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COVER NOTE

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Delegations will find attached document SWD(2014) 23 final PART 1/2.

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PART 1/2

COMMISSION STAFF WORKING DOCUMENT

Part 1: Evaluation of the Internal Market Legislation for Industrial Products

Accompanying the document

the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee

A vision for the internal market for products

{COM(2014) 25 final}

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Glossary and use of terms

Glossary

AB	Accreditation Body
ADCO	Administrative Co-operation
ADR	Alternative Dispute Resolution mechanism
BAU	Business-as-usual
CA	Conformity Assessment
CAB	Conformity Assessment Body
CE	Conformité Européenne
DoC	Declaration of Conformity
EA	European co-operation for Accreditation
EO	Economic operators
EQ	Evaluation question
ESO	European Standardisation Organisation
EU	European Union
FTE	Full-time equivalent
IA	Impact assessment
ICSMS	Information and Communication System on Market Surveillance
IM	Internal market
MSAs	Market Surveillance Authorities
NANDO	New Approach Notified and Designated Organisations Information System
NB	Notified Body (Bodies)
NBGs	Notified Bodies Groups
NLF	New Legislative Framework
NRTL	Nationally Recognized Testing Laboratory
ODM	Original design manufacturer
OEM	Original equipment manufacturer
PCP	Product Contact Point
PSMSP	Product Safety and Market Surveillance Package

Glossary and use of terms

R&D	Research and Development
SCM	Standard Cost Model
SDoC	Supplier's Declaration of Conformity[1]
SME	Small or medium-sized enterprise
TD	Technical Documentation
TFEU	Treaty on the Functioning of the European Union
UK	United Kingdom

Internal Market Directives/ Regulations

ATEX	Directive on Equipment and protective systems intended for use in potentially explosive atmospheres
CPR	Construction Products Regulation
EMC	Electromagnetic Compatibility Directive
GAD	Gas Appliances Directive
LD	Lifts Directive
LVD	Low Voltage Directive
MD	Machinery Directive
MID	Measuring Instruments Directive
OED	Outdoor Equipment Directive
PED	Pressure Equipment Directive
PPE	Personal Protective Equipment Directive
REACH	Registration, Evaluation, Authorisation and Restriction of Chemical substances Regulation
R&TTE	Radio and Telecommunications Terminal Equipment Directive
RoHS	Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment
SPVD	Simple Pressure Vessels Directive

A full list of Internal Market directives and regulations within study scope is provided in

[1] The terms "manufacturer's declaration of conformity" and "self-declaration of conformity" are synonymous with SDoC.

Glossary and use of terms

Table 1.1.

Notes on the use of terminology

- The terms: internal market legislation for industrial products and Union harmonisation legislation have been used interchangeably in the report.
- When referring to specific internal market legislation, a distinction has been made between (i) product-specific harmonisation legislation and (ii) horizontal harmonisation legislation.

Introduction and background 1

This Staff Working Document builds on the Evaluation of Internal Market Legislation for Industrial Products was carried out for the European Commission's DG Enterprise and Industry by the Centre for Strategy & Evaluation Services (CSES)[2], supported by our partner organisations, Panteia and Oxford Research.

Drawing on evidence gathered through the research, the evaluation provides an independent evaluative judgment on the current state of play in the development and modernisation of the body of internal market legislation for industrial products. It does not represent the official view of the European Commission.

1. Introduction and background

Section 1 provides an overview of the evaluation's objectives and scope and outlines the methodology adopted. The subject of the evaluation, the overall policy and legal context and recent developments in the regulatory architecture are then set out.

1.1 Evaluation aims

The objectives of this evaluation are, in summary, to:

- Examine how far the overall body of internal market (IM) legislation for industrial products and the regulatory approach is fit for purpose and to what extent they constitute an effective means of addressing barriers to the functioning of the EU's internal market for industrial products;
- Evaluate the *relevance* and *coherence, efficiency, utility, effectiveness and impact* of Union harmonisation legislation and address a series of specific evaluation questions[3];
- Identify and analyse any gaps, loopholes, inconsistencies and duplication in IM legislation for industrial products or in administrative requirements for economic operators;
- Assess the costs and benefits of Union harmonisation legislation for economic operators and the impact on strengthening industrial competitiveness;
- Assess the cumulative impacts of, and interaction between legislation and compliance requirements[4].
- Make recommendations as to how the efficiency and effectiveness of IM legislation for industrial products (including structures and institutional actors to support its implementation) could be improved so as to strengthen industrial competitiveness and

[2] The study is part of Lot VI of the Framework Contract for the Procurement of Studies and other Supporting Services on Commission Impact Assessments and Evaluations (2008/S146-195858).

[3] A summary of the key evaluation questions specified in the specifications is provided in Section 2.1

[4] A typology and conceptual framework showing how cumulative impacts have been assessed through the research is provided in Section 2.3.

to create more favourable conditions for growth and jobs;

- Identify possible simplification measures through a preliminary analysis of the potential impacts, and a comparison of the appropriateness and feasibility of the different options to feed into a possible future impact assessment.

Since the mid-1980s, the EU *acquis* for industrial products has gradually expanded, and there are currently more than 30 directives and regulations covering specific areas of industrial products (e.g. pressure equipment, gas appliances) and horizontal directives that apply across many different product groups, such as the RoHS (hazardous substances), REACH (chemicals) and Ecodesign. A distinction can be made between two different types of legislation falling within scope:

- **Product directives** – Directives that address specific types of products, such as the Pressure Equipment Directive (PED) and the Recreational Craft Directive; and

- **Horizontal directives** – that cover a broad range of product groups. Examples are the Low Voltage Directive (LVD), the Machinery Directive and the RoHS Directive.

Although evaluations of individual pieces of IM legislation (directives and regulations) have been undertaken, this study is the first overarching strategic review of IM legislation for industrial products in 25 years. As such, it provides an opportunity to: assess the fitness for purpose of the regulatory architecture for ensuring the free movement of industrial products; consider the extent to which further improvements could be made to strengthen coherence, efficiency and effectiveness and to take stock of progress already being made through the New Legislative Framework's (NLF's) modernisation agenda.

There is a strong backwards-looking aspect to the evaluation. Progress to date has been reviewed and any problems have been identified and analysed, either in the legal framework itself, or in the implementation regime. There is equally an important forward-looking element, since the study has examined the extent to which Union harmonisation legislation is fit for purpose for the internal market of the 21st century, and whether any simplifications or further changes are necessary.

Strengthening the effectiveness of the internal market for industrial products was identified as a priority in the October 2012 update on an Integrated Industrial Policy[5]. The European Commission therefore committed to carrying out an evaluation of the EU *acquis* in the area of industrial products to assess the coherence and 'fitness for purpose' of the regulatory framework. The study is especially timely because 2012 was the 20th anniversary of the establishment of the internal market. The study will make a contribution to the objectives set out in the Single Market Act I[6] and follow-up Communications[7] to maximise the contribution of the internal market in industrial products to achieving the Union's growth and employment objectives, in line with the Europe 2020 strategy for smart and inclusive growth. In particular, the evaluation provides a technical input to the *Roadmap for the Reform of the*

[5] COM(2012) 582
[6] COM/2011/0206 final
[7] COM(2012) 573 final

Internal Market for Industrial Products[8] expected in late 2013.

1.2 Evaluation scope and methodology

1.2.1 Evaluation scope

The study is ambitious in scope, since it covers not only most pieces of IM legislation, but also the workings of the regulatory regime, including European and national implementation structures. The focus of the study is on Union harmonisation legislation, although the specifications also required consideration of some issues relating to non-harmonised products.

The majority (though not all) pieces of IM legislation were within the study scope, as set out in the following table:

Table 1.1: Union harmonisation legislation within study scope

No	Year	Directive
1	1989	Directive 89/686/EEC on personal protective equipment (PPE)
2	1992	Directive 92/42/EEC on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels
3	1993	Directive 93/15/EEC on explosives for civil use
4	1994	Directive 94/9/EC on equipment and protective systems intended for use in potentially explosive atmospheres (ATEX)
5	1994	Directive 94/25/EC on recreational craft
6	1994	Directive 94/62/EC on packaging and packaging waste
7	1995	Directive 95/16/EC on lifts
8	1996	Directive 96/98/EC on marine equipment
9	1997	Directive 97/23/EC on pressure equipment (PED)
10	1999	Directive 99/5/EC on radio and telecommunications terminal equipment (R&TTE)
11	2000	Directive 2000/9/EC on cableway installations designed to carry persons
12	2000	Directive 2000/14/EC relating to the noise emission in the environment by equipment for use outdoors (OED)
13	2004	Directive 2004/22/EC on measuring instruments (MID)
14	2004	Directive 2004/108/EC concerning the electromagnetic compatibility electrical and electronic appliances, systems and installations (EMC)
15	2006	Directive 2006/42/EC on machinery (MD)
16	2006	Directive 2006/95/EC on low voltage devices (LVD)
17	2007	Directive 2007/23/EC on pyrotechnic articles
18	2009	Directive 2009/23/EC on non-automatic weighing instruments
19	2009	Directive 2009/105/EC on simple pressure vessels (SPVD)
20	2009	Directive 2009/125/EC establishing a framework for the setting of ecodesign requirements for energy-related products (Ecodesign)

[8] http://ec.europa.eu/governance/impact/planned_ia/docs/2013_entr_003_industrial_products_en.pdf

No	Year	Directive
21	2009	Directive 2009/142/EC on gas appliances (GAD)
22	2010	Directive 2010/35/EU on transportable pressure equipment
23	2010	Directive 2010/30/EU on the indication by labelling and standard product information of the consumption of energy and other resources by energy-related products (Energy Labelling Directive)
24	2011	Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

Some IM legislation was excluded because it has recently been subject to major revision, such as the Construction Products Regulation (2011) and Medical Devices Regulation (2012)[9]. It should also be noted that a further legislative initiative aimed at simplifying four IM directives is under consideration as part of a separate study[10]. Sectoral legislation is also outside the scope, since regulation in areas such as the chemicals and automotive sectors has recently been evaluated. The transposition of Union harmonisation legislation into national legislation was formally outside the scope. However, since one of the issues examined was whether directives or regulations are a more effective instrument in achieving internal market goals, some consideration was made as to the extent of divergence in the implementation of directives.

While environmental legislation falling outside the scope of Article 114 was beyond the scope, as part of the assessment of cumulative regulatory effects, through the case studies, it was necessary to consider the interaction between IM legislation for industrial products and other legislation applicable to products. A series of EU regulations have been adopted in the past 10 years that impose additional costs on industry, such as the WEEE Directive (2012/19 EC), the Energy Performance of Buildings Directive and product--specific regulations such as the F-gas regulation (842/2006 EC).
The second main area of focus has been on assessing how well the regime works to support the implementation of Union harmonisation legislation at European and national level, including the role played by different institutional actors, coordination mechanisms and support structures.

The scope also included a review of progress made through recent initiatives to help modernise Union harmonisation legislation such as the New Legislative Framework (2008), the Alignment Package of 9 Directives that forms part of the NLF's implementation (2011) and the proposals set out in the "Product Safety and Market Surveillance Package" (2013). These and other recent relevant developments are set out in Section 1.4. This was essential given the need to take stock of what simplification measures have already been undertaken, or are planned in the near future, before considering what further simplification measures

[9] The Commission adopted a "package on innovation in health" consisting of the "Communication on safe, effective and innovative medical devices and in vitro diagnostic medical devices" (26 September 2012)
[10] The separate study is reviewing the PED 97/23/EC; Personal protective equipment (PPE) 89/686/EEC; Appliances burning gaseous fuels 2009/142/EC; and Cableway installations designed to carry persons 2000/9/EC

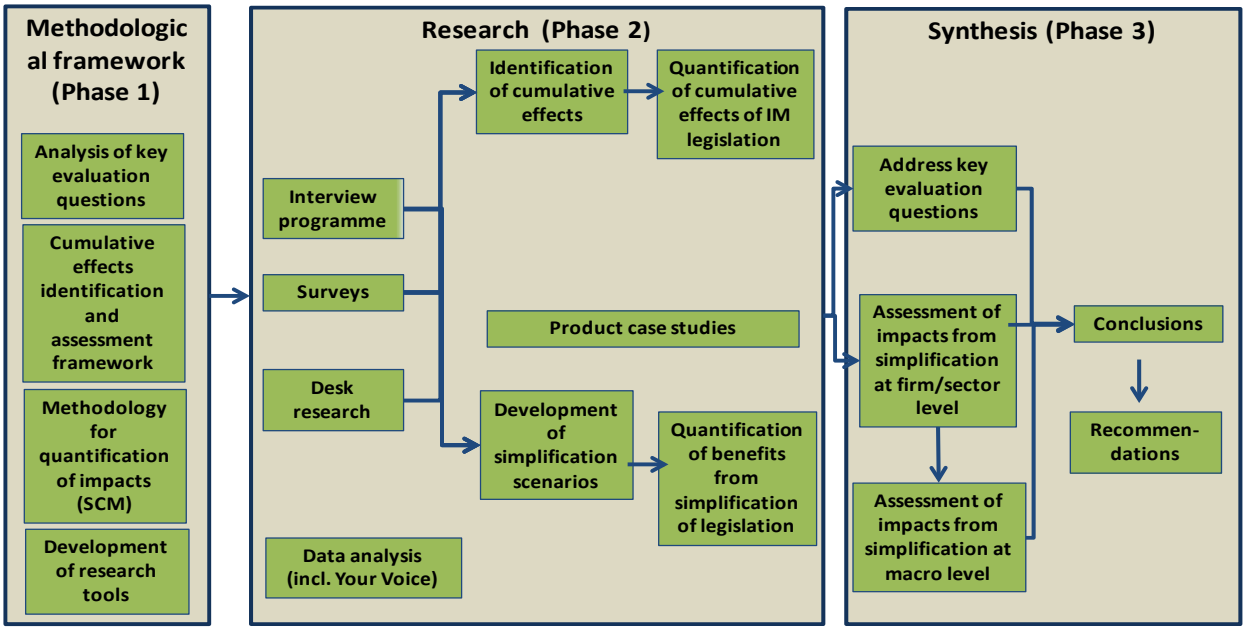
might also be considered.

1.2.2 Methodological approach

The research has been carried out using a number of different research tools that have allowed us to verify and to cross-check the evidence in accordance with triangulation principles. These include: extensive desk research, two different online surveys, carrying out a major interview programme with more than 200 stakeholders, undertaking product-based case studies across 10 selected product categories, and analysing the results of DG ENTR's Your Voice online consultation.

The following diagram shows the interconnection between the different phases and elements of the study.

Figure 1.1: Methodological framework by phase and research and data analysis tools



Introduction and background 1

Desk research involved a review of a wide range of documents and a bibliography is provided in Appendix B. Among the documentation reviewed were key EU legal texts and non-binding guidance produced by the Commission to support the implementation of Union harmonisation legislation overall, and guidance on specific Directives and Regulations. Relevant findings from evaluations and impact assessments carried out focusing on individual pieces of IM legislation have also been reviewed[11].

Two **online surveys** were carried out with (i) Notified Bodies and members of Notified Body Groups and (ii) Accreditation Bodies. The survey of Notified Bodies received 128 responses, which equated to 11.4% of the total viable sample of 1116 Notified Bodies contacted. The number of responses achieved represents a 95% confidence level with an 8% margin of error. The response level was positive given the problem of survey fatigue and contact problems[12].

The distribution of responses from NBs by country in the sample broadly reflects the distribution in the total population of NBs across Europe (distribution by country is provided in Section 2) and was representative by size of the NB in terms of the number of employees. Certain smaller EU countries (e.g. Bulgaria and Czech Republic) are over-represented, while a few countries (e.g. France) are comparatively under-represented in the sample.

In terms of the pieces of legislation covered by the NBs that responded to the survey, the participating NBs cover all pieces of IM legislation under investigation. The most common are the Personal protective equipment (27% of respondents), the Machinery Directive (24.6%), the Pressure equipment Directive (18.9%), the Low Voltage Directive (18.9%). Good coverage of all conformity assessment procedures (Modules) has also been achieved, with all procedures covered by at least 35% of participating NBs. EC-type examination (Module B) is the most common procedure (84% of respondents).

While the majority of Notified Bodies primarily serve their national markets (67% indicate that national market represent more than 50% of the their turnover from conformity assessment services), there are also NBs with a more international character (43% indicated that firms in other EU countries represent more than 10% of the turnover and 34% referred to a similar share of turnover for firms in non-EU countries).

The survey of **Accreditation Bodies** attracted 20 responses out of a total of 32 contacted[13] 62.5%) including all Member States with a large manufacturing base as well a range of smaller Member States. It is provides a broad geographical coverage. Additionally, a few Accreditation Bodies were interviewed, which ensured a high level of coverage of this stakeholder group.

[11] Impact assessments (IAs) have only been compulsory since 2006 and while IAs relating to Union harmonisation legislation have been reviewed, legislation that predates this period was not subject to an IA process.

[12] Out of 1826 notified bodies listed in the NANDO database there were 136 duplicate entries and in the case of 648 NBs, no email address was provided, or it was incorrect (non-functioning) or missing. The CSES team conducted its own desk research and identified alternative contact details for 74 NBs.

[13] 28 Member States plus Iceland, Liechtenstein, Norway, Switzerland and Turkey

201 interviews have been carried out[14]. The extensive **interview programme** with key stakeholders included the broad spectrum of stakeholders such as national competent authorities, market surveillance authorities, Notified Bodies and members of NB groups, ADCOs, Product Contact Points, industry associations and individual firms. An overview is set out in the table below:

Table 1.2: Interview programme – Number of interviews completed

	Total
EU industry associations and stakeholders	31
National industry associations	9
Individual firms (e.g. manufacturers, importers, large/small firms)	62
European Commission officials	12
National authorities (market surveillance authorities, Accreditation Bodies, and chairmen/women of the ADCO groups).	77
Notified Bodies Groups/ organisations at EU level	4
Notified Bodies	1
Consumer, environmental organisations and trade unions representatives	1
Standardisation organisations	1
Total	**201**

A total of 62 firms were interviewed, together with 19 industry associations for the product-based case studies, out of a total of more than 220 firms contacted. It should be stressed that only a small number of Notified Bodies Groups were interviewed and Notified Bodies because as noted above, a large-scale survey was undertaken with Notified Bodies.

CSES also carried out an analysis of the 144 responses to the **Your Voice Consultation**[15] organised by the European Commission carried out between January and April 2013 as part of the roadmap initiative "Reforming the internal market for industrial products". The consultation received response from industry associations and individual firms across a broad range of sectors such as manufacturing and ICT, and from public authorities, organisations providing professional, scientific and technical services, wholesale and retail, consumer organisations and individual citizens. The findings have been integrated into this report and CSES provided DG ENTR with a summary analysis of the consultation results. The analysis has also been integrated into the various parts of the report.

Last but not least, in consultation with the Commission, the project team selected 10 product categories for the case study research, eight in harmonised sectors and two in non-harmonised sectors (ski/Snow footwear and bicycles). A number of selection criteria were used, such as ensuring that the product included professional users, products in which SMEs have a strong presence among manufacturers, the need to include intermediate not only final end products, etc. The case studies selected were:

- Electric motors

[14] Some interviewees were interviewed twice either because of the complexity of the information needed for the cases, or because they were interviewed in a different capacity, first in their role within an industry association and secondly in relation to their firm.

[15] http://ec.europa.eu/yourvoice/ipm/forms/dispatch?form=IMIP&lang=en

- Laptops
- Domestic Refrigerators and freezers
- Lifts for persons
- Gardening equipment
- Instruments & appliances for measuring, testing and navigation
- Air conditioners
- Integrated circuits
- Ski/Snow footwear (non-harmonised)
- Bicycles (non-harmonised)

The full versions of the 10 case studies are in Appendix C. These were carried out using a combination of desk research, statistical analysis and interviews with relevant firms and industry associations. For each case study, we analysed relevant data sources (e.g. Eurostat Prodcom and SBS data, industry data). Section 5 provides a summary overview of the findings through the case study research.

1.3 Recent developments in Union harmonised product legislation

Since Union harmonisation legislation is complex and there have been a number of significant developments in the legal framework since the mid-1980s, it is necessary to provide a factual overview as to how the basic regulatory architecture works, and to summarise steps taken by the Commission to improve and modernise the regime supporting its implementation (e.g. the legal framework on market surveillance and accreditation.

1.3.1 Introduction

Since January 1993, the Internal Market ("IM") has ensured the free movement of goods, services, people and capital within the European Union (EU). Article 114 of the Treaty on the Functioning of the European Union (TFEU)[16] provides the legal basis for Union harmonisation legislation for industrial products. The objectives are to promote approximation through technical harmonisation measures and to ensure high levels of protection for safety and health, consumers and the environment. An assessment of the intervention logic is set out in Section 2.2.

1.3.2 Harmonised products and the New Approach Directives

In 1985[17], the New Approach was adopted as the principle regulatory mechanism for harmonised product legislation under which the "essential requirements" in respect of safety and health are set out in the applicable internal market legislation.

The legislative framework is non-prescriptive and technology-neutral with detailed technical implementation dealt with through standardisation. Economic operators are then free to determine how they demonstrate compliance with the essential requirements, typically following European harmonised technical standards, or an alternative means of showing that presumption of conformity has been achieved.

[16] Consolidated Version of the Treaty on the Functioning of the European Union, 26.10.2012
[17] Council Resolution 85/C 136/01 of 7 May 1985 on a new approach to technical harmonization and standards.

Introduction and background 1

After two decades, the "New Approach" gained recognition and acceptance across many industrial sectors as a method for achieving the effective operation of the internal market in industrial products, while ensuring that minimum common technical standards are met. In order to improve the effectiveness of the regulatory framework under the New Approach Directives, the New Legislative Framework (NLF) was adopted in 2008. The aim was to retain the central tenets of the New Approach but to reinforce the regulatory system's effectiveness, improve transparency and remove any remaining obstacles to the free movement of industrial products. In 2008, in order to support the NLF's implementation, two EU regulations and a decision were adopted as part of a broad package of measures. In the area of harmonised products, the "Goods Package" consists of:

- **Regulation (EC) No 765/2008** sets out the requirements for accreditation and market surveillance relating to the marketing of products and Decision 768/2008/EC on a common framework for the marketing of products. The Regulation applies to harmonised products; and

- **Decision 768/2008/EC** on a common framework for the marketing of products. The Decision lays down common principles and reference provisions. This includes harmonised definitions and general obligations for economic operators, rules for CE marking and a "menu" of conformity assessment procedures. The Decision provides a general framework for future legislation which will harmonise the conditions for placing products on the market.

1.3.3 The Alignment Package

On 21 November 2011, the Commission adopted an "Alignment Package" to align nine Directives with the common rules and approaches outlined in the NLF, taking into account the "toolbox" set out in Decision 768/2008/EC, namely: Low Voltage Directive (2006/95/EEC), Electromagnetic Compatibility Directive (2004/108/EC); ATEX Directive (94/9/EC); Lifts Directive (95/16/EC); Simple Pressure Vessels Directive (2009//105/EC); the Measuring Instruments Directive (Directive 2004/22/EC); Non-automatic Weighing Instruments Directive (2009/23/EEC); Civil Explosives Directive (93/15/EEC); and Pyrotechnic Articles Directive (2007/23/EC). In addition, there are a number of other Directives subject to a broader revision that includes an alignment to the model provisions of Decision 768/2008/EC.[18].

1.3.4 Non-harmonised products

Until 2008, the mutual recognition principle was implemented under Decision 3052/95/EC. Regulation (EC) No 764/2008, also known as the Mutual Recognition Regulation, provides a common framework for mutual recognition in the area of non-harmonised products. This relates to the application of the mutual recognition principle in the area of non-harmonised products. Regulation 764/2008 complements two other pieces of EU legislation:

- **Directive 98/34/EC[19] and the TRIS notification procedure** - which requires the

[18] Recreational Craft, Personal Protective Equipment, Radio and Telecommunications Equipment Directive, RoHS Directive, Medical Devices.

[19] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services

Member States to notify the Commission and each other of any draft 'technical regulations' for products before they are adopted in national law; the Directive is a *preventive* measure that allows the Commission and Member States to verify that any new technical rule is compatible with EU law before it is adopted; in contrast, the Regulation 764/2008 is a *corrective* measure that ensures the correct enforcement of national rules on a case-by-case basis; and

- The **General Product Safety Directive**,[20] which requires the safety of all consumer products to be assessed in accordance with European standards, Community technical specifications, codes of good practice, the state of the art and expectations of consumers; except where national rules apply, the Directive applies to all consumer products (whether harmonised or not), whilst Regulation 764/2008 applies to all non-harmonised products (whether likely to be used by consumers or not). Through the new Product Safety and Market Surveillance Package, a new proposed regulation is expected to replace the 2001 GPSD by 2015.

Approximately 25% of intra-EU trade is in the non-harmonised product area. In the absence of Union harmonisation legislation, each Member State can adopt its own national technical rules in relation to issues such as weight, size, composition, labelling and packaging or, indeed, to apply no rules at all. National legislation must still comply with the requirements of Articles 34–36 of the Treaty on the Functioning of the European Union (TFEU). In order to prevent national technical rules from inhibiting trade, the TFEU also forms the basis of the "mutual recognition" principle. According to Articles 34-36, Member States are obliged to accept products lawfully marketed in another Member State (and which are not subject to EU harmonisation legislation) even when the product does not fully comply with the technical rules of the Member State of destination. Since 2008, the NLF has helped to drive the modernisation agenda to ensure that IM legislation for industrial products is fit for purpose and that present inconsistencies are eliminated. Following the adoption of the two Regulations and Decisions mentioned earlier concerned with setting out a common regulatory framework and common arrangements for market surveillance and accreditation measures, there have been a series of further developments that form part of the NLF and its follow-up.

1.3.5 Product Safety and Market Surveillance Package

In order to improve consumer product safety and to strengthen market surveillance of products on the internal market, the Commission proposed a new package of legislative and non-legislative measures, the "Product Safety and Market Surveillance Package" on 13 February 2013. This builds on the overarching framework provided by the NLF.

The PSMSP consists of a number of elements, namely a Proposal for a Regulation on consumer product safety, replacing Directive 2001/95/EC on general product safety; a Proposal for a Regulation on market surveillance of products, a Multi-annual plan for market surveillance until the expected coming into force of the Regulations in 2015. The final part is an implementation report on Regulation (EC) No 765/2008 setting out requirements for accreditation and market surveillance relating to the marketing of products. Overall, the Package is intended to enable better coherence of the rules regulating consumer products identification and traceability and improved coordination of the way authorities check

[20] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety

products and enforce product safety rules across the European Union. More specifically, the Commission highlights a number of key changes to be introduced by the Package:

- Alignment of the general obligations of economic operators to ensure the safety of consumer products with clearer responsibilities for manufacturers, importers and distributors;

- More effective tools to enforce safety and other product-related requirements and to take action against dangerous and non-compliant products through a single set of rules for market surveillance;

- Creation of a more co-operative system of market surveillance across the EU; and

- Streamlined procedures for the notification of dangerous products and synergies between the existing Rapid Alert Information System (RAPEX) and the Information and Communication System for Market Surveillance (ICSMS).[21]

The proposed Regulation on the Market Surveillance of Products responds to the confusion said to be caused by the current "three-tier" system of market surveillance which results from the fact that market surveillance rules and obligations for economic operators are laid down in several different pieces of EU legislation. For example, the General Product Safety Directive[22] creates overlaps in relation to harmonised products intended or likely to be used by consumers. Such overlaps have been criticised by the European Parliament and stakeholders in industry and national administrations. In order to improve the effectiveness of the regulatory regime, the proposed Regulation would merge the rules on market surveillance of the General Product Safety Directive, Regulation (EC) 765/2008 and many sector-specific pieces of Union harmonisation legislation into a single legal instrument that applies horizontally across all non-food sectors. There would be no distinction between consumer and professional products or between harmonised products and non-harmonised products for the purposes of market surveillance.

[21] Ibid.
[22] Directive 2001/95/EC of 3 December 2001 on general product safety.

Evaluation framework and typology of regulatory simplification

2

2. Evaluation framework and typology of regulatory simplification

2.1 Evaluation questions

The specifications for this evaluation set out a number of high-level evaluation issues under the headings of (i) relevance and coherence (ii) efficiency (iii) effectiveness and fitness for purpose and (iv) impacts. In the following table, we summarise the evaluation questions (EQs) that have been considered by the evaluation. In order to address the overall objectives of the evaluation, it has been necessary to revise some of the questions set out in the task specification and to introduce additional questions.

Table 2.1: Evaluation Questions

No.	Evaluation Question
	Relevance and Coherence – Section 3
EQ1	• Is harmonised product legislation (supported by voluntary technical standards) a relevant response to the problems and needs identified in the intervention logic?
EQ2	• Are directives the most suitable legal instruments for the purposes of technical harmonisation in the relevant fields or should directly applicable regulations (requiring little or no transposition) be used?
EQ3	• Is there evidence of gaps, loopholes, inconsistencies and duplication across Union harmonisation legislation and in the corresponding administrative requirements for economic operators?
EQ4	• How coherent is the approach to definitions and product scopes in the various legal texts? (e.g. components, spare parts)
	Efficiency of the implementation regime – Section 4
EQ5	• What is the overall picture in relation to the efficiency of IM procedures, mechanisms and structures to support its implementation?
EQ6	• How efficient is the conformity assessment process?
EQ7	• How well do Notified Bodies serve the conformity assessment process
EQ8	• Are conformity assessment bodies sufficiently regulated or are more stringent rules are needed?
EQ9	• Is it appropriate to allow different elements of a conformity assessment to be performed by different bodies?
EQ10	• What are the challenges for national competent authorities in monitoring the activities of Notified Bodies located outside the EU? How far is it appropriate – if at all – to open up Europe's conformity assessment market to third countries?
EQ11	• Should third-party conformity assessment be required for all industrial products?
EQ12	• What are the benefits of accreditation for enhancing the single market for products (and services) and how could it best be used to support single market initiatives?

Evaluation framework and typology of regulatory simplification

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No.	Evaluation Question
EQ13	• Should accreditation be made compulsory for the purposes of demonstrating the technical capacity of conformity assessment bodies in the regulated sector?
EQ14	• Is the current regime for the Declaration of conformity satisfactory?
EQ15	• Is the current regime of CE marking satisfactory? Are there ways to improve the interaction between CE marking and other compulsory and voluntary markings enshrined in EU legislation?
EQ16	• What contribution is made by support and co-ordination mechanisms such as Administrative Co-operation Working Groups and Product Contact Points?
EQ17	• What are the main challenges facing market surveillance authorities?
EQ18	• How effective is the co-operation between market surveillance authorities?
EQ19	• Should non-harmonised/non-consumer products be covered by common EU market surveillance rules?
	Costs of Compliance and Scope for Simplification - Section 5
EQ20	• What steps do firms take to ensure compliance with IM legislation? What costs do they incur?
EQ21	• How far is there scope for administrative and regulatory simplification of Union harmonisation legislation? To what extent is there scope for merging different directives?
EQ22	• How far will administrative simplification bring about benefits for economic operators in terms of reduced administrative burdens?
EQ23	• To what extent can the benefits of administrative simplification be quantified?
EQ24	• What benefits from simplification can be identified for the wider economy?
	Effectiveness and Impacts – Section 6
EQ25	• What, if any, are the barriers (regulatory/ non-regulatory) to the effective functioning of the internal market for industrial products stemming from IM legislation for industrial products?
EQ26	• Are there specific regulatory barriers to the development and free movement of innovative products, including products integrating key enabling technologies (KETs)? Are there any legal gaps not already covered by IM legislation for industrial products?
EQ27	• Are there specific regulatory barriers to the development and free movement of green products? Are there any legal gaps not already covered by IM legislation for industrial products?
EQ28	• To what extent is legislation adapted to the challenges presented by e-Commerce?
EQ29	• How are SMEs (micro, small and medium-sized) affected by IM legislation for industrial products and how do they cope with the requirements? Is there scope to alleviate the burden on the different SME categories without compromising

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No.	Evaluation Question
	the overarching objectives of the legislation?
EQ30	• Are there barriers to trade stemming from the way legislation handles the relation between services and products which are part of the same value chain?
EQ31	• The specific situation of business-to-business (B2B products) which are developed and supplied to be used by professionals for the development of other products: Do these products require a special treatment?
EQ32	• Overall, how effective is IM legislation for industrial products as a mechanism and means to achieve the objective of improving the functioning of the internal market?
EQ33	• Overall, how effective is IM legislation for industrial products as a mechanism and means to achieve the objective of ensuring a high level of health and safety and consumer protection?
EQ34	• Overall, how effective is IM legislation for industrial products as a mechanism and means to achieve the objective of ensuring a high level of environmental protection?

2.2. *Intervention logic*

2.2.1 Problem definition and identification of needs

The starting point was to define the problems and needs that Union harmonisation legislation seek to address. The counterfactual situation prior to the introduction of harmonised technical product regulations at EU level was also considered. Prior to the introduction of the internal market for industrial products, there was significant market fragmentation due to there being different national legislation and technical standards in different Member States. There were regulatory barriers to cross-border trade and customs tariffs. There were practical barriers to exporting industrial products, and it was more difficult to find out what national legislation was applicable in another Member State.

Prior to the advent of an internal market in industrial products, there was a lack of a level playing field and fair competition since national regulations and administrative requirements were more burdensome in some EU countries than in others. In some cases, such as machinery, there was the absence of a national equivalent to the Machinery Directive. In order for industry and SMEs to benefit from the potential economies of scale that stem from the elimination of barriers to cross-border trade, there was a need for technical harmonisation measures.

2.2.2 General, specific and operational policy objectives

The **general objectives** underlying IM legislation for industrial products are set out in Article 114 of the Treaty (TFEU). This provides the legal basis for the adoption of approximation measures. In adopting such approximation measures, Union harmonisation legislation should ensure a high level of protection as regards safety and health, environmental and consumer protection.

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A number of **specific objectives** then relate back to these overarching general objectives, such as in the case of harmonised products: ensuring access to the internal market and fair competition; developing harmonised rules across the EU for placing products on the market, preventing unsafe and unhealthy products entering the market, etc. The circulation of non-harmonised industrial products is intended to be ensured by the application of the mutual recognition principle. Under the goal of environmental protection, the Industrial Policy Communication (COM(2010) 614) also mentions the role of IM legislation in promoting a more resource-efficient and sustainable European economy.

Balancing the economic objectives relating to the internal market are the social and environmental objectives within Article 114 relating to the prevention of unsafe and unhealthy products from entering the market and the minimisation of harmful environmental impacts. Whilst not incompatible with the internal market objectives, these objectives reflect the need to protect against a "race to the bottom", whereby producers of harmful products are able to undercut other producers. Here, clearly the adoption of recent IM Directives such as the Ecodesign Directive and energy labelling requirements has potential to contribute to this objective.

Although Article 114 provides the sole legal base for Union harmonisation legislation, the effective implementation of Union harmonisation legislation should also contribute – albeit indirectly - to the achievement of EU industrial policy objectives. Article 173 (TFEU) provides the basis for EU industrial policy and is an important part of the wider policy backdrop. However, since IM legislation does not differentiate between European economic operators and those from third countries, since it is concerned with ensuring a level playing field within the internal market, industrial competitiveness is a subsidiary objective.

Operational objectives provide the basis for evaluating the immediate activities and effects associated with Union harmonisation legislation. They relate to concrete actions taken at EU level, including formal activities, namely i.e. introducing directives and regulations and setting standards, as well as defining administrative requirements. For instance, Regulation (EC) 764/2008 establishes a framework for the implementation of the mutual recognition principle and mechanisms for non-harmonised products to be recognised, Decision 768/2008/EC provides a common framework for the marketing of products. They also include "soft" interventions, including providing practical support to industry and promoting harmonisation with global trading partners.

2.2.3 Intervention logic mapping diagram

An intervention logic diagram is provided on the following page (Figure 2.1) setting out the **hierarchy of objectives.** This ranges from the general (strategic) policy objectives through to specific and operational objectives. In the next sub-section, we describe the specific mechanisms by which the objectives are pursued.

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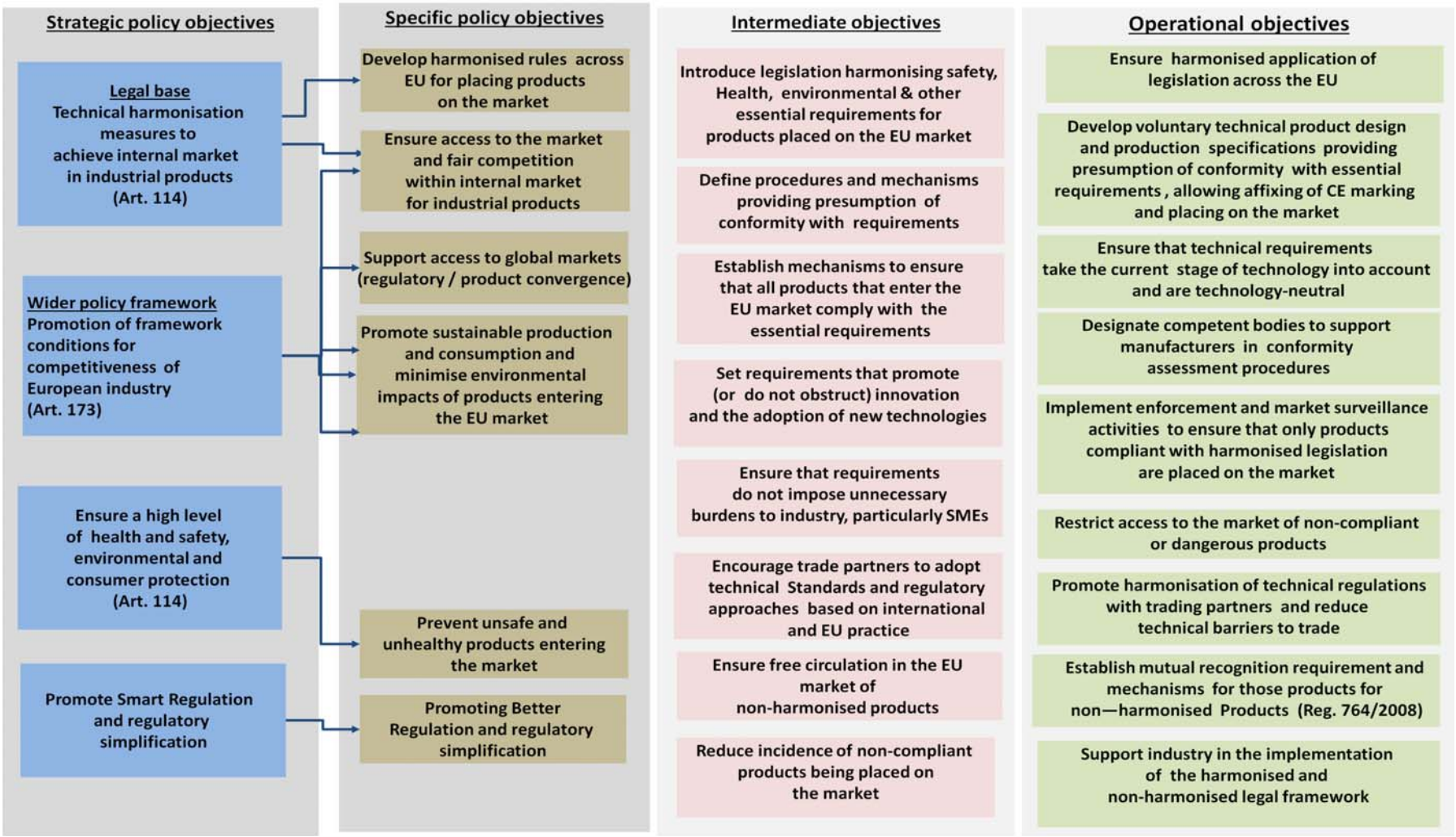
Figure 2.1: Intervention logic - IM legislation for Industrial Products



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2.2.4 Division of competence between the EU and national levels

At **EU level**, the European Commission is responsible for the development of Union harmonisation legislation for industrial products and its periodic review and revision. It also has an important overarching role in monitoring and evaluating its implementation. The Commission is also responsible for mandating EU standardisation bodies to develop technical standards and for setting up appropriate mechanisms and support structures to ensure its effective implementation. It is also responsible for coordination aspects relating to market surveillance.
In order to strengthen the effectiveness of IM legislation and its implementation, a number of different institutional mechanisms have been set up at EU level, such as ADCO Groups and Notified Bodies Groups. These promote information exchange and facilitate the discussion of the main challenges in the implementation of Union harmonisation legislation. In addition, information tools have been developed to support the implementation regime, such as the NANDO Database of Notified Bodies across EU28 and the ICSMS, the internet-supported information and communication system for the pan-European market surveillance. Furthermore, EU guidance documents have been developed for economic operators as to how to ensure more effective compliance with IM regulations (Blue Guide, specific legislation).

Turning to the **national level**, a number of mechanisms and structures that support the implementation of Union harmonisation legislation are the responsibility of the Member States. Member States are responsible for the development of national implementing rules and for nominating the necessary competent authorities, and have responsibility for designating Notified Bodies – including determining whether accreditation mechanisms are required and for monitoring the operation of NBs. Further responsibilities include the provision of support and guidance to economic operators to ensure effective implementation, market surveillance and enforcement.

In the non-harmonised area, Member States are required to follow a notification process where they consider that products should not enter their national market, to establish national product contact points and to submit an annual report on implementation. Product Contact Points also provide information and guidance since 2008.

Finally, manufacturers and other economic operators are expected to comply with requirements and follow the various conformity assessment procedures while at the same time – mainly through the industry associations – participate in the development of technical standards and the working groups set up to monitor the implementation of IM legislation. Other relevant stakeholders – e.g. consumer, environmental groups and trade unions – also participate in this process.

For all these activities, the Commission, the Member States, industry and stakeholders all dedicate certain resources in the form of human and financial inputs. The level of these inputs has a significant effect on the overall efficiency of the legal framework. An assessment of how effective a role is being played by the various institutional actors involved in supporting the implementation of Union harmonisation legislation is provided in Section 4 (efficiency).

2.2.5 Mechanisms and structures

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The implementation of Union harmonisation legislation is underpinned by a number of mechanisms and structures that help to ensure effective implementation. These are summarised below, with a distinction between EU and national level implementation, monitoring and enforcement activities:

EU level - Harmonised products

- Mandate EU standardisation bodies to develop technical standards
- Review and evaluate implementation of legislation and propose amendments /changes to Directives and Regulations to reflect technological developments, address implementation problems and economic and technical feasibility
- Create Notified Body coordination groups
- Develop information/support structures to assist industry and stakeholders in implementation of legislation (e.g. NANDO, ICSMS online information and communication system for pan-European market surveillance)

Non-Harmonised products

- Third countries
- Conclude Mutual recognition agreements to reduce costs of testing and certification in other markets

National Level (Member States)

- Appoint national competent authorities in respect of specific IM legislation
- Appoint national Accreditation Bodies
- Transpose EU Directives into national legislation
- Designate Notified Bodies to carry out conformity assessment
- Establish national Accreditation Bodies to accredit Notified Bodies
- Conduct monitor and enforcement activities to ensure compliance with the legislation
- Communicate to other Member States decisions (notify) for approval, withdrawal of products
- Lay down rules and penalties for non-compliance
- Participate in support/coordination structures/groups (ADCOs)
- Develop support structures for industry (industry)

Non-harmonised products

- Operating Product Contact Points
- TRIS notification system (98/34 notification procedure)
- Submit annual reports on implementation of Regulation 764/2008

Industry and stakeholders

- Comply with legal requirements
- Participate in support structures for development of technical standards
- Participate in working groups monitoring the implementation of legislation (e.g. ADCOs, Notified Bodies Groups)

The human resources required at EU and national level in order to promote an effective internal market in goods form an important part of the intervention logic since they are the processes that need to be implemented efficiently in order to bring about the effective

implementation of IM legislation. An assessment as to how effective some of the different aspects of the framework for the implementation of IM legislation for industrial products (including the role of different institutional actors) is explored in Section 3 of this report (efficiency).

2.2.6 Effects and impacts

The final stage in the logic mapping was to assess the full and effective implementation of IM legislation for industrial products in order to check what sort of effects and impacts should materialise at different levels, namely:

- **Effects on economic operators -** strengthened access to the internal market and global markets, leading to greater economies of scale and enhanced firm-level competitiveness, cost-efficiencies through regulatory and product convergence at European level and to some extent also globally.

- **Effects on users and consumers -** reduce incidence of non-compliant products placed on market, promoting more sustainable consumption

- **Impacts on the internal market** – such as promoting an increase in intra-EU trade, strengthening market access, promoting fairer competition and a level playing field

- **Impacts on health, safety, the environment and consumer protection –** through the setting of essential requirements, IM legislation's effective implementation should help to prevent unsafe and unhealthy products from being placed on the market, and the environmental impacts of products should be minimised.

- **Wider impacts on industrial competitiveness and innovation –** although not explicit objectives in the legal base, Union harmonisation legislation has the potential to strengthen competitiveness, e.g. through the promotion of industry consolidation with manufacturing firms being able to operate across the internal market, rather than in national markets, with greater economies of scale, effects from the development of a body of Union harmonisation legislation in promoting global regulatory convergence and convergence in technical standards, enhanced take-up of innovation and RTD results (through a technology-neutral approach).

The extent to which the different types of effects identified through the logic mapping have been substantiated through the research is examined later in this report, in particular in Section 6 (effectiveness and impacts).

2.3 Typologies of simplification and support measures

The Commission has sought to make improvements to strengthen the coherence and effectiveness of internal market legislation and the support structures and mechanisms that support its implementation at EU and national levels. This has been achieved through the framework of the NLF (and the current Alignment Package) with an effort to modernise the legal framework and to promote greater consistency between different IM legislation in order

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to reduce administrative burdens for economic operators. In addition, through periodic reviews and recasting of individual IM directives and regulations, efforts have been made to promote regulatory simplification.

