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PART 2/2

COMMISSION STAFF WORKING DOCUMENT

Part 2: Results of the case studies

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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INTERVIEWS COMPLETED

Commission officials

No	Name of organisation	Unit	Position/ relevance/ Directive responsible
1	DG ENTR	Unit F5 – engineering industries	Machinery Directive
2	DG ENTR	Unit F5 – engineering industries	Machinery Directive
3	DG ENTR	Unit F5 – engineering industries	RTTE, EMC, LVD Directives
4	DG ENTR	Unit E4 - Key Enabling Technologies (KETs) and ICT	KETs
5	DG ENV	Unit C1 - Sustainable Production & Consumption Unit	Green products
6	DG ENTR	Unit F5 – engineering industries	Lifts Directive
7	DG ENV	Unit C2 Waste Management, RoHS.	RoHS Directive
8	DG ENTR	Unit F5 – engineering industries	ATEX Policy Officer - Mechanical Engineering Assistant Policy Officer
9	DG ENTR -	Unit F5 – engineering industries	Team Leader Electrical and Electronic Product Regulation
10	DG ENTR	Unit F5 – engineering industries	Policy officer National seconded expert
11	DG ENTR	Advanced Manufacturing Unit	Policy officer
12	DG ENTR	Unit F1 - REACH and nano-technologies	Policy officer

Stakeholders

No	Type of stakeholder	Name of organisations	Sector/product category/thematic area
1	Consumer group	ANEC	General
2	EU Accreditation body	EA (European Cooperation for Accreditation)	Network of accreditation organisations
3	EU Industry association	AQUA	Measuring instruments - water meters manufacturer
4	EU Industry association	Business Europe	General
5	EU Industry association	CECE (Committee for European	Machinery -

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No	Type of stakeholder	Name of organisations	Sector/product category/thematic area
		Construction equipment)	construction equipment
6	EU Industry association	CECED	Electrical equipment
7	EU Industry association	CECIMO	Machinery - machine tools
8	EU Industry association	CECOD	Measuring instruments – Petrol pumps
9	EU industry association	CEMA (European Agricultural machinery)	Machinery (Agriculture machinery)
10	EU industry association	EBI	Recreational crafts
11	EU Industry association	EFCEM	Machinery - Catering equipment
12	EU Industry association	EFESME - European SMEs in the lift industry	Machinery - Lifts
13	EU Industry association	EFTA - European Free Trade Association	General
14	EU Industry association	EGMF - European Garden machinery Federation	Machinery - Gardening equipment
15	EU industry association	EMOTA, the European Multi-channel and Online Trade Association	E-commerce
16	EU Industry association	EPBA - European Portable Battery Association	Electrical and electronics
17	EU Industry association	EPIC the European Photonics Industry Consortium	Semiconductors
18	EU Industry association	European Safety Federation	PPE
19	EU Industry association	European Semiconductor Industry Association	Semiconductors
20	EU Industry association	European Small Business Aliance	SMEs
21	EU Industry association	Eurovent	Air conditioners
22	EU Industry association	EVA	Machinery
23	EU Industry association	Federation of Environmental trade associations	Air conditioners
24	EU Industry association	Federation of the European Sporting Goods Industry	Snow/ski - wear
25	EU industry association	FEM (European Federation of Materials Handling)	Machinery/ Lifts
26	EU Industry association	FESI	Personal protective equipment
27	EU industry association	GSMA	Mobile
28	EU Industry association	Orgalime	Mechanical and electronics industry

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No	Type of stakeholder	Name of organisations	Sector/product category/thematic area
			association
29	EU Industry association	Petroleum Equipment installers and maintenance federation	Petrol pumps
30	EU Industry association	T&D Europe	Electricity Transmission and Distribution Equipment and Services Industry
31	National industry association	Safety Assessment Federation Ltd	Pressure, Machinery, Lift,
32	National industry association – Denmark	Confederation of Danish Industry (DI)	Multiple Directives
33	National industry association – Germany	VDMA	Machinery
34	National industry association – Germany	ZIV	Bicycles
35	National industry association – Germany	ZVEI	Electrical and electronic products
36	National industry association – Italy	ANCMA	Bicycles
37	National industry association – Netherlands	FEDA	Electric motors
38	National industry association – Netherlands	RAI	Bicycles
39	National industry association – Sweden	Teknikforetagen	Multiple Directives
40	National industry association- Netherlands	FME- CWM Netherlands	General
41	Notified bodies organisation	Association of notified bodies for medical devices	medical devices
42	Notified bodies organisation	European ATEX Notified Bodies Group	ATEX
43	Notified bodies organisation	European Coordination of Notified Bodies for PPE	Personal protective equipment
44	Notified bodies organisation	Explosives Notified Bodies group	Explosives
45	Notified body	CECOC	CIVEX, Pyrotechnics
46	Standardisation organisations	CEOC - European Confederation of Organisations for Testing, Inspection, Certification and Prevention	Pressure equipment

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National authorities

	Directive/Role	Country	Name of Organisation
1	Outdoor noise	Belgium	ADCO Chairman
2	ATEX, Low voltage, EMC	Belgium	FPS Economy SMEs, Self-Employed and Energy Directorate-General Energy Infrastructure & Controls
3	Gas applicances	Belgium	FPS Economy SMEs, Self-Employed and Energy Directorate-General Energy Infrastructure & Controls
4	General	Belgium	Service Public Fédéral Economie, P.M.E., Classes moyennes & Energie
5	General	Belgium	National Contact point – Ministry of Economy
6	Gas appliances/Pressure equipment	Bulgaria	State Agency for Metrological and Technical Surveillance
7	Machinery/ Pressure equipment/PPE	Cyprus	Department of Labour Inspection - Ministry of Labour and Social Insurance
8	Lifts/ ATEX	Cyprus	Ministry of Labour and Social Insurance Department of Labour Inspection
9	EMC/ Low voltage	Cyprus	Ministry of Communications and Works Department of Electromechanical
10	Pressure equipment/ ATEX	Czech Republic	Czech Trade Inspection
11	Machinery/ Cableways/ Lifts	Denmark	Danish Working Environment Authority
12	MID/NAWI	Denmark	Danish Safety Technology Authority
13	Medical devices	Denmark	Danish Medicines Agency Inspection & Medical Devices
14	National contact point	Denmark	Danish Business Authority
15	Low voltage	Denmark	ADCO Chairman
16	Accreditation body	Denmark	Danak
17	Machinery	Estonia	Technical Surveillance Authority Industrial Safety Division
18	Outdoor noise	Estonia	Technical Surveillance Authority Industrial Safety Division
19	Machinery, PPE, Cableways	Finland	Ministry of Social Affairs and Health
20	MID/NAVI, Pressure Equipment, Low Voltage	Finland	Ministry Employment and the Economy
21	17 Directives	Finland	TUKES (Safety Technology Authority, Electrical Safety)
22	MID/NAWI	France	Ministère de l'économie, de l'industrie et de l'emploi - DGE/Sous-direction de la métrologie, de la normalisation, de la qualité et de la propriété industrielle - Bureau de la métrologie

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	Directive/Role	Country	Name of Organisation
23	Low voltage	France	Ministère du redressement productif
24	Machinery/Lifts/PPE	Germany	Federal Ministry of Labour and Social Affairs
25	Multiple	Germany	Ministry for the Environment, Climate Protection and the Energy Sector
26	Pressure equipment	Germany	Institution/Authority Bundesministerium für Arbeit und Soziales
27	Accreditation body	Germany	DAkkS - Deutsche Akkreditierungsstelle GmbH
28	EMC	Germany	ADCO Chairman
29	20 Directives	Greece	Ministry of Development - General Secretariat of Industry - Directorate of Industries Support
30	EMC/RTTE	Greece	Ministry of Infrastructure, Transport and Networks
31	Multiple directives	Iceland	The Icelandic Consumer Agency
32	PPE	Ireland	ADCO Chairman
33	ATEX	Ireland	ADCO Chairman
34	outdoor noise	Italy	Agenzia per la Protezione dell'Ambiente e per i Servizi Tecnici (APAT)
35	Market surveillance authority	Italy	Istituto Superiore per la Protezione e la Ricerca Ambientale - ISPRA
36	EMC	Latvia	Ministry of Economics
37	Market surveillance authority	Latvia	CONSUMER RIGHTS PROTECTION CENTRE OF LATVIA
38	MID/NAWI	Luxembourg	Ministère de l'Economie et du Commerce extérieur -ILNAS
39	Multiple Directives	Luxembourg	Inspection du Travail et des Mines
40	Pressure equipment	Lithuania	Institution/Authority Ministry of Economy of the Republic of Lithuania (Industry and Business Department)
41	National authority – internal market problems	Lithuania	Ministry of Economy SOLVIT Lithuania
42	Mutual recognition national contact point	Lithuania	Enterprise Lithuania
43	Machinery	Malta	Regulatory Affairs Directorate
44	ATEX, SPVD, PED, Lifts, MD, PPE	Netherlands	Ministerie van Sociale Zaken en Werkgelegenheid
45	EMC, RTTE	Netherlands	Agentshap Telecom
46	General	Netherlands	Ministry of Economic Affairs
47	General	Netherlands	National contact point
48	MD,Lifts, PPE	Netherlands	Inspectie SZW
49	Lifts, ADCO	Norway	Chairman of ADCO group, Special adviser of Norwegian Building Authority
50	Medical devices	Norway	Norwegian Directorate for Health and Social Affairs

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	Directive/Role	Country	Name of Organisation
51	Cableways, Railroad	Norway	Norwegian Railroad Authority
52	Multiple Products (Accreditation, Conformity Assessment, Standards, Market Surveillance)	Norway	Ministry of Trade and Industry
53	Medical Devices	Norway	Norwegian Directorate for Health and Social Affairs
54	National authority – internal market problems -	Poland	SOLVIT
55	RTTE/EMC	Romania	National Authority for Management and Regulation in Communications (ANCOM)
56	MID/NAWI	Spain	CENTRO ESPAÑOL DE METROLOGIA - National body in charge of metrology
57	Machinery/Lifts/ATEX/	Slovenia	Ministry of the Economy Directorate for Internal Market Division for technical legislation
58	EMC	Slovenia	Ministry of the Economy
59	PPE/ Low voltage	Slovenia	Ministry of Economic Development and Technology
60	RTTE	Slovenia	Market Inspectorate of the Republic of Slovenia
61	MID/NAWI	Sweden	Swedish Board for Accredition and Conformity Assessment (SWEDAC)
62	RTTE	Sweden	Post and Telecom Agency
63	EMC/ Low voltage/ATEX	Sweden	Swedish National Electrical Safety Board
64	Machinery, PPE	Sweden	Swedish Work Environment Authority
65	National contact point	Sweden	Ministry of Foreign Affairs, Department of Internal Affairs
66	PPE	Sweden	Swedish Consumer Agency
67	Mutual Rec. + Services Directive	Sweden	National Board of Trade
68	EMC	Switzerland	OFCOM - Federal Office of Communications - Section Market access and conformity
69	Accreditation body	Switzerland	SAS - Swiss Accreditation Service
70	Machinery	UK	Department for Business, Innovation and Skills

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	Directive/Role	Country	Name of Organisation
			(BIS) Environmental & Technical Regulation Directorate
71	Lifts	UK	Department for Business, Innovation & Skills
72	Explosives	UK	Mines, Quarries and Explosives Policy Health and Safety Executive (HSE)
73	Pressure equipment/ATEX	UK	DEPARTMENT FOR BUSINESS, ENTERPRISE AND REGULATORY REFORM (BERR)
74	RTTE/EMC	UK	Environmental & Technical Regulation Business, Innovation and Science
75	Low voltage	UK	Department for Business, Innovation and Skills (BIS) - Environment and Technical Regulations Directorate
76	PPE	UK	Department for Business, Innovation and Skills
77	Accreditation body	UK	UKAS - United Kingdom Accreditation Service

Case study interviews

Case number	Product	Interviews with firms completed	Interviews with organisations	Names of organisations
1	Electric motors	9	2	ZVEI (Germany) FEDA (Netherlands)
2	Laptops	4	1	Digital Europe
3	Domestic Refrigerators	3	1	European Committee for Domestic Appliances
4	Lifts for persons and goods	8(1)	3	EFESME - European SMEs in the lift industry, European Lifts Association - ELA, European Lifts Components Association (ELCA)
5	Gardening equipment	5	1	European Garden machinery federation
6	Petrol pumps	5	2	CECOD PEIMF
7	Air conditioners	8	2	Federation of Environmental trade associations Eurovent

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Case number	Product	Interviews with firms completed	Interviews with organisations	Names of organisations
8	Integrated circuits	8	1	European Semiconductor Industry Association
9	Ski /Snow footwear	5	1	Federation of the European Sporting Goods Industry
10	Bicycles	6	3	ANCMA (Italy) RAI (Netherlands) ZIV (Germany)
Total		**62**	**17**	

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Case studies

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The case studies in this document are part of the Evaluation of Internal Market Legislation for Industrial Products carried out for the European Commission's DG Enterprise and Industry by the Centre for Strategy & Evaluation Services (CSES)[1], supported by our partner organisations, Panteia and Oxford Research. The case studies reflect the opinion of the persons and organisations that were interviewed. This document should not be considered as representative of the Commission's official position.

CASE STUDY 1 – ELECTRIC MOTORS

1. Introduction – objectives of the study

The product group examined in this case study is electric motors. The aim is to analyse the applicable IM legislation, assess the costs associated with the implementation of the applicable IM legislation, identify areas of overlaps and conflicts between the different parts of the legislation that may lead to problems and costs to the industry and identify and assess the benefits of possible simplifications. The rationale for the selection of these product groups was that:

- Electric motors are covered by a large number of IM Directives and Regulations;
- There is a large number of professional users in the sector;
- The sector represents a high share of total manufacturing (see industry structure below). Hence demand for electric motors is closely related to manufacturing processes and investments in the manufacturing industry[2].

The case study is based on desk research and interviews with two national industry associations representing manufacturers of electric motors and nine in depth interviews with manufacturers of electric motors operating in Europe, four large size manufacturers, one medium and four small.

2. Product definition and description of structure of the sector

Product definition

The product group examined in this case study is electric motors. An electric motor is a device which converts electric energy into mechanical energy[3]. These types of motors are widely used in machine tools, household appliances, power tools and other electrical appliances and equipment. There are two main types of electric motors. These are the so-called AC and DC motors. Around 50% of the demand in the European Union is for AC motors. Further distinctions can be made by output in kW or by type of motor (single-phase, multi-phase).

Electric motors are covered under PRODCOM code 27.11 that includes the following 21 different sub-categories:

[1] 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).

[2] Report 'Trends and segments for electric motors' by the Dutch Center for Encouraging import from Developing Countries (CBI) – 2011. http://www.cbi.eu/system/files/marketintel/Trends_and_segments_for_electric_motors.pdf

[3] Definition taken from 'EUP Lot 11 Motors' by de Almeida, Ferreira, Fong and Fonseca (2008). See http://www.eup-network.de/fileadmin/user_upload/Produktgruppen/Lots/Final_Documents/Lot11_Motors_FinalReport.pdf

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- 27111010 - Electric motors of an output <= 37.5 W (including synchronous motors <= 18 W, universal AC/DC motors, AC and DC motors)
- 27111030 - DC motors and generators of an output > 37,5 W but <= 750 W (excluding starter motors for internal combustion engines)
- 27111053 - DC motors and generators of an output > 0,75 kW but <= 7,5 kW (excluding starter motors for internal combustion engines)
- 27111055 - DC motors and generators of an output > 7,5 kW but <= 75 kW (excluding starter motors for internal combustion engines)
- 27111070 - DC motors and generators of an output > 75 kW but <= 375 kW (excluding starter motors for internal combustion engines)
- 27111090 - DC motors and generators of an output > 375 kW (excluding starter motors for internal combustion engines)
- 27112100 - Universal AC/DC motors of an output > 37,5 W
- 27112230 - Single-phase AC motors of an output <= 750 W
- 27112250 - Single-phase AC motors of an output > 750 W
- 27112300 - Multi-phase AC motors of an output <= 750 W
- 27112403 - Multi-phase AC motors of an output > 0,75 kW but <= 7,5 kW
- 27112405 - Multi-phase AC motors of an output > 7,5 kW but <= 37 kW
- 27112407 - Multi-phase AC motors of an output > 37 kW but <= 75 kW
- 27112530 - Multi-phase AC traction motors of an output > 75 kW
- 27112540 - Multi-phase AC motors of an output > 75 kW but <= 375 kW (excluding traction motors)
- 27112560 - Multi-phase AC motors of an output > 375 kW but <= 750 kW (excluding traction motors)
- 27112590 - Multi-phase AC motors of an output > 750 kW (excluding traction motors)
- 27112610 - Alternators of an output <= 75 kVA
- 27112630 - Alternators of an output > 75 kVA but <= 375 kVA
- 27112650 - Alternators > 375 kVA but <= 750 kVA
- 27112670 - Alternators of an output > 750 kVA.

Industry structure

Enterprises

According to data from Eurostat there were around 14,000 enterprises in the electric motors sector in the period of 2008 – 2010, which were concerned with the manufacturing of these motors. As mentioned before this concerns NACE code is 27.11 (Manufacture of electric motors, generators and transformers), which is broader than only electric motors.

Table 1: Number of enterprises – electric motors, generators and transformers sector (NACE 27.11)

2008	2009	2010
14,697	14,272	14,544

Source: Eurostat, Structural Business Statistics.

The following table shows the production value for the years 2009 and 2010. It shows a sharp increase from 2009 and 2010. This is not in line with the number of employees, which stayed stable around 2.5 million during the same time period.

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Table 2: Production value (in million €) – electric motors, generators and transformers (NACE 27.11)

2009	2010
45,530.38	53,606.02

Source: Eurostat.

Products

Based on the Eurostat PRODCOM data for 2009, the total market size for electric motors was around 733.5 million units or EUR 10.5 billion in production value[4]. In the following table an overview is provided of the different PRODCOM indicators and their export/import value for the year 2009. In Europe 293.2 million electric motors, generators and transformers were produced. The corresponding production value was 12.3 billion euro's. The sector has exported a value of 4.2 billion, while imports amounted to 2.4 billion. This confirms the view that most motors are still produced in (Western) Europe given the highly automated production processes present in those countries[5]. Table A1 in the Annex gives a detailed description of all codes and the production, import and export values.

Table 3: Production, import and export value – electric motors, generators and transformers (2009), PRODCOM CODES: 2711010 to 27112670[6]

	Quantity (units)	Values (€)
Production	293,264,097	12,309,392,520
Import	543,812,581	2,433,820,520
Export	103,498,097	4,261,409,780
Total EU market (Production + imports - exports)	733,578,581	10,481,803,260

Source: Eurostat PRODCOM.

Tables 4 and 5 show numbers of units sold and value data for the four most common technologies of motors. 91% of all electric motors sold in Europe in 2010 are small power range motors, namely under 750W. In this year, only 0.01% of the motors sold had a very large power range, 9% were medium range motors.[7].

Table 4: Electric motors and generators sold by type in EU27 (thousand units, 2010)

	Power range					
	≤ 750 W		> 0,75 ≤ 375 kW		> 375 kW	
Technology	**units**	**%**	**units**	**%**	**Units**	**%**
DC Motors and Generators	12,176	56	4,417	21	1	5
AC Single-Phase	67,019	29	6,379	30	n/a	n/a
AC Multi-Phase	11,700	5	10,175	49	28	95
Universal	23,288	10	n/a	n/a	n/a	n/a
Total	230,123	100	20,970	100	30	100

[4] Including production and import, excluding export.

[5] Report 'Trends and segments for electric motors' by the Dutch Center for Encouraging Import from Developing Countries (CBI) – 2011. http://www.cbi.eu/system/files/marketintel/Trends_and_segments_for_electric_motors.pdf

[6] The table in the appendix provides an overview of the data of per PROD-COM CODE.

[7] Source: EuP lot 30: Electric Motors and Drives (2012), table 2-3 and 2-4 - http://www.eco-motors-drives.eu/Eco/Documents_files/EuP-Lot30-Task-2-2-Dec-2012.pdf

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Source: EuP lot 30: Electric Motors and Drives (2012).

Table 5: Revenue data for electric motors and generators by type EU27 (millions €s, 2010)

	Power range					
	≤ 750 W		> 0,75 ≤ 375 kW		> 375 kW	
Technology	**Value €**	**%**	**Value €**	**%**	**Value €**	**%**
DC Motors and Generators	1,762	39	515	11	64	5
AC Single-Phase	1,365	30	805	17	n/a	n/a
AC Multi-Phase	805	18	3,384	72	1,142	95
Universal	576	13	n/a	n/a	n/a	n/a
Total	4,508	100	4,705	100	1,207	100

Source: EuP lot 30: Electric Motors and Drives (2012).

3. Analysis of applicable IM legislation and standards

Identification of relevant IM legislation

Electric motors are covered by seven different pieces of legislation. This legislation is divided into three categories:

- Health and safety (Low Voltage Directive, Machinery, RoHS Directive on hazardous chemicals, REACH, ATEX directive),
- Electromagnetic compatibility (EMC Directive); and
- Energy consumption (Eco-design and the respective implementing measures)

The following directives are applicable to electric motors:

- Low Voltage Directive: LVD is applicable to all electric motors, except extra low voltage and high voltage;
- Machinery Directive: the MD is applicable for high voltage electric motors (high voltage electric motors are considered as partly completed machinery). It should be mentioned that in general electric motors are used in machines, for which the MD is applicable. So, although the MD is not applicable to most electric motors, MD is applicable to the machines with electric motors;
- Directive on Electromagnetic Compatibility (EMC): EMC is applicable to all electric motors. Some interviewees mentioned that EMC is not relevant to electric motors, because electric motors do not cause disturbances. There only might arise problems when other components are added (such as control units).
- ATEX: ATEX is only applicable to electric motors that are used in specific areas (explosive atmospheres).
- RoHS: Refers to the use of chemicals (such as lead).
- Reach: Refers to the use of chemicals (such as copper lamination).
- Ecodesign: Ecodesign is applicable to a large part of the electric motors (see below).

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The table in the appendix provides an overview of relevant IM legislation for the electric motors, including the basic administrative requirements.

The most important directives is terms of impacts are considered to be the Ecodesign (EuP for IEC-motors) and ATEX. ATEX (if applicable) is considered the most burdensome since it requires third party certification.

Ecodesign is a relatively new Directive in relation to electric motors. Electric motors which have to comply with the Ecodesign directive are called IE-motors or IEC-motors. For these motors there are rules for energy efficiency. EC Regulation 640/2009 implements the European Ecodesign Directive for electric motors. It contains requirements for the design of electric motors. The Regulation was published on 23 July 2009 and entered into force on 12 August 2009. There are several efficiency levels in the regulation. Minimum requirements are IE2 from 2011, IE3 or IE2 combined with a variable speed drive (VSD) for motors above 7.5 kW from 2015 and IE3 or IE2+VSD for motors above 0.75 kW from 2017. Because of the clear timetable enterprises can anticipate on the new efficiency levels. Also international standards are developed before a new level comes into force. Every new level means for enterprises that they have to design new electric motors, which stimulates innovation. Some interviewee noticed that the new efficiency levels are used in the market as a commercial tool.

Analysis of gaps, overlaps, inconsistencies and duplication

Most interviewees mention that there are no gaps, overlaps, inconsistencies and duplications in the IM legislation, that there is no scope for simplification and that there are no big issues that justify opening up directives. The NLF has resolved most issues, such as differences in definitions of producers and importers.

For the Ecodesign regulation, there is a gap at the moment. When the motor can be used in environment temperatures of more than 40 degrees, or higher than 1.000 meters, then Ecodesign is not applicable. This is because special purpose motors (such as motors designed to be used at high altitudes or temperatures) need to remain in the market as they fulfil a specific function. However, it was noticed that there are enterprises that put a nameplate on a normal product that it can be used in an environment temperature of 41 degrees and in that way they escape from the Ecodesign regulation. This problem is already recognized and an amendment to the Regulation has been launched and should be published soon.

Some interviewees mentioned that there are sometimes inconsistencies in directives and sometimes there are duplications in standards. But they say that these are not very obvious and that they are unavoidable looking at the huge amount of regulation. They do not experience these overlaps as troublesome. Because of the increase in the number of directives there is a risk of more inconsistencies. For enterprises it is difficult to have a full overview of all directives. In practice, these gaps are solved in a pragmatic way.

An interviewee mentioned a problem with the ATEX-directive. According to him it is a problem who is responsible for a product with an ATEX-certificate from the manufacturer, that is repaired by another (certified) enterprise.

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4. Analysis of costs of compliance with IM legislation

Introduction

The information presented in this section is based on the in-depth interviews with nine manufactures of electric motors. The firms range in terms of size and production volume. From six respondents data on administrative costs were collected, four large size manufacturers, one medium and one small.

Table 6: Basic information on the firms interviewed

Firm	Specific/main product	Firm size	Annual sales from product	Main markets
A	Electric motors	Large (>1000 employees)	3,500,000 units	--
B	Electric motors	Large (>1000 employees)	25,000 units	100% of sales in the EU
C	Electric motors	Large (>500 employees)	900,000 units	80% of sales in the EU
D	Electric motors	Large (>500 employees)	260,000 units	60% of sales in the EU
E	Electric motors	Medium (250-500 employees)	600,000 units	98% of sales in the EU
F	Electric motors	Small (<250 employees)	15,000 units	80% of sales in the EU
G	Electric motors	Small (<250 employees)	40,000 units	100% of sales in the EU
H	Electric motors	Small (<250 employees)	20,000 units	100% of sales in the EU
I	Electric motors	Small (<250 employees)	20,000 units	100% of sales in the EU

Before we briefly discuss the process steps some remarks need to be pointed to understand the typical situation for electric motors:

- In this case study we identified seven directives which are applicable to electric motors. But in general not all directives are applicable to all electric motors. The applicable directives for electric motors differ between companies, depending on which type of motors they produce. For example, the ATEX directive is only applicable to motors which are used in explosive atmospheres.
- Lots of companies do not produce bare electric motors. Often frequency converters, controllers, software, etc. are added to the electric motors. These added components are often also covered by legislation individually or in combination with the electric motor. For example, some interviewees mentioned that electric motors themselves do not produce interferences and the EMC directive actually is not very relevant, but when frequency converters or controllers are added this causes interferences which make the EMC directive very relevant. Another interviewee mentioned that the Machinery directive was not applicable to the electric motors they produce, but that their customers use the electric motors in their machines. These machines are covered by the Machinery directive. This leads to customer requirements with regard to the supplier of the electric motors in line with the Machinery directive. In general, interviewees

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indicated that it is difficult for them to distinguish between the processes to comply with the obligations for the electric motors and the processes to comply to the obligations for the added components, because for the manufacturers it is one integrated process.

- Most of the directives relevant for electric motors exit already for a relative long time. They do not change that much and companies are used to comply with these directives. It is incorporated in their processes. Only the Ecodesign implementing regulation is relatively new and has at the moment the largest impact on companies. The regulation requires that electric motors, covered by the regulation, have to reach certain levels of energy efficiency in several steps. For some manufacturers/models [as indicated in section 1.6 the requirements are not more stringent than elsewhere in the world and do not mean that all models need to be redesigned, only a number of them. Typically ecodesign means redesign for 20% of the existing models. Since other jurisdictions such as the US already had strict requirements, many motors already complied and the ecodesign regulation simply stopped the dumping of the poor efficiency ones on the EU market], this does not require simple adjustment of existing models, but complete electric motors have to be redesigned. When asking about internal market legislation for electric motors, most interviewees start with the Ecodesign regulation, because this regulation is the current issue and has the major impact on the companies. Other directives are more viewed as business as usual. The Ecodesign regulation causes extra costs for the companies, but on the other hand most interviewees use the new requirements as strategic issues in their markets. They recognize the impact of electric motors on energy use in the world and that improving the energy efficiency of electric motors is very important. They try to be the first with the development of more efficient motors in the market.

The following steps can be identified in the process of placing electric motors to the market:

- Familiarisation with applicable/relevant obligations
- Introduction of processes or changes to product design and production processes to ensure compliance with substantive obligations
- Conformity assessment procedures and relevant documentation
- Declaration of conformity or other statement of compliance and CE marking

Familiarisation with applicable/relevant obligations

To comply with the applicable internal market legislation companies need to have knowledge of the applicable directives and of the standards. As mentioned, the applicable directives for electric motors differ between companies, depending on which type of motors they produce. For example, the ATEX directive is only applicable to motors which are used in explosive atmospheres and the Ecodesign directive is not applicable to all motors because this directive includes several exceptions.

In general, the companies are linked to information sources on Directives and on standards or they have their own system. For example a smaller Dutch producer is a member of the NEN-connect network. This is a digital platform which shows the different standards and directives which are of interest for producers of electric motors. The platform sends an automatic message when the standards are updated and changes need to apply. When this message arrives, the firm examines the change and decides if they have to change their design. Furthermore, companies buy standards and get all technical features to comply with.

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One interviewee mentioned that they participate in standardisation groups to be informed in a very early stage about the backgrounds of the legislation and standards. For them these backgrounds are necessary for the correct application of the requirements.

The average costs for familiarisation with applicable/relevant obligations of the interviewed companies amount to approximately 0.2% of turnover. More than 90% of these costs are cost of human resources.

Introduction of processes or changes to product design and production processes to ensure compliance with substantive obligations

For developing new electric motors and production processes the companies have to comply with the requirements of relevant directives. For most directives working in accordance with the relevant standards is incorporated in the development, testing en production processes of the enterprises. At the moment the Ecodesign implementing regulation requires that electric motors are more and more energy efficient in several steps. To comply with these efficiency requirements enterprises have to redesign some models [as indicated in section 1.6 the requirements are not more stringent than elsewhere in the world and do not mean that all models need to be redesigned, only a number of them. Typically ecodesign means redesign for 20% of the existing models. Since other jurisdictions such as the US already had strict requirements, many motors already complied and the ecodesign regulation simply stopped the dumping of the poor efficiency ones on the EU market. Although this causes extra costs, several respondents mentioned that these developments also offer new opportunities in their markets.

For most producers of electric motors testing is the most costly step to comply with the relevant Directives. But on the other hand most interviewees would also test a lot when there were no directives and standards. This is needed to develop and sell safe products. This is especially the case for ATEX-motors because these motors are used in explosive atmospheres.

The average costs for compliance with requirements (product design and testing) of the interviewed companies amount to approximately 0.6% of turnover. 74% of these costs are cost of human resources, 23% are costs for testing equipment and 3% are costs for third parties.

Conformity assessment procedures and relevant documentation

This step is concerned with preparing technical documentation, which causes costs for employees of the enterprises, and with conformity assessment. Conformity assessment is especially related to inspection of notified bodies. This is the step that causes most of the external costs. This is especially relevant for ATEX-motors. For ATEX- motors it is mandatory that a notified body inspects the designs of these motors and test motors to get the required marking. This is only needed when companies produce motors that are to be used in explosive atmospheres.

The average costs for conformity assessment procedures and relevant documentation of the interviewed companies amount to approximately 0.3% of turnover. 57% of these costs are cost of human resources, 32% are costs for third parties and 11% are costs for testing equipment.

Declaration of conformity or other statement of compliance and CE marking

Drawing up declarations of conformity and CE marking is not viewed a big issue for the interviewees. Compared to the other steps this is a minor step, not very complex and not very costly. The average costs for declaration of conformity or other statement of compliance and CE marking of the interviewed companies amount to approximately 0.1% of turnover. More than 90% of these costs are cost of human resources.

Business as usual

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Companies were asked to differentiate between Business As Usual cost (BAU) and cost specifically due to the internal market regulation. Part of the activities obliged by IM legislation companies would perform anyway. For example, a firm may carry out product testing so as to check the quality and safety of products. Such costs are known as 'business as usual' (BAU) costs. Respondents mentioned that the largest shares of the activities that cause the administrative costs are business as usual. If there were no directives and standards the enterprises would have their own quality and safety standards. To meet these standards companies also have to test their products. Some enterprises mentioned that without directives they would spend less on some external tests (costs of third parties). On average, 73% of the costs of human resources spent on compliance activities is considered as business as usual by the interviewed companies. For the costs of third parties this average is 67% and for the costs of testing equipment 87%.

5. Assessment of costs of IM legislation for the whole sector

Data collection

Based on the information provided by interviewees, the average costs of complying with IM legislation have been estimated. Out of six respondents, data on costs were collected, four large size manufacturers, one medium and one small. In principle the respondents are manufacturers. But some of them also have some trading activities (import of motors). Cost data have been collected for activities relating to electric motors, especially manufacturing, but the respondents could not distinguish between the compliance costs for the manufactured and the imported motors. The data collection was focussed on the costs to comply with the following legislation: Low Voltage Directive, Machinery Directive, the Directive on Electromagnetic Compatibility (EMC), ATEX, RoHS, Reach and Ecodesign.

The six interviewed companies were asked to give estimates of the costs of human resources, costs of third parties and costs of testing equipment for total compliance activities (top down approach). Also data on time and tariff were asked (bottom up approach), but this did not result in sufficient usable data. For the testing equipment the costs for the last five years are collected to calculate the average cost per year. Next the interviewees were asked to distribute these costs of human resources, costs of third parties and costs of testing equipment over the identified steps of the compliance process (familiarisation, compliance with requirements, conformity assessment, DoC and CE marking and other) and they were asked which parts of these costs are considered as business as usual.

Estimation of costs

All costs are collected as totals for enterprises. The cost estimates for the whole sector are based on turnover. All costs were calculated as percentages of turnover and this was then used to weight the results. The data collected with two SMEs did not show clear differences – in terms of costs as a percentage of turnover - as compared to the data for large enterprises. Therefore, there were no grounds for making a distinction in the calculations. In other words, it has been assumed that the compliance costs as a percentage of turnover are the same for large enterprises and for SMEs.

Based on the results from the six respondents, in Table 7 the estimates of compliance costs for the sector of electric motors are presented as percentages of turnover. The costs were standardised by calculating averages of the percentages. To estimate the compliance costs for the whole sector of electric motors we followed the following steps:

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- for each type of costs (cost of human resources, costs of third parties and costs of testing equipment) the costs were calculated as a percentage of the turnover of electric motors, averaged over respondents (first row in Table 7)
- the distribution of the costs over the different process steps is again an average of the estimated distribution from the respondents, as a percentage of the annual compliance costs (see distribution over process steps in Table 7)
- we then determined the average percentages of business as usual (as percentage of annual compliance costs, per cost type), to distinguish between the total compliance costs and the regulatory burden related to the internal market legislation (last 2 rows in table 7).

Table 7 - Estimate of average compliance costs (%)

	Cost of human resources for total compliance activities	Costs of third parties	Costs of testing equipment	Total
Annual costs (% of turnover)	0.95%	0.13%	0.18%	1.26%
Of which (% of annual costs; is the distribution over process steps)				
- Familiarisation	19.17%	8.50%	2.50%	15.65%
- Compliance with requirements (product design and testing)	49.00%	15.00%	80.00%	50.16%
- Conformity assessment	16.67%	71.50%	16.67%	22.15%
- DoC and CE marking	13.50%	5.00%	0.83%	10.79%
- Other	1.67%	0.00%	0.00%	1.26%
And of which (% of annual costs)				
- Business As Usual (BAU)	73.33%	68.00%	86.67%	74.76%
- Regulatory burden	26.67%	32.00%	13.33%	25.24%

Source: CSES study

To calculate an estimate of the overall costs for the whole sector we used the value of the total EU market according to Eurostat PRODCOM, namely € 10,5 billion in 2009 (see table 3). Applying the percentages in table 7, led to the figures presented in the table 8.

Table 8 - Estimate of compliance costs for the whole sector of electric motors (€)

	Cost of human resources for total compliance activities	Costs of third parties	Costs of testing equipment	Total

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Total Annual costs	€ 99,175,627	€ 13,159,638	€ 19,368,345	€ 131,703,610
Distribution over process steps:				
- Familiarisation	€ 19,008,662	€ 1,118,569	€ 484,209	€ 20,611,440
- Compliance with requirements (product design and testing)	€ 48,596,057	€ 1,973,946	€ 15,494,676	€ 66,064,679
- Conformity assessment	€ 16,529,271	€ 9,409,141	€ 3,228,057	€ 29,166,470
- DoC and CE marking	€ 13,388,710	€ 657,982	€ 161,403	€ 14,208,094
- Other	€ 1,652,927			€ 1,652,927
- Business As Usual (BAU)	€ 72,728,793	€ 8,948,554	€ 16,785,899	€ 98,463,246
- Regulatory burden	€ 26,446,834	€ 4,211,084	€ 2,582,446	€ 33,240,364

Source: CSES study

6. Benefits of Internal Market legislation

Most interviewees in the sector of electric motors are very satisfied with the IM directives, the standards and the harmonisation of their sector which replaced regulations in 27 countries.
It has reduced administrative burdens for enterprises rather substantially – even though it has not been possible to quantify and, nowadays, the interviewees suggested they could hardly imagine a situation without harmonisation.

The firms also consider as particularly positive the fact that – through their industry representatives or even as individual firms – they can be involved in the development of the IM directives and the standards. While it may be time consuming this involvement reduces the risks of the development of too complex and inconsistent requirements with high administrative burdens for companies. It also provides certain level of predictability and this is the reason that most compliance activities are considered as business as usual for companies.

At the same time, some firms pointed to the benefits from specific pieces of IM legislation in terms of the promotion of innovation in the sector. The Ecodesign Directive has had an important impact in the case of electric motors market by introducing energy efficiency requirements with a clear timetable. According to the evaluation of the Ecodesign Directive it has pushed for a faster adoption of the more efficient IE2 category that would have happened in the absence of the Ecodesign.

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However, the evaluation concluded that the requirements are less demanding that those in the US or Canada where IE3 level motors are already dominant[8].

7. Simplification and improvement options

Most interviewees in the sector of electric motors are very satisfied with the IM directives, the standards and the harmonisation of their sector. It is mentioned that the IM directives replaced regulations in 27 countries. This reduced the administrative burdens for enterprises substantially. The interviewees are used to the harmonisation of the sector. They can hardly imagine a situation without harmonisation. Furthermore, it is mentioned that the sector was involved in developing the directives and the standards. This involvement reduces the risks of too complex regulation, inconsistent regulation and high administrative burdens for companies. We have already seen that most activities to comply with the IM legislation are business as usual for companies.

Some respondents mentioned some gaps and inconsistencies, but these were already described in section "3 Analysis of applicable IM legislation and standards" under "Analyses of gaps, overlaps, inconsistencies and duplication". These gaps and inconsistencies do not affect compliance costs.

It is not surprising that companies cannot mention important options for simplification and improvement of IM legislation.

Fewer audits from notified bodies

A small enterprise that produces about 15,000 electric motors a year mentioned that fewer audits from notified bodies could save some costs. This is related to conformity assessment (inspection by notified bodies) and is only relevant for ATEX-motors (motors that are to be used in explosive atmospheres). For ATEX-motors it is mandatory that a notified body inspects the designs of these motors and test motors to get the required marking. But, when the rules or standards are changed a bit, all ATEX-motors have to be inspected again. According to the respondent, this should not be necessary. At the moment, the costs for this respondent for notified bodies are on average about € 12,000 a year. The market for ATEX-motors is a small part of the market for electric motors. With the assumption that fewer audits would lead to a reduction of costs for notified bodies of 10%, the total savings would be about € 300,000.

Reduce the frequency of changes in standards

The small enterprise that produces electric motors mentioned that changes of standards could occur less often. Changes in standards cause costs for getting the new standard and corresponding certification. On the other hand, another respondent mentioned that especially the ATEX-requirements are getting higher and higher, but this is necessary for safety reasons. Cost savings would very much depend on the implementation. To estimate cost savings we use the following assumptions: 25% reduction of the costs for purchase of standards (familiarisation costs to third parties), 10% reduction of costs for human resources for familiarisation and 5% reduction of costs for assessment and preparation. With these assumptions the total savings would amount to about € 1,990,000.

More examples to explain more difficult requirements

A large enterprise mentioned that it is sometimes difficult to understand the requirements from IM-legislations. They do not know from the legislation what is needed because explanations are not clear

[8] CSES (2012), Evaluation of the Ecodesign Directive – Final report

enough. It would be helpful when there are some more examples to explain the requirements. This would reduce the costs of familiarisation somewhat. When a reduction of 5% of familiarisation costs is assumed, the total cost savings would amount to about € 250,000.

8. Overall conclusions

The case study examined alternative and direct current electric motors. Total EU market for electric motors in 2009 was 733.5 million units and €10.5 billion in value. 91% of all electric motors sold in Europe in 2010 are small power range motors, namely under 750W.

Electric motors are covered by seven different pieces of IM legislation covering aspects of health and safety (Low Voltage Directive, Machinery, ATEX), electromagnetic compatibility (EMC), energy consumption (Ecodesign Directive) and chemicals use (RoHS Directive on hazardous chemicals, REACH).

Based on the information collected during the study it is estimated that the total annual costs of compliance with IM legislation for the firms in the sector are around €130 million, although more than 70% of this is considered to be part of business as usual, namely costs incurred even in the absence of legislation. The estimated net annual costs directly linked with the legislation are around €33 million, no more than 0.3% of the annual turnover of the sector. Substantive compliance costs are significant (around 50%) of the total and are primarily linked with ensuring compliance with the Ecodesign and the ATEX Directives. Still, there are also important costs for familiarisation with the legislation (15%) and conformity assessment procedures, including in particular the costs for notified bodies in relation to the ATEX Directive.

Despite the costs, most firms in the sector of electric motors are satisfied with the IM legal framework and the harmonisation of the sector legislation. By replacing regulations in 27 countries it has reduced administrative burdens for enterprises rather substantially – even though it has not been possible to quantify. In addition they is a positive view of the opportunity to be involved in the standards development process to ensure that requirements are not too complex while also ensuring a certain level of predictability. In parallel, the Ecodesign Directive requirements have effectively pushed for the faster adoption of the more efficient IE2 motors, even if not for the IE3 level which is already widely adopted in the US and in Canada.

In terms of possible simplification, the feedback provided suggested there is limited scope for changes and there are no gaps, overlaps, inconsistencies and duplications in the IM legislation. The possibility of reducing the frequency with which standards are replaced as a way to bring certain cost savings, introduction of guidance document to facilitate familiarisation and possibly the reduction of the number of audits from notified bodies. In total it was indicated that savings of up to €2.5 million of total costs could possibly be achieved for the sector.

9. Sources of information

Publications

- Report ‘Trends and segments for electric motors’ by the Dutch Center for Encouraging import from Developing Countries (CBI) – 2011. www.cbi.eu/system/files/marketintel/Trends_and_segments_for_electric_motors.pdf
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- Almeida, Ferreira, Fong and Fonseca (2008), 'EUP Lot 11 Motors'. www.eup-network.de/fileadmin/user_upload/Produktgruppen/Lots/Final_Documents/Lot11_Motors_Final Report.pdf
- Anibal de Almeida, Hugh Falkner, João Fong and Keeran Jugdoyal (November 2012), 'EuP lot 30: Electric Motors and Drives, 2nd Draft'. www.eco-motors-drives.eu/Eco/Documents_files/EuP-Lot30-Task-2-2-Dec-2012.pdf
- Eurostat PRODCOM

Interviews:

- 2 with national industry associations
- 9 interviews with enterprises (especially producers); from 6 respondents data on administrative costs were collected.

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Annex

Production, import and export value per PROD-COM CODE

Table A1: Production, import and export value – electric motors, generators and transformers (2009), PROD-COM CODES: 2711010 to 27112670

PRODCOM CODE/INDICATORS	Export values (000s)	Import values (000s)	Production Quantity (000s)	Production Value (000s)	Total
27111010 - Electric motors of an output <= 37.5 W (including synchronous motors <= 18 W, universal AC/DC motors, AC and DC motors)	429,581,300	814,922,340	74,545,678	825,041,147	1,210,382,187
27111030 - DC motors and generators of an output > 37,5 W but <= 750 W (excluding starter motors for internal combustion engines)	278,747,230	386,366,040	104,390,496	1,407,085,735	1,514,704,545
27111053 - DC motors and generators of an output > 0,75 kW but <= 7,5 kW (excluding starter motors for internal combustion engines)	49,647,610	55,532,980	6,000,000	261,370,719	267,256,089
27111055 - DC motors and generators of an output > 7,5 kW but <= 75 kW (excluding starter motors for internal combustion engines)	31,837,520	15,936,700	1,000,000	200,000,000	184,099,180
27111070 - DC motors and generators of an output > 75 kW but <= 375 kW (excluding starter motors for internal combustion engines)	41,158,050	20,115,000	21,021	45,698,243	24,655,193
27111090 - DC motors and generators of an	43,932,440	36,989,480	1,600,000	61,635,219	54,692,259

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PRODCOM CODE/INDICATORS	Export values (000s)	Import values (000s)	Production Quantity (000s)	Production Value (000s)	Total
output > 375 kW (excluding starter motors for internal combustion engines)					
27112100 - Universal AC/DC motors of an output > 37,5 W	140,273,990	121,276,880	21,783,407	495,727,677	476,730,567
27112230 - Single-phase AC motors of an output <= 750 W	120,770,450	129,836,810	56,520,199	1,195,803,791	1,204,870,151
27112250 - Single-phase AC motors of an output > 750 W	50,438,620	49,425,060	6,300,000	132,175,642	131,162,082
27112300 - Multi-phase AC motors of an output <= 750 W	191,938,140	77,272,170	10,000,000	667,498,083	552,832,113
27112403 - Multi-phase AC motors of an output > 0,75 kW but <= 7,5 kW	324,722,000	133,198,120	6,359,618	1,455,629,073	1,264,105,193
27112405 - Multi-phase AC motors of an output > 7,5 kW but <= 37 kW	198,759,480	62,888,110	1,189,773	663,563,780	527,692,410
27112407 - Multi-phase AC motors of an output > 37 kW but <= 75 kW	110,315,070	43,175,790	192,619	304,180,879	237,041,599
27112530 - Multi-phase AC traction motors of an output > 75 kW	91,719,690	11,825,180	14,000	300,000,000	220,105,490
27112540 - Multi-phase AC motors of an output > 75 kW but <= 375 kW (excluding traction motors)	171,106,750	49,028,550	54,834	422,095,148	300,016,948
27112560 - Multi-phase AC motors of an output > 375 kW but <= 750 kW (excluding traction motors)	111,558,390	24,443,830	21,331	454,592,720	367,478,160
27112590 - Multi-phase AC motors of an	630,921,610	55,401,750	11,593	1,003,373,605	427,853,745

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PRODCOM CODE/INDICATORS	Export values (000s)	Import values (000s)	Production Quantity (000s)	Production Value (000s)	Total
output > 750 kW (excluding traction motors)					
27112610 - Alternators of an output <= 75 kVA	114,769,970	85,838,450	3,142,975	326,940,309	298,008,789
27112630 - Alternators of an output > 75 kVA but <= 375 kVA	63,040,220	29,373,550	66,725	177,975,375	144,308,705
27112650 - Alternators > 375 kVA but <= 750 kVA	75,541,500	10,966,450	18,434	135,533,843	70,958,793
27112670 - Alternators of an output > 750 kVA	990,629,750	220,007,280	31,394	1,773,471,532	1,002,849,062
Electric Motors, generators and transformers	**€4,261,409,780**	***€2,433,820,520***	**293,264,097 units**	***€12,309,392,520***	***€10,481,803,260***

Source: Eurostat PRODCOM database, all values (€s, units) are in thousands

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Summary of IM legislation covering electric motors

Table A2 – Summary of IM legislation covering electric motors

Name of legislation	Main issue addressed	Who is responsible?	Requirements for economic operators
LVD 2006/95/EC *Directive on low voltage machines*	Health & Safety (low voltages machines)	Technical documentation should be provided by the manufacturer. Declaration of conformity procedures and CE marking can be followed by both the manufacturer or his authorized representative (art. 8)	According tot art. 2 of the directive, all products should meet the safety requirements set out in annex I. -Testing according to relevant standards (art. 5) -Development of technical file[9] -Declaration of conformity and CE marking (art. 8) -Mark with information (type, voltage, etc,) -Installation instructions and manual for final consumer (with translations)
Machinery 2006/42/EC *Directive on machinery*	Health & Safety (machinery)	Manufacturers or his authorized representative (art. 5)	- Ensure satisfaction of health and safety requirements Annex I - Technical file (Annex VII) -Provide necessary information (instruction) - Conformity procedures (art. 12, art. 13 for not finished machines) - CE marking (art. 16) - EC declaration of conformity in accordance with Annex II, part 1, Section A and ensure that it accompanies the machinery - Construction file and risk assessment which contains: (i) a list of the essential health and safety requirements applied and fulfilled (ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks, (ii) the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,

[9] See Guidelines on the Application of Directive 2006/95/EC, paragraph 22 (page 14) for a list of required documents. Link: http://ec.europa.eu/enterprise/sectors/electrical/files/lvdgen_en.pdf

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Name of legislation	Main issue addressed	Who is responsible?	Requirements for economic operators
			(iv) any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the manufacturer or his authorized representative, (v) a copy of the assembly instructions for the partly completed machinery
EMC 2004/108/EC *Directive on Electromagnetic Compatibility*	Electromagnetic compatibility	Manufacturer (and, for the CE marking (art. 7) his authorized representative)	- fulfill the protection requirements mentioned[10]. -Testing according to standards -Development of technical file -EC Declaration of conformity and CE marking (art. 7, 8 and Annex II) -Installation instructions and manual for final consumer -Meet essential requirements (art. 5 and Annex I) -Other marks and information (art. 9)
ATEX 1994/9/EC *Directive on Equipment and protective systems intended for use in potentially explosive atmospheres*[11]	Health & Safety (equipment and protective systems intended for use in potentially explosive atmospheres)	The directive carries obligations for the person who places products on the market and/or puts products into service, be it the manufacturer, his authorized representative, the importer or any other responsible person	-Risk assessment (see paragraph 4.3 guide) -Products should meet the health and safety requirements as set out in the Annex II of the directive (see article 3), -Meet the required testing to relevant standards -Development of technical documentation for testing purposes -CE Marking
RoHS (2011/65/EC) *Restriction use of hazardous substances*	Use of hazardous chemicals (Health and environment – art. 1)	Manufacturers are mainly responsible (art. 7) Secondly, art. 8 lists responsibilities of authorized representatives. Thirdly, art. 9 lists obligations of	-Assure no substances listed in annex II are used (art. 4) The following measures are required from the *manufacturers*: -Assure production in line with requirements directive (art. 4 and 7a) -Collect compliance statement from suppliers (material declarations) -Technical file with supplier declarations and own analysis tests

[10] See the Guide for the EMC Directive (2004/108/EC), page 23.

[11] http://ec.europa.eu/enterprise/sectors/mechanical/files/atex/guide/atex-guidelines_en.pdf

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Name of legislation	Main issue addressed	Who is responsible?	Requirements for economic operators
		importers. Lastly, art. 10 lists obligations for distributors.	(internal production control, art. 7b) -Declaration of conformity (art. 7c) -Declaration of conformity to be kept for 10 years (art. 7d) -CE marking of the product -Procedures for production to remain in conformity (art. 7e) -Register of non-confirming and recalled products and informing distributors (art. 7f) -Identification mark on each product (art. 7g and 7h) -Take measures if they have reason to believe non-conformity (art. 7i) -Provide information if so requested by a competent national authority (art. 7j)
REACH (1907/2006/EC) *Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals*	Use of chemicals (Health and safety)	Manufacturing, authorized representative (art. 4) or importer.	Collect statement from suppliers stating that he is in compliance with requirements (REACH compliance statement) Register and notification of the substances to the Agency.
Eco-Design Directive 2009/125/EC and Implementing Regulation 640/2009 *(Design and sustainability)*	Energy consumption/ efficiency	Manufacturer or his authorized representative is in general responsible. However, art. 4 of the directive lists specific requirements for the importer if the manufacturer is not established within the community.	Meet the ecodesign requirements as described in Annex I (art. 3 regulation) -Testing (conformity assessment – art. 4 regulation) -Declaration of Conformity and CE marking (art. 3&5 regulation) -Complying with the mentioned conformity procedure in the appendix, -Information in instruction manual for minimizing energy-use -Comply to the proper energy efficiency levels (IE2 or 3) -Instructions for consumers on sustainable use

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CASE STUDY 2 – LAPTOPS

1. Introduction

Common aims of case studies

The aim of the product cases is to assess how Internal Market (IM) legislation for industrial products affects economic operators (manufacturers, importers and distributors). The applicable Union harmonisation legislation specific to each product is mapped out and an assessment of any gaps, loopholes, inconsistencies and duplication is provided. The costs of regulatory compliance (administrative and substantive) in meeting IM regulatory requirements are then assessed.

Specific aims of case

The rationale for the selection of laptops[12] as a product group was that:

- A key issues highlighted in the specifications was how far Union harmonisation legislation is 'fit for purpose' in facilitating – or at least not hindering - process / product innovation. Since laptops are characterised by a high level of innovation and technological change, they provide scope to explore this issue.
- Laptops are dominated by a small number of global manufacturers. This allows us to consider how IM legislation affects multinational companies that produce laptops for both the European internal market and other markets globally.

The case study was carried out using desk research and interviews. With regard to data sources, the main sources used were Eurostat SBS (2 digit NACE code level) and Prodcom data (8 digit NACE), sectoral studies and market research reports.

2. Product definition and description of structure of the sector

Information and data on market size and structure for the laptop industry is presented. Recent industry developments and market trends are also summarised.

Product definition and data availability

The product group within scope is laptops (also commonly referred to as notebooks). Other types of IT products, such as palm-top organisers, desktops and printers are outside the scope.

Eurostat SBS and Prodcom data extends more widely than laptops alone[13] and covers the manufacture of computers and peripheral equipment. It was therefore only possible to obtain data at a sufficient level of disaggregation for some variables. In order to supplement Eurostat data and to compensate for data gaps, we have also made use of industry data from industry associations and other market data available through previous studies.

[12] Laptops can be defined as a portable computer to be operated for extended periods of time without a direct connection to an AC power source.

[13] NACE codes 2620 includes: Laptop PCs and palm-top organisers, Point-of-sale terminals, ATMs and similar machines capable of being connected to a data processing machine or network Desk top PCs and Laptop PCs and palm-top organisers, among other categories of peripherals.

