure of using the up-to-date standard. Most stakeholders (93%) also expressed positive opinions about the quality and usability of existing standards, although there was less agreement that these then did a good job of explaining rules, guidelines and definitions.

Mechanisms relating to non-compliance

Three-quarters of respondents (74% of 328) rated the efforts of national authorities in **monitoring adherence to MD requirements** as having limited or no effectiveness.

Most also believed that the number and frequency of inspections (83%) and the likelihood of being inspected (80%) were both too low, while a majority (57%) said that the typical time from market entry to inspection was too long. Even national authorities were generally critical. Half thought the number/frequency of inspections in their own country was too low, while a majority (83%) believed the likelihood of being inspected was too low (83%) and that the number of products that had never been assessed was too large (71%).

Most respondents claimed that insufficient staffing was the key barrier to the identification and removal of non-compliant products. Incorrect targeting and lack of cooperation were much less frequently cited. Of the additional explanations given, most highlighted a lack of staff knowledge and competence, that removal of non-compliant products was not prioritised, or that there was a lack of consistent implementation across Member States. Several also commented on a lack of coordination with customs staff, or communication across borders, while others noted that authorities were more concerned with consumer products.

Efficiency

Costs to different actors

The targeted consultation asked the main stakeholder groups to estimate the number of days and other **costs incurred** in relation to key activities relating to the MD:

- National authorities (n=10) devoted between 3 and 400 days per annum to the MD (excluding market surveillance) – an average of 80 days each. One also indicated that ~10 meetings per year in Brussels cost ~€10,000 per organisation. Authorities (n=7) also estimated that 84 days and €6,429 were incurred for MD standards development.
- Market surveillance authorities (n=7) indicated that the staff effort involved in an 'average' machinery-related inspection was between 0.5 and 15 days (3 days on average), and that 60 such inspections were undertaken each year. None could provide information on additional costs.
- European industry associations (n=36) estimated that they devoted between 1 and 1,500 FTE days of effort each year to the MD (102 days on average). Only one provided information on other costs, which they estimated to be €670 per day of effort. Associations (n=33) also estimated that 93 days of effort and €13,074 in other costs were incurred by each organisation on standards development for the MD each year.
- Industry (n=29) provided estimates of the time and costs they incurred for their last conformity assessment relating to the MD. The average cost was 1,393 days and €105k in other costs for self-assessment, 33 days and €275k for EC-type examination, and 4 days (no cost information given) for approval of full quality assurance. They also indicated that a company undertakes these three types of

conformity 14.5, 1.3 and 0.4 times each year respectively[66]. Industry (n=20) also estimated that it incurred between 1 and 5 days of effort per machinery-related inspection (3 on average), as well as costs averaging €1,000 per inspection - with 0.3 such inspections per year on average.

Benefits realised

Businesses were asked to assess the extent that the MD achieves more than would be achieved otherwise (in its absence) in terms of **reducing costs**. Nearly all (92%) believed it had reduced costs, including 21% that believed it had to a large extent.

Furthermore, businesses were also asked to estimate the additional cost of complying with the regime in a non-EU market where the MD did not apply. However, most highlighted that because they meet the requirements of the MD (and associated standards), the additional cost is often minimal (i.e. MD requirements serve as a good basis for meeting requirements / demonstrating conformity elsewhere). Their comments suggest an additional 1-2% (of total cost) to meet slightly different requirements, and another 1-2% (of total costs) to undergo compliance to these.

In addition, nearly all targeted industry respondents (80%+) agreed that **other benefits** included: that the CE mark is recognised outside the EU; that one standardisation system saves time and money; that Harmonised Standards saves time in finding appropriate technical specifications; and that self-certification cuts certification costs significantly.

Whether costs are reasonable and proportionate

Two thirds of respondents (69%) also believed that **benefits outweighed costs**, while only 18% believed that costs outweighed benefits. The response from industry was the most mixed. In their comments, some justified a negative assessment because of the scale of costs incurred, combined with decreased competitiveness due to insufficient surveillance to prevent non-compliant products entering the market.

Potential to reduce inefficiencies, burdens and costs

Most respondents to the consultations highlighted **disproportionate costs** arising from time and resources spent on documentation (e.g. translations). Other areas mentioned included testing of products by third parties, finding / buying standards, and risk assessment procedures.

[66] Companies providing data employ over 10,000 people each on average, well above the sector average (~32 people). It was therefore scaled down estimates accordingly in the main report when calculating for the whole sector.

The PC also asked what areas a **future revision** of the MD should aim to address, which might improve efficiencies or reduce costs. Over 150 comments were received, including:

- Adapting the MD to fit / integrate with the New Legislative Framework
- Adapting the MD to ensure suitability for new developments
- Simplification of risk assessment process
- Improvements to the definitions of / demarcations between types of machinery
- Improved convergence / harmonisation with other legislation
- Ensuring compliance to the MD, through increased / improved inspection

Coherence

A majority reported that the MD was largely coherent and complementary to both national and other EU legislation. The fit with international legislation was generally considered 'moderate'.

The main issue (reported by half) was that the same product is regulated by two or more directives (additional burden). Others pointed to issues with different definitions and divergent interpretations, the potential for regulatory arbitrage (i.e. choosing less stringent rules) and the potential for multiple inspections.

The two pieces of legislation most often cited as overlapping / inconsistent with the MD were the Low Voltage Directive and the Electromagnetic Compatibility Directive (EMC) 2014/30/EU.

EU Added Value

The targeted consultation asked whether the MD achieves more in relation to its objectives than would be achieved otherwise. All respondents agreed it added value, both in facilitating the internal market and ensuring the health and safety requirements of machinery, and a majority reported it did so to a large extent. In addition, 92% of respondents believed that the MD reduced costs, compared to what might be the case otherwise (national legislation).

How responses were used

The responses were used to evaluate all aspects of the MD, in particular its continued relevance and added value as well as associated costs and benefits.