A typological framework was developed in order to assess what steps have already been taken towards regulatory and administrative simplification, and to strengthen the implementation of Union harmonisation legislation through measures and support actions. This was an essential step in order to be able to examine the future scope for further simplification measures and possible measures to strengthen efficiency and effectiveness more generally. The typology consists of three main aspects:

- **Regulatory simplification measures** relating to Union harmonisation legislation for industrial products (horizontal and vertical/ sectoral legislation);
- **Administrative simplification measures** (for economic operators, national authorities and market surveillance actors); and
- **Non-legislative support actions** that strengthen the efficiency and effectiveness of regulatory implementation and the enforcement and monitoring of IM legislation.

The validity of this typological framework has been tested through the research. Examples of existing simplification measures have been identified and analysed in the sections dealing with efficiency and effectiveness respectively (Sections 4 -6). The mapping was a crucial starting point in exploring the potential scope for further simplification. The typology provides a framework for presenting the conclusions and recommendations relating to simplification measures.

2.3.1 Regulatory simplifications and clarification measures

Regulatory simplifications can take different forms such as:

- **Changing the structure of legislation relating to the internal market for industrial products** - the possibility of a horizontal regulation to replace Decision 768/2008; overcoming regulatory fragmentation in market surveillance by combining different pieces of legislation;
- **Merging different directives or regulations –** combining different directives or regulations where there is scope to do so e.g. Machinery Directive and Outdoor Noise Equipment Directive;
- **Updating IM legislation for industrial products using the <u>same</u> regulatory instrument –** periodic reviews of legislation leading to the codification and recasting of individual directives and regulations, or groups of legislation aligned in parallel;
- **Updating IM legislation through the use of a <u>different</u> regulatory instrument –** transition from an EU regulation to a directive;
- **Repealing EU legislation** –in cases either where legislation has proven to be obsolete

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altogether, or where Union harmonisation legislation has been replaced by recast or codified IM legislation.

Simplifications and clarification measures can either be applied to individual pieces of legislation or to groups of regulations and directives through recasting and codification[23] exercises. Through the NLF, an effort has been made to promote regulatory simplification through the adoption of the common elements set out in Decision 768/2008 within the Alignment Package, without any major changes to the substance of the legislation. Where legislation has been updated, opportunities have been taken to provide clarity as to definitions, the scope (for instance, whether spare parts and components are included) and in making administrative requirements more consistent. The proposed typology of regulatory simplification measures relevant to IM legislation for industrial products is set out in Table 2.2, and is supported by concrete examples:

[23] The codification of directives means bringing into one legal text the original directive and its successive amendments.

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Table 2.2: Typology of regulatory simplification and clarification measures

Type of simplification measure	Simplification – short description and key benefits	Union harmonisation legislation
Changes to structure of IM legislation (horizontal)	**Proposal for a horizontal Regulation on the Market Surveillance of Products (PSMSP).** The proposal would bring into a single piece of legislation applying across all non-food sectors rules on market surveillance. Making the rules more accessible. Benefits Simplification of Union rules on market surveillance and reduced market fragmentation – combining market surveillance rules scattered across different legislation e.g. General Product Safety Directive, Regulation 765/2008 and sector-specific legislation into a single Regulation.	PSMSP - COM(2013) 74 final
Changes to structure of IM legislation (vertical)	**Merging IM directives and regulations** Merging IM legislation could help to maximise synergies, minimise overlaps and inconsistencies and reduce administrative burdens for economic operators.	• Machinery Directive (2006/42/EC) and Outdoor Noise Efficiency Directive (2000/14/EC)[24] • PED (97/23/EC) and SPVD (2009/105/EC) Directives • PED (97/23/EC) and transportable pressure equipment (99/36/EC) Directives

[24] The possible merging of the MD and Outdoor Noise Emissions Directive is being explored through a technical study for DG ENTR which began in early 2013.

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Type of simplification measure	Simplification – short description and key benefits	Union harmonisation legislation
Updating IM legislation (using same regulatory instrument)	**Recasting and codification of directives** There is no fixed timetable for reviewing and recasting legislation. Periodic reviews of IM legislation provide an opportunity to review and simplify legislation and to apply lessons from practical experiences of the legislation's implementation through recast directives. **The New Legislative Framework (NLF)** and **alignment of groups of IM regulations** Decision 768/ 2008 introduced a common framework for marketing products to ensure greater consistency between IM legislation. The Alignment Package will implement the NLF's common approach across 9 directives (common definitions of economic operators, their obligations and responsibilities).	• Machinery Directive 89/392/EEC recast in 2006/42/EC • RoHS Directive 2002/95EC, recast (2011/65/ EU)[25] • PPE Directive 89/686/EEC, revision process on-going • R&TTE Directive 1999/5/EC revision process on-going with proposal for new "Radio Equipment Directive"
Updating IM legislation (using a different regulatory instrument)	**Replacing directives with directly applicable regulations** Benefits: no national transposition requirements with reduced scope for differences in interpretation between Member States, uniformity across the internal market, legal certainty for economic operators.	Examples of industrial product legislation where Regulations have replaced Directives: • Cosmetic Products Regulation (1223/2009/EC) • Construction Products Regulation (305/2011/EC) • Proposal for a Regulation on medical devices (COM(2012) 542
Repealing EU legislation	EU regulations can include periodic review clauses so that any which are no longer relevant or have become obsolete can be repealed.	IM legislation under the New Approach covers broad harmonised product areas

[25] The recast RoHS Directive adopted many of the common elements set out in the NLF and provided greater clarity on which product groups that were formerly exempted are now within scope.

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The updating of Union harmonisation legislation, through recasting and codification allows for clarifications to be made. This may include, for instance, clarifying the demarcations between directives, a clearer presentation of the scope and definitions of key terms, and updating the list of product groups falling within scope, widening and clarifying product exclusions, and taking into account industry developments and innovation, for instance, accommodating new product groups that did not exist when the legislation was first drawn up.

Given that there has already been a substantial amount of legislative revision across IM legislation for industrial products, it is worth an assessment as to the value of legislative review processes. Such improvements are not always concerned with simplifications, but are rather part of on-going efforts to improve the overall coherence and effectiveness of the regulatory framework.

Table 2.3: Clarifying legislation

Clarifying the borderline and delineation between Directives	The MD 2006/42/EC clarifies the borderline between the scope of the Machinery Directive and the Low Voltage Directive to provide greater legal certainty. It also sets out clearly the delineation between the MD and the Lifts Directive and ensures mutual exclusivity.
Clearer presentation of scope and definitions of the key terms	NLF: provides a clearer definition of the obligations for different economic operators e.g. manufacturers, importers and distributors. Previously, responsibility for product safety was entirely on manufacturers.
Widening and clarifying exclusions of products	EMC: the Directive allows the display & demonstration of non-compliant equipment at trade fairs, exhibitions etc. provided that a sign indicates that the equipment may not be marketed or put into service until it has been brought into compliance and that electromagnetic disturbances are avoided. EMC: Apparatus intended for a fixed installation and not otherwise commercially available may be exempt from the Declaration of Conformity, CE marking, etc. EMC: Where new editions become available and are to be applied it does not necessarily mean that a complete EMC re-assessment of an existing product is necessary. The evaluation may be restricted to those modifications directly affecting the apparatus concerned. R&TTE: radio receivers and fixed-line telecommunications terminal equipment will be excluded from the proposed new Directive and will instead fall within the scope of the EMC Directive and, depending on power supply voltage, either the Low Voltage Directive or the General Product Safety Directive. R&TTE: - the proposed new “Radio Equipment Directive” will introduce an exemption for components used for pre-production

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	purposes not placed on the market.

2.3.2 Typology of administrative simplification measures

In order for the overall regulatory regime to work effectively, economic operators need to demonstrate that they have complied with the essential requirements set out in Union harmonisation legislation in order to achieve presumption of conformity. Since the adoption of the New Approach, and its subsequent evolution through the NLF, which will help to modernise Union harmonisation legislation itself, administrative requirements for economic operators have been set out in the legislation. Examples are CE marking requirements, which have been in place since 1993 indicating a product's conformity with EU legislation and the obligatory steps before a product can bear CE marking, such as producing a Declaration of Conformity (DoC).

Although in principle, administrative requirements for economic operators are clear (CE marking, DoCs, self-certification or third party conformity assessment depending on the IM legislation and safety risk involved), in practice, anomalies and differences between EU legal texts have emerged. This is partly due to the fact that the overall volume of legislation has increased, and the fact that legislation has evolved piecemeal. This was explicitly recognised through the adoption of the NLF in 2008, which provides a framework for coordination and ensuring a more common approach.

Requirements for DoCs currently vary between Directives in relation to information that needs to be provided, and whether the DoC needs to be placed together with the product or can be in the accompanying manual alone. The date when a product is considered as having been placed on the market may also vary. In some instances, products are considered as being on the market from the date of publication of an information notice in the EC Official Journal (OJ) whereas for other IM legislation, presumption of conformity applies from the date when the DoC is signed off by the manufacturer. The review allowed us to identify different types of administrative simplification measures. The typology includes examples of simplifications that have been introduced through the NLF, and examples of administrative simplifications specific to particular IM directives or regulations.

Table 2.4: Typology and examples of administrative simplification measures

Type of administrative simplification	Examples
Common approach to conformity assessment	The NLF (Decision 768/2008): common approach across Union harmonisation legislation to conformity assessment through a standard suite of modules with a new more consistent lettering system. These are gradually being integrated into IM legislation, for instance through the Alignment Package Legislators can choose from these modules in drawing up IM legislation. Art. 4 refers to the need to "avoid imposing modules which would be too burdensome in relation to the risks covered by the legislation concerned".
Standardised template	The NLF (768/2008) sets out common procedures for

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Type of administrative simplification	Examples
and information requirements for DoCs	producing DoCs and a standard format across different applicable IM legislation.26 The NLF also provides a suggested standard template for a DoC.
Removal of requirement to notify placing on the market	R&TTE: a revision in the proposed new Radio Equipment Directive to remove the requirement to notify the placing on the market of equipment using frequency bands which are not EU-wide harmonised.
Identification of apparatus	EMC: There is flexibility in the requirement that apparatus be identified by "type, batch, serial number or any other information allowing for the identification of the apparatus", allowing the manufacturers to choose their own means of identifying an apparatus for regulatory purposes.
Unused administrative provisions (i.e. choosing not to enforce them)	R&TTE: the relevance of some of the administrative provisions in the Directive has been questioned, e.g. various kinds of small equipment such as RFID tags or cochlear implants, emit radio signals that are unlikely of causing harmful interference.[27]
Lighter regime for SMEs	CPR: offers simplified procedures for the drawing up of declarations of performance for SMEs. However, concerns about how this operate in practice.
Lighter requirements on technical documentation	EMC: Declaration of Conformity and technical documentation to be made available on request does not need to be an original document but can be a copy. Technical documentation can be kept in any format, for example as a hard copy or CD-ROM.
Electronic processes, e.g. forms, reporting, notification procedures, NANDO	CPR: allows use of electronic forms for the submission of information and of online databases for registering products.

2.3.3 Typology of non-legislative support actions

The third strand of the typology (in addition to regulatory and administrative simplifications) is **non-legislative support actions.** There are many examples of support actions and these help to promote the efficient and effective implementation of Union harmonisation legislation. These are essential in closing the "gap" between formal legislative texts and the situation on the ground. The table below provides a typology of non-legislative support actions, supported by examples.

Table 2.5: Typology of non-legislative support actions

[26] Article R10 relates to Declarations of Conformity in Decision 768/2008. Annex III to the Decision specifies the form the DoC must take and states that by drawing it up, the manufacturer takes responsibility for the product's compliance.

[27] Example of a potential simplification that has been identified but not yet implemented.

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Types of non-legislative support actions	Examples
Information, guidance, advice and publicity (customised to difference audiences)	• Guidance and handbooks, e.g. EU Blue Guide covering Union harmonisation legislation (2000, with revision during 2013) • Guidance on individual harmonised directives and regulations (EU, sometimes also national) • Website information – e.g. DG ENTR and national competent authority websites responsible for specific harmonisation legislation • Expert groups • Technical assistance visits and consultations • Communication campaigns
Coordination of activities between Member States	• GRAS-RAPEX • Coordination of cross-border surveillance activities • Joint enforcement • European cooperation on market surveillance (e.g. ADCO)
Pooling of information, experience and expertise	• EU-level dialogue bodies • Portability of test reports • Collection of information on enforcement, etc. • Databases, e.g. ICSMS, public platform for complaints and injuries • Traceability systems and information • Exchanges of officials, e.g. market surveillance authorities
Common methodologies	• EU general risk assessment methodology for products • Common approach to market surveillance of e-commerce • Common risk-based approach to customs product safety and compliance controls
Benchmarking	• Performance Benchmarks for market surveillance
Studies and research	• Feasibility studies • Impact assessments and evaluations • Stakeholder and public consultations

A number of stakeholders at EU and national level have an important role to play in implementing support actions. These may be taken by the Commission at EU level or by national authorities at Member State level. The Commission has a vital role in terms of ensuring overall coordination of support actions. It is also directly involved in some activities, such as the development of non-binding guidance on the application of IM legislation and in ensuring that cumulative experiences of implementing legislation are built into this guidance (e.g. Blue Guide, specific guidance).

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National authorities, notably competent authorities and market surveillance authorities are also involved in implementing support actions on the ground, for instance in communication, awareness-raising and information campaigns about administrative requirements for economic operators (manufacturers, distributors & importers), especially SMEs. Market surveillance authorities may also launch dedicated campaigns about specific issues, for instance, problems relating to non-compliant products and/ or documentation, awareness-raising about impending deadlines e.g. timescales for different thresholds of chemical products within the REACH Regulation coming into force.

Sectoral bodies and industry associations may also implement actions in support of their members. One of the advantages of non-legislative support actions is that they do not need to be negotiated or require legislative changes. Some care is needed in their design and use, since support actions do not replace the requirements of the legislation; they should help clarify rather than contradict the legislation. Among the wider target audience of such measures are: end-users & consumers, researchers and the media.

Relevance and coherence 3

In Sections 3 – 6, we set out the detailed findings from the evaluation research. The analysis draws on a number of data and information sources, namely desk research, online survey work, an analysis of the results of the Your Voice Consultation, an extensive interview programme and ten product case studies. At the end of each sub-section, we list the main Research Findings (RFs) that have emerged from the analysis of the evidence presented. These numbered RFs have in turn informed the overall conclusions in Section 7, thus ensuring that each conclusion is evidence-based.

3. Relevance and coherence of Internal Market Legal Framework

The **relevance** and **coherence** of Union harmonisation legislation were assessed through the evaluation. Among the issues considered were whether the intervention logic is appropriate and meets the identified needs of economic operators, consumers and end-users, whether directives or regulations are the most appropriate regulatory instrument for IM legislation for industrial products to achieve key objectives, and the overall coherence of the regulatory framework.

3.1 Relevance

EQ1: Is harmonised product legislation a relevant response to the problems and needs identified through the assessment of the intervention logic?

Technical product harmonisation legislation which sets essential requirements that avoid being too prescriptive, supported by voluntary harmonised technical standards, has been a highly relevant mechanism for the achievement of the objectives set out in Article 114 of the TFEU. Technical approximation measures were viewed by industry and national authorities as an appropriate mechanism for ensuring an effectively functioning internal market with high levels of product safety and health, environmental and consumer protection. However, ensuring that the implementation of legislation leads to the achievement of such objectives relies on effective market surveillance to ensure that non-compliant products are not placed on the market (see sections on efficiency and effectiveness).

In assessing the relevance of technical product harmonisation legislation, the "counterfactual" situation was considered i.e. problems that existed prior to the adoption of Union harmonisation legislation under the New Approach and the establishment of an internal market in industrial products. As is well documented in the seminal Cecchini studies in the late 1980s[28] and in subsequent studies to assess the benefits of the internal market[29], the situation prior to the adoption of the internal market was characterised by regulatory fragmentation and legal uncertainty for economic operators, with different national technical regulations and standards for industrial and consumer products across EU12[30]. The New Approach Directives provided a mechanism for addressing these problems through a common, harmonised EU-wide approach to meeting the essential requirements. This was highly relevant to achieving the objectives of an effectively functioning internal market in

[28] Cecchini report on the Cost of Non-Europe, Paolo Cecchini, 1988

[29] "The European Challenge 1992 – the Benefits of the internal market, "Paolo Cecchini with Michel Catinat and Alexis Jacquemin, 1992

[30] It should be recalled that it is difficult to achieve a counterfactual that provides a like for like comparison given that the EU only had 12 members when the New Approach was adopted.

products, with a level playing field and fair competition for economic operators.

Prior to the adoption of Union harmonisation legislation, each Member State imposed obligations on economic operators in the interests of safety, health and consumer protection. This meant that there were considerable regulatory and non-regulatory barriers to trade in goods because of the different requirements in different countries.

This meant that economic operators had to treat each EU Member State as a separate market, with its own rules. Although difficult to quantify, doing business on a cross-border basis in this operating environment imposed considerable regulatory compliance costs on economic operators. The adoption of successive vertical and horizontal Union harmonisation legislation was therefore highly relevant to addressing the identified needs of European industry. IM legislation for industrial products has been a highly relevant instrument to address the needs of economic operators. The approximation of product legislation through internal market legislation has been relevant in promoting industrial competitiveness because regulatory convergence at EU level (supported by voluntary technical standards) has made it easier for economic operators to access the whole internal market. It has promoted access to new markets within the internal market, promoted economies of scale and industry consolidation, led to fairer competition and a level playing field between economic operators.

In some instances, no national regulatory frameworks were in place prior to the adoption of EU legislation, therefore harmonised IM legislation addressed regulatory gaps enabling economic operators to develop a larger market for their products, while ensuring high levels of product safety and protection. For instance, until the adoption of the Machinery Directive in 1989, many national legal frameworks did not sufficiently regulate the safety and usage of electrical and mechanical machinery, despite the high level of risk involved for those operating such machinery. In these sectors, EU legislation largely preceded the development of national legislation, which was relevant in preventing the emergence of different national regulations which would otherwise have led to higher administrative burdens for regulatory compliance for economic operators.

Feedback through the interview programme from across the broad spectrum of stakeholders in the area of internal market legislation for industrial products confirmed that overall, there was broad satisfaction with the overall regulatory framework and with recent efforts to modernise and strengthen it, most notably through the NLF. An industry association commented that “IM legislation is effective because it sets out common requirements for placing products on the market and eliminates barriers to the free movement of the products. It is also very effective in ensuring common minimum standards”. While there is always scope to improve the efficiency and effectiveness of IM legislation for Industrial Products, from a relevance perspective, the regulatory framework is considered to be relevant to identified needs in that it is flexible, responsive and often used as a model for the development of industrial product regulation globally.

Overall, the intervention logic underpinning the regulatory framework - and the link between different levels of objectives - is broadly coherent. It allows the development of appropriate pieces of legislation that can facilitate the functioning of the internal market whilst offering protection for consumers, health and safety and the environment. Since the internal market in industrial products is crucial to the creation of growth and jobs, there may be scope to include broader policy objectives relating to competitiveness and innovation. An area of the logic

behind Union harmonisation legislation that is less coherent is the lack of a policy as to whether directives or regulations are the most appropriate mechanism for achieving objectives. This question is addressed in detail below.

Research Findings (RFs):

- (RF1) The situation prior to the adoption of Union harmonisation legislation was characterised by regulatory fragmentation with different national regulations and technical standards for industrial products across EU12.
- (RF2) Prior to the adoption of Union harmonisation legislation, there were many gaps in the regulation of products posing a potential risk to health & safety, consumer protection or environmental protection.
- (RF3) In the absence of Union harmonisation legislation, economic operators would face barriers to trade and higher costs as a result of different national regulatory regimes for many products.
- (RF4) In the absence of Union harmonisation legislation, there would be potential risks to health & safety, consumer protection or environmental protection, in cases where national regulatory regimes were inadequate.

3.2 *Coherence of instruments*

3.2.1 Directives or regulations?

EQ2: Are directives the most suitable legal instrument for the purposes of technical harmonisation or should directly applicable regulations be used?

Introduction

Since the New Approach[31] was adopted in 1985, more than 30 harmonised pieces of internal market legislation have been adopted, the majority of which were EU directives, which were the preferred regulatory instrument during the early stages in the development of Union harmonisation legislation, when the internal market for products was less integrated, and there was a need to allow for greater flexibility during national transposition. In the past 10 years, however, the use of regulations has become more common when new legislation has been introduced (e.g. REACH Regulation, 2006, Fertiliser Regulation, 2003). Moreover, following periodic legislative revision processes to recast legislation, a number of pieces of internal market legislation that were formerly Directives have been recast as Regulations. Examples of Directives that have evolved into Regulations are the EU Cosmetic Products Regulation (1223/2009/EC), the Construction Products Regulation (305/2011/EC) and the Proposal for a Regulation on Medical Devices (COM(2012) 542).

According to feedback from the Commission obtained through this study, among the reasons for this trend are that there is now longstanding experience of implementing New Approach Directives under harmonised product rules and the internal market for industrial products is much better integrated. There is consequently greater support among stakeholders for harmonisation to be supported by an appropriate regulatory instrument that avoids minor

[31] Council Resolution 85/C 136/01 of 7 May 1985 on a new approach to technical harmonization and standards.

divergence in transposition when directives are transposed into national legislation. The use of regulations rather than directives by the Commission has not explicitly been stated as a Commission policy due to the need to retain flexibility. The most appropriate regulatory instrument is given due consideration as part of impact assessment processes prior to the introduction of new, and the revision of existing legislation.

Advantages and disadvantages of Directives

Harmonisation directives set out the legal framework and essential requirements while leaving Member States flexibility to adopt national implementing rules to achieve the legislation's general objectives. A summary of the advantages and disadvantages of directives is now provided, followed by examples of stakeholder feedback as to the merits and drawbacks of using directives:

Table 3.1: Advantages and disadvantages of directives

Directives - advantages
Flexibility for Member States as to how European legislation should be transposed into national legislation, for instance as regards: • Whether national implementing provisions should be incorporated into new legislation at national level, or through the modification of existing legislation. • The form and national legal instrument used in transposition, which is left up to Member States (Article 288 TFEU). There is no obligation to create a single national measure where all the provisions are located. • The transposition process into national legislation provides an opportunity for national competent authorities to strengthen their knowledge about the specific implementation details of each Union harmonisation directive. This helps to build capacity before legislation is implemented, since national implementing rules are needed irrespective of which regulatory instrument is used. • Flexibility for Member States as to whether particular product groups designated as being of lower risk should be excluded from scope (e.g. optionality clause under the MID). This would be difficult to achieve through regulations.
Directives - disadvantages
• Minor regulatory divergences - directives help to ensure a minimum level of harmonisation across the EU, but there is minor divergence in the interpretation and application of legislation between Member States in some instances. • Lack of synchronised timing across EU28 of the entry into force of Union harmonisation directives. • Most manufacturers do not use national legal texts but refer to European legislative texts on product safety and to the applicable European technical standards. This was

seen as leading to duplication in legal texts, whilst resources could be better used elsewhere.

- There is a perception – albeit a largely erroneous one - among some economic operators, that some Member States impose additional national requirements through gold-plating
- The risk that a two tier approach as regards consumer and safety protection may emerge if Member States use the 'optionality clause'[32].

The feedback gathered through the research in relation to the advantages and disadvantages of Directives are now examined in further detail.

Stakeholders in some Member States were in favour of retaining Directives as the main regulatory instrument to implement Union harmonisation legislation. For instance, a market surveillance authority in **Germany** commented that *"Directives provide extra room for manoeuvre through the transposition process into national legislation and the development of national implementation rules. Directives work well for sectoral (or "vertical") Directives such as the Machinery Directive, LVD and the Outdoor Noise Directive"*. A market surveillance authority in **France** commented that "Directives are a better legal instrument, since national implementing rules are required for the effective application of internal market legislation at national level. Regardless of the instrument, public administrations still need to be nominated as competent authorities".

A national body in charge of metrology in **Spain** commented that Directives are preferable for the MID. "The optionality clause is useful since it provides the option of not regulating products that are not considered to be of serious concern to safety and consumer protection in each EU country". The same interviewee also stressed that the transposition process provides an opportunity to build knowledge and capacity among relevant national competent authorities about forthcoming Union harmonisation legislation.

A government Ministry interviewed in the **Netherlands** stated that the question of the relative merits and drawbacks of directives and regulations respectively is complex. Whilst at first sight, regulations appear to be a more effective instrument because they are directly applicable, national legislation still sometimes has to be adjusted and national implementing regulations drawn up.

As regards the disadvantages of using directives, a number of interviewees have pointed to regulatory divergence in the application of Union harmonisation legislation due to minor differences following national transposition processes in the interpretations and/ or application of the law. A detailed assessment as to the effectiveness of national transposition was outside the study scope (see Section 1.2). However, since the issue of the merits and drawbacks of the use of regulations and directives was one of the evaluation questions, we have considered this issue in general terms.

[32] Interim Evaluation of the Measuring Instruments Directive examined the extent to which a two tier market concerning consumer protection and competition has developed and if there is difference in the case of Member States have not opted to require legal metrological control (optionality). 17 countries have opted out from the Directive for one or more instruments. The only product area where optionality was linked with unfair competition concerned taximeters.

Evidence from the interview programme, Your Voice Consultation and CSES online surveys found that stakeholders perceive there to be regulatory barriers due to differences between Member States in national interpretation and in the application of IM rules[33] However, only a few detailed examples were provided as to these barriers (see Section 4 – efficiency).

Some national competent authorities stated that there was less scope for divergent interpretation in the national transposition of Union harmonisation directives than in other areas of EU legislation due to the nature of such approximation laws. Moreover, those that downplayed the significance of minor divergences in the transposition and interpretation of legislation pointed out that many Member States have transposed European legislation in a way that text that remains close to the original spirit and intention of the law.

A major industry association in the electronics and IT sectors commented that *"The transposition process can create problems, and requires industry to engage in active monitoring of how legislation has been implemented into different national laws, and any translation issues that may result in misapplication of IM legislation. However, the internal market should be a single legal jurisdiction"*.A further drawback mentioned by interviewees relating to the use of directives is the difficulty in ensuring synchronised timing of the entry into force of IM legislation, since transposition processes mean different timelines in each Member State. This was mentioned by stakeholders such as some national competent authorities, industry representatives and individual manufacturers. National transposition processes also take time and require human resources yet the research found that many manufacturers do not even read national legislation, but take European legal texts as their reference point. A number of market surveillance authorities suggested that resources currently used by national competent authorities to transpose directives into national legislation could instead be redirected towards improving the effectiveness of market surveillance.

Advantages and disadvantages of regulations

EU regulations are directly applicable, although they still require the development of national implementing rules. The research found that the use of regulations rather than directives can have a number of benefits in contributing to the achievement of internal market objectives. A summary of the advantages and disadvantages of regulations is now provided, followed by an assessment of some of the stakeholder feedback received:

Table 3.2: Advantages and disadvantages of regulations

Regulations - advantages
• Regulations are directly applicable and do not require transposition (with the exception of the need to develop implementing rules) • Synchronised timing of the entry into force of regulations across the internal market

[33] The extent to which this was due to the transposition process itself, as opposed to misinterpretation and misapplication of the original intention of EU legislation by national competent authorities and market surveillance authorities was difficult to assess (since the transposition process itself was outside the scope of the evaluation).

- Uniformity in application with reduced scope for differences in interpretation, thereby ensuring greater legal certainty and a level playing field for economic operators
- Potential to reduce the overall volume of Union harmonisation legislation by eliminating the need for transposition into one or more pieces of national legislation (most economic operators follow European legislation anyway).
- Potential scope for cost savings and the use of human resources among national competent authorities for alternative purposes if civil servants are not tied up in national transposition processes.
- Regulations may be a more appropriate instrument for pieces of horizontal Union harmonisation legislation, such as common rules on market surveillance and for placing products on the market (the latter is currently in the form of a decision).

Regulations - disadvantages

- There would still be a need for a minimum set of national implementing regulations to be developed, but arguably with less scope than is the case for directives to tailor these according to national-specific situations.
- Less flexibility to accommodate national-specific interpretations, although generally there is only limited room for manoeuvre in this regard (e.g. optionality clause within the MID).

The research identified support among some stakeholders for the greater use of regulations to implement Union harmonisation legislation in future.

Some Member State authorities appear to be more willing than in the past to use EU regulations as a mechanism for regulating harmonised products over time. This reflects strengthened confidence in the regulatory framework for harmonised industrial products and the level of integration of markets.

Support was especially strong among industry associations and individual firms, since industry has a clear interest in internal market legislation for industrial products being implemented on as uniform a basis as possible since divergences in application and interpretation between Member States - albeit minor - causes legal uncertainty for economic operators. A number of companies interviewed stated that regulations help to reduce the risk that unexpected regulatory barriers are experienced in particular national markets within the internal market. An EU industry association in the field of safety noted that industry tends to prefer regulations over directives because “Regulations are clear, and there is no need for national transposition. This means that all actors are on the same playing field”.

There was support among many national competent authorities for the greater use of regulations, although this view was not shared by all Member States (see comments under the advantages of directives). A number of competent authorities noted that regulations could help to reduce the overall volume and administrative costs of legislation since national legislation transposed from Union harmonisation legislation is largely duplicative. Moreover,

the majority of economic operators follow European legislative texts and harmonised technical standards in managing compliance with IM legislation, often in conjunction with European guidance on IM legislation. This renders national legislation somewhat redundant, although there remains a need to develop national implementing regulations, regardless of which regulatory instrument is used.A national Ministry in **Romania** commented that *"EU Regulations would eliminate the administrative costs of the transposition process by significantly decreasing the resources needed to transpose and implement legislation and in the application of particular terms and concepts"*. A market surveillance authority in **Slovenia** noted that *"Regulations lead to more coherent and uniform application, especially in respect of horizontal issues such as market surveillance and general product safety"*. Support for the adoption of regulations across IM legislation was not universal.

Among the potential disadvantages of using regulations identified by a small number of stakeholders were the lack of flexibility for Member States to take national-specific contexts into account. For instance, under the Measuring Instruments Directive (MID), there is an 'optionality clause' which allows scope for Member States to opt out of EU requirements to regulate particular product groups, if they classify them as low risk, or if a particular market segment is not present.

Although there is no universal consensus among stakeholders on this matter, the evidence points to the conclusion that in future, the Commission should consider using regulations as the preferred legislative instrument for Union harmonisation legislation so as to ensure synchronised timing in Directives coming into force.

A number of national authorities suggested that a gradual transition to using regulations rather than directives would help to avoid regulatory fragmentation within the internal market due to differences in the interpretation and application stemming from national transposition. At the same time, there are likely to be product groups such as measuring instruments for which directives are more appropriate. The possibility of using directives should be retained.

Research Findings:

- (RF5) Directives allow a minimum level if flexibility for Member States to ensure that national-specific operating contexts are taken into account during the transposition process into national legislation. However, in many cases, Member States transpose the Directives very close to the original European legal texts. Economic operators typically refer to the text of the Directive rather than to the relevant national legislation.
- (RF6) Among the advantages of Regulations are the synchronised timing of their entry into force.
- (RF7) The rationale for using Regulations rather than Directives has not been explicitly stated by the Commission.
- (RF8) The EU should retain the possibility of using both regulatory instruments to maximise flexibility, but clarify the criteria for determining the choice of regulatory instrument.

3.2.2 Gaps, loopholes, inconsistencies and duplication

EQ3 - Is there evidence of gaps, loopholes, inconsistencies and duplication across Union harmonisation legislation and in the corresponding administrative requirements for economic operators?

Over a 30 year period, the gradual accretion of IM legislation has resulted in inconsistencies arising between the different requirements set out in some IM legal texts and in the administrative requirements set for economic operators. This does not appear to be a universal problem that affects the overall body of IM legislation. Indeed, only 16% of Notified Bodies responding to the study suggested that there were any such problems related to those Directives for which they had been notified. However, where gaps, loopholes, inconsistencies and duplication do exist, they can cause significant difficulties for those operating in the relevant sectors. The can include:

- Legal uncertainty for economic operators;
- Inconsistences in administrative requirements leading to unnecessary minor differences in the templates produced for CE marking; and
- Higher administrative costs not only in complying with these requirements but also in terms of familiarisation with the requirements.

Examples of inconsistencies and duplication were identified through the interview programme and Your Voice consultation and are provided in the following table.

Table 3.3: Examples of gaps, loopholes, inconsistencies and duplication in IM legislation

Product area	Applicable directives	Problem type	Examples of gaps, loopholes, inconsistencies and duplication
Printers	LVD and Machinery Directive	Gap	Unclear demarcation between the LVD and the MD with regard to the definition of industrial printers. Lack of text in LVD as to when printers should be considered as being within the scope of the LVD Such text is however provided in the MD, which explains clearly that the Directives are mutually exclusive.
Pressure equipment	PED	Gap	Since the Directive was adopted, new product groups have come to market with evidence of new innovations. The definition of product groups consequently remains unclear and as to whether particular spare parts and components are within scope. Over-reliance on guidance for legal interpretation on product scope leading to legal uncertainties.

Product area	Applicable directives	Problem type	Examples of gaps, loopholes, inconsistencies and duplication
Non-road mobile machinery	Machinery Directive	Gap	Mobile machinery is within the scope of the MD, but the MD does not include requirements for road circulation of this machinery. These remain non-harmonised and subject to national requirements.
Cables	EMC Directive	Gap	Cables are not currently included within the scope of the EMC-directive
Electrical appliances under 50V	LVD Directive	Gap	Under the LVD, appliances under 50V are not covered. In practice, the GPSD provides a framework, but safety is not covered through harmonised requirements. There is no need for a declaration of conformity and CE marking. Doubtful whether voltage should be the most appropriate criteria. Energy usage of a product is today more important, but low voltage products presently excluded from the LVD with high energy-efficiency may not necessarily be safe.
Multiple products	R&TTE and Medical Devices Directive	Inconsistencies in requirements	Products where multiple legislation is applicable may face differences in CE marking requirements. This can result in conflicting requirements for integrated products. Problem should be solved since the proposed Medical Devices Regulation requires CE marking. See evaluation question on "CE marking" in efficiency section.
Multiple products	Declarations of Conformity Examples: MD, LVD, R&TTE and EMC Directives	Inconsistencies in requirements	Differences in CE marking requirements between the MD, LVD, R&TTE and EMC Directives (where the CE marking must be placed on product, detailed addressee information that has to be provided on the DoC). Where multiple legislation is applicable to a given product, problems in terms of differences in requirements for the format / layout of the DoC, and whether the DoC has to be provided along with the product/ product documentation.
Multiple products Example:	Spare parts and components	Gaps and loopholes	Lack of legal clarity as to whether spare parts and components are included within IM legislation

Product area	Applicable directives	Problem type	Examples of gaps, loopholes, inconsistencies and duplication
Pressure equipment	Pressure Equipment Directive, ATEX Directive		Inadequate definitions of spare parts and components. Confusion as to whether spare parts and components are distinct from one another or synonymous within scope of Directives. See evaluation question on spare parts and components.
Equipment and noise-emitting machinery	Machinery Directive, Outdoor Noise Emissions Directive and EMC Directive	Overlaps	There is a dedicated Directive on noise (Directive 2000/14/EC). However, the MD also covers issues relating to noise, pressure and electromagnetic compatibility. This raises the possibility of these IM regulations being merged.
OSH vehicles	Machinery Directive	Overlaps	Overlaps between requirements in the Machinery Directive concerning OSH vehicles that need to be EC-type approved
Non-road mobile machinery	Non-Road Mobile Machinery Directive and ATEX Directive	Conflicting requirements	Technical conflicts between Directive 97/68/EC (non-road mobile machinery) and the ATEX Directive. Stage IIIB engines are unable to be manufactured or adapted to conform to the technical requirements of both directives.
Construction Products	ATEX Directive, Construction Products Regulation	Unclear demarcation	Unclear demarcation between the ATEX Directive, and the Construction Products Regulation
Multiple products	PED and Simple Pressure Vessels Directive	Unclear demarcation	Unclear demarcation between the PED and Simple Pressure Vessels Directive

Whilst these specific issues do cause difficulties, some of these problems are already being tackled through the NLF, which has the potential to eliminate inconsistencies between IM regulations, for instance, through the introduction of a common approach to definitions, a clear explanation of the responsibilities and obligations of different economic operators in the distribution chain, and greater standardisation of administrative requirements, for instance in relation to CE marking and the development of DoCs.

It was, however, recognised that the horizontal provisions of the NLF (Decision

768/2008/EC) have not yet been implemented in full. There remains unnecessary duplication of administrative tasks to ensure compliance with differing requirements relating to the definitions of common concepts (e.g. placing on the market, manufacturer), the obligations of economic operators, conformity assessment procedures, CE marking, DoCs, etc. There are also differences between IM directives as to when the presumption of conformity becomes effective (e.g. first national publication or in official journal).

Stakeholders were therefore in broad agreement about the importance of the Alignment Package which was seen as a critical part of implementing the NLF through standardising the format and requirements for producing DoCs in line with Decision 768/2008/EC. Likewise, CE marking requirements are being made more common through the common framework which is gradually being introduced across more Union harmonisation legislation. The on-going process of alignment is gathering pace and this will gradually eliminate inconsistencies.

It was interesting that there was sometimes a perception among industry that there were problems as regards overlaps between different pieces of legislation, which on closer inspection were found not to be the case in practice. For instance, in respect of the Ecodesign Directive, there were perceived among some industry stakeholders to be overlapping and conflicting energy efficiency requirements between the implementing regulations concerning motors and fans within the Ecodesign Directive. However, upon investigation, it was found that there are no "overlapping and conflicting" requirements for electric motors (under Regulation 640/2009) and fans (under Regulation 327/2011).

Regulation 640/209 establishes minimum energy efficiency requirements for electric motors (sold alone or integrated into products). These requirements address the minimum energy efficiency class of the motor according to an internationally used IEC standard. Regulation 327/2011 addresses the minimum efficiency of fans, understood as products composed by an electric motor combined with an impeller. If the impeller is sold alone it is assumed that a motor complying with its relevant legislation will be used. The Regulation on fans calculates the efficiency of this product as the quotient between the energy transmitted to the gas and the electric energy used. Both Regulations appear to be complementary since they address different aspects of the typical systems used. Moreover, industry was consulted during the development of both Regulations and has not contested them.

The recasting of individual pieces of legislation also provides an opportunity to accommodate industry developments and changes in product groups. For instance, as noted earlier, problems relating to product scope (for instance, new products not being covered other than through supporting guidance to the legislation rather than in the legislation itself) and to the inclusion or exclusion of spare parts and components can be addressed through legislative revision processes. However, some industry stakeholders, especially for older Directives such as the PED believe that such a recasting exercise is long overdue.

Another important issue is whether the common framework for the marketing of products (as set out in Decision 768/2008/EC) will result in unnecessary duplication in IM legislation. Although there are many benefits of introducing a more common approach to product harmonisation rules across the regulatory framework, the length of legal texts of individual IM directives will double. An alternative approach would be to adopt a legally-binding horizontal "umbrella" regulation setting out common elements across IM legislation which

was advocated by some stakeholders interviewed. Several competent authorities, market surveillance authorities and industry associations were in favour of a restructuring of the legal architecture from a Decision to a Regulation.

Such a horizontal Regulation would eliminate the need to lengthen IM legislation unnecessarily, which was considered to be duplicative and not SME-friendly. Unlike Decision 768/2008/EC, it would also be legally binding. However, there were differing views on this point, with some stakeholders preferring all the relevant text to be included in each Directive (typically, operators involved in the production or marketing of products that only have to comply with a single Directive) and others preferring to have the common text presented only in a horizontal regulation or directive.

A horizontal national regulation has already been adopted based on Decision 768/2008/EC in Germany. This provides a regulatory umbrella and overall framework under which sectoral legislation at national level stemming from IM product legislation is structured. There may be scope for other Member States to adopt such an approach, drawing on the experience of Germany.

Although this issue is not one of urgency, it would be more coherent in our view, at least in the medium term to introduce a horizontal Regulation. Although there would not be many quantitative savings (other than minor effects through reduced familiarisation time), this would strengthen the coherence of the legislation and SMEs in particular would appreciate legislation being kept as short as possible.

Research Findings (RFs):

- (RF9) There are several instances of gaps, loopholes, inconsistencies and duplication across the body of IM legislation; but these are relatively modest in number and minor in substance given the size of the body of legislation.
- (RF10) Many of the outstanding instances are being addressed by the NLF and/or the Alignment Package, e.g. standard format and requirements for DoCs and CE marking.
- (RF11) Decision 768/2000/EC has not yet been implemented in full, resulting in some duplication of tasks for economic operators. The limited legal weight of a Decision may have had some impact in this regard.
- (RF12) Recasting Directives and Regulations provides an opportunity to eliminate gaps, loopholes, inconsistencies and duplication.
- (RF13) There may be merit in a horizontal Regulation for the marketing of products based on Decision 768/2000/EC (which would be legally-binding and limit the length of subsequent Directives) compared to the inclusion of all the relevant text within a single piece of legislation).

3.3 *Coherence of definitions*

EQ4: How coherent is the approach to definitions and product scopes in the various legal texts (e.g. components, spare parts)?

3.3.1 Definitions of economic operators

Strong support was identified through the interview programme for the improved definitions

of economic operators and their obligations set out in Decision 768/2008/EC and gradually included in the legislation, most notably through the Alignment Package. For example, Recital 20 of Decision 768 states that *"it is necessary to distinguish clearly between the manufacturer and operators further down the distribution chain. It is also necessary to distinguish clearly between the importer and the distributor, as the importer introduces products from third countries to the Community market. The importer has thus to make sure that those products comply with the applicable Community requirements"*. It was recognised by all interviewees that there were advantages in having common definitions of economic operators (manufacturers, importers and distributors) and in clarifying their respective responsibilities. Since different economic operators are involved at different points in the supply chain, there was strong support that they should assume their respective responsibilities for ensuring regulatory compliance with IM legislation. Ultimately, this should lead to strengthened market surveillance and improved product safety.

A number of industry associations asserted that the NLF was a significant improvement in strengthening the coherence of the implementation regime for Union harmonisation legislation because obligations for different economic operators are clearly defined. There was also seen to be a fairer sharing of the burdens between different economic operators in terms of their responsibility for ensuring that products placed on the market meet regulatory compliance requirements. Although manufacturers should continue to have primary responsibility for many aspects of product safety and health, *"the implementation of the NLF will make all economic operators more diligent with regard to regulatory compliance and product safety"*.

Ensuring that other economic operators take their share of responsibility for ensuring regulatory compliance was viewed as beneficial in terms of the overall fairness of the regulatory framework and the distribution of administrative costs and burdens. Market surveillance authorities also viewed the sharing of responsibility positively, since there is now greater clarity for economic operators about what their role is and their obligations including the requirement to respond promptly to requests from market surveillance authorities to provide technical information and documentation. Decision 768/2008/EC states that *"Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by national authorities, and should be prepared to participate actively, providing the competent authorities with all necessary information relating to the product concerned"*.

However, the importance of a practical approach by market surveillance authorities was also stressed. A number of industry associations suggested that there could be delays and inefficiencies if market surveillance authorities first approach distributors and importers since manufacturers have much of the technical information needed that provides evidence to support the DoC. Moreover, many manufacturers are reluctant due to commercial sensitivities to release the full technical file to other actors in the distribution chain. It can therefore save considerable time if market surveillance authorities approach manufacturers directly in the first instance. Overall, the NLF was viewed as having made a significant contribution to strengthening common definitions of economic operators in legal texts, although there are some concerns about how realistic it is for importers and distributers to retain all the information needed by market surveillance authorities.

Research Findings (RFs):

- (RF14) Stakeholders support the common definitions and general obligations in Decision 768/2000, e.g. distinguishing between manufacturer, importer and distributor. (Stakeholder views)
- (RF15) Definition of responsibilities is seen as fairer, e.g. importer and distributors are required to cooperate with market surveillance authorities. (Stakeholder views)
- (RF16) The definitions within Decision 768/2000/EC should be applied consistently across the whole body of IM legislation, as and when individual Regulations and Directives are recast.

3.3.2 Product definitions and scope

Union harmonisation legislation sets out the "essential requirements" and is designed to be technology-neutral. A broad description is provided in EU legislation of the product groups falling within scope. In order to keep the legal texts concise, detailed descriptions of product sub-groups are not typically included. Non-exhaustive lists of products within scope are sometimes also provided in the annexes of IM legislation, and/ or through clarifications provided in the accompanying guidance.

Sometimes products within scope are updated annually through the activities of Working Groups on different IM directives and regulations. These consist of the Commission, Member States and industry stakeholders and discuss issues relating to the practical application of IM legislation. This allows for the updating of guidance, which although not legally binding provides practical support for economic operators as to whether their product falls within scope.

The research identified **a variety of approaches across different pieces of IM legislation to the definition of products within scope**. Examples of the way in which different IM legislation addresses these issues across a sample of vertical and sectoral directives are provided in the following table:

Table 3.4: Treatment of definitions and product scope

Examples of IM legislation and type	Treatment of definitions and product scope
Machinery Directive (sectoral)	Art. 2 - general definitions are provided of 'machinery', and other broad product areas within scope are listed (safety components, lifting accessories, interchangeable equipment and partly completed machinery). Different categories of machinery, lifting equipment, etc. are then set out in further detail in annexes.
PED (sectoral)	Any pressure equipment that consists of a pipe, vessel, safety accessory or a pressure accessory and operates at >0.5 bar is considered to fall within scope. Legislation is non-product specific so that it can capture the full range of relevant products. However, lack of clarity as to whether specific components are included within scope (see detailed example).
EMC (sectoral)	The recitals state that the equipment covered by this Directive should include

	electrical apparatus and fixed installations. The definitions cover broad product areas rather than specific product sub-groups, e.g. equipment, apparatus and fixed installations.
Ecodesign Directive (horizontal)	Definitions are provided in the implementing regulations for specific product groups e.g. air conditioners and comfort fans, household dishwashers, household refrigerating appliances. Since ecodesign regulations are developed in specific product sectors, the scope of products covered is clear.
RoHS Directive (horizontal)	RoHS II (2011) is very specific about the specific product groups that are exempted from RoHS and in in setting out the six banned hazardous substances.