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Market size and structure

The size and structure of the laptops market is now considered. The main variables presented are the number of enterprises, employees and production value, and the value of imports and exports. According to data from the PRODCOM database[14], the total market for laptops is around €24.6 billion. Market studies available provided similar estimates (€24.4 billion)[15]. According to the same data source, a total of 79 million laptops units are sold annually within the EU.

Table 1: EU laptop market size (2011) – estimate based on PRODCOM data for product code 26201100 - Laptop PCs and palm-top organisers

Exports quantity (million units)	Value of exports (billion €s)	Imports quantity (million units)	Imports value (billion €s)	Production quantity (pairs)	Production value (billion €s)	**Consumption volume (million units)**	**Consumption value (billion €s)**
8.8	3.3	80	25.6	7,800,000	2.25	**79**	**24.6**

Source: Eurostat Prodcom data

A leading EU industry association suggested a lower figure for laptops alone. According to industry data, the current market size for laptops can vary significantly and is about 32 million - 48 million units per annum. This is a more accurate figure since palm-top organisers were not examined. PRODCOM data confirms that laptops manufacturing is mainly carried out outside the EU, commonly in East Asia. The value of imports into the EU is more than 9 times greater than of imports.

Global laptop producers are commonly involved throughout the value and distribution chain (e.g. from initial design, through to manufacturing and direct distribution to consumers and businesses). In recent years, since the price of laptops has gone down considerably, manufacturers have had to adjust the value chain. Accordingly, there is strong reliance of manufacturers on ODMs (Original Designed Manufacturers). ODMs are suppliers that supply parts or final parts for laptops and under the modular approach to complying with IM regulations (see later in this case), may assume responsibility for the compliance of the particular product modules/ parts that they produce.

Industry structure and employment

A small number of major global laptop producers dominate manufacturing and distribution activities. It was estimated that there are only about 20 large firms in total and industry data shows that five multinationals have approximately a 60% share of the global market (Hewlett-Packard, Dell, Acer, Lenovo and Toshiba).

Additional information about market share in Europe was obtained by searching the Amadeus database (now called ORBIS) of Bureau Van Dijk on laptops. This confirmed that top

[14] It is not clarified by the definition but it is also possible that this category covers portable tablets.

[15] Data from the 2011 Euromonitor report for computers.

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manufacturers have a very high market share. For example, HP has an estimated 21.5% share of the market, ACER 11.4%, Lenovo: 11.4% and Asus 11.2%. Data for other firms was not available.

Looking beyond the leading global manufacturers, there are also SMEs in the laptops sector. These build bespoke desktops and notepads in relatively small volume (as little as a few hundred units). Data from Eurostat's Structural Business Statistics were of limited use since NACE code 2620 "Manufacture of computers and peripheral equipment" extends well beyond laptops. This shows that there were 6,963 enterprises in 2008. An alternative data source was the ORBIS database (Bureau Van Dijk) which provides information on active enterprises in Europe.

The ORBIS database lists a total of 7094 firms under NACE code 2622 for 2013 – similar to the Eurostat figure. However, a keyword search with the "economic activity description" field with the term "laptops" produced a list of 66 manufacturers. 3 of these are large firms and the remaining 63 are SMEs. 8 of these firms were the headquarters of firms and the remainder were branches and included as one or more subsidiaries of the large manufacturers. In total, on the basis of the information collected, we consider that the number of firms resulting from the use of the ORBIS database provides a realistic estimate of the number of firms affected by internal market legislation.

In terms of employment, the total computers and peripheral equipment sector employed almost 1.1m people across Europe in 2008. There had been a reduction in employment to 884,000 by 2010. However, this relates to the whole of NACE 2620 (including desktops, palmtop organisers and many other types of IT equipment). The European industry association interviewed confirmed that the number of employees in the laptops sector involved in manufacturing is very low. Nevertheless, laptops are an important industry, when combining different aspects of the value chain from manufacturing through to distribution (wholesale, retail) and aftersales and servicing activities.

Key industry trends and challenges

This case does not allow for a detailed review of key industry trends and challenges. However, recent developments and key features of the laptop industry are worth noting. These are, in summary:

- The importance of economies of scale and scope to be competitive, with a high level of market concentration in manufacturing and distribution among a handful of leading global firms.
- A decline in laptop sales and prices in a maturing industry. Increasing competition from product groups such as tablets, smart phones and the advent of alternative data storage solutions such as cloud computing, which reduces the need for high computing power in portables.
- Convergence between the mobile phone and ICT markets (including the entrance of new manufacturers that have diversified away from Smart Phones into tablets and notebooks.
- Strong capacity for innovation and technological change[16].

[16] Examples of technological change are increased processing power with reduced power consumption through investment in energy-efficient technologies

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- Changes to the business model and organisation of the value chain within the laptop industry:
    - Increased use of ODMs in manufacturing processes.
    - Leading brand names moving away from selling hardware alone to combining these with add-on services such as technical support.

3. Analysis of applicable IM legislation and standards

Summary of applicable IM legislation

A mapping exercise was undertaken to identify relevant applicable IM legislation for laptops. In summary, the main legislation that is applicable is:

- The Low Voltage Directive (LVD) - 2006/95/EC
- Electromagnetic Compatibility Directive (EMC) 2004/108/EC
- R&TTE Directive (1999/5/EC)
- RoHS Directive (2011/65/EC)Ecodesign for Energy-related products Directive (ErP) 2009/125/EC
- REACH Regulation (EC 1907/2006)
- Packaging and packaging waste (2004/12/EC)

The detailed mapping of applicable legislation is provided as an annex. This summarises the main issues addressed through the legislation (e.g. product safety, energy-efficiency), the key administrative requirements for manufacturers and examples of relevant (voluntary) technical standards. The mapping of the legislation was based on desk research and discussions with individual manufacturers. It should be noted that environmental legislation applicable to laptops such as the WEEE Directive (design for end of life and recyclability) is outside the scope.

Overall, the IM regulatory framework affecting laptops was regarded by interviewees as being relatively stable in terms of the core applicable legislation. For instance, the EMC Directive has been in place since 1989 and although this was recast in 2004, there were no major changes. The LVD is one of the oldest Single Market Directives and was adopted even before the "New" or "Global" Approach came into being in the early 1970s. The R&TTE Directive has been in place since 1999.

However, further successive IM regulations applicable to laptops have been adopted in the last decade, such as the RoHS Directive and REACH Regulation and the setting of Ecodesign requirements for energy-related products (ErPs). Firms interviewed stated that the introduction of new IM regulations have had a much greater impact on the industry than their predecessors.

There are currently general requirements common to electrical products used in households and offices, and concern standby and off-mode electric power consumption and Power consumption for information technology equipment (ITE). However, specific requirements will soon apply following the adoption of Regulation 617/2013 (Ecodesign requirements for computers and computer servers), of which some requirements will be mandatory from 1 July 2014 and others from 1 July 2016. In addition, there exists a voluntary energy labelling for laptops used as office equipment, called 'Energy Star'. This is an endorsement label for the

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most efficient appliances developed by the US, which is also applied in the EU for office equipment).

Conversely, standards are always changing and being updated, which requires technical work both during the development stage and in order to comply with new or updated technical requirements.

Alternative routes to regulatory compliance - laptops

There are two alternative routes to regulatory compliance for laptops. If a laptop is defined by the manufacturer as a **"radio product"**, then the R&TTE Directive alone can be applied. Since the Directive incorporates requirements relating to electrical safety and checking for Electromagnetic Compatibility, this means that the LVD and EMC Directives themselves do not need to be applied, since this would be duplicative.

However, if the laptop is considered to be a piece of "**electrical equipment"** containing a radio part within it, then a modular approach can be followed in which the R&TTE, LVD and EMC Directives are treated separately for compliance purposes. This can be especially beneficial for manufacturers in a situation in which different manufacturers and / or ODM suppliers are responsible for producing different parts of the product since they can then assume responsibility for the compliance of specific product modules rather than for the whole product. An explanation as to how these approaches work in practice, and the advantages and disadvantages of each approach from the perspective of manufacturers is highlighted in the following table.

Table 2: A modular approach to compliance with IM regulations

Compliance route	*Description*	*Compliance requirements – analysis of differences*	*Advantages and disadvantages*
R&TTE Directive alone	Complying with IM regulations using the R&TTE Directive only. This means that the whole laptop is treated as a single radio product.	• DoC must be placed together with the product • Product must be CE marked Notification requirements for non-harmonised radio frequencies Laptops with Wifi Radio Module Class 1 and 2 must include an alert mark next to the CE mark	*Advantages* • Only one Directive is applicable rather than three • Legal clarity - responsibility for whole product is sole responsibility of manufacturer *Disadvantages* • Cannot divide up compliance responsibilities between different components / parts manufacturers. • Additional labelling marking requirements compared to the EMC-D/LVD (e.g. alert mark next to CE mark,

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			information on restrictions of use, etc…). • Making information available for the user which are not required for the LVD and the EMC (e.g. DoC placed with the product).
A modular approach - R&TTE, EMC and LVD Directives applied separately	Modular approach - the laptop itself is treated as a non-radio product and the R&TTE Directive is only applied to the radio module. Other parts of the laptop are subject to the EMC and the LVD	DoC must be placed together with radio module Only the radio module would potentially need the alert sign (Class 2) Notification requirements for radio frequencies (only for radio module part)	*Advantages* • Division of responsibility for compliance between manufacturers responsible for different components / parts of laptop • Manufacturer producing other parts of laptop under LVD and EMC don't need to consider requirements specific to the R&TTE Directive e.g. alert sign, DOC with product[17] • Manufacturers of other parts do not need to provide a DoC to user (only upon request by a MSA)

Feedback is now provided by manufacturers interviewed about their views on the overall IM regulatory framework and their experiences of complying with IM legislation. There are different views among industry as to which approach is preferable. Firms interviewed all appreciated the flexibility afforded by Union harmonisation legislation to determine whether to follow the R&TTE Directive alone, or to adopt a modular approach as and when appropriate. Interview feedback is now considered on this matter.

Firm C treats laptops as a single radio product and complies with the R&TTE Directive alone and assumes responsibility for the product's compliance. The LVD and EMC Directives are not applicable because the essential requirements under these Directives are already included within the R&TTE Directive. *"The main benefit of a modular approach was dividing up responsibility among manufacturers for different parts of the laptop, depending on the module concerned. However, as a manufacturer, we prefer to take sole responsibility for regulatory compliance"*. This was considered as beneficial when considering their obligations towards consumers and in terms of minimising risks.

[17] A DoC only needs to be provided with the product by manufacturer responsible for radio part (since only R&TTE Directive has this requirement).

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Conversely, in Firm A and Firm B, the modular approach is followed and compliance with the LVD, EMC and R&TTE Directives respectively is addressed separately. The modular approach was considered to be more efficient in a situation in which multiple manufacturers are involved in producing the end product since the manufacturer of each part is able to assume responsibility for their specific part. In a competitive market place, it was considered that suppliers need to take responsibility for the quality of their product lines and it was believed that this had helped to strengthen standards in the components market.

In Firm A, a different member of the regulatory compliance team deals with each of these Directives and conformity assessment testing is also carried out separately by different teams. The firm pointed out that under the modular approach, the manufacturer of the final product retains ultimate responsibility for product compliance. In the full version of the DoC[18], a list of all modules that can be used for each product model is provided. This has been made available online by all leading laptop manufacturers. The modular approach was however seen as an effective mechanism for optimising regulatory compliance processes and procedures, with advantages in allocating responsibility to different manufacturers at different modules/ stages in the production process.

Firm A commented that *"Since due diligence needs to be carried out on each product, the modular approach allows us to provide better information to Market Surveillance Authorities about how compliance has been achieved through each product module. If an MSA asks for further information or raises questions about a product, then the manufacturer or ODM supplier concerned that carried out conformity assessment tests and produced technical documentation relating to that specific module can provide technical information as to how regulatory compliance has been achieved under that module".*

According to an industry association, most but not all laptop manufacturers follow the modular approach. This depends on the manufacturer's business model and how the manufacturing of laptops is organised. Some laptops are designed and manufactured by a single manufacturer, whereas others are produced by multiple manufacturers and ODM suppliers, each responsible for different parts / modules and components within the laptop. For example, Firm C is directly involved in all aspects of manufacturing and does not generally outsource production (although it may source components from suppliers), whereas most firms in the sector (including Firms A and B) use an increasing amount of outsourcing to ODM suppliers for manufacturing. This trend has been accelerated by downward pricing pressure for laptops and competition from smartphones, tablets and cloud computing.

4. Analysis of costs of compliance with IM legislation

In this section, we provide:

- A summary of how laptop manufacturers meet IM compliance requirements from a business process point of view, highlighting any differences in approach between manufacturers.
- An estimate of the costs of complying with IM regulations (administrative and substantive compliance costs)
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[18] In the laptops industry, it has been agreed that an abbreviated version of the DoC is provided together with the product with more detailed regulatory compliance information provided online.

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Interview programme

In order to carry out the quantitative research, four interviews have been carried out with global manufacturers (three with laptops manufacturers and one with a leading manufacturer of chips and processors)[19]. In addition, two discussions were carried out with a European industry association. An overview of the firms interviewed is provided in the following table:

Table 3 – Overview of firms interviewed - laptops

Firm	Product category	Firm size	Annual sales from product in the EU
A	Laptop manufacturer	Large	3 million units/ annum. Market share - 19-20% of EU market
B	Laptop manufacturer	Large	4 million units/ annum. Market share – 25-26% of EU market
C	Laptop manufacturer	Large	NA - but circa 8-10% of EU market
D	Components manufacturer	Large	NA - but no. of laptop chips and components numbered in the millions/ annum

Although there were challenges in persuading firms to take part, the firms interviewed are all globally recognised players in the laptops industry and account for a market share of c.a. 50-55% of the total market. There are an estimated total of 15m annual laptop sales in Europe. Unlike for other products, no SMEs were interviewed, since the laptops industry is dominated by large manufacturers (see Section 2).

Overview – how do laptops manufacturers manage regulatory compliance?

In this section, a description is provided of the way in which laptops manufacturers manage compliance with IM regulations. Five main steps were identified in harmonised product sectors in order to place products on the EU market. These five steps were defined for all the harmonised product cases and have been used as the basis for carrying out discussions with manufacturers to ascertain information about how they manage compliance processes and the costs involved:

- Familiarisation with the applicable/relevant obligations – preparatory actions
- Introduction of processes or changes to product design and production processes to ensure compliance with substantive obligations
- Conformity assessment procedures and relevant documentation
- Declaration of conformity or other statement of compliance and CE marking

[19] There were difficulties in persuading more firms to participate. Some companies approached were concerned about commercial sensitivities, while others did not believe that they would be able to collect such complex data at the product level because they produce so many different product platforms.

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- Other activities related to obligations posed by authorities

The way in which manufacturers manage each of these five steps and feedback received on the type of costs involved is now provided.

Reference should also be made to the previous section, which highlighted that there are alternative routes to achieving compliance for laptops. Clearly, whether a given manufacturer has decided to follow the R&TTE-D alone, or a modular approach in which they comply with the R&TTE-D, EMC-D and the LVD-D separately will have implications in terms of the way in which manufacturers organise their business processes relating to compliance and testing.

Step 0 – Engagement in EU policy and legislative-making processes and in standardisation-related activities

The firms interviewed recognised that it was in their direct interest to participate in influencing the form, content and implementation of Union harmonisation legislation. Since large manufacturers dominate the laptops sector, they commonly participate directly in EU legislative-making and standardisation development processes, for instance by taking part in working groups meetings on particular Directives and in standardisation processes. They also make an indirect contribution, for instance, by providing feedback through the main European industry association, Eurodigital, who in turn participate in EU regulatory processes and in consultations on specific IM regulations.

The aim of this participatory approach is to ensure that industry feedback influences and shapes the form of new IM legislation. Taking part in policy and legislative-making processes enables firms to better anticipate regulatory developments affecting laptops well in advance of the entry into force of IM legislation. It also allows industry to shape the requirements for manufacturers, which is especially important when the potential burden could be significant and other appropriate but equally effective solutions are possible. Among the examples of legislation where industry input was felt to be especially important were RoHS, REACH and the drawing up of Eco-design implementing regulations.

Firm B agreed that active participation in EU regulatory development processes was vital and stressed that they invest considerable time in monitoring key developments well in advance of new regulations and technical standards being adopted and coming into force. Firm C commented that *"In order to ensure that we are effective in managing compliance, we take part in the policy-making process and this facilitates our understanding of how regulatory requirements should be interpreted and implemented. It is important to have both direct and indirect communication channels with legislators (e.g. participating in industry associations, responding to public consultations, attending meetings and workshops, direct email contact etc.)"*.

The preparatory phase prior to legislation and standards being adopted requires human resources. Firm B commented that they worked approximately 75% FTE on IM legislation and that they spent a lot of time following new regulatory developments. This requires attending 6 industry meetings in Brussels per year of 2 days' duration, contributing to the preparation of industry responses to proposed EU regulatory developments, etc.

However, although this does take some time and resource commitment on the part of industry, the scale of administrative costs incurred should be set in context. It is in industry's strong interest to monitor EU regulatory developments and standardisation processes closely as part of an active approach to managing compliance with IM regulations. This helps

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manufacturers to better anticipate how changes in the regulatory regime applying to the products that they manufacture is likely to affect their industry. This can in turn help to reduce substantive compliance costs by ensuring that upcoming or new requirements are factored into the product design process from the outset.

Moreover, large global manufacturers also employ thousands (and sometimes tens of thousands) of staff and can spread the cost of engaging in EU policy and legislative-making processes across sales volumes that amount to millions of units per year in the EU. Although there are only a few laptop manufacturers that are SMEs, such firms may find it more difficult to dedicate resources to Step 0.

Step 1 - Familiarisation with applicable legislation and relevant information obligations.

Taking part in the early stages of the formulation of legislation as part of preparatory work to help laptops manufacturers better anticipate forthcoming legislative developments, updates to technical standards, etc. (Step 0) is closely linked to Step 1, which is concerned with familiarisation with the applicable legislation and relevant information obligations once IM regulations have been adopted.

Manufacturers invest considerable human resources in familiarisation with the applicable regulatory and administrative requirements. Since the sector is dominated by approximately 10 large global manufacturers, these firms have dedicated regulatory compliance departments who not only work on familiarisation, but brief their colleagues in other departments as to (i) which legislation is applicable (ii) which technical standards could be utilised (iii) whether there are any forthcoming regulatory changes likely that need to be considered in product design (iv) preparatory work needed on documentation (mainly the preparation of a DoC and of a technical file for each product.

There was a lot of variance in the percentage of time firms estimated that familiarisation took as a proportion of total time spent by internal staff over the 5 process steps. For instance, Firm A estimated that about 10% of staff time was devoted to familiarisation, whereas the equivalent figure for Firm C was 15%. For Firm B, however, this was estimated at 40% (Firm D did not provide an estimate).

Such divergence among manufacturers will depend on the role and perceptions of the interviewee and how the amount of time spent on compliance is divided between different compliance activities and business functions. Since in many cases, the interviewee was located in Europe, and was themselves involved in monitoring regulatory developments, they did not always have the details of the amount of human resources involved in testing activities for compliance, which are often carried out in a different Member State or outside the EU. It was interesting to note that requesting data from colleagues particularly those located outside Europe was seen as challenging and would take considerable time and that the quality of the information eventually provided may not be well thought through.

More generally, it was difficult to quantify how many staff are working on compliance for any given product group, since most laptop manufacturers produce a wide range of electrical and IT products. Regulatory compliance teams typically work across a number of different product groups, are overseeing different applicable IM regulations, as well as differences in the technical standards which are specific to particular product groups. This means that it is often difficult to estimate precisely how much staff time is spent on familiarisation broken down to a particular product group. This was the case for instance with Firm C, which has a

team of 13 FTE staff working on compliance with IM regulations and a further 13 FTE staff with EU environmental regulations.

Laptop manufacturers interviewed noted that they spent much less time on familiarisation in regard to long-established IM legislation, such as the LVD and EMC Directives, where the requirements have not changed that fundamentally in 20-30 years. They spent much more time preparing their firms to meet new regulatory requirements stemming from recently adopted IM legislation. Examples cited in this regard from the past few years were the RoHS Directive (RoHS II was adopted in 2011), the REACH Regulation (which entered into force on 1st June 2007). For instance, Firm D, a global manufacturer of microchips and compressors commented that there had been a lot of preparatory work for RoHS and REACH. There was a need for specialist compliance staff to liaise internally across different business functions such as R&D in order to ensure that the firm was fully compliant and REACH-ready.

In the near future, the introduction of new implementing regulations for Ecodesign specific to laptops was viewed by firms interviewed as being likely to require significant familiarisation time. An Ecodesign implementing measure was adopted in 2013 for computers and servers in June 2013[20]. Laptops manufacturers already have some familiarity with Ecodesign requirements through the requirements on Standby and Off-mode (Regulation EC 1275/2008) which apply to electronic devices generally.

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Lastly, in order to help industry to minimise the burden of EU legislation, the development of guidance materials was seen as invaluable in saving time for familiarisation costs. For instance, a components manufacturer in the laptops industry commented that the development of guidance for Ecodesign requirement on standby and off-mode was especially important, given the technical complexity involved. However, aspects related to standby and off-mode for laptops are now included in the new ecodesign regulation for computers and computer servers and no longer in the horizontal regulation on standby and off-mode.

Step 2 - Changes to processes or changes to product design and production processes

Like other industrial products, laptop manufacturers have to incorporate regulatory requirements into R&D and product design processes. However, it was difficult to obtain cost estimates from manufacturers. In instances when data was not available at all, the main reasons were that:

- Where manufacturers carry out conformity assessment testing internally, the testing often takes place in laboratories outside Europe for global consumer products such as laptops. Since laboratories work on products designed for the global market, data on testing costs specific to European IM regulations is often not collected by the manufacturer.
- Laptops manufacturers are increasingly reliant on ODM suppliers to carry out testing at the product design stage. ODM suppliers do not usually break down their prices to reveal the specific costs of regulatory compliance (and associated conformity assessment tests) since they provide their client(s) with a total estimated price.

[20] COMMISSION REGULATION (EU) No 617/2013

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- Manufacturer that make extensive use of ODM suppliers carry out random "spot" testing of products as part of quality control procedures but only at the point when a product model is already on the market (e.g. checking of product batches about to be shipped).

Industry found it difficult to quantify expenditure on substantive design costs. Firm A pointed out that the business model makes it difficult for laptops manufacturers to disaggregate costs. "There is lot of global leveraging and in the notebook business a lot of manufacturing is outsourced this work is, the certification are more and more included in the final price offer and not always quantified, if it is quantified, the price is on global scale mixing a lot of items. In addition, there are difficulties in calculating the leveraged cost of testing modules, which nowadays are carried out on an outsourced basis by OEM suppliers. Consumer notebooks are now totally managed by the outsourcing partner and therefore we totally lost control of that type of costs especially as annual aggregate and related to EU. Somehow by passing the ball we avoid to ask to avoid the risk to have our outsourced partner to revise the agreements, assuming that it is their task to keep tests costs low".

Even in those instances when data was available to the manufacturer, they were unwilling to share this data because it was considered to be commercially sensitive. Although some data imputations have been made by our team (see table quantifying these costs), the feedback received was mainly qualitative.

It was observed that **by anticipating changes to IM regulations, firms are able to help minimise substantive compliance costs**. As noted above, large firms follow EU regulatory development processes closely, and are usually aware about changes to IM legislation and administrative requirements well in advance of these becoming mandatory and also follow standards development processes. Since laptop products are designed with knowledge of current requirements under IM regulations (and those likely in future) in mind, and the core legislation has been relatively stable in the past decade, this helps to avoid lots of changes to produce design or to products already on the market due to changes in requirements.

Another observation from the research was that some types of costs, such as substantive changes to product design once products have already been placed on the market in the EU are probably lower for laptops than for say air conditioners due to **differences in the product development lifecycle and the duration of the product's lifecycle post-placement on the market.** Whereas for an air conditioner, this lifecycle is typically 10-12 years (see Ecodesign Preparatory Studies[21]), for laptops it is around 2-4.

If changes are required due to changes in IM regulations (and/ or updates to voluntary technical standards), these are usually identified well in advance by laptop manufacturers. Any necessary changes can therefore be factored into the design phase when new product models under development, which helps to reduce substantive compliance costs.

It is less common – though not unknown - for laptops to have to be temporarily withdrawn from the market or for modifications to have to be made to existing models. Rather, new laptop platforms under development take these changes into account directly and existing models are simply phased out in line with their planned product timeframe.

[21] Preparatory studies for Eco-design Requirements of EuPs, Lot 3 Personal Computers (desktops and laptops) and Computer Monitors, IVF Industrial Research and Development Corporation, 2007 (for the European Commission's DG TREN)

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Some examples of substantive costs were however identified over and above the initial R&D and product design phase. For instance, interviewees stated that the introduction of some IM regulations had resulted in them incurring substantial additional costs, even if these were difficult to quantify. For instance, under REACH, there was a need for chip makers supplying laptop manufacturers to invest in R&D to identify and test possible substitute chemicals for use in the production of micro-chips.

The **most costly pieces of IM regulations were perceived as being those IM regulations introduced in the past five – ten years**. This is partly because new IM regulations require more familiarisation time, but mainly because whereas the classical New Approach Directives were concerned with product safety, more recent regulations have more environmental and health-focused requirements in their objectives (e.g. concerned with restricting the use of dangerous chemicals, hazardous substances, and ensuring improved levels of energy efficiency).

There may therefore be a need under these regulations to make significant changes and to plan for these changes, for instance, in respect of product design and specifications, the type of components and parts used, the substances and chemicals used, etc.

Both Firm B and Firm D regarded the introduction of RoHS and REACH as having been burdensome for laptops manufacturers and components makers (e.g. of chips and micro-processors) respectively. Firm D commented that while recognising the environmental benefits, there were significant costs associated with achieving REACH compliance. These are examined in Table 4.

Table 4: Industry concerns about legal uncertainty for downstream users under REACH regulation

A concern among industry in relation to the REACH regulation was that there was perceived legal uncertainty as to which substances might be outlawed in future following substance evaluation or subject to restrictions and authorisation requirements. These concerns are particularly acute in terms of the potential cost implications from a downstream user perspective. There is not only uncertainty as to whether chemicals that are currently critical for some laptops components could be banned or restricted, and replacing them with alternatives could potentially be costly. This was viewed as especially problematic by Firm D. For instance, the substance, gallium arsenide, is widely used and without it microchips cannot be produced. However, there is no viable product substitute. The substance is currently being reclassified under the CLP Regulation as part of the Adaptations to Technical Progress (ATP) to the CLP. This specific substance is currently also being assessed under the Community rolling action process substance evaluation by Latvia. However, there are presently no common criteria for undertaking substance evaluation in order to fast-track particular chemicals. In Firm D's view, before banning or requiring authorisation for substances that could really disrupt the supply chain, there should be a more detailed impact assessment for downstream users. Since REACH is at a relatively early stage in the process of identifying harmful chemicals that need to be subject to authorisation, restrictions and phased out, there is considerable legal uncertainty and unpredictability for downstream users at the present time. Currently, manufacturers cannot plan for the future effectively and this was said to impose costs. Firm D noted that since a technology-driven development cycle from basic R&D through to

high-volume manufacturing takes 10 years. Planning is therefore needed as to which substances can be legally used under IM regulations for the next 15-20 years and investment decisions need to be taken about semi-conductor production facilities which can be very high-cost. Such legal uncertainty may deter investment.

There can also be substantive compliance costs associated with **ensuring that products already placed on the market meet requirements set out in updated harmonised technical standards**, even though there is a transition period before new standards must be used for products and products that have used the former standard to be slowly phased out. For instance, in the area of electrical safety, in March 2013, a large multinational announced that it had temporarily withdrawn a desktop PC product from the market because it was not compliant with Amendment 1 of IEC 60950-1, an updated standard on electrical safety. The firm concerned was reported to be redesigning the product in order to allow it to continue to be sold in future.

Table 5: Differences in the cost of modifying products to reflect the updating of standards – a comparison between Europe and the US

There are differences between Europe and the US as to whether products can remain on the market once new and updated technical standards have been introduced. Firm B commented that the differences between the US and European regulatory systems affects the costs of modifying products in order to update technical standards, once these are placed on the market.

In the EU, there is a transition period during which manufacturers that apply harmonised standards must update products in accordance with the new technical standard, usually within 2-3 years of a product being placed on the market. This imposes costs on the European laptops industry compared with other geographic regions. In contrast, in the US, once a product is already on the market[22], then even if a new, updated technical standard has been introduced, products using the old standard can continue to be legally sold in the US . However, any new products in the development pipeline are required to conform with the new, updated standard.

Step 3 - Conformity assessment procedures and relevant documentation.

The applicable **conformity assessment** modules that need to be followed will depend on which alternative route to compliance the manufacturer has decided to select. As set out in detail in Section 3, if the modular approach is applied, then appropriate testing will need to be carried out for the EMC-D, LVD-D and the R&TTE-D respectively, whereas if the product is classified as a radio product, then only the CA procedures applicable under the R&TTE-D will need to be applied[23].

[22] There is no direct equivalent to the concept of "placing a product on the EU's internal market" as set out in Decision 768/2008

[23] The conformity assessment procedures that are applied by manufacturers under the R&TTE-D are in summary (II) Internal production control (iii) Internal production control plus specific apparatus tests (IV) Technical construction file and (V) Full quality assurance).

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The laptop manufacturers interviewed use the Suppliers' Declaration of Conformity (SDoC) as the main conformity assessment route to meet the essential requirements for applicable IM regulations. Many manufacturers also choose to use a third party to carry out testing in respect of some IM directives, although this is not mandatory. This is a common approach (for instance for the LVD to check electrical safety) since many manufacturers prefer to use external conformity assessment bodies either to carry out all the testing or to check a sample of products that have already been checked by the manufacturer using internal testing. This approach was seen as helpful in minimising risks and in reassuring consumers, which is important, since there are reputational management issues at stake.

Industry confirmed that the flexibility of carrying out conformity assessment internally using the SDoC was appreciated. Since the majority of laptops are produced by global manufacturers using large in-house testing facilities, it was felt that manufacturers could ensure product safety equally as well as third party conformity assessment. Firm B commented that *"there is no evidence that SDoC makes products any less safe compared with the use of mandatory third party testing, so long as the system is underpinned by robust market surveillance"*.

There were difficulties in obtaining data on the costs of internal and external Conformity Assessment Procedures, for the reasons already set out in Step 2 (e.g. commercial sensitivity of data, internal testing costs not shared between different business divisions globally, difficulty in obtaining accurate data when testing carried out outside EU by manufacturer or when outsourced to ODMs).

Nevertheless, some estimates on the annual costs of external conformity assessment, were obtained. For instance, Firm A estimated that across the 30-40 different product platforms launched annually on the EU market, it spends approximately 800000– 1m EUR per year on third party conformity assessment. In addition, it estimated that in-house testing costs approximately 10000 EUR / regulatory model. A distinction was drawn here between a "regulatory model" on which compliance is built and a "marketing model" i.e. a firm may develop many different models for marketing purposes, but there are a much smaller number of basic platforms on which basic compliance is built. However, it was not possible to obtain estimates of the one-off and recurring costs of internal laboratories and testing and of the purchase equipment.

The applicable conformity assessment mechanism is defined in each implementing measure and conformity is generally based on internal design control or on a quality assurance management system. Implementing measures may also make provision for modules, but this is typically Module A unless explicitly stated otherwise. In the case of the forthcoming Ecodesign requirements for computers and computer servers (Regulation 617/2013), when these start to apply, the applicable conformity assessment procedure will be the internal design control system set out in Annex IV of the Ecodesign Directive or the management system for assessing conformity set out in Annex V of the Directive.

Since large firms dominate the laptops market, no SMEs were able to be interviewed. Some feedback was nevertheless obtained on SMEs. According to the industry association, Eurodigital, it can be challenging for SMEs to test products for Ecodesign requirements. Firm D, which is a global manufacturer of chip and micro-processors confirmed that it assists smaller manufacturers in carrying out testing to meet Ecodesign requirements, which currently apply only to standby power mode), but will be replaced by requirements applying

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to computers and computer servers as a whole through Ecodesign implementing regulation 617/2013.

Feedback was received from two global laptops manufacturers on the costs of standards. It was pointed out that a distinction needs to be made between harmonised standards and wider standards and technical specifications that are used by the industry but which are not directly linked to complying with IM legislation.

Although the purchase of harmonised standards is voluntary, since the leading laptops manufacturers follow these standards, they are regarded as being part of the overall costs of compliance (even if they only account for a small percentage of the overall costs). There are just a few harmonised standards that meet the essential requirements set out in IM legislation and are included in the Declaration of Conformity (DoC) for laptops. In analysing costs, only the purchase of these harmonised standards should be considered. The same standards can often be applied not just to other types of laptop models but also to other product devices horizontally. For instance, ETSI EN 300 328 relates to 2,4GHz WiFi technology, regardless as to whether the device concerned is a laptop or an MP3 player. We therefore asked firms to estimate the proportion of the costs of standards solely relating to laptops and to IM legislation.

Firm A stated that the cost of purchasing a single standard, especially those related to the EMC and to electrical safety under the LVD is typically around 80 EUR. There are cheaper prices when obtaining updates for standards that have already been purchased. A manufacturer of laptops will typically follow some 30-40 standards in total (of which only a few are harmonised standards needed to build compliant products). However, as noted above, once a complete set of standards has been purchased, these can then be used across multiple laptop models.

An alternative option for large manufacturers is to purchase a company license, which then gives them the right to purchase a certain number of single licenses (typically 50 licences for all IEC standards purchased). The cost is approximately 40,500 EUR, which is a one-off cost, but which can be used to cover multiple laptop products (and other devices). The cost of purchasing standards specific to the laptops segment of Firm A were estimated to be in the order of 5000 EUR per year across multiple product models. The cost is higher for large firms than for SMEs because SMEs can purchase standards with a single user license, whereas to share the knowledge internally, large firms must by a company license, or at the least a license for multiple users.

One of the interviewees commented that “companies need to operate smartly in terms of the way in which they deal with buying standards otherwise they may waste money, even if the cost of standards is a relatively small part of the whole. The cost of buying standards is not normally attributed to the cost of an individual product, rather that the purchase of a complete set of standards is needed in order to build multiple laptop platforms”. In this respect, there are similarities to the costs of purchasing laboratory equipment in that this is a pre-requisite and part of the "set up" costs for being a manufacturer in the sector.

According to the interviewee in Firm A, “some European Standardization Organisations such as ETSI adopt a more industry-friendly approach since the standards that they develop are free (in effect, they are paid for by industry who pay to participate in the standards development process for ETSI standards. The amount payable is dependent on the type of membership, the size of the company, and the participation that it has in the standards

development process". Firm C noted that "*some companies are more CENELEC-oriented and either purchase individual standards or have a subscription, whereas others are more ETSI-oriented and pay subscriptions to be involved in the standardization process (as standards are indeed freely available). Other laptops manufacturers are involved in the development of both CENELEC and ETIS standards, so the cost of their participation in standardisation making processes (and in purchasing standards) is higher*".

Step 4 - Declaration of Conformity (DoC) or other statement of compliance and CE marking.

Producing documentation - the DoC and the technical file

In common with other industrial products, having first carried out conformity assessment procedures, laptop manufacturers are required to produce a DoC and technical file and to keep this updated for 10 years following placement on the market.

The preparation of the DoC itself is straight forward since this involves producing a sheet of A4 setting out the applicable IM regulations, and commonly also a list of the voluntary harmonised standards that have been applied in order to meet the essential requirements. However, there are administrative costs associated with the regulatory checking and updating of DoCs due to the high cumulative frequency of regulatory changes, both legislative and those resulting from updates to harmonised technical standards. Decision 768/2008 states that DoCs shall be kept "continuously updated".

Internal systems and procedures need to be put in place to ensure that these documents are updated regularly. Updating DoCs between two and four times each year – depending on the firms' internal procedures – is a significant burden in terms of human resource costs. Industry noted that although producing an individual DoC was not difficult, the cumulative effects can be burdensome, since global firms have hundreds of different product models (and variants of each product model) and each DoC then has to be kept under continual review.

In Firm A, the dedicated European compliance team working on IM regulations includes 4 staff solely involved in the development and updating of compliance documentation, with regular internal review procedures put in place for (i) checking, maintaining and updating DoCs and (ii) checking that technical files are as complete as possible. This was regarded as resource-intensive.

There was a perception that there is now a longer timeframe to check that product documentation is administratively compliant with the applicable IM regulations. It was noted that while it previously took 5 days to undertaken an internal procedures to review DoCs and technical documentation and check that these are up to date, the procedure now takes up to 20 days. This was attributed to IM legislation becoming more numerous and complex, for instance, as a result of the introduction of the RoHS, EuP and Ecodesign Directives.

Although some firms viewed the requirement to provide a paper copy of the DoC together with the product under the R&TTE Directive as burdensome, the administrative costs are not that significant thanks to an agreement with TCAM[24] for manufacturers to use the so-called "short form of a Declaration of Conformity". This is an abbreviated compliance statement

[24] TCAM is the Telecommunications Conformity Assessment and Market Surveillance Committee and was officially established by the R&TTE directive.

localised in all languages and a weblink is provided to the full declaration which is available in English only, but can be translated at the specific request of MSAs.

Translation requirements for DoCs – uncertainty for manufacturers?

Two laptops manufacturers interviewed commented that they faced legal uncertainty since it is unclear whether there is a formal requirement that DoCs should be translated into local languages or should continue to provide a local language version of a DoC upon request as has been the case for many years.

The wording in the NLF has led to uncertainty for industry as to what translation requirements apply to DoCs in order to meet compliance requirements. There is ambiguity in the wording in Decision 768/2008 which states that "The DoC shall be translated into the language or languages required by the Member State in which market the product is placed or made available". This ambiguous wording causes uncertainty for the laptop industry, which had previously produced DoCs in English only. One firm commented that "*If a translation requirement were to become compulsory, this would be administratively burdensome. Also, for whose benefit would this be, since regulatory compliance information – unlike an instruction booklet which is directly is concerned with consumer safety –is only to help facilitate the work of MSAs*". The argument put forward is that it is cheaper for global businesses to produce DoCs in English only and the benefits of translating the DoC are minimal given that the applicable legislation is well known and is available translated in all EU languages.

A further concern related to translation was that since the NLF, upon reasoned request by a Market Surveillance Authority (MSA), part of the technical file may be required to be translated. While the reasons for this were understood, since many test reports and other important information for MSAs may not even be in a European language, there were concerns that this could constitute a significant administrative burden for manufacturers. The problem is that there is no clear definition as to what constitutes a "reasoned request".

Step 5 - Other activities related to IM information obligations.

Traceability requirements

The Commission has strengthened traceability requirements for industrial products in order to better enable MSAs to trace the provenance of products and to be able to contact the manufacturer to obtain regulatory compliance information, and parts of the technical file such as tests reports more easily. In Decision 768/2008, there is a specific requirement for products (at least for the packaging) to provide addressee information for the manufacturer and importer(s).

The move towards strengthening traceability is understandable since so many products are manufactured in third countries and MSAs need to be able to contact the manufacturer that produced the product more easily. However, industry has concerns about the administrative burdens that this might impose and also the constraints on product design if such information has to be provided on the product itself.

However, both the industry association and two firms were concerned about the potential administrative burdens of traceability requirements and the difficulty of conforming with such requirements, while at the same time producing attractive, consumer-appealing products. This point extends beyond laptops alone to other products such as smart phones. It

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was argued that traceability requirements may risk compromising product aesthetics from an industrial design point of view (in instances where labelling has to be provided on the product itself). E-labelling was viewed as a possible solution to avoiding having to have too much information on products and packaging.

A further issue identified relating to information obligations related to marking requirements under the R&TTE Directive. This affects laptops using Class II Wifi devices.

Table 6: Marking requirements affecting laptops using Class II wifi devices

Alongside the CE mark, an additional alert mark (a circle with an exclamation mark in the middle) has to be provided on laptops next to the CE mark. This was regarded by Firm C, which follows the R&TTE-D alone as unnecessary first because the CE mark should already cover all safety-related aspects of products and secondly since the alert mark is not understood by consumers. Although the costs involved in adding labels to products are small, the multiplication of labelling requirements (linked to IM regulations and product safety, but also energy-efficiency, waste disposal) has cumulative effects. For example, it places constraints on manufacturers as to where the marking and labelling information should be placed in order to ensure compliance, and may serve to detract from producing an appealing product (again, this depends whether there is scope to put such information discretely on the product e.g. on the underside of the product, under the battery, etc).

5. Assessment of costs of IM legislation for the whole sector

In this section, we provide an assessment of the costs of complying with IM legislation in the laptops sector. The data is based on data and supporting qualitative information provided by four manufacturers. Although the analysis is based on a small number of firms, these can be considered as representative, since they collectively account for a significant share of the market. In the case of laptops, the three firms that took part collectively account for 45-50% of the market and all four participants are global manufacturers.

There were challenges in carrying out the analysis since there were data limitations as regards the costs of product testing, for reasons already explained in our assessment of the five steps in Section 4. Nevertheless, it was possible to arrive at quantitative estimates, since some manufacturers were able to provide more detailed information than others.

Extrapolation of costs and cost saving from the firms to the sector

The following table summarises the costs per unit and total estimated costs for industry. A list of key assumptions made is provided in footnotes. The cost estimates take into account information provided by the firms that took part in relation to the five process steps described in Section 4.

The costs are related to turnover. In the first column, we seek to distinguish between different types of costs. The distinction between one-off and recurrent costs has been taken into

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account in the analysis, and some costs, such as the costs of purchasing laboratory equipment have been annualised[25].

Table 7 – Summary of main costs of compliance for laptops manufacturing industry

Types of cost	Unit of measurement	Unit cost[26]	Total quantity	Total costs (annualised)
Compliance with admin. requirements				
Familiarisation	(Manufacturers / cost per year)	€ 402,000	10[27]	€ 4,020,000
Preparation of DoC and technical documentation	(Manufacturers / cost per year)	€ 1,206,000	10	€ 12,060,000
Standards purchase	No. of standards	€ 80	30-40	€ 5000[28]
Substantive compliance and Conformity assessment (internal)[29]				**€ 9,000,000**
R&D and Product design	Models	€ 800,000	10[30]	€ 8,000,000

[25] These costs were annualised in order to arrive at comparable annual costs, using a system similar to firms' accounting for depreciation. For some questions, we also asked questions in the SCM questionnaire about how much they spent on testing equipment over a 5 year period, which had to be annualised.

[26] All unit costs are based on the interviews with at least 3 respondents answering each figure.

[27] Turnover is used to upscale the parameter estimates. The average respondent has a market share of about 10%. The same approach was adopted for the DoCs.

[28] Approximately 30-40 standards need to be purchased in order to develop a compliant laptop product. However, once purchased, these standards can then be used across multiple product platforms. We have assumed an average annualised cost of 5000 EUR since larger firms may purchase a group license rather than buy standards individually.

[29] Here, substantive compliance costs are concerned with building in compliance requirements to product design during new product development phase and where necessary, making modifications to products that have already been placed on the market.

30 Based on one respondent and its market share, the total number of models was estimated at 200. The average respondent runs 20 models, so the quantity is 10 (200/20).

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Types of cost	Unit of measurement	Unit cost[26]	Total quantity	Total costs (annualised)
Testing (internal)	Models	€ 5,000	200[31]	€ 1,000,000
Testing equipment[32]				No data
Conformity assessment (external)				**€ 3,000,000**
Consultancy/advisory services (product design)				€ 0
3rd party Conformity Assessment by notified bodies	Models	€ 15,000	200	€ 3,000,000
Total (excluding testing equipment)				**€ 28,080,000**

The total estimated costs of regulatory compliance by the laptops industry are in the order of 28m EUR on an annualised basis. However, it should be noted that there was difficulty in obtaining data from firms on all the variables (for reasons explained in our assessment of the five steps in Section 4 and in some cases, further expanded upon below). For example, there were difficulties in obtaining estimates of BAU and for the purchase of testing and laboratory equipment.

Business as Usual (BAU) costs were not taken into account in the calculations (these are the costs that firms would be undertaking anyway regardless as to whether internal market legislation was in place, for instance product performance testing and safety testing as part of internal quality management procedures). The main problem was the lack of consistency in the estimates provided by firm and the absence of firms being willing to provide quantitative estimates generally in two cases.

Among the two firms that did provide data, there was divergence in interpretation among firms as to whether compliance costs meet the requirements of IM legislation. Firm A estimated that approximately 30% of the time spent by internal staff on regulatory compliance would be necessary anyway as part of the internal planning and quality management procedures necessary to ensure a safe product and to produce documentation

[31] Number of models (see above footnote). The same is done for 3rd parties.

[32] No data was available on the costs of purchasing testing equipment because for commercial sensitivity reasons, the firms concerned were unwilling to share this data.

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about the product and safety elements. Conversely, Firm C commented that *"since all compliance-related activities are ultimately related to IM legislation, there is no element of compliance costs that can be considered as BAU"*.

Some costs are one-off costs, whereas other costs are recurring. Other types of costs are more nuanced, and represent a combination of one-off and recurring costs. Examples of costs that are clearly one-off include the purchase of laboratory and testing equipment, R&D costs, third party conformity assessment costs and the purchase of standards. Other costs are evidently recurrent, such as the recalibration of testing equipment. However, the picture is more nuanced for other types of compliance costs, which are both one-off and recurring. For example, the cost of the preparation of a DoC and technical documentation mainly occurs prior to a product being placed on the market. However, in addition to these one-off costs, there are also recurring costs linked to the need to update and maintain a DoC for 10 years post-placement on the market. In addition, there is a need to update technical documentation, for instance, to reflect new spare parts and components that are introduced as replacements once a product is already on the market. As regards product design, the costs are mainly one-off, but there could also be recurrent costs if regulatory changes are made and modifications to product design are needed once the product is on the market.

With regard to the total estimate of firm size, although the total number of firms in the industry was estimated to be approximately 60, the top 10 firms account for a very high market share, so the calculations have been made based on compliance cost data provided by leading global firms and then extrapolated. It was estimated that compliance with administrative requirements amounts to 57.2% of total costs (14.3% for the familiarisation stage and 42.9% for the preparation of technical documentation associated with the product and the DoC. Another major cost was the substantive compliance costs associated with the R&D and product design phase to ensure that compliance requirements are factored into new product development. These were significant and estimated to be circa 8m EUR per annum (28.5% of the total).

No substantive compliance costs were identified linked to withdrawing laptops from the market and making modifications to products due to changes in regulatory requirements and/ or in technical standards among the firms that participated (although one or two examples of product withdrawals resulting from regulatory requirements were identified through the desk research. The low incidence of product withdrawals and design modifications reflects the fact that leading global; manufacturers are fully aware of regulatory changes well in advance of these being introduced, and factor these into the R&D and design phase. This is made possible due to the fact that there are relatively short development lead times for laptops, so current models on the market do not have to be replaced, since they rapidly become old models and are superseded by new models that are compliant with new regulatory requirements.

A further significant cost was carrying out conformity assessment. Although the SDoC procedure was usually followed by manufacturers, as noted earlier, several interviewees stated that they made use of a combination of in-house laboratory and testing facilities and external conformity assessment services. This depended on the individual Directive concerned. For instance, it was common to outsource at least some aspects of testing for standards relating to the LVD Directive to a third party, since these relate to electrical safety.

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As noted earlier, it was difficult to obtain data on the costs of setting up testing laboratories (one-off costs) and on the recurrent annual costs of recalibration. The reasons for the absence of data were explained earlier and include the commercial sensitivity of the data, the lack of data availability internally within organisations because the information is not shared between different business divisions globally and because testing costs are hidden due to the use of OEM and ODM suppliers.

The costs of internal testing were estimated to be 3.5% and the costs for external testing in the region of 10.7% of the total regulatory costs of compliance. However, the estimates of internal testing costs are probably an under-estimate and reflect the staff time involved in carrying out testing and some laboratory costs. The quantification exercise took into account information concerning the 'Business as Usual' (BAU) scenario, i.e. the estimated percentage of compliance costs linked to IM regulations that related to activities that the firm would undertake anyway irrespective of whether there was Union harmonisation legislation.

6. The benefits of internal market legislation

It is important that the benefits of IM legislation are considered and not only the costs. It is difficult to establish a counterfactual since the laptops industry mainly emerged after the internal market came into being. Nevertheless, those interviewed confirmed that it was preferable to have a single set of internal market legislation across the Union rather than different pieces of national legislation.

Although the administrative costs of complying with IM regulations appear quite high overall, the benefits of IM regulations can help to offset the costs. Firm A and Firm C pointed out that there are benefits for laptop manufacturers in complying with IM regulations through "leverage" on their investment in regulatory compliance in the EU. The manufacturers that took part sell millions of units per year in Europe alone. They are able to leverage and recoup some investment in compliance through tapping into cost synergies achieved by using compliance with IM regulations as the basic building block for meeting compliance requirements across different jurisdictions globally. Test data and the results of conformity assessment procedures and technical documentation can be used, at least in part, even if the precise specifications may differ due to differences in technical standards. This helps manufacturers to offset the costs of regulatory compliance in other jurisdictions globally.

Firm D commented that it made significant investment in being compliant with RoHS in advance of European legislation coming into force. Since the firm was RoHS-compliant, this then allowed the firm to leverage its investment since more than 40 different jurisdictions have subsequently adopted a RoHS-type regulatory regime and changes to the recast RoHS Directive in Europe have subsequently often been made to other regulatory regimes.

Further examples of benefits were identified, such as energy-efficiency savings and environmental benefits from energy-saving requirements, both those common to all electrical appliances (e.g. requirements for stand-by power mode). The new Ecodesign implementing regulation –for computers (desktops & laptops) and computer servers has the potential to bring about cost reductions through energy savings. Although such requirements can be costly for part of the industry [ecodesign typically means redesign for 20% of the existing models] at least during the early stages of implementation, there are potential benefits in terms of strengthened industrial competitiveness through promoting investment in innovation to make products more energy-efficient.

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7. Analysis of simplification options

Gaps or loopholes, inconsistencies or duplication in IM legislation.

Before providing an assessment of possible simplifications, we first summarise the extent to which there were gaps or loopholes, inconsistencies or duplication in IM legislation.

As noted earlier, there are differences in the requirements for the DoC between the R&TTE, LVD, and EMC Directives. The requirement to provide a DoC together with the product under the R&TTE Directive is inconsistent with the requirement under the LVD-D and EMC-D where the DoC does not have to be placed with the product, but must be available on request by an MSA.

This issue is well known to both industry and the Commission. The intention through the NLF (Decision 768/2008) is to use a common template for a DoC in future. This is being implemented through the Alignment Package. However, a final decision has not yet been taken as to whether this requirement under the current R&TTE-D will be dropped when the recast Directive is aligned.

Manufacturers are well aware of minor differences in requirements at least under longstanding core IM directives applicable to laptops (and other electrical products). Such anomalies in information requirements for DoCs between IM Directives) have existed for many years.

However, there can be unintended consequences that may increase industry costs due to legal uncertainty and possible delays in products reaching the market. Manufacturers can face uncertainty since they do not know how familiar MSAs and customs in different Member States are with differences in requirements for DoCs between IM regulations. This can create a situation in which MSAs and / or customs may mistakenly believe there to be administrative non-compliance because the DoC is not together with the product, even if this is not needed because the R&TTE Directive is not applicable to the specific products being transported, or in instances where laptops are being transported and are part of mixed packages. If there is incorrect interpretation of the requirements, even temporary, this imposes costs on industry through time delays in products reaching wholesalers and / or the retail marketplace.

For example, Firm A, which manufacturers laptops, printers and other electronic and IT equipment, noted that there have been instances when inconsistent approaches have been applied by MSAs and customs authorities. The absence of a DoC together with some products has been questioned, and this has held up shipments or product containers.

An interviewee commented that "*Retail packaging is usually specific to a product, whereas wholesale packaging when shipping products into Europe may contain a mix of different products batched together in boxes. Some of these products may fall under the scope of the R&TTE Directive, while others do not. This can cause uncertainty for industry as to what labelling should be placed on packaging and which documentation should be included to satisfy the authorities*".

Apart from this issue, the desk research and interviews did not identify any major gaps or loopholes, inconsistencies or duplication in IM legislation affecting laptops.

Scope for regulatory and administrative simplification

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Through the discussions, manufacturers were asked about the extent to which there was scope for regulatory and administrative simplification within IM regulations. A review of feedback in respect of possible simplifications is first provided, followed by an assessment of the potential benefits of these simplifications and the possible cost savings.

Although there is a requirement for the DoC to be placed together with the product under the R&TTE-D, an agreement has been reached between industry and TCAM[33] so that laptop manufacturers are only required to provide a **short-form version of the DoC** together with the product. The full DoC is then made available electronically. This not only saves printing costs but is a more efficient way of organising the review and updating of DoCs.

Global laptop manufacturers were in favour of the **provision of as much regulatory compliance information online as possible** to reduce administrative costs. They already provide a lot of regulatory information online through dedicated compliance websites listing all the applicable legislation and technical standards applied to the product. Such websites often also provide access to more detailed compliance information not only the full DoC for each product model. Examples of such websites are provided as a footnote[34].

For instance, Firm A provides a searchable database of the DoCs for all its models online but also provides for the German market a statement of voluntary conformity assessment with the Geprüfte Sicherheit ("Tested Safety") or GS mark, a voluntary certification mark for technical equipment. Firm B provides various compliance documents online such as the DoC, technical information on product safety, evidence of compliance with the EMC and environmental safety sheets.

The provision of such information online is designed to ensure that Market Surveillance Authorities (MSAs) are able to obtain further regulatory information about product models. It was argued that electronic labelling or e-labelling [35] should be adopted more widely in future by manufacturers so as to strengthen the efficiency and effectiveness of the EU's Market Surveillance System. Having access to this information online would help to:

- **Reduce paperwork costs -** printing DoCs and user instructions.
- **Reduce inefficiency in requests by MSAs for compliance information from economic operators (general) –** the NLF has led to a shift in responsibility away from manufacturers alone through the setting of common definitions and obligations for economic operators (including importers and distributors). However, there is a need to ensure that information is requested in the first instance directly from the manufacturer.

[33] Telecommunications Conformity Assessment and Market Surveillance Committee

[34] Regulatory compliance websites of leading laptop manufacturers – examples are: the HP Technical Regulations EuroBase - http://www8.hp.com/uk/en/certifications/technical/regulations-certificates.html, http://www.dell.com/content/topics/global.aspx/about_dell/values/regulatory_compliance/dec_conform?c=us&cs=&l=en&s=corp&~ck=anavml and http://www.lenovo.com/social_responsibility/us/en/ec_doc_notebooks.html

[35] There is already a precedent for electronic labelling in order to provide regulatory compliance information, since this approach has been adopted through EU Commission Regulation 207/2012 on the electronic labelling of medical devices. The provision of instructions for use in electronic form for professional users is designed to help to reduce the environmental burden and to improve competitiveness by reducing costs whilst at the same time maintaining safety.

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It was viewed as inefficient for MSAs to approach importers for technical information about the product that only the manufacturer has access to. An email address or weblink direct to the manufacturer would eliminate unnecessary contact with other economic operators.

- **Reduce inefficiency in requests by MSAs for compliance information from manufacturers -** there is a risk that MSAs turn to branch offices in Member State to request basic compliance information, where there may only be a sales and marketing function in the given Member State. However, this fails to appreciate how global firms operate or manage compliance[36]. When contacting global firms, MSAs need a mechanism for requesting information directly from the compliance department. This would save resources both for MSAs and manufacturers. Ensuring that manufacturers provide direct email contact to their compliance department is essential.
- **Provide as much compliance information online as possible** - information should be more easily accessible to MSAs and a cultural change is needed in that MSAs should be less insistent on receiving information in paper copy. This would strengthen efficiency by avoiding unnecessary requests for basic compliance information such as the full versions of DoCs by MSAs if the DoC for each model can be downloaded instead through a dedicated website for regulatory compliance or a compliance section of a corporate website.

Similarly, in regard to the provision of **technical documentation to MSAs upon request,** there could be efficiency savings (reduced printing costs, less time to respond to requests) if this were as a rule to be done electronically. Currently, some MSAs may accept the provision of such technical information online but others prefer to receive information in paper form. It would be more efficient if manufacturers were able to provide information through **secure data transmission** when requested to provide part or all of a technical file.

The requirement to provide **instructions for use** in paper copy was regarded as costly. Instructions for use are already available in electronic form in most instances. The possibility of only having these available electronically in future was raised. This has already been 'piloted' for professional users under the Medical Devices Regulation. Arguments in favour are that most consumers have access to broadband internet, and this could potentially lead to cost reductions and environmental benefits. However, even if industry supports this idea, there could be concerns that providing use instructions information online only could undermine consumer safety for those affected by the "digital divide". Although the vast majority of consumers have access to high-speed internet, not all do so. Digitally excluded groups of consumers could not do without a paper copy of the instructions.

The most realistic possible simplifications identified by laptops manufacturers, and the potential benefits are summarised in the following table:

Table 8: Proposed simplification measures, benefits and possible savings - laptops

Proposed simplification	Explanation	Benefits
Removal of	Currently, under the R&TTE-D,	Less marking requirements on

[36] Global firms will tend to centralise their compliance function through their European HQ.

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Proposed simplification	Explanation	Benefits
unnecessary marking requirements on the product itself[37], such as the Alert Sign. 	laptops with Wifi Radio Module Class 1 and 2 must include an alert mark next to the CE mark. The Alert symbol is regarded as superfluous by industry. CE marking covers all aspects of product safety for consumers and the information is relevant to MSAs and Member State authorities responsible for radio frequency. It is not useful for consumers.	product Reduced cost of product marking (less familiarisation costs, printing the mark itself).
Eliminate inconsistencies between IM legislation in requirements for DoC. No longer require DoC to be placed with the product (R&TTE-D only).	There are currently differences in administrative requirements for the DoC between the R&TTE-D, EMC-D and the LVD-D respectively. These are already being tackled through the Alignment Package.	Reduced costs of a single common template for a DoC (rather than multiple templates) Reduced uncertainty for manufacturers (eliminate risk of delays to product shipments)[38].
E-labelling and wider provision of compliance information electronically. Basic information – full DoC, technical	More regulatory compliance information could be made available by manufacturers online specific to particular models. The market surveillance system needs to be overhauled so that	<u>For manufacturers</u> Reduction in printing costs (e.g. DoCs) Reduction in human resource costs of responding to requests from MSAs for info.

[37] The exclamation is known as the "alert symbol" is found on any device that includes a Class 1 or 2 Wifi module and supplements other CE markings. The reason why the mark has been introduced is because Member States have restrictions on various frequency bands—for example, a wireless device operated outdoors in France can only use frequencies between 2.4 GHz and 2.454 GHz. When a device can follow all these restrictions, it is said to work on "harmonized frequency bands" and is called a "Class I device". Class II devices must however carry the extra alert symbol so that users know the phone might try and operate on frequency bands that are not allowed to be used in certain countries. However, consumers are not familiar with the alert sign and this information could be provided online instead on the regulatory compliance section of websites directly to MSAs.

[38] 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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Proposed simplification	Explanation	Benefits
standards that have been applied, safety data sheets could be provided online. Technical documentation could be provided through secure data transfer, given commercial sensitivities.	manufacturers are to provide most regulatory compliance information online, rather than in paper copy.	For MSAs Easier and more efficient access to regulatory compliance information specific to each model. Resources freed up to carry out more technical checks.

Although difficult to quantify, based on the feedback received about the order of magnitude of efficiency savings, possible reductions in the costs of compliance for the laptops industry if these savings were to be implemented is now provided.

Table 9 – Estimates of possible reductions in the costs of compliance - laptops

	Unit of measurement	Reduction per unit	Total quantity	Total cost reduction
Removal of unnecessary marking requirements on the product itself , such as the Alert Sign.[39]	Market share	€ 32.160	10	€ 321.600
Eliminate inconsistencies between IM legislation in requirements for DoC. No longer require DoC to be placed with the product (R&TTE-D only).[40]	Market share	€ 241.200	10	€ 2.412.000
Total				**€ 2.733.600**

[39] Less marking requirements on product. Reduced cost of product marking (less familiarisation costs, printing the mark itself). Assumed: 2% reduction familiarisation, 2% reduction preparation etc..

[40] Reduced costs of a single common template for a DoC (rather than multiple templates). Assumed: 20% reduction DoC. Reduced uncertainty for manufacturers (eliminate risk of delays to product shipments) is not quantified..

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The order of magnitude of cost savings from simplification measures is relatively modest compared with the total estimated compliance costs. This partly reflects the fact that there are not any major problems with current legislation, but rather a concern with eliminating minor inconsistencies in administrative requirements.

However, there could potentially be **more promising cost savings for industry from a gradual transition towards providing more compliance information online.** However, these savings are very difficult to quantify. Reduced printing costs are only a small element of the potential cost savings since the transition to electronic compliance is more about improving organisational efficiency for manufacturers in updating compliance information and facilitating access to up to date compliance information for MSAs. There would be savings from being able to contact the right department directly through email contact, with efficiency savings for both the manufacturer and the MSA.

(ii) Measures to improve the effectiveness and efficiency of the regulatory landscape and help to remove uncertainty.

In addition to possible simplification measures, manufacturers noted that the costs of compliance could in some cases be kept in check if the Commission were to take steps to ensure that current ambiguities in the IM regulatory framework are eliminated, since this would remove legal uncertainties with regard to what the requirements are. In particular, legal clarity should be provided that DoCs do not need to be translated into all EU languages. This would help to avoid the risk that over time, MSAs start to demand the translation of DoCs into all EU languages as a compliance requirement, which would result in significant additional costs.

8. Overall Conclusions

- Laptop manufacturers appreciate the flexibility provided by IM legislation and the fact that there are alternative routes to achieving regulatory compliance (following the R&TTE Directive alone vs. a modular approach).
- The compliance costs for manufacturers that follow several individual pieces of IM legislation under the modular approach are broadly similar to the costs of following a single Directive (R&TTE-D), since similar product safety tests are required under the R&TTE-D (e.g. to ensure electrical safety, electro-magnetic compatibility).
- A modular approach can however be advantageous in allowing compliance responsibilities to be divided up between different manufacturers specific to the part of the laptop that they produce and the corresponding applicable module, while the manufacturer retains ultimate responsibility for compliance of the final whole product.
- There were difficulties in obtaining data on substantive compliance costs during the R&D and product design phase, especially for testing costs. This was due to commercial sensitivity reasons in some cases, and the extensive use of ODM and OEM suppliers by most laptop manufacturers in others.
- Qualitative feedback suggests that substantive costs are lower for laptops than for certain other types of industrial products (e.g. air conditioners) when regulatory changes are introduced because the lifecycle of a laptop model is shorter. Therefore, new requirements can be built into the development and customisation of new models, rather

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than having to adapt or replace components or to adapt product platforms used as the basic building block for developing new products variants.

- There is strong support among manufacturers for the increased provision of compliance information to Market Surveillance Authorities (MSAs) and users/ consumers electronically and for e-labelling. This may offer scope for efficiency savings and a reduction in the administrative costs of updating compliance information.
- There are concerns that since the adoption of the NLF, there is legal uncertainty for manufacturers resulting from the ambiguous wording in Decision 768/2008 as to the translation requirements for DoCs.
- Since the DoC is primarily intended for MSAs rather than for users/ consumers, if this requirement were to be interpreted in a stricter way in future, then there is a risk that this would result in considerable additional administrative costs. The current practise is that the translation of DoCs is only available upon request by MSAs.
- Divergent requirements for DoCs between IM regulations can cause uncertainty when manufacturers are shipping mixed products in large containers, some of which require a DoC together with the product under the R&TTE-D, while other products do not because they do not contain a radio part. There is a risk that different administrative requirements for different types of products may confuse customs authorities and lead to unnecessary and costly delays.

9. Sources of information

References

- Eurostat Structural Business Statistics Database and PRODCOM
- Data from the 2011 Euromonitor report for computers.
- Lot 3 Personal Computers (desktops and laptops) and Computer Monitors Final Report (Task 1-8)
- Guidance documents on the LVD and EMC Directives

Interviews

- Interviews with 4 global manufacturers, 3 of laptops and one of computer chips
- Several interviews with the European industry association, Digital Europe.

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Annex 1 –Mapping of IM Legislation (Laptops)

Table 10: Mapping of applicable IM legislation and administrative requirements for manufacturers

Name of legislation	*Main issues addressed (safety, environment, other)*	*Main administrative requirements for manufacturers*	*Relevant standards (note: illustrative only)*
Core legislation			
Low Voltage Directive (LVD) - 2006/95/EC	Health & Safety (electrical)	Supplier's Declaration of Conformity (SDoC) Testing according to relevant harmonised standards or alternative means of achieving presumption of conformity Preparation of technical file Declaration of conformity and CE marking Installation instructions and manual for final consumer (with translations)	10. EN 60950-1:2006 Information technology equipment - Safety -- Part 1: General requirements 11.
Electromagnetic Compatibility Directive (EMC) 2004/108/EC	Electromagnetic compatibility	Testing according to relevant harmonised standards or alternative means of presumption of conformity Development of technical file Declaration of conformity and CE marking	Electrical safety standards IEC 60950 (IT equipment safety), EN 60950 (and American standard UL 60950)[41]. EN 55024:2010 IT equipment (Immunity characteristics) Limits and methods of measurement CISPR 24:2010 EN 61000-3-2:2006 - Part 3-2: Limits for harmonic current emissions (equipment input current <= 16 A per phase) EN 55022, (Radiated emissions), IEC 61000-2-2 and IEC 61000- 3-3, EN 61000-3-3:2008 - limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with

[41] These standards are similar and can be considered broadly harmonised.

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			rated current <= 16 A per phase and not subject to conditional connection IEC 61000-3-3:2008[42].
Radio equipment and Telecommunications Terminal Equipment R&TTE Directive (1999/5/EC)	Radio bandwidth frequency	Manufacturers must carry out testing to ensure that R&TTE devices do not cause any harm to PST Networks and do not violate power and frequency spectrum allocations on a country by country basis. Declaration of conformity and CE marking	The R&TTE is applicable to laptops that include radio devices e.g. modems and/or wireless communications interfaces (e.g. WiFi, Bluetooth). 12. EN 55024:2010 Information technology equipment - Immunity characteristics - Limits and methods of measurement 13. CISPR 24:2010 14. EN 55022:2010 Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement CISPR 22:2008 (Modified)
RoHS Directive (2011/65/EC)	Use of hazardous chemicals	Collect compliance statement from suppliers (material declarations) Technical file with supplier declarations and own analysis tests Declaration of conformity to be kept for 10 years	Although the 2002 RoHS Directive did not require CE marking, the new 2011 Directive does so.
Ecodesign for Energy-related Products Directive (ErP) 2009/125/EC.	Ecodesign requirements		ErP establishes a framework for setting Ecodesign requirements for energy-related products (ErPs). Through product-specific Implementing Measures, mandatory, Ecodesign requirements are set. Two implementing measures are currently applicable under the ErP. • External power supplies that are shipped with the notebook (Regulation 278/2009/EC with regard to ecodesign requirements for no-load condition electric

[42] When designing a computer or laptop, EMC technical standards influence the design phase because they set the parameters as to what is possible or not.

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			power consumption and average active efficiency of external power supplies) • General requirement applicable to electrical electronic office equipment on standby and off-mode power consumption (Regulation 1275/2008/EC with regard to Ecodesign requirements for standby and off-mode electric power consumption of electrical and electronic household office equipment. • The above are applicable to general electrical products. However, for laptops these implementing regulations will be superseded by Regulation 617/2013 (Ecodesign requirements for computers and computer servers) which will be mandatory from 01.07.2014. •
Wider applicable legislation where CE marking does not apply			
REACH Regulation (EC 1907/2006)	Use of chemicals	REACH compliance statement from suppliers	15.
Packaging and packaging waste (2004/12/EC)	Packaging	Declaration of Conformity	16.

Annex 2 - Voluntary environmental labels

In addition to Union harmonisation legislation, there are a number of voluntary environmental labels at European and national levels relevant to laptops such as the EU Ecolabel for portable computers[43]. Examples of the requirements in order to qualify and be able to display energy efficiency markings

[43] The Ecolabel for portable computers can be awarded for desktops or laptops with a system unit, display and keyboard combined in a single case which can be used with an internal battery. This product group also covers devices equipped with touch screen keyboard.

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on products are that “Power management settings should be 10 minutes to screen off (display sleep); 30 minutes to computer sleep”.

There are also national voluntary labelling schemes within the EU such as Blue Angel (Der Blaue Engel), a German certification system for environmentally-friendly products and services and Nordic Swan, the official sustainability Ecolabel for the Nordic countries. There are also international voluntary energy-efficiency labels such as Energy Star (US), which is for office equipment also applied in the EU. Other schemes include TCO Certified, an international sustainability certificate for IT products which incorporates a range of criteria to ensure that the manufacturing, use and recycling of IT products is carried out in an environmentally-friendly, socially responsible and sustainable manner. Such labelling initiatives have strong potential to promote resource efficiency, and are often adhered to by major manufacturers, even if there is no regulatory requirement to do so. There are links here with IM regulations that require manufacturers to assess the energy efficiency of products, notably the Ecodesign implementing regulation for computers and computer servers, for which the setting of the requirements took into account the work done for the development of Energy Star.

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CASE STUDY 3 – DOMESTIC REFRIGERATORS AND FREEZERS

1. Introduction – objectives of the study

The product groups examined in this case study are refrigerators and freezers for domestic use, also known as cold appliances. The aim is to analyse the applicable IM legislation, assess the costs associated with the implementation of the applicable IM legislation, identify areas of overlaps and conflicts between the different parts of the legislation that may lead to problems and costs to industry and identify and assess the benefits of possible simplifications. The rationale for the selection of these product groups was that:

- Refrigerators and freezers are covered by a large number of IM Directives and Regulations, 8 in total;
- The sector is dominated by a few (around 20) large manufacturers; and
- The conclusions drawn from an assessment of these specific products could be used to draw conclusions on the compliance costs for a broader category of electric domestic appliances since most of the products within this group are covered by the same pieces of legislation.

The case study is based on desk research, the interview with the EU industry association representing manufacturers of refrigerators and freezers (CECED) and three detailed interviews with manufacturers of domestic appliances, one medium size firm (350 employees and total turnover of 150 million) and two large multinationals selling over 2million units and occupying more than 2000 employees. The final text of the analysis was reviewed by CECED that provided additional comments. However, this should not be considered as an endorsement of the conclusions from the side of CECED.

2. Product definition and description of the sector

Product definition (products included/excluded)

The product group examined in this case study are refrigerators and freezers for domestic use, also known as cold appliances. According to standard EN 153 they are “electric mains-operating refrigerating appliances”. According to standard EN 15502:2006 refrigerating appliances are “factory-assembled insulated cabinets with one or more comportments and of suitable volume and equipment for household use, cooled by natural conversion or a frost-free system whereby the cooling is obtained by one or more energy consuming means”. There are two main type of refrigerating appliances, compression type and absorption type. The main appliance categories are:

- Simple refrigerators (no freezer compartment);
- Refrigerator-freezer (with at least one refrigerator and one freezer compartment);
- Food freezers; and
- Frozen-food storage cabinets

Data on the market size of the specific product group are derived mainly from Eurostat PRODCOM database and are complemented by market studies. In the PRODCOM database the specific products are covered under the code 27.51.11 (Refrigerators and freezers of household type) with the following subcategories:

- 27511110 - Combined refrigerators-freezers, with separate external doors

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- 27511133 - Household-type refrigerators (including compression-type, electrical absorption-type)
- 27511135 - Compression-type built-in refrigerators
- 27511150 - Chest freezers of a capacity <= 800 litres
- 27511170 - Upright freezers of a capacity <= 900 litres

According to PRODCOM database data for 2011 the total market for refrigerators was close to 24.6 million units with a value of the market of EUR 4.8 billion sold/annum. Other data sources suggest a somewhat smaller market size of 17-20 million[44] cold appliances sold on an annual basis. Refrigerators represent around 42% of the market, combined units 38% and freezers 20%.

The majority of domestic refrigerators are electric powered. However, gas refrigerators and freezers (of the absorption type) are also available used either as mobile (e.g. for camping, recreation vehicles and boats) or fixed at home. Data on the specific market segment are not available since PRODCOM codes do not differentiate depending on the source of power. According to the Evaluation of the gas appliances Directive[45] there are a few large firms in Europe producing gas refrigerator. The 2005 preparatory study for the development of Ecodesign implementing measures for domestic refrigerators and freezers[46] refers to a total of 0.7-0.8 million of absorption refrigerators sold annually in Europe, 0.3 million of which were gas refrigerators. A according to the competitiveness report of the gas appliances sector they do not have a noteworthy role in the total market.[47]

Available PRODCOM data also indicate that the total volume of production within Europe is around 15 million units with a value of €3.8 billion. Of these, 3.4 million units are exported (value of €0.9 billion) while there are also around 12.7 million units imported from third countries (estimated value of €1.9 billion). Thus, according to the PRODCOM, imported refrigerators represent around 50% of the market of refrigerators and freezers. However, it should be noted that a significant part of leading refrigerators and freezers brand are designed in Europe but manufactured outside Europe and subsequently imported.

Industry structure

Concerning the structure of the industry, Eurostat Structural Business Statistics are not particularly helpful. The relevant NACE statistical code covers the whole range of domestic appliances (27.51 - Manufacture of domestic appliances[48]) and as a result they do not allow developing an accurate picture of the sector (e.g. number of firms, turnover, employment). Nonetheless, there were 2,200 enterprises[49] active in the manufacturing of electric domestic appliances (annual turnover of 41 billion and close to 195 thousand people employed in 2011), 31,000 wholesalers of electric

[44] Topten (2012), Cold appliances: recommendations for policy design
May 2012, http://www.topten.eu/uploads/File/Recommendations_Cold_May%202012.pdf
[45] RPA (2011), Ex-Post Evaluation of the Gas Appliances Directive- Final report
[46] ISIS (2007), Preparatory studies for Ecodesign Requirements of EuPs – Lot 13: Domestic refrigerators and freezers – Final report
[47] Ecorys (2009), Study on the Competitiveness of the EU Gas Appliances Sector - Within the Framework Contract of Sectoral Competitiveness Studies – ENTR/06/054 - Final Report, http://ec.europa.eu/enterprise/sectors/pressure-and-gas/files/study_competitiveness_eu_gas_appliances_final_en.pdf
48 Besides refrigerators and freezers this category includes a range of appliances including: dishwashers and washing machines, vacuum cleaners, hair dryers, radiators and heaters, microwave ovens, electric ovens, grills and toasters, coffee makers, electric cookers, food grinders and mixers, electric blankets.
[49] The data from Eurostat refer to individual enterprise units, many of which are subsidiaries of the few large manufacturers that dominate the refrigerators market and are present in most EU national markets.

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appliances (€159 billion turnover and 267,000 people employed). Some guidance on the share of the refrigerators and freezers sub-sector may be provided by PRODCOM data according to which refrigerators and freezers represented around 15% in terms of value sold of all domestic appliances[50]. This would imply a total number of 29,000 employees in the manufacturing of refrigerators and freezers.

Table 1 – Data on market size and industry structure for cold appliances

Parameter	Data
EU Market size	PRODCOM (2011): € 4.8 billion (24.6 million units) Market reports: 17-20 million (2010)
Production volume/value in Europe	PRODCOM (2011): € 4.8 billion (15 million units)
Imports	PRODCOM (2011): €1.9 billion (12.7 million units)
Exports	PRODCOM (2011): €0.9 billion (3.4 million units)
Number of enterprises (2010)	Market reports: 10 large multinational firms with multiple brands cover around 85% of EU market sales Eurostat: Manufacturing (NACE 27.51): 2,212 (all electric domestic appliances); Wholesale (NACE 46.43): 30,900; Retail (47.54): 54,500
Number of employees (2010)	NACE 27.51: 194,200 (all electric domestic appliances) Wholesale (NACE 46.43): 267,000 Retail (47.54): 269,000

Source: Eurostat

According to data from Euromonitor market research for 2012, 10 large size companies – most of them present in the market with multiple brands – represent more than 85% of the market in Western and Eastern Europe. At the product/brand-name level the market is rather fragmented since only 1%[51] of the models are sold under the same name in all EU markets.

Additional information for the number of firms can be derived from the ORBIS database of Bureau Van Dijk. From the total of 2,568 enterprises active in the 27.51 a search within the economic activity description field using the keywords “refrigerators” OR “freezers” produced 101 records. The list included all major producers as well as smaller manufacturers some of which are active in the commercial refrigerators and freezers market. A market share list from Euromonitor market research database suggested that 22 manufacturers capture 98% of the market in Western Europe and 90% in Eastern Europe (including non-EU countries). Thus, we consider that a total number of 100 firms provide an upper limit in terms of firms affected by the relevant IM legislation for refrigerators and freezers.

3. Analysis of applicable IM legislation and standards

On the basis of desk research and the input from firm interviews we have identified the list of applicable pieces of Internal Market legislation, the basic administrative requirements and the relevant harmonised standards that can be used by manufacturers to meet the essential requirements. According to the input from industry 95-99% of manufacturers do make use of the standards in the case of refrigerators, and more general for domestic appliances.

[50] All products for which the first 4 digits of the PRODCOM code is 2751.

[51] Electra report - Twenty solutions for growth and investment to 2020 and beyond, http://ec.europa.eu/enterprise/sectors/electrical/files/electrareport_en.pdf

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Refrigerators are covered by 9 different pieces of IM legislation covering a range of aspects:

- **Health and safety** (Low Voltage Directive, Regulation on materials and articles that come in contact with food, RoHD Directive on hazardous chemicals,). In the case of gas refrigerators and freezers the Gas appliances Directive is applicable. Furthermore, the Pressure Equipment Directive (97/23/EC) applies for those refrigerators and freezers that include piping and other pressure vessels (compressors, containers of refrigerants, heat exchangers) with internal pressure above 0,5 bar.
- The General product safety Directive is also applicable but does not introduce additional requirements to refrigerators since these are covered by the other more specific pieces. It does introduce however other obligations, mainly of administrative nature;
- **Electromagnetic compatibility** (EMC Directive); and
- **Energy consumption and noise** (Eco-design and Energy labelling Directives and the respective implementing measures).

In addition, certain requirements arise from the F-GAS Directive concerning the use of fluorinated gases used in refrigerators, as downstream users of chemicals included in articles under REACH Regulation and also in relation to the use of packaging (Packaging Directive). We should also note that the WEEE 2002/96/EC Directive is also applicable to refrigerators - and is identified as rather burdensome for manufacturers - but it is a piece of legislation that is outside the scope of this study.

Table 2 – Summary of IM legislation covering refrigerators and freezers and the relevant standards

Name of legislation	Main issue addressed	Requirements for economic operators	Relevant standards
LVD 2006/95/EC	Health & Safety (electrical, flammable refrigerants)	Testing according to relevant standards or alternative solutions Development of technical file Declaration of conformity and CE marking Include information ensuring that the product can be used safely and in applications for which it was made	IEC/EN 60335-1 IEC/EN 60335–2-24
Directive 2009/142/EC on Appliances Burning Gaseous Fuels (GAD)	Health and safety of gas appliances	Testing according to relevant standards or alternative solutions Development of design documentation Declaration of conformity and CE marking	EN 732
General product safety Directive	Health & Safety	Provide identification of the product by a product reference Carry out sample testing of products, keep a register of complaints and keeping distributors informed of such monitoring (voluntary)	

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Name of legislation	Main issue addressed	Requirements for economic operators	Relevant standards
		Inform authorities of dangerous products and actions taken to prevent risk Co-operate with the authorities upon request	
Pressure equipment Directive	Health & Safety	Testing according to relevant standards or alternative solutions Development of design documentation Declaration of conformity and CE marking	EN 378-2:2008+A2:2012[52] EN 12178:2003[53] EN 12263:1998[54] EN 12284:2003[55] EN 14276-1:2006+A1:2011[56] EN 14276-2:2007+A1:2011[57]
Regulation on materials and articles that come in contact with foodstuff 1935/2004 and Regulation 10/2011 on plastic materials and articles intended to come into contact with food	Health & Safety	Chemical analysis and migration tests of the materials used (in cabinet, door, shelves and accessories) Establish information collection system providing information on the source of materials (traceability) Declaration of compliance	
EMC 2004/108/EC	Electromagnetic compatibility	Testing according to standards Development of technical file Declaration of conformity and CE marking	EN 55014-1 EN 55014-2 EN 61000
Eco-Design Directive 2009/125/EC	Noise	Testing Declaration of Conformity and CE marking	IEC 60704-1 IEC 60704-2-14 IEC 60704-3

[52] Refrigerating systems and heat pumps - Safety and environmental requirements - Part 2: Design, construction, testing, marking and documentation
[53] Refrigerating systems and heat pumps - Liquid level indicating devices - Requirements, testing and marking
[54] Refrigerating systems and heat pumps - Safety switching devices for limiting the pressure - Requirements and tests
[55] Refrigerating systems and heat pumps - Valves - Requirements, testing and marking
[56] Pressure equipment for refrigerating systems and heat pumps - Part 1: Vessels - General requirements
[57] Pressure equipment for refrigerating systems and heat pumps - Part 2: Piping - General requirements

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Name of legislation	Main issue addressed	Requirements for economic operators	Relevant standards
(Implementing Regulation 643/2009 related to domestic cold appliances)		Information in instruction manual for minimising noise	ISO 8960
	Energy consumption/ efficiency	Testing Technical file with results of studies and explanations of design choices made and the management system Declaration of Conformity to be kept for 10 years and CE marking Information in instruction manual for minimising energy-use	EN 62301 - IEC 60301 EN 153/ EN ISO 15502
Energy Label Directive 2010/30/EU and implementing Regulation 1060/2010	Energy consumption/ efficiency	Testing according to harmonised standard Technical file with results of studies and explanations of design choices made and the management system Development of product fiche Placing of energy label	IS015502
F-GAS on fluorinated gases 842/2006	Climate change	Information on the gas contained in the instruction manual and relevant label on product	
RoHS (2011/65/EC)	Use of hazardous chemicals	Collect compliance statement from suppliers (material declarations) Technical file with supplier declarations and own analysis tests Declaration of conformity to be kept for 10 years	
REACH	Use of chemicals	Collect statement from suppliers stating that he is compliance with requirements REACH compliance statement	
Packaging and packaging waste (2004/12/EC)	Packaging	Declaration of Conformity	Standard EN 13427

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The analysis and the discussions with manufacturers did not indicate the presence of conflicting requirements that could be seen as creating either or uncertainty or problematic trade-offs in relation to the design of the product.

Turning to the administrative requirements, a number of applicable pieces of IM legislation (LVD, EMC, Eco-design and Energy-Label, Regulation concerning articles in contact with foodstuff, RoHS) require the development of a technical files following testing, which in most cases is done according to the specific technical standard. The discussions did not point to any conflicts or overlapping activities in relation to the development of these technical files. The main concern is the size of these files and the work required to develop and update them. It is also often difficult to keep all the required information and to get from suppliers the complete technical files. Suppliers sometimes send only parts of the technical file (e.g. the test reports, energy consumption reports) or do not provide technical information at all (only the DoC) due to concerns about confidentiality and this means that certain testing needs to be redone.

The General Product Safety Directive also introduces certain requirements including the mandatory product identification or the voluntary conduct of tests of marketed products and the keeping of a register of complaints.

The review of the requirements of the Declaration of Conformity indicate minor differences in terms of the terminology used (e.g. under the LVD there is a reference to the "description of the product" whereas under the EMC, the "identification of the apparatus") or similar but the same requirements in terms of the information to be provided (e.g. under LVD it is required to provide the date when the CE mark was affixed to the product whereas under the EMC, the date that the declaration of conformity was signed). However, the discussions so far did not suggest any conflicts or problems for the manufacturers.

4. Analysis of costs of compliance with IM legislation

The information presented in this section is based on the in-depth interviews with 3 manufactures, one small and two large size firms[58].

Table 3 - Basic information on the firms interviewed

Firm	Firm size	Annual sales from product in the EU	Main markets
A	Small (ca. 350 employees)	Ca. 350 thousand units	Ca. 100% of sales in the EU
B	Large (>1000 employees)	2 million units	Ca. 100% of sales in the EU
C	Large (>4000 employees)	1.8 million units	80% of sales in the EU

On the basis of the discussion with firms the process followed by manufacturers of refrigerators to ensure compliance with the IM legislation includes:

[58] It has not been possible to collect data from a manufacturer of gas refrigerators. However, some data on costs of the gas appliances were available in the evaluation of the Gas appliance Directive and are included in the relevant sections of the report.

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- familiarisation with the applicable IM legislation and the respective requirements, identification and purchase of relevant standards and in some cases other preparatory actions in training of staff.
- introduction of changes to the product design and the production process to ensure compliance with the requirements
- conformity assessment procedures including the relevant testing and the development of the technical file, the use of notified bodies for certification if/when required, preparation of declaration of conformity (DoC), CE marking and placing in the market
- other activities in response to requests of the market surveillance activities

Preparatory actions: Familiarisation with relevant legislation and purchase of standards

A common practice among most economic operators (not only manufacturers but also distributors) is to develop a database where all applicable legislation is indicated, the relevant harmonised standards are listed along with links to the technical file which demonstrates how the essential requirements are met (see below). The databases are continuously updated to reflect changes in the legislation, to standards or any information related to the technical files. In the case of both small firm A and large C around 1 FTE is allocated solely to the management and update of the database which covers all domestic appliances products produced by the firm. Additional staff working in product development and testing makes use of the database and contribute to maintaining and storing information in the database.

Sophisticated relational databases are also used among larger size companies[59] in order to manage the complexity of keeping track with IM legislation, standards and amendments, but equally ensuring that relevant links are kept under each product group to technical documentation required by the firm itself for monitoring regulatory compliance, risk management and quality assurance purposes.

The majority of manufacturers in the sector rely on the use of European harmonised standards in order to meet the essential requirements. In the case of refrigerators the number of mandatory harmonised standards is around 20 but additional standards (e.g. related to quality management) are also often used by firms. While there is no fixed period for revisions of those standards, their average life span is around 6-8 years. Data from two firms indicate that the average annual expenditure for purchase and/or update of technical standards is usually in the range of €700-1,000.

Compliance with the applicable IM legislation

Ensuring compliance with the applicable IM legislation often requires changes to existing product design or new product development. Furthermore, the introduction of new products requires product design work and testing to ensure that the new products are in compliance with requirements.

The small size firm A indicated that in total around 7-8 engineers work full time in product design and quality for all products in the production line, around 10% of which focusing on refrigerators (0.8 FTE). However, since Firm A outsources most of the manufacturing to OEM suppliers in third countries, suppliers absorb most of the compliance costs in their own design process prior to production. Nonetheless, around 0.5-1 FTE is allocated to the testing of all products which includes testing according to harmonised standards and also reliability checks on a periodical basis. Tests for the EMC and LVD Directives take place in the firm's premises while other tests are conducted

[59] In 2012, the firm interviewed had a turnover of EUR 150 million and 350 employees. Around 10% of the turnover came for the sales of refrigerators. The firm is a subsidiary of a larger enterprise

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outside. It was estimated that the total annual costs for testing and certification for all products produced account to €200k/year including the expenditure for testing equipment with costs for refrigerators around €20-30K for the 20-30 models of refrigerators that are placed in the market on an annual basis (around €1k/model).

For large firms B and C, 5% of the total number of employees in the specific product line is working on product development activities, around 100 for firm B and close to 300 for Firm C. For the development of a new product Firm B usually spends 1-1.5 year (i.e. 100-150 FTE), 80-90% of which is allocated to the product development and product quality testing. Firm C indicated that a typical product development project - leading to basic model with multiple variants – has duration of 3 years and a budget of up to €100 million. For the large size firm B, testing for product quality and internal market legislation are rather closely linked and it was not possible to get specific estimates of testing costs.

Thus, some of the above costs are not directly linked to IM legislation and firms select to incur as part of their own product quality strategy. However, it was not possible to get estimates of the shares of costs that should be linked to IM legislation. For Firm C more than 60% of the total costs are linked with product design activities, around 50% of which (€30 million) is directly linked to compliance with Internal market legal requirements.

Among the different tests, the firms made reference to those related to RoHS which require an examination of the substances in the materials used for fridge appliances. Firms B and C stated that the most costly tests linked to the IM legislation are those related to the Ecodesign Directive for energy efficiency and noise. A typical noise chamber costs around €1 million while for the costs of equipment for energy efficiency testing for the Ecodesign Directive – which is used for a range of products – are around €100 k. Of course, these are generally one-off investments on equipment that may last for more than 5 or 10 years. The tests for EMC and LVD Directives were also considered as costly due to equipment costs but no specific figures were made available. According to Firm B a rather problematic point appears to be the tests concerning the Regulation on the materials and articles the come in contact with foodstuff. The current provisions of the legislation are considered as rather unclear (making reference to materials that "may" come in contact with foodstuff) and often lead firms to perform a broader range of tests than what could be the case if the provisions were more specific.

Conformity assessment procedures

The last part of the process includes the preparation of the technical file, the inspection of the notified bodies and certification, preparation of the DoC and the required information manual and the placing of the CE marking.

The results of the necessary tests is also brought together in a technical file and the remaining documentation, parts of which also need to be translated to English. According to the IM legislation this information needs to be stored for at least 10 years and updated whenever there are changes. Significant time is often dedicated for the collection of information from suppliers of specific components or finished products.

While not necessary for all the pieces of applicable IM legislation, Firm A uses the services of a third party (Notified body) for conformity assessment. This is part of the firm's risk management strategy and introduces costs that are higher than those necessary to meet the minimum requirements imposed by IM legislation. The costs for certification for all products is included in the €200k/year indicated earlier.

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Large Firm B indicated that around €100k is spent on an annual basis for third party services that most often go beyond the minimum required (e.g. testing of production facilities) while Firm C tries to keep the costs of third party to the minimum and spends no more than €10-20k for third party certification. Firm C also stated that there are 3 FTE working on the preparations of DoCs and ensuring that CE marking is appropriately applied in all products. In total, while a specific figure was not provided, Firm C estimated that the conformity assessment procedures and preparation of documentation represents no more than 15% of the total budget allocated to the development of a new model. Firm C also indicated that the requirement for placing an energy label on each appliance adds a cost of around €1/appliance.

Firm A suggested that there is some confusion in relation to the information and level of detail to be included in the DoCs and whether legislation and the relevant standards need to be included but this was not shared by the representatives of large Firms B and C. Still, even for small Firm A this part does not represent a sizeable cost. The firms interviewed did not indicate any problem with the requirement for a single declaration. However, CECED indicated that some of manufacturers may find it problematic as they have separate departments each having responsibility for preparing conformity statements within their own competence. In such case, the requirement for a single DoC may introduce some costs for changes to structures and procedures. Unfortunately, none of the firms was able to provide more specific estimates of the time and resources allocated to these activities. However, on the basis of the information provided this did not appear to represent sizeable part of the total costs.

In relation to gas refrigerators falling under the Gas Appliances Directive, the evaluation of the Directive found that the introduction of GAD led to additional costs, particularly with regard to testing/certification and labelling/CE marking. [60] *However, the costs of testing and certification for all types of gas appliances – not only gas refrigerators – were estimated at around 0.1% of the annual sales value of gas appliances. Response to market surveillance authorities*

Market surveillance authorities make requests for technical information and possibly for testing of products approximately once a month although this varies significantly among countries. The amount of time dedicated to respond to enquiries from market surveillance authorities varies depending on the nature of the request (e.g. what information is required from the technical file, which Directive the request relates to, or whether information in relation to conformity of all applicable legislation has been asked for). Typically, authorities give to firms 10 days to respond to requests. The Ecodesign, RoHS, EMC and energy labelling Directives are those for which there are most often requests for information by the market surveillance authorities. A common perception is that big firms tend to be asked more frequently than SMEs to provide technical information. The large firm interviewed indicated that the related resources dedicated are difficult to estimate but are generally part of the work of the 10 FTE dedicated to compliance.

Business as usual

All firms indicated that they would probably conduct large part of the tests, primarily those related to product safety, even in the absence of the legislation and that production quality management would still be part of internal procedures irrespective of the regulatory framework requirements. Even parts of the costs for tests from third parties could be considered as part of a business as usual (no IM legislation) scenario. Even more demanding product reliability tests – that are voluntary under the GPSD - are often conducted by established firms that want to ensure the quality of their products.

[60] RPA (2011), Ex-post evaluation of Directive 2009/142/EC on appliances burning gaseous fuel, http://ec.europa.eu/enterprise/dg/files/evaluation/03_2011_finalreport_gas_en.pdf

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Similarly, given that issues such as energy efficiency are the focus of consumer organisations related tests would also have to take place – even if not demanding – in the absence of relevant requirements under the Ecodesign and Energy labelling Directive. Thus, large parts of the testing costs incurred – on average up to 50% - are considered as business as usual. Even the product design is in most respects not driven by the legislation but primarily by the general product development process. The main concern for manufacturers is when requirements introduced do not provide sufficient lead time in which case these design costs cannot be integrated in the product design cycle.

5. Assessment of costs of IM legislation for the whole sector

On the basis of the information provided we have attempted to estimate the costs of compliance for the whole refrigerators sector. The provided figures include the information concerning the Business as usual scenario. Assumptions have been made concerning the number of firms affected since, besides the 10 large firms indicated by EGMF there are also a number of smaller size manufacturers particularly in the professional market segment. As indicated in section 2, the calculations for the whole sector were based on an estimated number of 100 firms, an annual turnover of €4.8 billion and a number of units sold/year of €24.6 million.

The table overleaf summarizes the analysis of the costs for different aspects. The main point is that the estimated cost for compliance activities for the whole of the domestic refrigerators and freezers sector is around €160 million/year. Around 60% of this (€86 million) is considered as directly resulting from the internal market legislation while the remaining 40% are costs that would most probably occur even in the absence of legislation. Total substantive compliance costs – product designs related activities, testing and testing equipment – are estimated between 80-90% of the total compliance costs while administrative costs (information collection, preparation of technical files, DoC) represent 10-20%.

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Table 4 – Summary of main costs of compliance for domestic refrigerators industry

	Unit of measurement	Average cost/unit	Total quantity	Industry wide costs/year
Own human resources occupied on compliance activities				
Total	Per annual turnover	2.9% of turnover	€4.8 billion	€140 million
Familiarisation with legislation				5-10%
Share of product design and testing activities				80-90%
Conformity assessment (technical file preparation, information manual, DoC and CE marking)				5-10%
Share of human resources costs in absence of IM legislation (BaU)				40%
Net human resources compliance costs				€86 million
Costs of testing equipment				
Total	Per annual turnover	0.33% of turnover	€4.8 billion	€16 million
Share of expenses even in absence of IM legislation		Ca. 48%		
Net costs for testing equipment				€8.3 million
Costs of third parties				
Total	Per annual turnover	0.5% of turnover	€4.8 billion	€2.6 million
Net third party costs – only for IM		60%		€1.8 million
Total annual compliance costs	**Per firm**	**€1.59 million**	**100**	**€158.6 million**
l net compliance costs		**0.86 million**	**100**	**€86 million**
Substantive compliance costs				80-90%
Administrative costs				10-20%
Share in total industry turnover				**0.2%**
Basic assumptions:	Total units sold: 24.6 million/year Market size: €4.8 billion Number of firms affected: 100 (20 large and 80 small)			

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6. Benefits of Internal Market legislation

The discussions with the three firms and CECED underlined the contribution of the EU legislation in relation to its prime objective, the creation of the internal market for goods. Two of the firms and CECED, indicated that there have been cost savings in comparison to the situation when they had to comply with different pieces of national legislation covering the same aspects in different ways and with different procedures. For the third respondent, however, any such benefits are offset by the increasing compliance costs of the more demanding requirements of the EU legislation.

Another benefit identified is the opportunity provided through the participation of CECED and the large size manufacturers in the CENELEC and IEC standard setting procedures, to avoid or reduce any contradictions between EU and international standards. This contributes, to a certain extent, towards the development of of rather similar requirements at an international level and facilitates the access to even broader markets.

On the other hand, firms were sceptical of the contribution of the legislation to new product development and innovation, even though it was recognised that the Ecodesign Directive – together with the Energy labelling Directive has had a role in promoting the development and adoption of more energy efficiency appliances.

7. Analysis of simplification options

While the administrative costs are reported to be rather sizeable, the discussions with firms did not point to significant potential for changes to the internal market legislation that could lead to measurable benefits. The common concern of firms whenever they were asked to identify possibly simplification or improvement options was that the focus should be on proper enforcement of internal market legislation, particularly in relation to the Ecodesign Directive. There is a general view – albeit with no specific data to support this – that issues like energy efficiency performance are not given priority by authorities and that non-compliance can provide a competitive advantage, especially in the low cost market segments[61].

The input from the interviews pointed to only two examples of possible change in the legislation that should be expected to bring sizeable costs savings. The first concerned the **need for clarifications of the materials and articles that need to be tested under Regulation on materials and articles** that come in contact with foodstuff 1935/2004. Addressing the existing ambiguity as to which materials need to be considered could save costs from additional tests. Not all interviewees identified this as a problem but, according to one large manufacturer, up to 50% of the costs of the tests related to the specific Regulation could be avoided. Specific figures were not made available and the specific tests are not considered particularly costly and the potential savings are not expected to be more than a few thousands Euros per firm and, at most, a few hundred thousand for the whole sector[62]. More generally though, CECED suggested that clearer provisions can ensure that firms do not have to spend unnecessary time and resources.

A second proposal made by one manufacturer was the removal of the requirement for the provision of an energy label in each refrigerating product. The manufacturer claimed the energy label costs €1/appliance. For the estimated 24.6 million appliances sold in 2010 this would mean annual savings of up to €24 million for the whole sector. There was however no detailed evidence presented to

[61] Firms were not able to provide specific data.

[62] On the basis that other firms did not identify this as a problem this is possibly and overestimate of the possible savings.

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corroborate this by industry. . However, unless another equally effective and less costly approach is identified to provide this type of information to consumers, we consider that such a cost cutting measure is neither desirable nor justified. The use of energy labels is a particularly effective tool for providing information to consumers and promoting energy efficient consumer products and this is a view supported by CECED. Still, possible improvements to the Energy Labelling Directive are currently under investigation[63].

More relevant though, CECED indicated that the **more extensive use of pictograms** like the energy label can bring important savings in terms of translation costs for information manuals. CECED did not provide estimates of the possible savings from such a measure but, on the basis of information from other sectors, translation costs of these manuals to cover all EU countries are around €3,000 for each model. For large firms with more than 100 models this may means costs above €100k in total over a period of 3-4 years. Additional costs may arise if there are significant changes to the legislation of the standards. While the use of pictograms will not eliminate the costs for translation, reducing them by 20-30% can still lead to considerable savings for firms that sell across Europe, as most large manufacturers do.

Our own analysis of the legal framework did not indicate obvious duplications or overlaps among the applicable Directives and the discussions with industry representatives did not indicate problematic areas. CECED made reference to problems arising from the use of the terms "placing on the market" and "making available" in the RoHS Directive[64]. While there have been clarifications in the form of the guidance there are still cases that national authorities and manufacturers interpret these terms differently, causing problems to manufacturers. Since there is no information on the frequency of the occurrence of any such problems and the specific implications it is not possible to estimate specific cost savings for the sector.

Finally, in relation to the existing proposal for **mandatory single Declaration of Conformity** under the New Legislative Framework, the input provided by CECED and all firms interviewed was that maintaining flexibility – namely allowing manufacturers to decide whether to use a single or multiple DoCs – is preferable for firms in the sector. The organisation structure of some manufacturers often means that different units deal with different Directives and a single DoC could be problematic. With the modern IT systems we consider that this should not be a problem for manufacturers although it would require some initial adaptation costs. More important though is that the discussions did not indicate measurable cost saving from such a change. The small benefits from less paperwork could also be counterbalanced by a more frequent need to upgrade the single DoC whenever there are changes to the relevant standards or the legislation.

On the basis of the above saving potentials were estimated for each individual firm and, where possible, for the whole sector.

Table 5 - Summary of simplification/improvement options examined

Change proposed	Expected benefit/problems	Estimated savings potential
Remove requirement for provision of energy label in each product	Saving of costs of up to €1/appliance Loss of information concerning	Total of up to €24 million* for the sector

[63] Evaluation of the Energy Labelling Directive, http://www.energylabelevaluation.eu/eu/home/welcome

[64] According to article 3 of the RoHS Directive 'making available on the market' means any supply of an electrical and electronic equipment (EEE) for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge; 'placing on the market' means making available an EEE on the Union market for the first time;

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	energy efficiency Loss of competitiveness for manufacturers of high-quality products	
Use of pictograms (such as the energy label) for the provision of information in a standard common format across the whole of the EU.	Saving of translation costs for information manuals.	€3,000/model – Depending on firm size possible savings of up to €100k/firm
clarification of materials and articles to be tested under in relation to Regulation on materials and articles that come in contact with foodstuff 1935/2004	Eliminate some of the additional tests conducted due to the ambiguity what parts are covered	Expected to be no more than a few thousand Euros/firm and a few hundred thousand for the whole sector
Mandatory single Declaration of Conformity	Reduced paperwork More frequent need to upgrade the single DoC whenever there are changes to the relevant standards	Overall, no significant (if any) cost savings expected

**note – the estimate of €1/appliance was made by a manufacturer of domestic refrigerators and has been used for the simplification estimates. However, this could not be corroborated through the other interviews.*

8. Overall conclusions

The product groups examined in this case study are refrigerators and freezers for domestic use, also known as cold appliances. The total market for refrigerators in 2011 was close to 24.6 million units with a value of the market of EUR 4.8 billion sold/annum. Refrigerators represent around 42% of the market, combined units 38% and freezers 20%. The total volume of production in Europe is around 15 million units with a value of €3.8 billion while imports represent around 50% of the market. Significant part of leading refrigerators and freezers brand are designed in Europe but manufactured outside Europe and subsequently imported. In total, around 10 large size companies – most of them present in the market with multiple brands – represent more than 85% of the market in Western and Eastern Europe and 22 manufacturers capture 98% of the market in Western Europe and 90% in Eastern Europe (including non-EU countries).

Cold appliances are covered by 9 different pieces of IM legislation that cover health and safety aspects (Low Voltage Directive, Regulation on materials and articles that come in contact with food, RoHD Directive on hazardous chemicals), electromagnetic compatibility (EMC Directive), energy consumption and noise (Ecodesign and Energy Labelling Directive). The Gas appliances Directive and Pressure Equipment Directive are also applicable to a small share of cold appliances.

The analysis suggests that cost for compliance activities for the whole of the domestic refrigerators and freezers sector is around €160 million/year, representing no more than 0.2% of annual turnover. Around 60% of this (€86 million) is considered as directly linked to the implementation of the internal market legislation while the remaining 40% are costs that would most probably occur even in the absence of legislation (business as usual). Substantive compliance costs – costs related to product design, testing and testing equipment – are estimated between 80-90% of the total

compliance costs while administrative costs (information collection, preparation of technical files, DoC) represent 10-20% of the total. The compliance costs are driven primarily by the compliance with environmental legislation (mainly the Ecodesign Directive) which, in contrast to health and safety aspects, is not considered as business as usual.

The discussions with firms did not point to significant potential for changes to the internal market legislation that could lead to measurable cost savings. The priority – from the point of view of industry- is to ensure the proper enforcement of internal market legislation, particularly in relation to the Ecodesign Directive, to ensure fair competition.

Specific improvements identified concerned the need for clarifications of the materials and articles that need to be tested under Regulation on materials and articles that come in contact with foodstuff 1935/2004 that could save up to 50% of the testing costs related to this Regulation. An extensive use of pictograms like the energy label is also expected to bring measurable savings (of a possible order of tens of thousands of Euros for large firms). There is also no clear view as to possible savings from the adoption of a mandatory single Declaration of Conformity. Maintaining flexibility – namely allowing manufacturers to decide whether to use a single or multiple DoCs – is considered preferable for many firms in the sector and there are no measurable cost saving from such a change.

The firms in the sector underlined the contribution of the EU legislation in creating an effective internal market for goods that have led to cost savings in comparison to a situation in which they had to comply with different pieces of national legislations. However, the increasing compliance costs linked to more demanding requirements of the EU legislation may have offset these savings. The industry also benefits from the participation in the standard setting procedures that helps avoid contradictions between EU and international standards. Firms are sceptical concerning the contribution of the IM legislation to innovation even though it is recognised that the Ecodesign Directive has had a role in promoting the development and adoption of more energy efficient appliances.

9. Sources of information

References

- Eurostat Structural Business Statistics Database and PRODCOM
- Euromonitor Market research data on consumer appliances
- Text of applicable IM legislation and relevant standards
- Guidance documents of LVD and MC Directives
- Input from one medium and one large manufacturer/importer of refrigerators and freezers.

Interviews

- Interview with industry association: CECED
- 3 interviews with manufacturers of refrigerators/freezers

Lifts case study

D

CASE STUDY 4 - LIFTS

1. Introduction - objectives of the case study

This case study assesses how IM legislation affects different economic operators involved in the manufacture, import and distribution of lifts for persons (covered under the Lifts Directive 95/16/EC). In order to help shed light on the interaction between different types of IM legislation, and issues around whether there are sufficiently clear demarcations between such legislation, it also however addresses other types of lifts covered through the Machinery Directive 2006/42/EC, including lifting hoists, lift platforms and escalators and certain types of lifts for goods not covered by the Lifts Directive. The applicable Union harmonisation legislation specific to each product is mapped out and an assessment of gaps, loopholes, inconsistencies and duplication is provided. The administrative costs – and to the extent possible substantive compliance costs – in meeting these regulatory requirements are then assessed.

The rationale for the selection of lifts was that:

- The lifts sector, while dominated by four large firms, has a large number of small and medium-sized enterprises ("SMEs");
- The lifts sector has longstanding experience of implementing IM legislation since the Lifts Directive was adopted in 1995;
- The Lifts Directive 95/16/EC is one of nine Directives that form part of the Alignment Package. It is important to examine stakeholder views on how the alignment process has had an impact on strengthening the coherence of IM legislation; and
- The case demonstrates the advantages of having a clear delimitation in IM legislation in defining the borderline between different Directives in order to ensure legal clarity for economic operators.

The case study is based on interviews of EU-level and national industry associations, manufacturers and installers of lifts and manufacturers of safety components for lifts, as well as analysis of key legislative documents and published reports.

2. Product definition and structure of the sector

The lift industry is dominated by four very large companies (Kone, Otis, Schindler, ThyssenKrupp Elevator), of which three are European (one non-EU) and one from the USA. These four companies and their subsidiaries have a high combined share of the European market, estimated at 60%.

The lifts industry has undergone substantial changes as a result of globalisation, with evidence of increased industry consolidation in statistics on market structure.[65] The estimated size of the lifts market in Europe, according to the Europe SME lifts association (EFESME) was about €15 billion in in 2009. However, this extends beyond manufacturing and the placing of products on the market (covered by IM legislation). Lift manufacturing and installation only accounts for one third of the total market size, while the remainder is made up of after-sales services (maintenance 41%, repair 7%, and modernisation 18%). The total number of lifts in operation in the EU was estimated at about 4.7 million units. Further data has been obtained for 2009 from NACE and PRODCOM on the size and structure of the lifts industry. "Lifts and escalators" fall within the NACE classification "manufacture of lifting and handling equipment".

[65] http://www.lift-report.de/index.php/news/361/373/Industry-report---Lifts-and-escalators-an-industry-in-flux

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NACE data shows that there are over 9,500 enterprises in the lifts sector, the great majority of which are SMEs, although there has been a decline in the number of lifts companies in the 2008-2010 period (the latest period for which data was available), reflecting on-going industry consolidation processes.

Table 1: Number of enterprises – lifts sector

Nace Code	2008	2009	2010
28.22	9,970	9,720	9,525

- Source: Eurostat

The production value of lifts is shown in the following table. The data shows that in parallel with the economic and financial crisis there was a major downturn in the lifts industry but that the production value has since stabilised.

Table 2: Production value of the lifts sector (€ thousands)

Nace Code	2008	2009	2010
28.22	59,072.38	42,603.23	43,688.83

- Source: Eurostat

In the following table, Prodcom data shows that a total of about 255,000 lifts (and skip hoists) were produced in Europe in 2012, of which the majority were electrical lifts and the remainder hydraulic.[66]

Table 3: Sales volumes for lift manufacturing industry (2012)

	Units	Median price (€)	EU27 production value (€000)
Sales volumes			
28221630 (electrically-operated lifts and skip hoists)	133,000	18,242	2,157,000
28221650 (lifts and skip hoists excluding electrically-operated)	122,000	14,207	802,766
Total sold volume	255,000	-	2,959,766

- Source: Eurostat

Manufacturing in the lifts sector is strongly export-oriented and has generated a significant volume of exports, although the interviews found that a lot of manufacturing that used to take place within the EU has been moved to lower-cost producer countries outside the EU. The table below provides a summary.