In examining how coherent and comprehensive product definitions and scope are, it should be recalled that there is a **trade-off between ensuring clarity and legal certainty** for economic operators, while at the same time **avoiding hindering innovation** through having too detailed descriptions of product categories and sub-categories that fall within scope.

The research found that although the definition of products falling within scope is sufficiently clear for most technical harmonisation regulations, this is not the case for all EU legal texts. Indeed, although a given IM directive or regulation may provide a clear definition of product scope, economic operators may still face difficulties in understanding whether their product falls within the legislation's scope, for instance, for specialised products, components and spare parts. In some instances, this may represent a gap or duplication in the text itself, in which case, there may be a need to update the text as and when the legislation is recast. In other instances, it may be sufficient to provide supporting guidance that provides the necessary clarification, without the need to revise the text of the legislation itself.

For instance, a Notified Body in Lithuania stated that there are legal gaps in relation to **product scope** within the **PED**, in terms of the types of pressure vessels covered. Some regulatory gaps have emerged because of the time that has elapsed since the Directive was adopted (1997). New types of pressure vessels have been developed since the legislation was drawn up. Although such products are addressed in PED supporting guidance, the situation is unsatisfactory because manufacturers point to the legislative text and only want to address the minimum legal requirements. For instance, there is very little in the legislation about large boilers, with manufacturers having to rely on the guidelines. The lack of legal clarity means that sometimes it is down to producers to interpret the guidance.

In a previous evaluation of the PED, a number of national authorities have stated that pressure accessories should be built according to the PED in order to enhance the safety of pressure equipment. A detailed examination of the issue may lead to the finding that safety aspects and market surveillance activities would be enhanced if the wording was amended. Although this has potential to strengthen product safety, the implications would need to be considered in terms of the overall burden on industry before changes are made.

Research Findings (RFs):

- (RF17) There has been a variety of approaches to the definition of products and scope.

Product definitions are usually broad, with non-exhaustive lists sometimes provided in Annexes.
- (RF18) There is often a trade-off between providing legal clarity and allowing innovation, i.e. not having overly-detailed descriptions of product categories.
- (RF19) Whilst there will need to be a variety of approaches to the definition of products and scope, there may be potential for greater consistency. This might involve broad definitions clearly stated in the main text of legislation, with specific definitions of categories and sub-categories defined in Annexes and clarified by the various Working Groups, with suitable adjustments and fine-tuning over time.

3.3.3 Definitions of spare parts and components

A key study issue was whether there are difficulties in the regulatory framework in terms of the definition of spare parts and components.

An industry association in **Germany** commented that they *"regularly receive questions as to whether components and spare parts placed on the market are within the scope of, and need to comply with IM legislation"*. A further problem identified was that even when a definition is provided, and the intention is to cover components and spare parts through IM legislation, the scope may be narrowly defined resulting in a situation where some components and spare parts are covered, but others are not formerly covered, but are mentioned in supporting guidance documents.

Although safety components are within the **Machinery Directive's** scope, other basic machinery components such as screws fall under non-harmonised legislation. This can create confusion for economic operators as to which parts of a machine are harmonised and which components are non-harmonised. A market surveillance authority in Germany (that participated in the MD ADCO at EU level) noted that the definition of "partially completed machinery" in the Directive has caused confusion among manufacturers in understanding whether their product falls within scope.

An Evaluation of the **Pressure Equipment Directive (PED (97/23/EC)** undertaken in 2012 identified examples of legal uncertainties in relation to product scope specifically in the area of safety and pressure accessories[34] (including components and spare parts for high pressure equipment). A number of manufacturers stated that the definition of pressure accessories in the PED is unclear which has resulted in uncertainty with regard to product scope. When the Directive was first introduced, industry understood the Directive to apply to all pressure accessories.

However, after an examination of the wording, it was found that a large proportion would no longer be covered. This was supplemented with a guideline in supporting guidance that apparently "removed up to 70% of pressure accessories from the PED's scope". These pressure accessories are now manufactured according to 'sound engineering practices' in the Member State where the manufacturer is based. Some industry representatives are consequently confused as to whether pressure accessories are within the PED's scope and continue to manufacture according to PED requirements. In addition, some manufacturers

[34] Under the PED, 'Safety accessories' can be defined as devices to protect pressure equipment against pressure limits being exceeded and 'Pressure accessories' as devices with an operational function and having pressure-bearing housings.

consider that to bring consistency to the industry, the wording should be amended in order to fully cover pressure accessories.

With regard to the **ATEX Directive**, product definitions within scope were viewed as being generally clear and working well. However, the definition of components for explosives protection in the harmonised standard was found to differ to some extent from the definition provided in the Directive. National competent authorities interviewed did not believe however that this difference causes any particular difficulties.

Some ATEX components defined in the Directive are defined as equipment by the standard such as Ex blanking elements. However, there is arguably a good reason to do so. A component (as defined in the Directive) has to pass a conformity procedure together with the complete equipment again if it is to be used. But for some "components" the rules for their use are clear so that they can be assessed as equipment, although they do not have their own ignition source. It was recognised however by a member of the Ex Notified Body Group on ATEX that a general, clear definition is not easy to produce. This is rather a technical decision relating to explosion protection to handle some components as Ex equipment.

A further issue for the ATEX Directive is when components are incorrectly marked as equipment. Components have to be marked with the symbol "U" and to specify the certificate number. Equipment with special information for safe installation and use has to be marked with the symbol "X" following the certificate number. If a component has special conditions then these components will be marked with the symbol "U" only. But there are some components available on the market, which are marked with the symbol "X". However, this problem should be addressed by the market surveillance authorities (ADCO).

As far as feedback from industry is concerned, their assessment was that the definitions provided in IM legislation work reasonably well but are not always clear. One of the national product contact points commented that “sometimes the definitions are unclear and time needs to be spent discussing the meaning. An example is instruments used to measure electricity consumption because of fx suncells that provide electricity back to the grid”. It is unclear whether these fall within the scope of the **MID**.

Although the focus of regulatory compliance is on the end product placed on the market, economic operators involved in the upstream value chain are only affected indirectly. One major pan-European company producing components noted that “there is a general understanding among components and spare parts manufacturers that they must help the client to meet regulatory requirements relating to end-user products, even if it is not explicitly mentioned in IM legislation that they are covered”. Among the potential problems associated with lack of clarity on product definitions and scope are legal uncertainty among economic operators as to how to deal with these product areas and divergent practices between economic operators as to whether they consider components and spare parts as falling within the scope of IM legislation. Some may choose to ensure that they are fully compliant, whereas others may not, giving them an unfair competitive advantage.

Approaches will inevitably need to vary across different pieces of IM legislation in line with the nature of the products covered. However, there is a need to set out guiding principles for the definition and inclusion of spare parts and components in the legislation. These should aim at:

- having a safe, compliant end-product (therefore the responsibility is with the final assembler);
- facilitating the supply of components that will ease the production of compliant products (therefore, component manufacturers should be subject to the legislation in some cases);
- ensuring a clear "paper-trail" from producers of components to producers of end-products, so that manufacturers and market surveillance authorities can be sure that the end product is compliant; and
- ensuring that products remain compliant after spare parts have been fitted.

Research Findings (RFs)

- (RF20) It is not always clear whether spare parts and components are covered by the legislation or not.
- (RF21) Where spare parts and components are included, there is a lack of consistency in wording, e.g. inconsistent definitions between spare parts and components.
- (RF22) Guidance from the European Commission is crucial to facilitating understanding of definitions of spare parts and components.
- (RF23) There is a need for the Commission to set out guiding principles for the definition and inclusion of spare parts and components in the legislation, which should be applied as and when individual pieces of legislation are introduced or updated.

Efficiency of the implementation regime 4

4. Efficiency of the implementation regime

In this section, an assessment of efficiency is provided focusing on the implementation regime underpinning the regulatory framework at EU and national levels. The extent to which procedures, mechanisms and structures are effective, and whether they represent an efficient way of achieving the legislation's objectives, was a central feature of the assessment.

4.1 Overall picture

EQ5: What is the overall picture in relation to the efficiency of IM procedures, mechanisms and structures to support its implementation?

A number of procedures, mechanisms and structures have been put in place to support the implementation of Union harmonisation legislation, ranging from conformity assessment bodies that support economic operators by carrying out third party conformity assessment to help them achieve presumption of conformity through to national Accreditation Bodies, which play an important role in ensuring that conformity assessment services are efficient and effective.

Although the majority of stakeholders were positive with regard to the role of Union harmonisation legislation as a mechanism for achieving an internal market in industrial products, they also pointed to a number of areas where there remains scope to improve the efficiency and effectiveness of the regulatory framework and the mechanisms and structures that underpin its implementation.

The responses to our survey of Notified Bodies (NBs) and Accreditation Bodies point to some of the main weaknesses in the implementation system for Union harmonisation legislation (see table 4.1). The majority of NBs (61%) viewed market surveillance as being the weakest point in the implementation of IM legislation while 42% expressed the view that that are also problems with the development of technical standards and in the operation of Notified Bodies (38%). Accreditation Bodies were most concerned about the amount of time that it takes to develop technical standards and the transposition process of EU Directives into national legislation, which may lead to divergent interpretation and application.

Table 4.1: Most common problems indicated in relation to the implementation of IM legislation for industrial products

	Notified Bodies		Accreditation Bodies	
Answer Options	**Per cent**	**No.**	**Per cent**	**No.**
Legal provisions/requirements to place goods on the market	17.0%	16	25%	3
Development of technical standards	41.5%	39	33.3%	4
Transposition of EU Directives to national legislation	25.5%	24	41.7%	5
Conformity assessment procedures	16.0%	15	0.0%	0
Market surveillance activities	60.6%	57	33.3%	4
Operation of Notified Bodies	38.3%	36	16.7%	2

Answered the question		**94**		**12**
No answer provided		**34**		**8**

In the following section, we examine some of the above aspects in more detail on the basis of input from the interviews, the surveys and additional desk research. A more detailed assessment of regulatory and non-regulatory barriers is provided in Section 6 (effectiveness).

Research Findings (RFs)

- (RF24) Market surveillance is considered the weakest part of the implementation regime for IM legislation, followed by the development of technical standards and the operation of Notified Bodies (Survey of Notified Bodies and Accreditation Bodies).

4.2 Conformity assessment of products

EQ6: How efficient is the conformity assessment process?

Conformity assessment procedures demonstrate that a product, before being placed on the market, conform to the essential requirements of the applicable IM legislation. Conformity assessment can be carried out by public authorities, manufacturers or Notified Bodies. There has been a system of conformity assessment since 1993. The modules for the conformity assessment procedures to be used in Union harmonisation legislation were initially set out in Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives.

The conformity assessment modules have subsequently been updated as part of the NLF through Regulation 768/2008. The recitals to the Regulation state that "It is necessary to offer a choice of clear, transparent and coherent conformity assessment procedures, restricting the possible variants. This Decision provides for a menu of modules, enabling the legislator to choose a procedure from the least to the most stringent, in proportion to the level of risk involved and the level of safety required". The conformity assessment procedure required therefore varies depending on the product in question, and across different IM directives and regulations.

Regulation 768/2008 states in the recitals that "The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the complete conformity assessment procedure. Conformity assessment should therefore remain the obligation of the manufacturer alone". Feedback from economic operators during the interview programme confirmed that although Notified Bodies play an invaluable role within the regulatory implementation system, manufacturers are well placed to carry out their own conformity assessment, provided that self-certification is backed up by rigorous market surveillance in order to ensure that the system is not abused by rogue operators.

One of the advantages of the NLF is that it has clarified the different responsibilities and obligations of economic operators. Although it remains the case that the manufacturer is responsible for carrying out the appropriate conformity assessment procedure, importers are also responsible for playing their part by ensuring that the appropriate conformity assessment

procedure has been carried out by the manufacturer, and that the technical documentation has been drawn up, that the product bears the required conformity marking or markings and is accompanied by the required documents.

The current conformity assessment system has various advantages. It provides for a suite of different modules for EU legislators for individual IM regulations. Once the legislation has been drawn up and the relevant modules selected, then the overall system of conformity assessment and the different conformity assessment procedures involved are well known by economic operators, Notified Bodies and market surveillance authorities since they have been in operation since 1993.

Many IM regulations allow economic operators to adopt Module A, self-certification, which allows manufacturers the flexibility either to carry out conformity assessment themselves or to have an independent third party Notified Body do so. Among the feedback received though the interview programme was that flexibility for economic operators in determining which conformity assessment procedure to follow was appreciated by industry and SMEs.

Among the interview feedback was the suggestion that manufacturers that are highly familiar with carrying out conformity assessment procedures under different modules should be allowed to do so using a self-declaration. “When manufactures produce only one type of product they are less familiar with general conformity assessment processes. However, if manufactures are used to performing conformity assessment procedures for other product categories that fall under more demanding modules, they should also be allowed to do using a self-declaration because they know the processes and how to test products sufficiently”.

It is not clear how such a system would work in practice, given the difficulty in checking the competence of individual economic operators. A stakeholder working with SMEs in Belgium pointed out that “while self-certification is often possible, a lot of economic operators do not know or do not have the means to deal with internal production control or performing the necessary checks”.

The survey responses indicated that there was a generally positive view with regard to the role of different conformity assessment procedures as an implementation mechanism to ensure products’ compliance with regulatory requirements and for manufacturers to achieve presumption of conformity. Only 15% of Notified Bodies indicated that there were any problems with the procedures, while none of the Accreditation Bodies surveyed considered CA procedures to be problematic.

Among the eight manufacturers that responded to the survey, none suggested that conformity procedures pose an obstacle to the function of the internal market. Similarly, there was a positive assessment of conformity assessment procedures through the discussions across a broad range of stakeholders in the area of industrial products and interviews with individual manufacturers. Broad satisfaction with the current suite of conformity assessment modules was also confirmed through the surveys of notified and Accreditation Bodies.

In terms of the appropriateness of the different modules, most industry stakeholders stated that they fit well into existing manufacturing processes and allow firms the necessary flexibility. There were only limited examples where the modules were not considered to be fit for purpose. For instance, it was suggested that for personal protective equipment, Module H is too generic and not appropriate.

There were concerns however about the challenges in ensuring a uniformly high level of quality of services across Notified Bodies throughout the EU in carrying out conformity assessment procedures.

In order to ensure a **consistent level in the quality of the performance of conformity assessment across the Union**, it is necessary to strengthen the requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of Notified Bodies must fulfil and crucially to ensure that Member States apply these requirements on a uniform basis. One of the problems identified through the research was variations in the quality of third party conformity assessment services being provided, which risks undermining the internal market, for instance, where economic operators having already had their products tested by third parties are required to do so again in another Member State because of a perceived lack of confidence in the Notified Bodies carrying out conformity assessment procedures in another Member State.

Research Findings (RFs)

- (RF25) Roles are clear, i.e. manufacturer carries out conformity assessment and importers check that the technical document relating to conformity assessment is supplied and the CE marking applied.
- (RF26) Manufacturers appreciate the choice of modules relating to conformity assessment (Survey of NBs and ABs; Stakeholder interviews; Case studies)
- (RF27) Self-certification by economic operators should not be allowed under all Modules (except Module A); it would be too hard to check the competence of operators. (Survey of NBs and ABs; Stakeholder interviews; Case studies)
- (RF28) Some operators are unsure which Modules apply to their products and whether third party conformity assessment is required. (Survey of NBs and ABs; Stakeholder interviews; Case studies)
- (RF29) There are concerns about a lack of uniformity in quality of conformity assessments undertaken across EU28. In some instances, economic operators have had to re-submit their products for testing because of a lack of confidence in conformity assessments undertaken in other countries. (Survey of NBs and ABs; Stakeholder interviews; Case studies)
- (RF30) There may be merit in strengthening the requirements on Member States relating to notification of Notified Bodies and take steps to ensure consistent fulfilment of these requirements across EU28.

4.3 Notified Bodies

4.3.1 Performance of Notified Bodies

EQ7: How well do Notified Bodies serve the conformity assessment process?

Notified Bodies play an important role in the implementation of the IM legislation, particularly for legislation where third party conformity assessment is mandatory. According

to the NANDO database[35], there are a total of 1826 Notified Bodies (although the review of the database indicates some duplicate records). It is also unclear whether all bodies in the list are operating since the information in NANDO is updated on the basis of information provided by Member States.

On the basis of the information available, Notified Bodies' distribution across Europe mostly reflects the distribution of the population, although there are some exceptions to this broad trend. For example, the UK has more than twice as many NBs as France, despite being of a similar size. Similarly, the Netherlands has many more NBs than Romania, despite being somewhat smaller.

[35] Nando (New Approach Notified and Designated Organisations) Information system, http://ec.europa.eu/enterprise/newapproach/nando/index.cfm

Table 4.2: Number of Notified Bodies by country

Country	Number	Country	Number
Austria	58	Italy	218
Belgium	50	Latvia	24
Bulgaria	41	Lithuania	21
Croatia	n.d.	Luxembourg	7
Cyprus	3	Malta	n.d.
Czech Republic	38	Netherlands	68
Denmark	36	Poland	81
Estonia	11	Portugal	34
Finland	28	Romania	37
France	102	Slovakia	33
Germany	336	Slovenia	18
Greece	35	Spain	106
Hungary	31	Sweden	45
Ireland	4	United Kingdom	230
Norway	21	Japan	2
Iceland	4	Liechtenstein	1
Switzerland	47	Turkey	29
Canada	1	United States	26
Grand Total			**1826**

In terms of the distribution of Notified Bodies by the area of legislation covered, key Directives (Machinery, Lifts, Low voltage, EMC) are covered by more than 100 NBs while there is a particularly high number of Notified Bodies that cover the NAWI Directive.

Table 4.3: Number of Notified Bodies by Directive

Directive	Number	Directive	Number
Active implantable medical devices	20	Medical devices	77
ATEX	64	Noise emissions for outdoor	70
Cableway installations	23	Non-automatic weighing systems	255
EMC	171	Personal protective equipment	114
Explosives	13	Pressure equipment	36
In vitro diagnostic medical devices	26	Pyrotechnic articles	13
Lifts	161	Recreational crafts	34
Low voltage	165	R&TTE	75
Machinery	164	Simple pressure vessels	96
Marine equipment	38	Toys safety	49
Measuring instruments	145	Transportable pressure equipment	127

Source: NANDO Database

Efficiency of the implementation regime 4

On the basis of the responses to the NBs survey, Notified Bodies are mainly private entities (62.5% of total) or public organisations (government-controlled) (37% of total). There also few that are non-for-profit organisation controlled by associations or jointly controlled by government and the private sector. The majority of NBs serve primarily firms in their country (67% indicate that national market represent more than 50% of the their turnover from conformity assessment services) but there are also few NBs with a clear international character (9% indicated that firms in other EU countries represent more than 50% of the turnover and 5.6% referred to a similar share of turnover for firms in non-EU countries).

In terms of size, the majority of Notified Bodies (54.5%) indicated that they occupy no more than 10 Full time equivalent (FTE) in conformity assessment services and only 13% occupy more than 50 FTE. However, this is not necessarily a reflection of their size. More than 66% indicated that, besides conformity assessment services, they also provide other services to firms.

As regards the role of Notified Bodies, the main issue raised by a number of stakeholders (industry as well as national authorities) is the inconsistency in conformity assessment procedures. A number of stakeholders interviewed stated that this was a significant problem pointing to varying technical capacity and experiences among Notified Bodies, inconsistent interpretation and application of guidelines and requirements. For a number of national authorities the business orientation of many NBs means that they are prepared to be rather flexible in order to gain or maintain clients.

The survey of NBs also supports this view. Some 37% of Notified Bodies suggested that the application of conformity assessment procedures is very or somewhat inconsistent, while 25% that they are quite or very consistent. Similarly balanced is the view of Accreditation Bodies (see Table 4.4). Detailed comments provided by survey respondents pointed to differences in understanding, interpreting and implementing requirements and also varying levels of strictness in terms of adhering to the requirements. At the same time, industry stakeholders interviewed suggested that there are also differences in the approach adopted concerning the use of test results from other laboratories – including those carried out by manufacturers directly.

Table 4.4: How consistent is the application of conformity assessment procedures among Notified Bodies across the EU?

	Notified Bodies		Accreditation Bodies	
Answer Options	**Per cent**	**No.**	**Per cent**	**No.**
Do not know	12.8%	15	10%	2
Very inconsistent	10.3%	12	0.0%	0
Somewhat inconsistent	26.5%	31	20.0%	4
Neither consistent nor inconsistent	25.6%	30	40.0%	8
Quite consistent	23.1%	27	30.0%	6
Very consistent	1.7%	2	0.0%	0
Answered		**117**		**20**
No answer provided		**11**		**0**

Source: CSES survey

According to the survey responses the main reasons for the inconsistent application of

conformity assessment procedures appear to be the differences in the technical capacity of Notified Bodies (58% of respondents) and the variations in the transposition of IM legislation with different national implementation rules adopted between Member States (59%). Among Accreditation Bodies, 79% referred to differences between Member States, 32% to differences in the technical capacity of NBs but also to unclear provisions in EU legislation (58%).

As indicated by some national authorities, the weak technical capacity is a reflection of the large number of NBs at least in some countries, where there are a large number of Notified Bodies for a specific Directive. This leads to a limited level of business activity in carrying out conformity assessment for each NB and this may mean some NBs lack sufficient practical experience. However, according to the input from a few stakeholders in the sector, there is a consolidation process of the conformity assessment market – not only at the EU level but worldwide. There are few large NBs with subsidiaries inside and outside Europe that bring along the necessary technical capacity in most areas. Smaller size NBs are only expected to survive if they focus on niche markets, especially private ones. This is seen as an issue of concern for some authorities, to the extent that it means the firms in smaller markets may not have easy access to Notified Bodies and need to incur additional costs.

A considerable number of stakeholders argued that further cooperation amongst Notified Bodies at European level was what is mainly needed to guarantee a consistent interpretation of issues around implementing rules. In that respect the role of **Notified Bodies Groups** – presently operating in relation to only some Directives[36] – is seen as particularly relevant. The possibility of making participation in these groups mandatory was supported by a few stakeholders. Among the NBs that responded to the CSES survey, around 65% indicated that they consider NBGs are quite or extremely helpful in ensuring a greater level of consistency in the application of conformity assessment procedures.

For example, the Chairman of the NBG for the ATEX Directive reported that the role of the NBG had extended beyond coordination aspects to include discussions on technical problems relating to how to apply the Directive, conformity assessment procedures and the interpretation of standards. *"Through the ExNB-Group, any technical questions can be drawn to the attention of the ATEX standing committee which is the official partner from the EC side"*. The NBG is also able to publish clarification sheets providing guidance on the ATEX Directive, although these do not have legal weight. There are notified procedures for informing the standing committee about these sheets, some are annotated by the Commission and they are subsequently made available for the public. They provide interpretative guidance, such as how to use standards and as such are useful for manufacturers and users. However, it should also be noted that some NBGs suffer from low levels of participation. Furthermore, there are certain participation costs for the NBs (membership fees, possible travelling for meeting).

Most NBGs include a small secretariat working part-time to provide information on issues of relevance, the support necessary for an electronic information exchange system, meetings and possibly working groups to examine relevant issues and produce "Technical sheets for

[36] ATEX, Explosives, Medical devices, Machinery, Lifts, Pressure equipment, Personal protective equipment, Recreational crafts, R&TTE, Outdoor noise

coordination" that report the common position of the Notified Bodies[37].

The cost of their operation does vary, depending on the level of sophistication and may range from a few thousand Euros per annum to more than a €100,000. Annual fees for participation in the rather well developed Medical Devices Directive NBG are in the range of €2,300-4,500, to which there are additional costs for the most active members for travelling for meetings etc. Thus, while there are strong arguments in favour of some form of mandatory participation of NBs in broader coordination groups – such as the NBGs - there are also possible cost implications that need to be taken into consideration.

Research Findings (RFs)

- (RF31) Most providers of conformity assessment services do not operate at scale; most have few staff dedicated to conformity assessment. (Survey of NBs and ABs; Stakeholder interviews; Case studies)
- (RF32) Very few NBs operate transnationally at scale. (Survey of NBs and ABs; Stakeholder interviews; Case studies)
- (RF33) Many NBs deliver only a limited volume of conformity assessment services and therefore risk lacking technical capacity. (Survey of NBs and ABs; Stakeholder interviews; Case studies)
- (RF34) There has been a process of consolidation amongst Notified Bodies. (Survey of NBs and ABs; Stakeholder interviews; Case studies)
- (RF35) NBGs can be effective in ensuring greater consistency in conformity assessments, notably through facilitating discussions and issuing guidance on technical questions. (Survey of NBs; Interviews of NBs)
- (RF36) There is a need for measures to improve the low levels of participation in some NBGs, which is often linked to cost. These might include mandatory payment of membership fees or EU funding for their operations.

4.3.2 Regulation of Notified Bodies

EQ8: Are conformity assessment bodies sufficiently regulated or are more stringent rules needed?

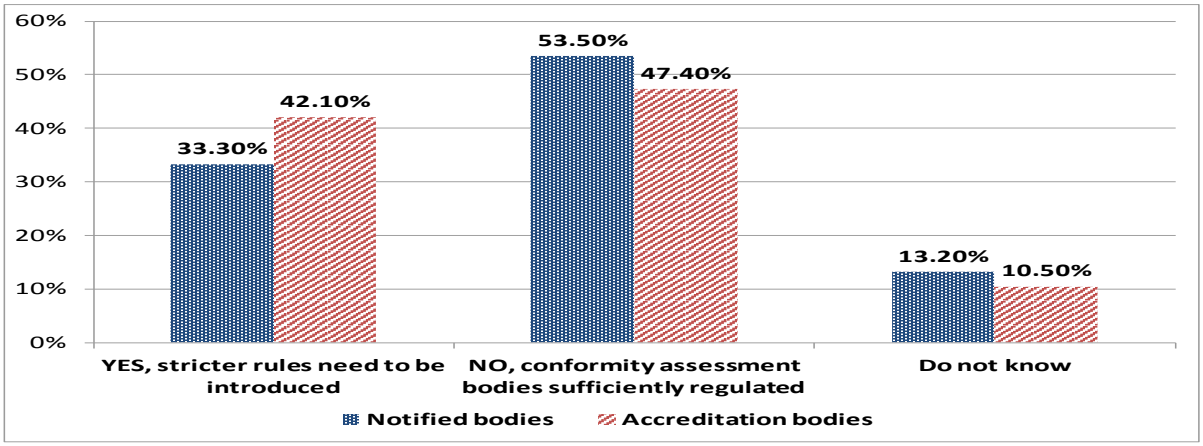
While there are concerns raised on the consistency of Notified Bodies, there are diverging views on the extent that the introduction of a more stringent regulatory framework for NBs is appropriate. Some stakeholder consider that stricter rules – including mandatory accreditation – are necessary and other consider that current rules are appropriate but that Member States are often not consistent in enforcing them. It is also considered that in many cases the problem is the absence of expertise and facilities among some national authorities.

Among survey respondents, most Notified Bodies were against the adoption of more stringent rules (53.5% consider that NBs are sufficiently regulated while 33% were in favour of more stringent rules) while the responses of Accreditation Bodies provided a more balanced picture (47% against in comparison to 42% in favour). The fact that there have not

[37] See example of NB for Personal protective equipment: http://ec.europa.eu/enterprise/sectors/mechanical/documents/legislation/personal-protective-equipment/notified-bodies/index_en.htm

been any major or recurrent problems relating to product safety in Europe was provided by some Notified Bodies as an indication that there is no need to impose more stringent rules on Notified Bodies' operations. For other respondents, the New Legislative Framework – in particular, Decision 768/2008/EC – has had a positive impact by making conformity assessment requirements clearer.

Figure 4.1 - Is it necessary in your view to introduce more stringent rules concerning the operation of Notified Bodies?



Source: CSES survey

Research Findings (RFs)

- (RF37) It is uncertain that more stringent regulation of NBs will improve the quality and reliability of conformity assessment services. A greater priority is to increase the expertise and resources available to national authorities responsible for the notification process.

4.3.3 Conformity assessment by different bodies

EQ9: Is it appropriate to allow different elements of a conformity assessment to be performed by different bodies?

There was limited feedback on the question of allowing different elements of conformity to be performed by different bodies. On the one hand, there are concerns about the capacity to control the quality of those bodies while, on the other, use of multiple bodies provides access to the technical capacity and experience with multiple pieces of IM legislation that may not be available within a single body.

Among the Notified Bodies that responded to the CSES survey, 43.9% were against and 37% in favour. Similarly, among Accreditation Bodies, 42% were against while 37% were in favour. Among national authorities, the main concerns raised in relation to the possibility to subcontract different parts of the conformity assessment process is that there are greater difficulties in assessing the capacity and competence of these bodies, particularly when they are located outside the EU. Ensuring the quality of NBs located outside the EU is already a challenge and existing subcontracting practices make this even more problematic, particularly in relation to products where third-party certification is mandatory.

On the other hand, the discussion with industry stakeholders indicates that the flexibility provided is appreciated and possible necessary in the case of products covered by multiple pieces of legislation, particularly covering very different technical areas. It is unlikely that a single Notified Body – particularly a small one – will have the necessary technical capacity. At least one Notified Body from Lithuania seemed to challenge this view suggesting that, while integrated products may theoretically require different Notified Bodies to be involved in assessing compliance with different IM regulations, in practice most NBs are used to testing products for multiple pieces of applicable legislation. It has not been possible to assess what is the current practice but it logical to expect that not all bodies will have the necessary facilities and expertise, particularly the smaller ones. Allowing manufacturers to use multiple bodies or Notified Bodies to subcontract the work to third parties can be seen as important for maintain many NBs in the market and ensuring high level of competition in the market.

A Notified Body interviewed in Lithuania stressed that although integrated products are becoming more common, which theoretically may require different Notified Bodies to be involved in assessing compliance with different IM regulations, in practice, NBs are used to testing products for multiple applicable legislation.

In conclusion, the analysis identified mixed views on this issue and no clear consensus. However, while the use of multiple bodies may pose certain challenges, ensuring the quality of all bodies involved in conformity assessment – including those in third countries – remains to be the key issue. If this is properly addressed, the use of multiple CA bodies should be seen as providing the necessary flexibility and helping to promote competition and supplier diversity in the NB market.

The discussions with industry stakeholders and authorities indicate that while the flexibility provided is appreciated, the main concern with subcontracting different parts of the conformity assessment process is that there are greater difficulties in assessing the competence of these bodies. On balance, the need to ensure quality of conformity assessments would tend to outweigh the benefits of flexibility. The broad trend towards consolidation of NBs would appear to be creating better capacity within individual NBs to carry out all elements of the conformity assessment process.

Research Findings (RFs)

- (RF38) Allowing different elements of CAP to be performed by different bodies can enable the necessary technical capacity to be made available. However, this creates difficulties in assessing the capacity and competence of sub-contracted NBs. On balance, the need to ensure quality of conformity assessments would tend to outweigh the benefits of flexibility in allowing different elements of a conformity assessment to be performed by different bodies. (Survey of NBs and ABs, stakeholder views)

4.3.4 Conformity assessment by different bodies

EQ10: What are the challenges for national competent authorities in monitoring the activities of Notified Bodies located outside the EU? How far is it appropriate – if at all – to open up Europe's conformity assessment market to third countries?

An issue raised by national competent authorities (responsible for appointing Notified

Bodies) was the difficulty in assessing the capacity of NBs in carrying out conformity assessment services located outside the EU, including the subsidiaries of foreign-owned NBs located in the EU. Here, the main concern was whether such NBs are sufficiently well regulated to ensure a common level of quality and consistency in testing necessary to ensure confidence in third party conformity assessment within the EU. The concern was that there are currently problems in assessing their performance.

This concern was shared by representatives of manufacturers that were interviewed. Many of these made particular reference to bodies providing conformity assessment services in third countries where, as claimed, the capacity of national authorities to control their quality is limited. It was claimed that branches of European Notified Bodies that operate in third countries are often less strict in assessing that the requirements and the procedures under the different modules are followed. The Chairman of the ExNBG commented that "in theory, there are no differences between NBs in terms of the quality of conformity assessment services that are being provided, but in practice there are quite differing levels of knowledge and experience". Given these difficulties, it does not seem appropriate to open up Europe's conformity assessment market to third countries until the performance of NBs in those countries can be assured.

Research Findings (RFs)

- (RF39) There has been particular concern over the quality of conformity assessments undertaken by Notified Bodies in third countries. (Survey of NBs and ABs; Stakeholder interviews; Case studies).
- (RF40) It does not seem appropriate to open up Europe's conformity assessment market to third countries until the performance of NBs in those countries can be assured. (Survey of NBs and ABs; Stakeholder interviews; Case studies).

4.3.5 Necessity of third party conformity assessment

EQ11: Should third-party conformity assessment be required for all industrial products?

A further proposal made by some stakeholders is the introduction of mandatory third-party certification. Currently the involvement of a Notified Body is only mandatory in the case of certain Directives while in others it is only required for certain categories of products defined in the Directives (see table below).

However, in relation to the total volume of products third party certification under Modules B-H is mandatory for only a small share of products placed in the market overall, since this mainly applies to higher risk products, which tend to be produced in lower quantity. One estimate provided by an interviewee suggested that no more than 5% of the total volume of products are subject to mandatory third party conformity assessment.

Table 4.5: IM Directives depending on requirement for third party certification by a Notified Body

Mandatory	Mandatory for certain	Not mandatory

	products	
Active implantable medical devices Gas appliances Cableway installations Explosives Pyrotechnic articles Lifts Noise emissions in the environment	Ecodesign Simple pressure vessels ATEX Hot water boilers In-vitro diagnostic Measuring Instruments Medical Devices Personal protective equipment Pressure equipment R&TTE	EMC Low voltage NAWI Recreational crafts Machinery[38]

The Supplier's Declaration of Conformity (SDoC) route for conformity assessment is allowed under many IM directives and regulations. From the point of view of manufacturers, this was appreciated since it gives them the necessary flexibility as to whether to carry out the applicable conformity assessment modules using in-house testing alone, a combination of in-house testing and external conformity assessment or solely third party conformity assessment. The findings from the case study research showed that different approaches are adopted by manufacturers. Some firms may choose to meet conformity assessment mainly based on SDoC but choose to outsource testing with harmonised standards for particular directives (especially the LVD since the safety of the consumer / end-user is at stake), even where non-mandatory. This was viewed as providing them with added reassurance and in helping to manage reputational risk

Among stakeholders interviewed, there was broad support for continuing to make third party certification mandatory in the case of high-risk products. The use of third party certification is in principle based on a risk-based approach. However, there was an absence of a clear justification for the use of third party certification requirements based on the level of risk alone in all cases. Generally speaking, under the Machinery Directive (MD), the SDoC can be used for almost all types of mechanical and electrical engineering products. Since 2010, it has also been possible to use the SDoC procedure under the MD – at least if harmonised technical standards are applied – for the higher-risk categories of products set out in Annex IV of the Machinery Directive. Conversely, third party CA is required for all products covered by the Outdoor Noise Directive. Hence, according to some stakeholders, the mandatory third party certification regime does not appear to always be based on the level of safety risk of products.

[38] Under the Machinery Directive, the SDoC procedure generally applies. Although the categories of machinery listed under Annex IV were previously required to carry out 3rd party conformity assessment, since 2010, this has only been mandatory if the manufacturer does not follow the harmonised standard.

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In the case study research, many firms indicated that, at least for the Machinery Directive, even where a requirement for mandatory third party conformity assessment has been removed (as was the case for the categories of machinery in Annex IV that formerly required mandatory 3rd party CA), this did not necessarily lead to a sudden reduction in demand for third party conformity assessment 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.

Among stakeholders there are only few – mainly national authorities - that support the view that a mandatory third party certification for all products would be appropriate and helpful in improving the effectiveness of the internal market. Most industry representatives were however not in favour of extending mandatory third party CA beyond the current situation, since the SDoC has helped to improve safety standards for products. Among the feedback received was that any such development would create additional costs for industry and would also potentially lead to delays in time-to-market.

Even among Notified Bodies – which one would probably expect to favour such a development – less than half (46%) of survey respondents were in favour of introducing a mandatory third party conformity assessment for all categories of products and 41% were against. Among Accreditation Bodies, 32% were in favour. Those in favour suggest that self-certification under Module A does not provide a sufficient guarantee that the minimum essential requirements have been met even though there is recognition that such a requirement will create additional costs for industry. At the same time they suggest that self-regulation allows non-compliant products to enter the market and leads to unfair competition.

Among those not against any change in the current requirements, many claimed that the introduction of mandatory third party certification should be assessed on a product by product basis on the basis of some type of risk-assessment. For example, in the case of the Low Voltage Directive, certain products that are not covered could be considered as posing significant risks and third party certification was seen as being justified.

In terms of the costs implications of the mandatory use of third parties, the data collected indicates that the average cost of conformity assessment – excluding testing costs that would have to take place even in the absence of third party certification – is in the range of €30-50k/firm/annum or €3-4k on a per product basis. According to the data from the case studies, the fees to third parties do not represent more than 5% of the total compliance costs incurred by firms. Furthermore, as indicated, even when not mandatory, it is common among firms to outsource parts of the conformity assessment to third parties either because of limited resources – particularly among SMEs – or simply as a result of their own risk-averse approach. Concluding, third party certification should be expected to introduce a small but not insignificant administrative cost for a wide range of sectors. As indicated by some industry stakeholders, it is not the fees that represent the main concern but the possible delays and the negative effects in terms of time-to-market.

Research Findings (RFs)

- (RF41) Many manufacturers voluntarily submit their products third party conformity assessments, either because they value the credibility offered by independent assessment or because they lack the resources or expertise to undertake it in house. (Stakeholder

interviews)
- (RF42) There is a strong case for high-risk products to require third party conformity assessment. Other products should be considered on a case-by-case basis, given that manufacturers value the opportunity to choose between SDoC or third-party conformity assessments. (Stakeholder interviews; Survey of NBs and Accreditation Bodies)
- (RF43) There is a need to clarity the principles and circumstances under which third party conformity assessments is required or not, e.g. via guidance from the European Commission.

4.4 Accreditation

4.4.1 Benefits of accreditation

EQ12: What are the benefits of accreditation for enhancing the single market for products (and services) and how could it best be used to support single market initiatives?

Regulation 765/2008[39] introduced a common legal basis for accreditation from January 2010. There are currently 33 Accreditation Bodies, covering all Members of the EEA, Switzerland and Turkey. Thus, while not mandatory to establish an Accreditation Body, all countries have selected to do so.

According to the Regulation, accreditation is voluntary. However, certain countries (e.g. Lithuania, Slovenia, and Luxemburg) accreditation is mandatory while in others (e.g. Germany) accreditation is only necessary in relation to certain categories of products.

The feedback received on the role of accreditation is rather mixed. In general, industry and national authorities were positive about its role in ensuring minimum levels of quality in the provision of conformity assessment services by Notified Bodies.

This was also the view of most Accreditation Bodies that responded to the survey (85% said that accreditation has been quite or very helpful towards the operation of the Internal Market). It is argued that accreditation has helped in strengthening confidence in conformity assessment processes and is a useful tool for ensuring greater consistency and improved technical expertise among Notified Bodies across Europe.

The discussions with interviewees found that Regulation 765/2008, which requires each Member States to set up a single national Accreditation Body, has been positive in making progress towards a more uniform approach to accreditation across EU28. In some countries, such as Germany and Italy, this has led to organisational restructuring at national level. This restructuring was viewed positively since national Accreditation Bodies are now formally under the responsibility of Member States authorities, whereas previously there were competing Accreditation Bodies in the private sector, for instance, in Germany, which undermined the objective of promoting quality and consistency in accreditation across the EU.

[39] Regulation 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

The national Accreditation Body in Germany commented that there is a public interest argument for having a robust accreditation system in place underpinned by appropriate procedures and assessment criteria for carrying out accreditation. *"Accreditation is an appropriate tool to demonstrate that conformity assessment bodies are competent to carry out relevant tasks for which they are notified so that businesses and consumers have full confidence in the work of NBs and conformity assessment bodies"*. Their British and French counterparts expressed similar views, but they also emphasised that compulsory accreditation would guarantee high levels of professionalism and expertise among Notified Bodies across Europe.

However, there were also concerns raised by industry and national authorities regarding the consistency of accreditation across the Union, which was viewed as varying greatly. A number of conformity assessment bodies pointed out that there is a need to build on the progress already made through the NLF in strengthening common approaches to accreditation and developing practical tools, guidance documents and criteria for national Accreditation Bodies carrying out the accreditation of Notified Bodies.

The European co-operation for Accreditation (EA) argued that accreditation has a role to play in raising the quality of conformity of services but agreed that there is currently a risk that different national Accreditation Bodies adopt different approaches. In order to address this problem, it is contributing to a process of putting together the main requirements for accreditation and the preferred standards to be used. The basis on which NBs should be accredited should be determined on a more consistent basis at EU level. *"The process of strengthening accreditation will involve Member States' national Accreditation Bodies, the European Commission and NBs"*. There was general support among Accreditation Bodies for EA to take the lead in this area, given that it has a remit to coordinate work on accreditation at European level. It was also pointed out that progress made by the ISO in developing international standards on accreditation should also be taken into account[40].The Notified Bodies that responded to the survey were generally positive about the role that accreditation has played in improving the effectiveness of the Internal Market: 45% were highly positive assessment ("very" or "quite"), whilst 46% were fairly positive ("moderately" or "somewhat"). Accreditation was seen as having made a positive contribution to enhancing the quality and consistency of conformity assessment services. It was also pointed out that a number of Notified Bodies have ceased their operations since the introduction of accreditation in a number of Member States, an indication of their low quality and how accreditation can serve as a mechanism for helping to raise standards. However, more Notified Bodies focused on the differences of approaches followed among different Accreditation Bodies both in relation to the processes for carrying out accreditation and the assessment criteria that are applied. Furthermore, many Notified Bodies suggested varying levels of expertise and technical capacity of Accreditation Bodies to carry out their accreditation role. Additional problems of the accreditation mentioned included:

- Lengthy accreditation process: in some countries it can sometimes take close to two

[40] See for example ISO/IEC 17011:2004 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies and ISO/IEC 17025:2005 "general requirements for the competence of testing and calibration laboratories".

years.
- Doubts concerning the appropriateness of harmonised standards (EN17020, EN17021, EN17025) used for accreditation that have not been designed for the type of tasks that Notified Bodies perform.

Table 4.6: Has the accreditation of Notified Bodies contributed to the effectiveness of the internal market for industrial products?

	Notified Bodies		Accreditation Bodies	
Answer Options	**%**	**No.**	**%**	**No.**
Not at all	17.4%	16	0.0%	0
Somewhat	21.8%	20	5.0%	1
Moderately	23.9%	22	0.0%	0
Quite	23.9%	22	40.0%	8
Very much	20.8%	12	45.0%	9
Total		**92**		**18**
skipped question / don't know		**36**		**2**

Source: CSES survey

Research Findings (RFs)

- (RF44) Stakeholders confirm the benefits of accreditation: i) strengthening confidence in conformity assessment and ensuring consistency of conformity assessments; ii) improving technical expertise and professionalism among NBs; iii) promoting consolidation of NBs; iv) driving out poor quality NBs; (Stakeholder interviews; Survey of NBs; Your Voice consultation)
- (RF45) Concerns relate to the consistency of accreditation across EU28. There is a need for the basis for accreditation to be specified more explicitly at EU level, in order to limit national variations and inconsistencies. (Stakeholder views; Survey of NBs; Your Voice consultation)

4.4.2 Compulsory accreditation

EQ13: Should accreditation be made compulsory for the purposes of demonstrating the technical capacity of conformity assessment bodies in the regulated sector?

Despite mixed views on the accreditation procedure and its effectiveness, there appears to be significant support towards mandatory accreditation across the EU. Among Accreditation Bodies almost all were in favour while, even among Notified Bodies, more than 68% of survey respondents agreed that the accreditation of NBs should become compulsory. Accreditation is seen as a positive step for ensuring minimum levels of quality and consistency by most Member State authorities. It is considered necessary in order to strengthen the quality and technical capacity of conformity assessment services of NBs. Furthermore, it can lead to a consolidation process with larger NBs better placed to respond to conformity assessment requirements for products that are becoming increasingly integrated. Rather high support was indicated according to the Your Voice consultation

(51/96), primarily among industry representatives (43/73) and less so among public authorities (4/15).

There is still scepticism among a range of stakeholders referring to possible adverse impacts from compulsory accreditation, particularly in smaller Member States in Central and Eastern Europe. There are fears that there may be reduced number of NBs and less competition if a consolidation process takes place. Mandatory accreditation will also lead to costs for Notified Bodies but also delays. The accreditation processes can be expensive and time consuming and a few examples provided indicate that in some cases the whole process may exceed 2 years. Such delays in the context of mandatory accreditation could create problems in the operation of Notified Bodies while the additional costs incurred may lead to the closure of smaller NBs and/or pass through to firms. It should be noted though that no such impacts were reported from national authorities where accreditation has been mandatory even before Regulation 765/2008.

An alternative approach proposed by one Accreditation Body was the possibility to make accreditation mandatory only for Notified Bodies wishing to be notified for certain Directives or product areas. This is based on the example of Germany where it is mandatory for NBs to be accredited by the national Accreditation Body (DAKKS) in order to be notified for certain product areas such as construction. A risk based approach focusing on the high risk product could be used to assess for which products areas and Directive accreditation should be mandatory.

Another alternative approach was proposed by the UK's National Measurement Office on the basis of the 'peer-approval' scheme in place in the UK, whereby organisations such as local authorities can be approved as NBs without accreditation, but using a similar process. The costs of peer assessments being lower than those of accreditation, this approach allows organisations that have been performing product verifications for a relatively long time to stay in business without lessening the standards.