Table 4: Production value – lifts sector (2010)

	Export values (000s)	Import values (000s)	Production Value (000s)	Apparent consumption (Production+ Imports- Exports)

[66] It should be noted that skip hoists are not lifts and are not subject to the Lifts Directive. However, Eurostat does not provide further disaggregation of Prodcom data.

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28221630 - Electrically operated lifts and skip hoists	599,774,450	37,947,640	2,343,821,623	1,781,994,813
28221650 - Lifts and skip hoists (excluding electrically operated)	165,383,210	17,338,000	628,899,470	480,854,260
Total	**765,157,660**	**55,285,640**	**2,972,721,093**	**2,262,849,073**

- Source: Eurostat

With regard to employment, various industry surveys indicate a total European workforce in the lifts for persons sector (manufacturing, installation and servicing) of between 15,000-18,000 people.[67]

3. Analysis of applicable IM legislation and standards

This section maps out relevant Union harmonisation legislation since the study seeks to provide estimates of the costs associated with complying with IM legislation (dividing these costs into administrative costs and substantive compliance costs). Reference is also made to applicable environmental legislation where this has a major impact on manufacturers of industrial goods. However, in the quantitative analysis, we do not seek to quantify the impact of such legislation, rather only IM legislation for industrial products.

In the first table, relevant applicable IM legislation for lifts for persons is mapped out. The table shows that, unlike some of the other product cases, the lifts sector is subject to relatively few pieces of Union harmonisation legislation.

Table 5: Legislation applying to lifts

Applicable legislation	Scope of products included	Main administrative requirements for economic operators
Lifts Directive 95/16/EC	Lifts for persons, persons and goods or goods alone (if the carriers is accessible) with speeds of more than 0.15 m/s	• Conformity assessment - obligation of the installer of lifts or manufacturer of safety components • Produce a DoC (note: DoC required for both installation of lifts and for each safety component) • Keep technical documentation copies of EC type-examination certificates and their additions for a period of 10 years from the date on which the safety component was last manufactured or the date on which the lift was placed on the market • 'CE' marking - must be visibly affixed to lifts or to certain safety components of lifts • Rules relating to manufacturing apply to both installers of lifts and to manufacturers of lift safety component (or authorized representatives)
Lifts Directive (COM(2011) 770 final) Proposal for a	As above	**All economic operators** Traceability obligations - identify name of installer, manufacturer, name / ID number of Notified Body having carried out conformity assessment

[67] Elevators and Escalators - A Global Strategic Business Report 10/12

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Applicable legislation	Scope of products included	Main administrative requirements for economic operators
Directive on the harmonisation of the laws of the Member States relating to making available on the market of lifts and safety components for lifts (recast)		**Installers and manufacturers** Conformity assessment remains the obligation solely of the installer or the manufacturer of safety component **Importers** • Verify that the manufacturer of safety components has carried out the applicable conformity assessment procedure and has drawn up a technical documentation. • Verify that the safety components for lifts are correctly marked and accompanied by the required documents. • Keep a copy of the DoC and indicate their name and address on the product, or where this is not possible on the packaging or the accompanying documentation.
EMC Directive	Applies to lifts for persons	Testing products for Electromagnetic Compatibility interference Conformity assessment procedure for apparatus mandatory CE marking on apparatus required in accordance with Annex V.
Machinery Directive 2006/42/EC	Lifts for goods only Slow-moving lifts (speed less than 0.15 m/s) Construction site hoists Lifting platforms for persons with impaired mobility	Manufacturers • Ensure conformity assessment procedure for lifting machinery carried out • Produce a DoC (note: DoC required for both installation of lifts and for manufacture of each safety component) • Keep technical documentation copies of EC type-examination certificates and their additions for a period of 10 years 'CE' marking - must be visibly affixed to lifts or to certain safety components of lifts • Construction file and risk assessment. The latter should contain: (i) a list of the essential health and safety requirements applied and fulfilled; (ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks; (iii) the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards; (iv) any technical report giving the results of the tests carried out either by the installer or manufacturer or by a body chosen by the manufacturer or his authorised representative; and (v) a copy of the assembly instructions for the partly

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Applicable legislation	Scope of products included	Main administrative requirements for economic operators
		completed machinery.

The Lifts Directive covers Lifts for persons (and goods). Article 1(1) states that the lifts to which the Directive applies are those "serving buildings and constructions". The Directive is clear as to whether spare parts and components are included, since it covers both lifts and safety components for lifts, both of which must be CE-marked. Likewise, other Directives that apply to different types of lifts such as Directive 2000/9/EC relating to Cableways (e.g. chair lifts, drag lifts) also applies to safety components and also to sub-systems.

A number of different types of lifts are **excluded from the Directive's scope**, namely:

- lifting appliances whose speed is not greater than 0,15 m/s;
- construction site hoists;
- cableways; including funicular railways;
- lifts specially designed and constructed for military or police purposes;
- lifting appliances from which work can be carried out;
- mine winding gear;
- lifting appliances intended for lifting performers during artistic performances;
- lifting appliances fitted in means of transport;
- lifting appliances connected to machinery and intended exclusively for access to workstations including maintenance and inspection points on the machinery; and
- rack and pinion trains, escalators and mechanical walkways.

The legislation applies to goods alone if the carrier is accessible i.e. a person may enter it without difficulty, and fitted with controls situated inside the carrier or within reach of a person inside the carrier. Other types of lifts to carry goods are included within the scope of the Machinery Directive 2006/42/EC.

A **Guide to the Application of the Lifts Directive 95/16/EC** has been drawn up by the Commission following consultation between the Member States and lifts industry representatives, standardisation bodies, Notified Bodies and users of lifts. The guidance takes into account practical experiences of the Directive's implementation and draws widely on the discussions and conclusions of the Lifts Working Group.

The guidance sets out which types of lifts fall within the directive's scope and which are excluded. This was viewed as being helpful for economic operators in ensuring that there is a clear understanding about the delineation between Directives. For example, the scope of the Lifts Directive and the Machinery Directive are mutually exclusive, but the Lifts Directive includes relevant requirements of the MD. Moreover, since 29 December 2009, Article 24 (1) of the revised Machinery Directive modifies the list of exclusions of the Lifts Directive. For example, the lifts with a travel speed not greater than 0.15 m/s are now excluded from the scope of the Lifts Directive and are subject to the Machinery Directive. Construction site hoists are excluded from the scope of the Lifts Directive. They are no longer excluded from the scope of Machinery Directive.

Process of revising and updating legislation

Before considering whether there are any gaps, overlaps, inconsistencies and duplication in IM legislation affecting the lifts sector, it is necessary to review how the regulatory framework has

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evolved. Two main legal developments can be noted relevant to EU legislation affecting lifts:

- The Lifts Directive has been subject to regulatory amendments to make the definition of product scope – and the delimitation between the Lifts Directive and the Machinery Directive – clearer. The consolidated legal text reflects this.
- The current legal framework has been reviewed and through the Alignment Package, a recast Lifts Directive will be adopted (circa 2014).

Since the Lifts Directive was adopted in 1995, the former Machinery Directive (89/392/EEC) was updated through regulatory amendments to reflect the provisions in the Lifts Directive. In particular, Recital 27 of the recast MD states that *"The application of the Directive to a number of machines intended for lifting persons requires a better delimitation of the products covered by this Directive with respect to those covered by Directive 95/16/EC"*. Consequently, an amendment was made to the Lifts Directive 95/16/EC to clarify the borderline between the two Directives' scope.

Directive 95/16/EC is now being aligned with the NLF through the Recast Directive 2011/0354 (COD) on the harmonisation of Member States' laws relating to making available on the market of lifts and safety components for lifts. Although most changes to the Lifts Directive as a result of the alignment package will be minor, such as stronger coherence through common definitions and responsibilities for economic operators, there may be some safety benefits.

Analysis of gaps, overlaps, inconsistencies and duplication

Overall, the evidence suggests that IM legislation affecting the lifts sector is coherent. First, unlike some other Union harmonisation legislation, the delimitation between directives (e.g. the Lifts Directive and Machinery Directive) has been clearly specified by the recast of the Machinery Directive in 2006. This ensures that there is mutual exclusivity between the Directives, which provides clarity for economic operators. Whilst the Lifts Directive does not distinguish electrical and hydraulic lifts, such a distinction is made in the relevant standards and is viewed as a logical by manufacturers, installers and other industry stakeholders.

A minority of the companies interviewed also highlighted obstacles caused by legislation relating to construction products and/or buildings. For example, one company suggested that the Construction Products Regulation was not consistent in terms of its references (or lack thereof) to steel structures used in lifts or to the fire-testing of lift landing-doors. Another mentioned that the application of "local building standards" to buildings hosting lifts could serve as a barrier to the free movement of lift units across Europe.

4. Analysis of costs of compliance with IM legislation

Feedback was obtained on how companies in the lifts sector ensure compliance with the relevant Directives (listed in Table 5 above). In order to ensure their compliance with the legislation, the large manufacturers tend to employ specialist staff at their research and development centres and production sites, as well as in their distributing companies (typically nationally-based) that are responsible for installation, service and maintenance. Compliance must be ensured at the design and development stage (typically a one-off task for each new or revised product) as well as at the installation stage for each individual lift unit. It should be noted that the EU legislation only relates to new products; service, maintenance and renovation (including of lifts pre-dating the Lifts Directive) is covered by national legislation that differs from country to country.

Lifts differ from many other industrial products in that compliance has to be undertaken in three main phases, which may take place at different sites in different countries. New lift models are,

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firstly, *designed* to take into account IM legislation. For the big four manufacturers, design tends to be undertaken at specialist research and development (R&D) centres, given the obvious economies of scale. For example, one of the firms interviewed has eight R&D centres globally, of which three are in the EU. Second, new lifts must be *manufactured* to comply with the legislation. Again, the manufacturing of lifts may often be done centrally to make use of economies of scale. The same firm has multiple global production sites, of which three are in the EU. Last, the installers of lifts must ensure that *installed* products satisfy a proper conformity assessment undertaken on site before they become operational. In contrast to the design and manufacturing of lifts, installation is typically done by nationally-based firms given the need for proximity. The four large firms have operating companies or authorised distributors in each of the 27 Member States and in many other countries worldwide. SMEs clearly differ from the four global players in that respect, since design and production is more likely to take place at the same site.

At each phase, the task of ensuring compliance is very different. Designing a new lift product or model is clearly a lengthy task, undertaken some considerable period before the product is placed on the market. The design process involves intensive testing, whether required by the legislation or not. At the design stage, the requirements of the legislation must be taken into account and thus limit the options for design but without creating a specific additional stage in the process; the requirements are "designed in" to the product. The manufacture of lifts in compliance with the legislation is relatively straightforward, provided that the product has been designed to comply and provided that the lift is made according to the specification. However, the installation of lifts tends to require numerous refinements to ensure the lift functions well within its environment. These refinements result in a corresponding need for repeated checks to ensure compliance with the legislation, as well as with health and safety requirements in general.

The particular nature of this production chain also creates specific costs and benefits compared to other products. There is the need for specialist staff that have expert knowledge of the legislation at all sites, i.e. the locations where R&D, production and installation take place. This is in contrast to a product such as mobile phones, for which there is no separate "installation" phase; once such products leave the production site, the manufacturer can be sure that the product is compliant (unless it is tampered with at a later stage). Compliance is thus a "decentralised" task, creating the need for communication between disparate sites at different points in the production chain, e.g. for feedback from installers to designers about the practical difficulties faced in complying with the legislation at the point of installation. However, the nature of the product (i.e. physically large and fixed in a certain location) facilitates enforcement of the regulation and market surveillance; products can be tracked and traced much more easily than other products, making it hard for rogue or ill-informed manufacturers to place non-compliant products on the market. Similarly, end-users are unlikely to purchase non-compliant products inadvertently, e.g. via a website.

The size of the four largest manufacturers enables them to employ specialist compliance staff in-house. As a result, the general approach in the lifts industry is to gain approval of the installer's full quality assurance system under Module H, which avoids the need for EC type-approval of each unit installed. However, the system used tends to vary according to the nature of the building; other Modules tend to be used for unusual buildings. Two of the companies interviewed pointed out that they would tend to comply with the harmonised standards as much as possible, reflecting the fact that the Lifts Directive covers a very specific product, unlike some other directives. Compliance with harmonised standards also makes exporting easier to third countries that have unilaterally adopted the EU standards (e.g. many of the Asia-Pacific countries) and also simplifies maintenance.

Feedback from industry associations was that European standards play an important role in

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supporting the compliance of SMEs with EU legislation, since almost all SME producers of lifts use ropes and follow such technical standards. However, the four large manufacturers do not use standards in order to comply with the essential requirements, since they use belts. There is a reluctance among the biggest industry players to be involved in standardisation because of concerns about maintaining competitive edge and because newer types of lifts are patented.

Preparatory actions: familiarisation with relevant legislation and purchase of standards

For the two large companies interviewed, the process of **familiarisation with legislation** was not unduly costly. Their very large size makes it affordable to employ staff specialising in EU and other legislation. For example, such staff are a very small part of the workforce for the big four players with more than +40,000 employees worldwide. Moreover, the availability of specialist staff allows the large companies to be well-connected to the European Commission and to participate in various forums and working groups at EU level, which helps familiarisation.

The greatest costs related to familiarisation with the legislation tend to occur when there are changes in the harmonised standards or in the interpretation of those standards, e.g. by national authorities. One interviewee reported that the cost of familiarisation with applicable requirements was not particularly costly, nor was purchasing the relevant standards. (Standards in the UK typically cost between £50 and £300 each). However, reviewing the existing harmonised standards could take time, as could the process of familiarisation across a large company, given the need for constant communication of the information obligations of the legislation to a much wider group of people. For example, the requirements of the legislation are just one part of the knowledge required by those installing lifts; those staff would not necessarily be as pro-active as the compliance officers in ensuring that their knowledge remained up-to-date, hence the need for continued communication as well as regular training. None of the companies interviewed incurred costs in using external consultants to support preparatory work.

Compliance with the applicable IM legislation

Changes to the requirements of the legislation or to the standards have the greatest potential to impose costs on manufacturers where they require changes in **processes and product design**. Indeed, the nature of lifts requires very considerable investment to be undertaken in the design and development of new products over long time-periods. Where changes occur in the legislation on a regular basis or at short notice, they have the potential to impose substantial costs on manufacturers.

However, the companies interviewed pointed out that the costs of adapting processes and product design are much less where changes in the legislation are announced some time before they come into effect. In general, lift products are continually evolving, e.g. in response to technological innovations and the R&D centres of the large companies are constantly seeking to improve their products, whether through new models or new versions of existing models. The development process involves constant checking of prototypes to ensure safe and effective functioning, as well as compliance with the legislation. Whilst such checks are time-consuming, they are seen as part of the overall development cost. Indeed, it becomes hard to separate out the cost of checking compliance with the legislation from the cost of other checks. As one interviewee stated, “the product specification is not costly as you have to do it anyway; in that sense, the Directive just limits your options, it doesn’t create costs”.

Conformity assessment procedures

The companies interviewed were unanimous in highlighting the additional costs imposed by **conformity assessment procedures** both in development and installation. The development of a

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new or revised model tends to require continual refinements to the product. When a product is designed, it has to be considered by a notified body and go back each time it is revised (as part of the overall development process). Manufacturers/installers are required to retain the product certification at each stage of development, which creates a cost. It would appear therefore that it is not so much the cost of the developing a product that conforms to the legislation which is burdensome but the cost of checking conformity. Such costs tend to be additional and therefore costly. As noted above, approval of the installer's full quality assurance system under Module H avoids the need to have each individual unit checked.

Within the conformity assessment procedure, it would appear that the main costs are imposed by the requirement to collect all information required for technical reports. For example, collecting information from third party suppliers of components can be particularly burdensome due to the lifecycle of the product. The compilation of test reports is equally important and burdensome but tends to be viewed as a "business as usual" cost, since the manufacturers operate their own test procedures and compile test reports in any case. Similarly, product identification requirements (e.g. serial number) and the maintenance of technical information for at least ten years tend also to be seen as "business as usual" costs, in the latter case, because the life-cycle of a lift is 25-30 years. It may be possible to reduce some costs by allowing increased use of electronic documentation.

The large manufacturers tend to undertake their own tests themselves, using in-house staff and following quality assurance systems approved under Module H. Clearly, such costs are significant, given the need for full-time staff. However, the cost of notified bodies tends to be modest; one manufacturer reported that third party notified body inspections are only used to verify its quality assurance system. No company reported their own internal reviews of technical documentation to be particularly burdensome, given the availability of in-house staff; one of the companies mentioned that such reviews were undertaken by the global headquarters. In the case of lifts, periodic inspections of installed products are the responsibility of the customer and, in any case, fall under national rather than EU legislation.

Declaration of Conformity and CE marking

Overall, the **Declaration of Conformity and CE marking** do not appear particularly burdensome for manufacturers, except for the requirement to keep information up to date, e.g. in relating to changes in the harmonised standards or in the legislation. Since each lift installed represents a unique product, the information has to be created every time, which creates an administrative burden if the DoC is to be kept up-to-date. However, since the CE marking and DoC also have to cover the equipment and environment surrounding the lift, this step can be particularly burdensome in a minority of installations. Since, typically, the lift manufacturer will not have constructed the surrounding environment, e.g. the hoistway, the process of issuing the DoC and CE marking can prove problematic. For example, one company reported that some customers may pressure the lift installer to issue a DoC (e.g. by withholding payment) in cases where the customers themselves have not fulfilled their own obligation to develop a compliant environment for the lift.

Other activities necessary to comply with IM legislation

None of the companies interviewed referred to costs resulting from any **other activities** required by the legislation.

Analysis of administrative costs for each relevant step indicated

Since the Lifts Directive refers to a very specific product, this Directive accounts for the majority of administrative costs. However, the administrative costs tend to be minimised by the fact that the

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harmonised standards of the Lifts Directive have been developed to take into account the regulatory compliance requirements applicable to lifts set out in other relevant directives, notably the Electromagnetic Compatibility Directive (EMC). This means that if a manufacturer follows the standard and carries out a conformity assessment based on the standard, they will have met their regulatory obligations across all relevant pieces of legislation.

Similarly, products covered by the Machinery Directive (e.g. escalators) and using the harmonised standards of that Directive will in meeting these requirements have also complied with the EMC requirements since they are incorporated into the standard. Two companies referred to the need to take into account the Ecodesign Directive, with respect to the buildings in which lifts are installed. One of the companies also referred to the need to comply with the ATEX Directive on occasions, i.e. in potentially explosive atmospheres.

None of the firms were able to provide detailed costs for every step in the process. However, we can make some statements based on the evidence available.

- **Familiarisation with legislation** is undertaken in-house by the large companies using specialist staff; one company stated that each of its national subsidiaries had at least one compliance officer and one final inspector, both of which would possess in-depth knowledge of the legislation and would keep themselves up-to-date; the same company estimated that the total number of compliance and inspection officers across the EU to be around 100. The other company referred to six specialist staff ("Blue collar" operators, i.e. technicians and associate professionals) in one of its nationally-based distributing companies (in a medium-size country).
- **Processes and product design**: the large manufacturers tend to undertake their own tests, using in-house staff and following quality assurance systems approved under Module H, which serves to minimise cost; in addition, one large company suggested that changes to the legislation could incur costs of €550k-€600k if they require changes to the reference numbers for lift products.
- **Conformity assessment procedures**: The Lifts Directive is the most burdensome piece of legislation, particularly the requirement for compulsory third party conformity assessment procedures and the supporting technical documentation; this is much more detailed than the other Directives. Lift manufacturers undertake their own extensive testing of their products both in development and in installation to ensure quality and safety; in most cases, such checks can readily encompass the requirements of legislation. To a large extent, the testing required by conformity assessment would therefore tend to represent a "business as usual" cost rather than an additional cost imposed by the legislation.
- The administrative requirement related to conformity assessment procedures undertaken in the product development stage are quite high initially, but occur only once (for each model or version). The larger companies do not incur costs of notified bodies in the installation of lifts, except in special cases where those lifts do not follow the harmonised standards; one national subsidiary in a medium-sized country referred to the need to use a notified body for the certification of lift units around 3 or 4 times per year at a cost of €500 per time, i.e. €2k per year – a cost described as "minimal compared to the cost of installing lifts". The administrative burden associated with conformity assessment is quite high as inspections have to be undertaken for each new lift installed. There is also the cost of buying and maintaining testing equipment; one subsidiary of a large company reporting that cost to be around €5k per year depending on the frequency of tests.

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- **Declaration of Conformity and CE marking**: in general, this task is not seen as particularly costly, except that gathering the information required for the DoC takes time. The possibility to issue a single DoC covering all Directives significantly reduces the administrative costs of this step.

Compliance costs

As for administrative costs, most compliance costs relate to the Lifts Directive, which in any case requires compliance with the EMC Directive. Again, no firm was able to provide detailed costs for every step in the process. However, we can make some general statements based on the evidence available.

Where changes occur in the legislation on a regular basis or at short notice, they have the potential to impose substantial costs on manufacturers in the design and development of products and production processes. For example, one 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, additional documentation for the conformity assessment process, costs for sales companies, training for sales and production staff, updating sales literature.

In the long run, particularly where changes in the standards or in the legislation are introduced with sufficient notice, the costs of compliance are inseparable from the "business-as-usual" costs of designing and developing new products and production processes. It may be that the legislation or the standards exclude some options for design or production that would have delivered cost-savings, but these potential "missed savings" were not specifically mentioned by the companies interviewed.

Conclusions

It would appear that the main determinants of the level of compliance costs are the regularity and notice period of any changes in the legislation or in the harmonised standards. New or revised models are continually being designed and developed to reflect technological advances. Provided that changes are not made too frequently and are signalled well in advance, manufacturers appear able to design and develop compliant products without incurring additional compliance costs; to a certain extent, compliance is "designed in". Changes brought in at short notice can impose very significant costs, as units already in production have to be revised; this can prove particularly problematic where contracts have already been agreed with customers. Frequent changes in the legislation or, particularly, in the harmonised standards also impose a significant compliance cost by requiring extensive information and retraining of staff to ensure that "front-line" staff, e.g. lifts installers are aware of, and apply the revised standards.

For the large companies interviewed, it is clear that the administrative burden represents a somewhat modest financial cost compared to total costs/turnover, as evidenced by the number of specialist staff compared to the total workforce. SMEs may face a difficult choice between incurring the overhead involved in having specialist staff and not keeping up to date with changes in the legislation. Moreover, they rarely have the capacity to engage in the various processes at EU level related to setting standards.

Overall, it would appear that the various Directives applying to lifts are consistent and streamlined, i.e. compliance with harmonised standards of the Lifts Directive implies compliance with the other Directives. This consistency limits the costs of compliance and, particularly, the administrative burden associated with the legislation. It may therefore be safe to conclude that any negative cumulative impacts of the legislation are modest. Moreover, it is reasonable to assume that most, if

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not all, Member States would introduce legislation covering lifts in the absence of the Lifts Directive, given the risks to safety inherent to this product. The EU legislation may therefore have reduced compliance costs and the administrative burden by enabling the application of harmonised standards and a consistent compliance process across all 27 Member States. However, EU legislation does not apply to services, maintenance and renovation. Any risks to safety must therefore be covered by national legislation, which will inevitably vary from country to country. It may be worthwhile for the Commission to explore the possibility of bringing service, maintenance and renovation of lifts within the scope of EU legislation or to find ways to encourage a gradual, voluntary convergence in the requirements of national legislation.

5. Assessment of costs of IM legislation for the whole sector

On the basis of the information provided, we have attempted to estimate the costs of compliance for the installation of lift units, including electrically-operated (NACE 28221630) and other (NACE 28221650). In offering such estimates, we have taken into account certain characteristics of the sector and of firms therein.

First, companies involved in the manufacture and installation of new lifts typically also undertake modernisation, repair and maintenance, which are not subject to EU legislation. For that reason, we have estimated costs of compliance as a proportion of production value rather than of the total revenues of such companies. Total revenues for manufacture and installation are based on multiplying median prices (sourced from PRODCOM) against the total number of units sold by each company.

Second, the estimates in the table below do not include data from manufacturers of components. Of course, the manufacturers of components must comply with the relevant legislation and this imposes a certain cost. However, those compliance costs differ in nature from the costs incurred by manufacturers and installers of lift units and are therefore excluded from the table.[68] For example, conformity assessment of new components is a one-off event, whereas each new lift unit must be assessed at the installation stage. Information from the interviews of such companies has instead informed the qualitative text above.

Third, the companies interviewed were generally unable to separate substantive compliance costs (in product design, manufacture and installation) from business-as-usual costs. All interviewees agreed that changes in the legislation or in the standards introduced at short notice tended to impose very significant substantive compliance costs. In particular, any units already in production or already manufactured but not yet installed required technical adaptations in order to be compliant with the legislation, which proved costly. However, the level of any short-term adaptation costs would depend entirely on the precise nature of the change. Moreover, manufacturers are continually innovating in search of higher quality and lower costs (not least in response to demand) and average production costs tend to be falling (e.g. due to increasing economies of scale). In this dynamic situation, the companies interviewed tended to report that, given time to adjust, they could "design in" the requirements of the legislation without necessarily incurring substantive compliance costs. None of the companies was able to state how their products would be different in the absence of legislation. For those reasons, the table below offers no estimate of substantive compliance costs.

[68] To a certain extent, the compliance costs incurred by manufacturers of components might be passed on to the manufacturers and installers of lift units through higher prices for components. However, it is beyond the scope of this study to determine the extent to which that happens.

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Fourth, the companies interviewed stressed that they undertake extensive testing during the installation process for reasons of safety and quality and would do so in the absence of EU legislation. Although the conformity assessment process imposes a significant cost in terms of staff time required to check installations (e.g. under Module H) and compile technical reports, such costs tend to be inseparable from business-as-usual costs. In that sense, it might be possible to conclude that the conformity assessment process determines the format of testing during the installation without necessarily being more expensive than the tests that installation companies would undertake in the absence of EU legislation. SMEs may differ in that respect, as they are more likely to use Notified Bodies and thus incur a direct financial cost, which can be significant; of course, many reputable SMEs would submit their products for third-party testing in the absence of EU legislation, so it is impossible to determine the additional burden imposed by the legislation.

The table below suggests that the costs of compliance may be around £26m p.a. for a production volume of 255,000 units. This represents around 0.89% of total revenue of €2,960m from manufacture and installation of whole units in the EU. To this cost must be added the significant but unquantifiable costs just described. However, the companies interviewed were unanimous in reporting that the cost of complying with EU legislation was less than under a "benchmark" scenario in which national legislation differed from country to country.

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Table 6: Summary of main costs of compliance for installation of lift units

	Unit of measurement	Average cost/unit	Total quantity	Industry wide costs/year	*Explanatory notes*
Human resources expended on compliance					
Familiarisation with legislation	Per annual turnover	0.26%	€2,959.766m	€7.696m	*Staff responsible for participating in EU-level processes, identifying legislative requirements and informing the wider company, e.g. Codes Officers.*
Informing and training staff in legislative requirements					*Significant cost but impossible to quantify, typically consisting of small amounts of time spent by a large number of individuals*
Product design and testing activities					*Inseparable from business-as-usual costs. Significant in the short-term (i.e. adaptations to changes in the legislation or in the standards). Negligible in the long-run.*
Checking compliance in design and production	Per annual turnover	0.16%	€2,959.766m	€4.736m	*Compliance and inspection officers at sites responsible for R&D & production*
Conformity assessment (technical file preparation, information manual)					*Inseparable from business-as-usual costs*
Declaration of Conformity & CE marking	Per annual turnover	0.00%	€2,959.766m	€0.000m	*Negligible*
Total human resources compliance cost				€12.432m	*In addition to non-quantified costs of training, product design and testing, etc.*
Costs of testing equipment					*Cost of testing for reasons of*

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	Unit of measurement	Average cost/unit	Total quantity	Industry wide costs/year	*Explanatory notes*
					quality, health & safety are impossible from costs of testing required by the legislation. Production sites typically serve EU and global markets, therefore impossible to separate cost of testing equipment required by EU legislation from testing equipment that would be needed in the absence of legislation.
Costs of third parties					
Purchasing standards[69]	Per annual turnover	0.01%	€2,959.766 m	€0.296m	*Typical cost = €2k per company per year.*
External consultants	Per annual turnover	0.00%	€2,959.766 m	€0.000m	*No reported instances of use of external consultants*
Notified Bodies (Module H)	Per annual turnover	0.04%	€2,959.766 m	€1.184m	*Typical cost is €25-30k for a national subsidiary of a major manufacturer (responsible only for installation).*
Notified Bodies (fees for testing specific products)	Per unit	€200-1000	n/a	n/a	*Units deviating from the standards require specific approval but typically form a very small proportion of total installations.*
Total annual compliance costs	**Per**	**0.89%**		**€26.344m**	

[69] As an indicative example, UK standards under the Lifts Directive are typically priced between £50 and £300. See: http://shop.bsigroup.com/.

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	Unit of measurement	Average cost/unit	Total quantity	Industry wide costs/year	*Explanatory notes*
	annual turnover				
Total net compliance costs				n/a	*Inseparable from business-as-usual costs.*
Substantive compliance costs				n/a	*Inseparable from business-as-usual costs.*
Administrative costs				**€26.344m**	*Excludes substantive compliance costs, which are inseparable from business-as-usual costs*
Share in total industry turnover				**0.89%**	
Basic assumptions:	Total units sold: 255,000 units per year (NACE: 28221630 and 28221650) Market size: € 2959.766 million (PRODCOM) Weighted median price per unit: €16,312 (NACE 28221630 and 28221650)				

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6. The benefits of internal market legislation

It is important that the benefits of IM legislation are considered and not only the costs. It is impossible to establish a counterfactual since it cannot be known how the industry would have developed in the absence of legislation. They highlighted the following benefits.

First, the firms and industry associations interviewed were unanimous in the view that it was preferable to have a single set of internal market legislation across the Union rather than different pieces of national legislation. Costs of components have also been kept down, where suppliers can provide a certificate from a Notified Body, which prevents the need for the manufacturer to undertake additional checks, which would be necessary in the absence of EU legislation.

Second, the legislation was reported to have helped drive up safety standards across Europe. There has there been a "levelling up" of what were different national standards, with EU standards set at a high level. The legislation has also introduced new requirements that have driven up safety even beyond the level of the previous best of the national standards; the requirements relating to emergency telephone systems were mentioned in that regard.

Third, EU legislation has provided opportunities for export to third countries. Indeed, many third countries were reported to be basing their legislation on the Lifts Directive, which helped EU companies exporting into those countries as well as third countries exporting into the EU; of course, this is also of particular benefit the largest companies, who operate globally, with R&D, production and installation distributed across companies in different countries worldwide.

Fourth, the replacement of national legislation with EU legislation had enabled economies of scale to be captured by producers, leading to consolidation of the market. The New Approach Directives have tended to support the competitiveness of EU industry.

7. Analysis of simplification options

The interviewees identified limited scope for regulatory or administrative simplification. A common view was that the legal framework worked well and that it would not be appropriate to make frequent changes to the EU regulatory framework since manufacturers benefit from a stable legal framework. However, it was recognised that there would be some benefits and minor administrative cost savings from certain changes being made to the legislation. For instance, a number of potential benefits can be noted in relation to the proposed recast Lifts Directive – the first three changes suggested in the table below. Some practical tools may also help reduce costs for industry, such as making abstract versions of standards freely available and creating national databases of lifts.

Table 7: Summary of proposed simplifications/changes and expected benefits

Change in regulatory and administrative requirements	*Potential impacts/ benefits*	*Estimated saving potential*
Common definitions	Better understanding of product scope and delimitation between different types of lifts	Unquantifiable
Common text on the responsibilities of economic operators	Clearer definition of responsibilities of economic operators will strengthen the legislation's coherence. Benefits for economic	Unquantifiable

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Change in regulatory and administrative requirements	*Potential impacts/ benefits*	*Estimated saving potential*
	operators marginal, but potential safety and health benefits	
Retain current numbering of the Annexes to the Lifts Directive	Reduced cost of updating documentation	Unquantifiable
Free provision of abstract versions of standards	Reduced unnecessary expenditure on standards	Indicative saving of €60-€350 per standard unnecessarily purchased

8. Overall conclusions - lifts

Lifts for persons are a harmonised product group for which there is one overarching piece of legislation. The Lifts Directive 95/16/EC (LD) incorporates different elements of product safety (including electrical safety) that for other product groups would be covered separately by the LVD. Other Directives, such as the EMC Directive also apply. IM legislation affecting the lifts sector was found to be coherent with no specific gaps overlaps, inconsistencies or duplication identified. The Machinery Directive 2006/42/EC (MD) applies to certain types of lifts, but the delimitation between the two Directives is clearly specified in the 2006 recast of the MD. This ensures mutual exclusivity between Directives and clarity for economic operators.

The "big four" lift manufacturers account for some 60% of the EU market, estimated at €15 billion in in 2009 (EFESME). NACE data shows that there are over 9,500 enterprises in the lifts sector, the majority of which are SMEs. A particular characteristic of the lifts sector is that the manufacturing of lifts only accounts for one third of total market size, while the remainder is made up of after-sales services (maintenance 41%, repair 7%, and modernisation 18%). Whereas manufacturing activities and initial installation are regulated through IM legislation, once installed, lifts fall under national in-service inspection regimes. The costs of lifts maintenance and the costs linked to periodic servicing once in use are a significant cost, but are note linked to European legislation.

The Lifts Directive accounts for the majority of administrative costs, although such costs are minimised by the fact that the relevant harmonised standards take into account the compliance requirements of other relevant directives, notably the Electromagnetic Compatibility Directive (EMC). This means that if a manufacturer follows the standard and carries out a conformity assessment based on the standard, they will have met their regulatory obligations across all relevant pieces of legislation. Familiarisation with legislation is undertaken in-house by the large companies using specialist staff. When developing products, the large manufacturers tend to undertake their own tests, using in-house staff and following quality assurance systems approved under Module H, which serves to minimise cost. The requirement for compulsory third party conformity assessment procedures and the supporting technical documentation tends to be the most burdensome requirement of the legislation. However, the firms emphasised that much of the required testing would be undertaken in the absence of legislation, for reasons of product safety and quality. The administrative requirement related to conformity assessment procedures undertaken in the product development stage are quite high initially, but occur only once. In contrast, the administrative requirement related to conformity assessment procedures in the installation process are higher, as as inspections have to be undertaken for each new lift installed. The task of producing the Declaration of Conformity and CE marking is not particularly costly.

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Based on the research, the costs of compliance may are estimated at €26m p.a. for a production volume of 255,000 units across the EU. This represents around 0.89% of total revenue of €2,960m from manufacture and installation of whole units in the EU. However, the companies interviewed were unanimous in reporting that the cost of complying with EU legislation was less than under a "benchmark" scenario in which national legislation differed from country to country. Clearly, these costs are more onerous for SMEs than for large companies that can spread compliance costs among a large number of units.

There is limited scope for simplification of the legislation and manufacturers currently benefit from a stable legal framework. Some minor administrative savings could be realised in the recasting of the LD, namely providing common definitions of different types of lifts, providing common text on the responsibilities of economic operators and retaining the current numbering of the Annexes to the LD. Some practical tools may also help reduce costs for industry, such as making abstract versions of standards freely available which would save companies around €60-€350 per abstract purchased unnecessarily (out of a total cost of around €2,000 spent each year by a typical company).

9. Sources of information

References

- Eurostat Structural Business Statistics Database and Prodcom
- Text of applicable IM legislation and relevant standards
- Guidance documents of Lifts Directive and Machinery Directive
- Dispan, J. (2007), Industry report - Lifts and escalators – an industry in flux, IMU Institute Stuttgart
- Elevators and Escalators - A Global Strategic Business Report 10/12

Interviews:

- 3 EU industry associations: European SMEs in the lift industry (EFESME), European Lifts Association (ELA), European Lifts Components Association (ELCA)
- 1 national lift association
- 8 manufacturers of lifts
- 2 manufacturers of lift components

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CASE STUDY 5 – GARDENING EQUIPMENT

1. Introduction – objectives of the study

The case study examines gardening equipment with focus on three specific categories, chain saws, lawn mowers and brush cutters. Gardening equipment can be electric, battery powered or petrol based and they are used both by consumers and professionals.

The aim is to analyse the applicable IM legislation, assess the costs associated with the implementation of the applicable IM legislation, identify areas of overlaps and conflicts between the different parts of the legislation that may lead to problems and costs to industry and identify and assess the benefits of possible simplifications. The rationale for the selection of these product groups was that:

- Lawn mowers are covered by a rather large number of IM Directives and Regulations, 8-10 depending on the type of product;
- The sector is dominated by a few large manufacturers; and
- The conclusions drawn from an assessment of these specific products could be used to assess with some level of confidence the administrative and compliance costs to the broader category of domestic appliances since most of the products within this group are usually covered by the same pieces of legislation.

The case study is based on desk research and interviews with the EU industry association representing manufacturers of gardening equipment (EGMF) and five in depth interviews with manufacturers of gardening equipment operating in Europe, two large manufacturers, two medium and one small.

2. Product definition and description of structure of the sector

The focus of case study has been three types of gardening equipment, chain saws, lawn mowers and brush cutters. These categories represent the main sales volume of the broader garden machinery equipment group of products that also includes various types of trimmers, vacuums and blowers, leaf blowers, leaf collectors, motor hoes (<3 kW), scarifiers, shredders/chippers and pruners. Gardening equipment are used both by consumers and professionals although there are often differences in terms of engine power and features and some products that are typically used by professionals (e.g. garden tractors). The following paragraphs provide a more formal definition of the three products under examination on the basis of the relevant EN standards:

Lawn mowers[70]

According to EN standard EN836 a lawnmower is “a walk-behind or ride-on grass cutting machine or a machine with grass-cutting attachment(s) where the cutting device operates in a plane approximately parallel to the ground and which uses the ground to determine the height of cut by means of wheels, air cushion or skids, etc., and which utilises an engine or an electric motor for a power source. The cutting devices are either rigid cutting elements or non-metallic filament line(s) or freely pivoting non-metallic cutter(s)”. A lawnmower may be a walk-behind or ride-on grass cutting machine or a machine with grass-cutting attachment(s) where the cutting device is rotating about a horizontal axis to provide a shearing action with a stationary cutter bar or knife (cylinder mower).

[70] The definition comes from EN 836

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Chain saws

A chainsaw (or chain saw) is a portable mechanical saw, having teeth that are linked to form an endless chain, rotated about two pivot points by a power mechanism that can be an electric motor, a gasoline engine, compressed air, hydraulic power.

Brush cutters[71]

A brush cutter is a combustion-engine driven portable hand-held unit fitted with a rotating blade made of metal or plastic intended to cut weeds, brush, small trees and similar vegetation. The cutting device operates in a plane approximately parallel to the ground.

Market size and industry structure

Data available from Eurostat PRODCOM database already provide relatively detailed data on the level of production and trade of chain saws, lawnmowers and cutters. The following PRODCOM codes fit rather well with the specific product groups under examination:

- 28241180 - Electro-mechanical hedge trimmers and lawn edge cutters
- 28304010 - Electric mowers for lawns, parks, golf courses or sports grounds
- 28304030 - Mowers for lawns, parks or sports grounds, powered non-electrically, with the cutting device rotating in a horizontal plane
- 28304050 - Motor mowers for lawns, parks or sports grounds, powered non-electrically, with the cutting device rotating in a vertical plane or with cutter bars
- 28304070 - Non-motorized mowers for lawns, parks, golf courses or sports grounds (such as push cylinder mowers) (excluding with the cutting device rotating in a horizontal plane)
- 28241123 - Electro-mechanical chainsaws
- 28241260 - Chainsaws with a self-contained non-electric motor

The data analysis suggests a total market size (production+ imports – exports) of around €2.5 billion for those categories with a total volume of 23 million chain saws, lawn mowers, trimmers and cutters sold. Imports are, according to PRODCOM, close to 60% of to total consumptions. Our interviews with manufacturers suggest that this is a reflection of the important role of non-EU producers (US firms are particularly strong in certain segment) but also the fact that many EU producers have transferred part of their production capacity outside Europe but with most of the production re-imported to the EU. Along with the US market (50% of the global sales), the European market remains the most important market for gardening equipment (35%).

Table 1 – PRODCOM data for Lawn mowers, trimmers, cutters and chain saws (2010)

Product code	Export quantity (000s)	Export value (millions)	Import quantity (000s)	Import value (million €s)	Production quantity (000s)	Production Value (million €s)	Total quantity (000s)	Total Value (million €s)
28241180	650	23	5,881	122	1,510	63	**6,741**	**162**
28304010	340	28	1,461	64	2,826	169	**3,947**	**205**
28304030	264	62	1,774	389	3,375	862	**4,885**	**1189**
28304050	7	11	194	88	21	36	**208**	**113**

[71] The definition comes from EN ISO 11806

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Product code	Export quantity (000s)	Export value (millions)	Import quantity (000s)	Import value (million €s)	Production quantity (000s)	Production Value (million €s)	Total quantity (000s)	Total Value (million €s)
28304070	49	4	187	6	150	23	**288**	**25**
28241123	180	16	1,317	49	517	51	**1,654**	**84**
28241260	99	13	2,817	192	2,341	564	**5,059**	**743**
Total	**1,589**	**157**	**13,631**	**910**	**10,740**	**1,768**	**22,782**	**2,521**

Source: Eurostat

Data from the European garden machinery federation (EGMF) deviate slightly from PRODCOM suggesting a EU market size of around 15.1 million gardening equipment products of which around 6 million are lawnmowers and 3 million are brush-cutters. There are also 3 million hedge-trimmers and 4.5 million chainsaws sold on an annual basis[72]. According to another study[73], around 4.5 million lawnmowers are sold annually in the EU with chain saws, hedge trimmers and lawn trimmers also being at a 7-digit level.

According to an earlier study[74] around 90% of sold lawnmowers on the European market are of the walk-behind type with cutting blade widths up to 50 cm, while the sales of ride-on is around 300,000 units.

Data from the UK[75] indicate that the consumer market represents around 60% of the total gardening products market with the remaining directed to professional users. Another study[76] raised the consumer segment in the whole of the EU to 75%. Lawn mowers represent around 40% of the consumer gardening equipment market in the UK (based on retail sales) with another 35% going to various types of power tools such as chain saws, cutters and trimmers.

Professional equipment has a relatively short lifespan of 2 years with an average usage of 150 hours per year. Consumer equipment has a lower usage rate of around 5 hours per year with a typical lifespan of several years[77].

Table 2 – Data on market size and industry structure

Parameter	Data
EU Market size (2012)	EGMF: 10 million units for the whole Europe (39 countries) PRODCOM : 22.7 million units, € 2.5 billion
Production in EU27	PRODCOM : 10.7 million units, € 1.8 billion
Imports	PRODCOM : 13.6 million units, € 0.9 billion

[72] http://www.egmf.org/en/economic-information/

[73]Data from the UK indicate that the consumer market represents around 60% of the total gardening products market with the remaining directed to professional users. Lawn mowers represented around 40% of the consumer gardening equipment market in the UK (based on retail sales) with another 35% going to various types of power tools such as chain saws, cutters and trimmers.

[73]According to the EGMF, its members sell in Europe more than 6 million lawnmowers, 4.5 million chainsaws, 3 million brush-cutters and 3 million hedge-trimmers on annual basis

[73] http://ec.europa.eu/enterprise/sectors/mechanical/files/noise/iastudy_noise_finrep_en.pdf

[74] 'Lawn Mover Noise and Vibration Control' study (Tetteroo & Bockhoff, 2006) cited in http://ec.europa.eu/enterprise/sectors/mechanical/files/noise/iastudy_noise_finrep_en.pdf

[75] http://www.britishgardenshed.co.uk/uk_market.htm

[76] NOMEVAL (TNO, 2007)

[77] http://ec.europa.eu/enterprise/sectors/mechanical/files/noise/tno_nomevalrep12-12-07_en.pdf

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Parameter	Data
Exports	PRODCOM : 1.6 million units, € 0.16 billion
Number of enterprises (2010)	20 large firms
Number of employees (2012)	30,000 employees (EGMF) 120,000 in dealers

Source: Eurostat

Industry structure

Eurostat data are not particularly useful when it comes to analysing the structure of the industry. There are two relevant NACE codes (28.24 - Manufacture of power-driven hand tools; 28.30 - Manufacture of agricultural and forestry machinery) which are much broader in scope and do not allow for meaningful conclusions.

The information provided by EGMF suggests that the consumers market is dominated by 20 large size companies that occupy around 30,000 employees. This has been the result of a significant consolidation phase in the last twenty years which has led to few large players bringing together small and medium size manufacturers while retaining the brand names and the production units across Europe. Brand awareness is relatively high among consumers, and technological barriers also make it difficult for new competitors to enter the market. The tendency is explained by the high fixed costs faced by individual product lines. According to one estimates that development costs correspond to 5% of its turnover[78]. The 13 members of EGMF- including both large multinationals and smaller size firms - cover almost 75% of the European market. The main players in the market – although this may differ in the different sub-sectors – are Husqvarna (SE), Stihl (DE), Bosch (DE), Global Garden Products (IT), MTD (US), Toro (US), John Deere (S), Stanley Black and Decker (US), Echo (DE), TTI (HK) and Makita. [79]

In the professionals market there are a few SMEs producing a wide variety of models and there are 147 brands and 1500 models for lawnmowers. Still, around 80% of the European market for professional handheld internal combustion engine powered equipment is covered by 4 European companies. SMEs are niche players, with specialised knowledge of specific client needs.

3. Analysis of applicable IM legislation and standards

Chain saws, lawn mowers and brush cutters (gardening equipment) are covered by a large number of IM Directives and Regulations covering a range of aspects:

- **Health and safety**: The Machinery Directive (2006/42/EC) is the main applicable legislation for all products. In the case of electricity/battery powered products requirements of the Low Voltage also apply but not the procedures and information obligations that are covered by the Machinery Directive. In the case of lawn mowers, brush cutters self-certification (Module A) can be used for conformity assessment. In the case of chain saws which are included in Annex IV, third party certification from a notified body is required.

[78] SME Test Study on possible policy options for reviewing the Noise Directive + Impact Assessment Study on possible policy options (concerning conformity assessment procedures) for reviewing the Noise Directive), http://ec.europa.eu/enterprise/sectors/mechanical/files/noise/smetest_noise_finrep_en.pdf (p.59)

[79] Data retrieved from Euromonitor international Passport database (accessed from British library)

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- The **General Product Safety Directive** (2001/95/EC) is also applicable but does not introduce additional requirements to refrigerators since these are covered by the other more specific pieces of legislation. It does introduce however other obligations, mainly of administrative nature;
- **Electromagnetic compatibility**: The EMC Directive (2004/108/EC) applies to all powered gardening equipment.
- **Noise**: The Outdoor Noise Directive (2000/14/EC) is particularly relevant to gardening equipment and introduces requirements concerning the sound power level which needs to be measured under specific conditions. It also requires that manufacturers submit a copy of the Declaration of Conformity (DoC) to the Member State authorities and the Commission.
- **Pollutant Emissions**: Gardening equipment have been covered by the Directive 2002/88/EC on Gaseous Emissions of non road mobile machinery (NRMM) since 2004. It covers spark ignited (SI) engines (petrol engines) up to 18 kW for engines installed in and held and non-handheld equipment such as lawn and garden machines. Certain small SI engine applications (including some trimmers) were exempted from the Stage II emission limits but these exemptions expired at the end of the first quarter of 2011. However, it should be noted that many manufacturers of gardening equipment purchase the engines from dedicated suppliers which have the responsibility to ensure compliance with the NRMM.
- **Chemicals**: Both RoHS Directives and REACH Regulation certain obligations to manufacturers of gardening equipment in terms of the chemicals included in the equipment. As downstream users, under REACH gardening equipment manufacturers need to ensure that the products do not contain substances of very high concern and, if they do, they need to pass information to their customers.

In addition, for certain type of gardening equipment products there are additional pieces of IM legislation applicable:

- for battery based products the Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators
- for products with remote control features using wireless technology, the RTTE Directive is also applicable

The following table analyses the main requirements arising for economic operators as a result of the different pieces of IM legislation and indicates the relevant harmonised and other standards applicable.

Table 3 – Summary of IM legislation covering refrigerators and freezers and the relevant standards

Name of legislation	Issue addressed	Requirements for economic operators	Relevant standards[80]
Machinery (2006/42/EC)	Safety	Requirements concerning safety and health of lawn mowers Information warnings and pictograms	EN 836 [81] EN ISO 5395-1/2/3 [82]

[80] The list of standards is not exhaustive. Furthermore, not all standards identified are applicable to all products.
[81] safety of powered lawnmowers
[82] safety of electrically powered lawn mowers

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Name of legislation	Issue addressed	Requirements for economic operators	Relevant standards[80]
		Conformity assessment on the basis of self-certification (module A) – Except for chain saws Develop technical file to be available upon request of authorities Declaration of conformity Marking of product (CE marking, name of manufacturer, type, series, year of construction)	EN 11681-2[83] EN ISO 11806 EN 60335-2-91/ EN 60335–2-77/EN 60335-2-107/EN 60745-2-13
LVD 2006/95/EC	Health & Safety	Testing according to relevant standards or alternative solutions (other requirements under Machinery)	EN 60335-1
General product safety Directive	Health & Safety	Provide identification of the product by a product reference Carry out sample testing of products, keep a register of complaints and keeping distributors informed of such monitoring (voluntary) Inform authorities of dangerous products and actions taken to prevent risk Co-operate with the authorities upon request	
EMC (2004/108/EC)	Electromagnetic compatibility (for electric powered equipment)	Testing according to standards Development of technical file Declaration of conformity and CE marking	EN 61000-6-1 EN 61000-6-2 EN 61000-6-3 EN ISO14982
NRMM Emissions (97/68/EC and amendments)	Emissions of ride-on combustion engine powered lawn mowers	Application for type approval of engine or engine type Information dossier Testing of engines Approval by technical service Affix label with EC type approval marking with ID number and information on engine type and trade mark	
Outdoor noise Directive (2000/14/EC	Noise	Meet sound level requirements (Stage II levels for most gardening equipment) Conformity assessment (Modules A and control by notified bodies, G,H)	EN ISO 3744**: 1995** [84] ISO 10884:1995/ISO

[83] Machinery for forestry - Portable chain saws - Safety and testing requirements
[84] Determination of sound power levels and sound energy levels of noise sources

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Name of legislation	Issue addressed	Requirements for economic operators	Relevant standards[80]
)		Declaration of conformity Place CE marking and marking of the guaranteed sound power level Send copy of DoC with information on measured and guaranteed sound to national authorities and the Commission (complete information in database)	9207:1995/ISO 11094:1991[85] EN ISO 22868[86] EN ISO 11094[87] EN ISO 4871[88]
REACH	Use of chemicals	Collect statement from suppliers stating that products are in compliance with requirements concerning chemical content of components Test the content of articles of products for substance of very high concern (not mandatory) Issue REACH compliance statement	
RoHS	Use of hazardous chemicals	Collect compliance statement from suppliers (material declarations) Develop technical file with supplier declarations and own analysis tests Declaration of conformity to be kept for 10 years	
Batteries Directive (2006/66/EC)	Heavy metal content and labelling of batteries	Forbids placing on the market batteries/ accumulators containing mercury or cadmium Design products so that batteries can be removed Information on the type of battery used Contribute to costs for establishment of battery collection schemes at national level (applies in some cases)	
Packaging and packaging waste	Packaging	Declaration of Conformity	Standard EN 13427

The review of the various requirements and the discussions with manufacturers pointed to a few issues in relation to the implementation of the legal framework and the requirements:

- large number of applicable pieces of legislation makes the whole system complex and increases legal uncertainty. The changes to the different pieces of legislation or the relevant standard in different periods also means that, quite often, firms need to introduce changes to product design,

[85] Test area standard for different categories
[86] noise test for internal combustion lawn mowers, brush cutters, trimmers
[87] test code of airborne emissions for powered mower
[88] Declaration and verification of noise emission values of machinery and equipment

procedures, declaration forms or produced information manual which larger or smaller cost implications;

- an area of concern indicated by some firms is the problematic relationship between the Machinery and the outdoor noise Directive. A key issue indicated is that for the measurement of sound power level which falls under the Outdoor Noise Directive there is still reference to the outdated 1995 version of the ISO/EN 3744 standard while, for those products not covered by the outdoor noise, but covered by the Machinery Directive the most recent 2010 version is used. More generally, in the recent consultation[89] 80% of the respondents expressed the wish to merge the methods of measuring noise emissions required under both directives into a single Harmonised Standard;
- duplication in parts of the certification process – mainly the fees to the third parties - in the case where manufacturers sell to other firms products similar to those they sell under their own brands with only minor- cosmetic – differences (e.g. different color). For these products, which are identical with those that have already undergone conformity assessment but have a different name (model number), manufacturers are required to pay additional fees;
- firms indicate that, while there have been clear benefits from the harmonisation of the applicable legislation, there are significant problems with market surveillance which, in their view, means that much cheaper, lower quality and arguably non-compliant products circulate in the market;
- the review of the requirements of the Declaration of Conformity indicate minor differences in terms of the terminology used or the type of information to be provided. However, the discussion with industry did not suggest important conflicts or problems. Still, the alignment process across all Directives is considered rather welcome.

4. Analysis of costs of compliance with IM legislation

The information presented in this section is based on the in-depth interviews with 5 manufactures of gardening equipment. The firms range in terms of size and production volume. They also have different approaches in terms of the level of testing and other R&D activities they perform that are not a direct result of the legislation which is a reflection of their size and position in the market.

Table 4 - Basic information on the firms interviewed

Firm	Specific product considered	Firm size	Annual sales from product	Main markets
A	Brush cutters	Large (>1000 employees)	1 million units	50% of sales in the EU
B	Lawn mowers	Large (>1000 employees)	1 million units	90% of sales in the EU
C	Lawn mowers	Medium (250-500 employees)	200,000 units	90% of sales in the EU
D	Lawn mowers	Small (<250 employees)	15,000 units	100% of sales in the EU
E	Chain saws	Medium size (250-500)	100,000 units	50% in the EU

[89] Public consultation on the revision of Directive 2000/14/EC on noise from outdoor Equipment, http://ec.europa.eu/enterprise/sectors/mechanical/files/noise/public-consultation/report_en.pdf

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On the basis of the discussion with firms the process followed by manufacturers of gardening equipment to ensure compliance with the IM legislation includes:

- familiarisation with the applicable IM legislation and the respective requirements, identification and purchase of relevant standards and in some cases other preparatory actions in training of staff.
- introduction of changes to the product design and the production process to ensure compliance
- conformity assessment procedures including the relevant testing and the development of the technical file, the use of notified bodies for certification if/when required, preparation of declaration of conformity (DoC), CE marking and placing in the market
- other activities in response to requests of the market surveillance activities

Preparatory actions: Familiarisation with relevant legislation and purchase of standards

Familiarisation with IM legislation and the respective requirements represents a first task for all firms. Almost all firms indicated that this is not a particularly demanding part of the process and it usually corresponds to no more than 0.1-0.2 FTE of a member of the legal compliance team. However, most firms also indicated that the R&D or homologation departments try to monitor developments in the legislation and one of them even performs a scenario analysis aiming to prepare for alternative scenarios.

All firms interviewed indicated that they maintain a database of the relevant pieces of legislation which is continuously updated and also includes information in relation to the relevant/applicable standards. Maintenance and update of the database usually occupies an employee of the firms compliance/homologation department on a part-time basis. The sophistication of the database tends to be greater for larger size firms.

In relation to use of standards all firms consider them crucial in the conformity assessment process. The information provided suggest that firms typically spend €500-€2,000 on an annual basis for the purchase and update of standards and the reading licences for their various departments for a single product line (e.g. lawn mowers), for which 15-20 different standards are applicable.

Compliance with the applicable IM legislation.

Ensuring compliance with the applicable IM legislation often requires changes to existing product design or new product development. Furthermore, the introduction of new products requires product design work and testing to ensure that the new products are in compliance with requirements. While in most cases new product development is driven by market demand there are also cases where product development and R&D activity are primarily driven by legal requirements. More specifically, most firms indicated that the Non-Road Mobile Machinery (NRMM) and the Outdoor Noise Directives have led to significant level of investment. In the case of the NRMM, some firms purchase the combustion engines from suppliers and do not perform own research.

Large size Firm A indicated that around 3% of its annual R&D budget of €50-60 million invested to the development of a new product is directly related to ensuring compliance with internal market legislation (circa €4 million). On top of that they have made one of investments of around €10 million in tooling/equipment during the last five years. Small size firm D indicated annual costs for product design of €200-300k while medium size Firm C around €2 million. The amounts invested on product design vary depending on the firms' size but, on the basis of the data provided, the total investment on an annual basis is around €500,000 for every 100,000 units of production.

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Testing of products is an important part of these costs. It includes tests directly related to the IM legislation but also product performance and durability. For the large scale producers, these tests take place primarily in-house on an ongoing basis while for smaller firms these are often outsourced. Firm B suggested that around 15% of the budget and time of the 30 researchers and engineers working full time in the R&D department with around 30 FTE allocated to tests required by IM legislation for product homologation. The other firms indicated costs in the range of €200-700k.

Certain directives (NRMM, Outdoor noise) require specific testing facilities. Large size manufacturers may purchase for their internal controls while in other cases these may be outsourced to specialised labs. Estimates for the one-off costs for the purchase of testing equipment from large Firm A are around €30 million covering all products in the product line and all applicable Directives. €5 million were spent for chemical analysis equipment for REACH testing and €5 million for a sound chamber for outdoor noise tests. However, it should be noted that REACH related testing is not mandatory and it reflects the specific policy of this company that is not replicated among the smaller size manufacturers. Most other firms indicated smaller size investments in the range of 100-1,000,000 which were also confirmed from another data source (€0.6 million for noise measuring room).

The discussion with firms suggest that, on average, around 50% of the testing activities are directly related to IM legislation while the remaining is part of the quality and durability testing of products. The outdoor noise and the NRMM are for most firms the pieces of IM legislation that introduce most costs.

Conformity assessment procedures

The information provided from manufacturers is that the whole process of conformity assessment of a new product tends to last around 9 months in total. This includes the preparation of the technical file, the inspection of the notified bodies and certification, preparation of the DoC and the required information manual and the placing of the CE marking.

The estimated time for the preparation of technical file for a single product ranges from 40-100 hrs[90] with around half of the time required whenever there are significant changes to legislation.

In terms of the use of notified bodies, which is mandatory in the case of the Outdoor Noise Directive, all firms indicated that they are used even when a third party is not mandatory. The data provided suggest that the annual budget of firms for services of Notified Bodies is in the range of €30-80k, around €4,000 for a single product.

The costs for notified bodies increase for firms that produce multiple variants of the same model with the same technical characteristics. Customs authorities often do not allow the placing of products on the market if the model is not the same as that indicated in the label attached. As suggested, the current label does not allow for the provision of information that will allow to identify both the basic model and its variant. There is additional administrative work created for every new variant of the same basic model (i.e. same product with only differences in colours and brand name). This also means costs for new labels, changes to relevant references in the instruction manual and fees (around €700/product and additional time of around 4 weeks) to notified bodies every time they need to certify that the initial technical file is also appropriate for the new model.

The interaction of the CE marking with other labelling appears also somehow problematic for some of the firms and introduces costs that, in principle they need not incur. More specifically Firm B

[90] One firm indicated 300hrs but this deviated from all others.

indicated that while the firm did not consider it necessary to apply for the German GS mark, it was in practice obliged in order to be able to sale in the German market as many retailers do not accept products without the GS mark. The cost for the GS mark certification of each model is around €1,200 and this needs to be renewed every 5 years for a bill of around €700. There is also a €800 annual fee charged by GS. In total, the annual bill for Firm B to get the GS mark certificate for all its lawn mower products placed in the German market is around €32,000.

Provisions of relevant information in the instruction manuals are also included in all Directives. There were no specific data provided for the time to develop the information manual. For most firms these are seen as part of the overall time for the conformity assessment process. Translation costs are also relevant here with average costs of around €3,000 for each different model.

In the case of products covered by the Outdoor Noise Directive additional information provision obligations arise since firms are required to submit information included in the DoC to the national and European authorities. One firm estimated that it can take up to 80 hours for the 20 different brush cutter models in its production line.

Certain information collection obligations arise from REACH Regulation. The main work is the collection of information from suppliers to ensure that no SVHCs are included. In the case of Firm A, around one FTE is allocated to the collection of this information from suppliers. One of the firms also conducts its own testing of the chemical content of certain components with annual costs for all products are around €500k. However, this is rather the exception. Most other firms are limited to the collection of declaration of conformity from their suppliers which is the responsibility of the purchases department.

Finally, under the NRMM there is the obligation to submit data to the national and European Database. While there are some problems with the process – sometimes difficult to update and problematic when introducing a new model with lower noise emissions – firms could not provide specific data on the specific time allocated and suggested that it is part of the work of the compliance/homologation department.

Business as usual

The discussion with firms indicates that a rather important part of the activities and the respective costs would not have taken place in the absence of the legislation. Firms estimated that, in total, between 10% and 35% of the compliance costs (substantive and administrative) would have incurred even in the absence of any legislation

5. Assessment of costs of IM legislation for the whole sector

On the basis of the information provided we have attempted to estimate the costs of compliance for the whole of the gardening equipment sector. The provided figures include the information concerning the Business as usual scenario (i.e. the fact that 10-35% of the product development costs should be expected to occur irrespective). Certain assumptions have been made concerning the number of firms affected since, besides the 20 large firms indicated by EGMF, there are also a number of smaller size manufacturers particularly in the professional market segment.

The table below summarizes the main costs per unit and for the total of the industry. As is evident costs for product design and testing represent more than 85% the total costs of compliance.

Table 5 – Summary of main annual costs of compliance for gardening equipment manufacturing industry

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	Unit of measurement	Average unit cost	Total quantity	Industry wide costs/year
Familiarisation with legislation/support actions				
- human resources	per manufacturer	€ 11,520	100[91]	€ 1,152,000
- costs of purchase of standards	per manufacturer and per product line	€ 1,250	500[92]	€ 625,000
Compliance with IM-legislation requirements				
- Product (re)design and testing	per 100.000 units	€ 500,000	22.7 million/year	€ 113,500,000
Share of product design and testing costs that would apply even in the absence of the legislation				10-35%
Net product design and testing costs				**73,775,000-€102,150,000**
- Testing equipment[93]	per manufacturer	€ 100,000	100[21]	€ 10,000,000
Share of product design and testing costs that would apply even in the absence of the legislation				10-35%%
Net costs for testing equipment				**€1,000,000-€3,500,000**
Conformity Assessment				
- Preparation of technical file	per single model	€ 2,100	375[94]	€ 787,500
- Costs of notified bodies	per single product	€ 4,000	375[23]	€ 1,500,000
- requirement for new labelling	per single model (once in four years)	€ 700	375[23]	€ 262,500
- translation costs	per single model (once in four years)	€ 3,000	375[23]	€ 1,125,000
Other				
- Submission of information for outdoor noise Directive	per manufacturer	€ 2,400	100[21]	€ 240,000

[91] We have assumed 20 large size firms (members of the EGMF) and 30-80 small firms
[92] On the basis of an average of 5 product lines on average per manufacturer
[93] Investment in testing equipment is usually one-off and last for at least 5 years. The costs provided here have been estimated on an annual basis.
[94] Number based on an assumption of 15 models/firm once in four years

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	Unit of measurement	Average unit cost	Total quantity	Industry wide costs/year
- Collection of REACH information	per manufacturer	€ 25,000	100[21]	€ 2,500,000
Total				**€85,467,000-111,342,000**

The estimated costs for the sector are in the range of €85-112 million/year which represent 3-5% of the total annual turnover of 2.5billion of the sector. This is a rather high share but the administrative costs – namely excluding product design and testing - are no more than 10%-15% of the total costs and less than 0.3% of the annual turnover of the sector.

6. Benefits of Internal Market legislation

The discussions with industry representatives and individual firms provided quite strong support of the success of the IM legislation towards achieving its prime objective, the creation of the internal market for goods and the avoidance of the costs arising from having to comply with different pieces of legislation covering the same aspects in different ways and with different procedures. According to one firm the harmonisation of EU legislation has possibly saved up to 80% of administrative costs for a firm selling across the EU. In the past there firms employed personnel travelling around Europe on an ongoing basis to ensure that products meet requirements and also had to send specimen of each new products to be tested in each of the EU Member States. These were important costs that the harmonised EU legislation has significantly reduced. As indicated by two of the firms interviewed, mainly as a result of these costs in the past firms would not enter markets where they expected only very few sales. From their point of view, the IM legislation has significantly reduced the threshold for exporting in other EU countries.

In terms of access to global markets, the views of the industry representatives was that there is still quite some work to be done towards the alignment of international requirements. Lastly, as regards the role to new product development and innovation the general view is that the requirements introduced are technologically neutral and do not pose specific barriers.

7. Analysis of simplification options

The discussions with industry pointed to a few areas where changes to the internal market legislation could lead to sizeable savings and in some cases it was possible to make an estimate of possible cost savings. The simplifications examined are analysed below.

Merging Machinery and Outdoor noise Directives

This is a proposal that has come from various sources and there is currently a dedicated study examining this proposal in detail. In general the industry appears positive towards such a development on certain conditions. The EGMF representative suggested that a merger with the Machinery Directive can bring important benefits only if there is no actual change to the Machinery Directive and the relevant outdoor noise requirements are only added as an appendix to the Machinery Directive. This will also mean that Module A (self-certification) will be available for ensuring conformity with the outdoor noise requirements, that the relevant and updated harmonised standards related to the Machinery Directive will be used.

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It is also expected to bring savings in relation to paperwork for DoC, reduce – if not eliminate - the cost of notified bodies, streamline the market surveillance procedures and also ensure that testing of products take place on the basis of the more up-to-date harmonised standards in the Machinery Directive and outdated limits and test codes included in the text of the Outdoor Noise Directive are avoided. Three of the five firms interviewed indicated that they expect savings from fewer tests for sound testing (up to 20% of the total of the noise tests required for the Machinery and the Outdoor noise Directives according to large Firm A) needed and the human resources for the preparation and update of the documentation involved. Furthermore, on the basis of the data provided, a small reduction of testing costs (5%) could lead to sizeable savings of €3.5- €5 million annually, around 4% of the estimated total compliance costs for the sector. To that one could add the savings from a reduction of human resources allocated to preparation of technical files and Declarations of Conformity and the costs of notified bodies. Nonetheless, given the small share of administrative costs in the total compliance costs (10-15%any simplifications will not have a sizeable impact on the costs for the sector. Even a sizeable 20-30% reduction of administrative costs will not bring more than 2% reduction to the total compliance costs. For the whole gardening equipment sector this could be an equivalent of €1.6-2.3 million savings on an annual basis.

It should also be noted though that an alternative scenario where the requirements and processes of the Outdoor Noise Directive are adopted (e.g. mandatory third part certification) is expected to lead to higher costs and not to savings[95].

Single harmonised standard covering all pieces of legislation

Most firms are in favour of a single standard covering all applicable legislation. Besides the savings from the purchase of standards – which represent a very small cost – industry representatives referred to greater legal certainty and the benefit for firms – particularly SMEs that lack technical expertise – of working with a single document. The potential cost savings are mainly related to the costs of familiarisation with requirements and a possible efficiency savings in the testing of products and the development of technical files. There were no estimates of the expected cost savings from the introduction a single standard provided by the firms interviewed. However, on the basis of the costs estimated provided above, a 20% efficiency savings in relation to the human resources and time for familiarisation with legislation, the purchase of standards and conformity assessment procedures could not lead to a cost reduction of more than 0.2% of the total turnover of the sector. However, at the firm level a possible saving of up to €3,000 annually can be significant for small firms.

On the other hand, one firm also pointed to the significant one-off costs for the industry for the development of the relevant standard. More important though, there is also the danger that the standard development process – already often considered slow, complicated and not accessible to firms with limited resources – will become more complex and the process for the development of the standard even longer.

Reduce frequency of changes to standards

Four of the five firms interviewed and EGMF indicated that a possible reduction in the frequency of changes to harmonised standards as a possible cost saving measure. There have been frequent changes to harmonised standards related to outdoor noise in the last year almost once a year – although on average the analysis of the frequency of update of the harmonised standards is around 4-5 years.

[95] This appears to be a position taken by Orgalime that representatives of a much broader range of manufacturing sectors. See http://www.efcem.eu/media/uploads/dopp_on_merger_md-noise_final.pdf

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From the administrative costs side it can lead to less frequent changes to Declarations of conformity and replacement of manuals which can possibly lead to savings of up to €5k/firm. For large firms it also means less human resources allocated to the standards development process. In addition, less frequent changes to standards will lead to less frequent need for investment in testing equipment investments and product design activity to meet new requirements for existing models. The savings in such case may be significant. In theory an increase in the period of renewal from 5 to 6 years for all standards could possibly lead to a reduction of compliance costs linked to testing and product design of up to 17% although in practice this would probably be smaller due to the fixed costs involved irrespective of the frequency of changes to standards and requirements.

However, although in terms of cost savings such a measure could be justified in the case of very frequent changes, as a general principle it is probably not appropriate. Given the central role of standards in the implementation of the legislation and the integration of new technological development there are important concerns that less frequent changes will hinder technical progress and essentially award firms that are not investing in new technologies.

Include information on Declarations of conformity to identify model variants

As indicated in the analysis of the costs of compliance firms that produce products to be sold under their clients brand names often need to produce new labels, change references in instruction manuals and pay fees to notified bodies for each variant. It is suggested that a change to the DoC to include references to variants to basic models that will identify the product even if sold under a different brand will bring savings to firms of €700-1000/model. Given that there are no data on the share of the OEM market and the number of products under this label it is not possible to estimate the possible savings. The EGMF representative indicated that share of such products is rather high in the low quality and cheap segment of the market.

Clearly, for firms selling only products with their own brand there will be no savings. For firms selling as OEMs the annual savings will depend on the number of different variants sold to different clients. On the basis of the information provided it could be up to a few thousand Euros annually. The share of such products in the market is also not clear. Furthermore, it depends as to whether the OEM transfers these costs to the final dealer or manufacturer that sells under their own brand and which are the ones ultimately responsible for the product.

Table 6 - Summary of simplification/improvement options examined

Change proposed	Expected benefit/problems	Estimated saving potential
Introduce single standard covering all IM legislation	Increase clarity/easier to work (especially for SMEs) Reduce costs for standards Longer/more complicated process for the development of standard	Saving of €500-1,000 annually on purchasing of standards Total efficiency savings for testing and conformity procedures of up to €3,000/firm One-offs costs for industry for development of standards
Merging of Machinery and Outdoor noise Directives	Different definitions and test codes will be abolished Reduction of costs of notified bodies if self-certification under Machinery Directive is adopted	Cost savings of up to 4-5% of testing costs (€3.5-5 million/year) But limited overall savings expected (no more than 1.2% of

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	Possible efficiencies for testing Efficiencies in relation to the Declarations of Conformity and technical files	total costs)
Reduce frequency of changes of standards/coordinate changes	Reduce uncertainty Reduced costs for replacement of all manuals Saving on investment for testing equipment and product design expenditure	Up to €5k/firm for administrative costs Up to 17% savings in product design and testing costs from an increase in the period for renewal of standards by one year.
Changes in the in DoC allowing to identify a model and the variants	Reduce costs for conformity assessment for firms operating as OEMs	Up to €1000/model. A few thousand Euros annually for small number of firms.

A final suggestion made by a couple of manufacturers was the possibility to include footnotes within the text of the applicable pieces of legislation to explain and clarify the intentions of the different provisions. This is expected to improve readability and address any uncertainties that may lead to lost time – in terms of human resources - during the various stages of the process. The manufacturers could not provide indications as to what would be the possible time savings from this. Given the cost estimates provided earlier and the fact that human resources represent only a small part of these costs, the possible savings are most probably less than 1% of the total costs. Furthermore, we should note that is not very different from the guidance documents that have already been developed for a number of Internal Market Directives.

8. Conclusions

Gardening equipment covered in this case study includes chain saws, lawn mowers and brush cutters. These categories represent the main sales volume of the broader garden machinery equipment group of products which also includes various types of trimmers, vacuums and blowers, leaf blowers, leaf collectors, motor hoes, scarifiers, shredders/chippers and pruners. The total annual market size of gardening equipment is estimated at around €2.5 billion for those categories with a total volume of 23 million sold. The consumer segment of the gardening equipment market is dominated by 20 large size companies while in the case of professional equipment there is a greater number of SMEs serving niche segments.

Gardening equipment is covered by more than 10 different pieces of IM legislation (Directives and Regulations) covering a range of aspects including health and safety, environmental aspects (noise, pollutants, toxic from batteries).

For the whole sector the estimated annual costs are in the range of €85-112 million which represent a rather significant 3-5% of the total annual turnover of €2.5billion of the sector. This is driven by the high compliance costs associated with the environmental IM legislation (outdoor noise, outdoor

emissions) both of which required changes in the design and rather sizeable costs for testing equipment (one-off) and on-going testing of products, only a small proportion of which is considered to be "business as usual" for most firms. Administrative costs – such as costs for documentation, fees to notified bodies, the preparation and updating of technical files, purchasing standards, the development of manuals - are no more than 10%-15% of the total costs and no more than 0.3% of the annual turnover of the sector.

The analysis also identified a number of possible simplification options with sizeable cost saving potential. The merging of the Machinery and Outdoor Noise Directives could bring relatively sizeable cost savings if it were to integrate the outdoor noise requirements within the Machinery framework and maintaining the key aspect of self-certification that can bring important savings in terms of costs for testing and for notified bodies. Since administrative costs are still no more than 10-15% of the total costs the possible savings will not be more than 1-2% of the total compliance costs. Other possible simplifications examined were the possibility of adopting a single standard covering all applicable pieces of legislation and a reduction of the frequency of updates. Both can have important costs savings but also introduce the risk in terms of the effectiveness of the standard development process.

Additional cost savings may arise - in terms of reduction of fees to notified bodies - by introducing changes to the DoC to include references to variants to basic models. This will affect primarily the low end of the market that very often includes OEM products produced by a manufacturer that are then sold by the clients brand names. The savings may be up to a few thousand Euros per firm annually.

Irrespective of the sizeable costs of compliance, industry is rather supportive in terms of the role of IM legislation towards developing an internal market for goods and eliminating the costs arising from having to comply with different pieces of national legislation. As indicated by some the firms, as a result of these costs firms often not enter markets where they expected only very few sales. The legislation is also seen as technology neutral and does not pose specific barriers. There is however, more work to be done towards the alignment of international requirements.

9. Sources of information

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Interviews

- Industry association : European Gardening equipment manufacturers associations (EGMF)
- 5 interviews with manufacturers of lawn mowers, chain saws and brush cutters

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CASE STUDY 6 – FUEL DISPENSERS (MEASURING INSTRUMENTS)

1. Introduction - objectives of the study

This case study focuses on fuel dispensers which are classified as instruments and appliances for measuring, testing and navigation (hereinafter measuring instruments) and are covered under the Measuring Instruments Directive 2004/22/EC. The manufacturing of fuel dispensers is also regulated by a number of other pieces of EU legislation, such as ATEX and the Petrol Vapour Recovery Directives.

The rationale for the selection of fuel dispensers was that:

- The sector, while dominated by four large firms, also includes a large number of SMEs;
- The legislation allows for the use of internationally-agreed normative documents, as an alternative to the use of harmonised standards;
- The MID 2004/22/EC is one of ten Directives that form part of the Alignment Package; and
- The case has the potential to demonstrate the advantages of coherent interaction and clear demarcations between different pieces of legislation, in order to ensure legal clarity for economic operators.

The information presented in this case study was obtained from a variety of sources including Eurostat data, official EU documents, industry association documents and interviews with four major firms in the sector.

2. Product definition and description of structure of the sector

Product definition

Fuel dispensers are classified under NACE code 28.13 (manufacture of other pumps and compressors) and correspond solely to the PRODCOM Code 28131105: petrol and oil dispensing pumps.

Fuel dispensers are described as machines combining a pump and point-of-sale (POS) system and pumping fuel into motor vehicles. A Point of Sale (POS) system is a system for managing the sales of goods. The term refers to the software and hardware associated with check -out stands, and all of the bundled features which are included.

A modern fuel dispenser is typically divided into two main parts: an electronic part containing an embedded computer to control the action of the pump, drive the pump's displays, and communicate to a sales system; and secondly, the mechanical section which in a self-contained unit has an electric motor, pumping unit, meters, and valves to physically pump and control the fuel flow.

Market size

Fuel dispensers have an annual life cycle of 12 years and, on this basis, there are currently around 300,000 fuel dispensers installed across the EU[96]. The size of the European market can be estimated on the basis of a total production value of around €360 million in 2012 based on a unit price of around €1,100[97]. According to PRODCOM data on fuel dispensers, around 16% of the production of

[96] Figure also obtained after analysing PRODCOM annual production statistics
[97] PRODCOM data from 2012

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Europe is exported outside EU while imports represent no more than 3% of the market.

PRODCOM data shows that a total of about 350,000 petrol and oil dispensing pumps were produced in Europe in 2012. Manufacturing in this sector is strongly export-oriented and has generated a significant volume of exports, although the interviews found that a lot of manufacturing that used to take place within the EU has been moved to lower-cost producer countries outside the EU.

Table 1: Production and value of petrol and oil dispensing pumps in EU27 in 2012 – PRODCOM Code 28131105

Export Quantity (Units)	Export Value (€)	Imports Quantity (Units)	Imports Value (€)	Production Quantity (Units)	Production Value (€)	Consumption Value € (Production + Imports - Exports)
347,309	148,672,970	245,102	15,171,090	349,038	357,890,334	224,388,454

Source: Eurostat

Industry structure

There are around 20 producers of fuel dispensers for petrol stations[98]. The major manufacturers include Gilbarco, Tokheim, Petrotec and Dresser Wayne with a presence across Europe and more than 60% market share[99]. The remaining manufacturers are present in only a few Member States. It is also estimated that the main companies in the sector employ around 10,000 employees without referring to importers or local distributors[100]. Altogether, the petrol pump sector employs about 14,000 to 16,000 workers[101].

3. Analysis of applicable IM legislation

As noted above, the manufacture of fuel dispensers is covered by the Measuring Instruments Directive 2004/22/EC and by a number of other Directives, such as ATEX and the Petrol Vapour Recovery Directives. The table below provides a summary.

Table 2: EU Legislation applicable to fuel dispensers

Applicable legislation	Issue addressed	Requirements for economic operators
Directive on Measuring Instruments (MID) 2004/22/EC	Legal metrological control	• Conformity assessment: obligation of the installer/manufacturer • Produce a DoC • Keep technical documentation copies of EC type-examination certificates and their additions for 10 years • CE marking and additional metrology marking must be visibly affixed to products
ATEX Directive	Risks relating to	• Conformity assessment – either by the manufacturer or a

[98] CSES (2010), Interim Evaluation of the Measuring Instrument Directive
[99] Ibid;
[100] Ibid;
[101] PRODCOM data, 2010; cf. CSES (2010), Interim Evaluation of the Measuring Instruments Directive, page iii

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Applicable legislation	Issue addressed	Requirements for economic operators
(94/9/EC)	equipment used in potentially explosive atmospheres	subcontractor of the manufacturer to a Notified Body • Produce a DoC • Keep technical documentation copies of EC type-examination certificates and their additions for a period of 10 years • CE marking must be visibly affixed to products • Additional markings of certain components for safety purposes
Petrol Vapour Recovery Directive (94/63/EC)	Reduction of emissions	• Conformity assessment with administrative fee charged by the Member State • Marking (pictogram sticker) certifying the equipment includes a petrol vapour recovery system
National Emission Ceiling Directive (2001/81/EC)	Reduction of emissions	• Same as above given that the directive relates to the reduction of emissions of volatile organic compound (VOC), i.e. petrol vapour • Administrative requirements depend on specific national measures
EMC Directive (2004/108/EC)	Electromagnetic compatibility (for electric powered equipment)	• Testing products for Electromagnetic Compatibility interference • Conformity assessment procedure for apparatus mandatory • CE marking on apparatus required in accordance with Annex V.
LVD (2006/95/EC)	Health and safety	• Conformity assessment – either by the manufacturer or a subcontractor of the manufacturer to a Notified Body • Develop a technical file (see Annex IV of LVD) • Produce a DoC • Keep technical documentation copies of EC type-examination certificates and their additions for a period of 10 years • CE marking must be visibly affixed to products • Provide installation instruction manual for installers

The nature of fuel dispensers is such that they require regulation covering different perspectives, notably accuracy and reliability in measurement, minimisation of the risks of explosion and protection of the environment. This inevitably requires multiple pieces of legislation, creating the risk that the overall framework is not coherent.

The interviews with the major companies in the sector suggest that the EU legislative framework pertaining to fuel dispensers has in fact become more coherent over the years, albeit with some gaps and inconsistencies remaining. Whilst EU legislation on measuring instruments dates back to the early 1970s, MID represented a considerable simplification, since it replaced eleven previous directives, all covering different products.

The ATEX Directive was introduced in 1993. Hitherto, manufacturers were required to satisfy different national legislative requirements in each country in which they operated, whilst meeting

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European requirements on MID. Since the introduction of ATEX, each manufacturer has been able to gain certification from one Notified Body for its sales across the EU. MID and ATEX side-by-side have thus served to reduce barriers to the free movement of goods in the internal market – as evidenced by the process of consolidation in the industry over the last two decades, as manufacturers exploit economies of scale. Indeed, the technical parts of fuel dispensers now tend to be the same across different Member States. Moreover, the credibility of this legislative framework has also assisted manufacturers in their efforts to export to third countries. MID was also reported to be consistent and complementary to the more recent RoHS Directive.

The consistency of the legislative framework for fuel dispensers is also enhanced by the use of internationally-agreed normative documents, namely those of the International Organization of Legal Metrology (OIML). This has tended to make European products immediately marketable to third countries that apply the OIML standards. The one downside of this approach is, however, that EU manufacturers exert less influence on the specification of the standards than they do on EU standards, such as those of the ATEX Directive.

Despite this generally positive situation, there are still some inconsistencies among the applicable Directives and Regulations. More specifically, the definition of "large-scale fixed installation" within RoHS is criticised as being too vague. Definitions applicable to fuel dispensers also appear to differ between Directives, with for instance the EMC Directive treating a dispenser as a single machine, whereas MID treats it as a collection of several measuring instruments[102].The MID Annex MI-005 distinguishes between individual measuring systems (i.e. fuel dispensers) and self-service arrangements (of fuel dispensers).

There remains debate over the desirability of having an annex of the MID devoted exclusively to fuel dispensers. Annex MI-005 covers "measuring systems for continuous and dynamic measurement of quantities of liquids other than water"[103] and defines and covers all the relevant essential requirements for metrology (and refers to voluntary standards that give presumption of conformity can be more specific). It therefore can be applied to the case of fuel dispensers and, indeed, it defines flow ranges specifically for fuel dispensers. However, the industry associations and manufacturers consulted were of the view that an annex specifically devoted to fuel dispensers would be preferable and ease the process (and thus the costs) of compliance.

It was also reported by the companies interviewed that some fuel dispenser products or components covered by ATEX and PED are not covered by MID, e.g. automatic feed nozzles and pressure valves. Although these components are not directly relevant to measuring, they can have an effect on accuracy of measurement. As a result, certification requirements can differ for each piece of legislation. According to the companies and industry associations interviewed, this can lead to conflicts between approval bodies which results in an unnecessary multiplication of conformity tests and an increase in administrative work.

A major issue is the fact that EU legislation does not address the connection between fuel dispensers and forecourt point-of-sale (POS) systems, which are not covered by EU legislation. Indeed, it was reported that it was impossible for MID-approved fuel dispensers to be connected to equipment with national certificates only such as pre-MID POS systems. . Since retailers, including small supermarkets, have contracts with POS systems providers, this can cause difficulties[104]. Moreover, the legislation does not cover the provision of regular checks and recalibration of fuel dispensers

[102] EMC Article 2 (a) (b) (c), Annex MI-005

[103] Annex MI-005

[104] There is a period of transition up till 2016, after which all new POS must be MID compliant

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once installed; as with other New Approach Directives, MID is only concerned with the placement of a product on the market and its installation. Whilst this does not affect the free movement of products, it does affect the free movement of services, with such services tending to be provided mostly by nationally-based operators.

It was also proposed by some of the companies interviewed that the legislative framework (notably MID) needs to be extended to cover additional types of fuel dispensers, particularly compressed natural gas dispensers (CNGD), which are currently subject to national legislation. Although mutual recognition under Art 34 of the TFEU applies to CNGD, this is only valid when countries accept this. CNG is regulated under OIML R139[105] and for many years, each country has required its own type approvals. Whilst mutual recognition could be a means of allowing products to circulate freely, the risk is that national authorities to allow such products to be placed on the market in the absence of national certificates. In contrast, liquid natural gas dispensers (LNGD) are subject to MID despite accounting for lower volumes of trade. There are around 5,000 to 10,000 petrol stations equipped with CNGD while there are only around 100 stations equipped with LNGD across Europe. CNG is for cars while LNG is for trucks. CNGD are available in petrol stations along with normal MID-approved fuel dispensers and LPG dispensers, while LNGD are most likely to be found in dedicated petrol stations. Given the barriers to the circulation of CNGD products, the risk is that manufacturers face higher costs than if such products were covered by EU legislation and are be unable to exploit economies of scale in production.

4. Analysis of costs of compliance with IM legislation

Analysis of the costs of compliance has been based on interviews with four large companies that serve the EU27 market and export globally, as well as two industry associations. The table provides information on the firms interviewed.

Table 3: Basic information on the firms interviewed

Firm	Specific/main product (if a specific sub category)	Firm size	Annual sales from product	Main markets
A	Pumps & dispensers	Large (4,000 employees)	10,000 units	50% of sales in the EU
B	Pumps & dispensers	Large (>1,000 employees)	15,000 units	82% of sales in the EU
C	Gasoline Dispensers, payment solutions for petrol stations	Large (5,400 employees globally)	Not known	60% of sales in the EU
D	Fuel management and dispensing systems, service station hardware	Large (3,200 employees)	15,000 units	33% of sales in the EU

[105] International Organisation of Legal Metrology (OIML) R139: Compressed gaseous fuel measuring systems for vehicles

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Step 1: Familiarisation with the legislation and relevant obligations, as well as preparatory actions

For all the companies interviewed, identifying and reviewing the requirements of the legislation, the relevant standards and the resultant information obligations is a relatively costly activity. Two companies offered an estimate of the relative share of this task in the overall cost of Step 1: 50% and 60% respectively. Membership of the relevant industry associations at EU and/or national level, e.g. CECOD, is vital to this task and, of course, involves a membership fee. Whilst membership of industry associations serves a wider purpose (and is thus a business-as-usual cost), much of the rationale for and benefit of membership is related to receiving information about the legislation and the standards – and also to being able to influence the legislation and the standards at the EU level.

As well as receiving information through the industry associations, all the companies employed at least one staff member dedicating most or all of their time to this task. These individuals typically participate in the various working groups and committees relating to the legislation (e.g. through CEN) and within the relevant industry associations. Although such participation is costly, this investment of time is considered to be worthwhile by the companies, given the benefit arising, i.e. in terms of being able to influence the legislative process and receive information in good time.

For the companies interviewed, the cost of identifying the legislation and the relevant standards and reviewing its requirements mostly consisted of the staff costs of these individuals. For example, Firm A employed three staff (out of 4,000) with responsibility for overseeing compliance: one in the UK (also the European head office), one in Germany and one in Italy. Firm D employed one person in each of the 5-6 different national offices, each spending perhaps 50% of his/her time on this task. Similarly, Firm C employed between 3 and 5 heads at senior engineering level (out of a total workforce of 5,4000) to understand the legislation and train manufacturing people and QA people – as well as to undertake tasks related to other steps, i.e. checking the manufacturing process, finding practical solutions to compliance issues, gaining approvals, etc.

Training staff was seen as the next most costly element of Step 1. It is routinely provided by all the companies interviewed, for new staff and for existing staff, as and when there are changes to the legislation and/or the standards. The true cost of such training can be hard to identify, since it may often be incorporated into wider training of staff. One Firm suggested it accounted for 15% of the costs of Step 1, whilst another suggested a figure of 25%.

Use of external consultants to aid the familiarisation and preparatory process appears to vary widely between the companies interviewed. Two companies stated that they very rarely used consultants, whilst two others suggested that the use of consultants accounted for around 10% of the costs of Step 1. One Firm stated that it only used consultants when entering new national markets, which might thus explain this discrepancy. It might be safe to conclude that consultants are rarely used for the "routine" task of ensuring familiarity with the legislation but can be used when additional support is needed to identify the requirements relating to new products or new markets.

Purchasing the standards (of Directives other than MID) also presents a direct financial cost for all companies interviewed (although the MID normative documents are made available free-of-charge on the Europa website), although participation in standards committees at EU level sometimes provides access to the standards free-of-charge. For the companies interviewed – all large – the cost of standards was not seen as prohibitive. Two suggested it accounted for only 5% of the costs of Step 1. Another quoted a figure of €1.2k for each standard purchased, which was not seen as particularly burdensome relative to its revenues. However, such costs would inevitably be more burdensome for SMEs.

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Two companies, as well as one EU-level industry association, highlighted that the most significant costs in Step 1 resulted from having to address differing interpretations of the legislation and of the standards in different countries. Such difficulties were said to arise not from the text of the legislation or of the standards, but from insufficiently clear guidance or, indeed, a lack of guidance. The resulting costs tended to relate to the time spent negotiating with national authorities, market surveillance authorities and Notified Bodies, as well as delays in placing products on the market (although neither firm was able to specify the precise cost, which is not therefore included in the table below).

Overall, all the companies and the industries associations interviewed highlighted the fact that most of the costs incurred in Step 1 were no higher than the previous situation in which national legislation applied. Indeed, the fact that the MID standards are also based on the internationally-agreed OIML normative documents means that there has been a degree of continuity in the processes followed, with the EU legislation reducing costs by bringing a more uniform approach. Given this situation, it would seem that the main scope for reducing costs associated with Step 1 relate to facilitating a more uniform interpretation of the legislation applying to fuel dispensers (i.e. MID, ATEX, EMC, etc.) and encouraging a more consistent application and enforcement in different Member States.

Step 2: Changes to product design and production processes to ensure compliance with substantive obligations

The nature of fuel dispensers and related products is such that design, development and manufacture require extensive testing for the purposes of safety, accuracy and reliability. It is clear that national legislation already imposed quite stringent requirements in most countries, particularly those where national standards were based on internationally-agreed normative documents. The EU legislation also places stringent requirements on manufacturers, with a consequent need for extensive testing and risk analysis, as well as subsequent changes to product design and production processes. For example, the one firm offering an estimate of substantive compliance costs, Firm B, reported that substantive compliance costs had amounted to €3.2m over the last five years (equal to around 3% of turnover), of which €2m on changes to product design and €1.2m on changes to production processes. Whilst these are one-off costs for each specific product that is certified, the fact that each large firm is continually bringing new products to market mean each incurs such costs on an annual basis.

It is, however, impossible to separate such costs from the business-as-usual scenario, particularly in a context of on-going technological development and innovation. Indeed, reputable manufacturers of high-quality products undertake extensive testing and risk analysis of any new product in any case. To a certain extent, such activities therefore represent a business-as-usual cost. Overall, the legislation has perhaps represented more of a burden for manufacturers of poorer-quality products, who have had to operate to higher standards, with less potential to undercut other suppliers on the basis of low price.

Of the companies interviewed, all agreed that testing related to compliance with substantive obligations posed a considerable cost. Indeed, testing and risk analysis is undertaken throughout the year at all the companies interviewed, involving a mix of internal staff and external costs. Firm D suggested that testing might account for up to €1m of its annual revenue of €15m (i.e. just less than 7%). Firm B reported that testing accounted for around €500k out of annual revenues of €20m (i.e. 2.5%). Firm C reported annual testing costs of €50-€150k for each of its four European factories, i.e. €200-600k p.a. Whilst such costs are clearly significant, it is not possible to separate them from a

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situation in which national legislation prevails or from the "business-as-usual" cost, given the emphasis that reputable manufacturers would place on product safety, accuracy and reliability.

In general, the companies were unable to give accurate data on the cost of testing equipment related to compliance with the EU legislation. For example, Firm D stated that most testing was undertaken at the firm's main laboratory in the USA; the cost of testing for the EU market was therefore inseparable from the cost of testing products for all global markets – particularly, where international, rather than EU standards apply. Firm A reported that it spent around €40k p.a. on testing equipment for the purposes of compliance (mostly linked to the EMC Directive) in relation to sales of around 10,000 fuel pumps per annum (equivalent to an average cost of €0.25 per unit).

Firm A did, however, highlight one very specific cost arising from the legislation and which could not be considered as a business-as-usual cost. One effect of the MID has been to require calibration of fuel dispensers (e.g. to match fuels) to take place in the factory rather than on-site (i.e. at the fuel retailer's forecourt). Previously, this calibration would take place on site, with the appliance then checked by a local trading standards officer, which Firm A considered to be easier. Although the fee for the local trading standards officer was not cheap (e.g. €50 per nozzle, so €300 for a pump with six nozzles), it was paid by the customer. However, under Module B (type approval) of MID, the Notified Body now has to verify the product and the calibration has to be undertaken at the factory. This creates difficulties as the precise conditions of the installation environment (i.e. the retailer's forecourt) cannot be known and recreated in the factory. Enforcement authorities tend not to allow subsequent adjustments to be made on site, whereas previously the manufacturer could send staff to tweak the product on site. Whilst Module F allow verification and calibration at the forecourt, this option

As a result, Firm A reported that it was required to spend a lot of time in the factory, continually refining weights and measures equipment to ensure the product is legal. Overall, the legislation was reported to have introduced a liability for the manufacturer, for which no obvious practical solution had been found. The consequent cost included €120k on testing facilities for LPG, as well as around €250k in staff time over the last six years, equivalent to perhaps €100 extra per dispenser under MID compared to the previous situation.

Step 3: Conformity assessment procedures

Under the MID, manufacturers can choose from a number of conformity assessment procedures, namely Modules B+F, B+D, H1 or G. This creates a variety of approaches and therefore differing costs, with some manufacturers subject to periodic inspections of their quality systems by Notified Bodies (e.g. under Modules D and H1) and others having the conformity of specific products verified, e.g. under Modules B and F.

The companies interviewed were unanimous in reporting that the fees of Notified Bodies represented the costliest element of Step 3. The one firm that offered an estimate of the proportion of total costs in this step accounted for by Notified Bodies fees suggested a figure of 55%, of which 35% relating to initial inspections and 20% to periodic inspections. All the companies offered estimates of the financial costs of the fees of Notified Bodies and those estimates demonstrating a degree of consistency. An initial inspection of a fairly routine nature (e.g. permeation tests or other minor adjustments) was said by two companies to cost up to about €4k, whereas testing of components such as valves, motors or junction boxes was said by another firm to cost €10-20k. The same firm reported that it undertook around six of such tests each year, representing a total cost of about €100k in Notified Body fees (i.e. 0.5% of total turnover). More extensive tests for entirely new products or processes might cost €40k-50k each. In addition to the initial inspections, it is also necessary for each

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firm to have periodic inspections by Notified Bodies in order to retain their certification. Figures quoted by one firm included €15k-25k for both the MID and the ATEX Directives, with another firm quoting a figure of around €30k for such periodic inspections across its three European facilities for the same two Directives.

Whilst the cost of Notified Bodies' fees was reported to be high, the companies agreed on the benefits of gaining certification. One firm made a favourable comparison to the situation prevailing before the introduction of the New Approach Directives, stating that the current costs were relatively low. The same firm reported that it was able to use its MID and ATEX certification globally, in the former case because of the use of OIML standards by MID. Moreover, it was also reported that OIML certification from some EU Member States tended to have more credibility than certification gained in some third countries.

Manufacturer's own internal checks were also reported to be costly, albeit less than the cost of Notified Bodies. However, to a large extent, these tended to be a business-as-usual cost, with such checks undertaken continuously and routinely – and likely to be undertaken in the absence of legislation.

Similarly, the preparation of technical documentation in advance of conformity assessment, compilation of test reports, production identification requirements and maintenance of technical information for ten years were reported to be costly in terms of internal staff time. Indeed, one firm suggested that such activities could account for several hundred thousand euros each year in staff time, whilst another suggested that such activities could account for around 35% of the total costs of conformity assessment. Preparation of technical documentation related to ROHS was said by one firm to pose a particularly high cost. In addition, two companies reported very high costs of translation of documents related to conformity assessment, although such costs may be inextricable from the general costs of translating instruction manuals – estimated at around €100k p.a. by one firm (against sales of 10,000 units and turnover of "tens of €millions" per year).

Step 4: Declaration of Conformity and CE marking

The companies interviewed were unanimous in reporting that the Declarations of Conformity and use of the CE marking were much less costly than Steps 1, 2 and 3. However, the preparation of a Declaration of Conformity could be made more complicated – and therefore more costly – by the need to collect information, DoCs and compliance statements from suppliers of components. Depending on the number of components and of suppliers, this could in some cases be costly and manufacturers need to build such requirements into their contracts with suppliers.

The compliance statements that will be required under ROHS and REACH were expected by one firm to impose a significant cost as and when they become mandatory. However, at this stage it was not possible to estimate the cost of producing such statements.

The requirement to apply CE marking was reported by all the companies to pose very little cost. Indeed, it was easily incorporated into the manufacturing process. None reported any particular additional financial cost. However, the companies and industry associations reported some confusion around the application of CE marking. This included a lack of clarity around whether the CE marking needed to be placed only once on each pump installation or on each nozzle. It was also suggested that consumers had limited awareness of the significance of the CE marking, with national standards, such as the British Standard markings, being more widely-recognised in each country.

As with the technical documentation, translation of the Declaration of Conformity was reported to be expensive. Three of the four companies reported a very high cost of translation, whilst another

reported it to be moderately high. One firm reported that it was necessary to translate Declarations of Conformity four times a year, at a cost of around €8k p.a. In order to minimise costs and the potential for error, another firm reported that it replicated the text from the various language versions of the official documentation as far as possible. Again, such translation costs are bound up with the wider cost of translating instruction manuals. However, given that fuel dispensers are sold only to businesses and not to consumers, one firm suggested that there should perhaps be flexibility over the requirement (imposed by most Member States under the terms of Article 6 of the MID) to provide such documentation in the language of the customer, provided that the customer has sufficient numbers of staff fluent in the language proposed by the manufacturer. In that way, it might be possible to reduce the number of translations required, particularly into the less-spoken EU languages where it less difficult to spread the cost of translations over a large volume of sales.

Conclusion/Summary

Overall, Directive 2004/22/EC on measuring instruments (MID) is appropriate for the sector. It provides a good legal and technical base, which allows technical progress to take place. In order to reflect technical progress, the instrument-specific annexes might need amendment from time-to-time via the comitology process set out in Article 16 (Functions of the Measuring Instruments Committee).

On average, around €800k per year are spent by major manufacturing groups on activities linked to compliance. Direct administrative compliance costs represent just over 10% of the total costs of compliance-related activities. Investments in terms of product design, manufacturing equipment represent major compliance-related expenditures (around 35-40%).

5. Assessment of costs of IM legislation for the whole sector

On the basis of the information provided, we have attempted to estimate the costs of compliance for the whole sector. The figures in the table below include information concerning the "business-as-usual" (BAU) scenario.

Table 4: Summary of main costs of compliance for the firms interviewed

	Firm 1	Firm 2	Firm 3	Firm 4	Average	Total
Turnover	€ 20m	€ 20m	€ 600m	€ 15m		€ 1,091,666,667
Compliance Costs FTE						
- costs FTE yearly	€ 72,000	€ 260,000	€ 420,000	€ 330,000		
- costs FTE yearly / turnover	0.36%	1.30%	0.07%	2.20%	1%	€ 5,372,250
Business As Usual (BAU) FTE		30%	30%		30%	€ 1,611,675
Compliance costs FTE		70%	70%		70%	€ 3,760,575
Compliance Costs - third party fees	€ 41,667	€ 500,000	€ 500,000	€ 1,000,000		
- costs third parties	0.21%	2.50%	0.08%	6.67%	2.4%	€ 12,367,014

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	Firm 1	Firm 2	Firm 3	Firm 4	Average	Total
/ turnover						
Business As Usual (BAU) third parties		50%	50%		50%	€ 6,183,507
Compliance costs third parties		50%	50%		50%	€ 6,183,507
Compliance Costs - testing equipment	€ 160,000	€ 100,000	€ 500,000			
- costs testing equipment/turnover	0.80%	0.50%	0.08%		0.46%	€ 2,773,519
Business As Usual (BAU) test equipment		20%	20%		20%	€ 554,704
Compliance costs test equipment		80%	80%		80%	€ 2,218,815
Total compliance costs	€ 273,667	€ 860,000	€ 1,420,000	€ 1,330,000		€ 20,512,782
Business As Usual (BAU)		€348,000	€476,000		41%	€ 8,349,886
Compliance costs		€512,000	€944,000		59%	€ 12,162,897
Total compliance costs as % of Turnover	1.5%	4.5%	0.25%	9%		

The assessment of costs of IM legislation for the whole sector is based on the figures obtained from the four major companies in the sector representing 60% of the market. The figures in the far right column are an extrapolation of the data obtained from the four major firms and represent the total turnover and compliance costs for the whole of the EU petrol pumps sector.

The annual turnover for the whole sector is estimated at €1.1bn. Total compliance costs are estimated at €20.5M for all the companies in the sector, representing around 2% of their combined turnovers. For the largest of all four companies (firm 3) compliance costs represent 0.25% of the turnover. For the smallest (firm 4), compliance costs amount to around 8.5% of the total turnover. Across the four companies, around 60% of the compliance costs relate to compliance with EU Internal Market legislation.

Administrative compliance costs FTE represent around 0.5%-1% of companies' annual turnover on average. Costs range from just under €100,000 to over €400,000 for larger companies. On average, they make up 30% of Business As Usual costs to a firm on a yearly basis. The remaining 70% relate to EU IM legislation compliance requirements.

Administrative and non-administrative compliance costs towards third-parties are of around €500,000 on average for the companies in the sector. These costs represent around 2.5% of companies' annual turnover and make up 50% of their Business As Usual costs.

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Testing equipment costs for compliance activities averaged around €100,000 per firm annually. For larger companies, testing equipment can cost over €500,000. These costs are also dependent on the number of factories owned by companies. These costs represent around 0.5% of companies' annual turnover in the sector and make up 20% of Business As Usual costs. In other words, testing equipment expenditures at firm level mostly relate to the necessity to comply with the MID requirements and other environment-related requirements introduced by various EU legislative measures.

According to PRODCOM data, the production value of each individual petrol pump unit ranges between €1,000 and €2,000. This corresponds with the data obtained from the individual companies when dividing their annual turnover by the number of units they produce per year. When dividing the individual companies' annual turnover by their total compliance costs, it is possible to see that compliance costs account for between 0.25% and 9% of the production value of a single unit (See Table 4).

6. The benefits of internal market legislation

It is important that the benefits of IM legislation are considered and not only the costs. It is impossible to establish a counterfactual since it cannot be known how the industry would have developed in the absence of legislation. They highlighted the following benefits.

First, the firms and industry associations interviewed were unanimous in the view that it was preferable to have a single set of internal market legislation across the Union rather than different pieces of national legislation. This was highlighted as being particularly important for the ATEX Directive, which replaced very differing, and therefore burdensome, national legislation. As a result of MID, the technical parts of petrol pumps tend to be the same in each Member State, which also helped limit the cost of maintenance, serving and repair. Costs of components have also been kept down, where suppliers can provide a certificate from a Notified Body, which prevents the need for the manufacturer to undertake additional checks, which would be necessary in the absence of EU legislation.

Second, EU legislation has provided opportunities for export to third countries, such as Turkey and the USA. Again, the ATEX Directive in particular was seen as being beneficial in that respect; it is considered to be highly recognised and respected in non-EU jurisdictions, with some third countries using it to inform the design of their own legislation and/or accepting ATEX certificates issued in the EU. For example, the USA was reported to be changing its explosive standard in line with the international explosive standard which is already well-aligned with those of the ATEX. This provides export opportunities for EU producers and helps keep production costs down. Moreover, accreditation in respect of MID also promoted global exports as the standards are the same as those of OIML.

Third, the ATEX standards were seen as not only safe but also as reasonable for manufacturers. This reflects the possibility of industry to help set the standards.

Fourth, the replacement of national legislation with EU legislation had enabled economies of scale to be captured by producers, leading to consolidation of the market. The New Approach Directives have tended to support the competitiveness of EU industry. Although the large manufacturers retain their strength in their home markets, the legislation has enabled a degree of consolidation and economies of scale.

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7. Analysis of simplification options

The analyses of the applicable legislation and the discussions with firms and industry representatives have indicated some areas for possible improvements and simplification.

Introduction of a specific annex for fuel dispensers in MID directive

There is no specific annex on fuel dispensers in the MID Directive (although MI-005 does cover such products, as part of its wider focus on "liquids other than water"). In particular, manufacturers report that MID does not adequately address the connection between fuel dispensers and forecourt POS systems and that additional national certification is often required. A specific annex for fuel dispensers should prevent different interpretations by the manufacturer and Notified Bodies in respect to the devices permanently connected to a meter, which needs to be considered during a conformity assessment. Overall, this would clarify the scope of the MID with respect to fuel dispensers.

It is estimated that creating a specific annex for fuel dispensers in the MID directive would result in a significant reduction in compliance costs overall. For example, one firm suggested that its compliance costs might fall by as much as 35%. Full-Time Equivalent (FTE) compliance and third-party compliance costs[106] in particular would be reduced as a specific annex on fuel dispensers would facilitate compliance work through greater harmony in Member States' interpretation of certification requirements.

Understand SSD as sub-assemblies for petrol stations

Simplification efforts should focus on adapting the sub-assembly definition in order to introduce the possibility to certify sub-assemblies in more categories of measuring instrument, including fuel dispensing systems, and keep the necessity to certify nevertheless the complete measuring instrument.

The sub-assembly approach is for the time being very limited in MID as it is not foreseen in some fields such as measuring systems of liquids other than water although these instruments are modular in most cases. Fuel dispensing systems are by essence composed of parts manufactured separately by different providers and assembled by the manufacturer of the complete instrument.

The lack of a sub-assembly approach for measuring system for quantities of liquids other than water deeply complicates the application of the MID for manufacturers, not only for the self-service devices linked to fuel dispensers, but for all kind of measuring systems. This is mainly due to the fact that manufacturers of complete measuring systems are not able to demonstrate the compliance of some critical parts that they do not manufacture.

If such a modification is accepted it would facilitate the approval process for manufacturers. It would also mean fewer problems in the MID application for manufacturers of fuel dispensers. It would especially facilitate the revamping of some measuring instruments and it would remove unclear situation concerning the responsibility of the conformity of the complete instrument.

WELMEC guide 8.8 provides an appropriate base for this implementation. It is desirable that its application is ruled by European Commission in order to be recognised and applied by all Notified Bodies in European countries with no distortion.

Considering Self-Service Devices as sub-assemblies of fuel dispensing systems, thus not requiring

[106] FTE: The ratio of the total number of paid hours during a period (part time, full time, contracted) by the number of working hours in that period; Third-party compliance costs: external quality control/product safety auditors

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separate MID certification, would lead to a 5-10% cut in compliance costs, particularly in testing equipment costs. The current MID interpretation is driving up compliance activities and costs across the industry, including extending national approvals. It also slows down investment in technology.

Address link to Points-of-sale

Still in relation to sub-assembly, there is a particular issue of combining old non-MID certified points of sales with new MID-certified fuel dispensers in petrol stations (and the reverse) which is seen as a major limitation for the development of the market in a number of countries. This is also commonly known as the 'mix and match' issue, which broadly concerns the capacity to combine old and new components whereby a system approved under old national legislation cannot be upgraded with an MID certified component without first seeking MID approval for the complete system. This means new components of a system cannot be installed without the manufacturer of the fuel dispenser upgrading the system. Petrol station owners that want to revamp part of a system are forced either to upgrade old non-MID dispensers or points of sale stations or to buy complete new systems. An extension of the sub-assembly principle in the MID to measuring instruments other than water would certainly remedy this problem. However, this situation is only provisional and will end in 2016 (Art 23 MID), after which date no assemblies can be put into use that are not fully compliant with the MID. In fact, many Member States are already requiring this to be the case, as a matter of consumer protection.