Whilst the accreditation process requires improvement, there would be appear to be a difference between perception and experience; the experience in EU15 suggests that compulsory accreditation is not particularly problematic, whereas in EU12 the fears expressed might not necessarily be based on experience. There is clearly a learning process that the relevant bodies in Member States must follow. On that basis, it would seem appropriate to make accreditation compulsory, over a reasonable timescale with appropriate guidance and discussion at EU level, e.g. to limit the duration and cost of the accreditation process, encourage co-operation and mutual learning between Accreditation Bodies. Whilst alternatives to accreditation do exist, these do not appear to be simpler than wholesale compulsory accreditation and would not address the underlying problems.

Research Findings (RFs)

- (RF46) The accreditation process can be costly and lengthy, e.g. taking up to two years. ABs may lack expertise and may vary too much in their approach to accreditation. There are also doubts concerning the appropriateness of harmonised standards used for accreditation. However, these difficulties can often be overcome, provided that ABs learn over time. (Stakeholder interviews)
- (RF47) It would seem appropriate to make accreditation compulsory, over a reasonable

timescale with appropriate guidance and discussion at EU level. (Stakeholder interviews; Survey of NBs and ABs; Your Voice consultation)

4.5 Declaration of Conformity

EQ14: Is the current regime for the Declaration of Conformity satisfactory?

Declarations of conformity (DoCs) are a key element of the New Approach Directives. They constitute a statement by the manufacturer that the requirements of all legislation applicable to a product have been fulfilled. The intention of the NLF is that a single DoC shall be drawn up containing all information required for the identification of EU legislation to which the declaration relates and giving the publication references of the acts concerned. Once the product has been placed on the market, manufacturers and importers (or their authorised representatives) should keep the DoC for a period of time specified by the relative legislation, typically reflecting the lifecycle of the product and the level of risk.

The stakeholder feedback found that the current process of preparing a DoC is broadly appropriate and effective, although there are inconsistencies between IM directives as to the precise administrative requirements. Of those interviewees offering a response, more than half specifically expressed their satisfaction with DoCs and saw no need for any fundamental revision. Such interviewees covered a broad spread of sectors including domestic appliances, electronic equipment, cableways, lifts, gas appliances, pressure equipment and protective clothing. The general tendency of interviewees was to view DoCs as a useful rather than a crucial part of the conformity and compliance process. None of the interviews suggested that the current regime was unsatisfactory.

The most commonly-reported difficulty related to products imported from third countries for which the DoCs were incorrect, fake or non-existent or for which there were doubts on the conformity assessment procedure used. As a result, it was reported that some importers may have unwittingly placed non-compliant products on the market. Much of the problem appears to lie in the relationship between importers and third country manufacturers. Many importers face the practical difficulty of not receiving the DoC, as when the product is supplied to them, particularly when it is not mandatory that the DoC accompanies the products.

Others have faced the problem of a 3rd country supplier completing a DoC but then supplying a non-compliant product; one enterprise mentioned that the only solution for them has been to incorporate any liability into the contract with that supplier. Some stakeholders also reported a lack of clarity over responsibility for the compliance of products imported from third countries. For example, under the New Approach, it is required that that the name of the authorised representative of any third country manufacturer be recorded in the documentation. However, it may be the case that the importer is not specifically contracted to be the representative of the manufacturer, particularly where there are several importers of the same product. Where importers change the trademark and type of the products, they are considered to be the manufacturers and therefore have to establish the DoC; this complicates market surveillance, because there is no way to trace the different trademarks and types corresponding to a same product.

A minority of interviewees reported difficulties with DoCs that tended to reflect a lack of awareness or understanding on the part of economic operators. For example, some

interviewees highlighted the risk that manufacturers issue a DoC without understanding the requirements, the standards that need to be covered, and the need to update the DoC as and when they produce revised versions of any particular product.

One interviewee suggested that this was particularly true of components suppliers, as they may have less awareness of the legislation than the manufacturer of a final product (in this case, fuel dispensers). Whilst the legislation does provide clarity over where responsibilities lie (i.e. with the body that completes the DoC), there are potentially difficulties in long supply chains, for example, where type-approvals are issued by a different manufacturer to the one that does the DoC. It was also reported that there had been inconsistent interpretations of when DoC should be made available for installations, i.e. at the time of installation or upon request from the market surveillance authority. Another difficulty mentioned (by a small number of stakeholders) was the need for greater clarity in the documentation so that the information provides a better identification of the product and its components and the conformity assessment undertaken.

Decision 768/2008/EC provides a model structure for DoCs and stakeholders welcomed efforts through the Alignment Package to standardise the template. They also stressed that flexibility should be retained as to whether to choose to produce a single DoC for all applicable IM legislation or a separate DoC for each piece of legislation. However, Decision 768/2008/EC also proposed that a *"single declaration shall be drawn up in respect of all Community acts applicable to the product containing all information required for the identification of Community harmonisation legislation to which the declaration relates"*.

This was confirmed through the interview programme with industry associations consulted at EU and Member State level in favour of retaining flexibility. There was a divergence of opinion as to whether it is preferable to have a single DoC covering all Directives that relate to a product or a different DoC for each Directive (although few interviewees offered any comment on this question). One in two respondents (24/47) to the Your Voice consultation and a lift manufacturer interviewed as part of the case study stated a clear preference for a single DoC covering all Directives. In contrast, only three respondents to the Your Voice consultation were in favour of a customised DoC for each piece of legislation.

Nevertheless a number of EU and national industry associations were against this suggestion and advocated that each economic operator should be free to choose whether to produce a single or multiple DoCs depending on what best fits with their administrative procedures. What is still generally accepted is that there should be a single template for all DoCs and this is also broadly supported by the responses to the Your Voice Consultation (42/47). A national competent authority suggested that some companies may find it easier to produce several DoCs depending on their procedures for quality assessment.

Another issue that has caused debate is the proposal in the revised LVD Directive which is part of the Alignment Package to require a **colour picture of the product for the DoC**. There is already a requirement for a colour DoC for the Toys Directive. However, this was as viewed by industry associations and individual manufacturers interviewed as adding unnecessary administrative burdens. A colour picture would not show whether the product is safe. A global manufacturer of IT products pointed out that manuals for electrical and ICT products are normally in B&W and this would therefore impose additional costs with no added value.

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Some stakeholders also suggested that the information requirements of the DoC were too onerous, given their purpose. For example, one interviewee mentioned that recent legislation had introduced unnecessary new information requirements, for example, identification numbers on products and a physical address instead of just a website. One market surveillance authority also suggested that it was unnecessary for the DoC to follow the product, since consumers tended to ignore it and market surveillance authority could access the same information from other sources.

With regard to the **cumulative regulatory effects linked to administrative requirements**, there are high levels of administrative burdens associated with the frequency of updating DoCs. This can be a problem for all economic operators, but is an especially significant burden for large firms that manufacture, import and/ or distribute large numbers of products. Although not a legal requirement to list the harmonised technical standards that have been adopted in conjunction with the list of applicable IM regulations on a DoC, many economic operators choose to do so. A large multinational in the ICT sector stated that they have more than 1,000 products and update DoCs once every 3 months for regulatory purposes. The company pointed out that across their product range, there are frequent legislative updates of IM regulations and updates to standards.

Based on the evidence, there does not appear to be a need for any fundamental revisions of the DoCs and none of the stakeholders interviewed suggested the process of completing the DoC itself was particularly onerous. Issues arising tend to relate to non-compliance, whether wilful or inadvertent (e.g. due to a lack of understanding). In many cases, such non-compliance results from a broader failure to comply with the legislation rather than specifically to the DoCs. There might be some scope to simplify requirements relating to the information required to be presented in DoCs and also to the provision of DoCs with products, provided that they are available as necessary (e.g. provided to market surveillance authorities).

To help economic operators, it would be appropriate to allow them the choice as to whether to produce a single DoC covering all relevant Directives or a separate DoC for each Directive. There may also be some practical steps that can be taken, such as improving the provision of information to manufacturers in order to raise their awareness of the requirements of Directives, or findings ways to facilitate the cross-checking that certificates have been officially delivered, e.g. via databases.

Efficiency of the implementation regime 4

Research Findings (RFs)

- (RF48) Despite some minor inconsistencies between different pieces of legislation and irregularities in DoCs for products imported from third countries, the current DoC regime is satisfactory and the model structure for DoCs provided by Decision 768/2008/EC is useful. (Stakeholder consultations; Your Voice Consultation)
- (RF49) The balance of views is in favour of a single DoC covering all pieces of applicable legislation and a minority prefer multiple DoCs or the flexibility for operators to choose. (Stakeholder interviews; Your Voice Consultation)
- (RF50) There does not appear to be any particular benefit in requiring economic operators to supply a colour picture of the product (Stakeholder interviews)
- (RF51) Given the text of Decision 768/2008 and the fact that DoCs are relatively easy to produce, it is recommended that a single DoC be required for each product, covering all applicable pieces of legislation. This should be applied in all updates to the legislation.

4.6 CE marking

EQ15: Is the current regime of CE marking satisfactory? Are there ways to improve the interaction between CE marking and other compulsory and voluntary marking schemes?

The CE marking system has been an integral part of Union harmonisation legislation since 1993. The general principles governing CE marking were updated as part of NLF in Regulation (EC) No 765/2008[41] while Decision 768/2008/EC sets out the rules on the affixing of CE marking to products to be integrated into Community harmonisation legislation. As such, CE marking is a manufacturer's declaration that the product meets the requirements of all applicable IM legislation. CE marking should be the only marking of conformity indicating that a product is in conformity with Community harmonisation legislation. However, for higher risk products, there are also sometimes additional labelling requirements in addition to the CE marking (see below).

The majority of stakeholders indicate that overall the CE marking is appropriate and operates rather effectively even if there are still issues to be resolved. The analysis of the responses to the Your Voice consultation also found that the majority of survey respondents did not perceive there to be any problems in relation to the use of CE marking (33 out of 47) and did not support a change to the overall approach.

There was however, a divergence of opinion on the question of providing additional information together with the CE mark. More than half of respondents indicate that this is not necessary, whilst around one third suggested that additional information should be presented, such as the applicable legislation or the number of the Notified Body in the case of conformity based on a third party conformity assessment module. However, as indicated by one stakeholder in relation to this last point, the inclusion of the Notified Body number is not appropriate since it can undermine the equivalence of self-certification under Module A where no Notified Body is involved with other conformity assessment procedures.

[41] Regulation (EC) No 765/2008 of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products

Efficiency of the implementation regime 4

Among consumers, awareness of CE marking is relatively high, with 66% of respondents to a recent Eurobarometer survey reporting that they were familiar with the logo. This was higher than for four other logos, namely those signifying products detrimental to health if not used properly (64%), recyclable paper products (55%), ecological products (17%) and organically farmed products (16%). Familiarity was generally higher in EU15 than EU12, with respondents in Bulgaria (38%) and Romania (32%) demonstrating least awareness, perhaps reflecting their status as the newest Member States. Familiarity was highest in France and Luxembourg (both 84%), followed by Sweden (79%), as well as in one non-Member State, namely Iceland (81%). More men (70%) were familiar than women (62%). Those aged over 55 years (55%) and those suffering various forms of socio-economic disadvantage were less familiar than the population as a whole. Overall, these findings suggest that, given time, consumers can be made aware of the CE marking and that greater efforts should be made to promote awareness in those countries scoring lowly in the Eurobarometer survey.

Low awareness amongst some groups of consumers was not seen by the stakeholders to be a particular problem, except where consumers wrongly believed that the CE marking was a guarantee of product safety or quality. One hypothetical example offered was that of an oven installed in a new building that might receive the CE marking in line with the Construction legislation; in this instance, the CE marking might lead a user to assume wrongly that the oven has been tested for safety. However, this was not a concern that was broadly shared among stakeholders. Given that it is mainly a declaration of conformity with legislation, many stakeholders consider that it is not particularly important that consumers have a proper understanding of the meaning of the CE marking.

Perhaps more importantly, some stakeholders reported that low awareness amongst manufacturers was a common cause of inappropriate use of CE marking, with some applying the CE mark without knowing what it means. This issue might best be addressed through a combination of enhanced market surveillance to guarantee proper use of the CE marking and maintain confidence as to its role, as well as efforts to promote awareness of the requirements and significance of the CE marking amongst manufacturers, particularly those in third countries. Encouragingly, there was some recognition that the Commission's recent efforts to promote awareness had proved useful. The Commission has, in fact, corrected one misconception regarding the supposed "China Export" mark in response to a question posed by a Member of the European Parliament.[42] This mark was said to take the form of a symbol identical to the CE mark, except that the letters were closer together. In its response, the Commission confirmed that no such mark existed and that the said mark constituted the CE marking as foreseen in the European legislation without respecting the dimensions and proportions prescribed therein. The Commission also highlighted the importance of market surveillance as well as its constant discussion with Chinese authorities to ensure that Chinese exporters respect Community legislation.[43]

Whilst there is broad satisfaction with the current CE marking regime, a number of issues were raised by stakeholders in relation to specific products or directives. First among these were differences in CE marking requirements between IM Directives, with concerns raised about the need to provide a greater level of information on some directives than on others.

[42] Written Question by Zuzana Roithová (PPE‑DE) to the Commission, 27 November 2007.
[43] Answer given by Mr Verheugen on behalf of the Commission, 9 January 2008.

For example, directives such as the MD, LVD, R&TTE and the EMC[44] require the CE marking or the address information to be provided. The Personal Protective Equipment Directive was also mentioned as requiring additional, perhaps unnecessary information.

Inconsistencies in requirements between IM Directives were also mentioned as caused difficulties in specialist areas with specific regulatory arrangements that, until recently, did not require CE marking. For instance, the Medical Devices Directive 93/42/EEC covered the placing on the market and putting into service of Medical Devices but did not require CE marking, since a different regulatory approach applied. However, under the new proposed Medical Devices Regulation (October 2012), CE marking will be required, which can cause particular difficulties in relation to integrated products that include smart functionality.

Table 4.7: Example of inconsistencies between IM Directives in relation to CE marking

Medical devices that incorporate a radio part fall under the Medical Devices Directive (MDD; 93/42/EEC) and the R&TTE Directive (Directive 1999/5/EC). Manufacturers must then determine which Directive should apply for instance in respect of CE marking. Under the R&TTE Directive, products must carry a CE marking whereas under the Medical Devices Directive there is a special regulatory regime and products cannot be CE marked. This causes uncertainty for manufacturers in specialist product areas. *Note - both Directives are currently subject to revision. In the case of Medical Devices, the European Medical Device Regulations were proposed by the Commission in October 2012, and in the same month, the revision of the R&TTE Directive through the proposed new "Radio Equipment Directive" to align it with the NLF. Nevertheless, new legislation will not come into effect until 2015 so these problems remain.*

There was also a call for clarity regarding CE marking on products/assemblies with multiple parts. For example in the case of petrol pumps, it was reported that Member States follow different approaches; some require the placing of a single CE marking on the pump, whilst others require a CE marking on each nozzle of the same pump. In the first case, once a nozzle is defect the whole pump is out of use. In the second, the remaining nozzles can still be used.

A few stakeholders expressed a view on the interaction of CE with other voluntary markings. Those stakeholders that did offer a view did not see any particular benefit from aligning the CE marking with voluntary markings, given that consumers are generally unaware of the significance of the CE marking. Since the CE marking only relates to regulatory compliance with IM regulations, there does not appear to be any merit in combining it with quality marks, such as the voluntary GS marking (Geprüfte Sicherheit or "Tested Safety") in Germany. A number of industry representatives pointed out that although the German GS is not compulsory, it is often requested by retailers and wholesalers can be considered as a non-regulatory barrier to placing products in the German market. This was considered to be a particular problem in the case of gardening equipment (see case study in Appendix C). However, this is more a matter of market pressure and wide recognition of the mark among GS consumers rather than one of confusion with the CE marking.

There is perhaps a need for the Commission to state more explicitly the purpose for which CE marking is intended. If CE marking is specifically intended to inform consumers, there is a

[44] The Machinery Directive, Low Voltage Directive, R&TTE Directive and the EMC Directive respectively

need for a marketing campaign to raise awareness, and for additional information requirements, such as a clear explanation in product manuals of the meaning and implications of the CE marking for the product in question. Many stakeholders interviewed however did consider it to be particularly important that consumers fully understand the meaning of CE marking. If the main target audience of CE marking is market surveillance authorities, it might be possible to reduce information requirements, if such information is already provided elsewhere, e.g. in the DoC. For example, it might be possible to remove the obligation of putting a CE marking on the product manual when this is already on the product or to offer the possibility to use electronic CE marking on products such as mobile phones.

The Commission should perhaps also clarify the significance of CE marking for economic operators and consider the information that such operators might require from suppliers. There is also the continued need to improve awareness among manufacturers, importers and distributors regarding the significance of CE marking and the obligations that it imposes on them.

A number of further issues were identified in relation to how effectively CE marking works. Some stakeholders interviewed stated that there was evidence of inappropriate placement of CE marking on non-harmonised products (ladders were mentioned as an example). Furthermore, more thorough market surveillance is necessary to guarantee proper use of, and to maintain confidence in the CE marking system.

A few stakeholders suggested that while CE marking requirements are well understood by economic operators, there can be additional product labelling requirements in addition to CE marking. For instance, in the case of the Personal Protective Equipment Directive and for products falling under category 3 (higher-risk protective equipment and clothing) in addition to the CE marking, a digital code must be included on the product from the NB that carried out the conformity assessment process. In the case of the Measuring instruments along with the CE marking, the metrological marking (M), the last two digits of the year in which the conformity marking was affixed and the identification number of the Notified Body should also be included. While there are some administrative costs, firms and industry stakeholders interviewed did not suggest that these represent a sizeable cost.

While the majority view among stakeholders was against any changes to the CE marking regime, there were also a few suggestions for improvements by some interviewees and respondents to the Your Voice consultation. Close to two thirds (59/96) of respondents to the Your Voice consultation indicated that it should not be necessary to provide any additional information alongside the CE mark, but around one third (34/96) proposed that some reference to the applicable legislation needs to be presented (either direct reference of with an additional marking) and 18 proposed that the Notified Body is also included in the case of conformity based on a third party (as is already the case for the MID). However, as pointed out by several stakeholders, the inclusion of the Notified Body number can undermine the equivalence of self-certification under Module A, where no third party certification is required.

Another suggestion made by a few firms in the ICT/electronics sector was the possibility of introducing of electronic CE marking for products with displays (e.g. mobile phones) while another was the possibility of removing the obligation of putting a CE marking on the manual of a product when this is already on the product.

Overall, given the evidence presented, it would seem that there is no need to change the overall approach to CE marking. There is however a continuing need to ensure through the NLF that there is greater consistency in CE marking requirements between IM directives and regulations, given that many products must comply with multiple applicable legislation. There may also be issues around the need to state the specific Directive to which a CE marking corresponds when placed on a product. With the growth in e-commerce, there may also be issues around the control of imported goods, which the NLF struggles to address.

Research Findings (RFs)

- (RF52) CE marking is appropriate and effective and the logo enjoys a high level of awareness amongst consumers (Stakeholder interviews; Your Voice consultation; Eurobarometer survey)
- (RF53) There is no particular benefit to be gained from aligning the CE marking with voluntary markings (Stakeholder interviews; Eurobarometer survey)
- (RF54) There are some minor difficulties relating to inappropriate markings, although these can be addressed through awareness-raising activities and continued market surveillance. (Stakeholder interviews)
- (RF55) There is no need for any fundamental change in CE marking, although there is a need to bring greater consistency and avoid having different requirements for different pieces of legislation and address the issue of products with multiple parts. This can be addressed through the NLF, as and when legislation is updated.

4.7 Role of support and coordination mechanisms

EQ16: What contribution is made by support and co-ordination mechanisms such as Administrative Co-operation Working Groups and Product Contact Points?

Administrative Co-operation Working Groups (ADCO) are in operation for a number of Directives[45]. Their role is to improve coordination and consistency in terms of the interpretation of requirements and market surveillance. ADCO groups are in operation for almost all Directives.

The interviews indicate that ADCO groups are particularly valued by national stakeholders for their potential to bring together the Commission, national authorities and industry representatives to discuss and often address issues that arise. ADCOs have also a strong role in developing guidance that assist authorities and economic operators. For example, in relation to the Pyrotechnics Directive the relevant ADCO group has published a list of what is banned in different countries informing potential importers. It is a rather common view among national authorities that each Directive and Regulation should have an ADCO group.

Stakeholders expressed concerns about the low level of participation or the limited expertise of representatives of some Member States that participate in the meetings. The absence of some Member States tended to weaken the potential to address problems caused by non-compliant manufacturers in those countries. It is suggested by some ADCO coordinators that there is need to strike a different balance in the participation of generalists, policy experts and technical experts participating in ADCO groups. Furthermore, most national authorities call

[45] Machinery, LVD, Ecodesign, EMC, Pressure equipment, Lifts, Recreational crafts, PPE, ATEX, Outdoor noise

for a greater coordination between ADCOs and working group meetings.

A number of national authorities called for increased financial support from the Commission for attending of meetings as well as technical assistance to fund ADCO activities, such as research and guidance. They also call for higher visibility of ADCO activities and meeting through the commission websites. Interviewees agreed strongly on the need for provision of information at national level because of the inevitable variations caused by transposition of Directives into national law, and also because national bodies had the networks, contacts and language skills to provide effective information services to economic operators in their own country. One national body also highlighted the importance of providing advice on VAT and other tax issues involved in trading across borders, alongside the information and advice relating to the product legislation.

Interviewees expressed divergent views regarding the value of national Products Contact Points (PCPs). Stakeholders in some countries suggested that PCPs were effective and providing a useful service. For example, one PCP had started to organise coordination meetings for Notified Bodies, whilst two others reported good relations with PCPs in other countries. However, others suggested that the concept of PCPs was poorly understood and that PCPs had a very low profile. Since many economic operators request and receive information directly from national authorities, it may be necessary to review the role of PCPs in order to determine their potential to add value to the services provided by national authorities and industry associations.

Research Findings (RFs)

- (RF56) ADCO are valued by national stakeholders for their role in facilitating discussion and action on issues of common concern and in developing guidance for national authorities and economic operators, though their potential is sometimes limited by low levels of participation and/or Member State representatives lacking the necessary expertise. (Stakeholder interviews)
- (RF57) The effectiveness of ADCO could be enhanced by greater visibility (e.g. on the Europa website), EU funding for participation and by EU technical assistance funding, e.g. for research, publication of guidance, etc. (Stakeholder interviews)
- (RF58) Product Contact Points are providing a useful service in some countries, though in others they have a low profile and their role is poorly understood. (Stakeholder interviews)
- (RF59) There is a need to clarify the role of PCPs and introduce practical actions to strengthen their effectiveness, e.g. facilitate a network at EU level.

4.8 Market surveillance

4.8.1 Challenges facing market surveillance authorities

EQ17: What are the main challenges facing market surveillance authorities?

Market surveillance is a Member State responsibility, although the Commission has an important overall monitoring and coordination role. Effective market surveillance and

regulatory enforcement is a crucial mechanism for ensuring the efficient and effective implementation of IM legislation for industrial products. It is vital for ensuring product safety and health and for promoting fair competition and a level playing field among economic operators. In order to strengthen the current approach to market surveillance, the EU adopted Regulation 765/2008 setting out common market surveillance rules and the Commission has proposed a Regulation on Market Surveillance as part of the wider Product Safety and Market Surveillance Package (PSMSP), as described above in section 1.3.5.

As noted earlier, market surveillance is inherently challenging and is considered by many stakeholders (e.g. 60.6% of NBs responding to our survey) to be the most problematic part of the IM regime for industrial products. Indeed, the impact assessment accompanying the PSMSP highlights a number of challenges, which have also been confirmed by the research undertaken for this evaluation.

A first challenge is the relatively **high levels of non-compliant products** entering the market, although instances of non-compliance often relate to minor administrative irregularities rather than to serious breaches of the essential requirements. There is evidently a balance to be struck between preventing non-compliant products from entering the market and avoiding the imposition of unreasonable requirements on responsible economic operators. It is also reported that there are relatively **few withdrawals of non-compliant products** from the market, although the RAPEX information systems has helped to raise awareness of high-risk products (see section 4.82 below). However, the 2006 public consultation on the New Legislative Framework (NLF) found that 87% of operators considered there to be unfair competition due to the presence of non-compliant products on the internal market[46]. Evidence from a number of evaluations and impact assessments suggests that non-compliant products account for a sizeable share of the market in certain sectors. This is confirmed in data provided by market surveillance authorities[47].

For example, the impact assessment[48] on the proposed "Radio Equipment Directive" to replace the R&TTE Directive cited evidence from European Market Surveillance Authorities (MSAs) that presently between as little as an estimated 28% and 56% of products were fully compliant with the essential requirements. Administrative compliance has been estimated at an even lower level by MSAs at about 20%. In the case of the Ecodesign Directive, non-compliance was estimated to be 10- 20%[49]. In other areas (e.g. Gas Appliances, Personal protective equipment) the existing studies indicate non-compliance levels of no more than 5-10%[50] and there are also cases – such as explosives – where, according to the relevant evaluation study[51], there are very few cases of non-compliance.

However, this is also a possible illustration of authorities giving a higher priority to products more directly linked to public safety issues. Estimates from market surveillance authorities

[46] EC (2012), Product Safety and Market Surveillance Package - COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT , http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=swd:2013:0033(51):FIN:EN:PDF
[47] EC (2012), Commission Staff Working Document, Annexes to the Impact Assessment, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2013:0033(52):FIN:en:PDF
[48] Proposal for a Directive of the European Parliament and of the Council on the harmonisation of laws of the Member States to the making available on the market of radio equipment
[49] Evaluation of the Ecodesign Directive (2009/125/EC) - Final Report
[50] Impact assessment study on the review of the Gas Appliances Directive 2009/142/EC
[51] Evaluation on dg enterprise and industry legislation – Cosmetics and Explosives Directives

and enterprises collected in 2006 also ranged from 1% for recreational craft to 30% for the Electrotechnical sector and even up to 50% for luminaires. Similar findings were obtained in three market surveillance campaigns carried out by the Administrative Cooperation group (ADCO) for the implementation of the Electro-magnetic Compatibility Directive focusing on Energy Saving Lamps, Power Tools and Consumer Entertainment Electronic Products. The level of technical non-compliance was 23% for the Energy Saving Lamps, 20% for the Power Tools and 50% for the Consumer Entertainment Electronic Products while according to the ADCO machinery NOMAD study around 80% of products do not comply with noise requirements.

A second challenge, related to the first, is the difficulty in **ensuring the traceability of products**, which was stressed by a number of interviewees, so that market surveillance authorities can obtain technical documentation not only at the point when products are placed on the market but for up to 10 years following their placement on the market. The limited traceability of products and of manufacturers strongly hinders market surveillance authorities in carrying out their work and improvements in this area would help to strengthen the efficiency and effectiveness of MSAs. However, it should be noted that economic operators were not generally favourable towards traceability requirements, and in particular, were against the introduction of requirements to register in databases. A major EU industry association stated that "the manufacturer is already legally responsible for ensuring regulatory compliance and for producing the DoC to achieve presumption of conformity. Traceability has become a religion and imposes unnecessary administrative burdens on economic operators, such as compulsory registration schemes and the requirement to put the address of the responsible economic operator on the label."

A market surveillance authority in the **UK** commented that concerns about the administrative burdens of registration schemes extend beyond industry to some public authorities. "The proposed new registration scheme under the new R&TTE is intended to improve the traceability of products. However, it risks causing a bigger divide between good and bad providers; by creating more hoops to jump through, it will discourage some economic operators from complying and could also give greater competitive advantage to non-compliant providers".

A Product Contact Point in **Sweden** pointed out that, although there has been a lot of discussion about traceability in the context of the Alignment Package, its value and importance depends on the type of product concerned, the directive or regulation in question and whether it is a professional or a consumer product. "When we refer to professional products where economic operators are known to one another, the extent to which there is really a need for traceability requirements should be reconsidered since this imposes unnecessary administrative requirements".

A third challenge is the **difference in approaches taken to market surveillance in different countries**, for example, how likely MSAs are to carry out testing themselves, as opposed to requesting technical information from economic operators. Such differences may undermine the internal market since there could be variations for economic operators in their experiences, for instance, the type and frequency of requests for information from market surveillance authorities, the likelihood of having products tested, etc. Different approaches to market surveillance often reflect different levels of resources and technical expertise available to MSAs in each country; some stakeholders were of the view that the level of

resources and expertise was insufficient in some countries.

One MSA in **Sweden** noted that "We test a broad selection of products ourselves and do not only ask manufactures to submit papers on the use of products. We also test a broad selection of products from different geographic origins both within and outside the EU. We do identify dangerous products and even where products are generally compliant, remarks are made for three-quarters of products tested". Another MSA in **Romania** noted that market surveillance needs to be "highly coordinated and capable of reacting rapidly. However, market surveillance has not kept pace with developments in the Union's regulatory framework, which could be overcome through the use of an "intelligent" model. This means that "random checking" will not be mathematically random, but will instead be focused on a risk-based approach and the identification of potential problem products and economic operators that have previously been non-compliant. Wholesalers, distributors etc. who are known by experience to comply with the rules may therefore expect a fewer inspection visits".

Encouragingly, stakeholders reported that market surveillance had improved and become more consistent across different Member States through the measures included in the NLF and, in particular the common rules on market surveillance set out in Regulation 765/2008. Some Member States (e.g. Greece, Ireland, Slovenia) had made significant changes to their market surveillance systems, such as the creation of national market surveillance authorities and the development of market surveillance programmes, as a direct response to the requirements of Regulation 765/2008.

Research Findings (RFs)

- (RF60) Market surveillance is considered to be the weakest part of the implementation system, partly due to the inherently difficult nature of the task and in part due to varying levels of resources and technical expertise available in different countries. (Stakeholder interviews; Survey of NBs)
- (RF61) There are high levels of non-compliance for some products, low levels of product withdrawals and a need to strengthen the traceability of products. However, there is the need for MSAs to differentiate between minor instances of non-compliance with administrative requirements and serious instances of non-compliance with essential safety requirements. (Data from previous studies; Stakeholder interviews)

4.8.2 Co-operation and information sharing between market surveillance authorities

EQ18: How effective is the co-operation between market surveillance authorities?

Through the evaluation, we also assessed the extent to which mechanisms and tools put in place to facilitate cooperation between market surveillance authorities and information sharing are working effectively, notably the Rapid Alert Information System (RAPEX) and the "ICSMS" tool (Information and Communication System for Market Surveillance.

Regulation 765/2008 includes a reference in the Regulation to the RAPEX system and has highlighted the importance of this exchange information mechanism for market surveillance in the Single Market. The report on the implementation of Regulation 765/2008 provides feedback on the added value of RAPEX. "Reference to the RAPEX system in the Regulation

has extended the obligation to send RAPEX notifications to all goods falling within the scope of EU harmonisation legislation, including products for use in a professional context (e.g. industrial machinery) and products which may harm public interests other than health and safety (e.g. environment, security etc.). This has contributed to the protection of workers and the environment, although the total number of new notifications has been limited during the first two years of implementation".

However, a market surveillance authority in **Ireland** noted that "RAPEX has not led to many notifications for harmonised products for professional users and the ICSMS has been more useful in practice". Whereas RAPEX was viewed as being useful in informing market surveillance authorities and the Commission about high-risk products, and the database is useful for reporting purposes on products presenting serious risks, **ICSMS**[52], the general information support system for market surveillance also has an important contribution in ensuring that there are mechanisms in place for exchanging information between market surveillance authorities, joint working and for virtual communication and cooperation.

The tool provides a single portal containing information on specific products (product description, test results, in cases of non-compliance identified any remedial measures taken etc.). Two of the actions set out in the Multi-annual plan for market surveillance refer to ICSMS (Action 2: Maximise the benefits of ICSMS and Action 3: Create synergies between GRAS-RAPEX and ICSMS). A small number of stakeholders referred to ICSMS during the interview programme.

A market surveillance authority in **Germany** stressed the importance of the need for greater synergies between RAPEX and ICSMS. "ICSMS is a great operational tool to communicate with different market surveillance authorities in other EU Member States. Among the advantages of using the system are that it is available in all languages across EU28. Documents can be uploaded and although there is no automatic translation of all documents, most phrases are translated. This solves one of the practical difficulties in ensuring effective market surveillance - language problems can be a barrier to finding out about dangerous products and for avoiding duplication of effort between market surveillance authorities in different countries".

ICSMS was not seen as duplicating RAPEX but rather complementing it. It was pointed out that it is only available in EN and it does not provide a tool for communicating and collaborative working between market surveillance authorities, which ICSMS does.

The need to examine the scope to merge different databases on market surveillance that feed into Member State reporting requirements to the Commission was highlighted. For example, a market surveillance authority in **Belgium** noted that "Each year, Member States have to prepare a report on market surveillance carried out and set out the plan for the coming year. There are several databases that are useful, such as Circa, RAPEX, ICSMS. The Commission should investigate whether merging of databases is possible and should study the value added of each database".

Research Findings (RFs)

[52] ICSMS provides an internet-based platform for the comprehensive exchange of information between all the market surveillance bodies. The tool has an internal area for the use of market surveillance authorities that can also be used by customs authorities and EU officials.

- (RF62) RAPEX and ISCSMS are viewed as useful in informing market surveillance authorities. (Interviews of MSAs)
- (RF63) There is scope to increase the complementarity and synergy between RAPEX and ISCMS. (Interviews of MSAs)

4.8.3 Risk-based and systems-based authorities

The proposed Market Surveillance Regulation is based on a risk-based approach to market surveillance (of both harmonised and non-harmonised products). 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. A market surveillance authority in **Germany** commented that "*Market surveillance authorities should focus on checking non-conformity, since this is easier to perform against the regulatory requirements. If instances of product non-conformity are identified, and it is judged that these are likely to lead to a risk or to a serious risk, then these products should be alerted through the RAPEX system.* Although they were in favour of having common elements in Union harmonisation legislation built into a horizontal regulation, market surveillance should continue to be based on an assessment of product compliance with IM regulations.

However, the report on the implementation of Regulation (EC) No 765/2008 published in February 2013 as part of the PSMSP asserted that progress has already been made in the development of a **risk assessment methodology**. It was noted that the existing RAPEX Guidelines already provide for the risk assessment methodology for consumer goods, and are an important reference point for Member States. Moreover, in 2011, the Commission set up a Risk Assessment Task Force composed of Member States' experts whose role was to assess: (i) whether the existing methodology, whose main focus is on non-harmonised products, could suitably take into account the legal requirements of harmonised goods; (ii) how to address the need to assess risks to public interests other than health and safety, which are not taken on board by this methodology.

Through the research, we reviewed good practice in carrying out market surveillance (given the broad focus of our study, only selected examples are possible). In the **Netherlands**, a systems-based approach to market surveillance based on risk has been adopted. This was recognised by interviewees in other countries such as **Latvia,** as being an interesting, and potentially transferable example. An explanation as to how the system works is provided below:

Table 4.8: A systems-based and horizontal approach to market surveillance and regulatory enforcement[53]

In the Netherlands, the government adopted the "Vernieuwd Toezicht" (Renewed Surveillance Programme) in 2008. The aim is to strengthen the efficiency and effectiveness of market surveillance activities by fostering better relationships with economic operators and by raising awareness among enterprises about their legal obligations under product safety and environmental legislation.

[53] Source: Systeemtoezicht en Horizontaal Toezicht, conceptleidraad voor de Rijksinspecties, Begrippen en randvoorwaarden, December 2012
http://www.inspectieloket.nl/vernieuwing_toezicht/programma_systeemtoezicht/

Efficiency of the implementation regime 4

A distinction is made between (i) horizontal enforcement and (ii) system-based enforcement. These two different types of enforcement are already being applied by some government inspections agencies. *Horizontal enforcement* involves combining regulatory enforcement with horizontal activities and support actions for enterprises.

Implementing a horizontal approach refers to the development of mutual cooperation between government and society. Horizontal enforcement is based on building mutual trust and a working relationship between government and economic operators based on the development and implementation of quality management systems to strengthen regulatory compliance. The agreements are set out in a covenant based on a partnership-based approach which is published on the inspection agency's website. The provision of relevant information, the exchange of knowledge, and if relevant the monitoring of business activities are sufficient to consolidate compliance.

S*ystem enforcement* focuses on the enforcement of quality and assurance systems and more specifically on the development of a strategy for companies to set up robust regulatory compliance procedures, documentation to measure the results achieved, interventions committed and the defects. Surveillance in general takes place on the basis of periodical (administrative) inspections. Surveillance is not aimed at checking whether individual regulations have been complied with. The confidentiality of the government in the enterprise is still based on inspection.

The application of horizontal and system-based approaches means that that one agency may apply the horizontal system and another may apply a system-based approach, while others adopt elements of both approaches. Through the application of a horizontal and system-based approach, the inspection can reduce the administrative burdens for enterprises/institutions which take their responsibility and do not injure the confidentiality received from the government. In addition the surveillance institutions are in the position to focus their capacity to enterprises performing not correctly.

An example of a surveillance authority that applies the system approach is the Food and Consumer Product Safety Authority (Voedsel en Warenautoriteit). The systems-based approach is targeted at larger manufactures and EU importers based on the following criteria: position in the value chain (manufacturer, EU importer or major distributor); they must have a relatively large share of the market;, regularly included on RAPEX or often having defects found during product inspections; their willingness to invest in strengthening business-processes aimed at ensuring the safety of products.

Research Findings (RFs)

- (RF64) There is a need for better definition and clarification of risk and how to assess it in the proposed Market Surveillance Regulation, building on the proposed risk assessment methodology in the PMSP. (Analysis of legal text; Interviews of MSAs)
- (RF65) There is a need for guidance on the relative merits of the alternative approaches to market surveillance and the circumstances under which each type of approach should be adopted. (Analysis of legal text; Interviews of MSAs)

4.8.4 Market surveillance of non-harmonised products

EQ19: Should non-harmonised products be covered by common EU market surveillance rules?

Since the evaluation begun, in February 2013, the Commission published a Proposal for a Regulation on the Market Surveillance of Products, which is part of the wider "Product Safety and Market Surveillance Package" to improve consumer product safety and to strengthen market surveillance of products placed on the internal market. The Regulation, if adopted, will merge the rules on market surveillance of the General Product Safety Directive, Regulation (EC) 765/2008 and many sector-specific pieces of Union harmonisation legislation into a single legal instrument that applies horizontally across all non-food sectors. There would be no distinction between consumer and professional products or between harmonised products and non-harmonised products for the purposes of market surveillance. The Commission intends that this "one-tier" system will eliminate overlaps, close gaps and assimilate as far as possible the rules and procedures applicable to all non-food products.

The impact assessment accompanying the Product Safety and Market Surveillance Package considered the appropriateness of non-harmonised products being covered by common EU market surveillance rules, as well as the costs, benefits and possible issues that could arise from such an approach.[54] It offers a number of conclusions that have been reinforced and illustrated by the findings from the recent Your Voice consultation and by the consultations undertaken as part of the current evaluation.

First, the impact assessment suggests that market surveillance will be reinforced by the alignment of consumer product safety requirements with harmonised product safety requirements, through greater clarity and legal certainty. It notes that market surveillance is currently weakened by the differing requirements that currently apply to products with similar characteristics and safety properties, for example, toys and childcare articles.

Second, the impact assessment suggests that common EU market surveillance rules covering harmonised and non-harmonised consumer products will enable enforcement measures to be targeted directly at the source of any risks to safety. The proposed common rules will specify requirements concerning the identification of the manufacturer and/or the importer authorities. According to the impact assessment, this approach will also contribute to the non-discriminatory treatment of economic operators by market surveillance authorities of different Member States while allowing market surveillance authorities to track down non-compliant economic operators more quickly and at a lesser cost – by stopping unsafe products "at the source", i.e. where the product is manufactured or imported to the EU. This approach will also prove fairer and more effective by focusing on the operator primarily responsible for the placement of any risky product on the market, i.e. the manufacturer or importer, rather than the final distributor.

Third, the impact assessment suggests that the costs imposed on (responsible) operators by common EU market surveillance rules may be negligible in many cases. For example, many

[54] Commission Staff Working Document: Impact Assessment Accompanying the document - Product Safety and Market Surveillance Package, SWD(2013) 33 final

producers do not use separate production lines for harmonised and non-harmonised products and therefore already apply harmonised product safety requirements to all their products. Many also already establish technical documentation for non-harmonised products, even though not required to do so. In addition, the impact assessment notes that the size of the category of producers producing only non-harmonised products is extremely limited.

In contrast to the impact assessment's findings, stakeholders consulted in the current evaluation expressed some **misgivings about the application of common EU market surveillance rules to non-harmonised products**. A key issue raised was that of different national standards in areas that affect safety, such as electrical installations. Such differences mean that common EU rules might prove less effective, for example, potential risks are not assessed with sufficient consideration to the (national) context in which products will be used. Some stakeholders also pointed out that the Commission had ruled out imposing product safety requirements on non-harmonised professional products (i.e. products circulating only among professionals and never used by consumers, such as industrial machines, raw materials and semi-finished products) and that this risked creating a loophole.

Another issue raised by interviewees was the risk of **increased human resources and costs** resulting from the extension of common EU market surveillance rules to non-harmonised products. Stakeholders noted that it is more complicated for market surveillance authorities to carry out monitoring and surveillance for non-harmonised products since they must contact market surveillance authorities to ask whether products have been produced in line with national legislation, which is resource intensive and slows down the process. Therefore, it was argued by some stakeholders that a differentiated approach should continue to be adopted to market surveillance, depending whether products are harmonised or non-harmonised.

A stakeholder in **Romania** for example commented that common rules on market surveillance could lead to a high increase in costs in some Member States, if the provisions obliged the relevant bodies to perform complex tests. An increase in staff would be needed and the acquisition of additional testing equipment for those bodies, and investment would be needed in reorganising market surveillance systems, structures and personnel, with training to enhance capacity. A national competent authority commented that *"it is difficult to put in place common EU market surveillance rules for non-harmonized products because each Member State has its own specific national organisational set-up and practices"*. A market surveillance authority in **Germany** commented that it is much more difficult for market surveillance authorities to assess the risks associated with non-harmonised products, and this implies further resources.

Feedback from industry and MSAs highlighted some concerns regarding the proposal to remove the distinction between consumer and professional products. It is easier for MSAs to check consumer products before they are placed on the market whereas this is often not straight forward for B2B products (for instance, complicated machines) since these only appear when products are about to enter the market or already in use. Considerable technical expertise is needed to assess more complex industrial products. A 'one size fits all' approach to market surveillance as proposed in the PSMSP may be difficult to implement in practice, due to differences in how market surveillance activities are carried out between harmonised and non-harmonised products and differences between product types as to when it is feasible for MSAs to actually carry out testing and risk assessment of products (pre or post-placement

on the market).

The **absence of standards for non-harmonised products** was cited by a number of interviewees (market surveillance and national competent authorities) as a further complicating factor that means market surveillance in the non-harmonised product domain is resource-intensive. For instance, a competent authority in the **Netherlands** stated that the lack of EN standards means that it is consequently difficult for them to determine the regulatory requirements that should be checked for products placed on the market according to the mutual recognition principle. The resource implications of the proposed Regulation were also highlighted in **Denmark**. Market surveillance in the non-harmonised sector is more time consuming and costly and requires strong cooperation from market surveillance authorities in other Member States.

However, not all market surveillance authorities would have to make changes to their systems, processes and procedures if a common approach to market surveillance were to be adopted. For instance, a market surveillance authority in **Sweden** commented that "we have a tradition of working with both harmonized and non-harmonized products in the same way so common rules will not lead to many changes to our processes or ways of working".

Since market surveillance is a Member State responsibility, any extension of EU market surveillance rules should **take into account the willingness, technical capacity and resources available to market surveillance authorities** to fulfil any additional responsibilities that would be required of them. There may also be a need to provide support and guidance to manufacturers and other affected economic operators as a means of ensuring effective application of the legal framework and reducing unnecessary burden, as well as to national authorities.

Among the wider feedback from MSAs in relation to the proposal for a new regulation on market surveillance as part of the Product safety and market surveillance package (PSMSP)[55] (COM(2013) 74 final) was that there are concerns as to how realistic the suggested approach is for industrial products and whether there is too strong a focus on consumer products, and whether testing on a sampling basis is more realistic. One market surveillance authority commented that "There are contradictions in the PSMSP, which makes a distinction between industrial and consumer products, however for Regulation 765/2008, industrial and consumer products are integrated".

A concern among stakeholders with regard to the proposed Regulation within the PSMSP was that each Member State is required to set up a Market Surveillance Authority (MSA) with relatively minimal guidance from the Commission. There is a potential danger that this could result in 28 different sets of rules for the implementation of market surveillance arrangements, with divergence in risk assessment processes. Moreover, there are potentially additional costs associated with the implementation of the PSMSP, namely a new set of testing and evaluation laboratories could need to be set up by each Member State. It is intended that this will come at least partly from fines and levies from requiring manufacturers to carry out risk assessments when these are mandated by MSAs. However, there is an evident risk that different MSAs adopt different approaches, which could undermine the effective functioning of the internal market.

[55] http://ec.europa.eu/consumers/safety/psmsp/docs/psmsp-communication_en.pdf

Efficiency of the implementation regime 4

Research Findings (RFs)

- (RF66) Market surveillance will be reinforced by the alignment of consumer product safety requirements with harmonised product safety requirements, although this may depend on the extent to which market surveillance authorities are able absorb any increase in costs. (Impact assessment for PSMSP; Interviews of market surveillance authorities)
- (RF67) Common EU market surveillance rules covering harmonised and non-harmonised consumer products will enable enforcement measures to be targeted directly at the source of any risks to safety. (Impact assessment for PSMSP)
- (RF68) The costs imposed on responsible operators are likely to be negligible in many cases. (Impact assessment for PSMSP)
- (RF69) Different national standards for some products may reduce effectiveness of market surveillance. (Interviews of market surveillance authorities)

Costs of compliance and scope for simplification

5

5. Costs of compliance and scope for simplification

5.1 Introduction and approach taken

An important objective of the evaluation has been to understand the process by which industry complies with the legislation and to identify and quantify the costs incurred in compliance. Based on that, we have then identified ways by which the legislation and its implementation might be simplified in order to reduce those costs. Where possible, we have also attempted to estimate the financial benefits of the simplifications.