Addressing this problem would also reduce companies' compliance costs by around 5%-10%. Expenditures on testing equipment would be reduced and companies' administrative burden relating additional certification procedures would be alleviated.

Create a central site that gives manufacturers for each specific product a general view of the minimum requirements for compliance with European directives and standards

Currently, the online information on minimum requirements for compliance with IM legislation is categorised according to each piece of IM legislation as opposed to product type. In other words, manufacturers are first required to know which pieces of IM legislation apply to their product before they can check minimum requirements. Organising information on minimum requirements by product type would save manufacturers a considerable amount of time.

This would imply a reduction of between 50% to 75% in the time and cost spent by manufacturers on this task. This reduction in administrative compliance costs would depend based on the organisational and staff structure of the individual companies. This is a function that can normally be achieved by means of a EN standard. This task could be undertaken by the CEN.

Develop a European database for product certificates that could be consulted by all entities involved

Some further practical steps could be taken, such as setting up an EU-wide database for product certificates allowing for quick cross-checking that certificates have been officially delivered. This may require the merging of existing different databases on market surveillance that feed into Member State reporting requirements to the Commission. The EC should investigate whether merging of databases is possible and should study the value added of each database.

This effort of data simplification might reduce the time (and associated cost) spent by manufacturer's explaining and informing local verifiers/authorities, regarding certificates issues by up to 50%. Again, any reduction in costs would depend on the organisational and staff structure of the individual companies.

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Table 5: Summary of proposed simplifications and expected benefits

Change proposed	Expected benefit/problems	Estimated saving potential
Creating a specific annex for fuel dispensers in the MID directive would result in a	A specific annex on fuel dispensers would facilitate compliance work through greater harmony in Member States' interpretation of certification requirements.	35% reduction of compliance costs overall. FTE compliance and third-party compliance costs in particular would be reduced as
Consider Self-Service Devices as sub-assemblies for petrol stations.	The current MID interpretation is driving up compliance activities and costs across the industry, including extending national approvals. It also slows down investment in technology.	Consider SSD as subassemblies would abolish the requirement of separate MID certification for critical parts and therefore lead to a 5-10% cut in compliance costs, particularly in testing equipment costs.
Abolish the need for multiple certifications for systems combining old non-MID certified points of sales with new MID-certified fuel dispensers in petrol stations (and the reverse).	Petrol stations would no longer encounter problems for upgrading to MID. Expenditures on testing equipment would be reduced and companies' administrative burden relating additional certification procedures would be alleviated.	Addressing this problem would also reduce companies' compliance costs by around 5%-10%.
Create a central site that gives manufacturers for each specific product a general view of the minimum requirements for compliance with European directives and standards	Online information on minimum requirements is categorised according to each piece of IM legislation as opposed to product type. Organising information on minimum requirements by product type would save manufacturers a considerable amount of time.	This would save considerable time and money from an administrative point of view.
Develop a European database for product certificates that could be consulted by all entities involved	Merge existing databases into an EU-wide database for product certificates allowing for quick cross-checking that certificates have been officially delivered.	This would save considerable time and money from an administrative point of view.

Other proposed simplifications for which benefits are not quantifiable:

Introduce compulsory checks following installation of new fuel dispensing systems

Concerns have been raised about the lack of awareness of the need to re-verify after a new POS has been fitted and frequently it was discovered that such changes had been made without re-verification.

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(It should be noted that where the POS contains metrological software it concerns a new instrument in the sense of MID). Problems have arisen with dispensers that had been factory verified and installed without further checks being made, whilst it appears that legislation permits this. It is necessary to make re-verification compulsory to guarantee that newly-installed POS are operating as accurately as possible. This follows reports that some retailers have suffered high losses from newly installed dispensers, before the error was discovered through routine stock reconciliation.

Extend MID to cover Compressed Natural Gas (CNG) dispensers

Given the evidence of trade barriers in the sense of Art 34 TEU the MID could be extended to cover Compressed Natural Gas (CNG) dispensers given the large market expansion for natural gas vehicles caused by the rise in petrol prices and efforts to reduce air pollution emissions (See Section 3). The MID already covers cryogenic Liquefied Natural Gas (LNG), however its market remains limited compared to the CNG market. Companies would be able to invest in CNG-based technology and exploit economies of scale. No cost savings here would occur but firm profits could potentially rise.

Extend possibilities of amendments via comitology

Extending possibilities of amendments via comitology would avoid future problems and create a better understanding between different stakeholders. Any suggestions for new proposals should be made in consultation with industry stakeholder committees in line with smart regulation whereby full account is taken of all alternatives to regulation. For instance the field of water and heat meters, the legal framework is “fit-for-purpose”, particularly because of the possibilities for amendments via comitology.

8. Overall conclusions

This case study focused on fuel dispensers which are machines combining a pump and point-of-sale (POS) system and pumping fuel into motor vehicles. In other words, fuel dispensers combine an electronic part containing an embedded computer measuring fuel sales and a mechanical section to physically pump and control the fuel flow.

There are around 20 manufacturers of fuel dispensers in Europe, amongst which are four major players with more than 60% of the market share in Europe and a significant presence worldwide. The total production value for petrol pumps in Europe was of around €360 million in 2012 based on a unit price of around €1,100. A total of about 350,000 petrol and oil dispensing pumps were produced in Europe in 2012.

The manufacture of fuel dispensers is mainly covered by the MID and by a number of other Directives, namely: ATEX, the Petrol Vapour Recovery Directive, the EMC Directive, the Low Voltage Directive and the National Emissions Ceiling Directive. The nature of fuel dispensers is such that regulations covering different perspectives are required, notably on accuracy and reliability in measurement, minimisation of the risks of explosion and protection of the environment.

The assessment of costs of IM legislation for the whole sector was based on the figures obtained from the four major companies in the sector representing 60% of the market. Total compliance costs are estimated at €20.5M for the four major companies in the sector, representing around 2% of their combined turnovers. Around 60% of the compliance costs relate to compliance with EU Internal Market legislation (€12M) whilst the remaining €8.5M relate to business-as-usual compliance costs.

Administrative and non-administrative compliance costs towards third-parties are of around €500,000 on average. Familiarisation costs are reported to be significant in this particular sector.

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This is due to the need for company to address differing interpretations of the MID legislation and of national standards in different countries. Testing equipment costs for compliance activities averaged around €100,000 per firm annually. For larger companies, testing equipment can cost over €500,000. In summary, investments in terms of product design, manufacturing equipment represent major compliance-related expenditures (around 35-40%) for companies in the sector.

Overall, the MID Directive was deemed to provide a good legal and technical base enabling technical progress. The stakeholders interviewed recognised that harmonised internal market legislation can be very cost-effective, particularly in relation to the ATEX Directive, which replaced differing and burdensome national legislation. Furthermore, thanks to the MID, the technical parts of petrol pumps tend to be the same in each Member State, which therefore limits the cost of maintenance and repair. In general, the replacement of national legislation with EU legislation had enabled economies of scale to be captured by producers, leading to consolidation of the market.

As regards simplification, efforts should focus on adapting the sub-assembly definition. Manufacturers have estimated that considering Self-Service Devices as sub-assemblies of fuel dispensing systems, thus not requiring separate MID certification, would lead to a 5-10% cut in compliance costs, particularly in testing equipment costs. Simplification should also address the 'mix and match' issue whereby a system approved under old national legislation cannot be upgraded with an MID certified component without first seeking MID approval for the complete system. The manufacturers interviewed estimated that addressing this problem would also reduce their compliance costs by around 5%-10%.

9. List of interviews

- 2 interviews with industry associations: CECOD, PEIMF
- 5 interviews with manufacturers
- 1 interview with the European Commission DG Enterprise and Industry

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CASE STUDY 7 – AIR CONDITIONERS

1. Introduction – aims of the case study

Common aims

The aim of the case studies is to assess the way in which IM legislation for industrial products affects different economic operators across selected product groups. Union harmonisation legislation applicable to each product group is first mapped out and an assessment of any gaps, loopholes, inconsistencies and duplication is provided. The compliance costs in meeting these requirements are then assessed.

Specific aims of case

The rationale for the selection of air conditioners and air conditioning systems as a product group was that:

- Air conditioners and air conditioning systems are a significant industrial sector, particularly in southern European countries, with a large volume of products sold.
- There are only a relatively small number of firms overall in most market segments, and large firms dominate the market.
- The sector is one in which there is a high level of internationalisation in manufacturing and non-EU firms dominate some segments of the European market (especially for smaller and portable air conditioners). This has allowed market access issues to be considered.

The case study was carried out using a combination of desk research and interviews. The main data sources used were Eurostat SBS (2 digit NACE code level) and Prodcom data (8 digit NACE), sectoral studies and market research reports. Work carried out recently on Ecodesign requirements for air conditioners and air conditioning systems was also used, since this provides useful data on market size and structure[107].

2. Product definition and description of market structure

This case study focuses on air conditioners and air conditioning systems (both comfort air conditioning in buildings and portable air conditioning systems). There are a number of different types of air conditioners such as air-to-air, water-to-air, evaporatively-cooled, split and multi-split air conditioners air-to-air, water-to-air, and VRF (Variable Refrigerant flow) systems. Industrial chillers are also covered, wherever these incorporate air conditioning systems. The focus is on electrically-

[107] For instance, the F-Gas regulation (Regulation 842/2006 on certain fluorinated greenhouse gases) relating to greenhouse gases was considered by some air conditioning stakeholders interviewed to be one of the most burdensome pieces of legislation affecting the sector.

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driven air-conditioning appliances although gas burning appliance designs placed on the market were also taken into account, since a different legal regime applies under the GAD.

Selected sub-sectors within the wider HVAC industry, and heat and industrial pumps have also been included, but only where these are part of air conditioning and heating systems. There is a trend towards convergence of cooling and heating systems so air conditioning manufacturers often produce these items.

Data and information sources

An overview of sectoral data and key trends is now provided, drawing on Eurostat Structural Business Statistics (SBS) and Prodcom data. Since Eurostat datasets can be misleading in that they present data at a very high level of aggregation, we have also drawn on market research reports. Where data gaps have been identified, for instance, an accurate estimate of manufacturing employment in the sector, we have taken feedback from industry associations and individual manufacturers into account about since they have provided insights on market size and structure, recent industry developments and market trends.

Industry structure and employment

In the first table, we provide an overview of the sector, although it should be noted however that the data is at a higher level of aggregation than for air conditioners and air conditioning systems alone. Eurostat SBS data under NACE 28.25 includes the manufacture of refrigerating or freezing industrial equipment, including assemblies of components, the manufacture of air-conditioning machines, including for motor vehicles, non-domestic fans, heat exchangers, machinery for liquefying air or gas manufacture of attic ventilation fans (gable fans, roof ventilators, etc.).

Table 1: Manufacture of non-domestic cooling and ventilation equipment sector (NACE 28.25)

	2008	2009	2010
Number of enterprises	9,913	8,984	9,190
Number of employees	254,200	228,800	219,700
Production value	48,083.16	37,624.77	38,645.77

Source: Eurostat's SBS

The European industry association – Eurovent – speculated that Eurostat data may also extend to firms and employment relating to the installation and maintenance of air conditioners and air conditioning systems, not only to manufacturing. Given the unreliability of official data sources on the number of enterprises and employment, it has therefore been necessary to rely on market studies that provide industry data and on information provided by industry associations.

The **manufacturing industry for small air conditioners (<12 KwH) and comfort cooling systems is dominated by a small number of global manufacturers, especially from East Asia**. The market for single and multi-split air conditioners is dominated by Asian manufacturers and brands.[108] The five largest brands of air conditioners for domestic use in Europe are all Asian: Mitsubishi (Japan),

[108] Preparatory study on the environmental performance of residential room conditioning appliances (airco and ventilation), Economic and Market analysis, July 2008

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Daikin (Japan), LG Electronics (South Korea), Hitachi (Japan) and Toshiba (Japan). Outside East Asia, a number of other international manufacturers have a strong market share of the global air conditioner market such as Amana, Carrier, Lennox and Trane (US). In BRIC economies, such as China and India, there are also large manufacturers with high sales volumes, such as Haier, Gree and Midea (China) and Blue star and Voltax (India). Chinese companies also export a lot of small air conditioning products to Europe under an array of different, less well known brands.

It was not possible to obtain accurate data on the level of employment within the sector. However, it was noted by the industry association that there is a significant level of employment – greater than in manufacturing – relating to the installation, servicing and maintenance of air conditioners and air conditioning systems. Employees in these sectors are only indirectly affected by IM legislation, they are much more affected by environmental legislation, for instance, European legislation pertaining to the F-Gas regulation and pursuant legislation[109] setting out minimum requirements and the conditions for the mutual recognition for the certification of companies and personnel.

Some data on employment in Europe by international manufacturers was however obtained. It is important to point out that although non-EU firms dominate many areas of manufacturing and although a significant proportion of manufacturing also takes place outside Europe, manufacturers originating from East Asia have made a significant investment in setting up some manufacturing facilities in Europe, which has created a significant amount of European direct employment and indirect employment (suppliers/subcontractors of e.g. pumps and fans. According to Eurovent, an EU industry association, about 5000 direct jobs have been created and an estimated 15000 indirect jobs. A significant proportion of total employment in the EU in the air conditioning sector is for the subsidiaries of large international companies. Japanese, Korean and US air conditioning companies are well-represented.

For instance, the market leader Daikin has a factory in Belgium and two in the Czech Republic. Mitsubishi Electric has a factory in Scotland, whilst Hitachi has a factory in Spain. Among the reasons why global manufacturers are investing in developing manufacturing capabilities in Europe are: proximity to market, a need to strengthen their market share in Europe and to embed their position in the European market. Consequently, these companies are keen on monitoring and participating in European decision making processes, including the development of Ecodesign and Energy Labelling regulations.

It is **difficult to obtain a clear picture by country of origin of the brands of air conditioning manufacturers** since lesser-known brands sold on European markets can be subsidiary companies of international holding companies. However, a previous study for DG ENTR on the air conditioning sector citing Eurovent data[110] estimated that East Asia (particularly Japan and Korea), have a dominant market share with 60% and 13% respectively. These data estimates were checked, for instance with JRAIA (The Japan Refrigeration and Air conditioning Industry). They estimated that Japanese manufacturers share of the market is in the region of 50-60% in Europe.

The US has a 10% share of production, the EU has only an estimated 7% share, whilst Israel has 6% and China 5%. Notwithstanding the points above regarding international manufacturers setting up manufacturing facilities in the EU, a 2008 market study for the Commission confirmed that the

[109] For instance, pursuant to The F-Gas Regulation (EC) No 842/2006, Commission Regulation (EC) No 303/2008 of 2 April 2008 establishes minimum requirements and the conditions for mutual recognition for the certification of companies and personnel as regards stationary refrigeration, air conditioning and heat pump equipment containing certain fluorinated greenhouse gases

[110] It should be noted that this data is not publicly available, since it is proprietary.

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majority of small air conditioners for domestic use are manufactured and assembled outside Europe[111], with the exception of mini-chillers, where Europe has a stronger manufacturing base (although international manufacturers with manufacturing plants in Europe are also present in the market).

Although in absolute terms, Europe's market share is relatively low, European manufacturers have a higher market share in the production of high-end air conditioning systems produced in lower volume, and in specialised market segments. For example, an interviewee from a European manufacturer commented that "while East Asian manufacturers dominate small air-conditioning systems for comfort and office cooling, European manufacturers have a higher market share of large-scale industrial cooling systems. Europe also has a significant market share for other types of air conditioners such as precision air conditioning and chillers. For instance, the UK and Germany have a strong market position in respect of precision air conditioning (such as cooling systems for data centres). Although disaggregated data is difficult to obtain, interview feedback found that European manufacturers and the US also have a strong market share in respect of industrial refrigeration. For instance, Italy is strong in the chillers market. It is not possible to provide accurate data on the percentage of firms that are SMEs in the air conditioning industry. As noted above, at 4 digit NACE code level, it is difficult to obtain sufficient disaggregation through Eurostat. Discussions with industry associations confirmed however that at least for smaller air conditioners for domestic use, small comfort coolers and for portable air conditioners, the market is dominated by large firms. A further market study from 2012 (Lot 6, Ecodesign)[112] was only able to identify small numbers of SMEs manufacturing air conditioning systems, chillers and fan coils (not quantified).

Market size

Before providing information on the European air conditioner and air conditioning systems market, we first provide an indication of the size of the market globally.

Market research data was obtained by CSES directly from the industry on the air conditioning market globally in 2013. The data shows the relative importance of different geographic markets in million units and their respective global market share.

Table 2: World market for air conditioning in 2013

Geographic region	*No. of units (m. units)*	*Percentage share*
China	41.2	42.0
United States	14.35	14.6
Japan	9.58	9.8
Latin America	6.95	7.1
Europe	6.65	6.8
South East Asia	6.2	6.3
India subcontinent	4.87	5.0
Middle East	4.57	4.7
Africa	2.86	2.9

[111] Idem.

[112] Sustainable Industrial Policy – Building on the Ecodesign Directive – Energy-Using Product Group Analysis/2 Lot 6: Air-conditioning and ventilation systems, Part 2 Market Study, July 2012

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Oceania	0.91	0.9
Total	**98.14**	100.0

Source: JARN, the "Japan Air Conditioning, heating and refrigeration news" magazine, 25 May 2013

The data shows that 98.1m units were sold globally annually. The data confirms that China is the world's largest air conditioner market, although, as noted earlier, Japan and Korea are the biggest manufacturing companies for air conditioners sold on the European market. The **estimate of 98.1m units sold globally compares with about 6.65m units sold in Europe in 2012**, according to Eurovent figures. As will be demonstrated below, although European manufacturers have a relatively low market share globally in terms of sales volume, they have a higher market share for non-domestic air conditioning systems and for chillers.

Eurostat PRODCOM data provides an estimate of the total size of the air conditioners market for non-domestic air conditioners and ventilation. There is no equivalent data for domestic air conditioners and ventilation however. Data for 2010 suggests a total market of around €4.6 billion, with imports representing 38% of this total. In the case of window or wall air conditioning systems, imports are more than 50% of the total. It also demonstrates that air conditioning is quite a significant industrial sector, with total market size of almost 4.6bn EUR.

Table 3: EU 27 Value of exports, imports and production value in 2010

Prodcom code	***Category***	**Value of exports (€s)**	**Value of imports**	**Production value (€s)**	**Total (Production + imports-exports)**
28251220	Window or wall air conditioning systems, self-contained or split-systems	119,059,590	667,189,720	682,292,212	1,230,422,342
28251250	Air conditioning machines with refrigeration unit (excluding those used in motor vehicles, self-contained or split-systems machines)	508,839,700	880,691,590	1,651,035,022	2,022,886,912
28251270	Air conditioning machines not containing a refrigeration unit; central station air handling units;	327,782,600	206,526,710	1,465,437,087	1,344,181,197

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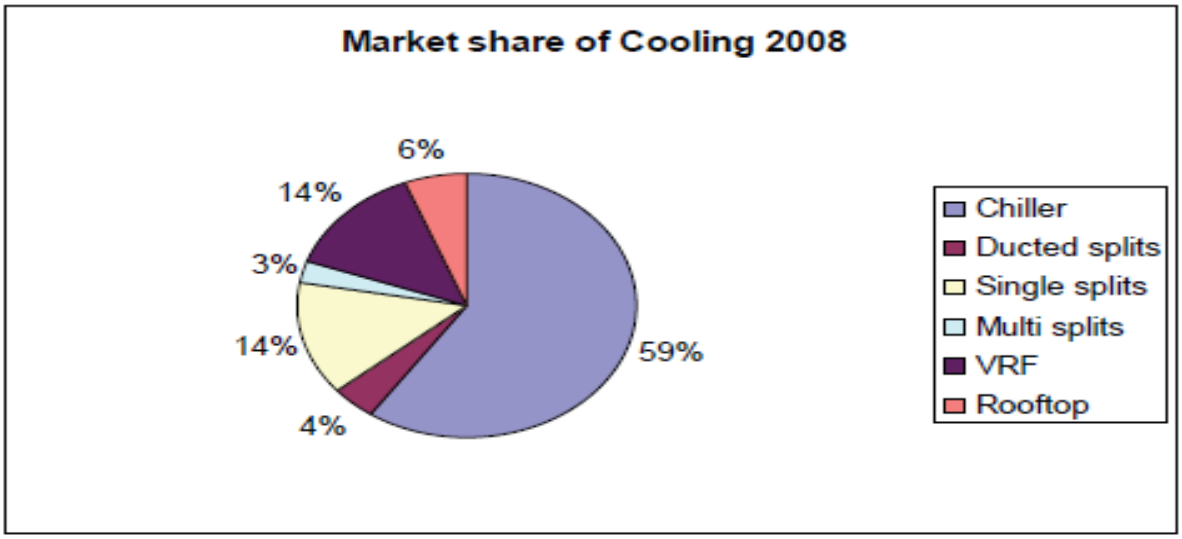
Total		**955,681,890**	**1,754,408,020**	**3,798,764,321**	**4,597,490,451**

Source: Prodcom,2010, Note: PRODCOM data refer to production sold.

In addition to Eurostat and Prodcom data, various market studies have also been consulted. A study undertaken for the Commission in 2008[113] noted that Southern European countries accounted for a large share of demand within the EU, reflecting climatic factors as a key demand driver. In the figure below, a breakdown of the market share for different air conditioning systems by type and cooling capacity is provided. The figure shows that chillers with air conditioning in them account for 59% of the market, and other types of air conditioning a much lower proportion. Single splits and VRF splits (ducted splits are not so easy to install in European households since most do not have duct space) each with a 14% share of the market respectively.

Figure 2: Market Share - Air Conditioning Systems by type and cooling capacity



Source: Sustainable Industrial Policy – Building on the Ecodesign Directive, July 2012 (*Note: single splits below 12 kW are excluded from the graph.)*

A 2012 study[114] on the impact of the Eco-design Directive provides an assessment of current market size and structure. However, according to the study "Extra EU-27 trade and Intra EU-27 trade are only available in Prodcom at the even more aggregated level of Procom code 28251 Non-domestic cooling and ventilation equipment. The Prodcom data are therefore of limited value for this analysis, being too aggregated"[115].

[113] Preparatory study on the environmental performance of residential room conditioning appliances (airconditioning and ventilation), ECODESIGN Lot 10, July 2008

[114] Sustainable Industrial Policy – Building on the Ecodesign Directive – Energy-Using Product Group Analysis/2 Lot 6: Air-conditioning and ventilation systems, Part 2 Market Study, July 2012

[115] The relevant Prodcom categories are: 28251220: Window or wall air conditioning systems, self-contained or split-systems. These products are within the scope of this case when used for comfort cooling and over 12 kW cooling capacity: smaller units are under Prodcom code 28251250: Air conditioning machines with refrigeration unit (excluding those used in motor vehicles, self-contained or split-systems machines). This category includes comfort-conditioning air conditioning chillers and chillers used for other air conditioning applications, and other products, 28251270: Air conditioning machines not containing a refrigeration unit; central station air, handling units; boxes and terminals,

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Prodcom data in respect of different types of air conditioning systems is now provided. The "apparent production" values are derived from the reported figures and do not take into account possible stock levels between production or import and sale). The first category of Prodcom data relates to air conditioning systems, self-contained or split-systems. The data shows that European manufacturing exports account for a small proportion of total sales.

Table 4: Window or wall air conditioning systems, self-contained or split-systems, Prodcom category 28251220, Million Euros

Year	*2003*	*2004*	*2005*	*2006*	*2007*	*2008*	*2009*
Exports	87	96	98	147	173	155	119
Imports	620	1,032	924	944	1,389	1,255	668
Production	1,148	1,343	1,264	1,101	1,396	935	682
Apparent consumption	1,681	2,279	2,089	1,898	2,612	2,034	1,231

Source: Eurostat, Prodcom

Prodcom data in respect of air conditioning machines with refrigeration units is now provided. Again, the level of imports considerably exceeds exports.

Table 5: Prodcom category 28251250: air conditioning machines with refrigeration unit (excluding those used in motor vehicles, self-contained or split-systems machines), million Euros

	2003	*2004*	*2005*	*2006*	*2007*	*2008*	*2009*
Exports	375	404	422	430	502	631	509
Imports	1,299	1,949	1,594	1,203	1,657	1,384	881
Production	1,607	1,779	1,566	1,699	2,095	2,364	1,651
Apparent consumption	2,532	3,324	2,738	2,473	3,250	3,117	2,023

Source: Eurostat, Prodcom (note – data on exports was not available in earlier years).

constant volume units and fan coil units (including air handling units and terminal units – including fan coil units - but also other component parts of central air conditioning systems).

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Lastly, the third Prodcom category examined was air conditioning machines not containing a refrigeration unit. Here, unlike in the first two areas, European manufacturing is comparatively stronger, with exports considerably exceeding imports.

Table 6: Prodcom 28251270: Air conditioning machines not containing a refrigeration unit; central station air handling units; vav boxes and terminals, constant volume units and fan coil units, million Euros

	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Exports	188	215	244	270	344	390	328	344	467	459
Imports	167	292	251	254	357	274	207	224	258	200
Production	1,474	1,270	1,253	1,531	1,682	1,777	1,465	1,550	1,676	1,736
Apparent consumption	1,453	1,347	1,260	1,516	1,696	1,661	1,344	1,429	1,466	1,477

Market research data

In the following table, data on the number of units sold annually in the EU based on product sales data from market research are now provided. The Prodcom figures are larger, which reflects the wider scope of Prodcom classifications.

Table 7: Comparison of Prodcom and Market Research Data (2009)

Air conditioning products	*Market Research (no. of units sold annually in EU)*	*Prodcom value*	*Prodcom category*
Chillers	85000	2384000	28251250
AHUs for air conditioning and fan coil units	184,000 + 1,140,000 = 1,324,000	1716000	28251270

Source: Market research data and Prodcom, Analysis presented in Sustainable Industrial Policy – Building on the Ecodesign Directive (DG ENTR).

The data presented above from the market research report draws on a number of sources, such as Eurovent sales data for EU27 for 2008 and 2009, market research reports from BSRIA for six countries (an extrapolation was made for EU27). Although the data is from 2008 and 2009, market research data provides a more accurate picture than Prodcom data since it is disaggregated for air conditioning and fans and for chillers[116].

Key industry trends and challenges

A number of key industry trends were identified through the research. These are, in summary:

- The adverse impact on the market of the global economic and financial crisis, with a significant drop in the numbers of air conditioning units sold in the European Union in 2008, 2009 and 2010, albeit with a recovery in 2011 and 2012.
- Convergence of cooling and heating products and systems.
- The integration of more energy-efficient technologies into air conditioners and cooling systems.

[116] The data is based on sales to end-users irrespective of whether they are imported, manufactured within EU27 or assembled from imported components. Import and export is only reported from a national perspective so intra-EU and extra-EU figures cannot be determined from this derived data.

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Annual turnover in the sectors under review has declined due to the **global economic and financial crisis**, in particular due to lower levels of construction activity. This has led to reduced demand for new air conditioning systems. However, demand for maintenance and repair services has been relatively steady during this period. Although initiatives to reduce energy consumption at EU and Member State level will help to boost demand for the installation of new, energy-efficient units in future, the number of units sold in the European market has declined overall in the past five years. The number of units has fallen sharply across the EU to 9.2m units in 2007, and further still to only 5m units in 2009. It has recovered somewhat during 2010 and 2011, but declined again to 6.65m units in 2012 (source: Eurovent).

There has been a trend towards **convergence in cooling and heating systems**, with integrated solutions becoming more common. Discussions with two air conditioning associations found that more diverse air conditioning solutions are needed.

A further key driver has been the transition towards the use of **more energy-efficient technologies and parts and components** in air conditioners and cooling systems. This has been driven globally by European legislation on Ecodesign implementing regulations to eliminate the worst-performing products.

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3. Summary of applicable IM legislation and standards

A mapping exercise was undertaken to identify applicable IM legislation and standards relevant to the air condition sector. The mapping of IM legislation was based on desk research and discussions with individual manufacturers and the information has been verified by industry associations. The main applicable legislation, is in summary:

- Low Voltage Directive (LVD) - 2006/95/EC
- Electromagnetic Compatibility Directive (EMC) 2004/108/EC
- Machinery Directive (2206/42/EC)
- Implementing Regulation on Ecodesign requirements[117], Regulation 206/2012 EC for air conditioning equipment below 12 kW.
- Regulation Ecodesign requirements for fans (327/2011 EC)
- Regulation Energy Labelling Air conditioners and comfort fans (626/2011 EC)
- Directive 2002/31/EC energy labelling of household air-conditioners
- Pressure equipment Directive 97/23/EC (PED)
- REACH Regulation (1907/2006 EC)
- RoHS Directive (2011/65/EC)
- Packaging and packaging waste (2004/12/EC)
- Regulation Ecodesign requirements electric motors (640/2009 EC)
- Regulation Ecodesign requirements glandless circulators (641/2009 EC)
- Regulation Ecodesign requirements water pumps (547/2012 EC)
- The Gas Appliances Directive (2009/142/EC) "GAD", which applies to gas-fired air-conditioning units

[117] A comprehensive overview of applicable legislation in the area of Ecodesign, the Energy Performance of Buildings Directive and the Energy Labelling Directive was produced recently as part of an Ecodesign preparatory study for air conditioning equipment above 12 kW – see www.ecohvac.eu, task 1, page 128-160.

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It should be noted that whereas for electrically-powered air conditioners, among the core applicable legislation is the LVD and the EMC, for gas-fired air-conditioning and/or heat pump appliances, the GAD may provide the main legal framework. The focus in this case however has not been on gas-fired air-conditioning. Since the HVAC sector is very large, we have sought to focus on other types of air–conditioning systems.
A more detailed mapping of the applicable legislation is provided as an annex to this case study. This provides a summary of the main issues addressed through the legislation (e.g. product safety, energy-efficiency), key administrative requirements for manufacturers and examples of relevant standards.

Although environment legislation is formally out of scope, an overview of applicable environmental legislation affecting air conditioners and air conditioning systems has been mapped out and is provided in annex, since the interaction between IM legislation and European environmental legislation has cumulative effects.

Assessment of gaps and loopholes, overlaps and inconsistencies

The study required an examination of the extent to which there were gaps or loopholes within specific pieces of IM legislation and overlaps and/ or inconsistencies between different IM legislation. The desk research and interviews found that there were no major problems, either in the air conditioning sector or for industrial chillers. However, a number of specific issues were however identified, although some of these have already been resolved.

For instance, there was legal uncertainty as to whether the original RoHS Directive (2002) should be applied to all air-conditioning systems or only to portable units. During a public consultation on the Directive's revision, some industry stakeholders argued for a clearer distinction in the RoHS Directive between 'appliances' and 'systems'. In the recast RoHS Directive (2011), it has now been clarified that there is an exclusion from RoHS for fixed installed cooling, air conditioning and refrigerating systems and heating systems designed for non-residential use. This has eliminated the legal uncertainty that existed prior to the recasting exercise.

One issue that does not yet appear to have been resolved is the need to develop more consistent definitions in IM legislation that affect the air conditioning industry so as to make the demarcation between the Machinery Directive (MD) and Low Voltage Directive (LVD) clearer. Although the Commission has taken steps in this regard previously and has incorporated clarifications into the guidance documents on the MD and the LVD respectively, two of the air conditioning manufacturers interviewed stated that there remains confusion among industry as to whether these directives are mutually exclusive, or whether both directives are applicable for certain types of products. A large European air conditioning manufacturing company commented in this regard that *"whilst it is clear in the legal text of the MD (2006) that there is mutual exclusivity i.e. manufacturers should not apply both the LVD and the MD, there are no such references in the legal text of the LVD to the types of product groups where the MD is not applicable"*[118].

Firm C noted that there can be temporary regulatory gaps due to the lead times in developing standards following the entry into force of new IM legislation. To respond to this challenge, manufacturers typically use the closest available standard in the first instance, and then the correct standard once available can be used by designers at a later stage in the design process.

A further issue related to divergence in the descriptions of similar technical requirements across industrial product legislation. An issue was identified in respect of possible duplication in technical

[118] The LVD applies to small air conditioners for domestic use, whereas the MD applies to larger air conditioning systems such as big chillers.

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standards. A number of manufacturers expressed the view that there are too many EN and ISO standards overall for air conditioners, and this can causes confusion for economic operators, since there are also overlaps between some standards. Manufacturers could be helped to select the most appropriate standards, for example, Firm D stated that *'there are many standards and sometimes there are common elements in the text that repeat themselves. There needs to be further consolidation and merging of standards'*.

4. Analysis of costs of compliance with IM legislation

10 interviews have been carried out as part of this case study, eight with firms, of which six firms provided sufficient quantitative data to be able to quantify the costs of compliance with IM legislation. Through the interviews, a good mix was achieved between firms of different size and market share. Two out of the top five global manufacturers were interviewed, as well as a large European manufacturer of air conditioners and an SME producing chillers. In addition, two interviews with industry associations have been carried out (see Section 8 – information sources). Comments and data have also been provided by an international industry association (JRAIA - the Japan Refrigeration and Air conditioning Industry). In the following table, basic information about the firms interviewed is summarised:.

Table 8 - Basic information on the firms interviewed

Firm	Product category	Firm size	Annual turnover and sales from product in the EU	Main markets
A	Air conditioners & air conditioning systems	Large	Turnover £600m – 800,000 units	98% of sales in EU28
B	Air conditioners & air conditioning systems	Large	Turnover (UK) €100m >200 units	Europe, the Middle East and Africa
C	Air conditioners & air conditioning systems	Large	NA but production in EU numbers in millions of units	80% of sales in EU28
D	Industrial chillers	Small	100 units	Ca. 100% of sales in EU28
E	Air conditioners & air conditioning systems	Large	500,000 units	33% EU 66% outside EU
F	Air conditioners & air conditioning systems	Large	€520m – 300,000 units	50% sales EU28 50% outside EU (mainly Russia)
G	Air conditioners & air conditioning systems	Large	Turnover £42m - 2,500 precision aircon / 500 chillers	80% UK 20% RoW (EU and Middle East (10%))
H	Air conditioners & air conditioning systems	Large	Turnover €200m No. of units not available	Europe, Asia, USA – evenly split

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It should be noted that sufficient data was obtained for SCM purposes from firms A, B, C, E, F and G. Firms D and H were not included in the SCM analysis. In the case of Firm D, this was because although data on human resources involved in compliance and testing was provided, this was an outlier as a % of staff costs compared with the total. In the case of Firm H, no data was available because they currently outsource manufacturing to ODM suppliers so do not have any information about compliance costs including testing.

In this section, a summary of how compliance with IM regulations is managed in enterprises in the air conditioners and air conditioning systems sectors is provided. This sets out the main steps required in order to place an air conditioner or air conditioning system on the market and considers the internal business processes necessary. This provides important contextual information for interpreting the costs of complying with IM legislation.

Overview as to how compliance is managed by air conditioning manufacturers

As mapped out in Section 3, a number of different pieces of IM legislation are applicable to air conditioners. This includes longstanding New Approach directives such as the LVD-D and EMC-D (applicable to all electrical appliances) and more recent legislation adopted in the last decade, such as the Ecodesign requirements (implementing regulations for air conditioners and fan coolers), Energy Labelling requirements and requirements under RoHS and REACH relating to substances used in the manufacture of air conditioners. Additionally, air conditioners are subject to environmental legislation such as the F-Gas Regulation 842/EC/2006[119] and its different implementing regulations and the Energy Performance of Buildings Directive 2010/31/EU (EPBD).

Large firms and SMEs manage the process of ensuring regulatory compliance with IM legislation in broadly similar ways. In large firms, there are commonly separate divisions dealing with different aspects of regulatory compliance: a regulatory compliance manager or department with overall responsibility for compliance (including following EU legislation-making and standardisation processes and familiarisation with the introduction of new and the revision of existing IM regulations and the applicable administrative requirements), a division dealing with research and development and product design, and a division responsible for carrying out conformity assessment procedures through product testing within in-house R&D and/ or testing laboratories.

Large firms are in an advantageous position compared with SMEs however since they can devote staff to the earlier preparatory stages in the development and recasting of IM regulations and in the development and revision of harmonised standards in order to anticipate and respond to regulatory developments. SMEs also try to follow and to anticipate regulatory developments.

SMEs also try to follow and to anticipate regulatory developments but they have less resources available to dedicate to this step. The European industry association pointed out that there is anecdotal evidence to suggest that smaller air-conditioning companies are leaving the market because of the complexity /cost of the regulation. It was difficult to verify this assertion since the smaller size segment of air conditioning companies were generally unwilling to take part in the case (although one small chillers firm did participate – and they were managing compliance with IM legislation). Five main steps were identified in the process of achieving regulatory compliance for the study and these have been used in order to quantify the current costs of compliance. The steps are:

- Familiarisation with applicable/relevant obligations

[119] There is currently a proposal for a revised regulation on fluorinated greenhouse gases - COM(2012) 643

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- Introduction of processes or changes to product design and production processes to ensure compliance with substantive obligations
- Conformity assessment procedures and relevant documentation
- Declaration of conformity or other statement of compliance and CE marking
- Other activities related to obligations posed by authorities

Firms interviewed commented that while these five steps broadly reflect the processes involved in achieving regulatory compliance, for large firms, there is in addition a preparatory step that can involve significant time resources, that of "keeping track of EU legislation and standards".

Any differences between firms in their approach to managing compliance are commented on and the extent to which these differences are dependent on firm size and on the number of products/models being produced.

The companies interviewed were asked to assess the proportion of time FTEs spend on each of the five steps of the above process. Each firm provided slightly different information on this aspect as a result of their internal set-up considering factors such as the extent to which they relied on third party testing services, as opposed to carrying out conformity assessment tests in-house.

However, familiarisation with IM legislation and the applicable administrative requirements was generally seen as quite time consuming (e.g. firm G mentioned that 30% of time was concentrated on this activity). The introduction of changes to product design and carrying out conformity assessment procedures were also seen as time-intensive (e.g. firm D invests 60% of time in total on these items). However, the production of a declaration of conformity and other activities stemming from regulatory obligations were generally seen as less time consuming (e.g. Firm A spends 20% of time in total in this regard). Staff specialising in regulatory compliance spend more time on familiarisation processes with IM legislation and less on the other five steps, whereas for laboratory staff (engineers working in R&D and in testing) the majority of their time is spent on carrying out product testing and on conformity assessment.

Familiarisation with relevant legislation and purchase of standards

Preparatory steps – taking part in EU legislation-making and standardisation processes

Several of the larger air conditioning manufacturers interviewed stated that they invest resources in following EU legislation-making and standardisation processes. The aim is to enable them to shape and influence the development of new and the revision of existing IM legislation.

This enables them to anticipate legislative changes so that new regulatory requirements or changes to existing requirements (and forthcoming updates to technical standards) can be incorporated from as early a stage in the product design process as possible. This enables them to minimise substantive compliance costs by factoring in new requirements from as early a stage in the product design and R&D process as possible.

Large firms interviewed often have dedicated staff specialising in regulatory compliance. They are therefore able to actively contribute to EU legislation-making processes, for example by participating in the work of EU industry associations[120], responding to public consultations, attending workshops

[120] EU industry associations provide an opportunity for industry to feedback their views on the revision of existing EU regulations and on the proposed introduction of new legislation, for instance, through Commission working groups that have been set up on specific directives and regulations e.g. working group on Ecodesign.

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with industry representatives in order to establish a consensus industry position on new legislative proposals and taking part in EU standardisation processes.

Taking part in this preparatory step involves time and human resource costs. Several of the large firms interviewed have full-time regulatory compliance teams consisting of between two and four FTEs. A senior manager at a large European manufacturer estimated that "*Contributing to the policy debate regarding Eco-labelling and Ecodesign took several years from the start of the discussions until the adoption of these regulations. Given that both regulations potentially have a significant impact on the air conditioning industry, during the 2 year period leading up to their adoption was the most intensive, and the amount of time spent on these regulations alone amounted to 0.5 FTE*".

However, there are clear benefits for industry in actively following regulatory development and standards-making processes. This enables large firms to influence policy and legislative-making processes likely to affect them. Industry may not always be happy with the end result, but at least has the opportunity to influence the process. More generally, this facilitates regulatory compliance because large firms are then able to anticipate forthcoming legislative changes and updates to technical standards. This investment in participating directly in EU policy and legislative making processes gives large firms a competitive advantage over their smaller rivals, who typically follow regulatory developments but lack the resource to follow new developments closely.

Familiarisation with applicable legislation and administrative requirements

Familiarisation activities are required to ensure that air conditioning firms are aware of the applicable legislative and administrative requirements. At least in middle and larger sized firms, this step requires input from dedicated regulatory compliance staff who assume responsibility for keeping track of regulatory changes and updates to harmonised technical standards. They are then responsible for briefing different business divisions about new regulatory developments, such as product engineers, product managers and sales teams.

In large firms, such as firm F, there is a division of 2-3 people providing specialist in-house expertise on compliance matters. Another large company, Firm B, mentioned that they employ a full-time regulatory specialist and one of their main tasks is to update product managers, engineers and country sales teams on new legislative developments and how these will affect different product categories. They also provide guidance to colleagues on how new IM legislation and changes to existing regulations should be interpreted. Whist only a small number of full-time regulatory specialists are employed, familiarisation with legislation is an activity that cuts across a number of business functions (e.g. country sales teams and product engineers). Consequently, it was estimated that the total number of FTEs involved in familiarisation with the legislation is equivalent to 15 full time staff. However, Firm H tended to use product safety consultants to provide specialist advice and consultancy support to assist them in the familiarisation process with new legislation. It should however be noted that there is an intention to move this function in-house in the near future.

In SMEs, familiarisation requires a significant effort, but there are less dedicated resources available. Firm D, an Italian firm manufacturing chillers employs a full-time manager who specialises in regulatory compliance to keep track of regulatory developments. The person concerned estimated that approximately 50% of their time was spent on familiarisation activities. The owner of the company also spends about 20% of their time on compliance matters (of which about half on familiarisation).

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Several interviewees commented that familiarisation with more IM directives and regulations introduced in the past five years take up a lot more time than other pieces of legislation. Whereas the legal and administrative requirements for long-established Directives such as the LVD and EMC are well-known to manufacturers and have not changed fundamentally in years , a lot more time is required for compliance specialists to familiarise with the requirements set out in more recent legislation, especially legislation with either environmental, consumer protection or energy-efficiency objectives, such as RoHS and the Ecodesign implementing regulations.

Currently, Ecodesign requirements only apply to small air conditioners under 12 kW and comfort fans under 125W. There is a separate measure that applies to fans of between 125 W and up to 500 kW even if they are included as a component in larger equipment, as detailed in the following sub-section.

Introduction of changes to product design and production processes to ensure compliance with substantive obligations The introduction of new legislative requirements under Union harmonisation legislation may require changes to be made to products either during the R&D and design phase, during the production process and in the case of fans integrated into products, also to products that have already been placed on the market.

The costs of making such changes depend how far in advance air conditioning manufacturers are aware about forthcoming changes and on the length of the product life cycle. The research showed that it is much more costly for manufacturers to make design changes to existing product platforms than it is to incorporate new requirements into new product platforms or those at a very early stage in their development.

An Ecodesign preparatory study noted that the life cycle of air conditioning platforms is typically between 10 and 12 years. The life cycle of an individual air conditioning model is longer than for other types of industrial products[121]. Therefore, the introduction of substantive obligations has a more significant impact on air conditioners.

Since basic air conditioning platforms form the basis on which products are updated through the development of new models and variants, there can be major costs if design modifications have to be made or particular components are withdrawn. Eco-design requirements were regarded as the most administratively burdensome piece of IM legislation. Implementing regulations setting out ecodesign requirements for air conditioners and comfort fans (Regulation EU 206/2012) applied from January 1st 2013 to units of <12KW. Since ecodesign targets the worst-performing products, redesign is necessary only for approximately 20% of existing models.

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Even though large air conditioning units and systems have not yet been made subject to ecodesign legislation, the main implication has been that lower-performing fans integrated into larger air conditioning systems and units have had to be replaced or taken off the market for testing, adaptation or permanent removal.

A large European manufacturer of air conditioning systems, Firm G, commented that although they only produce large air conditioning systems over 12 12 kW, they have already been affected by the implementing regulations. *"Ecodesign requirements have meant that changes have had to be made*

[121] In comparison, the lifecycle of a laptops platform in which different model variants are developed is in the region of 2 to 5 years. It is easier to integrate regulatory requirements into the development of new platforms rather than to invest in modifying platforms that have already been developed.

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to replace fans in older products. Sometimes, fans have had to be withdrawn by suppliers because they no longer meet the required performance threshold for energy efficiency" . In such cases, the firm has then had to identify alternative energy-efficient fans to incorporate as components into larger products, such as air conditioners used for cooling purposes in data centres.

This in turn requires updating the corresponding technical documentation and DoCs and further testing has had to be carried out. Both Firm F and Firm G confirmed that are indirect impacts as a result of fan products used as components being withdrawn, such as a finished unit having to be retested under the EMC Directive, because the old fan originally included as a component when the product was placed on to the market is no longer compliant and a new type of fan has had to be installed. Firm F commented however that 'it is difficult to quantify such substantive compliance costs' since no data is kept on the total costs incurred across a number of different products due to the replacement of fans.

The comments made confirm the findings from an earlier evaluation of the Ecodesign Directive undertaken by CSES that there are some specific issues in respect of the compatibility of ecodesign requirements for fans when these are integrated into other types of products such as machinery and air conditioning systems and larger air conditioners.

Firm C suggested that since the core product safety directives applicable to air conditioners change infrequently that the introduction of new (and updating of existing) technical standards is a greater administrative burden than the legislation itself. Firms A and B had difficulties in determining the exact number of FTE involved in carrying out conformity assessment procedures under IM legislation internally since a significant proportion of manufacturing takes place in Asia. It was therefore difficult for them to know the exact number of engineers involved, especially since the engineers work on products designed for the global market, which will then be designed and tested to meet dual or multiple regulatory requirements.

There can be difficulties for manufacturers in meeting regulatory requirements, while at the same time addressing end-user and consumer needs. For instance, the aim of increasing energy-efficiency is not always compatible with that of reducing indoor and / or outdoor noise.

Conformity assessment procedures

The Supplier's Declaration of Conformity (SDoC) can be applied by manufacturers for most types of air conditioners. Most manufacturers therefore carry out the majority of product testing in internal laboratories, but may also use an external third-party (on a voluntary basis) to carry out some aspects of testing. The use of a third-party provides a useful external validation that helps to ensure an additional guarantee for the enterprise.

A European industry association indicated that although the SDoC procedure can be applied to the LVD, most manufacturers prefer to use a third party. In addition, some firms also make use of external product safety consultants in order to provide advice and to help project manage the testing and compliance process. For example, Firm H uses 2 consultants who work on a working part-time basis for the company for approximately 3 months a year advising on regulatory compliance linked to testing.

Firm D (an SME with 64 staff) employs 7 FTE that deal with regulatory compliance / conformity assessment, 2 of who deal with following regulatory compliance requirements and 4 of who work in the internal testing department. Whereas the EMC and the LVD were believed to be the least burdensome, Ecodesign, the MD and the PED were regarded as the most costly pieces of legislation.

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The firm has invested in accreditation for internal production control under the PED in relation to chillers which has limited its reliance on third parties.

Given the relatively low number of units manufactured by the SME, the costs of complying with IM legislation per unit are higher when compared with large companies. This message was reiterated by Eurovent, the air conditioning industry association that SMEs face much higher regulatory costs per unit. In comparison, large air conditioning manufacturers are able to spread the costs of compliance across a large number of units produced and sold in European markets.

In Firm E, 11 FTE are employed as regulatory and conformity assessment specialists, 5 staff work on internal testing and R&D for air conditioning and 4 staff perform similar activities but working for heaters. Firm E suggested that the initial set-up costs for establishing internal testing functions is expensive. This includes for safety tests (€30,000 to €40,000) and performance tests (€30,000 to €40,000) and room and equipment instrumentation (€200,000). Annual costs include calibration services for instrumentation (€20,000) and replacing instrumentation, estimated at between €30,000 and €50,000.

Firm F commented that Ecodesign particularly in relation to fans is the most costly piece of legislation, followed by the EMC and the LVD. The MD was viewed as being less costly. In total, part of the job description of 20 product engineers is to work on compliance-related matters and this equates to about 10-15% of their time e.g. 2-3 FTEs. The firm spends on average €1 million on external testing per annum and this includes carrying out testing in respect of the EMC-D and the LVD-D. In addition, there are one-off costs associated with the purchase of equipment (€50,000) and annual costs for calibrating equipment (this relates to €20,000 for IM regulations).

In the case of the LVD Directive, one of the oldest New Approach Directives, most testing is carried out by an in-house laboratory with a 3rd party technician being present. However, many SMEs do not have such a laboratory facility and therefore have to send samples to a 3rd party for testing. This means that testing costs can be significantly higher, both in absolute terms and when spread across the total number of units sold. Perhaps surprisingly since the legislation is long-standing and well-embedded, Firm E suggested that the LVD was the most costly IM legislation[122] on the grounds that even if third party testing is not required, there is a need to validate internal test results and to use a notified body to test a random selection of products so as to provide additional reassurance that the product is safe.

In Firm G, conformity assessment procedures cut across the work of two specialised departments that have a combined annual budget of approximately €1.4 million. The development department is composed of 20 electrical and mechanical engineers and CAD designers. The test centre is composed of 6 engineers that evaluate designs and performance functionality. Overall, it is estimated that 3 FTE engineers spend 20 - 25% of their time ensuring that products are compliant. This includes the development of technical reports and product testing. With regard to salaries of staff working on compliance, one engineer has a salary of approximately €60,000 per annum; the costs of annual testing equipment were estimated in the region of €25,000.

[122] The reason why the LVD can result in high costs is due to the duration of the testing process which can take up to one month in a third party laboratory, even after the manufacturer has carried out testing in-house. The main mechanism chosen by manufacturers to achieve presumption of conformity with the LVD is through harmonised standards. Two standards are applicable for air conditioners: (i) EN 60 335-1 (general standard applying to household and similar electrical appliances) and Part 2 specific additional requirements for each category of appliances standard for safety requirements in household appliances and (ii) EN 60 335-2-40: specific requirements for electrical heat pumps, air-conditioners and dehumidifiers.

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Firm G commented that the Machinery Directive and Low Voltage Directives were less costly since the SDoC procedure can be applied. It was noted that some types of industrial air conditioning units must comply with the Pressure Equipment Directive (PED) . Here, complex tests need to be carried out by third parties, or if testing is carried out internally, there is a mandatory requirement that this must be carried out by a third party[123].

Declaration of conformity (DoC) or other statement of compliance and CE marking

Producing a DoC and CE marking was seen as less costly compared with the previous steps described. However, it was recognised that the minor administrative costs involved at the end of the compliance process are only possible once the preceding steps have been completed, which require investment by air conditioning firms.

Firm E stated that producing the DoC is neither problematic nor costly. Firm H stated that producing the DoC itself does not take up a lot of time, since the information contained in the DoC can typically be fitted on to one sheet of A4 paper. Rather, the conformity assessment procedures leading up to the DoC and the development of a technical file are the most time consuming aspect.

Other information obligations and administrative costs

Other administrative requirements under Union harmonisation legislation can however be costly. For instance, the requirement to translate instruction manuals into all EU languages was viewed as costly. Under the LVD Directive, an instruction manual must be supplied in the language where the product is sold. Some interviewees noted that instruction manuals are becoming bigger and more complex, with a requirement to "provide an ever-increasing number of safety warnings to consumers". Firm E suggested that industry would prefer to minimise the amount of text needed on products and to use pictorial symbols or warnings rather than written text that needs to be translated. This would help to reduce costs and reduce the length of compliance and other documentation that has to be provided with products.

Another point raised was that the administrative costs of producing energy labelling (as opposed to the testing of products to check their energy efficiency which is a substantive obligation and can be costly) have been kept to a minimum due to the use of pictograms rather than text. Pictograms were viewed as facilitating communication with consumers across the EU's multilingual market, without the need to spend money on translation or on producing lots of paper to accommodate translations into multiple languages.

5. Assessment of costs of IM legislation for the whole sector

An assessment was undertaken of the compliance costs of IM legislation for manufacturers in the air conditioners and air conditioning sector. As noted earlier, one chiller company was also included. Since the wider HVAC sector is very wide, not all categories of firm were interviewed (e.g. heating pumps firms). The aim was to have a narrower focus on air conditioning.

As noted in Section 4, the assessment was carried out on the basis of quantitative information provided by six manufacturers (from the eight interviewed in total). The costs are related to turnover. In the first column, we seek to distinguish between different types of costs. The distinction between

[123] This includes (PED) final observation of a pressure tests and (EMC) check for radiated and conductive emissions.

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one-off and recurrent costs has been taken into account in the analysis, and some costs, such as the costs of purchasing laboratory equipment have been annualised[124].

A summary of the estimated costs of compliance is provided below (it should be noted that the costs presented in the table represent the net costs after a deduction for "Business as Usual" costs has been taken into account).

Table 9 – Summary of main costs of compliance for air conditioners manufacturing industry

	Unit of measurement	Average cost/ year (total)	Estimated no. of firms	Total costs (annualised)
Compliance with administrative requirements				**€ 17.198.600**
Familiarisation	Manufacturers	€ 64,617	100[125]	€ 6,461,700
Preparation of DoC and technical documentation	Manufacturers	€ 106,169	100	€ 10,616,900
Standards purchase	Manufacturers	€ 1,200	100	€ 120,000
Conformity assessment (internal)				**€ 23.524.975**
Product design	Manufacturers	€ 96,597	100	€ 9,659,650
Testing (internal)	Manufacturers	€ 53,653	100	€ 5.365.325
Testing equipment	Manufacturers	€ 85,000	100	€ 8,500,000
Conformity assessment (external)				**€ 9,360,000**
Consultancy/advisory services (product design)	Manufacturers	€ 18,720	100	€ 1,872,000

[124] These costs were annualised in order to arrive at comparable annual costs, using a system similar to firms' accounting for depreciation. For some questions, we also asked questions in the SCM questionnaire about how much they spent on testing equipment over a 5 year period, which had to be annualised.

[125] Although there is a lack of data on market size and structure at a sufficiently disaggregated level in Prodcom and SBS data, we estimate that there are approximately 20 major manufacturers active in Europe, and perhaps some 80 small and medium sized manufacturers. Even market studies do not provide reliable estimates in this regard so this is a "best estimate".