More specifically, the analysis has attempted to estimate:

- costs of compliance with IM legislation faced by firms (see section 5.2);
- scope for regulatory and administrative simplification of IM legislation (section 5.3);
- potential cost savings from simplification options (sections 5.4 and 5.5); and
- macro-economic impacts of simplification measures on growth and jobs (section 5.6).

This task has been undertaken through ten case studies of specific product groups, of which eight focus on harmonised product groups and two on non-harmonised product groups. The table below lists the product groups covered by the case studies.

Table 5.1: Product groups selected for case studies

No	Product	Applicable Legislation
Harmonised product groups		
1	Electric motors	Core Directives - LVD, EMC, ATEX Other applicable IM legislation: REACH, RoHS, Ecodesign
2	Laptops	Core Directives - R&TTE, LVD and EMC Other applicable IM legislation: Ecodesign, RoHS, Packaging and Packaging Waste Directive
3	Domestic refrigerators and freezers	Core Directives - LVD, EMC Other applicable IM legislation: REACH, Ecodesign, Energy labelling, RoHS, Regulation on materials in contact with foodstuff
4	Lifts for persons	Core Directives - Lifts[56], LVD and EMC
5	Gardening equipment	MD, EMC, Outdoor noise, Non-road mobile machinery Emissions, RoHS, REACH
6	Fuel dispensers	MID, LVD, EMC
7	Air conditioners	MD, EMC, LVD, CPR, RoHS, Energy Labelling, PED[57], Ecodesign, Regulation 2000/2037/EC on Ozone Depleting Substances Regulation 2006/842/EC on Fluorinated Greenhouse Gases Regulation 2007/1494/EC on Labelling Requirements
8	Integrated	LVD, EMC, ATEX, RoHS

[56] The Machinery Directive applies to lifts for goods and to other types of lifts not covered by the Lifts Directive, the Cableways Directive applies to lifting appliances installed in outdoor mountain or urban sites.
[57] The SPVD is also applicable but only to certain types of air conditioners.

	circuits	
Non-harmonised product groups		
9	Ski/Snow footwear	Directive 94/11/EC relating to the labelling of materials used in the main components of footwear for sale to the consumer, Directive 94/62/EC on packaging and packaging waste, REACH, Mutual recognition Regulation 764/2008
10	Bicycles	Mutual Recognition Regulation 764/2008

For each of these ten product groups, the relevant legislation was reviewed, sectoral data on market size and structure was analysed and firms were interviewed in depth in order to identify the processes followed in compliance and the costs incurred. Data on costs was then analysed using the Standard Cost Model, the European Commission's prescribed tool for analysis of this nature in order to draw conclusions around the cost of compliance and the potential for cost savings from simplification of the legislation. Finally, macro-economic impacts were assessed through the application of a macro-economic model.

Attempting to quantify the costs of compliance, the potential for savings from simplification and the macro-economic impacts of legislation is clearly not without its challenges. Whilst the results presented in the sub-sections are based on recognised analytical techniques, we must highlight these challenges. In summary, these related to the following:

- **establishing the baseline:** whilst many firms have provided an indication of the situation prior to the introduction of Union harmonisation legislation, none were able to provide quantitative data on costs, given the time that has elapsed; similarly, it has not seemed useful to compare current costs against a hypothetical scenario in which no Union harmonisation legislation exists;
- **availability of data:** data on costs can clearly be commercially sensitive and many firms were unwilling to participate or reluctant to provide data; even where firms were willing, many simply did not collect data relating to certain costs of compliance; it was relatively straightforward to obtain data on the level of human resources working directly on compliance with administrative obligations, whereas data on product design and development and testing was less available;
- **disaggregation of data:** for most of the products in question, several pieces of IM legislation are applicable; moreover, most of the firms interviewed produced a range of products or models for both EU and global markets; it thus became difficult to isolate the cost of compliance with particular pieces of legislation from other costs and to relate those costs solely to production for the EU28 market;
- **establishing the "business-as-usual" scenario**, namely the costs that would be incurred in the absence of legislation; many firms found it difficult to accurately estimate the proportion of costs that they would incur in the absence of legislation, i.e. as part of the normal process of product design, development and testing.

European Commission guidance on the SCM makes clear that a distinction should be made between administrative and substantive compliance costs:

- **Administrative costs** - relate to the costs of preparing documentation and direct fees; and
- **Substantive compliance costs** - relate to any specific investments firms must make in

order to comply with the law.

It is widely recognised that there may be nuances and an unclear demarcation between the two types of costs because such costs are part of a continuum. Most notably, in the case of testing carried out as part of conformity assessment modules to comply with Union harmonisation legislation, the aim is neither to obtain an authorisation or certification. Rather, it is to demonstrate compliance with the essential requirements. Nevertheless, the guidelines suggest that conformity assessment should still be treated as a substantive compliance cost, even if the current definition does not exactly fit this area. However, some elements of the conformity assessment process are administrative, such as preparing the technical file and issuing the Declaration of Conformity.

Given this potential lack of clarify, the way in which we have defined administrative and substantive compliance costs in this study is summarised in the table below.

Table 5.2: Administrative and substantive compliance costs

Type of costs	One-off costs	Recurring costs
Administrative costs	• Familiarisation with IM legislation and standards • Notified Bodies fees for IM legislation and mandatory testing	• Development and updating of technical files • Production of a DoC and CE marking • Conformity assessment: preparation of technical files in parallel with testing activities
Substantive compliance costs	• Modifications to product design (during new product development phase/ R&D) • Modifications to product design once products have been placed on the market • Costs of temporarily or permanently withdrawing products from the market	• Conformity assessment: preparation of technical files in parallel with testing activities testing for conformity with the applicable modules defined in IM legislation

Source: CSES

The extent of administrative and substantive compliance costs was estimated for four stages in the process of compliance with IM legislation:

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1. Preparatory actions and familiarisation with the applicable legislation and relevant administrative obligations for economic operators

2. Substantive compliance: Introduction of processes or changes to product design and production processes to ensure compliance with substantive obligations

3. Conformity assessment procedures and the preparation of relevant technical documentation

4. Declaration of Conformity or other statement of compliance and CE marking

Costs incurred at each stage are now presented in the sub-sections that follow. Although a common approach was adopted to the eight harmonised product cases, in some instances it has been difficult to compare findings from the different cases due to the data limitations already described.

We then present estimates of the cost at sectoral level, for firms of different size and for public authorities.

5.2 Costs of compliance for firms

EQ20: What steps do firms take to ensure compliance with IM legislation? What costs do they incur?

5.2.1 Preparatory actions and familiarisation with the legislation

Familiarisation with IM legislation and the respective requirements is an important and ongoing task for all firms. Even though the amount of time that firms spend on familiarisation was found to vary, most firms indicate that they spend quite a lot of time on such activities, commonly 15-20% of the total in terms of human resources.

Many large firms have staff specialising in regulatory compliance (commonly around 2-4 staff). Since monitoring legislation is part of their everyday business, as part of the familiarisation process, they follow and input to EU policy and legislative-making processes. The firms interviewed recognised that it was in their direct interest to participate in shaping the form, content and implementation of Union harmonisation legislation. Furthermore, many of the large firms interviewed are actively involved in standards development processes. They are involved in discussions at the policy level and have a clear view of relevant developments, and of the dates for the introduction of new requirements or changes to relevant technical standards.

Among small firms, there is more of an ad-hoc approach to the familiarisation step, i.e. whenever there are major legislative developments or changes to standards, SMEs seem to find out about what changes are being introduced. They then assess whether any modifications are necessary for existing products or for new product development. SMEs find out about forthcoming changes through a number of information sources, particularly the relevant national and/ or EU industry associations – which charge a membership fee but provide updates on relevant legal developments.

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Some firms interviewed also maintain a database that identifies the relevant legislation and relevant/applicable standards for each of their products. Once developed, however, such a database is useful across different business functions since an overview of legal requirements is required by laboratory staff involved in testing, production engineers and product development departments. Some larger firms were found to have developed a more sophisticated database / information management system that goes beyond a simple spreadsheet. However, this can be costly and time consuming both to set up and to maintain. A suggestion was made that it would be very helpful if there were an online database or web portal where product group specific information about compliance, such as forthcoming legislative developments and the dates of updates to standards coming into effect was provided.

Firms in a few product sectors covered also referred to costs for staff attending training courses, either organised internally or through the use of external consultants. The true cost of such training is difficult to identify, since it may often be incorporated into wider staff training activities. In the case of petrol pumps, one company suggested that it accounted for 15% of the total costs of familiarisation, whilst another suggested a figure of 25%.

In small firms, the familiarisation step typically accounted for less than one full time equivalent (FTE), but sometimes additional external support was needed. For larger firms, given their engagement in EU policy and legislative-making processes and standardisation-related activities, the costs are often much higher, usually around 3-4 FTE (although in one case, as many as 15 staff were involved, although only part of their time was involved in familiarisation). This reflected a much more active approach to monitoring and shaping the development of IM legislation and technical standards.

Among other preparatory actions that involve cash costs for firms are the purchase of harmonised standards which, in the majority of cases, represent the preferred route to ensuring conformity with the applicable requirements. The costs of the purchase and/or update of standards for a specific product group does not account to more than €2,000 on an annual basis, and in many cases less than €1,000.

The amount of time for familiarisation varies depending on the year and what type of legislation has been introduced. For instance, long-established IM legislation was seen as much less burdensome during this step, compared with the introduction of new legislation. For example, for the laptops case, a significant resource input was required to input to the preparation of RoHS and once adopted, to ensuring that companies were RoHS-ready. In the case of air conditioners and air conditioning systems, the Ecodesign implementing regulations required substantial familiarisation time.

Currently, SMEs and large firms obtain information about IM legislation, technical standards and administrative requirements from a variety of sources, such as the legislative authorities, suppliers, industry and trade associations, market surveillance authorities, etc. However, among SMEs and especially micro firms, there is a low level of knowledge about IM legislation, and the specific requirements for different economic operators in the value chain (manufacturers, importers and distributors).

There is therefore a need to ensure that there is an easily identifiable “first port of call” available for firms in each Member State, particularly SMEs, to find out more about which

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IM legislation is applicable to their products and which standards could be applied to meet the essential requirements. Although the European Enterprise Network could potentially help in providing a signposting function, the European Information Centres (EICs) can only provide very general advice and are non-specialised, as is the case for the SOLVIT network, whereas PCPs have at least some specialist knowledge, since they are often located within national Ministries that are responsible for different national competent authorities.

Quite a number of manufacturers that took part in the case studies stated that one of the most significant challenges in respect of the familiarisation step is keeping track of changes in legislation and updates to standards, since there is a high cumulative frequency of changes. It was suggested that an online web portal could be developed at EU level funded by the Commission to provide a single reference point for firms to find out more about which legislation applies to their product, and what changes are being made to legislation and updates to standards.

It should be stressed that there is already a lot of relevant information available via the DG ENTR website about IM legislation, non-binding guidance, standardisation and Notified Bodies. The issue is whether it is feasible to move from the current legislation-based approach to a product-based approach, since this would be resource-intensive. Given the large numbers of technical standards, such a portal would only be able to follow a broad product category approach (since it would not be possible without significant resources to check the position for sub-categories of products. For instance, there are more than 700 different types of standards for machinery alone.

5.2.2 Substantive compliance with IM legislation

Having understood and familiarised themselves with the applicable essential requirements under Union harmonisation legislation for their product, firms then need to comply with these requirements (often using a voluntary technical standard) and with the appropriate conformity assessment procedures and CE marking requirements.

Either in the case of the development of new or modification of existing product models, this typically includes a period of largely overlapping research and development activities and product testing, the latter providing feedback on the former. The main cost drivers are the costs of human resources (research, engineers), materials, investment in testing facilities and in the costs of testing. Ensuring compliance with the requirements is sometimes the main driver of R&D and testing activities or may be only one among a number of considerations in new product development. The aim is to satisfy market demand and to ensure product quality. Thus, the share of these costs associated with meeting legal requirements (substantive compliance costs) can vary greatly. This is reflected in the input provided through the interview programme and case studies.

Aspects related to product safety may be linked to specific legal provisions but many firms indicate that such activities would take place even in the absence of IM legislation. In most case studies, the firms responded that testing for the Machinery Directive, Lifts Directive, Low Voltage Directive or the EMC Directive is largely part of their business as usual costs, i.e. what firms would do irrespective of whether European harmonised product legislation was in place. For instance, lift manufacturers undertake their own extensive product testing both during development and installation so as to ensure high levels of quality and safety. In

most cases, these checks, which are often part of internal quality management systems, readily encompass the minimum essential requirements set out in the legislation.

In contrast, firms very often consider that none of the costs of compliance with environmental (emissions, noise, energy efficiency) requirements are business-as-usual costs. An exception identified in this regard (material handling equipment) indicated that the share of investment in R&D and testing activities directly linked to IM legislation has recently increased from a typical 10-20% to more than 60% of the total R&D budget. . Another exception is the energy efficiency of domestic refrigerators and freezers [cf. case study].

The main reason indicated is the need to ensure compliance with Non-road Mobile Machinery Emissions and the Outdoor Noise Directives, both of which require dedicated testing facilities (the costs of a sound chamber to test for outdoor noise can be more than €1 million). However, there are also benefits and potential trade-offs with products' performance, requiring additional product design costs. In comparison, firms in the gardening equipment sector – a sector also covered by the NRMM and the Outdoor Noise Directives - indicated that 10-35% of product development and testing costs could be avoided in the absence of IM legislation.

Another Directive considered by some stakeholders as having created significant compliance costs for SMEs is the Ecodesign Directive, under which implementing regulations are adopted in relation to specific product groups. The evaluation of the implementation of the Ecodesign Directive in 2012[58] suggested sizeable costs for R&D, testing facilities and possible changes in production. The Ecodesign implementing regulations however only require redesign of the worst-performing products.

A survey organised by the Finnish Industry Association indicated that, on average, for each firm the one-off costs of setting up the necessary test labs were around €200,000 with an additional 1-2 FTE for relevant personnel. In the case of SMEs that use external labs to assess conformity, the cost per product is, according to information from the impact assessments, around €1,000 per product model-family. The testing of products also includes investment in testing facilities. Large firms usually invest in their own testing facilities while smaller firms use external labs more commonly, often those of accredited organisations that provide certification services (Notified Bodies). The costs involved are higher, but smaller firms often have no choice because they cannot afford the major upfront investment to set up a suitable laboratory and to purchase testing equipment.

Whether directly or indirectly linked to legal provisions, an important point identified through a number of the case studies (laptops, lifts) is that a high percentage of substantive compliance costs are integrated into firms' product design cycle. Large manufacturers account for a very significant market share and since they follow legislative-making processes leading to the adoption of IM legislation, they are typically aware well in advance of the adoption of the legislation what the requirements are likely to be, and they can therefore factor these in to R&D and design processes well in advance of the legislation coming into effect. A number of firms therefore indicated that even the costs for compliance with the Ecodesign implementing regulations could be significantly reduced when firms are

[58] CSES(2012), Evaluation and review of the Ecodesign Directive, http://ec.europa.eu/enterprise/policies/sustainable-business/ecodesign/review/index_en.htm

given significant lead times and can integrate the design and testing activities into their normal product development cycle[59]. It should be noted however that the product development cycle varies among sector. For example, in the case of laptops it is typically no more than 6 months, while in the case of air-conditioners it can be up to 3 years. Product development cycles are usually considered in the regulatory process establishing Ecodesign implementing regulations.

In contrast, frequent changes to requirements and standards can lead to sizeable costs for industry. It was also noted that regulatory changes for IM legislation are less frequent than changes to environmental legislation. However, the interaction between (and cumulative regulatory impacts of) IM legislation on the one hand and environmental legislation on the other can sometimes lead to additional administrative costs for industry.

While in general many safety-related directives are not viewed as particularly costly, frequent changes to the requirements or relevant standards can have cost implications requiring the sudden withdrawal and redesign of products. While it was not argued that individual pieces of IM legislation change too frequently (usually legislation is reviewed once every 10 years) since multiple legislation is applicable to a given product, and legislative review processes are carried out at different times, there is an almost constant process of monitoring for revisions. This is especially the case for technical standards, where amendments to standards can be especially frequent.

An example of the implication of changes to standards was provided in the laptop case study where a large multinational had to withdraw a specific desktop PC model that did not meet Amendment 1 of standard IEC 60950-1, a standard set of electronic safety requirements. Similarly, a manufacturer of air-conditioners estimated that it will need to use 75% of its development resources over a 12-18 month period to make necessary adjustments to meet the recently introduced requirements for fans under the Ecodesign Directive.

After the initial adjustments are made, the burdens associated with the Directive are expected to significantly reduce. A lift manufacturer suggested that any technical adaptation required by the legislation would cost around €500k-€1m in terms of new product development. Such costs would relate to ensuring conformity of design, a physical examination of 8-10 different product platforms to be certified but also additional documentation for the conformity assessment process, costs for sales companies, training for sales and production staff, updating sales literature.

Moreover, economic operators referred to additional risks arising for R&D and early stage product development investment if they do not know how IM legislation will develop over time, and the form that its implementation may take in future. It is difficult to provide typical values of substantive compliance costs across the whole industry. They vary depending on the product category and the firm strategy. The following table provides some illustrative examples from the case studies.

Table 5.3: Examples from the case studies – compliance with the applicable legislation

[59] We should note though that the product development cycle varies among sector. For example, in the case of laptops it is typically no more than 6 months, while in the case of air-conditioners it can be up to 3 years.

Product category	Example(s)
Domestic Refrigerators	A large firm typically spends 1-1.5 year FTE / firm, 80-90% of which is allocated to product development and product quality testing. Another large firm indicated that a typical product development project - leading to the development of a basic model with multiple variants – takes 3 years and requires and a budget of up to €100 million.
Gardening equipment	A large firm producing close to one million units indicated that around 3% of annual R&D budget of €50-60 million that is invested to the development of a new product is directly related to ensuring compliance with internal market legislation (circa €4 million). A small firm producing 15,000 units indicated investments for product design of €200-300k
Pumps and dispensers	A large producer of pumps and dispensers (over 1000 employees) estimated total compliance costs of €3.2m over the last five years, €2m on changes to product design and €1.2m to production processes.

5.2.3 Conformity assessment procedures

The conformity assessment procedure most commonly followed by manufacturers interviewed was the Supplier's Declaration of Conformity (SDoC). Among the steps needed as part of conformity assessment are carrying out product testing, the preparation of the technical file and the preparation of the DoC and the required information manual and CE marking. For product groups that have legislation that requires mandatory third party testing, an inspection by Notified Bodies and appropriate certification is required.

According to the common requirements set out in Decision 768/2008/EC, following the placing on the market, this information needs to be kept for 10 years following the placing on the market and to be updated whenever there are changes. This can require significant time and resources, for instance, checking and updating DoCs every few months, as and when legislation and standards are updated.

Significant time is often dedicated to the collection of information from suppliers of specific components or finished products. The estimated time for the preparation of a technical file for a gardening equipment product ranges from 40-100 hrs. The costs for conformity can vary depending on the need or not for third party certification. The data from the case studies suggests that the annual budget of firms for services of Notified Bodies is in the range of €30-80k, around €4,000 for certification of a single product and representing 20-25% of the total estimated costs for compliance. Similar figures were provided by manufacturers of fuel dispensers. Manufacturers of fuel dispensers – a product that requires third party certification - estimated that Notified Bodies fees represented 55% of the conformity assessment costs, 35% relating to initial inspections and 20% to periodic inspections. Data from the evaluation

of the Gas Appliances Directive[60] also refer to certification costs in the range of €1000/product. However, the input from a number of firms (gardening equipment, air conditioners, refrigerators) is that firms use NBs services to support them in testing and ensuring compliance even when third party certification is not mandatory.

The provision of relevant information in the instruction manuals and translation costs are also part of the administrative costs. Data for translation costs of these manuals to cover all EU countries ranged around €3,000 for each gardening equipment model. It should be noted here that every change to relevant standards or requirements lead to costs for the replacement of manuals. A producer of domestic appliances selling around 2 million units indicated that every time there is new legislation new information manuals need to be printed. The estimated cost at an annual basis was around €100,000k/year.

Sectors covered by the Outdoor Noise Directive (e.g. gardening equipment) need also to submit information included in the DoC to the national and European authorities. Estimates from the gardening equipment case were that it took approximately 80 hours for the 20 different models in its production line. The REACH Regulation and the RoHS Directive do not directly affect firms in the manufacturing sector that are downstream users. The main task is the collection of information from suppliers so as to ensure that no substances of high concern are included in any component.

Some large manufacturers may test components but more typically, the approach followed is to request and collect appropriate certificates from suppliers, to allocate part of a FTE on an annual basis for this activity. According to the recent review of the REACH Regulation[61], 50-70% of downstream users of chemicals (mostly in the non-food manufacturing industry with the exception of chemicals and plastics) have experienced an increase in the costs of managing information along the supply chain, typically in the form of additional workload for existing staff (small firms) or the hiring of extra staff (large firms).

As in the case of product design and testing, additional costs may also arise from the changes to regulatory requirements and the updating of relevant standards. There is a need to adopt information manuals and technical files. This can be particularly problematic for small firms that do not have the structures and mechanisms to follow developments on an on-going basis. The feedback provided suggests that it is mainly these changes that create important adjustment costs rather than the actual information obligations. This is seen as particularly problematic for small firms.

Frequent changes make the legal environment unpredictable but also introduce costs – sometimes sizeable – for firms that try to follow all development and to fit their information collection systems to the information obligations. The feedback provided suggests that it is mainly these changes that create important adjustment costs rather than the actual information obligations. This is seen as particularly problematic for small firms. It was noted that regulatory changes for IM legislation are less frequent than changes to environmental legislation. However, the interaction between and cumulative regulatory effects associated

[60] RPA (2011), Ex-Post Evaluation of the Gas Appliances Directive: http://ec.europa.eu/enterprise/dg/files/evaluation/03_2011_finalreport_gas_en.pdf
[61] CSES (2012), Functioning of the European chemical market after the introduction of REACH http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/review2012/chemical_market_en.htm

with the two can sometimes lead to additional administrative costs for industry.

A further finding was that although economic operators may not always be able to quantify costs, most firms were able to comment on the level of staffing involved and the broad cost parameters. There were however concerns regarding those areas of the regulatory framework where there is potential future uncertainty for economic operators with regard to the future costs of compliance, such as REACH. Given the very significant level of investment and long lead times required in order to bring some types of new products to market, there are concerns that the situation may change in the interim with potentially very high costs for industry.

Table 5.4: Legal uncertainty for downstream users – laptops case study

A large global components manufacturer in the electronics sectors expressed concern as to whether particular chemicals would still be in use in 10 years' time, and whether if not, substitute products are likely to be available. Product R&D operates according to long lead times and significant investment in the product development cycle is required to bring new innovative products to market. Economic operators, especially larger companies operating globally have to be inherently forward-looking in assessing how the regulatory landscape will evolve over time. The firm interviewed commented that "there is a great deal of legal uncertainty from a downstream user perspective. There is a substance called gallium arsenide and currently microchips cannot be made without it, but there is no viable substitute product. The substance is currently being reclassified under the CLP 5th ATP. There is a risk that the substance could be fast-tracked to being subject to an authorisation, which would impose major costs on industry. If a particular substance requires authorisation or is banned, then this could really disrupt the supply chain, and lead to legal uncertainty. REACH is delivering in terms of identifying harmful substances, but there should be a greater focus on assessing the impacts on impacts on downstream users."

5.2.4 Estimates of costs at sectoral level

On the basis of data inputs from firms across the eight sectors examined, we estimated compliance costs – administrative and substantive – at a sectoral level. In the table that follows, we provide summary information drawing on the data from the case studies focusing on:

- Total annual compliance costs (excluding business as usual costs) and their share in the sector turnover;
- The main cost drivers (phases of the process, type of activity) of administrative costs.

Various caveats should be added before presenting the summary findings with regard to the costs of compliance of IM legislation across 8 harmonised product groups. Firstly, there were difficulties in obtaining reliable quantitative data on cost parameters across all variables. Secondly, there were specific issues and assumptions made regarding cost drivers for each

case study. These are indicated in the footnotes in Table 5.5 that provide an aggregate of sectoral cost estimates for each case and explained in greater detail in the respective case studies in Annex C.

The total estimated annual costs of compliance of IM legislation across the 8 harmonised product cases were estimated at €342 million.

Table 5.5: Summary of findings – the annual costs of compliance of IM legislation across 8 harmonised product groups

Product group	Total annual compliance costs for the sector and share in annual turnover (%)
Electric motors	€ 33.2 million 0.3% of annual turnover
Laptops	€ 28.1m 2.0% of annual turnover
Domestic refrigerators/freezers	€ 86.0 million 0.4% of annual turnover
Lifts	€ 26.0 million 0.9% of annual turnover
Gardening equipment	€ 98.5 million 3.9% of annual turnover**
Petrol pumps	€ 12.2 million 1% of annual turnover
Air conditioners	€ 50.1 million 1% of annual turnover
Integrated circuits	€ 7.7 million <0.1% of annual turnover
Total	€ 342 million

**Notes (i) the reasons for this outlier are explained in the case study on gardening equipment (ii) reference should be made to the footnotes in the case studies setting out the quantitative findings in all cases, since the assumptions made underlying the data, any gaps and imputations used for particular cases needs to be spelled out.*

It is also important to note that it has not always been possible to clearly distinguish between administrative and substantive compliance costs in the quantitative assessment. There are grey areas where the delineation between different types of costs is unclear. For example, while conformity assessment costs are classified as being substantive costs, there are aspects of conformity assessment where administrative costs are incurred in parallel, such as the preparation of a technical file. These were explained in greater detail earlier in section 5...?. Where possible to do so, a differentiation between the two was made in individual case

studies.

This being said, we can still observe wide divergence in compliance costs between different harmonised product groups. In most cases, total annual estimated compliance costs do not exceed 1% of annual turnover. The notable exceptions in this regard were gardening equipment (3.9%) and laptops (2.0%). The explanatory factors as to why compliance costs were higher in these sectors were explored through the research. In the case of gardening equipment, the higher level of compliance costs was mainly because of the costs associated with environmental IM legislation (the Outdoor Noise Directive, non-road mobile emissions). In contrast to safety-related requirements which are very often considered to be "business as usual", costs of compliance with environmental legislation are considered additional for the firms in the sector and, according to most firms, rather demanding, particularly in terms of the testing required.

For gardening equipment, administrative costs were found to be only a small part of total compliance costs. This seems to be the case generally for many consumer products (gardening equipment, domestic refrigerators and air conditioners). Substantive compliance costs are the main driver of compliance costs because important aspects of product design and testing for safety are not considered by firms to be business-as-usual costs. In comparison, in the case of the lifts and electric motors, both products primarily addressed at professional users, substantive compliance costs (product design and testing) are generally considered to be business as usual and, as a result, the main focus of firms is on the administrative costs of the legislation,

In the case of laptops, the estimates provided may over-estimate the total compliance costs associated with Union harmonisation legislation. Since the industry is dominated by a small number of global manufacturers, it was difficult for them to provide compliance costs disaggregated by geographic region because they tend to design products for global markets and sometimes for multiple – or at least dual – regulatory requirements with some customisation of the product itself to local markets.

Ecodesign was perceived as costly by some manufacturers that took place in the electric motors case study. However, there was found to be a difference between perception amongst industry about the main cost drivers in terms of the type of legislation, and the actual costs. The Ecodesign Regulations do not require all products to be redesigned, only the lowest-performing electric motors (typically 20% of existing models). Since other major global jurisdictions, such as the US, already had strict requirements, many motors already complied and the Ecodesign regulations has simply prevented the dumping of poorly efficient electric motors on the EU market. Compliance costs only equated to 0.3% of turnover in the electric motors sector.

5.2.5 Compliance costs by firm size

There were differences between firms in the level of compliance costs (administrative, substantive) by firm size, although this was difficult to substantiate based on the limited numbers of SMEs that agree to take part in the study. SMEs were found to experience significantly higher costs / unit for regulatory compliance compared with large firms that are better able to spread the costs across a high number of units. SMEs also appear to have a higher percentage of staff involved in compliance-related activities (familiarisation, testing)

than large firms, although few are able to have individual staff members working full-time on compliance. Micro and small firms were also more likely to have to rely solely on external third party conformity assessment since many do not have their own in-house laboratory and testing facilities.

SMEs are also at a comparative disadvantage because large firms follow EU legislative-making and standardisation development processes more closely. As a result, they are more aware about proposed changes to IM legislation in advance and can factor in anticipated regulatory requirements prior to new IM regulatory requirements coming into effect at the product design stage, which lowers substantive compliance costs. Even if the number of SMEs that participated in the case studies was limited, the quantitative findings on compliance cost differentials were substantiated by a number of SME and industry associations in particular sectors (e.g. lifts, air conditioning).

The administrative burdens of compliance with Union harmonisation legislation were sometimes found to be disproportionate for micro enterprises. For instance, any manufacturer wishing only to place a product on the domestic market must still comply with IM legislation (including DoC and CE marking requirements) if their product is in the harmonised sectors. An example cited by a European SME association of the burdens were the Finnish woodcutters, where micro enterprises of 2 persons only producing products for the local domestic market had to go through the conformity assessment procedures and to CE mark, even though the products were sold untreated. Nevertheless, they are still subject to the REACH Regulation.

5.2.6 Costs for public authorities of monitoring product safety and regulatory enforcement

This study has not allowed for quantification of expenditure on national support mechanisms, structures and activities to support the implementation of Union harmonisation legislation, such as on market surveillance. However, some data was available in this regard through previous studies and impact assessments.

As far as public authorities are concerned, the available estimates on the number of product safety enforcement activities provided by national authorities suggest that a total of 3,000-4,000 product inspectors across EU28 are engaged in market surveillance and regulatory enforcement activities, with an annual budget of enforcement activities in the range of €100-150 million[62]. These figures are quite a high estimate, as they include enforcement activities relating to non-harmonised products. In addition, in order to assess the overall costs of the implementation of Union harmonisation legislation, other costs related to national implementation are the human resource costs for policy coordination through the role of national competent authorities, for instance, in the transposition of IM legislation, in the appointment of Notified Bodies, etc.

The feedback provided points to market surveillance as being the most resource-intensive aspect of the implementation of IM legislation for public authorities. From the small number

[62] Commission Staff Working Document - Annexes to the Impact Assessment Accompanying the document : Product Safety and Market Surveillance Package,
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2013:0033(52):FIN:en:PDF

of Member States that provided data on the resources allocated to IM legislation, more than 80% appears to be allocated to market surveillance activities. Compared to the situation prior to the introduction of the IM legislation, national authorities may have experienced some cost savings. According to the evaluation of the MID, for instance, many authorities indicated a substantial decrease in their workload in terms of dealing with applications for national certification. This reduction was most notable in countries with a small number of manufacturers of measuring instruments or where measuring instruments are imported on the basis of certification undertaken in other countries.

5.2.7 Conclusions on the costs of compliance with IM legislation for industrial products

Whilst most manufacturers could highlight the most costly compliance steps and pieces of legislation, few were able to quantify the costs incurred at each step with any accuracy. However, as the overall volume of IM legislation has grown, it was clear that the task of ensuring compliance with legislation and technical requirements set out in harmonised standards is resource-intensive.

A certain proportion of compliance costs were 'BAU' and would have been incurred by industry regardless as to whether there was a European regulatory framework in place. Many firms have well-developed internal safety testing procedures as part of quality assurance procedures and use third party testing for reputational reasons, even where not mandatory.

In all sectors, the process of adaptation to new technical requirements can be costly for manufacturers short-term, particularly when the transition period is relatively short. In the long-run, substantive compliance costs fall over time as manufacturers become more familiar with the requirements of the legislation. Industry is highly familiar with compliance requirements for long-established directives, such as the Machinery Directive, Low Voltage Directive and EMC Directive. Since the technical standards and administrative requirements are well-known, these can be factored in to design requirements from the outset.

Some legislation is more costly than others to implement. Ecodesign implementing regulations were often mentioned as costly, both because of the need for changes to be made to the worst-performing products. However, it should be noted that under Ecodesign Regulations, this does not mean redesigning all existing models, rather only the worst-performing, typically 20% of existing models. Moreover, products that have already been placed on the market are not effected by ecodesign; components and parts are not a specific aspect: ecodesign requirements are generic to the whole product. Substantive costs vary by sector. In sectors characterised by rapid technological innovation, the substantive requirements can usually be "designed into" the product; in that sense, the legislation sets parameters regarding what is possible without increasing the costs of design and production.

In other sectors, substantive costs tend to account for a relatively high proportion of total compliance, depending on the duration of the product lifecycle. For example, it is more difficult for manufacturers of products with a long lifecycle because they are more likely to have to make modifications – or to identify alternatives or substitutes - to products already on the market. This is more costly than factoring these into the initial design phase during the R&D process.

It is also worth noting that there has been a gradual accretion of IM legislation in the previous

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25 years and this has led to cumulative effects of regulatory compliance. While it has long been the case that multiple pieces of legislation may be applicable to a given product, when the New Approach was first adopted, it was perhaps not foreseen that the body of internal market legislation would grow to the level that it has. Moreover, the past decade has seen the introduction of a number of IM directives and regulations that apply horizontally across all product groups (e.g. REACH, RoHS, Ecodesign and Energy Labelling). The cumulative effects of regulatory compliance stem from the fact that manufacturers of industrial products must comply with a growing body of internal market and environmental legislation. It is the cumulative frequency of these changes and updates to legislation itself and to (voluntary) technical standards that result in cumulative effects and impose additional costs, for instance, familiarisation time to keep track of changes, integrating new requirements into R&D and the product design phase, making modifications to products already on the market.

Research Findings (RFs)

- (RF70) Familiarisation with the legislation accounts for a significant proportion of the total costs of compliance, estimated at around 15-20% for many firms. Much of these costs are in the form of staff time, around 2-4 FTEs in a typical large firm and >1 FTE in an SME.
- (RF71) Ensuring compliance with IM legislation is sometimes a key driver of R&D and testing activities or may be only one among a number of considerations in new product development
- (RF72) Testing equipment can account for massive costs that manufacturers might not otherwise incur. These affect SMEs disproportionately, as the cost is spread over at lower volume of production.
- (RF73) In the long-run, a high proportion of substantive compliance costs are integrated into firms' product design cycles and are therefore negligible. In that sense, the legislative requirements tend merely to set parameters around what is possible rather than imposing additional substantive compliance cost
- (RF74) In contrast, frequent changes to legislative requirements and standards can impose sizeable adaptation costs on industry, albeit one-off and short-term in nature.
- (RF75) A significant proportion of the costs of conformity assessment relates to the task of collecting information from suppliers, preparing technical files, checking and updating DoCs and maintaining technical files for 10 years. Such costs are greatly increased when there are changes to the legislation or the standards.
- (RF76) The costs of conformity assessment depend very largely on the need for third-party certification. Certification of a single product typically costs around €4k in NB fees, though annual certification of systems would be much higher.
- (RF77) In most sectors the costs of compliance do not exceed 1% of annual turnover, provided that much of the costs of product design and testing for safety can be considered business-as-usual costs.
- (RF78) SMEs experience higher compliance costs relative to their turnover, though few have individual staff members solely devoted to compliance. They are also more likely to rely on external third-party conformity assessment and less likely to follow and participate in the process of developing legislation and standards at EU level.

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- (RF79) Market surveillance activities are estimated to occupy 3,000-4,000 product inspectors across EU28 at a cost of around €100-150m per annum. This accounts for around 80% of the total cost to national authorities of developing, implementing and enforcing IM legislation.
- (RF80) The gradual accretion of IM legislation has required manufacturers to comply with a growing body of internal market and environmental legislation. Frequent updates to legislation itself and standards risk imposing cumulative costs, for instance, related to familiarisation time to keep track of changes, integrating new requirements into R&D and the product design phase, making modifications to products already on the market, updating DoCs, etc.

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5.3 Scope for regulatory and administrative simplification

EQ21: How far is there scope for administrative and regulatory simplification of Union harmonisation legislation? To what extent is there scope for merging different directives?

Although there was some support among stakeholders for the possible merger of specific pieces of IM legislation, stakeholders had differing views as to whether simplification was possible at all, and whether this would result in benefits, or simply risk making the regulatory framework more complex, with additional familiarisation costs for economic operators, at least in the short-term.

Through the research, a number of examples were identified where consideration could be given to the potential merger of specific IM directives and regulations in order to reduce the overall volume of IM legislation as part of a streamlining process. These are described in the table below.

Table 5.6: Possible simplification measures – mergers of directives

Type of simplification	Example	Key issues and possible simplification
Merger	Merging the Pressure Equipment Directive (97/23/EC) with the Simple Pressure Vessels Directive (SPVD)	There is support for merging the PED with the SPVD among some industry stakeholders but mainly national competent authorities. National officials would likely benefit from having to a single piece of legislation rather than two frameworks for pressure equipment. However, others favour retaining the status quo since simple pressure vessels currently benefit from a lighter regulatory regime. This issue was examined through the Evaluation of the PED[63] (CSES, 2012).
Merger	The Machinery Directive and Directive 2000/14/EC on Noise from Outdoor Equipment	The scope for merging the MD with Directive 2000/14/EC is under review. A technical study has been launched. A public consultation was carried out in 2010. Among the proposals under consideration are: simplifying the legislation by proposing revisions concerning noise data collection and methods of measurement.
Merger	EMC and the Machinery Directive	This was suggested by a minority of respondents to the Your Voice consultation.
Merger	RoHS and REACH	Both Directives apply to electrical and electronic equipment. Many stakeholders favour a merger or at least clarification of the relationship between

[63] http://ec.europa.eu/enterprise/dg/files/evaluation/evaluation-of-the-pressure-equipment-directive_en.pdf

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Type of simplification	Example	Key issues and possible simplification
		the RoHS and REACH, as well as better co-ordination between those involved in implementation of the two pieces of legislation.

The broad scope of this study does not allow for a detailed assessment of the feasibility of **merging different pieces of IM legislation for industrial products**. Given the complexity, a technical study would need to be carried out in respect of each proposed merger, supported by appropriate industry consultation. Indeed, this has already been recognised by the Commission and the **potential merger of the Machinery Directive and Outdoor Noise Equipment Directive** is the subject of a current study and stakeholder consultation. Although the report is not yet available, our interview with the Commission official in charge of the study indicated that at interim report stage, there is no clear consensus among stakeholders as to whether the two directives should be merged.

This finding was echoed in our study through the interview feedback. There were concerns among national competent authorities for instance as to the feasibility of combining these directives. For example, an MSA responsible for Directive 2000/14/EC in Italy was against the possible merger. "Although a merger could theoretically be possible, differences in the aims of the two pieces of legislation should be carefully considered. Whereas Directive 2000/14 seeks to reduce noise pollution and to protect the environment, Directive 2006/42/EC seeks to protect the safety of workers and users of the machinery". Moreover, in Italy, there are differences in the remit of the relevant competent authority responsible for Directive 2000/14/EC (Ministry for the Environment) and Directive 2006/42 (Ministry for Industry) respectively. Combining the two Directives was viewed as risking undermining market surveillance, because the existing enforcement framework reflects the different objectives established in both directives. In this case, a merger may not result in regulatory simplification and easing the work of enforcement authorities.

There is a need to reconcile two different internal market approaches since the Machinery Directive is one of the earliest 'New Approach' Directives whereas the Outdoor Noise Directive follows the 'global approach' concept. Practical challenges here are that whereas the MD focuses on horizontal risks and on extensive, broad-based 'families of products', the Outdoor Noise Directive follows a product-based approach. A further issue is that the MD works on the basis of manufacturers following voluntary harmonised standards whereas the Outdoor Noise Directive operates on the basis of "limit values".

There has also been a debate about the possibility of **merging the Directive on hazardous substances (RoHS)[64] and the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH),[65]** since both apply to electrical and electronic equipment. For example, the potential duplication of restriction procedures and criteria between RoHS and REACH has been highlighted, and similarly parallel systems for the assessment of chemical substances by chemicals specialists has emerged. This creates a risk

[64] Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment

[65] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

of inappropriate assessment of substances, unnecessary administrative burdens and conflicting requirements. Here, further future legal clarification would be useful, as and when further experience from REACH implementation is available.

Orgalime, the European Engineering Industries Association, had a similar view, and called for better coordination and structured, continuous communication between the different actors involved in the implementation of both pieces of legislation. They also stated that a clear decision is needed from EU regulatory authorities regarding the procedure that will apply in each case and consistent application of this decision by all bodies responsible for implementing REACH and RoHS.[66]

In response to these concerns, the Commission confirmed that when overlaps occur, the strongest restriction (i.e. the lowest maximum concentration) should be applied and that exemptions from the substance restrictions in RoHS 2 (as the 2011 recast to the 2002 RoHS Directive is known) may not be granted if they result in a weakening of the environmental and human health protection afforded by REACH. The Commission has also stated that a thorough analysis of the coherence of RoHS2 with REACH will be undertaken as part of the first review of RoHS 2, which is due by July 2014.[67]

However, it should be noted that the Commission officials interviewed from DG ENV were not in favour of such a merger, partly because of their position that there are major differences in aims and scope between REACH and RoHS, but equally because the RoHS Directive 2002 was recently recast. Indeed, although the RoHS Directive 2011/65/EU (RoHS 2) entered into force on 21 July 2011 and required Member States to transpose the provisions into their respective national laws by January 2013, so the new provisions have only just come into effect.

A further measure that could be adopted would be to **widen the scope of existing IM legislation to include further product groups**, both those already covered by IM regulations in principle, but where there is a lack of legal clarity as to whether they are included. Similarly, certain products may currently be excluded from the scope of certain directives and the rationale for including them may need to be strengthened over time.

There are clear **benefits for industry in the Commission providing non-binding supporting guidelines that provide information on the scope IM of directives and regulations, and ensuring that these are regularly updated.** This is particularly the case when 'grey areas' are identified where there is a perceived lack of legal clarity. This can lead to confusion as to which legislation should be applied and / or how legislation should be applied by enforcement authorities and manufacturers.

An example of a product group where there has been uncertainty as to which is the applicable legislation is 'cylinders for breathing apparatus', since these fall under both the Pressure Equipment Directive (PED) and Transportable Pressure Equipment Directive (TPED). This piece of equipment has been subject to much debate in relevant European level working groups and evidence has been presented that industry has struggled to understand which

[66] Orgalime Position Paper (2013), Ensuring a truly complementary, coherent and consistent implementation of REACH and RoHS2
[67] http://ec.europa.eu/environment/waste/rohs_eee/pdf/faq.pdf

legislation applies and which approach they should take to ensuring compliance. In response, the Commission Legal Services (CLS) has produced a written legal opinion on the question of whether cylinders for breathing apparatus are covered by the PED. It concluded that they are covered, but they could also be covered by the TPED rules as long as they don't fall within the PED exclusions. The Commission has suggested that they will produce a guidance note based on the CLS view and this will be drafted and agreed by the appropriate Working Group.

Although feedback suggests that industry and SMEs find the guidance very useful, some stakeholders commented that guidance to support the implementation of specific IM directives and regulations should be updated on a more timely and frequent basis in order to ensure that it remains fully up to date. The provision of **legal clarifications in areas identified through this study as being grey areas, and the** should help to provide better guidance for manufacturers in areas where there are grey areas, or where there is confusion among economic operators. However, it would be in the Commission's interest if responses such as these can be quickly developed in order to meet the needs of authorities and manufacturers.

In a similar vein, as noted in the section dealing with components and spare parts, our research found that there could be a strong rationale in having a more common approach to definitions and to their inclusion across IM legislation. This would help to strength the legal certainty of directives and clarify the scope of the terminology. In line with comments received from the air conditioning industry, prior to the introduction of legislation, research should be undertaken by the Commission on understanding the existing framework so common definitions can be immediately drawn upon with a view to ensuring that the legal text is immediately understood by all market participants.

An area where the scope of legislation could be extended relates to offshore equipment. Given the increasing risks relating to the work of the offshore industry, a number of industrial product directives are being considered for extension to the sector in areas where they do not currently apply. This includes the ATEX Directive, Machinery Directive and Pressure Equipment Directive. A study is underway to explore the impact of the extension[68].

In terms of widening scope of IM legislation, there clearly needs to be strong consideration of impacts and whether benefits are incurred for industry and users. It is likely that extending the scope may not result in simplification for all segments of industry specifically those that solely manufacture products under alternative arrangements. Often, benefits will be incurred in terms of strengthening safety and environmental protection but not in terms of lightening the regulatory load for industry.

Research Findings (RFs)

- (RF81) There may be scope for merging different pieces of legislation, such as PED and SPVD, MD and OED, MD and EMC, and RoHS and REACH, although this will require

[68] Study on the impacts of possible amendments to the ATEX Dir. 94/9/EC, the Pressure Equipment Dir. 97/23/EC and the Machinery Dir. 2006/42/EC with respect to equipment intended for use in the offshore oil and gas industry

in-depth consideration on a case-by-case basis.
- (RF82) Consideration of merging directives should take into account the differences between horizontal and product-specific harmonisation legislation.
- (RF83) Widening the scope of existing IM legislation to include additional product groups, particularly where there is a lack of clarity, may increase certainty for operators and thus help reduce costs of compliance.
- (RF84) There are clear benefits for industry from the Commission providing non-binding supporting guidelines that provide information on the scope IM legislation, particularly in any 'grey areas' where there is a perceived lack of clarity.