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	Unit of measurement	Average cost/ year (total)	Estimated no. of firms	Total costs (annualised)
3rd party conformity assessment by notified bodies	Manufacturers	€ 74,880[126]	100	€ 7,488,000
Total				**€ 50.083.575**

We now provide a short overview of the key assumptions made in order to arrive at the above annualised calculations.

The firms interviewed provided data on the level of human resources involved in compliance, for instance on familiarisation with the legislation and technical standards and on how much time and FTE staff are involved in the preparation and updating of DoCs and technical documentation. With regard to estimated salary costs for staff working on regulatory compliance, there were considerable differences between firms. As explained in Section 4, there were even major variations in staff costs *within* firms, depending which aspects of compliance were carried out in Europe and Asia. In order to provide a better basis for comparison between firms, we therefore sought information on human resources and applied a standard tariff using Eurostat data on average salaries. The figures used were €30 an hour, which equates to about €50000 year FTE.

Several firms were also able to provide data on the internal and external costs of testing. Where data was missing, imputations had to be made using data from those firms that did provide data. For instance, one of the top 5 global players provided data on their expenditure on third party conformity assessment, whereas the other was unable to, since testing and conformity assessment was carried out in Asia and the data was not available even internally. We therefore used data from those firms that were able to provide estimates and used this as the basis for assumptions about the level of expenditure for other firms (taking into account other data that was provided, such as the volume of sales units produced and sold in the European market, annual turnover and the number of product platforms manufactured annually).

Firms were asked to provide data on the costs of carrying out conformity assessment testing in-house, for instance their annual expenditure on conformity assessment procedures carried out internally(again taking into account the number of product platforms manufactured annually), and the one-off and recurrent costs linked to testing. This includes the one-off purchase of laboratory equipment and the annual (recurrent) costs of calibrating testing equipment. Not all firms were able to provide this data, either because of commercial sensitivity considerations, or because the information was not shared internally by particular divisions carrying out the testing (especially for the larger Asian manufacturers). Nevertheless, sufficient data was obtained to be in a position to make assumptions about the level of costs in a typical firm, depending on its size, sales volume and the number of product platforms manufactured per year.

[126] There were considerable differences in the estimates of compliance costs for large, medium and small air conditioning manufacturers, reflecting significant differences in the volume of units sold annually in Europe. Standardised parameters were estimated based on the data obtained, taking into account differences between firms of different size thresholds.

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In quantifying the annualised costs of compliance, we attempted to take into account which compliance costs were one-off and which were recurring. It is important to note that the distinction is often blurred between the two in the case of compliance with IM legislation. Examples of one-off costs are the purchase of laboratory and testing equipment, R&D costs, third party conformity assessment costs. Other costs are evidently recurrent, such as the recalibration of testing equipment. However, the picture is more nuanced for other types of compliance costs, which are both one-off and recurring. For example, the cost of the preparation of a DoC and technical documentation is mainly incurred prior to a product being placed on the market. However, in addition to these one-off costs, there are also recurring costs linked to the need to update and maintain a DoC for 10 years post-placement on the market. There is a need to update technical documentation, for instance, to reflect new spare parts and components that are introduced as replacements once a product is already on the market. As regards product design, the costs are mainly one-off, but there could also be recurrent costs if regulatory changes are made and modifications to product design are needed once the product is on the market.

"Business as Usual" (BAU) costs were also taken into account. A number of air conditioning manufacturers stated that a certain proportion (typically 20% to 30%) of product safety testing that they carry out can be considered as BAU since it forms part of internal quality assurance procedures. A number of firms stated that some testing would have been carried out anyway so as to minimise reputational risk even if there is no legal requirement to involve a third party in conformity assessment and the Supplier's Declaration of Conformity (SDoC) can be applied. It was common among manufacturers interviewed to involve a third party in testing for the Low Voltage Directive.

However, there was wide variance in estimates of BAU between firms. A number of firms suggested that approximately 50% of the human resources and cash costs of compliance were BAU, whereas other firms interviewed estimated the proportion to be lower, at 15-25%. An interesting finding was that several manufacturers noted a distinction in BAU depending on the objectives of different pieces of IM legislation. A distinction can be drawn between safety requirements, which were seen as an integral part of BAU and those IM regulations that related to environmental requirements, which were viewed as imposing additional compliance costs that would not occur in the absence of IM regulations. The most commonly cited example in this regard were the eco-design requirements.

Although firms may consider some types of environmental requirements as part of BAU, for instance, as part of their marketing strategy to differentiate products from competitors, the % of BAU costs was much lower. Firm C pointed out that the business as usual case is hypothetical and that it was difficult to provide an accurate quantitative estimate given that without EU regulation, national legislation would apply for safety and environmental requirements. It was suggested that this would create a more complex and fragmented regulatory landscape than is currently the case.

6. Benefits of Internal Market legislation

The research also indicated some important benefits for economic operators from the IM legislation. Air conditioning manufacturers do not have to design products that meet 28 sets of different national legislative and technical requirements. IM legislation has facilitated market access both for European and international manufacturers selling across the Single Market. Although the internal market has opened up competition to international manufacturers by reducing market access obstacles, it should be noted that as explained in Section 2, international manufacturers have also invested significantly in setting up European manufacturing plants, and this has created direct and indirect employment (estimated at 5000 and 15000 jobs respectively).

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Another benefit identified was the notion of "leverage on investment" from compliance with Union harmonisation legislation. Large air conditioning manufacturers – by dint of their global scale and scope - are in a position to leverage investment in regulatory compliance in the EU through the development of product platforms that are compliant with IM legislation and then customising products that are designed to meet stringent European safety, environmental and consumer protection requirements and either designing products for dual or tripe regulatory jurisdictions (e.g. the EU, the US and China) or utilising some of the results from the conformity assessment and testing process as the starting point for achieving compliance in other global jurisdictions, even if differences in technical standards mean that some adaptations / customisation of the product and / or retesting to different specifications may be necessary to meet the different regulatory requirements across different markets.

A further benefit of IM legislation is that it has encouraged the industry to speed up the integration of energy-saving technologies into air conditioners and air conditioning systems. Making air conditioning units and fans integrated into air conditioners more energy-efficient should help to reduce energy consumption and greenhouse gases. The Ecodesign regulations should also stimulate the use of inverters technologies in Europe. These enable air conditioning units to operate more efficiently by varying the speed of the compressor according to its thermal load. Again, there is potential here to contribute to reducing CO2 emissions.

Although interview feedback found that industry views the Ecodesign regulations as having led to increased costs, the regulations should over the medium-long term provide an impetus to strengthening competitiveness by encouraging the "phasing out" of older models and components.

7. Analysis of simplification measures

Through the discussions, air conditioning manufacturers were asked about the extent to which there was scope for simplification of IM legislation and administrative requirements for economic operators.

Simplification measures

There was support among interviewees to reduce the number of (voluntary) technical standards that manufacturers follow, since evidence of duplication between standards was identified (which could be eliminated through a review process to streamline standards). Although the use of such standards to meet the essential requirements is voluntary, in practise, most manufacturers use harmonised standards. Therefore, the costs associated with complying with these regulations are seen as being part of overall compliance costs.

Although responsibility for the development of standards is the responsibility of ESOs under a mandate from the Commission, several firms stressed that it can be difficult and time-consuming to determine which standards are applicable and most relevant to their specific product group. A possible means of overcoming this problem would be to develop product-specific standards for different types of air conditioning products. Using a single 'off-the-shelf' standard would help to reduce the amount of time firms spend in familiarising with multiple technical standards. The SME in the industrial chillers sector also supported the idea of developing a single integrated standard for industrial chillers that took into account all the relevant legislative requirements (e.g. the PED, Machinery Directive, LVD and the EMC).

A further suggestion to reduce the costs of compliance suggested by some large air conditioning firms that export globally was to explore the scope for mutual recognition schemes with third

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countries. This would facilitate exports and avoid products having to be subject to further conformity assessed in different jurisdictions, which is duplicative. For example, it was noted that in Australia, there is a requirement for third party testing of air conditioners and air conditioning systems, whereas the SDoC procedure can be applied in order to place a product on the internal market in Europe. A mutual recognition agreement between Europe and key trading partners such as the US, Russia, Australia and the BRICs would help to minimise the costs incurred by European industry in exporting air conditioning products to new jurisdictions.

A summary of possible simplifications identified through the interviews with air conditioning manufacturers is now provided. This provides a qualitative assessment of possible benefits:

Table 10: Proposed simplification measures, benefits and possible savings

Proposed simplification	Explanation	Benefits
Review technical standards to eliminate duplication and overlap between standards	There is a need to consolidate technical standards wherever these overlap so as to limit the overall number of technical standards.	Reduction in number of standards followed by manufacturers Time saving in familiarisation costs with standards
Integration of measurement methods for all IM legal requirements into a single technical standard.	Development of product-specific standards encompassing all[127]	Time saving in familiarisation costs with standards
Setting up mutual recognition schemes for conformity assessment procedures with major global jurisdictions	Whereas the SDoC is accepted under most IM regulations, 3rd party conformity assessment is mandatory in other jurisdictions (e.g. US, Australia). This can result in manufacturers having to retest products that have already been placed on the European market.	No double testing of products for conformity assessment purposes Reduced need for third party conformity assessment services.

In the following table, we then provide estimates of possible cost savings from these simplifications in so far as these were possible to quantify.

Table 11: Estimates of possible cost reduction costs of compliance for air conditioners manufacturing industry

	Unit of measurement	Reduction per unit	Total quantity	Total cost reduction
Review technical standards to eliminate	Manufacturers	€ 400	100	€ 40.000

[127] There are already examples within the IM regulatory framework of such standards (e.g. under the PED, where is a standard for boilers).

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	Unit of measurement	Reduction per unit	Total quantity	Total cost reduction
duplication and overlap between standards[128]				
Integration of IM legal requirements into a single technical standard[129]	Manufacturers	€ 9.693	100	€ 969.255
Setting up mutual recognition schemes for conformity assessment procedures across key global jurisdictions (e.g. EU, US, Russia, China, etc.)[130]	Models	n.a.		€ 374.400
Total				**€ 1.383.655**

It should be noted that the estimated simplification savings are approximate. It is difficult to quantify savings because manufacturers are themselves unable to quantify the expected level of benefits and cost reductions. Moreover, there is a lack of baseline data on many types of costs. For instance, in order to accurately quantify the cost savings of implementing a mutual recognition scheme, it would be necessary to have data on the costs of third party conformity assessment in third countries and the comparable costs in the EU for manufacturers of following the Supplier's Declaration of Conformity (SDoC) procedure. Estimating the latter is complicated by the fact that even when manufacturers use SDoC, they often carry out some testing themselves, while using a third party to undertake some aspects of testing on an outsourced basis. .

Measures to improve the effectiveness and efficiency of the regulatory landscape and help to remove uncertainty.

In addition to possible simplification measures, manufacturers noted that compliance costs could in some cases be kept in check if the Commission were to take steps to ensure that current ambiguities in the IM regulatory framework are eliminated, since this would remove current legal uncertainty with regard to what the requirements are. In addition, access to relevant information could be made more accessible thereby enhancing the efficiency of the 'familiarisation with the legislation step.

Familiarisation with legislation is a major cost for manufacturers. Currently, regulatory compliance specialists need to continually engage with industry associations, attend industry events and speak with their suppliers in order to keep track of upcoming regulatory developments. Manufacturers are

[128] Lower cost of purchasing standards (average 80 EUReach). 5 (=1/3 of total) fewer standards purchased a year = saving of 400 EUR per firm.

[129] 15% saving in familiarisation costs .

[130] No saving for manufacturers only exporting within EU. Estimated 25% reduction 3rd party CA per model exported to third countries. Assumed: 20% of models exported. Adds up to a reduction of 5% on CA. Note: this saving will only be relevant and measured in instances when CA was originally carried out in the EU.

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consulting national standardisation authorities to ensure that they keep abreast with ongoing updates and developments. A number of different sources are drawn upon to ensure that firms are fully informed. As a result, a lot of time and effort is being invested in this area and it is likely that not all firms are equally engaged in the process. To address this issue, the Commission could set up a centralised online repository for keeping track of the introduction of new, and changes to existing IM directives and regulations and updates in the applicable standards. This could provide details for individual product groups. This could reduce the human resources needed by manufacturers to keep track of regulatory changes. The familiarisation step is clearly an area where the Commission could help to create a level playing field for market participants and ensure that there is equal access to the latest regulatory information and development in the fields of standards.

In addition, the point was made that there is some ambiguity in the wording in the NLF as to the translation requirements for DoCs. The industry is accustomed to producing DoCs in EN and this has met the needs of Market Surveillance Authorities since the introduction of the New Approach. However the wording in the NLF is ambiguous as to whether the use of the relevant national languages is required or is EN is permissible[131]. Clarifying this matter with a view to retaining the longstanding linguistic approach of using EN would remove any ambiguity and sustain the current level of efficiency in this area.

Table 12: Proposed efficiency enhancing measures and benefits

Proposed measure	Explanation	Benefits
Provide clarity as to whether DoCs need to be translated into all EU languages	There is a need to remove ambiguity as to whether DoCs can be translated in EN for the EU market or if Member States translations are required.	Ambiguity for manufacturers will be reduced and the currently level of efficiency in producing DoCs will be maintained.
Development of an online repository of regulations and indication of the relevant standards (and where they can be purchased) for specific product groups and providing an overview of (future) updates and developments.	Currently ensuring that firms are up to date with legislation and standards requires investment in keeping abreast with developments in multiple areas with information being retrievable from several sources. This could be centralised and made more coherent.	Familiarisation with the legislation and standards represents a major cost for industry. Providing the most up to date information located in a single source will help to reduce costs in this area.

8. Overall conclusions

This case study focused on air conditioners and air conditioning systems. Since the HVAC industry is very broad, it was not possible to include all categories of air conditioner.

[131] Decision 768/2008 states that "The DoC shall be translated into the language or languages required by the Member State in which market the product is placed or made available".

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There were difficulties in obtaining reliable data on the air conditioning sector in Europe since Prodcom data was only available at a high level of aggregation. However, global market data shows that the manufacturing of small air conditioners (<12 KwH) and comfort cooling systems is dominated by a small number of global manufacturers, especially from East Asia (the EU has only an estimated 7% share). According to data on the size of the world market for air conditioning in 2013, global production was 98m units in 2013, whereas the size of the European market was about 6.65m units sold in 2012. European manufacturers have a stronger market share in niche markets such as chillers and high-end data cooling systems.

IM legislation applicable to air conditioners and air conditioning systems includes some of the core product safety directives such as the Low Voltage Directive (LVD) and the Electromagnetic Compatibility Directive (EMC). In addition, IM legislation with an environmental focus is applicable, for instance the Ecodesign implementing regulations for small air conditioners and comfort fans <12kwH. From 2015, the extension of ecodesign requirements through Lot 3 Ecodesign Implementing Regulations for larger air conditioners is likely to result in extra administrative costs for industry. These future costs are expected to be quite high compared with well-established IM legislation.

On the basis of information provided by the eight companies interviewed, most of whom were able to provide quantitative information, the costs of compliance with IM legislation were estimated at around €50.8 million, equivalent to c.a. 1% of annual turnover. Administrative compliance costs (familiarisation with the legislation and applicable administrative requirements, the preparation of a DoC and technical documentation) were estimated to be approximately €17.2 million. Substantive compliance costs, such as integrating IM regulatory requirements into product design and carrying out testing as part of conformity assessment procedures (internally and externally) were estimated at € 23.5 million per year.

The interviews with firms were consistent in pointing to the Ecodesign Directive as one the main current cost drivers of compliance-related activities. It was acknowledged however that the costs of the introduction of new legislation, whilst high in the short-term tend to diminish over time as the legislation becomes better embedded. The need to replace fans integrated into larger air conditioning systems already in the development pipeline or about to be placed on the market was a particular industry concern, since many fans do not meet eco-design requirements.

The air conditioning industry was broadly supportive of internal market legislation in providing a regulatory framework that avoids country-specific divergence across different national markets. However, they were concerned that their industry is especially impacted by the high administrative costs of IM legislation that has a strong environmental focus.

As regards the possible scope for simplification, there were no suggestions relating to IM legislation itself. Rather, proposed measures related to the need to eliminate duplication due to perceived overlap between different technical standards. The possibility of integrating all IM legal requirements into a single technical standard so as to overcome duplication was raised by two firms. Total potential savings were these and other measures, such as strengthening the mutual recognition of conformity assessment across different jurisdictions, were estimated to be €1.4 million.

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9. Sources of information - interviews

References - Sources

- Preparatory study on the environmental performance of residential room conditioning appliances (airco and ventilation), Economic and Market analysis, July 2008.
- Market research data and Prodcom, Analysis presented in Sustainable Industrial Policy – Building on the Ecodesign Directive (DG ENTR).
- A comprehensive overview of applicable legislation in the area of Ecodesign, the Energy Performance of Buildings Directive and the Energy Labelling Directive was produced recently as part of an Ecodesign preparatory study for air conditioning equipment above 12 kW – see www.ecohvac.eu, task 1, page 128-160.
- JARN, the "Japan Air Conditioning, heating and refrigeration news" magazine, 25 May 2013 Prodcom data, 2010.

Interviews

- 1 with a national association in the UK (FITA), and 1 with an EU Industry association (Eurovent).

- 7 interviews with manufacturers of air conditioners, 1 interview with a manufacturer of chillers (6 of the 8 discussions yielded quantitative data.

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Annex - Applicable IM legislation and standards

This Annex provides information that supplements the summary overview of the applicable IM legislation and standards in Section 3 of the case.

A mapping exercise was undertaken to identify applicable IM legislation relevant to the air conditioning sector. An overview of relevant legislation and of relevant technical standards is now provided. This draws on desk research and has subsequently been verified by industry associations and enterprises. There are differences in the applicable legislation and technical standards depending on the size of the air conditioning system and its intended purpose (e.g. domestic, industrial, fixed installations vs. portable air conditioners). For example, Ecodesign implementing regulations have only so far been introduced for air conditioning systems <12 kW, although as will be shown in this case study, the withdrawal of non-compliant fan products can also affect manufacturers of larger air conditioning and precision engineering systems which integrate such fans into their products. The PED is only relevant to larger air conditioning systems for industrial use.

Table 13: Overview of IM legislation and standards applicable to air conditioners and conditioning systems

Name of legislation	*Main issue addressed (safety, environment, other)*	*Administrative requirements for economic operators*	*Relevant standards*
Core legislation			
Low Voltage Directive (LVD) - 2006/95/EC	Health & Safety (electrical)	Testing according to relevant safety standards Development of technical file Declaration of conformity and CE marking Installation instructions and manual for final consumer (with translations)	Two applicable standards to achieve presumption of conformity for portable and household air conditioning: Part 1 EN 60335-1 (general standard applying to household and similar electrical appliances) Part 2 EN 60335-2-40 Particular requirements for electrical heat pumps, air-conditioners and dehumidifiers EN 50564:2011 Ecodesign – stand by and off mode:
Electromagnetic Compatibility Directive (EMC) 2004/108/EC	Electromagnetic compatibility	Testing according to relevant technical standards Development of technical file Declaration of conformity and CE	

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		marking	
Machinery Directive (2206/42/EC)	Safety	Development of technical file Declaration of conformity and CE marking Installation instructions and manual for final consumer (with translations)	Only applicable to air conditioning systems intended for industrial and/ or commercial use Requirements of the directive for cooling generators of ENTR Lot 6 are covered under the following standards: - EN 12693:2008 Refrigerating systems and heat pumps - Safety and environmental requirements - Positive displacement refrigerant compressors - EN 378-2:2008+A1:2009 Refrigerating systems and heat pumps - Safety and environmental requirements - Part 2: Design, construction, testing, marking and documentation
Gas Appliances Directive (GAD) 2009/142/EC	Specify the safety level required of appliances burning gaseous fuels by specifying design, operating characteristics and inspection procedures.		Two harmonised European standards have been cited in the OJEU under the GAD: (1) EN 12309-1:1999: Gas-fired absorption and adsorption air-conditioning and/or heat pump appliances with a net heat input not exceeding 70 kW - Part 1: Safety; and (2) EN 12309-2:2000: Gas-fired absorption and adsorption air-conditioning and/or heat pump appliances with a net heat input not exceeding 70 kW - Part 2: Rational use of energy[132]
RoHS Directive (2011/65/EC)	Use of hazardous chemicals	Collect compliance statement from suppliers (material declarations) Technical file with supplier declarations and own analysis tests	Note: since the 2011 recast Directive, there is an exclusion from RoHS for fixed installed cooling, air conditioning and refrigerating systems and heating systems designed for

[132] It is of particular interest that the latter standard deals with the energy efficiency of gas-fired air-conditioning appliances (the energy efficiency aspect may be subject to one or several of the implementing measures under the EcoDesign Directive).

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		Declaration of conformity to be kept for 10 years	non-residential use. CE marking has been applicable since the 2011 RoHS II recast.
Implementing Regulation on Ecodesign requirements[133]: Regulation 206/2012 EU for air conditioning equipment below 12 kW and comfort fans.	Energy consumption/ efficiency	Testing according to harmonised standard Technical file with results of studies and explanations of design choices made and the management system Development of product fiche Declaration of conformity and CE marking Installation instructions and manual	EN 14511:2011 Determination of Full load energy efficiency EN 14825 2011 Determination of part load energy efficiency EN 62301:2005 (CEN) Standby power consumption EN 12102:2008 Sound power level (CEN) Notes: • Applies from 1st January 2013. A regulation on Ecodesign requirements for equipment above 12 kW is in preparation.
Regulation Ecodesign requirements for industrial fans (327/2011 EU)	Fan efficiency	Development of technical file Declaration of conformity and CE marking Installation instructions and manual for final consumer (with translations	
Regulation Energy Labelling Air conditioners and comfort fans (626/2011 EU)	Energy consumption/ efficiency	Technical file with results of studies and explanations of design choices made and the management system Development of product fiche Placing of energy label	EN 14511:2011 Determination of Full load energy efficiency EN 14825 2011 Determination of part load energy efficiency EN 62301:2005 Standby power consumption (CEN) EN 12102:2008 Sound power level (CEN)

[133] A comprehensive overview of applicable legislation in the area of Ecodesign, the Energy Performance of Buildings Directive and the Energy Labelling Directive was produced recently as part of an Ecodesign preparatory study for air conditioning equipment above 12 kW – see www.ecohvac.eu, task 1, page 128-160.

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Other legislation			
			•
Pressure equipment Directive 97/23/EC (PED)	Safety of pressurized systems	Development of technical file Declaration of conformity and CE marking Installation instructions and manual for final consumer (with translations)	EN 378: 2012 environmental & safety requirements Note: only applies to larger air conditioners
REACH Regulation (1907/2006 EC)	Use of chemicals	Collect statement from suppliers stating that product is in compliance with requirements REACH compliance statement	
Packaging and packaging waste (2004/12/EC)	Packaging	Declaration of Conformity	
Regulation Ecodesign requirements electric motors (640/2009 EC)	Motor efficiency	Development of technical file Declaration of conformity and CE marking Installation instructions and manual for final consumer (with translations	
Regulation Ecodesign requirements glandless circulators (641/2009 EC)	Circulator efficiency (chillers)	Declaration of Conformity CE marking	
Regulation Ecodesign requirements water pumps (547/2012 EU)	Circulator efficiency (chillers)	Declaration of Conformity CE marking	

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The European Union's Ecolabel Regulation 66/2010 is a voluntary labelling scheme and can be awarded to products and services that have a lower environmental impact compared with other products in the same group. The label criteria were devised using scientific data on the whole of a product's life cycle, from product development to disposal. There is a link between the voluntary Ecolabel and compliance with Ecodesign regulations in that products bearing the Community eco-label are presumed to comply with the Ecodesign requirements stated in the applicable implementing measures.

Although EU environmental legislation is not formally within study scope, such legislation is particularly important in the air conditioning industry since it forms part of the overall body of EU legislation with which manufacturers must comply. A summary of the main environmental legislation that applies to air conditioners is summarised below:

Table 14: Overview of applicable environmental legislation affecting air conditioners and air conditioning systems

Name of legislation	*Main issue addressed (safety, environment, other)*	*Notes and references to relevant standards*
F-Gas Regulation (2006/842/EC)	Containment of greenhouse gases	F-gas regulation and its 10 supporting implementing regulations (leakage, certification personnel, labelling, etc.). Note: legislation under revision due to proposal to revise F-gas Regulation, COM(2012) 643 The aim is to reduce the emissions of fluorinates greenhouse gases covered by the Kyoto Protocol.
Implementing Regulations for the F-Gas Regulation Labelling F gas (1494/2007 EC)	Labelling Certification of technical personnel and companies Leakage	Personnel & company certification is mandatory and concerns personnel who install, maintain or service systems; leak check systems
Energy Performance of Buildings Directive 2010/31/EU (EPBD)	Energy Performance in buildings	Articles 15,16,17,18 deal with the inspection of air conditioning systems, but also the impact of national/ regional calculation methods e.g. SAP in UK, En EV in D, RT 2012 in F There are also a set of related standards developed under CEN TC 113 and CEN TC 228 Energy Performance of Buildings Directive. CEN Standard EN15251 (comfort conditions regarding temperature and humidity).
WEEE Directive (2012/19 EC)	Waste of electrical equipment	The scope is defined in the IA Annex of the WEEE directive (2002/96/EC). Air-conditioning products are dealt with in the IB Annex under 'Large household appliances', as 'Large cooling appliances', 'Air conditioner appliances', 'Other fanning, exhaust ventilation and conditioning equipment'.

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CASE STUDY 8 – INTEGRATED CIRCUITS

1. Introduction – objectives of the study

The product groups examined in this case study are integrated circuits. This covers a wide variety of products, sub-components and final applications as explained further in section 2, below.

The aim is to analyse the applicable IM legislation, assess the costs associated with the implementation of the applicable IM legislation, identify areas of overlaps and conflicts between the different parts of the legislation that may lead to problems and costs to industry. This case will also identify and assess the benefits of possible simplifications. The rationale for the selection of these product groups was that:

- Integrated circuits are a fully globalised product group, with important centres of European expertise integrated into the global value chain and which are directly impacted by European legislation
- Integrated Circuits are manufactured in stages, with a number of processes between the first step and the final application in a product. Costs are incurred at each stage of the production process
- Integrated Circuits are perhaps the single most prominent Key Enabling Technology, and are one of the key factors to realise the overall policy objectives of Europe 2020. As such, integrated circuits are the subject of a newly-released European strategy for micro- and nonelectrical components and systems
- Integrated circuits are a key input into a number of additional products and are used primarily by professional users.

This case study is based on desk research and qualitative interviews. In the first phase of the project, structured desk research was carried out in to establish an overview of the integrated circuit industry, identify relevant pieces of legislation and standards, and to identify companies within the industry. An interview with The European Semiconductor Industry Association (ESIA) was then carried out. Thirty-five companies were contacted for interviews. In the end, eight interviews with firms were carried out. The interviews covered one of the largest European-based manufacturers of integrated circuits, another large European manufacturer, one of the largest global manufacturers, based in Asia, and inputs from five smaller 'fabless' manufactures in a variety of applications. A number of companies declined to participate in the study, citing difficulty in assessing costs or, in many cases, confidentiality reasons.

2. Product definition and description of structure of the sector

According to the standardised language adopted by the International Electrotechnical Commission, a semiconductor is a device whose essential characteristics are due to the flow of charge carriers within a semi-conductor. According to IEC 521-10-03, this includes any *microcircuit in which all or some of the circuit elements are inseparably associated and electrically interconnected so that it is considered to be indivisible for the purpose of construction and commerce*. This includes a number of applications. The following PRODCOM categories have been used to outline the scope of the product group.

Products with
26112240 - Photosensitive semiconductor devices; solar cells, photo-diodes, photo-transistors, etc

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Products with
26113003 - Multichip integrated circuits: processors and controllers, whether or not combined with memories, co
26113006 - Electronic integrated circuits (excluding multichip circuits): processors and controllers, whether or n
26113023 -Multichip integrated circuits: memories
26113027 - Electronic integrated circuits (excluding multichip circuits): dynamic random–access memories (D R
26113034 - Electronic integrated circuits (excluding multichip circuits): static random–access memories (S–RAMs), including cache random–access memories (cache–RAMs)
26113054 - Electronic integrated circuits (excluding multichip circuits): UV erasable, programmable, read only m
26113065 - Electronic integrated circuits (excluding multichip circuits): electrically erasable, programmable, rea
26113067 - Electronic integrated circuits (excluding multichip circuits): other memories
26113080 - Electronic integrated circuits: amplifiers
26113091 - Other multichip integrated circuits n.e.c.
26113094 - Other electronic integrated circuits n.e.c.

As is clear by the range of product types, the product category of integrated circuits contains a number of sub-types. In general, integrated circuits are the building blocks of a number of technologies that make up micro- and nano-electronic components and systems. This includes the semiconductors used in all types of digital application used in electronics, automotive, and medical devices. In addition, integrated circuits are moving into an additional range of applications that further complicate the sector. New technologies such as wearable applications are driving breadth of integrated circuits into new product types.

Market size and Industry Structure

The global turnover of the semiconductor sector has been estimated at €230 billion in 2012, while the value of products comprising micro- and nanoelectronic components represents around € 1,600 billion worldwide and has grown by 5% per year since 2000.[134]

The starting point for the size of the European market is the Eurostat PRODCOM database, supplemented by additional market studies. In the PRODCOM database the specific product are covered under the code 261130-XX. Based on data, turnover is in the range of EUR 56.8 billion. Other sources suggest a somewhat smaller industry, with European turnover in 2011 amounting to EUR 30,3 billion.[135] The most comprehensive report outlining the profile of the Integrated Circuits market is the EU Trade in Electronics Sector Fiche, which is cited by the Industry Association as an authoritative source of market information. The Sector Fiche indicates a market size of

Industry Structure

Semiconductor products are multinational composites, and the industry is highly decentralised and diverse. The process of manufacturing can be broken down into discrete steps, with up to 600 sequential operations for each circuit. Final products are based on wafer processing, testing, and assembly, which generally take place in different places, often in different regions across the globe. The value chain is very complex and long, with the industry moving into even greater levels of fragmentation.

[134] European Commission. 2013.

[135] Semiconductors: Global Industry Guide. 2012. MarketLine

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Developing newer generations of chips, becoming smaller and more powerful at an exponential rate, requires a high degree of precision in the fabrication process and higher levels of investment. In the 1980s, a new business model emerged to help solve the need for constant investment, called the "foundry" model, comprised of different types of manufactures. Large foundries, called "fabs" are able to increase the volume of their production to a sufficient scope to allow them to update assembly and photolithography systems, and are more commonly located in the Asian Pacific region. The Taiwan Semiconductor Manufacturing Company (TSMC) is the world's largest dedicated independent semiconductor foundry, with its headquarters and main operations located Taiwan. As a corollary industry, the "fabless" semiconductor company model, is comprised of firms focused on design, marketing, and sale of circuits while benefitting from lower capital costs while concentrating their research and development resources on the end market.

The industry continues to bifurcate into two types of integrated circuit producers:

- **Integrated Device Manufacturers** (IDM) that design, manufacture and sell their chips. This includes firms in the United States (e.g. Intel), Asia (e.g. Samsung), and in Europe (e.g. STMicroelectronics, NXP, Infineon).

- **Fabless manufacturers** that design components and provide integrated circuit products and services to customers but outsources manufacturing to foundry companies. Fabless manufacturers often source their products from multiple foundries to optimise their supply chain and secure constant access to materials.

- A hybrid '**fab-light**' model has also emerged, which is based on maintaining some high-value manufacturing in-house but outsourcing the rest to a foundry.

The continued migration of production to 'low cost' labour countries combined with the continued high rhythm of technological change has driven companies to focus on core competencies, meaning that European firms are increasingly specialised in one component of the value chain.[136] The emergence of a networked model has allowed for – and subsequently encouraged – a greater degree of specialisation and opportunity for new entrants in highly-innovative areas of design, logistics, services, and computer-supported manufacturing.

This globalisation of the industry has also created a very long and complex supply chain in which European firms increasingly focus on collaboration and industrial partnerships. It is common for companies to rely on supply chains for most subcomponents, with third party testing occurring at various stages along the production phase, depending on the product type, country of origin, and intended final application.

The European industry is driven by a high research-intensity, with the highest R&D intensity of any sector in Europe, at 14.8 percent.[137] Industry clusters are important in the integrated circuits sector, given the high R&D intensity and the need to specialise. The most significant European clusters are located around Grenoble (France), Eindhoven (Netherlands), Dresden (Germany) and Dublin (Ireland), but other European clusters such as Catania in Italy also have global presence. It also appears that the leading clusters will reinforce their position as technology transitions to a new platform based on 450 mm wafers.[138] To sustain these clusters, European-wide supply chains have

[136] http://ec.europa.eu/enterprise/newsroom/cf/_getdocument.cfm?doc_id=7382

[137] The EU Industrial R&D Investment Scoreboard: http://iri.jrc.ec.europa.eu/scoreboard.html

[138] European Strategy for Micro and Nanoelectronic Components and System

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developed, with additional high-tech clusters in increasingly specialised fields (such as Helsinki and Vienna). Table 1 outlines key descriptive data on the European market.

The largest manufacturer is located in Taiwan (TSMC). Within the top 20 producers in terms of worldwide sales, only three are located in Europe: STMicroelectronics, Infineon, and NXP. Global rank among the largest European manufactures is provided in Table 2, below.

Table 2: Top European manufacturers - 2010

Global Rank	Company	Country	Revenue (million USD)	Market Share (percentage)
7	STMicroelectronics	France/Italy	10, 290	3.4
13	Infineon	Germany	6,226	2.0
17	NXP	Netherlands	4,021	1.3

While European manufacturers do not command a large global share, some producers of integrated circuits have established sites in Europe, including sales, design, and research along with some production as well capacity. In 2011, European production represented less than 10 percent of global production, down from a high of 16 percent only a decade earlier. Nevertheless, in Europe, micro- and nanoelectronics is responsible for 200,000 direct and more than 1,000,000 indirect jobs. [139]

Table 1 – Data on market size and industry structure

Parameter	Data
EU Market size	Market reports (2011) EUR 30.3 billion
Production volume/value in Europe	PRODCOM – Production Value (2010) – EUR 49.2 billion PRODCOM - Production Quantity: 11.415.218.521 units
Imports	PRODCOM - Value of Imports: 11.174.225.410 units
Exports	PRODCOM - EUR 8.8 billion
Number of enterprises	PRODCOM (2010) 6,984
Total Turnover	PRODCOM - EUR 56.8 billion

[139] http://ec.europa.eu/enterprise/sectors/ict/files/kets/hlg_report_final_en.pdf

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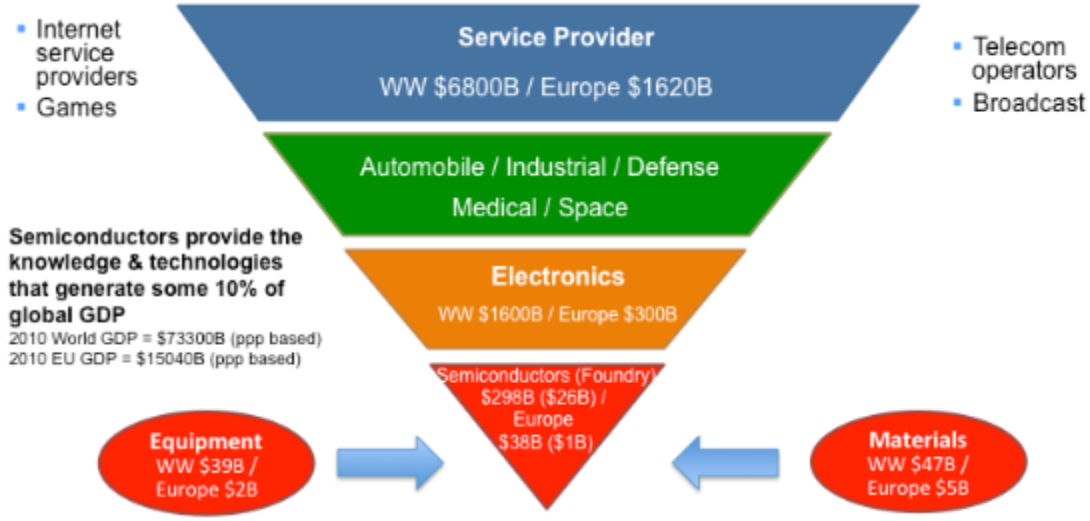
Number of employees	ESIA (2012) 200,000 direct employment PRODCOM (2010) 215,000

Source: Eurostat and market reports

The Final Report of the High-level Expert Group on Key Enabling Technologies[140] estimates that the European sector will enjoy a compound annual growth rate of 13 percent over the next years. But the industry data itself does not tell the complete story of the value of the integrated circuits sector to the overall European and global economy. Integrated circuits constitute a Key Enabling Technology (KET) and are valuable for the economic potential, their value-adding and enabling role, as well as their technology and capital intensity in terms of R&D and initiation investment costs.[141] The image below outlines the economic impact of the sector, both in terms of providing a market for suppliers of materials and equipment, moving up into direct employment and the subsequent industries enabled by the presence of software.

Figure 3: Value of Enabling Technology



Source: ESIA, 2010

3. Analysis of applicable IM legislation and standards

On the basis of desk research and input from firm interviews, we have identified the list of applicable pieces of Internal Market legislation, the basic administrative requirements and the relevant harmonised standards that can be used by manufacturers to meet the essential requirements.

[140] High-Level Expert Group on Key Enabling Technologies. Final Report. http://ec.europa.eu/enterprise/sectors/ict/files/kets/hlg_report_final_en.pdf

[141] High-Level Expert Group on Key Enabling Technologies. Final Report.

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In response to the internal market legislation, a number of **standards** have been developed, as outlined in table 2, above. Integrated circuits are highly technical and subject to broad international standardisation. Extensive standards exist. Given that the range of potential applications and sub-groups is limitless, only the major product-specific regulations have been reviewed. The table is meant to illustrate key standards that are aligned with specific requirements from internal market legislation, and is far from comprehensive.[142]

Standards vary according to the organisation issuing them. A number of standard-setting organisations exist, such as industry-led bodies (JEDEC), as well as the IEC and ISO/CEN. The IEC have been active in developing recent standards for the industry, as it focuses on the electronics industry.

Table 2 – Summary of IM legislation covering Integrated Circuits

Name of legislation	Main issue addressed	Requirements for economic operators	Relevant standards
RoHS (2011/65/EC)	Use of hazardous chemicals	Collect compliance statement from suppliers (material declarations) Technical file with supplier declarations and own analysis tests Declaration of conformity to be kept for 10 years	**EN 50581:2012** **IEC62321**
General product safety Directive	Health & Safety	Provide identification of the product by a product reference Carry out sample testing of products, keep a register of complaints and keeping distributors informed of such monitoring (voluntary) Inform authorities of dangerous products and actions taken to prevent risk Co-operate with the authorities upon request	**CENELEC: EN 60950-1:2006/A12:2011**
EMC 2004/108/EC	Electromagnetic compatibility, mostly in the	Testing according to standards Development of technical file Declaration of conformity and CE marking	**IEC 61000** **IEC 61967**

[142] A search for 'integrated circuits' on the British Standards Institute database resulted in 685 individual standards. http://shop.bsigroup.com/en/SearchResults/?q=integrated%20circuits

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Name of legislation	Main issue addressed	Requirements for economic operators	Relevant standards
	downstream applications of some integrated circuits		**IEC 62132**
Packaging and packaging waste (2004/12/EC)	Packaging	Declaration of Conformity	
REACH	Use of chemicals	Collect statement from suppliers stating that compliance with requirements REACH compliance statement	**IEC 62474**

The review of the various requirements and the discussions with manufacturers pointed to a few issues in relation to the implementation of the legal framework and the requirements:

- Of the regions that produce integrated circuits, Europe is the most highly-regulated region in the world and plays a key role in the development of global standards. Given the globalised nature of the industry, with highly developed supply chains, undue or particularly burdensome regulation can cause shifts in production location. The initial analysis suggests that most Directives place rather similar obligations on industry; namely, revise the design of some products and then subsequent requirements to test, document, and declare conformity to specific requirements.
- This uniformity in across the sector was pointed out in the interviews with firms as being a positive aspect of the current framework. The industry is in general agreement that the legislation and the surrounding legislative framework are fairly positive. However, specific instances of duplication and inconsistencies have been identified.
- The most specific piece of legislation relating to integrated circuits is the RoHS Directive, which has been in effect since 2006. It was recently updated, known as RoHS2 (2011/65/EU), to address some uncertainties raised by industry and to increase market surveillance. RoHS2 bans new electrical or electronic equipment containing lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyl and polybrominated diphenyl ether flame-retardants above specified thresholds and places documentation requirements throughout the supply chain.
- The interviews with firms consistently pointed to the RoHS Directive as the main driver of compliance-related activities. However, the interviews also emphasised that the RoHS-related procedures are part of a larger change to the industry that is now so deeply integrated in to the supply chain that it could not be isolated, even hypothetically.
- RoHS applies to integrated circuits produced in Europe as well as those entering the EU that are manufactured abroad. Due to the global nature of the industry, RoHS has become a *de facto* global regulation. China recently adopted most of the provisions through ‘China RoHS,’ which applies to the bulk of manufactured products. The RoHS concept is thus deeply integrated into the global industry and provides a framework for much of the supply chain.

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- RoHS provisions are also reinforced and complemented by REACH, Directive No 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals. The General Product Safety Directive introduces mandatory requirements concerning the product identification, cooperation with authorities when requested and a voluntary conduct of tests of marketed products, and the keeping of a register of complaints.

4. Analysis of costs of compliance with IM legislation

The information presented in this section is based on the in-depth interviews with eight producers of integrated circuits. The firms range in terms of size and production volume and a located at various points along the production chain.

Given that the integrated circuits industry is completely globalised, turnover has been estimated from the turnover from Europe or from the European subsidiary of global companies. Information has been taken from corporate reports. It should also be noted that even though turnover is from Europe, the overall activity is fully global, such as R&D taking place in Europe with manufacturing happening in other regions, generally in Asia).

Firm	Product/Application	Firm Size	Annual turnover from product (global)	Share of EU market (% of total firm turnover)
A	Fabrication	Large (>1000 employees)	3,900,000,000	33
B	Fabrication	Large (>1000 employees)	17,100,000,000	10
C	Fabrication	Large (>1000 employees)	4,368,000,000	20
D	Fabless - telecommunications	Medium size (250-500)	388,000,000	32
E	Fabless – consumer electronics	Small (<250 employees)	2,400,000,000	10
F	Fabless –touchscreen components	Small (<250 employees)	3,000,000	100
G	Fabless - general	Small (<250 employees)	6,000,000	15
H	Fab-lite - general	Medium size (250-500)	1,800,000,000	66

On the basis of discussion with the integrated circuit producers, IM legislation generates impacts on the following stages of the production process:

- Familiarisation with legislation and the purchase of standards
- Development of alternative designs and the associated testing of materials
- Seeking authorizations and exemptions, if needed, from RoHS and REACH lists of restricted substances
- Documentation of c Documentation of compliance - Testing, technical file and certification
- Monitoring the suppliers in the supply chain for compliance and switching to avoid non-compliance
- Declaration of conformity, CE marking and instruction manual

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- Response to market surveillance activities

A number of caveats are necessary.

- It should also be noted that while costs have been suggested at specific points along the path towards compliance with EU Internal Market legislation, specific data on the costs is not available for each step.
- The interviews have produced limited information on the specific impact. One key reason is that, as a result of the dominant use of the foundry model, much of the compliance costs are absorbed throughout the supply chain and not by an individual company. OEM suppliers in third countries are required to adhere to restrictions while also complying with design requirements set out by fabless producers.
- Compliance testing occurs very early in the supply chain and it is not possible to disaggregate compliance costs for the IC firms. In addition, firms have not been able to estimate the amount of resources involved in the design process linked directly to regulatory compliance versus design procedures relate to quality, reliability, or adherence to regulations and standards set out at an international level.

The general process followed by manufacturers to ensure compliance with the IM legislation includes the following closely interlinked steps, and any specific data on costs has been identified and noted.

Familiarisation with relevant legislation and purchase of standards

The introduction of new legislation places costs on firms, including the time and resources used to familiarise themselves with the legislation.

The purchase of standards is one approach to learning about the implications of specific relevant legislation, which generates financial costs. Interviews with firms suggest that no standard 'familiarisation period' can be feasibly created due to the differences in the requirements. Manufacturers, suppliers, distributors, and end producers of consumer products develop administrative systems or databases applicable requirements are organised. Databases are being developed to manage the complexity of keeping track with IM legislation, standards, and amendments.

However, the costs association with each of these features is dependent on the specifics of legislation, of the new provisions, the intended end use of the semiconductor, and of the product portfolio. Therefore, no general average can be derived, according to the interviews. Indeed, the interview respondents suggest that databases and tracking systems are a normal part of working in an industry with a long supply chain and diffuse set of suppliers.

The smaller fabless firm states that they rely on their suppliers as well as their customers to inform them of implications of the various pieces of legislation. Third party testing occurs, but it varies depending on the production chain. In terms of their suppliers, fabless manufacturers tend to create industry partnerships with 'fabs' that produce the raw inputs into the integrated circuits. In general, there are fewer and fewer producers and the fabs are highly involved in the discussions of standards and legislation. On the customer side, the main market for European producers includes some of the most highly-regulated industries, which are careful to conform to legislation. Therefore, according to the interview with a fabless manufacturer, the industry has knowledge of how to comply and this knowledge is shared up and down stream.

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Under REACH, the substance of very high concern (SVHC) "candidate list" can be updated annually and functions as a "living list".[143] As soon as a SVHC appears on the "candidate list", suppliers of articles containing the SVHC must forward information on the listed SVHC contained in the article (above a concentration of 0.1%) to recipients. The list is updated every 6 months, and even the larger firms have a very difficult time managing the speed with which the list is updated, though the industry has not produced data to demonstrate the burden. The European Chemical Agency (ECHA) engages in a highly structured public consultation every year, with consultation period of 45 days.[144] However, the participation of industry representatives is highly context- and product-dependent; nevertheless, this period of consultation generates discussion in advance of the introduction of changes, which allows for some familiarisation with the legislation.

According to the interviewees, manufacturers rely on **standards** to meet the essential requirements. Standards vary according to the organisation issuing them. A number of standard-setting organisations exist, such as industry-led bodies (JEDEC), as well as the IEC and ISO. The IEC have been active in developing recent standards.

Two interviews with small fabless producers suggest that smaller companies rely on standards, but that often changes are generally clearly articulated by customers and additional standards are not always purchased. The firm indicated that standards are purchased as needed, with some periods of time requiring the purchase of standards, as well as significant variation depending on the product line. Moreover, industry standards are often translated into customer specifications. Even in the absence of specific standards, producers would need to comply with customer specifications.

New costs have been introduced since the industry has shifted from voluntary industry standards created by JEDEC, which were free, to the IEC standard EN 50581:2012 was made available in 2012 by CENELEC related to **"**Technical documentation for the evaluation of electrical and electronic products with respect to restriction of hazardous substances." This standard must be purchased. The current prices for the identified standards covering a majority of the sector include:

Relevant Standard	**Price (EUR)** [145]
EN 50581:2012	43
IEC62321	252
EN 60950-1:2006/A12:2011	277
IEC 61000	187
IEC 61967	122
IEC 62132	122
IEC 62474	204

Given that the range of potential applications and sub-groups is limitless, only the major product-specific regulations have been reviewed (see table 1 above).

[143] An updated version of the "candidate list" can be found in the ECHA website: http://echa.europa.eu

[144] http://echa.europa.eu/en/web/guest/view-article/-/journal_content/512b7526-9dd6-4872-934e-8c298c89ad99

[145] The International Electrotechnical Committee is based in Switzerland and bases its prices on the Swiss Franc (CHF). Conversions use the following rate: CHF/EUR = 0.8147

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Development of alternative designs and the associated testing of materials

Internal market legislation generates two distinct costs on firms in terms of design choices. First, some manufacturers have had to redesign products to comply with restrictions on materials. Second, under the two most applicable internal market directives, RoHS and REACH, companies have an opportunity to petition for an exemption or authorisation from some of the limitation imposed by the legislation. Because two separate lists are created, with separate procedures for exemptions/ authorisation, there is a duplication of effort combined with a high degree of uncertainty about certain substances.

In terms of **redesign**, one important source of compliance costs has been the requirements of the **RoHS** Directive in relation to the use of lead, which is used in a number of components in the manufacture of integrated circuits. The industry is still in the process of phasing out lead. There were significant upfront costs for the conversion to lead-free packaging, and until recently the unique functionality of lead soldering was required for some components and packaging.

Exemptions have been obtained under RoHS to allow for the continued use of some lead in a limited number of applications. Thus, testing for compatibility and replacement programmes has been an ongoing activity for firms. A number of companies outlined a 'conversion roadmap' to demonstrate progress towards converting their product line towards compliance with RoHS.[146]

Large companies initiated compliance programmes in response to European regulations (especially RoHS) relatively early, while many smaller producers did not have the capacity or inclination to develop substitutes and only recently started to address this issue. RoHS compliance presents many product management and design decisions such as whether to bring products into compliance or to make them obsolete, or whether to make use of the currently granted exemptions.[147]

RoHS generated upfront costs of material substitution, given that many types of integrated circuits used lead soldering. While the interviews would not confirm the cost, some studies of the impact of RoSH suggest that the impact equals 1.9% of total turnover,[148] which is generated by the upfront costs of switching to lead-free components. This is roughly in line with a 2008 study which estimated that, generally, the average past and future one-off cost impact of RoHS lies between 1 and 2% of total turnover. However, these studies did not focus exclusively on integrated circuit manufacturers, nor did they document the precise source of costs.

Interviews with firms could not provide further information, though the interview with a large producer suggested that the RoHS compliance programmes are among the most pressing R&D and compliance issues for the industry, especially given the unique functions played by some substances, such as lead.

[146] See, for example, the chart created by NXP: http://www.nxp.com/about/corporate-social-responsibility/environment/lead-free-halogen-free/matrix.html#complete

[147] ESIA. 2009. Semiconductors: Enabling Sustainable Living in 21st Century Europe.

[148] Cited in http://www.nema.org/Policy/Environmental-Stewardship/Documents/081203%20RoHS%20impact%20assessment%20summary.pdf

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Seeking authorizations and exemptions

In terms of the authorization and exemption processes, some materials are critically important to the integrated circuits, both in terms of some harmful substances used in the production process while others are found in trace amounts in the final product due to their unique functionality in achieving performance goals for the product. The material development cycle in the semiconductor industry is typically 10-15 years, consisting of fundamental research, hazard and risk evaluation, demonstration and integration with manufacturing equipment (and sometimes the development of new manufacturing equipment or processes), and production. Where chemicals already used in manufacturing need to be replaced, ample time must be provided to develop substitutes for these chemical uses.

The large manufacturers stated in interviews that the requirements often serve as an impediment that is eventually overcome rather than a true barrier. No examples of specific instances could be presented where the use of a key substance could not be substituted or an exemption obtained. A review of company websites outlines the continued use of hazardous or dangerous materials in the production process, even though the substance does not end up in the finished product.

Nevertheless, the exemption and authorisation processes are very costly, according to the interviews, though no fixed amount is available. There are two aspects of the duplication that cause substantive costs. RoSH 2 and REACH apply to some of the same substances in the same products and processes, sometime resulting in duplication of administrative burdens. RoHS 2 provides rules on the restriction of certain hazardous substances in Electrical and Electronic Equipment (EEE), while REACH is a more general act regulating or restricting chemical substances. In terms of specific duplication, in a position paper from March 2013, Orgalime points out[149] that there is some overlap in the Directives. Four substances highlighted under RoHS2 for priority assessment, namely plasticisers BBP, DBP, DEHP and flame retardant HBCDD featured in the REACH Candidate list back in 2008 and are now also included in the list of substances subject to REACH authorisation in Annex XIV.

When seeking exemptions, there are two separate procedures that need to be followed and the two Directives do not recognise each other's lists of banned substances. In some cases, an exemption can be obtained in one list but not in another; in some of these cases, there could be a delay in obtaining the second exemption.

There appears to be inconsistency in the application of RoHS and REACH, especially in terms of valid procedures that are consistent for both Directives. The industry association, ESIA, points out that lists based around the REACH processes that target substances for *potential likely action* without any upfront risk review on whether or not the risk is managed in how the semiconductor sector uses the substance. This uncertainty creates barriers to product development without a full risk-based assessment taking place.

The overlap and inconsistency cause a duplication of effort and significant uncertainty for the industry, with the greatest effects in product development. So far, the interviews have produced limited information on the specific impact. One key reason is that, as a result of the dominant use of the foundry model, much of the compliance costs are absorbed throughout the supply chain and not by an individual company. OEM suppliers in third countries are required to adhere to restrictions while also complying with design requirements set out by fabless producers.

[149] http://www.orgalime.org/sites/default/files/PP_Complementary_REACH_and_RoHS_Mar13.pdf

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Compliance testing occurs very early in the supply chain and it is not possible to disaggregate compliance costs for the IC firms. In addition, firms have not been able to estimate the amount of resources involved in the design process linked directly to regulatory compliance versus design procedures relate to quality, reliability, or adherence to regulations and standards set out at an international level.

Documentation of compliance - Testing, technical file and certification

Testing has long been a normal procedure in the integrated circuits industry, either in-house or by specialised testing houses. With the emergence of RoHS and REACH, third party testing houses have emerged to fill the gap in internal capacity of some smaller fabless manufacturers. IDMs have in-house testing capabilities, and increasingly have started to offer testing services to their industry partners to help consolidate some of the processes within the supply chain.

Both RoHS and REACH require the development of a technical file following testing, most often following a specific standard created by the industry. RoHS2 introduces new requirements for companies to maintain technical files. This is a significant difference compared to the first version of the RoHS Directive, which did not prescribe any requirements for manufacturers to maintain compliance documentation.

Under the original RoHS, firms along the supply chain did not have this obligation; the final OEM manufacturer or importer who puts the finished branded equipment on the market in the EU incurred all the costs of managing the supply chain.[150]

As a result of major end users being required to monitor the supply chain, suppliers have long been encouraged through market pressure to maintain technical files, and this has long been a well-established practice in the integrated circuits industry.