5.4 Benefits of simplifying administrative requirements

EQ22: How far will administrative simplification bring about benefits for economic operators in terms of reduced administrative burdens?

Regulatory and administrative simplification – and greater consistency in requirements between IM legislation – should in principle lead to cost savings for economic operators (EOs) through reduced compliance costs. It is important to scrutinise possible simplification measures carefully, since there could be unintended consequences that may serve to increase administrative burdens and/or limit the scope for flexibility of economic operators, as well as reduce the effectiveness of the legislation (for example, in respect of product safety). There can also be unintended consequences that are the opposite of the good intentions of the regulator. Specific examples are now provided:

Table 5.7: The simplification of DoCs – advantages and disadvantages

Simplification	Expected benefits	Potential disadvantages
Decision 768/2008 – common template for declaration of conformity Requirement that manufacturers should produce a single DoC	Eliminate inconsistencies between DoCs under different IM directives and regulations Common template would mean less familiarisation time for EOs.	Less flexibility for EOs If a single DoC is produced, then the DoC may have to be updated more frequently.

Taking the example above, in Decision 768/2008/EC, there was a proposal that for manufacturers should be required to produce a single DoC covering all applicable IM legislation, although this should in theory help to reduce burdens for manufacturers. However, industry stakeholders were against the proposal even if it is designed to help reduce their administrative costs. Industry associations interviewed were strongly in favour of retaining the current flexibility to decide either whether to produce a single DoC covering all applicable IM legislation or instead multiple DoCs for each separate directive and regulation applicable. This is an example of where administrative burdens on firms could paradoxically be increased, especially for SMEs.

The rationale was driven by a concern among manufacturers of minimising cumulative

regulatory effects. Since there is a requirement in IM legislation and under the NLF to regulatory review and update DoC, their view was that If multiple legislation is applicable to a given product, and the manufacturer also decides (voluntarily) to list the technical standards used to achieve conformity with particular pieces of legislation, then the DoC has to be changed frequently, due to the cumulative frequency of legislative updates and amendments of technical standards.

In the next example, we examine the issue as to whether less legislation means that the costs for manufacturers and other economic operators are reduced. This might be said to be the **simplification conundrum**.

Table 5.8: Simplification – does less legislation mean less cost?

The **laptops case study** provided an example of a product group where there are **alternative routes to compliance with Union harmonisation legislation**. Manufacturers of laptops choosing to define their product as a radio product follow the R&TTE Directive whereas those that adopt a modular approach to compliance will comply with the R&TTE, LVD and the EMC separately. In practice, though, since the essential requirements under the LVD and EMC are already included within the R&TTE Directive, the manufacturer still checks for electrical safety and electromagnetic compatibility. The fact that manufacturers can in effect choose between different Directives to achieve regulatory compliance allows consideration as to whether a situation in which less regulation is applicable to a given product would result in cost savings for manufacturers. Among the findings were that broadly similar administrative requirements and testing as part of conformity assessment procedures will apply irrespective of whether one piece of legislation has been applied or three pieces of IM legislation separately. **Potential cost savings and impact of "simplification":** since manufacturers have different preferences, and both advantages and dis advantages can be identified of following a modular approach or the R&TTE-D alone, it is not possible to quantify the cost savings of a simplification measure in which only the R&TTE-D was applied. Indeed, manufacturers **prefer retaining the flexibility of different routes** to regulatory compliance. Although some benefits were identified of only following one piece of legislation, such as clear legal certainty that the manufacturer is solely responsible for legal compliance, there were **no cost savings per se**. Product testing, for instance for electrical safety, have to be performed irrespective of which route to compliance is adopted.

As noted earlier, the research identified examples of IM regulations where there may be scope to merge directives and regulations in future, such as the Machinery Directive and Outdoor Noise Directive, the Pressure Equipment Directive (PED) and the Simple Pressure Vessels Directive (SPVD). In assessing the potential benefits, there was a need to consider whether there could be cost savings for manufacturers resulting from the merger of IM legislation.

Mergers of IM legislation can be helpful in reducing **the cumulative effects of legislation**. However, combining legislation does not necessarily mean that manufacturers benefit from

cost savings. Indeed, it is difficult to make generalisations about whether merging Directives when there is scope to do so will necessarily lead to cost savings and is always the best approach. This is highly specific and depends on the objectives (e.g. safety and health, environmental) level of risk, and conformity assessment procedure applicable to the IM regulations in question that are under consideration to be merged.

As shown in the table illustrating alternative routes to compliance for the laptops case study, the extent of cost savings will depend on whether mergers of Directives involve substantive changes or are largely cosmetic in nature. Following a merger of IM legislation, similar requirements may still apply irrespective of the number of individual pieces of legislation applicable. For example, in the automotive sector, in order to bring about regulatory simplification, about fifty different Directives were revoked by one umbrella Directive and replaced by the direct application of the internationally harmonised UN Regulations. However, the regulatory fitness check of the type approval legal framework found that most manufacturers consider this change to have been largely cosmetic, since it has not led to any changes in the requirements themselves, or in the number of pieces of legislation involved. There can also be execution risks, since changing the structure of legislation requires additional familiarisation time for manufacturers with the new structure of the legal framework[69]

There are potentially risks in merging Directives in instances where the merger of two Directives may mean that the resulting legislative and conformity assessment requirements becoming more demanding than was previously the case. For instance, the current requirements for Simple Pressure Vessels are less strict in terms of the conformity assessment procedure that can be applied than for the PED. If the two were merged, then some manufacturers that apply the SPVD expressed concern that those producing only Simple Pressure Vessels may be subject to stricter requirements than they currently are.

Some manufacturers already apply the PED to manufacturing all types of pressure equipment and in this case merging the directives would not result in any changes per se. It would seem that the main benefits in this area would be to simplify the legal framework for authorities responsible for enforcing the directives and to strengthen the safety of pressure equipment for users (this last aspect is a key issue given the relocation of some parts of industry to areas outside Europe and the observation made in some quarters that non-conforming products imported from third countries have been identified on the Internal Market).

With regard to the possible merger of the Machinery Directive and Outdoor Noise Directive, it remains unclear if the latter Directives were to be merged with the MD which conformity assessment procedure would be adopted, and whether the Supplier's Declaration of Conformity, which is the mechanism allowed under the MD) would also apply for the Noise aspects, were these to be merged. Even if the SDoC approach were to be permissible for outdoor noise, there is not yet sufficiently robust data to show that third-party testing is more expensive than internal testing (often with some external observation) under the SDoC, which makes it difficult to quantify the potential cost savings.

Moreover, the cost differential with SDoC is not always clear cut, because many global

[69] CSES (2013), Fitness Check of the EU legal framework for the type-approval of motor vehicles.

manufacturers use third party testing anyway for reputational reasons and because third party testing results may be required and recognised on third country markets. In the short term, paying a consultant or Notified Body to carry out some tests is less costly than acquiring the necessary laboratory equipment and paying the recurrent costs (annual costs of calibration). There is also a need to invest in human resources to carry out testing internally.

Although on the one hand, making Union harmonisation legislation as consistent as possible between IM legislation is strongly supported by industry, given that industry is broadly satisfied with the current approach to regulating industrial products and placing products on the Internal Market, there are concerns about pursuing a regulatory simplification agenda if this were to radically depart from the current approach, which is one driven by flexibility and pragmatism.

In summary, the following potential costs and impacts might be expected to arise from the simplifications described here:

- There could be cost savings from **merging specific Directives**, but this depends on what form the combined IM regulations take, the conformity assessment system agreed and whether this differs from what preceded it, etc. It is therefore difficult to quantify and the benefits to industry may be spread unevenly if manufacturers are currently afforded the opportunity of currently selecting alternative regulatory routes. However, clear savings would be possible, where a single conformity assessment process can replace separate processes for each piece of legislation.

- **Reduced cumulative impacts of IM legislation through merging different pieces of legislation** - e.g. reversing the trend towards the gradual accretion of IM legislation which has led to cumulative costs (including those that arise from the updating of IM regulations and frequent changes in harmonised technical standards[1] the familiarisation costs). However, since the safety and technical requirements for more established New Approach Directives are well known to manufacturers, the savings might in practice be quite modest.

- **Lower costs of familiarisation** – reducing the volume of IM legislation through merging different pieces of legislation, would in time savings for manufacturers since they would have to follow less legislation. However, in the short term, at the point when Directives are merged, there may conversely be an increase in the amount of time required for familiarisation with applicable regulations. Benefits may result in the longer if manufacturers and authorities are required to take into account fewer pieces of legislation as part of their daily remit.

It should also be taken into account whether mergers reduce the overall regulatory complexity for stakeholders by reducing regulatory burdens or whether mergers benefit certain groups and not others e.g. a merger may not reduce the technical complexity for manufacturers but may add to the existing workload of public authorities since they would have to familiarise with the new legislation and then still to check all the requirements. This depends on the precise configuration of proposed mergers, whether the integration of the legislative is cosmetic (e.g. when the manufacturer still have to require with broadly the same requirements irrespective of whether multiple piece of legislation apply or only a single piece

of legislation.

Research Findings (RFs)

- (RF85) Where the legislation is simplified, e.g. through mergers of directives, economic operators may benefit from reduced costs of compliance through having to familiarise themselves and comply with fewer pieces of legislation and from streamlined conformity assessment procedures.
- (RF86) Any proposed simplification of the IM regulatory framework must be strongly evidence-based and supported by extensive industry consultation. Otherwise, there are risks that the regulatory framework which currently affords considerable flexibility for manufacturers and is effective in accommodating innovation could become less flexible, as well as the risk of unintended effects.
- (RF87) There are concerns that the possible merger of directives such as the MD and the Outdoor Noise Directive and of the PED and the SPVD could lead to more complex procedures form some types of products and be confusing for industry
- (RF88) Although mergers of directives may in some instances result in cost savings and other benefits, equally, in other cases, simplification may paradoxically lead to additional complexity for manufacturers. In addition, given that IM directives aim for a high level of technical safety, revising standards to be met in this area would ultimately undermine one of the key objectives of the legislation and the generally high levels of user satisfaction that have been attained.

5.5 Quantification of the benefits from simplification of Union harmonisation legislation

EQ23: To what extent can the benefits of administrative simplification be quantified?

Notwithstanding the difficulties identified in assessing the benefits of simplification outlined in Section 5.1, the evaluation considered the extent to which it may be possible to quantify the benefits of these simplifications. Some manufacturers and industry associations had useful contributions to make in generating ideas on possible regulatory and administrative simplification and suggestions as to how Union harmonisation legislation could be made more effective, they were not able to provide estimates themselves as to the level of potential cost savings. Although a quantification exercise was undertaken, it should be stressed that the research team had to develop most of the assumptions.

Among the types of simplifications that were considered include some of those examined in the previous section, such as merging IM directives and regulations and introducing a common template for the DoC, thereby reducing familiarisation costs. A distinction was made in our analysis between:

- Regulatory and administrative simplifications – these are distinct types of simplification measures, as explained in the typology (Section 2.3); and
- Specific simplifications relating to the eight product groups covered by the harmonised cases.

An example of the quantification exercise in relation to general benefits is provided in the following table. As explained above, the data is based on assumptions, some of which are

necessarily speculative in the absence of firms being able to provide either data or even a 'best estimate' themselves.

Table 5.9: Simplification measures for all industrial products - quantification of potential simplification savings

Proposed simplification	Explanation	Benefits and/ or disadvantages	Approximate savings
Ensure greater coordination in timing and updating of different pieces of IM legislation	Improve coordination in timing of regulatory review processes and recasting of IM directives and regulations. There are already examples of initiatives to strengthen coordination such as the Alignment Package which will involve the updating of 9 IM Directives in order to align these with the common provisions in the NLF). Ensure better synchronisation of the introduction of new, and revisions to existing IM legislation.	Minimise frequency of regulatory changes. Reduce cumulative costs of compliance. Also some disadvantages; less flexibility in terms of reacting on issues/new products/etc.; strong demands on firms/experts determining standards, etc.	20.0%
Eliminate inconsistencies in requirements for the DoC between different IM legislation. No longer require DoC to be placed with the product (R&TTE-D only). Ensure a common template for the DoC across all IM regulations	There are currently differences in administrative requirements for the DoC between the R&TTE-D, EMC-D and the LVD-D respectively. Across IM regulations, there are also slightly different layouts and information requirements for DoCs. These problems are already being tackled through the Alignment	Reduction in costs of producing a DoC. This would result from the use of a common template for a DoC rather than multiple templates. Reduced operational uncertainty for manufacturers (eliminate risk of delays to product shipments teaching the market[70].	0.2%

[70] Such delays can occur if customs and/ or MSAs mistakenly believe there to be a requirement for all electrical products to provide the DoC together with the product.

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	Package.		
E-labelling and wider provision of compliance information electronically. Basic information – full DoC, technical standards that have been applied, safety data sheets could be provided online. Given commercial sensitivities, technical documentation could be provided through secure data transfer.	More regulatory compliance information could be made available online by manufacturers. The market surveillance system needs to be overhauled so that manufacturers provide most compliance information online rather than in paper copy.	For manufacturers: Lower printing costs, e.g. DoCs. Reduced human resource cost of responding to requests from MSAs for information. For MSAs: Better access to compliance information specific to each model. Reduced time to obtain compliance information. Resources freed up to carry out more technical checks.	3.0%
Eliminate inconsistencies across Union harmonisation legislation as to whether CE marking is required. Example: before recent revision of Medical Devices Directive into a Regulation, there was no CE marking requirement but products faced conflicting rules.	Ensure uniform rules on CE marking across all relevant directives and regulations that require CE marking. Note: the Commission has already taken steps through the NLF and Alignment Package to rectify these inconsistencies.	Greater coherence in administrative requirements for economic operators	0.4%
Make changes to the DoC allowing to identify a model and the variants		Reduce costs for conformity assessment for firms operating as OEMs	0.1%
Setting up mutual recognition schemes for conformity assessment procedures	Discussions are currently taking place on the possibility of allowing for mutual recognition	Reduce costs for European manufacturers of third party conformity	0.2%

with major global jurisdictions	between the EU and US of conformity assessment through the framework of the TTIP	assessment in the US	

An assessment of possible simplifications is provided in each case study, together with a quantitative estimate of the potential savings (see Appendix C). Given some of the nuances associated with simplifications until the fine detail has been drawn up (explained in Section 5.5), the cost saving estimates provide approximate savings only.

Research Findings (RFs)

- (RF89) A number of simplifications have the potential to reduce the costs of compliance with the legislation, namely: i) greater coordination in timing and updating of different pieces of IM legislation; ii) Eliminating inconsistencies in requirements for the DoC between different pieces of IM legislation; iii) labelling and wider provision of compliance information electronically; iv) Eliminate inconsistencies across Union harmonisation legislation as to whether CE marking is required; v) Make changes to the DoC allowing to identify a model and the variants; vi) Setting up mutual recognition schemes with third-country jurisdictions.

5.6 Macro-economic impacts of simplification on growth and jobs

EQ24: What benefits from simplification can be identified for the wider economy?

5.6.1 Approach taken

The analysis presented here makes use of the estimated compliance costs and the savings potential from simplifications for the 8 product groups examined through the case study research. The basic assumption underlying the analysis is that any cost reductions from simplifications to IM legislation will be translated into savings in terms of firms' operational costs, labour productivity improvements and will eventually be passed on to consumers through lower prices . Lower prices of products should help to strengthen the international competitiveness of European manufacturers, thus boosting exports and reducing imports. Ultimately, this should lead to an increase of the Gross Domestic Product in sectors where regulatory and administrative simplifications are made. An increase of GDP should, in turn lead to increased employment within the sector.

However, in the short term, increased labour productivity should be expected to reduce employment, in turn reducing disposable household income and, as a result, the level of private consumption. Thus, whereas GDP in the sector concerned is increased at the macro-economic level, the impact of the reduction of compliance costs on GDP is uncertain. Employment effects are also not a priori certain, as the initial shock is a *ceteris paribus* reduction in the number of jobs.

The steps that were followed to carry out the quantitative assessment were:

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1. Development of a medium/long-term baseline scenario for economic development by defining a set of plausible values of the exogenous variables of the model.[71] These include the export volumes, consumption (household and government), investment (enterprises and government), imports, GDP and depreciation and its prices as well as labour costs and employment numbers. The baseline scenario was prior to regulatory simplifications being made of IM legislation.

2. Estimates of the level of cost savings linked to regulatory and administrative simplifications of IM legislation identified in the eight product groups examined in the case studies.

3. Development of an "alternative scenario" for economic development that takes into account the estimated reductions in compliance costs.

4. Comparison of the alternative scenario to the baseline scenario so as to estimate the impact of the compliance cost reduction on economic development.

Ideally, the estimation of the possible impact of simplification would be based on a model of the EU economy as a whole or of each individual Member State. Since this was not available, the PRISMA model for the Netherlands was used[72] and the costs reductions hypothesised for the EU economy were applied to an economic baseline scenario to determine the impact on growth and jobs for the Dutch economy. The results were then extrapolated to the EU level and the World Input-Output (WIOM) model was applied[73]. This approach could be justified on the basis that the core elasticities – mainly price elasticities – do not vary too much across EU countries. Further details about the PRISMA and World Input Output Model models used to carry out the quantitative analysis are provided in Appendix D of the main report, which provides a technical note to support the quantitative assessment of costs and the macro-economic assessment provided in Section 5.2 and 5.6 respectively.

The model variables that are directly affected are domestic final demand by category (household and government consumption, investment), demand in the private sector and labour productivity. Furthermore, exports should be expected to increase as a result of a reduction in prices. The impact on EU imports has also been taken from the PRISMA model. Taken together, changes in final demand and imports determined the extent of changes in GDP. On the basis of changes in GDP, employment effects were estimated making use of the expected changes in labour productivity.

5.6.2 Impact of simplifications

On the basis of the analysis of the eight sectors examined in the case studies, total compliance costs were estimated to be €342 million.

[71] It should be noted that in general macro-economic models tend to be log-linear. As a result the effects calculated do not depend strongly on the values of the exogenous variables. The log-linear behaviour has been seen to hold for the PRISMA and WIOM model used in this study.

[72] PRISMA is a macro-sectoral model Panteia has developed for medium/long- term scenario analysis in the Netherlands. See Box: Panteia's PRISMA-model for further information.

[73] Panteia's WIOM (World Input Output Model) is used; see the Box Panteia's World Input-Output Model (WIOM).

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In our analysis, a core assumption is that that these costs are borne by firms in the selected manufacturing sectors (NACE Rev. 2 divisions 24 -30 and 33; metallurgical industry under the PRISMA model). The total cost savings for the eight sectors were estimated to be around 11% of total compliance costs, or around €38 million. It has also been assumed that this cost reduction would be translated into a reduction in labour costs. At EU28 level, this means that labour costs (including the imputed wage of the self-employed) would decrease by 0.007% (see table 5.10) with an equivalent increase in labour productivity of 0.007% for the relevant manufacturing sector metallurgical industry.

Table 5.10: Current compliance cost and assumed cost reduction (EU28)

PRISMA model sector name	Relevant NACE Rev. 2 codes	total compliance costs (€m)	cost savings reduction		
			%	€m	in % labour costs [74]
Food industry	10 -12	0	0	0	0.00
Metallurgical industry	24 -30, 33	342	11	38	0.007
Chemical industry	19 -22	0	0	0	0.00
Other manufacturing	13 -18, 23, 31, 32	0	0	0	0.00
Wholesale trade	46	0	0	0	0.00

Source: Panteia

5.6.3 Estimation of impacts for the EU economy

Certain adjustments were made between the PRISMA and WIOM models extrapolating from the calculation of impacts to the EU28 economy as a whole. Firstly, the sectoral classification used in WIOM is more detailed than the one in PRISMA. Secondly, it makes use of the older NACE Rev. 1.1 classification of economic activities, whereas since 2008, PRISMA has used the NACE Rev. 2 industrial classification system. Thus, a correspondence table linking the two classifications has had to be used.

The results of the analysis are presented in Table 5.11. All final demand categories excluding government consumption are all positively affected by an 11% cost saving. Imports would also increase, even though by less than the impact on final demand. As a result, GDP would also be expected to increase. The basic conclusion is that the macro-economic effects of administrative and regulatory simplifications to IM legislation and the estimated cost savings are positive on balance. Exports are the main driving force behind this, and would benefit from lower costs and lower prices of exported goods in selected manufacturing sectors.

Table 5.11: Macro-economic impact of 11% reduction of compliance costs on selected products

Variable	% change (EU28)
household consumption	0.0005
government consumption	0.0000

[74] Including imputed wage self-employed

Investment	0.0002
Exports	0.0009
total imports	0.0006
GDP	0.0004

Source: Panteia; calculations with PRISMA and WIOM

Table 5.12 shows the estimated impact on growth and jobs in EU28. At the macroeconomic level, employment remains largely unaffected since the GDP increase is caused by an increase in labour productivity. In the metallurgical industry[75], only around 40% of the original increase in labour productivity of 0.007% would remain (0.003 against 0.007) due to the downscaling of enterprises in this sector, thus an increase in the share of SMEs that have a higher share of fixed costs and lower productivity levels.

Since the benefits in terms of labour productivity in the specific sectors under review are higher than the respective GDP increase, a small loss in the number of jobs should be expected. Conversely, in other sectors of the economy, the number of jobs created should be expected to increase.

Table 5.12: Impact on GDP and employment of 12% reduction in the compliance costs on selected products at EU28 level

Variable		metallurgical industry	Total economy
GDP	%	0.0008	0.0003
labour productivity (GDP per occupied person)	%	0.0028	0.0004
occupied persons	%	-0.0021	-0.0001
occupied persons	100s	-400	0.0003

Source: Panteia; calculations with PRISMA and WIOM

Conclusions from macro-economic assessment of the impacts of simplification

Research Findings (RFs)

- (RF90) The simplification of IM legislation has the potential to reduce the costs of compliance by around 11% of total costs of compliance, estimated at €342 million, i.e. a potential cost reduction of €38 million. This could lead to a total increase in GDP of €48 million, equivalent to a GDP multiplier of 1.26. The GDP-increase in the eight sectors under review in the metallurgical industry (of which the 8 sectors form part) amounts to almost €19 million. The number of jobs would decrease slightly, in particular in the sectors under review.

[75] It should be stressed that metallurgical industry is the sector shocked but that the shock refers to part (i.e., the eight sectors under review) of this sector only

Effectiveness, fitness for purpose and impacts

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6. Effectiveness, fitness for purpose and impacts

This section considers the overall effectiveness and fitness for purpose of Union harmonisation legislation. The extent to which the legislation is achieving the objectives set out in Article 114 of TFEU is considered. The benefits and impacts of IM legislation at different levels are also assessed, for instance, the effects on economic operators in opening up access to new markets, and at the sectoral level, the impacts on market size and structure and on strengthening industrial competitiveness of the promotion of intra-EU trade.

The specifications set out a number of broad-ranging but specific issues for consideration that fall under the effectiveness criterion. These include among others: the extent to which there remain any regulatory and non-regulatory barriers, whether there are any barriers to the development of innovative products and the use of advanced manufacturing processes in production and KETs. A number of specific challenges are then addressed such as whether the regulatory framework is fit for purpose in dealing with the market surveillance challenges posed by e-commerce with third countries, whether the legal framework is sufficiently friendly towards green products, whether the increasingly blurred inter-relationship between services and products leads to regulatory gaps, and the question as to whether there should be a distinction made in IM legislation between regulating products intended for professional use, as opposed to final consumers.

6.1 Regulatory and non-regulatory barriers

EQ25: What, if any, are the barriers (regulatory/non-regulatory) to the effective functioning of the internal market for industrial products stemming from IM legislation?

6.1.1 Regulatory barriers

Stakeholders confirmed that there has been considerable progress in addressing regulatory barriers to the free movement of products through Union harmonisation legislation since the New Approach was adopted in 1988, and the internal market launched in 1993. However, the perception amongst economic operators is that such barriers persist. For example, 89/96 respondents to a recent Your Voice Consultation on possible reform and simplification of the regulatory framework for industrial products, were view of the view that there remain regulatory barriers within to the internal market for industrial products.[76]

Research undertaken in the course of this evaluation identified four main types of regulatory barriers that may undermine the effective functioning of the internal market in industrial products.

The first main type of regulatory barrier is **differing or incorrect interpretations or applications of IM legislation** (including language-related difficulties) following its transposition into national law. This was most common regulatory barrier identified through the Your Voice consultation. It is difficult to provide a detailed assessment since the

[76] A note of caution is needed in taking this finding at face value given that some problems cited by interviewees and Your Voice respondents as being of a regulatory nature were found to be non-regulatory, such as national marking and energy labelling schemes.

efficiency and effectiveness of national transposition processes (and the incidence and nature of any infringement proceedings that may have been launched by the Commission against particular Member States) were not formally part of the study scope. Nevertheless, some feedback on this question was obtained from national authorities.

Among the feedback received was that, whilst in theory there is not much scope for divergent interpretations of Union harmonisation legislation, there are practical difficulties that may result in misinterpretations and misapplication of the law. For instance, although there are official language translations of each piece of IM legislation in all EU languages in the OJ, there is still potential for misinterpretation and misunderstandings during the process of transposing directives into national implementing regulations, even if these are uncommon. For example, it was reported that differences in translation had created divergences between the legislation applying in **Italy** and in other countries, as described in the text box below.

Table 6.1: Regulatory divergence in national transposition of EU Directives - Tunnelling machinery

Under the Machinery Directive (MD), a problem occurred 3-4 years ago that stemmed from misapplication of EU law due to translation issues during the transposition process. This led to a change in the original intended meaning of the legislation, in particular, whether tunnelling machinery fell within the scope of Annex IV, which sets out categories of machinery that may be subject to one of the conformity assessment procedures involving a Notified Body. In Italy, the translation into national legislation meant that a tunnelling machine fell within the scope of Annex IV. However, other Member States, such as France, Spain and the UK had a very different interpretation. An Italian company faced legal uncertainty as to whether it could place its product on the market. Although the misinterpretation problem was resolved by the Italian authorities, since the operating costs of a single tunnelling machine are about €1m a day, there was a cost associated with the prolonged uncertainty.

The above example illustrates why most economic operators and industry associations interviewed were almost universally in favour of regulations to ensure legal certainty (although views were more mixed on the advantages of regulations over directives among national authorities).

Examples were also identified of differences in interpretation as to whether technical standards meet the requirements of IM regulations or not. For instance, sanitary hot water equipment manufactured in accordance with EN 746-2 in industrial enclosures is sometime accepted by market surveillance authorities under Directive 2009/142/EC on Gas appliances (GAD). According to a respondent to the consultation, “this has serious implications to the detriment of the firm that made the placing on the market. There is a need to distinguish between equipment intended for domestic hot water for domestic or commercial use within the GAD and those intended for sanitary hot water industrial spaces that fit better within the scope of the Machinery Directive. The same problem can occur in other types of technological heating systems because it is not very clearly defined within the scope of the GAD”.

Anecdotal evidence suggests that it can sometimes be difficult for economic operators to have products accepted that have already been placed on the market in the home Member

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State where the economic operator is trying to place the product in circumstances where conformity assessment testing has been carried out in a country within the EU where the quality of testing services is not perceived to be of equal quality or as rigorous. Even if this is against internal market rules, and the manufacturer could potentially complain, this appears to be an issue in some countries. The scale of the problem is difficult to assess since it was difficult to identify concrete examples that could be cited. We detected that some economic operators may be reluctant to complain, in case they consider there is a risk for them to jeopardise their position in accessing particular national markets.

The problem of differing interpretations of legal requirements at national level can also extend to guidance issued by national authorities. For example, one of the enterprises consulted highlighted an example of two different national authorities issuing conflicting guidance about which legal requirements were applicable to economic operators.

Table 6.2: Conflicting advice and interpretation of IM requirements by MSAs

Example 1 - a firm in the Netherlands asked the German government what would be required to test a product for the REACH Directive. The national authorities agreed that tests could be made on a sample of several items and to then use the data obtained to make calculations for REACH across their product range. However, a similar request to the Dutch authorities resulted in different advice. The company was told that it must test each product from each supplier separately. Given the extra costs involved, a German exporter to Holland would thus have an unfair advantage over local producers. Example 2 - In 2007 the firm concerned asked the Dutch market surveillance authorities if the new standard for oil lamps should be followed, since there were many problems with this standard. Their reply was that this was not required. In 2008, products not meeting the new standard were taken off the market in Germany. This meant that the national authorities in Holland had to revise their advice and companies had to recall many items.

The second type of barrier was that of **additional national requirements**, most often introduced during the process of transposing Directives into national law, a process known as "gold-plating". These often concern the after-sale phase related to the use, service and maintenance of products and can lead to additional obligations to provide information or undertake testing, which can different between countries. For example, a 2004 survey of firms conducted by UNICE found that 115 of the 200 respondents had to introduce product changes and 92 had to conduct additional testing or gain additional certification. The perception of gold-plating was shared by several respondents to the Your Voice consultation, as well as by several of the stakeholders interviewed. For example, there reported to be diverging safety requirements for recreational crafts and related boat equipment.

It may however be the case that gold-plating is more one of a perceived problem than an actual barrier. The research identified few confirmed instances of gold-plating, in large part because many Member States have transposed the full text of the relevant Directive, as written. Moreover, many economic operators confuse national "voluntary" marking and labelling requirements with there being additional national mandatory requirements in the legislation, whereas in fact this is not the case.

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Another issue identified is that economic operators do not distinguish between products covered by harmonised IM legislation and those where only the principle of mutual recognition applies; indeed, the UNICE survey focused on both harmonised and non-harmonised products. Similarly, where national authorities require additional testing, this may reflect a lack of confidence in EC type-approval certificates issued in other countries rather than additional national requirements per se (as we discuss below). In other cases, national requirements in areas not covered by EU legislation may impinge on the free movement of harmonised products. For example, the installation of lifts (harmonised under the Lifts Directive) may be affected by national regulations relating to local building or fire safety standards, which are not harmonised across the EU.

We assessed how far the situation has changed in the past decade since the UNICE survey was undertaken. In the 2013 Your Voice Consultation carried out by the Commission on possible reform and simplification of the regulatory framework for industrial products, a high proportion of respondents perceived there to remain at least some outstanding regulatory barriers to the internal market for industrial products (89/96 respondents). However, a note of caution is needed in taking this finding at face value given that some problems cited by Your Voice respondents as being of a regulatory nature were actually non-regulatory, such as national marking and energy labelling schemes (see the next sub-section).

The third main type of barrier identified was the **lack of consistency in the recognition of EC type-approval certificates issued by NBs in other countries**. For instance, some countries do not recognise the calibration capability approval carried out in another country. As a result, according to one respondent, manufacturers in some countries, e.g. France, Germany, Portugal, Spain, Switzerland need to go through type-approval processes again, which is costly, even if they have already certified their products and followed EU technical standards. An example cited was Solar Thermal Collectors; even where products have already been certified under EN12975, the regulatory authorities in some countries (e.g. France, Ireland) have insisted on additional national certification requirements even though product testing had already been undertaken in another country. Another example was provided by a national authority in the UK: “Importers and distributors in different Member States may be reluctant to accept products from manufacturers and OEM suppliers unless they have been subjected to testing by a domestic NB, even if this goes against internal market rules. In practice, there is not always confidence that conformity assessment carried out by NBs in other countries are equivalent in terms of quality of services. Manufacturers may consequently be asked to have their products retested”.

The fourth main type of barrier was the differences between Member States as to whether products can be placed on the market if they have used an **older version of technical standards** or whether the most recent version must be used. There was a lack of certainty among economic operators and market surveillance authorities in some Member States as to whether products that have been legally placed on the market can remain on the market or should be withdrawn once updated product safety standards have come into force. This was raised for instance in relation to fuse sockets. Industry representatives indicated that there have also been cases where products are blocked by customs authorities because it is unclear what the legal position is in relation to products conforming to outdated standards, which can add to economic operators’ operational risks.

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The extent to which such barriers hinder the effective functioning of the internal market for industrial products should be seen in the light of the institutional and regulatory mechanisms for addressing the misapplication of EU law in national legislation. Under Article 258 of the TFEU, the Commission is responsible for ensuring that EU law is correctly applied. Consequently, where a Member State fails to comply with EU law, the Commission has powers to take action in case of non-compliance. It can bring infringement proceedings and, where necessary, refer cases to the European Court of Justice. There are also mechanisms such as the 98/34 notification procedure (and the TRIS database which stores these notifications) through which Member States must inform the Commission and other Member States about the adoption of draft national technical regulations for products. There is then an opportunity for Member State authorities to raise any concerns. An analysis of TRIS notifications was carried out as part of the desk research. This found that most problems identified related to non-harmonised products (a statistical analysis is provided in the working paper on non-harmonised products in Appendix E).

Incorrect application of EU law can also be tackled through soft measures such as awareness-raising to promote more uniform interpretation and consistency in the application of IM rules and through legal remedies (e.g. the possibility of launching infringement proceedings against particular Member States).

Research Findings (RFs)

- (RF91) Despite considerable progress, regulatory barriers to the effective functioning of the internal market persist, particularly in the form of differing or incorrect interpretations or applications of IM legislation, additional national requirements, lack of consistency in the recognition of EC type-approval certificates issued in other countries, and inconsistency in allowing the use of old versions of technical standards.
- (RF92) There is evidence to suggest the economic operators perceive the regulatory barriers to be greater than they are in reality. Reported instances of regulatory barriers often relate to non-harmonised product groups or to misapplication of IM legislation rather than to the text of the legislation itself.

6.1.2 Non-regulatory barriers

A number of respondents to the Your Voice Consultation identified non-regulatory barriers to the free movement of goods. Among the most commonly cited barriers were "soft law" requirements, quasi-legal instruments which do not have any legally-binding force.

Respondents pointed to a considerable number of **"voluntary" national marking and labelling schemes** that operate across different national markets. These were viewed by some respondents as being a *de facto* requirement in order to get products into the distribution chain, even if they are not legally required to place a product on the market.

The multiplication of labelling requirements was viewed by enterprise respondents as imposing a significant cost on manufacturers, and undermining the internal market, often without adding much value. In addition, such labelling requirements were viewed as causing confusion among consumers since there are a large number of national marking schemes and

labelling requirements. A further problem identified was that in some EU countries, being part of a national voluntary labelling and certification scheme has become a *de facto* requirement to avoid higher risk insurance premiums. An example was cited related to the use of a national certification system in France[77] (NF UPEC) for ceramic tiles.

A further illustration of a non-regulatory barrier was that in some product areas, **national certification scheme**s are in operation and those economic operators that are from another Member State that do have such certification may be unable to benefit in terms of having access to national financial incentive schemes. An example cited in this regard was in relation to certain types of renewable technologies where signing up to the national certification scheme was a requirement in the UK in order to access funding. In some Member States, respondents pointed to evidence that economic operators and public authorities may raise objections to the use of specific harmonised standards that deviate from established national practices and/ or national technical standards. This creates legal uncertainty as to whether economic operators will be able to use a single European standard across the EU or need to customise the standard in particular national operating environments to reflect national standards.

A further non-regulatory barrier identified was that national standards have been developed that are widely used but "voluntary" in some Member States. For instance, in Germany, in some sectors such as lifts, it is difficult in practise to sell products in the German market without meeting voluntary energy efficiency standard VDI 4707 for lifts, which is a German national standard, and displaying the appropriate energy efficiency labelling in the lift. A small lifts manufacturer from another Member State stated that "it is problematic for non-German firms wishing to place their products on the German market is that there are low levels of consumer confidence for manufacturers, assemblers and installers that do not meet the German national "voluntary" standard". This was confirmed through desk research. A Top 4 lifts company pointed out that "The VDI 4707 guideline has been published by the Association of German Engineers (VDI). Although this is an independent organization and as such, their standards are voluntary, the VDI 4707 is quickly becoming the key standard in the market worldwide"[78].

Research Findings (RFs)

- (RF93) Non-regulatory barriers, such as "voluntary" national labelling schemes, national certification schemes and national technical standards, are reported to affect the effective functioning of the internal market.

6.2 Barriers to the free movement of innovative products

[77] The French certification NF-UPEC is the product certification that testifies technical conformity of the product to the requisites required by the French standards.

[78] VDI 4707 measures and classifies elevators according to their energy performance. It defines an energy label and provides a figure for a "yearly nominal energy demand". Seven energy efficiency classes provide a transparent and factual overview when rating elevators according to their energy performance. They range from "A" to "G" with "A" being the best-in-class system. Measurements are carried out on actual elevator installations, not on theoretical models

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EQ26: Are there specific regulatory barriers to the development and free movement of innovative products, including products integrating key enabling technologies (KETs)? Are there any legal gaps not already covered by IM legislation for industrial products?

EQ26: Are there specific regulatory barriers to the development and free movement of innovative products, including products integrating key enabling technologies (KETs)? Are there any legal gaps not already covered by IM legislation for industrial products?

A characteristic of the New Approach to Union harmonisation legislation is that it is **technology-neutral** since the legislation only sets out the essential requirements. Manufacturers are allowed to determine for themselves how best to meet the essential requirements. An exception to this general rule is legislation such as the Ecodesign Directive, which aims to remove inefficient technologies from the market in favour of more environmentally-friendly technologies, as discussed in section 6.3 below.

It therefore does not matter from a legal point of view whether traditional or advanced manufacturing processes are used, since the same legal framework applies relating to the placing of the product on the market. For example, a laptop using very innovative nano-electronic components is still subject to the LVD and EMC Directives, in the same way that other domestic appliances, such as refrigerators are.

The fact that Union harmonisation legislation is non-prescriptive regarding the technical specifications that should be adopted means that by leaving detailed implementation to technical standards, the regulatory framework is sufficiently flexible. The more significant challenge is whether there are suitable technical standards that manufacturers can follow and whether such standards are updated sufficiently frequently to take new innovations into account. Whenever there is no suitable technical standard available because the specific innovation, new technology or advanced manufacturing process has not yet been taken into account, firms can use alternative means to demonstrate presumption of conformity, although this may be more costly since demonstrating conformity with harmonised technical standards tends to be cheaper.

Ensuring that the legislation does not pose barriers to the development and free movement of innovative products is also essential to the achievement of other EU policy objectives. For example, EU industrial policy seeks to promote the development and application of **Key Enabling Technologies (KETs)**.[79] A KET-based product is defined as a product induced by KETs and/or those produced by advanced manufacturing technologies. Examples of KETs are high-efficiency photonic LEDs; advanced batteries combining advanced materials and nanotechnologies for electro-mobility; biochips combining advanced materials, nano-electronics and photonics; nano-components used in nano-electronics. Clearly, the achievement of this objective in the industrial policy field is in part dependent on the legislation being sufficiently accommodating.

The majority of industry representatives and other stakeholders consider that that Union harmonisation legislation is sufficiently technology-neutral and does not impose particular restrictions or limitations on innovation. Indeed, IM legislation was not viewed by interviewees from industry as restricting manufacturers in either the use of innovative

[79] COM(2012) 582 final

materials, advanced manufacturing processes or in the incorporation of new technologies into products.

For example, the Machinery Directive can accommodate the development of 3-D printers as hardware, whilst the legislation applicable to the products produced by 3-D printers will be dependent on the type of product produced. In principle, assuming these products are placed on the market, they will be subject to the same product safety rules (and underlying technical standards) as any other industrial products. There are a series of legal issues raised by 3-D printing, such as the risk of dual-use and challenges in protecting IPR copyright, but such legal issues do not relate to product safety *per se*.

A further issue raised through the increased use of 3D printers investigated was who is legally responsible for the products produced by 3-D printing. Should this be the manufacturer of the 3-D printer, the designer of the 3-D printer, the company selling the 3D printer or the final industrial user or consumer that used the 3D printer to produce products that were then placed on the market. However, legal responsibility is clearer than it might appear at first sight. The manufacturer of printer hardware is responsible for the product under existing IM legislation (irrespective of how high-tech the printer is), while the user of the 3-D printing device is responsible for ensuring the safety of products that they manufacture.

There are also practical difficulties posed by the increased use of additive manufacturing technologies in terms of in ensuring effective market surveillance of products printed using 3-D printers. Whereas the quality of industrial and consumer products sold through conventional supply chains can be checked relatively easily by MSAs, it is much more difficult to check the quality of products produced in small quantities by individuals or micro firms, especially when the route to market may be through online commerce channels only.

There is also evidence that IM legislation has in some cases acted as a catalyst for promoting innovation. First, the functioning of the internal market has enabled some manufacturers to enjoy economies of scale in production, which allows them to invest more in research and development. For example, the consolidation of the lifts industry across Europe is acknowledged as having enabled the development of more extensive research and development centres, since such costs are spread across a larger number of units sold. Second, where essential safety requirements have been made more stringent over the years (as and when legislation is recast or when EU legislation replaces national legislation), this can create a new demand for certain products. Again in the lifts industry, EU legislative requirements relating to the incorporation of emergency telephone systems in new lift units were reported to have boosted the demand for such systems; this increased the incentive for firms to create innovative new products in the knowledge that they would be more likely to recoup investment costs.

In some cases, there is evidence that the lack of EU legislation may prevent the development and free movement of innovative products, such as products integrating KETs. There will inevitably be a tendency for legislation to lag behind the development of innovative products and technologies - legislation is rarely developed for technologies and products that do not exist! For example, in the case of products incorporating nano-materials (a KET), there is evidence that, in the absence of a regulatory framework at EU level, Member States are

introducing their own legislation, given the need to ensure health and safety in the production and sale of this particular product. Clearly for such products, there is a need to develop appropriate EU legislation to facilitate further development and application of such KETs. The text box below explores the case of nano-materials in more detail.

Table 6.3: Emergence of national legal frameworks in areas not yet covered by IM legislation – nanomaterials

Legislation on nanomaterials has to strike a balance between an effective regulatory framework that takes into account scientific risks in usage while at the same time promoting the development of KETs and avoiding impeding innovation. There is currently no legal framework at EU level or harmonised legislation on nanomaterials. However, a legislative framework on nanomaterials is evolving in some Member States because the nanomaterials sector is a promising emerging sector but there are concerns about ensuring that the risks are appropriately evaluated on a scientific basis. France is currently the only Member State with a legal framework regulating the use of nanomaterials and the French national authorities are setting up a national registration system for the use of nanomaterials. Several other EU countries are exploring the possibility of introducing national legislation, such as Belgium and Italy. Since over the next 5 years, different national legal frameworks may be developed, the question as to whether harmonised EU legislation should be introduced so as to avoid regulatory fragmentation and to ensure a level playing field for economic operators is under consideration through a second EU regulatory review. There are however concerns among industry stakeholders in relation to the possible development of EU legislation on nanomaterials that the second regulatory review at EU level to determine whether specific legislation is needed on nanomaterials would move more quickly. Consideration is already being given to amending the annexes of the REACH Regulation to take nanomaterials into account. It is challenging doing so without making changes to the REACH regulation itself. A consultation is currently being carried out on this topic by ECHA and the Commission. The Commission's view is that "The REACH approach to hazard assessment and risk characterisation, with its built-in flexibility, makes it overall suitable for nanomaterials". Furthermore, the Austrian environmental agency is carrying out a review of RoHS. This is taking place faster than the process of reviewing whether EU legislation on nanomaterials is needed.

There are a number of issues relating to the use of KETs and their integration into innovative products. Firstly, revisions to technical standards do not keep pace with technological developments. This does not necessarily prevent the application of such technologies, but does risk imposing costs on manufacturers who are required to use alternative means of demonstrating presumption of conformity in the interim period between a new technology being developed and technical standards being adjusted to reflect it. Since technical standards

provide the basis on which a significant percentage of manufacturers achieve regulatory compliance, it is important that standards are developed in a timely manner and keep pace with technological "state of the art".

The second difficulty is that multiple pieces of legislation may apply to innovative products, sometimes with blurred boundaries between them. Again, this would not necessarily prevent such products from being placed on the market, since many producers (particularly large firms), conformity assessment bodies and market surveillance authorities are used to dealing with such complexity. The risk would remain, however, that some producers, particularly, SMEs would lack the necessary resources to address the requirements of the legislation and thus be deterred from placing innovative products on the market. In these instances, there will be a continual need to monitor the situation and, where necessary, revise the legislative framework, either through recasting directives and regulations or through introducing entirely new pieces of legislation. There may also be a need to provide additional advisory support and guidance for SMEs, as and when it becomes evident that they are struggling to address the requirements of the legislation in respect of innovative products and KETs.

The Industrial Policy Communication also highlights the importance of **advanced manufacturing** (the use of innovative technology to improve products or processes). However, it is important to stress that IM regulations are not generally a hindrance to the development of advanced manufacturing, since this concerns intermediate production processes whereas the focus of IM regulations is on products intended for final use that are being placed on the market. There are issues as to whether IM regulations are sufficiently clear about the treatment of components and spare parts used in final products. Certainly, there is confusion among economic operators in some product areas and whether these are included within scope (see earlier analysis – evaluation question 2).

Research Findings (RFs)

- (RF94) IM legislation is sufficiently technology-neutral and tends to promote rather than limit innovation. (Stakeholder interviews; Product case studies)
- (RF95) A lack of EU legislation may hinder the development and free movement of innovative products, where Member States introduce their own legislation (Nano-materials case study)
- (RF96) Where technical standards do not keep pace with technological innovations, manufacturers may be required to use alternative ways of demonstrating conformity with the essential requirements of the legislation. (Stakeholder interviews)
- (RF97) Where multiple pieces of legislation apply to an innovative product, there is a constant need to monitor and, if necessary, revise the legislative framework and also provide guidance to operators. (Stakeholder interviews)

6.3 Barriers to the free movement of green products

EQ27: Are there specific regulatory barriers to the development and free movement of green products? Are there any legal gaps not already covered by IM legislation for industrial products?

Whilst IM legislation is generally intended to be technology-neutral, other areas of EU policy

aim to promote wider development and use of green products. For example, the Commission Communication "Building the Single Market for Green Products"[80] aims to facilitate a higher uptake of green products and of greener practices by companies in the EU market by contributing to the removal of potential barriers to the free circulation of green products in the Single Market. Evidence from the Your Voice Consultation suggests that green products are able to circulate, with the majority of industry representatives responding to the Your Voice Consultation (40/47) reporting that were no regulatory barriers to the movement of such products.

EU legislation has, in some cases, promoted the development and circulation of green products by aiming to remove inefficient technologies from the market in favour of more environmentally-friendly technology. For example, the Ecodesign, Outdoor Noise Directive (OND), and Non-Road Mobile Machinery Directives (NRMMD) have explicitly aimed to ensure that all products fulfil a minimum level of environmental performance and to ensure that they are freely traded across the EU[81]. As indicated by the recent evaluation, in the absence of the Ecodesign Directive, national measures would have been implemented leading to the creation of technical obstacles and market fragmentation that would operate against the development of green products. Similarly, RoHS and REACH have promoted the early phasing out of hazardous substances and dangerous chemicals respectively, and incentivised manufacturers to identify alternative substitutes. The recent review of REACH[82] concluded that, notwithstanding the important administrative costs, the information collection mechanisms, the registration and authorisation processes and the candidate list of hazardous substances have often acted as stimuli to product conception or innovation through the increased knowledge of substances and properties.

Evidence from the implementation of other pieces of legislation with environmental aims, such as the F-gas Directive, RoHS and REACH regulations, OND or the NRMMD, is rather mixed. Interviews of industry representatives highlighted a direct link of the requirements of the OND and NRMMD to the promotion of innovation in relation to less noisy and less polluting engines. However, it was also pointed out that the share of R&D activity linked to NRMM provisions is disproportionate (as suggested, up to 80% of the total R&D) leading to less progress made in relation to other equally important objectives such as product performance.

At the same time, it would appear that a number of non-regulatory barriers may exist to the circulation of green products. A first barrier may be the lack of a common definition of what a 'green product' is and what makes a 'green organisation'. As indicated by a national industry association in Italy, there is a "lack of harmonised criteria for applying different green terminology across different product types. This can lead to confusion and misleading advertisements for consumers, especially when the term "sustainable" is used." Another barrier can be national incentive schemes that promote the take-up of environmentally-friendly technologies; whilst these do not prevent non-national companies from supplying the

[80] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52013DC0196:EN:NOT
[81] CSES (2012), Evaluation of the Ecodesign Directive- Final report, http://ec.europa.eu/enterprise/policies/sustainable-business/ecodesign/review/files/ecodesign_evaluation_report_part1_en.pdf
[82] CSES (2012), Impact of the REACH regulation on the innovativeness of EU chemical industry, http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/review2012/innovation_en.htm

national market, they clearly put them at a competitive disadvantage (see text box below).

Table 6.5: Renewable Technologies incentives schemes for UK providers

In order to access UK Government Financial Incentive Schemes installers of Renewable Technologies must be certified under the MCS Installer Certification Scheme. Within the Scheme Rules there are requirements that compel additional product testing or completely restrict the installation of some specified product types that are otherwise freely available elsewhere in the EU. The Microgeneration Certification Scheme (MCS) (Document MCS012 requires manufacturers to submit PV and Solar Thermal products for UK Specific Roof Tests and Certification, in conflict with EN12975) UK - MCS Scheme (Document MIS3001 specifically restricts the Installation of In-Roof Solar Thermal Products that carry the European SolarKeymark Certification). The MCS Installer Certification Scheme is the only scheme recognised by the UK Department of Environment and Climate Change (DECC). DECC do not recognise Installer Certifications Issued by other EU Member States which appears to be in conflict with UK obligations under Directive 2009/28/EC Article 14-3.

There is also evidence that the free movement of green products is undermined by weaknesses in market surveillance. It is a rather common view among most stakeholders – including national authorities - that safety aspects are given priority and compliance with environmental requirements in relation to emissions, noise, energy efficiency are rarely examined given the limited resources of market surveillance authorities. As a result of this, firms producing in green products may face unfair competition from firms that either make false "green" claims or are allowed to avoid certain costs and compete on the basis of low prices. This view was supported by a small number of respondents to the Your Voice consultation (7/47) who identified a lack of appropriate market surveillance and enforcement of applicable environmental requirements (e.g. in the case of Ecodesign).

Research Findings (RFs)

- (RF98) There are few, if any, regulatory barriers that specifically relate to the development and free movement of green products. (Your Voice consultation; Previous evaluations of IM legislation)
- (RF99) EU legislation has done much to promote the development and free movement of green products by removing environmentally-unfriendly technologies from the market and phasing out hazardous substances. (Analysis of text of legislation; Previous evaluations of IM legislation)
- (RF100) Some non-regulatory barriers remain, e.g. lack of common definition on "green products", lack of harmonised criteria for green products. (Analysis of text of legislation; Stakeholder interviews)
- (RF101) Some market surveillance authorities prioritise unsafe products rather than products that fail to meet environmental standards. (Stakeholder interviews; Your Voice consultation).

6.4 Effectiveness in responding to the challenges of e-commerce

EQ28: To what extent is legislation adapted to the challenges presented by e-commerce?

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When the New Approach Directives were introduced in 1985, e-Commerce was in its infancy and accounted only for negligible levels of trade.[83] Since then, levels of e-Commerce have grown exponentially, now accounting for a significant share of all transactions. By making information more available, helping to link suppliers and purchasers across Europe and enabling better price comparisons, e-commerce has great potential to facilitate the free movement of goods across the EU. For example, a 2011 study for the Executive Agency for Health and Consumers estimated that an increase in cross-border on-line retailing from 3.5% to 15% of all sales would benefit consumers by €204.5bn p.a. (equivalent to 1.7% of EU GDP) through lower prices and increased choice.[84] However, the level of cross-border e-commerce within the EU has remained relatively low. A 2010 Eurobarometer survey found that only 7% of EU consumers had bought goods or services online in the previous year from a seller located in another EU Member State.

Whilst IM product legislation includes few, if any, references to e-commerce, the research has identified few particular problems related to e-commerce within the EU in respect of compliance with IM legislation; indeed, none of the stakeholders interviewed has suggested that e-commerce raises concerns that are different from other forms of trade.[85] For example, one interviewee compared e-commerce to telephone commerce, which has been undertaken for many more years.

E-commerce does appear to present some serious challenges where products are imported from **3rd countries** into the EU. Such challenges may require greater consideration by EU policy, which has tended to focus mostly on e-commerce within the EU.[86] Yet the scale of the problem would suggest the need for action at EU level; one market surveillance authority in Germany reported identifying 20,000 different compliant products offered for sale on the internet by 3rd country suppliers. According to those stakeholders that offered a view, the main problem with the legislation is the lack of clarity over when products are placed on the market and by whom.

Indeed, there appears to be ambiguity as to whether making available for purchase via on a retail website constitutes placement of the product on the market. Similarly, there is the question as to whether the purchaser of the product from a 3rd country supplier via a website is the importer or not. In effect, e-commerce allows the product value chain to be shortened, for example, by removing the need for wholesalers in many cases. Overall, the effect is to facilitate the import of non-compliant products, with consequent increased risks for purchaser. Reported problems include the sale of products without use instructions or warnings in an appropriate language, non-respect of guarantees and lack of effective legal redress. Whilst the definitions of importers and distributors provided by the NLF are reported to be helpful, it would appear that further clarification is necessary.

[83] For example, online ordering was a key feature of the Minitel system, introduced by France Télécom in Brittany in 1978 and extended nationwide in 1982. See: www.minitelfr.com.

[84] Civic Consulting (2011), Consumer market study on the functioning of e-commerce and Internet marketing and selling techniques in the retail of goods

[85] The 2011 Commission Staff Working Document on bringing e-commerce benefits to consumers highlights many issues relating to e-commerce in general but these tend not to relate specifically to internal market legislation for industrial products.

[86] For example, the 2009 Commission Communication on Cross-Border Business to Consumer e-Commerce in the EU, COM(2009) 557.

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In addition to problems of defining responsibilities, there are very significant practical problems in the **market surveillance of products sold on-line**. Whilst market surveillance authorities did not report any lack of legal authority to seize non-compliant products, they do, however, report considerable difficulties in the identification and interception of such products. Market surveillance authorities have fewer problems to identify industrial products imported into the EU via "traditional" routes, for example, through co-operation with border and customs authorities who can help them intercept bulk shipments of products that may be non-compliant. Similarly, market surveillance authorities have much fewer difficulties to identify and intercept products sold through conventional physical outlets. In contrast, goods purchased from third countries via the internet may be delivered to the end-user in single consignments via the conventional postal system, making it much harder to intercept potentially non-compliant products.

One interviewee commented that: *"It's relatively easy to intercept one shipment of 10,000 mobile phones at a port; it's almost impossible to intercept 10,000 mobile phones each of which has been posted individually from a third country"*. Moreover, even where market surveillance authorities identify websites selling non-compliant products, they may simply be unable to identify the supplier using the website.

The challenges raised by the difficulties in tracking and tracing products may be compounded by a degree of **ignorance amongst some of the parties**. In particular, providers of e-commerce platforms may be unaware that their platforms are being used to trade goods that are non-compliant. Similarly, end-users may be unaware that they are purchasing non-compliant products from a third-country supplier and unaware that they might not enjoy the same legal protection as they would in the case of purchases made within the EU. Some interviewees also suggested that there might also be a lack of clarity over the relative responsibilities of different parties; for example, to what extent should end-users be considered as importers of products? To what extent are e-commerce platform providers responsible for goods sold via their platforms? In fact, according to the limited liability provisions of the Electronic Commerce Directive,[87] it is the primary suppliers and not the intermediary providers acting as mere conduits, caches, or hosts of information that are liable for online content. However, the uncertainty expressed by some interviewees may indicate a need for better information to be made available.

Those interviewees that were able to suggest possible solutions to the challenges raised by e-commerce advocated a mix of legislative and pragmatic approaches. These solutions should perhaps be considered by the Commission as part of its wider consideration of the challenges of products sold on-line (i.e. Action 12 of the current Multi-Annual Market Surveillance Plan).[88] Two interviewees suggested a revision of current EU legislation relating to e-commerce in order to deal with non-compliant products. Here, it is perhaps worth noting that the E-Commerce Directive does not apply to services supplied by service providers established in a third country, which may suggest a gap between that particular piece of legislation and the body of IM legislation.

[87] Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce).

[88] Part of the Product Safety and Market Surveillance Package. See section 2.1.4 of this report.

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Another interviewee suggested that EU financial legislation should be revised to stop imports of non-compliant products from outside the EEA, i.e. by introducing the possibility to confiscate payments made for such products. One interviewee also suggested that individual end-users, not just companies, should be subject to the regulations if they purchase and import non-compliant products; however, this does not seem a practical solution, particularly for individual consumers who may be unwitting victims rather than "co-conspirators". Other interviewees highlighted practical action, such as co-operating with providers such as eBay to identify and remove non-compliant products from their websites, co-operation between market surveillance authorities and internet service providers over the use of domain names to supply non-compliant products, and agreements with 3rd country authorities, notably China, to avoid imports of non-compliant products. Since the Electronic Commerce Directive does state that cooperation with third countries should be strengthened in the area of electronic commerce, there is perhaps a case for ensuring that such co-operation includes a focus on industrial products.

Research Findings (RFs)

- (RF102) IM legislation poses few problems related to e-commerce within the EU. (Stakeholder interviews; EAHC study; Eurobarometer survey)
- (RF103) E-commerce with third countries presents serious challenges in the form of non-compliant products. This relates to ignorance or ambiguity over responsibilities for importing products or placing products on the market in the case of e-commerce. (Stakeholder interviews)
- (RF104) Market surveillance authorities face significant practical problems to trace and intercept non-compliant products imported from third countries via e-commerce. (Stakeholder interviews)
- (RF105) There is a need to review the body of legislation with respect to e-commerce with third countries and also promote practical approaches to market surveillance. (Analysis of legal text; Stakeholder interviews)

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6.5 Effectiveness in allowing SMEs to operate across EU28

EQ29: How are SMEs (micro, small and medium-sized) affected by IM legislation for industrial products and how do they cope with the requirements? Is there scope to alleviate the burden on the different SME categories without compromising the overarching objectives of the legislation?

The 2013 Commission Communication on Smart Regulation[89] commits the Commission to considering the needs of SMEs when developing EU legislation. This can be pursued in various ways, such as applying the micro-enterprise exemption, introducing lighter regulatory regimes for SMEs and ensuring regulatory fitness. However, since the objectives of product harmonisation directives are linked to health and safety, the protection of consumers and of the environment (in line with Article 95 of the TFEU), there are inherent limitations on the scope for SME exemptions and/or a lighter regulatory regime.

A 2011 Commission report on "Minimizing regulatory burden for SMEs - Adapting EU regulation to the needs of microenterprises" noted that "much legislation will remain applicable to SMEs and micros, covering fundamental public policy obligations, for example, product safety standards that are integral to trading throughout the single market".[90] At the same time, it must be noted that the cost of complying with EU legislation is likely to be much less than the cost of complying with the requirements of 28 different national legislative regimes; in some cases, this might be of disproportionate benefit to SMEs (compared to large enterprises that might be well-placed to meet different national requirements).

Unsurprisingly, there are very few examples of legislation being adapted to alleviate the burden on SMEs. The Battery Directive does exempt small enterprises from having to fulfil the responsibilities facing other producers in relation to waste.[91] The Construction Products Regulation also includes simplifications aimed at micro-enterprises.[92] New procedures were introduced when the previous Directive was revised for declarations of performance that need to be drawn up under the new regulation. This is meant to reduce the costs incurred. However, these two examples represent quite specific cases and it would be difficult to replicate these approaches more widely.

Stakeholders consulted for the current study were unanimous in their opposition to a differentiated approach to product harmonisation legislation because product safety is paramount. A common view expressed was that different rules or procedures for SMEs cannot be introduced since this would risk undermining the objectives of Union harmonisation legislation. As one German industry association with 1600 members commented, *"SMEs don't want exemptions – a safe product must be safe irrespective of the*

[89] Commission Communication on Smart Regulation: Responding to the needs of small and medium - sized enterprises COM(2013) 122

[90] Report from the Commission to the Council and the European Parliament: Minimizing regulatory burden for SMEs - Adapting EU regulation to the needs of micro-enterprises, COM(2011)803

[91] Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC

[92] Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC

size of the undertaking". Moreover, there was a concern that different rules or procedures for SMEs would make carrying out effective market surveillance activities more difficult and increase the administrative burden on authorities. Market surveillance authorities would need to check whether a given product was manufactured by an SME or a large firm and, in instances where different administrative procedures are being applied according to the size of the undertaking, to verify the equivalence of these procedures.

There was, however, wide recognition amongst stakeholders that SMEs potentially face a greater burden in complying with the legislation, which can serve to reduce competition in the internal market. The most common problems reported related to the diseconomies of scale facing SMEs in the compliance process. Indeed, SMEs are more likely than large enterprises to lack the resources to undertake activities that are required to comply with the legislation, such as testing or measurement. Similarly, SMEs are less able than large enterprises to employ specialist staff to ensure familiarisation with the legislation, disseminate information and promote compliance. They are also less able to participate in the work of bodies such as standards committees. Reflecting these difficulties, a small number of stakeholders went so far as to say that SMEs were more likely to be responsible for placing non-compliant products on the market, whether inadvertently (through lack of awareness) or deliberately (in order to reduce costs and without the need to protect a brand name).

Whilst the opportunities to adapt the requirements of the legislation to SMEs are very limited, there may scope to alleviate the burden in other ways. For example, it might be possible to set different requirements in the area of management systems (e.g. ISO 9001), with more demanding requirements for large firms than for SMEs. Similarly, any costs related to surveillance as well as fines could be made proportional to the size of the enterprise. Adaptations to registration fees could be used, as in the case of REACH. It might also be possible to provide standards in a greater range of languages, which would benefit all operators but particularly SMEs (for whom translation of standards represents a disproportionately greater cost). The Commission could also consider ways to support greater participation of SMEs in the standards committees and other fora at EU level, for example by providing greater help with costs; increasing the participation of SMEs would not only help the SMEs directly involved, but also help ensure that the legislation and the relevant standards are as "SME-friendly" as possible.

Given the greater difficulties that SMEs face in ensuring familiarity with the legislation, there will be a continued to need to promote awareness and understanding. Guidance is already available through the Blue Guide and some guidance documents such as the Machinery Directive are very comprehensive in scope already. As far as possible, the Commission should continue to ensure that all such guidance is clear and "SME-friendly". However, it has been reported that some guidance documents should be revised in order to make them clearer, such as the guidance on the PED which was viewed as confusing by some interviewees. For instance, a Notified Body commented that "One of the main problems with the PED is that there are gaps in the descriptive parts of the legislation in terms of covering all types of pressure vessels. Some of these gaps have resulted because the Directive is relatively old (1997) and new types of pressure vessels have been developed since the legislation was drawn up. Although such products are addressed in the supporting guidance to the PED, the situation is unsatisfactory because manufacturers point to the legislative text and only want to address the minimum legal requirements. For instance, there is very little in the legislation

about large boilers, only in the guidelines. The lack of legal clarity means that sometimes it is down to producers to interpret the guidance".

In the provision of information and advice, Member States clearly play an important role and there may be scope for some to expand current provision, including through the Product Contact Points. The Commission could support such an expansion through identifying good practice at the national level and promoting the replication of such good practice in other Member States. For instance, an initiative has been launched by the Health and Safety Executive (HSE) in the UK to simplify guidance for different product harmonisation directives and to make it more SME-friendly, which might inform similar approaches in other countries. Member States might also adopt other approaches, such as maintaining a list of accredited consultants from whom SMEs can purchase advice and receive support in ensuring compliance with EU legislation.

Research Findings (RFs)

- (RF106) There are inherent limitations on the scope to alleviate legislative requirements for SMEs without compromising health and safety, consumer protection and environmental protection and without making market surveillance much more difficult. (Stakeholder interviews; Commission report COM(2011)803)
- (RF107) SMEs potentially face a greater burden due to diseconomies of scale and are less able than large enterprises to participate in standards committees and other bodies at EU level. (Stakeholder interviews; case studies)
- (RF108) There are practical ways to help SMEs that could be encouraged and replicated across EU28, e.g. promoting participation in standards committees, guidance, etc.

6.6 Effectiveness in handling the relationship between services and products

EQ30: Are there barriers to trade stemming from the way legislation handles the relation between services and products which are part of the same value chain?

Technological change, increasing complexity of product and innovation in both product design and service delivery are changing the relationship between products and services that are part of the same value chain. Indeed, the distinction between product and service markets is becoming ever more blurred, in part because consumers increasingly demand high-quality after-sales services. "Products are integrated parts or enablers of a wider service. To put it differently, instead of selling a product with a service, there is a tendency of selling a service with a product (e.g. mobile phones)" [93].

Evidence from the current consultation suggests that EU legislation is struggling to adapt to this changing environment, which creates uncertainty as well as potential barriers to trade and risks to health and safety. Union harmonisation legislation relates to the initial placing on the market of products. Once products have been legally placed on the market, they are then free to circulate. Although as a general principle, IM product legislation should also apply to

[93] http://trade.ec.europa.eu/doclib/docs/2011/july/tradoc_148053.pdf see Chapter 1.5

product-related services, but the current regulatory framework in this regard does not appear to be clear.

Difficulties with the design and enforcement of legislation concern a number of different areas. One difficulty is the extent to which original suppliers are liable for the **on-going safety of products** and, consequently, the actions that they must take at the point of sale, as well as the extent to which they comply with any requirements. For example, manufacturers are typically required to provide sufficient information on the services that may need to apply to a product at a late date, in order for it to remain safe and useable. Yet stakeholders reported that some manufacturers failed to provide sufficient information or indeed any information at all in some cases.

Questions were also raised over the appropriate time period for product guarantees, with some stressing the need for different periods for different products. For example, it was noted that one of the requirements of the PPE Directive is that protective qualities must remain through the life of product; this created a potential uncertainty regarding the relative responsibilities of the manufacturer, customer and any later service provider. If the PPE product is subject to ageing, manufacturer must indicate this fact on the product or in the instructions, though they cannot control use. As one respondent noted: “use defines the lifetime of products and not just care and maintenance”.

For many products, it may be difficult to differentiate between the **supply and installation**. In some sectors, such as construction or lifts and elevators, it may simply be impossible to differentiate between supply and installation. For these products, the legislation must recognise that companies are not just selling products but a whole package that includes a service, i.e. installation. Where services and products are addressed by different directives, there is risk that suppliers will have to comply with two different notification procedures, creating an additional cost. Whilst this was highlighted as being problematic for construction products, for the lifts and elevators sector it was seen as less of a problem, since lifts and elevators are rarely, if ever, supplied without being installed. Moreover, lifts and elevators tend to be installed by the manufacturer, who therefore ensures compliance throughout the process.

In contrast, the case of “on-site blasting” of civil explosives highlights a potential inconsistency in the legislation. Since no explosive product exists until the supplier mixes the necessary materials on site, on-site blasting is specifically excluded from the current Explosives Directive, as it involves the provision of a service rather than a product. However, on-site blasting will be covered by the proposed new Regulation on consumer product safety, yet stakeholders report a lack of consultation with product-specific groups in the development of this new Regulation. As a result, the risk is that the technical side of the Regulation might not therefore prove appropriate and the industry will ultimately struggle to demonstrate compliance on issues such as on-site blasting.

Spare parts and components were also highlighted as causing difficulties, both in terms of their supply, as well as their use in after-sales service. These are evidently an integral part of the product lifecycle. However, the research found that there are differences between different IM legislation for industrial products as to whether spare parts and components are included within scope across different IM directives and regulations. Moreover, there is also

the very practical problem of fitting new components into old products, which raises the question of the extent to which a product can be altered (e.g. when new parts are fitted) and still comply with the requirements of the legislation.

This problem is particularly common for products with long lifetimes, where the original manufacturer might no longer be trading or the original component might no longer be available. Equally, the legislation may risk creating barriers to trade where it prevents independent manufacturers from developing new components that fit into products supplied by large manufacturers. Enterprises also face administrative burdens from the need to ensure that product-related information is kept up-to-date and because there are frequent changes to spare parts and components, they have to regularly update technical documentation. For instance, the serial numbers for parts and components change frequently.

As with supply and installation, **after-sales service** also raises the question of whether compliance is required under product directives or service directives. Again, this creates the risk of having to comply with two different notification procedures. As well as the potential for greater compliance, there is also the risk of safety issues. For example, the LVD was highlighted as one example of directive that fails to address the safety challenges raised by after-sales services, since it is only concerned with the placement of products on the market and not with after-sales, repair, renting to consumers, etc. Whilst the stakeholders consulted were generally aware of this difficulty, there were divergent views as to the most appropriate solution. Some called for an extension of relevant EU product directives, whilst others suggested that the regulation of services was better suited to the national level because of diversity of condition and contexts, which might prove difficult to address at EU level. However, even those stakeholders suggested that EU legislation might provide some sort of a framework on which national legislation could build; this might suggest the continued use of EU directives rather than regulations, which would allow Member States the opportunity to customise the requirements placed on after-sales service in line with national context.

One very specific dimension of after-sales service that was reported to be problematic was that of **the qualifications of staff**. For example, in countries such as Germany, certain services may only be carried out by certain enterprises or regulated professions. The construction sector was reported to be particularly affected by such restrictions. As a result, the potential to trade across borders was seen to be limited for companies providing a combination of product and after-sales service, with many having to limit their activities only to the provision of products. This also places a restriction on the mobility of labour in the EU internal market, both permanent and temporary. The solution to this problem would seem to be the reinforcement and acceleration of efforts to promote the mutual recognition of skills and qualifications across Europe, e.g. through the European Credit system for Vocational Education and Training (ECVET), which promotes better compatibility between the different vocational education and training (VET) systems in place across Europe and their qualifications. Whilst progress has been made in this area, it has tended to be undertaken in isolation to the design and implementation of internal market legislation. There might therefore be scope for the Commission to encourage greater co-operation and dialogue between the IM and VET policy spheres.

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Research Findings (RFs)

- (RF109) The increasingly blurred distinction between products and services creates uncertainty around: i) the extent to which original suppliers are liable for the ongoing safety of products and the appropriate time period for product guarantees; ii) differentiation between supply and installation; iii) coverage of spare parts and components; iv) after-sales service, i.e. whether covered under product or service directives; v) qualifications of staff required to undertake service and maintenance. (Analysis of legal text; Stakeholder interviews; Case studies)
- (RF110) There is scope for the Commission to reduce this uncertainty through a note highlighting the issues that need to be considered in any update of the legislation and setting out in generic terms how these issues could or should be addressed.

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6.7 Effectiveness with respect to business-to-business products

EQ31: The specific situation of business-to-business (B2B products) which are developed and supplied to be used by professionals for the development of other products: Do these products require a special treatment?

IM legislation covers a broad range of products for both industrial use and for consumers. Many of the more high-risk product categories from a safety point of view are primarily intended for use by professionals. In some Directives (e.g. Machinery), there are provisions (Article 17) suggesting that manufacturers need to take into account the intended use in the design and construction of a product and also in relation to the information materials and instructions to be provided which may differ between professional users and non-professional operators. However, in the case of other product harmonisation directives, there is no distinction in EU legal texts between products aimed at professional and non-professional users, since achieving a high level of protection in product safety is the main goal.

Base on the consultations, there appears to be a broad consensus among stakeholders that products developed and supplied to be used by professional users should not be given any special treatment as far as the essential requirements are concerned. A common view was that issues relating to product safety and the level of risk involved in specific product areas are similar irrespective of whether the intended user is a final consumer or a professional. However, the results of the Your Voice Consultation suggest that a significant number of stakeholders – including firms, public authorities and individual EU citizens – consider that some such products should be exempted from IM legislation (29 out of 86 respondents) or that simpler requirements – either in relation to labelling and information requirements or the essential requirements – are appropriate (15 out 87 respondents). For example, manufacturers, importers or distributors could be required only to retain information electronically relating to products intended for professional use rather than having to include paper-based information and material.

In total, around half of consultation respondents were in favour of special treatment for B2B products. It should be noted however that among firms in the manufacturing sector, the level of support for a differentiated approach was less clear. Less than one third were in favour of some form of special treatment. Support for exemptions primarily came from respondents in the transport sector[94]. There is therefore a need to ensure that due caution is given to interpreting the results.

Given the diversity and sectors, it is perhaps not surprising that there is a divergence of views amongst stakeholders. Based on a more detailed review of responses to the Your Voice consultation and to the consultation within the current evaluation, we can offer some more specific findings.

First, there is a category of products that by definition are not supplied to individual consumers. Examples of such products include lifts and elevators, which are never supplied without being installed and tested by professionals, whether employed by the manufacturer or some other company. Clearly, for such products there is no need to differentiate between

[94] A review of responses suggests that more than half of responses can be linked to a single organisation.

consumers and professionals and a single set of requirements is sufficient. However, such products typically require high safety standards to be respected, which would tend to limit the scope for any lessening of legislative requirements, including those relating to administrative documentation.

There are also some products that are very unlikely to be used by anyone other than professionals and which tend, in any case, to pose few safety risks. Some metrology instruments might be seen as falling into this category, where the purpose of legislation is to ensure accuracy of measurement rather than to address potential hazards. Feedback from stakeholders in sectors such as metrology suggests that the requirements of the legislation should not be relaxed, as standards must be maintained. However, given that professionals know that they have to buy products that meet the requirements of the legislation, there might be possibilities to relax the administrative documentation required.

At the same time, any relaxation of administrative requirements should only be undertaken after appropriate consultation with sector operators; many professional users have clear expectations regarding type-approval certificates, etc. and do not wish to undertake their own additional checks, which would be necessary in the absence of legislation. In the case of metrology, there are of course products such as fuel dispensers that do pose a safety hazard; however, where such risks are addressed by other directives, such as those relating to explosives, there might be scope to reduce the documentation requirements specifically relating to the Measuring Instruments Directive.

The types of products that raised most concerns amongst stakeholders are those intended for professionals and posing safety risks but that might ultimately be used by consumers. For example, many electric power tools are meant solely for use by trained professionals following prescribed safety measures. Yet such products can often be sold to or passed on to non-professional, untrained users without too much difficulty, creating considerable risks to safety. The consensus amongst stakeholders was that special treatment would therefore not be appropriate for these types of products. As one competent authority commented, “many industrial products placed on the market are initially designed for industrial purposes and then migrate to consumers. It would therefore be impossible to differentiate in the Directives between the intended product use between professional and non-professional users”.

Another category is products that are intended for professional use, being sold as **components**. Some of these products, such as components for lifts and elevators, are unlikely to be purchased by consumers, and would in any case pose no risk if purchased. For these products, some administrative requirements could perhaps be lightened, such as use of the CE marking and market surveillance activities might also be lighter. However, other products might be used by consumers, perhaps after resale by the original (professional) purchaser of the product. Although there are often specific distributors for such products, experience shows the ease with which non-professionals can often access them. An appropriate approach to take in these cases is perhaps to consider the likely risks that might be posed to consumers, with the legislation tending to “err on the side of caution”.

It is also the case that some components or products tend only to be used in very **controlled environments**, such as laboratories, research and development centres or test facilities. In these instances, it might be possible to label the products as 'parts' that are only required to

meet the essential requirements on the location of use, following a regime similar to that applicable for fixed installations under the EMC Directive. This means that CE marking, Declaration of Conformity or a formal EMC assessment before putting such products into service in a research environment would not be required. Furthermore, for such an exemption to apply under the EMC, there would need to be a direct link between providers and customers. The appropriateness of this proposal and how it might work in practice should be examined along with any possible definition issues that may arise.

Research Findings (RFs)

- (RF111) There is no scope to limit the essential requirements of products to be used by professionals, although for some products, there may be scope to reduce the administrative requirements. (Stakeholder interviews; Your Voice consultation; On-line survey)
- (RF112) There may be scope to reduce the requirements for components or products that are only to be used in controlled environments, e.g. laboratories, test centres, etc. These would have to be considered on a case-by-case basis, as and when legislation is updated. (Analysis of text of EMC).

6.8 Impact of IM legislation on the internal market

EQ32: Overall, how effective is IM legislation for industrial products as a mechanism and means to achieve the objective of improving the functioning of the internal market?

The Ceccini report[95] in 1992 found that Union harmonisation legislation for industrial products had already reduced inefficiencies due to divergent product standards in national technical product regulations. However, a number of major barriers to trade remained prior to the establishment of the internal market in 1992, notably:

- **Technical barriers to trade** – with differing national regulations across different Member States for specific industrial product groups; and
- **Administrative barriers –** a diverse range of national regulations across different Member States meant that businesses faced considerable red tape and administrative costs in finding out about national requirements.

Since 1992, there has been a steady accretion of the body of IM legislation and the existing evidence suggests that this has been accompanied by a sizeable increase in intra-EU trade. There are other factors and processes that have also played an important role in the development of intra-EU trade (including the introduction of the Euro currency and the EU enlargement, the broader processes of globalisation, improvements in transport infrastructure and reduction of transport costs, development of e-commerce) and it not possible to determine the extent of contribution of the Internal Market legislation. Nonetheless, the data on levels of intra-EU trade do suggest a degree of correlation. The available data for the period 1999-2011 show a clear increase in the general level of trade in goods as the share of EU GDP but also in terms of the intra-EU trade in almost all manufacturing sub-sectors.

[95] "The European Challenge 1992 – the Benefits of the internal market", Paolo Cecchini with Michel Catinat and Alexis Jacquemin, 1992

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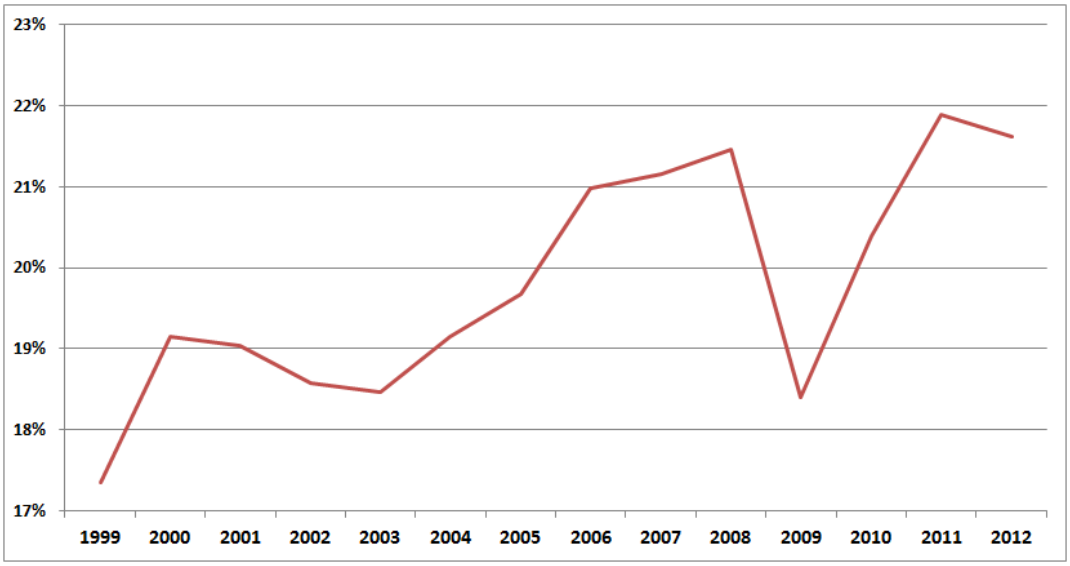
Furthermore, input from stakeholders and the analysis of the role of specific pieces of legislation affecting specific sectors also provides supportive evidence.

Figure 6.1 shows that over the 20 years since the Single Market's launch in 1992, intra-EU trade of goods has grown as a share of GDP by around 5%. Intra-EU trade represented around 17% of EU GDP in 1999 and close to 22% in 2011. Furthermore, intra-EU trade represents a very high percentage of GDP in most Member States, a level that has grown over the period 1999-2012.

Figure 6.1 Intra-EU trade in goods as share of GDP, 1999-2012 (average of export & import)



Source: Eurostat

Focusing on the manufacturing sector, the evolution of intra-EU trade in the three broad categories of industrial goods according to the SITC classification (Machinery and transport equipment, manufactured goods classified by material and other manufactured goods) has exceeded that of the growth of total value added of the EU manufacturing sector (see chart below).

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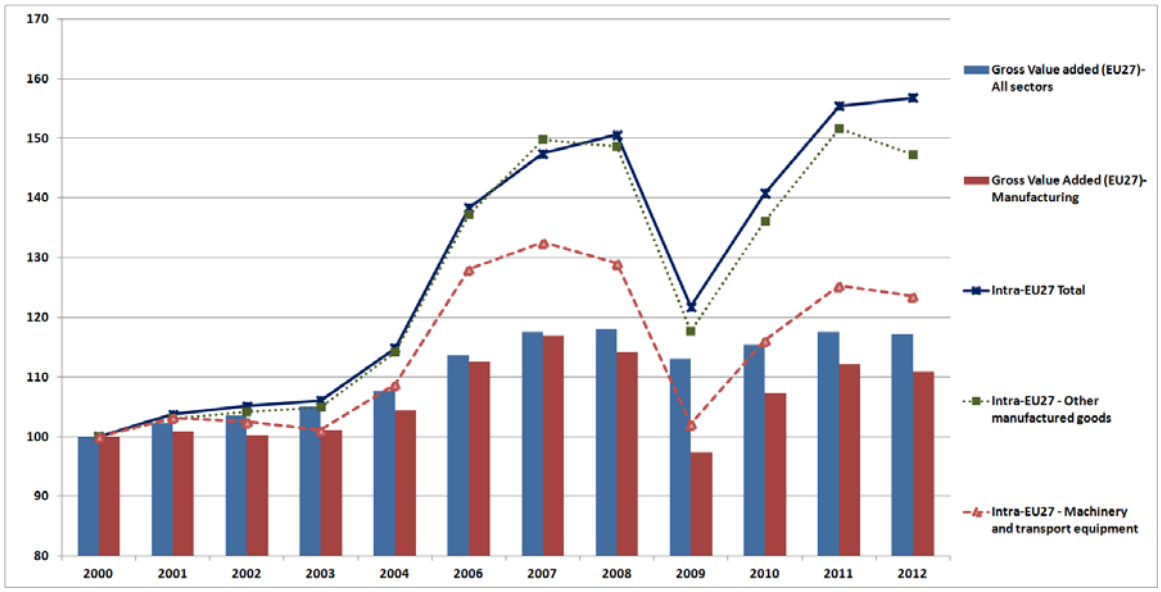
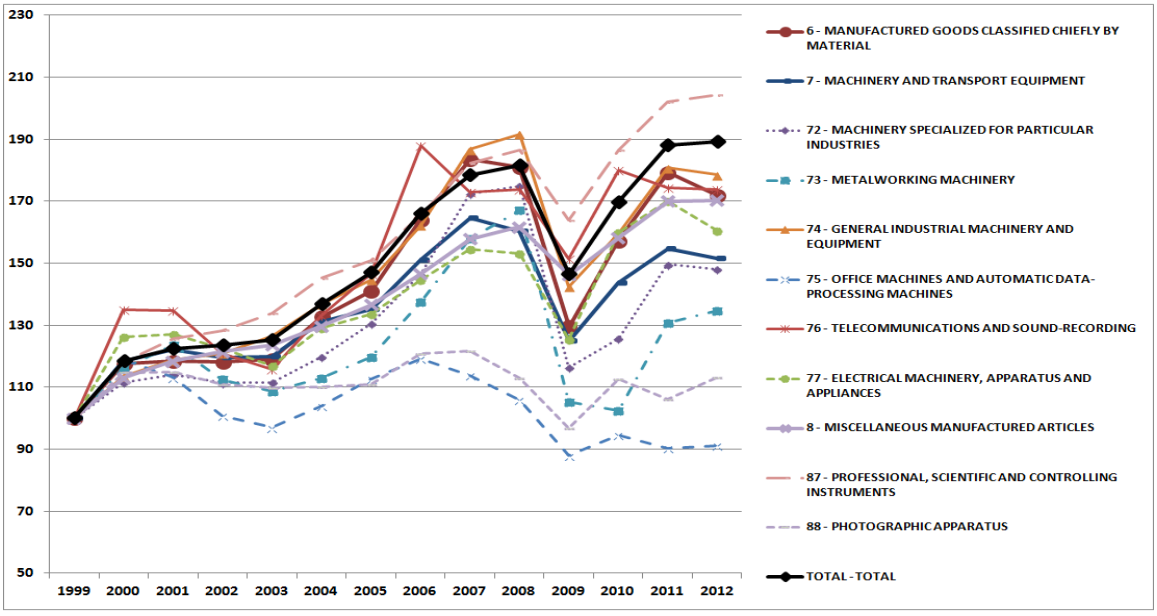
Figure 6.2 - Evolution of intra-EU trade (exports, 2000=100) in selected manufacturing sectors in relation to manufacturing gross value added



Source: Eurostat trade statistics

Figure 6.3 Evolution of intra-EU trade in selected manufacturing sectors (value of imports; 1999=100)

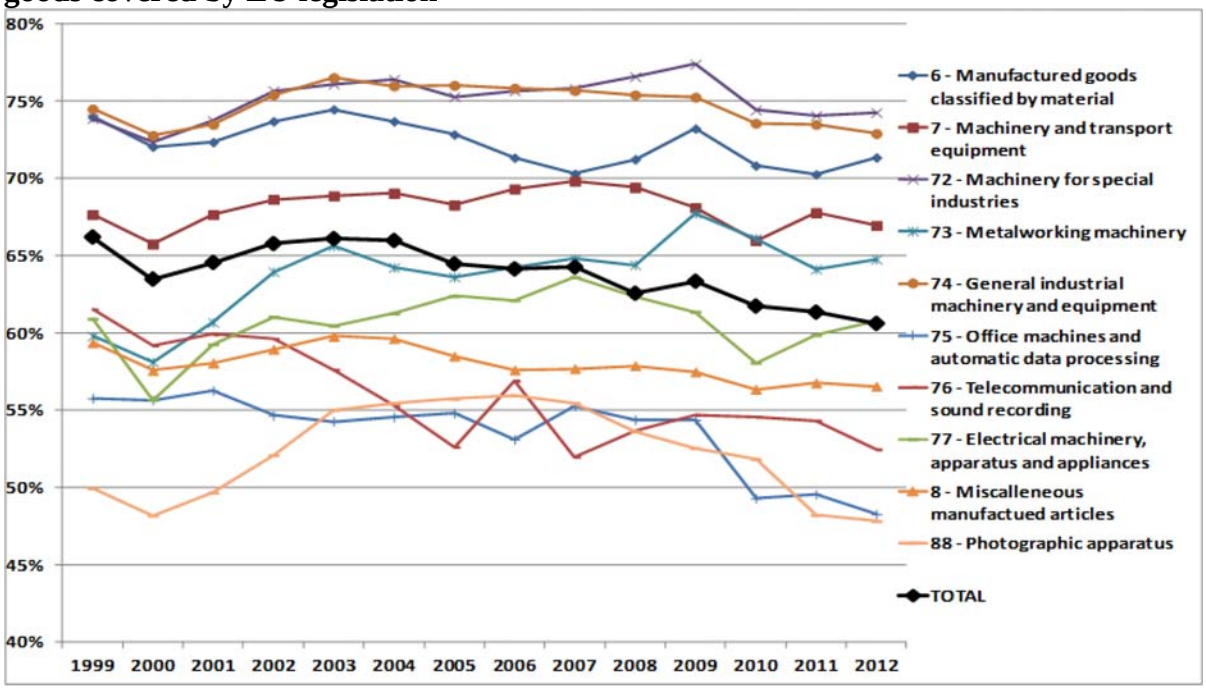


Source: Eurostat

Whilst there are differences between different sectors covered by IM legislation, most have experienced an increase in the level of intra-EU trade, particularly during the first half of the 2000s. Only three have shown a fall in the level of intra-EU trade since 1999 (i.e. office machine and automatic data processing, metalworking machinery, and photographic

apparatus), and this coincided with the economic and financial crisis of 2008.[96]
It should also be noted that in most sectors the level of imports from outside the EU has increased at a higher pace. As a result, in most cases, there has been a reduction of the share of intra-EU trade in the total level of trade (see figure below) reflecting the globalisation of markets, the increasing presence of non-European manufacturers in the European internal market but also, as illustrated in some of the case studies (e.g. gardening equipment, domestic refrigerators), the fact that many EU manufacturers have transferred the manufacturing of industrial products to outside the EU even though where these goods are destined for the EU market.

Figure 6.4 – Evolution of share of intra-EU trade in total trade of selected industrial goods covered by EU legislation



Source: Eurostat trade statistics

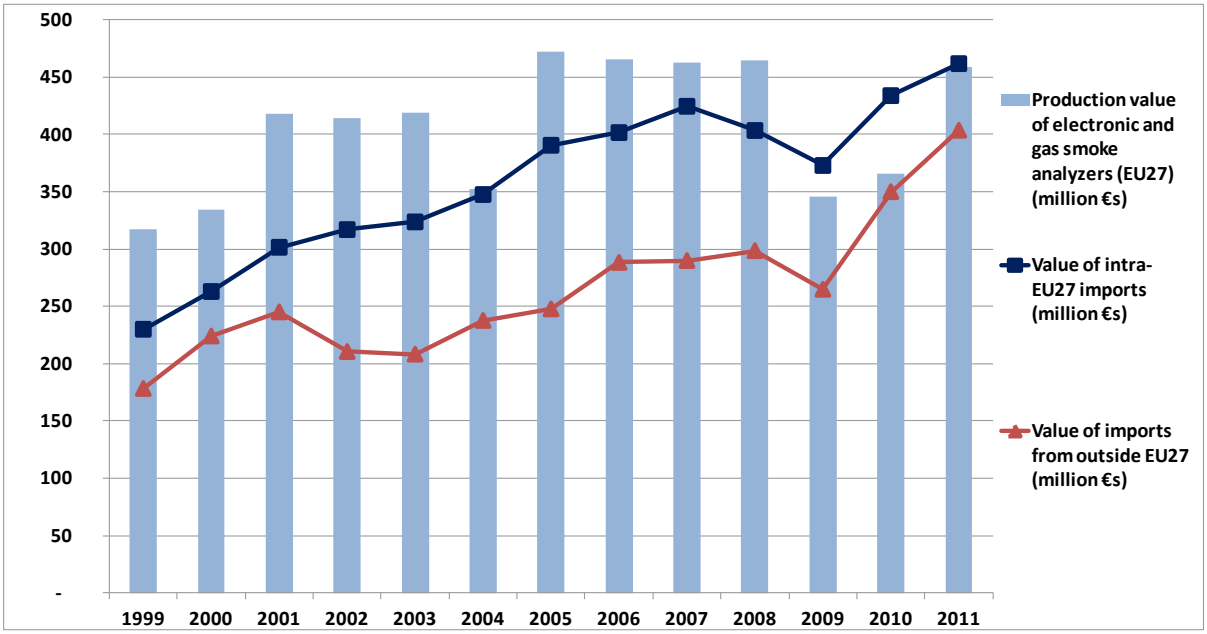
This data may, however, understate the positive role of the introduction of Single Market legislation and technical harmonisation requirements. A key limitation in relation to this task is that EU trade data are generally available only after 1999, a point of time when most of the EU Directives under examination were already in force.

More specific evidence can be found for those categories of products where harmonisation came only at a later stage. One such case is the exhaust gas analysers product group that is covered by the Measuring Instruments Directive (2004/22/EC) (MID). The MID was introduced in 2004 and entered into force in 2006. It covers a range of measuring instruments but most of them had already been harmonised, ever since the early 1970s[97]. Exhaust gas analysers was a new category covered by the MID. The available trade data for gas and

[96] See also table with detailed data in Appendix C.
[97] The MID repealed the relevant Directives.

smoke analysers (a category arguably broader than the exhaust gas analysers) suggest an increase at the level of intra-EU trade even before 2004 but an even greater increase in imports to the EU taking place since 2005/2006. According to one national officer responsible for the implementation of the Directive, the increase in the trade of exhaust gas analysers is clearly connected with the introduction of the MID.

Figure 6.5 - Evolution of trade (imports) for gas analysers inside and outside the EU



Source: Eurostat trade and structural business statistics. Note – the analysis did not include Croatia, EU28

The data are rather less supportive in the case of the recent harmonisation of legislation is pyrotechnic articles. Directive 2007/23/EC on pyrotechnic articles covers fireworks and pyrotechnic articles used in vehicles (airbags, seat belts) and related products. The Directive entered into force in 2010 although it provided for up to a three year period for its transposition into national legislation. Examination of the value of imports suggests a sizeable increase in the level of intra-EU trade of explosives and pyrotechnic products – in comparison with a slower development of extra-EU trade - but a much more gradual increase in the case of fireworks[98]. Imports from outside the EU (China is the predominant exporter) have increased much faster.

[98] The increase in the use of explosives is linked to a significant increase in the level of intra-EU trade of safety & detonating fuses, igniters, detonators. This product category is covered by the Explosives Directive 93/15/EEC.

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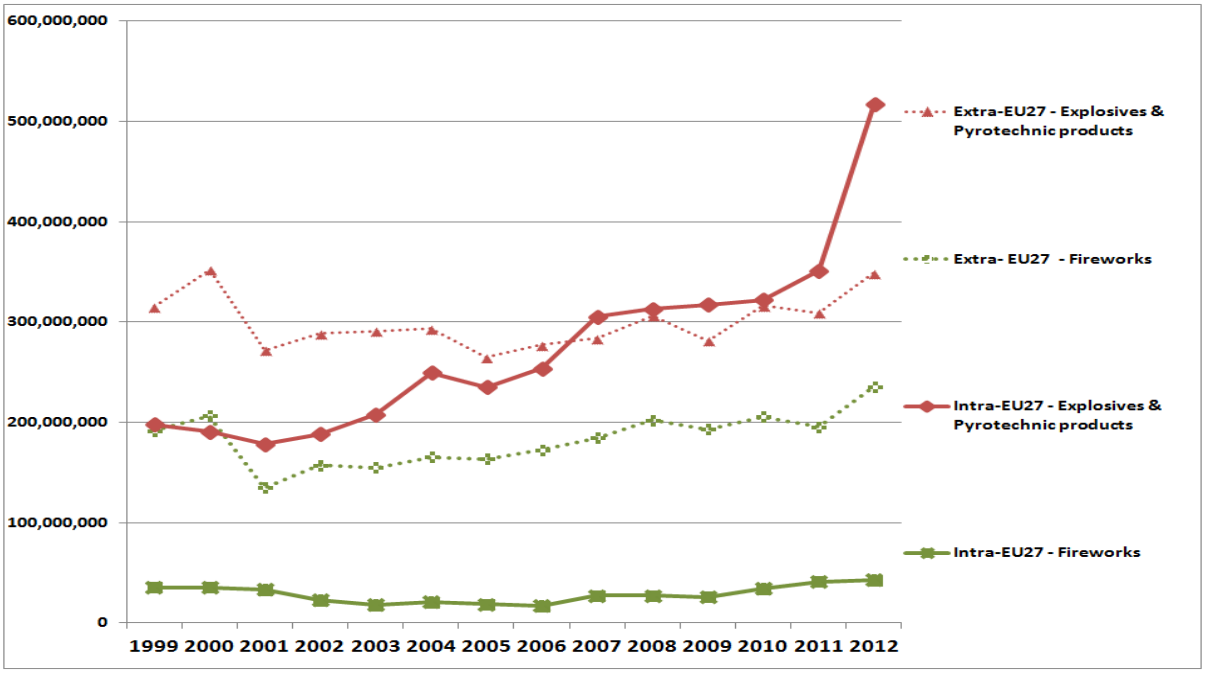
Figure 6.6 Evolution of imports (intra-EU and extra-EU) of explosives and pyrotechnic products (value in Euros)



Source: Eurostat trade statistics. Note – the analysis did not include Croatia, EU28

Amongst the Notified Bodies (NBs) and Accreditation Bodies (ABs) responding to the survey, a clear majority supported the view that IM legislation had helped ensure the harmonised operation of the internal market and ensured fair completion and access to the internal market. (See Table 6.6). Among the seven industry representatives that also responded to the survey, five indicated that IM legislation had been effective or very effecting in harmonising the operation of the internal market but only one considered it effective in terms of ensuring fair competition.

Table 6.6: What impact has Internal Market legislation for industrial products had in relation to the following policy objectives?

Objectives	Respondent	Positive or very positive	Neutral	Very negative or negative	Responses[99]
Ensure the harmonised operation of the internal market	NB	74%	22%	4%	78
	AB	100%	0%	0%	14
Ensure fair competition and access to the	NB	65%	27%	8%	83
	AB	93%	7%	0%	14

[99] After exclusion of "Don't know/not relevant" responses.

internal market					

Source: CSES survey

During the interview programme, most stakeholders (industry representatives and national authorities) also provided support of the role of the IM legislation in terms of the free trade of goods (see selected representative comments in the text box below). The main issue raised is the practical implementation and the fact that, national legislation and requirements applicable to the use phase can still effectively create obstacles to free trade of products.

Table 6.7: Selected comments of stakeholders on the contribution to the functioning of the internal market and free trade

The PPE directive is clear and everybody has to fulfil it, so it is a very good instrument in terms of free movement of goods. We have seen a huge boost for the industry in the early 90'ties as a result of the PPE directive. When it sometimes goes wrong it is in the interpretation in the individual countries. (EU industry association)
Benefits are the free movements of goods. But market surveillance is needed. (national authority)
The free movement of goods works well. There are some technical barriers and inconsistencies from specific Member States but the frameworks that do exist allow productive discussion when the inconsistencies occur and some form of resolution. However, it is important to stress that the concept of free movement does not cover the later phases of use of industrial products (but just the place into market and put into service) often subject to very restrictive national and local regulations. These restrictions may start immediately with the first use. (EU industry association)
The legislation has helped with the free movement of products; there are very few problems with exporting/importing across the EU. It's also quite easy to import from other countries such as the USA into the EU (EU industry association)
Overall positive – not significant issues – barriers have been removed Positive in terms of boosting exports inside EU (EU industry association)
There is still no guarantee of free movement due to the role of standards and national requirements (EU industry association)
IM legislation, especially New Approach legislation meets the needs of different types of economic operators in a great extent. We would encourage the use of New Approach also in other traditionally old approach sectors (chemicals, food,…). We estimate it [is] very effective relating to free movement of goods within the IM (National authority)
Better than before clearly but [there is] no complete harmonisation. There are issues related to use requirements at the national level [but] they are less and less of problem (EU industry association)
The IM legislation represents an overall effective mechanism for ensuring both free movement of goods and a minimum level of standards in health, safety and consumer protection (National authority)

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It has been very effective in ensuring free movement of goods. (National authority)

The market is in good shape. There is definitely free movement of goods according to minimum safety standards However, the level of enforcement does vary and this often depends on the culture of public bodies in diff MS (National authority)

These views are generally consistent with the conclusions of the recent evaluations of a number of Directives. In the case of Gas Appliances Directive (GAD)[100], it was concluded that "the GAD has made a significant contribution to free trade in gas appliances. Harmonising certification requirements has been a significant benefit for manufacturers, who previously had to fulfil varying national certification requirements". Indeed, this finding was supported by the respondents to the survey organised for that evaluation; some 60% of industry respondents and an even higher proportion of ministry respondents agreed that the GAD has had a positive impact upon the free movement of goods/services and cross-border trade, indicating that it contributed to the internal market and that it had led to an increase in cross-border trade and the free movement of goods.

The recent evaluation of the Pressure Equipment Directive also concluded that "Intra-EU trade in pressure equipment products over the period grew much more rapidly than overall production, suggesting that the Internal Market legislation in this area at least had a facilitating role. During the interview programme it was noted that the biggest increases in intra-EU trade were in products with a higher value and technical complexity". The survey of industry (51%) and other stakeholders suggested that the majority consider that the PED is more effective than the previous system of national regulation (with 24% giving a neutral response). Similarly, the 2007 evaluation of the Explosives Directives found that businesses around Europe have seen a decrease in the share of sales from national markets – from 82% to 67%. Businesses indicated that 15% of their sales came from elsewhere in the EU, up from just 9% in 1993.

Taken together, the existing evidence supports the conclusion that, while there are imperfections, EU harmonisation legislation has made a significant contribution to the free movement of goods/services and cross-border trade, reduction of national regulatory barriers and an effectively-operating internal market. Weaknesses exist in the practical implementation at the national level and, national requirements related to the use phase – which are still responsibility of Member States and outside the scope of the Internal Market legislation - can often reduce the effectiveness of the IM legislation.

There is, moreover, evidence that IM legislation has delivered benefits for economic operators that trade in global markets. Indeed, many stakeholders reported benefits from compliance with Union harmonisation legislation, since compliance costs can be 'leveraged'. For instance, once a given product platform is compliant with EU legislation, this can serve as a basic regulatory building block to customise products and documentation to meet compliance requirements for product safety and environmental legislation across other global jurisdictions. IM legislation is among the most stringent in the world and can therefore be used as a starting point for large firms in developing compliant products for different

[100] Directive 2009/142/EC of the European Parliament and of the Council of 30 November 2009 relating to appliances burning gaseous fuels.

regulatory jurisdictions globally. This is particularly true for products where third country authorities have developed their own standards to be consistent with those of the EU.

Research Findings (RFs)

- (RF113) The accretion of IM legislation has been accompanied by an increase in intra-EU trade in absolute terms and as a percentage of GDP. (Eurostat data)
- (RF114) Whilst the influence of IM legislation cannot be separated from other influence, e.g. global increase in trade, the consensus view is that IM legislation has made an important contribution (Stakeholder interviews; Survey of NBs and ABs; Results of previous evaluations).
- (RF115) Compliance with EU legislation can support economic operators trading in global markets, particularly where third country legislation and standards are based on those of the EU.

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6.9 Impact of IM legislation on health and safety and consumer protection

EQ33: Overall, how effective is IM legislation for industrial products as a mechanism and means to achieve the objective of ensuring a high level of health and safety and consumer protection?

In the IM legal base, high levels of **health, safety and consumer protection** are a key objective. Indeed, this is the overriding principle behind the setting of essential requirements (for safety and health) which underpin the New Approach[101].

In comparison with the situation prior to the introduction of harmonised Internal Market legislation, there are obvious advantages. Manufacturers had to operate in a highly fragmented market with different national regulatory requirements (including those relating to product safety). There were attendant higher risks, since manufacturers - especially from third countries - may not have fully understood different national requirements. There are clear benefits in having a single set of rules from the point of view of promoting product safety and ensuring that products do not have harmful effects on health. EU standards promote harmonisation and they have brought about a more uniform approach to the testing and conformity assessment of products.

Furthermore, horizontal IM harmonisation directives and regulations, such as RoHS and REACH have also served as a useful mechanism for promoting healthier products**.** In the case of RoHS, this has been achieved by restricting the use of hazardous substances in products. This has had an especially beneficial impact through the interaction between horizontal and product-specific Directives such as the Toys Directive.

Evidence gathered during the research suggests that IM legislation plays a positive role in ensuring high levels of health, safety and consumer protection. Stakeholders generally accept that the legislation has contributed to product safety and to the protection of the health of industrial users and consumers of products. The overwhelming majority of Notified Bodies and Accreditation Bodies responding to our survey expressed a positive view, with only very few suggesting that the impact had been negative. Five of the seven industry representative that responded to the survey were also positive concerning the contribution of IM legislation towards higher levels of safety and consumer protection.

Table 6.8: What impact has Internal Market legislation for industrial products had in relation to the following policy objectives?

Objectives	Respondent	Positive or very positive	Neutral	Very negative or negative	Responses[102]
Ensure high levels	NB	74%	19%	7%	84

[101] The term New Approach is becoming less frequently used in the context of the NLF. However, irrespective of the terminology, Union harmonisation legislation and horizontal and product-specific harmonisation Directives that fall within this body of legislation aim to ensure high levels of product safety.

[102] After exclusion of "Don't know/not relevant" responses.

of health, safety and consumer protection	AB	92%	8%	0%	13

Source: CSES survey

Individual comments from stakeholders (national authorities and industry representatives) also provide a positive view even if there are, again, question related to the practical implementation. The following table provides examples of the typical comments made during the interviews. In general, most respondents are positive even though there are again concerns on the practical implementation and the weak enforcement. Problems related to non-compliant products are generally considered to be due to the fact that the rules in place are not respected by all economic operators, poor market surveillance and enforcement.

Table 6.9: Selected comments of stakeholders on the contribution to ensuring high levels of health, safety and consumer protection

The level of enforcement does vary and this often depends on the culture of public bodies in different Member States. So yes the market works in terms of free movement but I'm not sure if the exact safety standards are always met in all circumstances (national authority)
The main benefits [on Internal market legislation] are Uniformity of good practice in market surveillance activities and uniform rules for safety and market access business (national authority)
It has been effective for health and safety. We have no big issues around that. (national authority)
Quality and safety is guaranteed on a sufficient level. (EU industry association)
Think that in the areas of health and safety there is scope for greater harmonisation – use of regulation would be preferable (EU industry association)
The minimal essential requirements provided for in the regulation are respected. Safety requirements are overall well understood and respected. They filter out fraudulent producers effectively. (national authority)
The body of IM legislation achieves the objectives of the internal market overall in ensuring common minimum standards in health & safety and consumer protection. Products are thoroughly controlled, particularly in France. However, certain Member States do not perform tests regularly and simply verify certification documents. (national authority)
IM legislation is an effective mechanism for ensuring free movement of goods and a minimum level of standards in health, safety and consumer protection. (national authority). We would encourage the use of New Approach also in other traditionally old approach sectors (chemicals, food,…). i) we estimate it very effective relating to free movement of goods within the IM ii) also very effective relating common minimum standards in health and safety, consumer and environmental protection. (national authority).

Another relevant aspect is the increasing awareness of suppliers of products. A recent Eurobarometer survey found that 86% of retailers selling consumer products felt well

informed about rules and regulations relating to product safety, which was an increase compared to the figure of 80% in 2009. Some 97% of retailers declared that they complied with all legislation dealing with the economic interests of consumers and 80% believed that their competitors also complied with the legislation. The same survey also showed that a large majority of retailers selling consumer products correctly identified the following statements about product safety as being true:

- Retailers must not place unsafe products on the market (only 9% gave incorrect responses);
- Retailers must be able to present technical documentation on the safety of their products (10% gave incorrect responses); and
- Upon the authorities' request, retailers must cooperate with the authorities to prevent risks posed by products which they supplied (10% gave incorrect responses).[103]

A large and increasing majority of retailers agreed that public authorities "actively monitor and ensure compliance with consumer legislation (79%) and product safety legislation (81%) in their sector in their country". Whilst these findings do not differentiate between products covered by EU IM legislation and those that are not, it does offer evidence of a general improvement in consumer protection.

From the point of view of consumer confidence, according to a recent Eurobarometer study, a growing majority of EU consumers agree that, in general, sellers and providers respect their rights as consumers (65%) and that they are adequately protected by the existing consumer protection measures (57%). Moreover, there has been an increased level of trust in the safety of non-food products, with only one in five consumers in 2010 (compared to one in four in 2009) considering that a significant number of products were unsafe.[104]

There is also evidence that there is still a significant distance to go in order to achieve high levels of product safety and consumer protection that satisfies consumer concerns. According to the February 2013 Product Safety and Market Surveillance Package, a considerable percentage of products on the market are non-compliant, which undermines consumer confidence. "*Notwithstanding legislation in place, unsafe and non-compliant products still find their way onto the market. People still suffer harm and harmful products still pollute the environment. Rogue traders persist - flouting the rules and undermining a clear level playing field for operators. This undermines the internal market and is a disincentive to businesses that invest a lot of resources in ensuring that the design and manufacture of their products is safe*"[105].

A recent joint market surveillance actions under PROSAFE (Product Safety Enforcement Forum of Europe) suggested significant levels of non-compliance often associated with unsafe products and a study of the IFIA on electrical products for household use in 2012 highlighted safety issues caused by a significant number of non-compliant products imported

[103] Flash EuroBarometer Report No 300 – Retailers' attitudes towards cross-border trade and consumer protection, March 2011.
[104] Flash EuroBarometer 299 – Cross-border trade and consumer protection, March 2011.
[105] COM(2013) 74 final

from the outside of the EU. While potentially biased by specific high-profile events, Eurobarometer data also indicate a decrease in confidence of consumers in the safety of products sold in the EU (25% in 2011 compared to 20% in 2010 think that a significant number of products are unsafe). Moreover, a study by the Consumer and Industrial Products Committee of IFIA39 on electrical products for household use performed in 2012 shows that there a significant number of non-compliant products with safety issues imported from the outside of the EU which circulate on the internal EU market.

The 2012 Annual Report on the operation of the Rapid Alert System for non-food dangerous products (RAPEX)[106] suggests that there are a quite high number of notifications of products. It notes that "throughout the last eight years, the number of notifications on dangerous products has increased year on year". While these have most frequently been related to clothing, textiles and fashion items (34% of all notifications, 668) – products that fall outside of internal market legislation – they were by toys that are covered by the Toys Directive (19% of notifications, 366) and another important category falling within the scope of IM legislation, electrical and electronic equipment (11% of notifications, 205). Lighting equipment is another category of products that was relatively often notified (3% in 2011). It should be noted that, according to the annual report, the increasing number of notifications are a reflection of enhanced market surveillance efforts and not necessarily an increase in the level of unsafe products.

Specific examples of non-compliance were also identified through the interviews and desk research. For instance, the impact assessment for the new "Radio Equipment Directive" cited evidence from EU Market Surveillance Authorities (MSAs) that only between an estimated 28% and 56% of products were fully compliant with the essential requirements. According to an interviewee from the Commission, levels of administrative compliance have been estimated at an even lower level by MSAs, of about 20%. Although this may include minor administrative non-compliance and does not imply that most radio products are unsafe, it illustrates the fact that non-compliance continues to be a major problem.

Research Findings (RFs)

- (RF116) IM legislation plays a positive role in ensuring high levels of health, safety and consumer protection. (Stakeholder interviews; Survey of NBs and ABs; Eurobarometer surveys on awareness of suppliers and on consumer confidence)
- (RF117) There remains a high number of non-compliant products, which undermines consumer protection and consumer confidence. (Stakeholder interviews; Eurobarometer survey on consumer confidence; Consumer and Industrial Products Committee report; PSMSP)
- (RF118) There has been an increasing number of RAPEX notifications, reflecting enhanced market surveillance but also the continuing problem of non-compliance. (RAPEX data; Interviews of MSAs)

[106] RAPEX system allows EU Member State market surveillance authorities and the European Commission to share information about dangerous products found on the European market quickly and efficiently and to inform consumers about potential risks to their health and safety.

Effectiveness, fitness for purpose and impacts 6

6.10 Impact of IM legislation on environmental protection

EQ34: Overall, how effective is IM legislation for industrial products as a mechanism and means to achieve the objective of ensuring a high level of environmental protection?

Finally, with regard to the objective of **environmental protection**, it should be noted that this has not been a prime objective of the majority of Internal Market Regulations and Directives. Recent pieces of IM legislation - such as the Ecodesign, RoHS, Noise emissions of outdoor equipment, Non-road mobile machinery emissions and Waste Packaging Directives have been based on internal market Treaty articles. The majority of Notified Bodies and accredited bodies responding to the survey supported the view that IM legislation had helped ensure a high level of environmental protection, although a sizeable minority appeared to be more sceptical. Among industry stakeholders, five out of seven were positive as to the contribution to environmental protection.

Table 6.10: What impact has Internal Market legislation for industrial products had in relation to the following policy objectives?

Objectives	Respondent	Positive or very positive	Neutral	Very negative or negative	Responses[107]
Ensure a high level of environmental protection	NB	51%	46%	3%	69
	AB	69%	31%	0%	13

Source: CSES survey

Furthermore, as indicated in section 6.3, IM legislation plays a positive role in the development of greener products and technologies but weak market surveillance and enforcement of environmental aspects often operate against this. Furthermore, for a number of industry stakeholders the interaction of IM harmonisation legislation and other legislation in the environmental fields (such as WEEE, the F-Gas Regulation) often leads to additional costs and even duplication of requirements increasing the cumulative regulatory effects of IM legislation.

- (RF119) IM legislation has made a contribution to environmental protection, albeit a modest one; this is not the primary purpose of most IM legislation and MSAs have not tended to prioritise environmental protection. (Analysis of legal text; Stakeholder interviews; Survey of NBs & ABs)

[107] After exclusion of "Don't know/not relevant" responses.

7. Conclusions and recommendations

This evaluation has considered a wide range of issues relating to internal market (IM) legislation for industrial products and the efficiency and effectiveness of mechanisms and structures to support its implementation. Among the cross-cutting themes examined were whether the legislative framework for Union harmonisation legislation demonstrates 'fitness for purpose' and whether there are any inconsistencies or instances of duplication between different pieces of IM legislation. The question of how far such legislation can accommodate innovation was also central.

While clearly it is premature at this stage to evaluate the efficiency and effectiveness of the New Legislative Framework (NLF) as a whole, an assessment was made of the, the extent to which follow-up initiatives, notably the Alignment Package has made a contribution to modernising and reforming the legislative framework. Among the issues considered were the extent to which there are cumulative regulatory effects (and compliance costs) of IM legislation. The costs and the benefits of internal market legislation for industrial products, and the possible scope for regulatory simplifications (and cost savings associated with these) were also assessed.

7.1 Conclusions

In this section, we present the conclusions of the evaluation. In each case, we highlight the Research Findings (RF) on which the conclusion is based, which provides the link back to the evidence presented in the main body of the report.

7.1.1 Relevance and coherence of the legislative framework

1. Overall, **the IM regulatory framework demonstrates a high degree of fitness for purpose**. Internal market legislation is relevant to meeting key EU objectives relating to the need for technical harmonisation measures in the area of industrial products, with high levels of protection for health and safety and consumers and, to the environment. (RF1, 2, 3, 4)

2. The **IM legislative framework has in-built responsiveness to adapt to change**[108]. Periodic review and recasting of various pieces of IM legislation over the past 25 years has helped to ensure that IM legislation continues to reflect industry-specific and technological developments. (RF9, 10, 11, 12)

3. In general, directly applicable EU **regulations appear to be a more effective regulatory instrument than directives** for implementing IM legislation. Regulations remove the risk of divergence in interpretation of European rules during national transposition and guarantee synchronised timing in implementation, although in many cases, Member States merely adopt the transpose the Directives as written. (RF5, 6)

4. **There is a need to clarify the circumstances under which regulations or directives should be used** and this clarification should guide the choice of instrument as and when

[108] Examples of changes in product groups include the placement of new products come on the market, technological developments, a move toward more advanced manufacturing processes, the use of different materials in products, the advent of smart / integrated products, etc.

legislation is introduced or revised. (RF7, 8)

5. The adoption of **common definitions of different economic operators based on Decision 768/2000/EC, together with a clarification of their respective obligations and responsibilities is contributing towards a more coherent IM legislative framework**. The definitions in Decision 768/2000/EC therefore merit application across the whole body of IM legislation (RF11, 14, 15, 16, 25)

6. It may be more practical to **set out common elements across the IM legislative framework in a horizontal regulation**, rather than incorporating the same additional text into each and every piece of IM legislation[109]. (RF13)

7. Instances of **gaps, loopholes, inconsistencies and duplication in IM legislation are relatively modest in number**. Many are being or will be addressed by the NLF, the Alignment Package and other recasts of the legislation. (RF9,10,12)

8. There is a need to bring **greater consistency to the definition of products and scope**. This might involve broad definitions clearly stated in the main text of legislation, with specific definitions of categories and sub-categories defined in Annexes and clarified by the various Working Groups, with suitable adjustments and fine-tuning over time. (RF17, 18, 19)

9. There is a **lack of clarity and consistency in the inclusion and definition of spare parts and components** in IM legislation, which should be addressed by guidance from the Commission. (RF20, 21, 22, 23)

7.1.2 Efficiency of the implementation regime

10. **Economic operators appreciate the choice of modules relating to conformity assessment**, although some are unsure which modules apply to their products and whether third party conformity assessment is required. (RF26, 28)

11. **Self-certification should not be allowed except Module A**, given the inherent difficulties in ensuring the competence of economic operators. (RF27)

12. **Conformity assessments undertaken across EU28 are of varying quality**, which often reflects a lack of technical capacity in some NBs, due to the fact that few operate at scale or transnationally. This may require action at EU level, namely the strengthening and more consistent fulfilment of requirements on Member States relating to notification of Notified Bodies, rather than more stringent regulation of NBs, as well strengthening Notified Bodies Groups. (RF29, 30, 31, 32, 33, 34, 35, 36, 37)

13. The need to ensure quality of conformity assessments would tend to outweigh the benefits of flexibility in **allowing different elements of a conformity assessment to be performed by different bodies.** (RF38)

14. **It does not seem appropriate to open up Europe's conformity assessment market to third countries**, given the concern over the quality of conformity assessments

[109] Given that a different approach has already been adopted through the Alignment Package, introducing a horizontal regulation should instead be a medium-long term aspiration.

undertaken by Notified Bodies in third countries. (RF39, 40)

15. It is not necessary to require third-party conformity assessments, except for high-risk products. However, there is a need to clarity the principles and circumstances under which third party conformity assessments is required or not. (RF41, 42, 43)

16. **Accreditation strengthens confidence in conformity assessment by encouraging consistency of conformity assessments and improving technical expertise and professionalism among NBs**. Given these benefits, it would seem appropriate to make accreditation compulsory, over a reasonable timescale with appropriate guidance and discussion at EU level. (RF44, 47)

17. **The accreditation process can be too costly, lengthy and subject to national variations and inconsistencies, reflecting in part a lack of expertise on the part of some ABs**. It may be possible to overcome these difficulties by specifying the basis for accreditation more explicitly at EU level. (RF 45, 46)

18. **The current DoC regime is satisfactory**, despite some minor difficulties and DoCs are relatively easy to produce. On that basis, it would be preferable for a single DoC be required for each product, covering all applicable pieces of legislation, in line with Decision 768/2008/EC and without the need for a colour photograph of the product. (RF48, 49, 50, 51)

19. Despite minor difficulties relating to inappropriate markings, **the CE marking regime is effective** and the logo enjoys a high level of awareness amongst consumers. (RF 52, 54)

20. **There is no need for any fundamental change in CE marking**, except to bring greater consistency and avoid having different requirements for different pieces of legislation and address the issue of products with multiple parts, which can be addressed as and when legislation is updated. (RF53, 55)

21. **Mechanisms such as Administrative Co-operation Working Groups and Product Contact Points play a useful role** in supporting understanding of the legislation and its implications. Their contribution could be enhanced by greater profile and, in the case of ADCO, by EU funding for participation and by EU technical assistance funding, e.g. for research or guidance. (RF56, 57, 58, 59)

22. **There is a lack of uniformity in approach to market surveillance across EU28 and differing levels of resources and technical capacity**. Existing levels of technical compliance checks are not considered adequate to ensure that non-compliant products are taken off the market and that non-compliant operators are not given an unfair competitive advantage This contributes to making market surveillance the weakest part of the implementation regime, which in turns leads to high levels of non-compliance, low levels of product withdrawals and a need to strengthen the traceability of products. (RF60, 61)

23. **MSAs are most effective when they differentiate between minor instances of non-compliance with administrative requirements and serious instances of non-compliance with essential safety requirements** which threaten health, safety and the environment.. In the first case, constructive dialogue with manufacturers can often prove effective. In the latter case, MSAs must typically resort to legal action. Clearly, to

achieve EU objectives, most effort must be given to the more serious instances of non-compliance. (RF61)

24. **RAPEX and ISCSMS play a useful role in informing market surveillance authorities**, which could be strengthened by greater complementarity and synergy between the two tools. (RF 62, 63, 118)

25. **There is a need for guidance on the relative merits of a risk-based approach versus a systems-based approach to market surveillance**, as well as for better definition and clarification of risk and how to assess it, building on the proposed risk assessment methodology in the PMSP. (RF64, 65)

26. **The PSMSP has the potential to reinforce market surveillance** by aligning consumer product safety requirements with harmonised product safety requirements and by extending EU market surveillance rules to all consumer products, which will enable enforcement measures to be targeted directly at the source of any risks to safety. This new regime may pose greater costs on MSAs, although the costs for responsible operators are likely to be negligible. (RF66, 67, 68, 69)

7.1.3 Costs of compliance and the scope for simplification

27. **Familiarisation with the legislation accounts for a significant proportion of the total costs of compliance**, estimated at around 15-20% for many firms and consisting largely of staff costs. (RF70)

28. **Compliance costs have a strong element of Business as Usual (BAU) Costs,** since ensuring compliance with IM legislation is important, but only one of many elements factored in to the product design and testing process by the firms. The fact that compliance is often taken into consideration from the outset makes the costs very difficult to separate costs such as testing equipment from BAU costs. (RF71, 72, 73, 77)

29. **The costs of conformity assessment depend very largely on the need for third-party certification and on the time taken to collate and store the necessary technical documentation** for the DoC. (RF75, 76)

30. **There is wide divergence in the level of total compliance costs across different product groups. However, the overall burden does not appear to be excessively burdensome**. In most - but not all cases - total annual estimated compliance costs (administrative, substantive) for the sector do not exceed 1% of annual turnover. (RF77)

31. **There are concerns among economic operators as regards the level of administrative costs and burdens associated with some IM compliance requirements**. For instance, traceability requirements were viewed as being insufficiently flexible and/ or disproportionate, examples were found of minor inconsistencies in administrative requirements between IM legislation, with ambiguity in translation requirements for DoCs since the NLF. (RF75)

32. **There are cumulative regulatory effects from the interaction between IM legislation and environmental legislation applicable to products**. Even though it is has always

been the case that multiple pieces of legislation are applicable to a given product, in recent years the overall body of Union harmonisation legislation has grown, as well as environmental legislation applicable to products[110]. (RF80)

33. **There is evidence that SMEs face higher compliance costs per unit than large firms** and cannot achieve leverage on investment in compliance costs in the same way that global manufacturers can[111]. However, since product safety is non-negotiable, there is limited if any scope for exemptions for SMEs or micro firms. (RF78)

34. **There are administrative burdens for industry resulting from the frequency of changes** due to the updating of legislation and even more so the updating of harmonised technical standards[112]. (RF74, 75)

35. **Since large firms participate much more actively in EU legislative-making and standardisation processes, they have a comparative advantages compared with SMEs**, since they become aware about the legislation earlier and factor it into the product design stage earlier, thereby lowering substantive compliance costs. Since they are often also involved in drafting standards, this reduces the extent to which the concerns of SMEs are taken into account and risks favouring large producers. There may be scope to take practical steps to support the involvement of SMEs in such processes (RF78, 107, 108)

36. **There is potential scope to simplify the body of IM legislation and its administrative requirements**, such as through merging directives, eliminating inconsistencies in administrative requirements and making a gradual transition towards electronic provision of compliance information by manufacturers to MSAs. Such simplifications have the potential to reduce the costs of compliance borne by operators. However, the extent to which such savings are realisable in practice would need to be explored in more depth. (RF81, 82, 83, 84, 85, 86, 87, 88, 89)

37. **Simplification of IM legislation might reduce the costs of compliance** by around 12%, although the extent of such savings will vary from product group to product group. (RF90)

7.1.4 Effectiveness, fitness for purpose and impacts

38. **Regulatory barriers to the functioning of the internal market persist** in the form of differing or incorrect interpretations or applications of IM legislation, additional national requirements, failure to recognise EC type-approval certificates issued in other countries, and inconsistency in allowing the use of old versions of the standards. However, there is evidence to suggest the economic operators perceive the regulatory barriers to be greater than they are in reality. (RF91, 92)

[110] Although environmental legislation was formerly out of scope, the cumulative effects of complying with a number of pieces of different legislation for a given product, both IM regulations and environmental, were considered.

[111] The on-going review of the Ecodesign and Energy Labelling Directives will specifically look into this question.

[112] Although individual pieces of legislation taken in isolation do not change that frequently, since multiple pieces of legislation and standards are applied, it takes considerable resource to keep track of these developments and to manage compliance accordingly (e.g. frequent updating of DoCs).

39. **IM legislation is technology-neutral and tends to promote rather than limit innovation**, provided that the legislation and the standards keep pace with technological innovations and that up-to-date guidance is made available. (RF94, 95, 96, 97)

40. **There are few, if any, regulatory barriers that specifically relate to green products**, although some non-regulatory barriers remain, due to a lack of common definition on "green products" and a lack of harmonised criteria. (RF98, 99, 100)

41. **Whilst the legislative framework is generally adequate in respect of e-commerce within the EU, EU, it is not operating effectively to prevent the import of non-compliant products from third countries.** This reflects a gap in between the E-Commerce Directive and the body of IM legislation and practical difficulties faced by MSAs. (RF102, 103, 104, 105)

42. **There are inherent limitations on the scope to alleviate legislative requirements for SMEs without compromising other objectives**, although SMEs potentially face a greater burden due to diseconomies of scale. There are, however, practical ways to help SMEs that could be encouraged and replicated across EU28, e.g. promoting participation in standards committees, guidance, etc. (RF106, 107, 108)

43. **The increasingly blurred distinction between products and services creates uncertainty in the implementation and enforcement of the legislation**, which could be addressed in any update of the legislation and setting out in generic terms how these issues could or should be addressed. (RF109, 110)

44. **There is no scope to limit the essential requirements of products to be used by professionals, except for components or products that are only to be used in controlled environments**, although there may be scope to reduce the administrative requirements for other products. (RF111, RF112)

45. **It is generally accepted that Union harmonisation legislation has led to reduced costs for industry when compared with a notional "counterfactual" situation of a fragmented market with 28 different sets of national regulations and standards** (as was the case before the internal market's establishment, albeit when the EU had only 12 Member States). (RF1, 3)

46. **The elimination of technical trade barriers through harmonisation measures is also associated with growth in cross-border intra-EU trade and industry consolidation**. This has allowed for economies of scale and scope to be achieved, which has helped to strengthen the industrial competitiveness of European economic operators. (RF113, 114)

47. **There are benefits for economic operators in investing in compliance with IM legislation, where they trade in global markets**. Once a given product is compliant with EU legislation, it can often be easily customised to meet compliance the requirements set by other legislative regimes, particularly where third country legislation and standards are based on those of the EU. (RF115)

48. **IM legislation plays a positive role in ensuring high levels of health, safety and consumer protection**, although there remains a high number of non-compliant products, which undermines consumer protection and consumer confidence. (RF116, 117)

7.2 Recommendations

In this section, we set out the recommendations from the evaluation, which draw on a wide number of research sources: the online surveys, the interview programme, the case study research with manufacturers and industry representatives and the Your Voice consultation. The conclusions section highlights the rationale underlying these recommendations. Where appropriate, we signpost which sections of the report the more detailed rationale can be found.

The recommendations are grouped together under the following headings: (i) Improving the architecture of Union harmonisation legislation; (ii) Strengthening the effectiveness of the regulatory framework; (iii) Improving the functioning of Union harmonisation legislation; (iv) Regulatory simplification; (v) Reducing administrative burdens for economic operators; and (vi) Strengthening the implementation regime for Union harmonisation legislation. Due account needs to be taken of existing and ongoing regulatory and administrative simplification measures and of efforts to strengthen consistency of the regulatory framework.

7.2.1 Improving the architecture of Union harmonisation legislation

Key issues relating to the architecture of Union harmonisation legislation are mainly set out in Section 3 (relevance and coherence). The recommendations reflect the evidence gathered from across a broad spectrum of stakeholders. However, in some cases, where there was no clear consensus, such as the possibility of introducing a horizontal regulation based on Decision 768/2008, we provide an independent evaluative judgement.

1. **Consideration should be given by the Commission to using regulations rather than directives as the primary instrument for implementing Union harmonisation legislation.** This would eliminate differences in the timing of national legislation entering into force across EU28, and reduce the risk of divergent transposition, interpretation and application.

2. **However, there should remain flexibility to adopt directives should it be more appropriate in specific circumstances.** Although the general policy would be that regulations are preferable to directives, if the Commission considered that a directive was more appropriate on the basis of an impact assessment (IA), it should clarify the rationale for using whichever legislative instrument is put forward in the IA.

3. **Periodic reviews should be undertaken of IM legislation for industrial products to ensure that the regulatory framework is consistent, and that there are no major gaps, loopholes, inconsistencies or duplication either in the legislation itself or between different pieces of IM legislation.** IM legislation should be reviewed once every 10 years as a minimum to ensure that legislation remains up to date and reflects industry developments and product innovation.

4. **A horizontal regulation based on Decision 768/2008 should be considered in the medium-term, setting out common definitions and other common elements that apply across Union harmonisation legislation.** Although not feasible in the near term, since a different approach has been adopted through the Alignment Package, a horizontal regulation would be more coherent and would reduce the length of legal texts in individual product regulations and directives.

5. **Non-binding guidance on complying with Union harmonisation legislation should be**

updated by the Commission on a more regular basis, **given its usefulness to manufacturers.** Where possible, it should give insight into the rationale for particular requirements or standards.

6. **In a number of areas within professional goods, the legislation applicable at the use phase (e.g. installations, maintenance) set at national level imposes additional barriers that reduce the benefits of harmonised legislation.** While such aspects are outside the scope of IM legislation itself, the development and provisions of IM legislation should take such aspects into consideration aiming to minimize any obstacles (to the extent possible).

7.2.2 Strengthening the effectiveness of the regulatory framework

Key issues relating to strengthening the effectiveness of the regulatory framework are set out in Section 6 (effectiveness, fitness for purpose and impacts).

7. **Legislative review processes leading to the recasting of existing IM legislation should be coordinated and synchronised so as to minimise administrative burdens for industry[113].** The research showed that there are cumulative effects in the form of increased administrative burdens for firms due to the high cumulative frequency of legislative changes and updates to technical standards.

8. Consideration should be given as to the feasibility (political/legal and practical) of introducing a specific date/year when new or amended pieces of IM legislation that have already been adopted come into force. This would also give SMEs more time to prepare.

9. **The Commission should give further consideration as to ways of strengthening the participation of SMEs in EU legislative-making and standardisation processes.** One possibility would be to ensure that SME representative associations are better represented in working groups on specific IM directives and regulations, with support provided for the costs of their participation where possible[114].

10. There should be a faster transition towards "e-market surveillance" in which economic operators will be expected to make as much compliance information available online as possible. This would promote more efficient and effective provision of two-way compliance information and data between MSAs and economic operators. This would also be more efficient for economic operators from an internal organisational perspective, given the need for periodic review and updating of DoCs and other technical documentation.

11. Economic operators should be allowed to make general regulatory information about specific products / models/ platforms available in online format only (e.g. DoCs). More sensitive technical documentation and supporting test data requested by MSAs could be transferred electronically via secure data transmission.

[113] Since IM legislation has in the past been updated at different times, there has been high cumulative frequency of regulatory changes for industrial products. Industry stated that it would be beneficial if there were to be coordinated updating exercises.

[114] There is already funding for NORMAPME which represents SMEs in standardisation but in an earlier study they reported that they still did not have enough resources to adequately follow standardisation processes.

12. **The Commission should actively promote cultural change among MSAs to encourage them to accept compliance information electronically.** Many MSAs prefer to have paper copies of compliance documentation (DoCs, technical files). One means to achieve this could be through the exchange of officials, as proposed in the Product Safety and Market Surveillance Package.

13. In order to facilitate the transition towards a paperless future for market surveillance, **market surveillance authorities (and customs authorities where appropriate) should be equipped with scanning equipment or smart phone readers that would link through to the compliance section of the economic operators' website or to a dedicated standalone website.** This is subject to resources being identified and requires joint investment by industry and MSAs.

14. **Economic operators should be given greater flexibility as to how they meet traceability requirements in order to promote greater use of e-labelling.** This would help to alleviate the major concerns that economic operators have with regard to current traceability requirements for products and packaging to provide full addressee information. These are seen as unnecessary and detract from product aesthetics and industrial design. E-labelling provides a viable alternative route to meeting the same requirements.

15. **When a currently non-harmonised product group becomes part of a harmonised product group, consideration should be given as to whether it is possible to integrate new product groups within existing pieces of IM of legislation, rather than proposing new legislation.**

7.2.3 Strengthening the implementation regime for Union harmonisation legislation

16. **The mechanisms to facilitate cooperation and the exchange of information between MSAs should continue to be supported and given appropriate funding**. EU funding for EU coordination and support actions relating to market surveillance through the PSMSP are critical and should be maintained if not further extended in coordination with MSAs aiming for the most efficient use of resources.

17. **IT-driven systems such as the RAPEX and the ICSMS information system should continue to be supported.** They serve different purposes/ functions and have proven vital to strengthening the effectiveness of market surveillance and regulatory enforcement.

18. **Although data is already collected by MSAs on the incidence of non-compliance of products checked, this should be further disaggregated by type of non-compliance.** At the minimum, comparable data should be available and this should be broken down according to whether instances of non-compliance are administrative or technical.

19. **The use of accreditation should be further strengthened** through a consistent approach in the area of harmonised products in line with Regulation (EC) No 765/2008.

20. **The operation of Notified Bodies Groups/Organisations could be strengthened and extended to all pieces of IM legislation, given their important role in promoting coordination and a more consistent approach among NBs.** A requirement could be introduced for active participation by Notified Bodies Groups for all Notified Bodies,

while taking into consideration the cost implications for the operation of smaller Notified Bodies. Extensive use of the appropriate information exchange systems (already in place among some of the existing Notified Bodies Groups) should help to keep the costs of participation low.

21. **The possibility of making the accreditation of Notified Bodies mandatory should be further considered, with priority given to Internal Market legislation that concern high risk product categories or issues of higher safety and consumer protection concern.**

22. **In order for the above to happen in practice, there could be a compulsory accreditation requirement for non-European testing house granted Notified Body status.** Concerns were expressed with regard to retaining confidence in the quality of the services provided by all Notified Bodies – European and non-European.

23. **Synergies should be fully exploited between different structures in the IM implementation regime, for instance between SOLVIT (which solves general problems relating to the non-functioning of the internal market and Product Contact Points (PCPs), which have more specialised knowledge about non-harmonised product legislation.** For instance, there could be referrals of cases from SOLVIT to PCPs, and staff working at SOLVIT contact points could be made better aware about coordination mechanisms and contact points for industry that specialise in issues relating to the implementation of internal market in industrial products.

24. **The role of the Product Contact Points should be expanded to harmonised products so as to provide a first point of contact for and basic information about Union harmonisation legislation to firms.** Many firms don't know who to turn to and there is a low level of knowledge among some smaller firms and micro enterprises about internal market legislation, and even whether harmonised or non-harmonised legislation applies to their product. This would both strengthen the visibility of PCPs while providing SMEs with a clear information source from where they can obtain information.

7.2.4 Reducing administrative burdens for economic operators

25. The SME Test should always be applied to internal market legislation so as to ensure that administrative requirements do not impose disproportionate burdens to SMEs. It should be reiterated however that there is only limited scope for SME exemptions from the legal provisions in IM legislation and for a lighter regime in terms of administrative requirements.

26. A single reference source could be developed at EU level for firms providing information as to what changes have been made to IM legislation and updates to standards and when these come into force. This could be funded by the Commission and delegated to an appropriate body (or operated through a technical service contract).

Such an information portal would save time and resources for industry, particularly SMEs. Economic operators signing up to the service could then receive email updates outlining upcoming changes and informing about when these will take place. Moving from a legislative-based to a product-based approach to informing economic operators about applicable IM legislation and voluntary standards would however be a technically demanding and resource-intensive exercise. This would also require the strong cooperation and support of

industry associations and ESOs, some of which already do relevant work in this area.

27. **The Commission should ensure that the administrative simplifications proposed through the NLF's Decision 768/2008 are fully implemented.** For instance, inconsistencies in requirements for DoCs between directives should be eliminated. However, there remains a need for adequate consultation to ensure that these changes ensure sufficient flexibility for economic operators.

28. **Economic operators should be allowed to continue to choose between producing a single DoC and a different DoC for each piece of applicable IM legislation.** Some economic operators prefer the latter approach, since it means that there is less frequent updating of individual DoCs when technical standards are updated.

29. **The current requirement for a DoC to be placed together with products in paper copy in the R&TTE Directive should be removed.** The short form of the DoC currently used is not necessary given that electrical manufacturers already provide the full DoC online.

30. **The Commission should provide clarity as to what constitutes a "reasoned request" for translating part of the technical file by an MSA (c.f. Decision 768/2008).** Safeguards should be put in place to ensure that MSAs requesting the translation of part of a technical file is the exception rather than norm[115].

7.2.5 Regulatory simplification

31. **Future simplification exercises should take into close account and give priority to previous and ongoing simplifications within the NLF framework, including through the Alignment Package.** It is crucial that industry is not over-burdened with too frequent legislative changes, since there have been many changes in the past decade, with others due to come into effect in the near future.

32. **Regulatory simplifications identified through the research[116] that involve the merger of different pieces of IM legislation should be subject to public consultation, and supported by technical studies.** Careful consideration is needed to ensure that proposed simplification measures enjoy sufficiently broad stakeholder support.

7.2.6 Extending the reach of IM legislation

33. **The Commission should promote international convergence in legislation on industrial products, since this could help to lower compliance costs for industry, thereby strengthening industrial competitiveness.** The Trade and Investment Partnership (TTIP) being negotiated between the EU and the US is an important step in the right direction, but further cooperation with regulators in other third countries that are key European export markets should be explored, such as China, Russia, Brazil, Mexico and Australia.

[115] Technical files can vary in length from hundreds to thousands of pages.

[116] Examples are the possible merger of the Machinery Directive and the Outdoor Noise Equipment Directive and the possible merger of the PED and the SPVD.