However, the practice remained *ad hoc* and incomplete, according to the large manufacturer interviewed. RoHS2 now puts more of a structured framework in place. Standard EN 50581:2012 was made available in 2012 by CENELEC related to **"**Technical documentation for the evaluation of electrical and electronic products with respect to restriction of hazardous substances"[151] to meet the needs of technical documentation.

Information obligations add an additional administrative cost. An important source of administrative costs is with REACH Regulation. REACH places a legal obligation on all EU suppliers to provide substance declaration information when they supply their outputs (components and sub-assemblies) to the next manufacturer in the supply chain. This could extend to contract manufacturers when they supply equipment to OEM clients, drawing on information which component suppliers are required to disclose to the contract manufacturer. However, the costs vary depending on the unit type and the size of the order.

150 https://www.bomcheck.net/assets/docs/Guide%20to%20REACH%20Requirements%20for%20component%20suppliers%20and%20equipment%20manufacturers.pdf

151 This European Standard specifies the technical documentation that the manufacturer needs to compile in order to declare compliance with the applicable substance restrictions. The documentation of the manufacturer's management system is outside the scope of this European Standard. http://www.cenelec.eu/dyn/www/f?p=104:110:3448161281810912::::FSP_PROJECT,FSP_LANG_ID:23432,25

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There are also certain synergies in the databases since many of the requirements are the same and industry standards are able to cover both Directives. A single technical file system can capture information pertaining to both RoHS and REACH. The General Product Safety Directive introduces mandatory requirements concerning the product identification, cooperation with authorities when requested and a voluntary conduct of tests of marketed products, and the keeping of a register of complaints.

Firms provided direct estimates of human resources dedicated to managing the technical files. The resources dedicated to managing these files vary significantly according to firm size and location in the production chain. For example, a small fabless producer (focusing on design and sales) with 25 employees reported that 1 FTE was required to address requests for documentation. A large global producer, with a staff of 24,000, stated that there are approximately 50 FTE dedicated specifically to compliance. In this latter case, approximately half of the staff time is normally dedicated specifically to RoHS. However, the total responsibility for maintaining the files is distributed across a number of additional staff resources, including sales staff, R&D, quality assurance, and management. Another large producer stated that the European-based team has a large legal team, with 42 people and one in-house council that focus on, among other domains, export compliance.

Monitoring the suppliers in the supply chain for compliance and switching to avoid non-compliance

Linked to the certification costs, firms in the downstream stages of the supply chain are required to verify the certification of their suppliers and then pass this information onto their clients. This places significant burdens throughout the supply chain. Although REACH and now ROHS2 place obligations on companies to pass on information, in practice it is the demands of customers that cause companies to collect stringent information, up to the standards of the eventual end-users.

A number of approaches have been adopted to monitor the supply chain. Downstream firms, especially larger firms operating with many suppliers, require relevant supplier to pre-register substances and preparations used in industrial (including engineering) processes and will monitor and support registration by suppliers.

As integrated circuits move from one producer to the subsequent stages of development, the common practice is to use a bill of materials (BOM) to document the materials and substances contained in the circuit. Ideally, suppliers will issue a Full Materials Declaration, which states all of the elements and substances that are contained in an integrated circuit. According to desk research and interviews, this is not consistently practiced. Confidentiality was raised as one potential barrier in obtaining all relevant information. In some cases, re-testing is required where there is a ‘break in the chain’ from one stage to the next. Confidentiality was also cited as one of the impediments to obtaining precise estimates; given that efficient management procedures are part of the value proposition of some companies, details were not forthcoming.

The main concern is the amount of detail that needs to be carried forward along the development process of integrated circuits. One difficulty that was mentioned by a large manufacturer was that there are potentially dozens of suppliers in any single component, and that it is often a problem if one of the intermediary suppliers has not kept adequate records. Often, the level of detail of a company’s record system is actually a selling point in terms of the appeal of using a specific supplier.

Some companies are encouraging smaller suppliers to pre-register their Bills of Materials on private platforms that offer industry-wide databases to manage certification and declarations of compliance.

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BOMCheck is the most developed platform.[152] Under this system, suppliers can create a vendor account and the purchasers can apply for a subscription that allows for verification of records. For the BOMCheck system, the subscription fee for suppliers is an annual fee of EUR 300. [153] More than one million RoHS and REACH Materials Declarations from over 3,100 suppliers have been uploaded to the system, as of June 2013.[154]

Declaration of conformity, CE marking and instruction manual

Based on a review of the websites of a wide sample of the industry, it appears that the standard practice is to post Declarations of Conformity on the company webpage. This does not appear to be particularly burdensome, and the interviews suggest that this is a common practice that is recognised by firms in the sector. Indeed, the introduction of REACH and RoSH2 could potentially redistribute costs across the supply chain rather than place all costs on the single point at which the final product is placed on the market, meaning that costs are transferred rather than altered.

Manufacturers within the EU must obtain a declaration of ROHS compliance for all the parts, components, and materials that they are using, while importers need to obtain a declaration of compliance from their suppliers.

The set-up costs do, however, include the time to carry out the conformity assessment and check that standard documentation has been obtained. Some of the larger downstream companies facilitate this process on behalf of suppliers, and it ensures a smoother process for identifying required documentation. Based on the interviews with firms, the CE Marking is recognised as a normal cost of doing business and is not seen as unduly burdensome.

The industry has adopted Design for RoHS compliance guidelines, though this is internal for each company and differs based on the application. The large manufacturer uses this design guideline internally, while the small fabless manufacturer relies on the foundry to check for the compliance of its designs before shipment.

Response to market surveillance activities

RoHS2 includes obligations for all EU Member States to perform systematic market surveillance including "*appropriate checks on product compliance on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples*". In contrast, RoHS1 did not prescribe any enforcement procedures that Member States were required to implement.

While the documentation requirements for compliance are burdensome, interviews did not yield specific instances of particular burdens with market surveillance beyond what would be expected under typical regulation. Under RoHS, firms have 28 days to provide sufficient documentation of conformity, and there is no suggestion in the available information that this is particularly burdensome.

[152] See the industry-led initiative, BOMCheck, developed by the European trade association COCIR and coordinated by the environmental consultancy ENVIRON, which sits on co-chairs the IPC 1752A materials declaration standard and serves as EMEA regional coordinator for the IEC 62474 materials declaration standard. https://www.bomcheck.net/

[153] See press release: http://www.prnewswire.com/news-releases/bomcheck-celebrates-more-than-1-million-rohs-and-reach-materials-declarations-from-over-3100-suppliers-211932871.html

[154] There is no limit to the number of part numbers that the supplier can load into the database or the number of customers that the supplier may have on BOMcheck.

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Both the fabless and the IDM interviewed state that while there are some occasions that surveillance authorities request information, by far the largest burden is on supplying information to client downstream, such as manufactures of electronics, automotive, or other industries. The interview respondents state that given the highly-regulated nature of the end manufacturers (automotive, industrial processes, telecommunications industries), some of which are very tightly regulated in Europe and other countries, there is a high burden on the supply chain to maintain records.

Large firms maintain structured protocols for responding to surveillance requests while the smaller firm relies on an *ad hoc* approach, rarely exceeding the 1 FTE that has been allocated to maintaining the technical file, reacting when necessary to supply information. Details of the document management system were not shared, though the firm was clear in that a standard approach to managing supplier documentation is sufficient for responding to requests. It was also stressed that requests from clients are normally the key source of inquiries and far outweigh any burden from surveillance agencies.

Business as usual

Some of the costs indicated above should be considered as part of a business as usual scenario, especially those related to information sharing. While the interviews focused on the impact of RoHS and REACH, all interviews stated that quality management would still be part of internal procedures irrespective of the regulatory framework requirements, and the information requirement would remain just as burdensome. The large company stated that in some instances, the Directives and corresponding standards are helping to simplify the information as it moves through the supply chain as common standards are imposed for all companies. Product reliability tests are often conducted by established firms that want to ensure the quality of their products, so information will always need to be shared.

Furthermore, the presence of significant legislation in other countries (e.g. China and Japan) means that important part of the documentation required and the significant costs of maintaining sophisticated databases would likely have been incurred even in the absence of EU legislation.

5. Estimation of Assessment of costs of IM legislation for the whole sector

Disentangling costs is limited, given the lack of information and the diffuse burdens across the supply chain. The complex and very long supply chain creates impacts for manufacturers far upstream and downstream, though it is difficult to estimate the distribution of the burdens. Moreover, interviews suggest that the impacts of pieces of legislation are highly context-dependent, ultimately differing based on the product portfolio of a company (number and types of products), as well as the location with the supply chain.

On the basis of specific cost information from four of the interviews, we estimated the administrative costs for the main cost elements identified and, on the basis of certain assumptions, to extrapolate to the whole of the EU industry. The interviews did not provide sufficient data to present cost details. The following table presents some information. The average figures from the interviews were upscaled using turnover.

Type of Cost	Estimated annual costs for the whole sector
Internal	€ 7.6 million
Third parties	€ 26 thousand
Testing equipment	€ 10 thousand

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Total	**€ 7.6 million**

As is evident, internal compliance costs represent the main cost element for the industry. The interviews suggest that internal processes and activities related to compliance were the highest share of the total costs. Compliance testing is linked to companies' R&D activities. Research and Development costs are inevitably high in the integrated circuits industry, which is a major factor explaining why integrated circuits are the most R&D intensive industry in Europe, according to the European Commission's R&D Scoreboard. Third party testing and testing equipment specifically for compliance with internal market legislation is marginal in terms of the overall R&D budgets. Again, a number of assumptions that have been made related to the costs need to be further examined and discussed with the relevant association.

6. Benefits of Internal Market legislation

The industry is in general supportive of the impact of internal market legislation. The major benefit is the degree of uniformity in application across the sector and across the global production industry. The market legislation and the surrounding legislative framework are fairly positive and appreciate the impact that a standardised set of regulations has created.

The logic of the system is supported by the interview participants. Producers at the earliest points in the production chain are required to document materials and processes, and then this information is passed forward and can be traced all the way to the final application. Interviews with larger manufacturers of integrated circuits are explicit in its praise for the design of the regulations in that they do not distort competition, either in terms of location or of the placement in the value chain.

The system is applied to all stages of development and does not place unduly high burdens on the final producer of products, as was the case under previous types of regulatory instruments. Under national systems that previously had not adopted the same approach as Europe, the final producer is required to monitor the supply chain, while under the European system the supply chain fairly well documented. Europe has essentially set the global standards for the industry. This standardardisation has spread globally, and now major producing regions have aligned their regulatory frameworks to align with Europe, with the China RoHS being the most explicit example.

Market access is greatly improved. The interviews suggest that it would be very difficult to imagine a scenario with different standards in individual member states, given the global nature of the industry and the composite nature of manufacturing and application to specific products. For example, while some reservations exist about the process to identify prohibited substances (with separate systems under REACH and RoHS), the industry appreciates a single set of procedures at the European level. Under separate systems, there would be a very high level of monitoring of regulations and a constant threat that one government would face pressure to ban a specific substance, which would disrupt the global supply chain.

The regulations help to standardise the information requirements throughout the supply chain and across products. All producers state that records keeping and monitoring of bills of material would be standard practice even in the absence of European regulations. The large company stated the Directives and corresponding standards are helping to simplify the information as it moves through the supply chain as common standards are imposed for all companies. Product reliability tests are often conducted by established firms that want to ensure the quality of their products, so information will always need to be shared. Information requests would still be sent from customers, and firms would still need to keep files to track the supply chain. However, the use of a single source of

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regulations has helped to standardise the types of information that are required and has limited the variation in the types of requests that come from later stages in the production chain.

Given the globalised nature of the industry, with highly developed supply chains, undue or particularly burdensome regulation can cause shifts in production location. The initial analysis suggests that most Directives place rather similar obligations on industry; namely, revise the design of some products and then subsequent requirements to test, document, and declare conformity to specific requirements. The interviews suggest that while there is some scope for improvement at the level of implementation, the overall system has generated simplification, a fair distribution of burden across the entire production chain, and avoids creating location decisions based on lower standards.

7. Analysis of simplification options

All respondents stated that the internal market legislation functions very well, and that while there is room for improvement, the functioning of the internal market legislation is well developed overall. Two concrete areas of focus emerged through the interviews. While there was a general consensus among interview participants that the two options would generate savings, the massive difference in size of the firms as well as the variation along points of the production chain meant that savings would be distributed differently for each of the firms.

Merger and simplification of exemption and authorization process under RoHS and REACH

There is an opportunity to simplify aspects of RoHS and REACH. The most immediate opportunity for simplification identified is the elimination of duplication found in the exemption and authorisation process for the same substance under both REACH and RoHS. The two processes could be made to recognise the list of the other; exemptions under one list would be automatically applied to the other. This would limit the duplication of the process of requesting authorizations or exemptions while also limiting uncertainty by only having a single list to manage. Firms at various points along the production chain emphasised that responding to requests for documentation constituted the largest source of ongoing costs, and that the presence of two lists with different cycles caused unnecessary burden.

The impact of this simplification is that firms would be able to manage a single process, which would reduce familiarisation, design, and administrative costs. It would also create consistency for the industry through a structured regulatory cycle, which would facilitate long-term product development planning, while limiting the amount of regulatory activity required by enforcement agencies. While the benefits are clear, interview participants were unable to estimate an approximate value for the savings.

Simplification could also involve re-structuring the way in which new substances are added to restricted lists. Interviews suggest that one of the reasons REACH compliance is difficult is due to the dynamic SVHC list, which introduces upfront costs but also high risk. The six month updating cycle causes a constant flow of documentation requests from customers, which could be better managed if a longer, more structured system existed.

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Simplification of information requirements

A second opportunity is found in the sharing of information, which could be simplified by limiting the types of information required so that a single validation or declaration would apply to all EU legislation, although the interviews suggest that these procedures are already part of the normal operation of a business in the industry. The industry representatives stated that one of the major benefits of European legislation is that it helped to standardise the reporting systems throughout the industry. Without common requirements, reporting systems would be splintered and would potentially place greater costs on the industry.

Given the complex and decentralised supply chain, adequate tracking measures and supply chain monitoring are in place for reasons other than EU internal market legislation. Standard technical documentation would be required by end product manufacturers in the absence of specific internal market legislation to comply with quality standards as well as a range of additional requirements, depending on the final application. China RoHS and the demands of end-users or final products put pressure on the supply chain create costs that would not be alleviated with any simplification.

Further simplification of information requirements could help to reduce burdens of collecting product information. Some industry-led measures to create a common platform, such as BOMCheck, could be supported by the relevant EU authorities, either by compelling its use or by strengthening cooperation with platforms. This would simplify the passing of information along the supply chain and improve the consistency of data.

8. Overall conclusions

This case study examined the role and costs of IM legislation for integrated circuits, the building blocks of a number of technologies that make up micro and nano-electronic components and systems. According to PRODCOM data, the European market for integrated circuits has a total market size of €56.8 billion while other sources suggest that the industry is somewhat smaller industry, around €30 billion. European manufacturers do not command a large global share and European production represented less than 10 percent of total global production in 2011.

The applicable IM legislation covers issues related to product safety only indirectly (through the General Product Safety Directive), electromagnetic compatibility (EMC) and focuses more on environmental impacts (REACH and RoHS Directives).

On the basis of information provided by some companies, the administrative costs for the sector were estimated at around €7.6 million. The interviews with firms consistently pointed to the RoHS Directive as being the main driver of compliance-related activities. However, the analysis also emphasised that RoHS-related procedures are part of broader changes within the industry that are now so deeply integrated into the supply chain that the compliance costs specifically linked to internal market legislation cannot be easily isolated. The industry generally believes that internal market legislation has had a positive impact and appreciates the fact that there is harmonised product legislation in this area. A major benefit is the degree of uniformity in application across the sector and across the global production industry.

Nonetheless, some potential scope for simplification was identified, in particular, the possibility of simplifying certain aspects of RoHS and REACH so as to eliminate duplication in the exemption and authorisation process for the same substance. A second area is the possible use of a single type of

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validation or declaration form to cover all EU legislation. Unfortunately, no estimates for possible cost savings resulting from these simplifications were provided by manufacturers interviewed.

9. Sources of information

- Eurostat Structural Business Statistics Database and PRODCOM
- Text of applicable IM legislation and relevant standards
- Policy and strategy documents published by the European Commission or relevant industry associations
- Industry Association: The *European Semiconductor Industry Association* (*ESIA*)
- Interviews with eight firms, varying in size, market share, and product applications.

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CASE STUDY 9 –SNOW-SKI FOOTWEAR

1. Introduction – objectives of the study

This case study focuses on the non-harmonized product group *snow-ski footwear*. While the product group is non-harmonized, some elements of the product are covered by harmonized legislation; namely, the *Labelling of materials in footwear (1994/11/EC) directive* and the *Packaging and packaging waste (2004/12/EC) directive.* Since the products are primarily non-harmonized, the aim of this case study is to assess the impact of national legislation and its consequences for the industry, including substantive and administrative compliance costs. Furthermore, the case study will cover the impacts of the two above mentioned IM directives as well as highlighting the important role of international standards in the production phase.

The main reasons for choosing the snow-ski footwear product group are:

- The snow-ski footwear category illustrates how regulations affects non-harmonized products and create both visible and hidden compliance costs for manufacturers;
- Although represented by relatively few economic operators the industry is comprised of a selection of both large manufactures as well as SMEs;
- Snow-ski footwear products are products with a high level of technical sophistication and have experienced rapid products development in recent years;
- Snow and ski footwear is a non-harmonized products category and thus does not have any specific regulations concerning only this product group. However, because it is non-harmonized product group there can arise problems in regards to differing IM standards.

Methodology

The findings of this case study are based on desk research and qualitative interviews. In the first phase of the project, structured desk research was carried out in order to establish an overview of the snow-ski footwear industry, identify relevant pieces of legislation and standards as well as identify companies within the industry.

Two interviews have been conducted with The Federation of the EU Sporting Goods Industry (FESI), which is the European industry association for snow-ski footwear producers; one in the beginning of the research phase and one in the final phase to verify collected data. Additionally, five interviews have been conducted with companies within the industry. Two large manufactures and three SME's have been interviewed As companies were regarded as an important source of information for the development of the case, a structured approach to recruiting companies was applied. Initially FESI contacted their members by email and phone, to inform about the study and set up interview appointments. Simultaneously, all identified non-FESI members were contacted by email and a minimum of two subsequent follow-up calls. All companies have received one email and a minimum of two subsequent telephone calls. For the companies where contact was established and relevant person/department was identified we have followed up with 3-4 phone calls. As mentioned above, five companies have agreed to participate.

2. Product definition and description of structure of the sector

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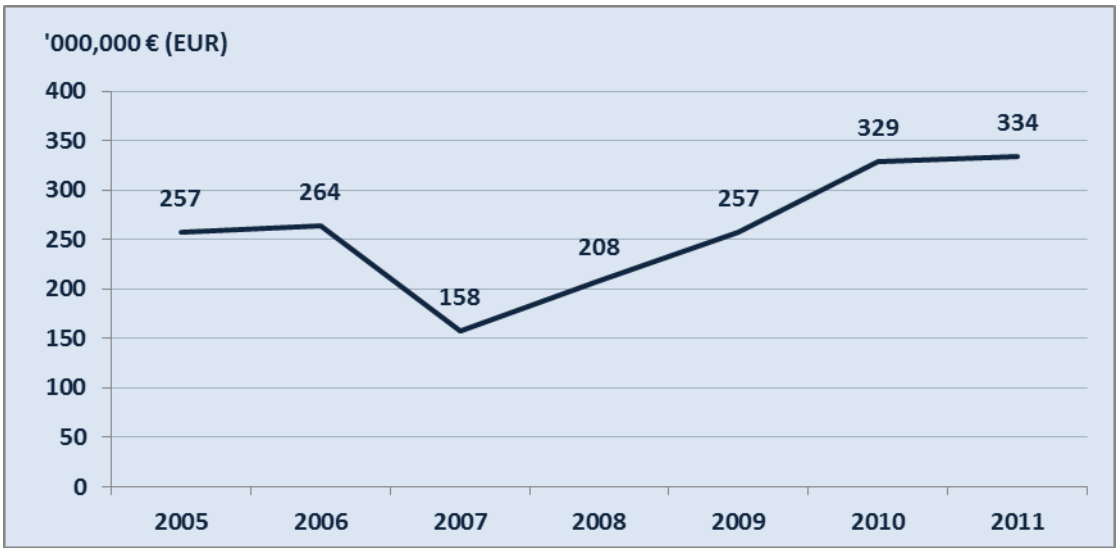
Study scope (products included/excluded)

The product group *snow-ski footwear* includes footwear products related to activities involving downhill and cross-country skiing. The primary products include alpine ski boots, cross country ski boots, snowboard boots and touring boots. The differences in the production methods and materials used between the various product types means that the applicable legislation and standards differ between the different product types. Snow-ski footwear is unlike other skiing equipment, such as helmets and goggles, defined as a recreational product and not a as a protective equipment.

According to the PRODCOM database the total size of the EU27 market for snow-ski footwear in 2011 was 4.93 million units (pairs) and a total EU production value of EUR 330 million. Figure 1 shows the development of the production value since 2005.

Figure 1: Annual production value of snow-ski footwear production in EU27 (PRODCOM)



Source: Eurostat

The PRODCOM code for *snow-ski footwear* is 32.30.12 which is a sub-category of *manufacture of sports goods* (32.30). There are no subcategories within snow-ski footwear and it is therefore not possible to analyze PRODCOM data for the different product types separately. The data presented in this section therefore captures the combined numbers for the manufacturing and production of all types of snow-ski footwear.

The vast majority of snow-ski footwear is alpine ski boots. FESI estimates that alpine ski boots represent around 90% of the total snow-ski footwear product category in terms of market size. The remaining product types (cross-country, snowboard, and touring boots) constitute small shares of the total market.

PRODCOM data for imports and exports shows that there is substantial trade of snow-ski footwear between the EU27 and the rest of the world. In 2011, the total EU27 export to the rest of the world amounted to 2.53 million units annually and a production value of around EUR 140 million. Imports into the EU27 totalled 2.17 million units with a production value of around EUR 40 million. Thus, according to the PRODCOM data, exports of snow-ski footwear products exceeded imports by around 350,000 units**.**

The numbers show that export value exceeded import value by almost €100 million and that the value of EU27 exports where about 3.5 the size of the value of imports into EU27. These numbers

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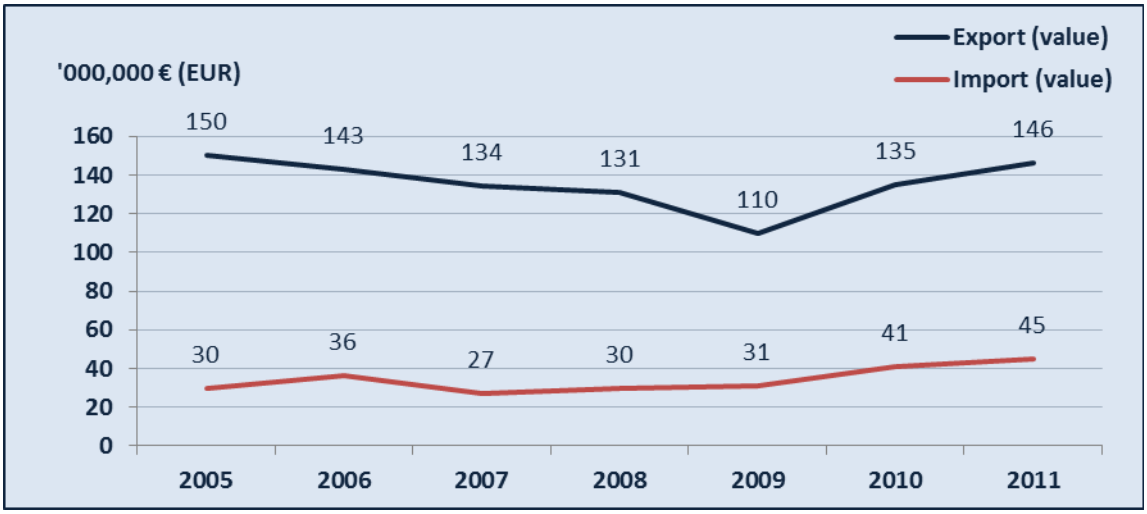
indicate that the value per unit exported is substantially higher than the value per unit imported. This relationship between the value of imports and exports is most likely due to the fact that the factors of production are higher within the EU27 than other producer countries, such as countries in Asia where a large share of imported products are produced.

Figure 2 illustrates the value of imports and export in the EU27 from 2005 to 2011. The graphs show that exports have recovered from the crisis-years and are now back at pre-crisis level. Imports have remained almost stagnant during the period, with a slight upward going tendency from 2007.

Figure 2: Export & Imports of snow-ski footwear in EU27 (PRODCOM)



Source: Eurostat

The PRODCOM database does not contain data on the export destinations. However, the two major markets for snow-ski footwear other than the European countries are the US and Japan[155] and these markets accounts for the vast majority of EU27 exports.

According to FESI, the global market for snow-ski footwear products is on a general level stagnating. This is mainly due to the fact that the alpine ski boot market, which constitutes the majority of the market, has been stagnating in recent years. The market for snowboard boots is currently declining whereas the touring boots market, which constitutes a very small share of total production, is growing.

Number of employees/businesses

The EUROSTAT structural business statistics (SBS) do not provide data specific to the snow-ski footwear industry[156]. The most relevant data on industry demography and employment is therefore only available for the *manufactures of sports goods (PRCCODE 32.30)*, where snow-ski footwear represents just one product category.

Looking at the overall data for manufacturers of sports goods, Eurostat data shows that in 2009 a total of 4,186 companies employed a total of 39,300 people[157]. The total production value of the

[155] FESI

[156] We have been in contact with Eurostat to confirm this

[157] Eurostat Structural business statistics (SBS)

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manufactures of sports goods was EUR 3,562 million in 2011[158]. The snow-ski footwear industry accounts only for a smaller share of this value.

A rough estimate of the number of employees in the snow-ski footwear industry can be developed by assessing the production value of the industry compared to the entire sporting goods industry. Our estimate of the number of companies is based on qualitative input from the European industry association (FESI). Comparing the total production value of EUR 3,562 million in sporting goods industry with the total production value of EUR 330 million in the snow-ski footwear industry it can be observed that the snow-ski footwear industry accounts for a little less than 10 % of the total production value in the sporting goods industry. Applying this relationship would suggest a total number of employees of around 4,000. This is the most accurate estimate possible and has been supported by FESI. Considering that Firm A interviewed for this study, which is one of the largest manufactures within the industry, employs an estimated 620 people in their ski-boot division, indicate that a total of 4,000 employees appears to be a realistic estimate.

In general, the snow-ski footwear industry is very competitive with only a small number of manufactures. Based on desk research, as well as the interviews with FESI, we estimate that the total number of snow-ski footwear producers in the EU amount to around 20. These numbers, which have been verified by FESI, includes all snow-ski footwear product categories. It should be noted that since many large manufactures produce several brands, the number of snow-ski footwear brands is higher than 20. On a global level an estimated 30 companies exist.

Industry structure

According to FESI, around 70 % of the world's production of snow-ski footwear is located in the EU. The countries with registered production include Italy, Romania, Estonia, Slovenia, Hungary, Austria, Czech Republic, Germany, and France[159]. Of these countries Italy accounts for the largest share of the market with around 50% of total production value. Historically these manufacturers have been located in the Veneto Region in northern Italy near the town of Montebelluna, where a textile and footwear cluster[160] has developed several decades ago. This cluster developed amoung leather production and as early ski boots were produced by leather materials production developed here.

Romania also accounts for a significant share of around 28% of total snow-ski footwear production. The remaining 22% is divided between the remaining countries[161]. Italy used to account for an even larger share of total production but in recent years some production has shifted towards Eastern European countries. None of the larger manufactures are headquartered in these countries but the production is carried out through subsidiaries or intermediaries.[162]

The remaining 30% of the global production outside Europe is mainly located in the US and in Asia. In the US producers are mainly smaller manufactures within the snowboard boot category. These are very specialized companies that target a niche within the market.

The companies within the snow-ski footwear industry represent on the one hand larger companies which are responsible for several ski boot brands but also small and medium sized companies. The

[158] PRODCOM

[159] PRODCOM

[160] http://www.clusterlink.com/acenet/new/pdf_acenet/Veneto%20Region.pdf

[161] Due to a low number of producing companies data on the remaining markets production value is not available in the PRODCOM database.

[162] One of the companies interviewed, for example, has outsourced all production to a Czech manufacturing company while continuing to design, market, and manage the company in Italy.

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larger companies, which often own several brands, are a relatively small group of companies. Some of these larger companies include K2 (Full Tilt) (US), the Tecnica Group (Nordica and Dolomite) (IT), Amer Sports Group (Salomon and Atomic) (FI), Völkl Sports GmbH (DE), Fischer Sports GmbH (AT), HEAD Sport GmbH (AT), Burton (US) and the Rossignol Group (FR).

In addition to the larger companies a range of smaller players within the snow-ski boot industry exist. Despite the strong technological development of snow-ski footwear products these smaller companies have been able to maintain a position in the market (some minor companies, however, have been acquired or integrated into the larger players). The small companies are often family owned businesses that produce very specialized ski boots. Some of these smaller companies include SCARPA (IT), Northwave (IT), Startex (Karhu) (FI), Andrew Shoes (IT), Garmont (IT), Dalbello (IT) and Black Diamond Equipment (US/IT), Dale Boot (US), Rome Snowboards (US), Mammut (CH), Ride (US).

Besides the companies mentioned here a range of very small producers exist. These companies are niche players and produce only a very limited amount of products.

To estimate the total turnover of the European snow-ski footwear industry, the turnover from FESI's members have been used.[163] The total turnover for FESI's members is between € 680-1620 million. Since the FESI-members represent 85% we can estimate that total turnover for the snow-ski footwear industry in the EU is € 800-1900 million.

Table 1 summarizes the numbers presented above on the market size and industry structure within EU27.

Table 1: Data on market size and industry structure – snow-ski footwear (PRCCODE: 32301200).

Parameter	**Data**
Market size (prod.value, EU27, 2011)	**€ 330 million** (4.93 million units (pairs))
Imports (prod.value, EU27, 2011)	**€ 40 million** (2.17 million units (pairs))
Exports (prod.value, EU27, 2011)	**€ 140 million** (2.53 million units (pairs))
Total Turnover (EU27)	Manufactures snow-ski footwear: **€ 800-1900 million** (2012)
Number of enterprises (EU27)	Manufactures of snow-ski footwear: **20 companies**
Number of employees (EU27) (2011)	Manufactures of snow-ski footwear: **4,000***

Source: Eurostat, FESI
*Estimate

[163] This is a close approximation of the industry, as FESI is the largest industry association and covers 85 percent of the total industry.

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3. Analysis of applicable IM legislation and standards

This section outlines the relevant regulatory requirements that manufactures within the snow-ski footwear industry face. Snow-ski footwear is primarily a non-harmonized product group and therefore not covered by harmonized IM legislation. Some aspects of the products, however, are covered by the harmonized directives. These aspects will be outlined below. Also, reference will be made to the applicable national legislation covering the product group.

In addition to the regulatory requirements, technical standards are central in the industry production. This chapter therefore also outlines the relevant technical standards that are relied upon in the production of snow-ski footwear.

Identification of relevant legislation and directives

As mentioned above the snow-ski footwear product group is a non-harmonized product group. However, some aspects of the products are covered by the harmonized EU regulations. The relevant directives and regulations are listed in Table 2.

Table 2: Overview of harmonized Union legislation covering snow-ski footwear

Name of legislation	Main issue addressed	Requirements for economic operators
Labelling of materials in footwear (1994/11/EC)	Labelling of Materials used in main components for footwear	- Labelling must be in the language of the receiving states or a language of their choosing - The manufacturer is required to provide further textual information if requested by member states - Labelling have to be affixed within each pair
Packaging and packaging waste (2004/12/EC)	Packaging	- Limit the weight and volume of packaging to a minimum in order meet the required level of safety, hygiene and acceptability for consumers; - Reduce the content of hazardous substances and materials in the packaging material and its components; - Design reusable or recoverable packaging.
EC Regulation on chemicals and their safe use (EC 197/2006) REACH	Deals with the Registration, Evaluation, Authorisation and Restriction of Chemical substances	- The following information on the manufactured or imported substance shall be included in the dossier in order to unambiguously identify the substance: o Substance name and related identifiers, molecular and structural formulae, if applicable o Information on the composition and purity of the substance

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		o Spectral data and analytical information to verify the identity and composition of the substance o Clear and concise description of the analytical methods
Mutual Regulation 764/2008	Laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State	- See national legislation

Source: EC Commission

As the table shows the product category is only subject to relatively few harmonized IM directives. These include the *Labelling of materials in footwear (1994/11/EC)* and the *Packaging and packaging waste (2004/12/EC)* directives. These are both directives that do not affect the specific production process but are related to the post production labelling of the products as well as the packaging of the finished products. Additionally, the *EC Regulation on chemicals and their safe use*, also referred to as the REACH regulation, also covers the production of snow-ski footwear. The specific requirements are listed in the table.

In addition to these pieces of legislation the snow-ski footwear products are covered by the *Mutual Recognition principle (764/2008)*. This means that products compliant with legislation in one member state can, on the basis of Mutual Recognition principle, also be legally marketed in other member states.

It should be noted that the *Personal Protective Equipment (89/686/EEC)* directive that applies to a range of sports equipment categories does not apply to ski-snow footwear since ski and snowboard boots have not been defined as protective equipment.

Since national legislation applies on the basis of the Mutual Recognition principle an assessment of the national legislation in the producing countries could be valuable. This would allow a comparison of the national legislative requirements related to snow-ski footwear in the producing countries.

Identification of international and EU wide standards

As indicated above international and EU wide standards are an important element in the design and production phase within the industry. These standards are used as a constant reference. Table 3 summarizes a list of the applicable standards within the snow-ski footwear industry. The relevant standards are published by both the International Standardization Organization (ISO) and the European Committee for Standardization (CEN). It should be noted that some of the larger producers also apply standards from national standardization organizations, such as DIN[164] in Germany and UNI[165] in Italy. These standards, however, are applied in other production than snow-ski footwear and have therefore not been included in the table below.

[164] Deutsches Institut für Normung (DIN)
[165] UNI Ente Nazionale Italiano di Unificazione (UNI)

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Table 3: Overview of applicable international standards

Name of standard	Product addressed	Main issue addressed
ISO 5355:2005	Alpine ski-boots –requirements and test methods	- Specifies the requirements, test methods and marking of ski-boots that are used with current systems of alpine ski-bindings with attachment at the boot toe and boot heel, the proper release function of which depends on the dimensions and design of the interfaces. - For ski-binding systems that function irrespective of the sole shape or that have different requirements for the sole dimensions, it is not always necessary for the ski-boot soles to comply with this International Standard in order to achieve the desired degree of safety.
ISO 9523:2008	Touring ski-boots for adults – requirements and test methods	- Specifies the dimensions and characteristics of the interface, requirements, test methods and marking of ski-boots with a rigid sole which are used with current systems of touring ski-bindings with attachment at the boot toe and boot heel, the proper release function of which depends on the dimensions and design of the interfaces. - For ski-binding systems that function irrespective of the sole shape or that have different requirements for the sole dimensions, it is not always necessary for the ski-boot soles to comply with this International Standard in order to achieve the desired degree of safety. - It applies to rigid touring boots. Boots with softer shells like Telemark boots are excluded as they do not have the necessary shell stability to act as part of the release systems.
ISO 11088:2006	Assembly, adjustment and inspection of an alpine ski/binding/boot (S-B-B) system	- ISO 11088:2006 specifies assembly, adjustment and inspection procedures for the binding mechanisms of skis, integrating in a practical way, the requirements of those International Standards which are related to skis, bindings and boots. - It is intended for all individuals and institutions concerned with those procedures, and especially for sports retailers. - ISO 11088:2006 is applicable to a ski/binding/boot/ system (S-B-B) for alpine skiing, of which at least one component is owned by the user.
ISO 11634:1996	Snowboard boots – Interface with snowboard bindings	- Specifies the dimensions and characteristics of the interface zone of the sole and parts of the shaft of snowboard-boots, to provide defined attachment conditions for the snowboard-binding
ISO 14359:1997	Winter-sports equipment	- Marking of parts made of polymer materials
ISO 22264:2006	Telemark ski-boots for adults --	- Specifies the dimensions and characteristics of the interface, requirements, test methods and marking of Telemark ski-

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Name of standard	Product addressed	Main issue addressed
	Interface with Telemark ski-bindings -- Requirements and test methods	boots with flexible sole which are used with current systems of telemark ski-bindings with attachment at the boot toe and boot heel, the proper function of which depends on the dimensions and design of the interfaces. - For Telemark ski-binding systems that function irrespective of the sole shape or that have different requirements for the sole dimensions, it is not always necessary for the Telemark ski-boot soles to comply with this International Standard in order to achieve the desired degree of safety.
ISO 14359:1997	Winter-sports equipment -- Marking of parts made of polymer materials	- Specifies the marking of all separable parts made of polymer materials (plastics), which are used in winter-sports equipment (e.g. ski boots, ski-bindings). It is not applicable to compound materials with duroplastic components (e.g. skis). - This International Standard specifies the minimum requirements for identifying materials. This is to enable a complete separation of polymer materials for recycling
EN 13427	Related to the Packaging - Requirements for the use of European Standards in the field of packaging and packaging waste	- This European Standard specifies requirements and a procedure by which a person or organization responsible for placing packaging or packed product on the market (the supplier) may combine the application of five (mandated) packaging standards and one (mandated) CEN report (in two parts). - These standards, along with the unrevised EN 13432:2000 'Requirements for packaging recoverable through composting and biodegradation – Test scheme and evaluation criteria for the final acceptance of packaging', were agreed to support the essential requirements of Directive 94/62/EC on packaging and packaging waste. They were developed under mandate from the European Commission.

Source: International Organization for Standardization (ISO) and European Committee for Standardization (CEN)

National legislation does not appear to be relevant. Desk research in various national databases and reports has not yielded any results. Similarly, interviewees have not been able to provide information on the various national legislative requirements. Rather than keeping track of national legislation companies are much more focused on the relevant technical standards that apply to the snow-ski footwear products.

Our interviews with the firms indicate that national legislation does not seem to be a primary concern among the companies, and does not appear to affect design or production decisions. The companies do not allocate any significant share of resources to keeping track of national legislation, and only marginal resources to tracking European legislation. Hence, there seems to be limited problems related to the adaptation to national legislation and, through the interviews, it was indicated that no specific problems related to varying legislation across different member states.

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4. Analysis of costs of compliance with IM legislation

This section describes and analyses the substantive and administrative compliance costs faced by companies. These costs were estimated based on the input provided by five companies – two large companies and three SMEs[166].

Firm	Product/Application	Firm Size	Annual turnover from product (global)	Share of EU market
A	Sporting good, including snow footware	Large 1,500	€161 million	Top three in Europe, with global reach
B	Snow foot ware	SME 25	€8 million	Small, mainly Europe
C	Snow foot ware	SME 30	Turnover not available	Small, mainly Europe
D	Snow footware	SME 30	Turnover not available	Small, mainly Europe
E	Sports equipment, including snow footware	Large200-250	N/A (3.4 million units sold)	Top Three in Europe, with global reach

The processes and procedures applied by manufactures of snow-ski footwear to ensure regulatory compliance with the applicable legislation include the following steps which are analysed in detail below:

- Familiarisation with relevant legislation and standards
- Purchase of standards
- Declaration of conformity, CE marking
- Customs clearance

Familiarisation with relevant legislation and standards

The interviews have indicated that companies within the industry do not pay particular attention to the national regulatory requirements. While the preparatory actions that newly established companies perform in order to map the regulatory environment would offer suggestions about the regulatory

[166] The companies represent typical companies within the industry and it is our impression that the information obtained are to a large degree typical for the sector. However, results should be interpreted with some care due to the relatively small number of interviewees.

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barriers, few recent start-ups exist. The manufactures within the snow-ski footwear industry are generally well-established companies that have been in production for decades.

As mentioned, some production of snow-ski footwear has recently shifted towards selected Eastern European markets. One of the consequences is that the production has been outsourced to specialized production companies that produce products for a range of companies.

One specific case is illustrative. One of the smaller companies (Firm C) interviewed has outsourced production to a producer in Czech Republic. They did not emphasise familiarization with national regulations in the production phase as important but trust that their specialized sub supplier is in control of the processes and the regulatory requirements. In this type of constellation, the company, to ensure compliance in the production phase, spends resources on occasional controls of the finished products to ensure compliance with regulatory requirements. In this phase around 2-3 employees are allocated to regulatory compliance control of the products. It was estimated that these employees spend around 10 % of their time on regulatory compliance. Hence, the total amount of time spent on regulatory compliance in the production phase for this one company amounts to around 0.20-0.30 FTE. Within the brand owner, which has outsourced production, there are not sufficient resources to monitor and follow legislation. However, the interviewee pointed out that the specialized producers, who manufacture products for several companies, are very aware of the regulatory environment. In that sense the process of familiarization with legislation in this type of constellation has been "outsourced" to the specialized producer along with the actual production.

In general, the allocation of human resources associated with regulatory compliance for the smaller companies, however, is primarily related to the design phase, where they represent a significant share of the costs. In the design phase regulatory, requirements related to harmful substances, restricted chemicals, or other limits on materials are considered. The primary focus, however, is primarily on the technical standards.

In the case of large firm A, an average of 3-4 employees work on ensuring that sample products fulfil necessary technical requirements. The employees, however, only spend about 25% of their time on regulatory compliance. Hence, the total amount of time spend on regulatory compliance in the design phase can be estimated to around 0.75-1 FTE.

For Firm C, a small firm, it was not possible to distinguish between compliance costs in the design phase and the production phase. However, it was estimated that the total level of human resources allocated to compliance costs amounts to 0.2-0.3 FTE's. This in turn represents less that 1 % of total turnover a year (specific information on annual turnover was not disclosed).

Within larger firms, familiarization and monitoring of relevant legislation is structured within the company and monitoring of both national and EU legislation is conducted. In terms of human resources, the larger companies allocate somewhat more resources than the smaller companies. For Firm A which sells multiple brands, one full time employee (FTE) is allocated to regulatory compliance. It was mentioned that the allocation of one full time employee does not represent a significant share of the total staff costs for this specific company (total of 640 employees). In addition to the one FTE, the company use specialized consultancies with expertise in legislative requirements and verification procedures. An estimate of these costs could not be provided.

Firm E estimated that a total of 2-4 FTE's were allocated to compliance issues. These FTE's were spread over different departments such as production (quality control) (1 FTE), the legal department (1-3 FTE), and the sales department also had ad hoc responsibility for checking on compliance issues based on requests from customers. In general, the firms in the sector did not indicate any specific

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difficulties in terms of monitoring or complying with legislation across different member states, nor have they pointed to specific problems in relation to placing products on the market.

Purchase of standards

As mentioned above the use of technical standards is a key focus area within the snow-ski footwear industry. The companies consulted in this study highlighted technical standards as a central element in their production processes. For the smaller companies there appear to be cost issues related to acquiring the standards and in general it was mentioned that the purchase and adherence to standards represents a major cost.

Within the larger companies the application of standards is also a key element. One of the companies interviewed, for example, has in-house UNI[167] and ISO committees, which focus on the applicable standards. The relevant standards for the snow-ski footwear industry have been outlined in Table 3 above. Table 4 summarizes the purchasing costs for the relevant standards.

Table 4: Price of relevant standards

Standard	Price
ISO 5355:2005	**99,5 EUR**
ISO 9523:2008	**75 EUR**
ISO 11088:2006	**70 EUR**
ISO 11634:1996	**41 EUR**
ISO 14359:1997	**47 EUR**
ISO 22264:2006	**60 EUR**
ISO 14359:1997	**47 EUR**
EN 13427	**-**

Source: International Standardization Organization

Requirements from market surveillance authorities (Declaration of conformity, CE marking)

One of the significant sources of regulatory costs highlighted by the companies is the cost related to certifications by third parties. This process has proven particular burdensome for the companies and costs have been allocated in the budget to service these requirements.

One of the major regulatory barriers the companies experience is the request for certifications of materials and samples for tests. This is the primary source of costs in estimating compliance costs during the design and production phase. The larger companies listed this type of costs as the most costly stage that the company faces in dealing with regulatory compliance obligations.

The smaller companies pointed out that the process of obtaining CE marking is also an extremely costly process. This is reinforced by the need to be tested several times a year, which leads to substantial costs.

Furthermore, Firm A experienced problems related to market surveillance activities outside the EU. One of the companies had to modify the design of a product even though it had fulfilled all the homologation tests, based on US regulations. While EU legislation is particularly relevant for EU producers, compliance costs arise from international sources of requirements.

As the snow-ski footwear industry is non-harmonized the above mentioned requirements are not set out in the IM directives. FESI states that such requirements should be included in national

[167] Italian standardization committee

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legislation, though they were not able to point to specific pieces of national legislation containing such requirements.

Customs clearance

In general the issue of customs clearance does not seem to be a general concern within the industry, though some companies highlighted customs barriers as major sources of costs. In one of the interviews, for example, it was highlighted that delivering supporting documents for customs clearance was one of the stages of regulatory compliance that the company takes into consideration when estimating the costs of regulatory compliance. From the perspective of the company, there is little difference between the legislation and the administrative barriers that the various pieces of legislation create.

Summary of costs

The companies interviewed for this study represent very different types of companies in terms of turnover, number of employees and available resources. The amount of resources allocated to administrative and substantive regulatory compliance processes vary widely from company to company.

Most companies interviewed do not disclose their total revenue, which means that it can be difficult to estimate the impact of compliance costs versus normal costs of doing business. The larger firm that allocates one FTE to regulatory compliance generates a total annual turnover of around € 400 million and employs 1,500 people. 41% of company revenue is generated from ski-boots. Thus the turnover for ski-boots is approximately € 165 million and employment 615. Taking these numbers into account the allocation of one FTE to regulatory issues cannot be considered a major cost. This was also confirmed by the interview. Furthermore, the interviewee estimated that the budget allocated to certification, advice and testing represented around 1-2% of the total investment budget.

The burden of compliance falls disproportionately onto the smaller companies. It is more difficult to separate the resources allocated to compliance issues since many processes in small companies are interlinked and employees share a range of different roles and responsibilities. However, resources dedicated to compliance costs are allocated in both the design phase and the production phase. Firm B has an annual turnover of €8 million while employing only 25 people. That makes this particular company a very small manufacturer within the industry. This small company allocates almost as many resources in the design phase (0.75-1 FTE) as one of the larger companies, which indicates that the regulatory requirements are fairly high in relative terms for a small manufacturer compared to a large manufacturer.

As mentioned throughout the case, technical standards are important elements within the industry both in the design and production phase, especially for small producers. Smaller manufacturers appear to be impacted to a greater extent than larger firms. The adherence to the standards was not mentioned either as a main cost issue for the larger companies interviewed.

Variation in national regulations or laws has not created problems for the industry. Problems related to the practical application of the mutual recognition principle and varying national legislation in different member states could potentially cause problems for companies. This, however, does not seem to be the case within the snow-ski footwear industry. None of the five companies interviewed has experienced problems related to national legislation, neither in terms of compliance nor in terms of placing products on the market in different member states. The issues were also discussed with FESI. Problems related to national legislation in different members states or the mutual recognition principle have not been brought up in meetings or discussions with their member companies. In

general, therefore, there seem to be very limited, if any, costs related to varying legislation across the member states as well as practical problems with the 'mutual recognition' principle.

Business as usual

Some of the costs described in the section above could be considered so-called business as usual (BAU) costs. This refers to costs that the company would have had to bear even in the absence of specific legislation. However, the concept of BAU costs does not apply in the same extent to snow-ski footwear since the product group is non-harmonized. Therefore, the premise of the BAU cost consideration applied in this study is to examine what costs companies would face in the absence of harmonized IM legislation. Since the harmonized IM legislation does not apply to the snow-ski footwear industry the premise of the BAU consideration would be *what costs companies would face in the absence of national legislation.*

Testing processes in all companies include a focus on performance, compliance with standards, and conformity with industry trends. Snow-ski footwear companies go through testing procedures that are not limited to regulatory requirements. These procedures are maintained to ensure product quality. In the snow-ski footwear industry, ensuring durability is a central element and even smaller producers go through intensive practical testing of the products, which integrates standards as well as performance testing.

5. Possible benefits from simplification or harmonisation

As the product group for this case study is non-harmonized, the sections above have used national legislation as a point of reference in examining the administrative and substantive compliance costs. The input provided through the interviews with companies and industry associations indicate limited problems from national legislation in the different Member States.

Production of snow-ski footwear is concentrated in relatively few European countries. There are no significant challenges in terms of varying legislation that would complicate the selling of the products and increase costs. Hence, there seems to be no real demand or even potential for simplifying current national legislation. On the question of whether harmonizing legislation would lead to lower costs for the industry, it was noted that since national legislation does not represent major obstacles, there would be little costs savings related to a harmonization of legislation.

Requirements for testing and documentation to third parties companies within the snow-ski footwear industry are a source of additional costs. In general, the companies interviewed were positive towards the fact that formulated requirements exist. However, it was stated that the requirements on the frequency and scope of testing impose significant costs to the manufactures. Hence, there could be scope for simplification of these procedures in order to reduce the processes involved in testing and documentation to third parties. The costs associated with these processes are particularly prohibitive in terms of developing new products, according to one of the interviewees. Thus, companies are positive towards requirements but would like to see them revised to decrease the costs they impose, especially the need for repeated testing.

Extrapolation of costs and cost saving from the firms to the sector

Given the limited amount of data in the relevant databases on the number of manufactures of snow-ski footwear within the industry, and possible variance between Member States given different national legislative environments and national standards, we have not attempted to extrapolate the substantive and administrative costs across the total number of manufacturers in the EU.

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6. Overall conclusions

This case study covered snow-ski footwear which includes footwear products related to activities involving downhill and cross-country skiing. Products such as snow-ski footwear are regulated at national level, non-harmonised and covered by the Mutual Recognition principle (764/2008). Certain aspects of the products are covered by Union harmonisation legislation. This includes the labelling of materials, packaging and also the use of chemicals under the REACH Regulation.

The total size of the EU27 market for snow-ski footwear in 2011 was 4.93 million units (pairs) with a total EU production value of EUR 330 million. The snow-ski footwear industry is very competitive with only a small number of manufactures with global reach. The total number of snow-ski footwear producers in the EU is around 20, occupying around 4,000 employees and representing around 70 % of the world's production. Despite the absence of harmonised EU legislation in this area, national legislation is not particularly relevant to snow-ski footwear due to the globalised nature of the market. This means that all products are developed with reference to, and in compliance with international standards that tend to be followed EU-wide.

While specific data on the compliance costs of meeting national regulations were not available from manufacturers, the most significant compliance costs identified were obtaining product certification from third parties and driven by the frequency of testing required. Meeting the requirements set out in technical standards was not mentioned as a key cost driver.

7. Sources of information

- Eurostat PRODCOM
- Eurostat Structural Business Statistics Database and PRODCOM
- International Standardization Organization
- European Committee for Standardization
- European Commission
- Input from interviews
    - Industry association: Federation of the European Sporting Goods Industry
    - Five companies

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CASE STUDY 10 - BICYCLES

1. Introduction – objectives of the study

This case study focuses on bicycles. Bicycles are covered by the Mutual Recognition Regulation (Regulation 764/2008/EC). This regulation applies to products which are not covered by Community harmonisation legislation, or to aspects of products falling outside the scope of such legislation. The main purpose of this case study is to assess the influence of the above mentioned regulation on the bicycle sector. In the Impact Assessment of Mutual Recognition Regulation in 2007 some cases in the bicycle sector were considered.[168] Furthermore bicycles are subject to the General Product Safety Directive (GPSD 2001/95/EC), that resulted in European standards on safety requirements for bicycles.

2. Product definition and description of structure of the sector

Product and market definition

This case study focused primarily on "regular" bicycles (The term "regular" is used here to distinguish them from Electrical Power Assisted Cycles, EPACs).

Since the importance of Electrical Power Assisted Cycles has sharply increased in recent years, certain aspects related to Electrical Power Assisted Cycles were also examined. Based on Directive 2002/24/EC (concerning the type-approval for two and three wheeled vehicles) the definition of an Electrical Power Assisted Cycle can be determined. These so-called Electrical Power Assisted Cycles are (article 1 (h)) "Cycles with pedal assistance which are equipped with an auxiliary electric motor having a maximum continuous rated power of 0.25 kW, of which the output is progressively reduced and finally cut off as the vehicle reaches a speed of 25 km/h (16 mph) or if the cyclist stops pedalling." Because of this exclusion, Member States define Electrical Power Assisted Cycles as bicycles as well. Bicycles with more power do fall under directive 2002/24/EC (concerning the type-approval for two and three wheeled vehicles). Nevertheless several Directives are applicable to Electrical Power Assisted Cycles (see below).

Market size

The following table makes use of PRODCOM data from Eurostat and shows information on production, imports and exports within the EU for the year 2009. The total European market has a value of 2.8 billion Euros. The table shows that the largest part (in value) of the bicycles on the European market are produced in Europe, that a large part is imported and that the export from Europe to third countries is limited.

Table 1: Production, import and export value – European bicycle sector (2009), PRODCOM CODE: 30921030 (Non-motorized bicycles and other cycles, without ball bearings) and 30921050 (Non-motorized bicycles and other cycles with ball bearings)

INDICATORS	*Values (€)*
Production	2,012,629,673
Import	925,093,260

[168] Impact Assessment of the REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision 3052/95/EC

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Export	96,857,400
Total EU market	2,840,865,533

Source: Eurostat PRODCOM.

According to a report[169] of COLIBI and COLIPED (COLIBI is the Association of the European Industry and COLIPED is the European Two-Wheeler Parts' & Accessories' Industry) around 20 million bicycles are sold on the European Market (EU-27) in 2011. This is a decrease of 2% relative to 2010, but an increase of 5.8% relative to 2000.

Table 2: European bicycle sales (EU27), 2000-2011

Year	*Sales (1,000 units)*	*Growth rate(%)*
2000	18,945	
2001	17,745	-6.33
2002	17,840	0.54
2003	20,206	13.26
2004	20,322	0.57
2005	20,912	2.9
2006	21,033	0.58
2007	21,344	1.48
2008	20,206	-5.33
2009	19,582	-3.09
2010	20,461	4.49
2011	20,039	-2.06

Source: EUROPEAN BICYCLE MARKET 2012 edition, Industry & Market Profile (2011 statistics), COLIBI and COLIPED.

According to the report, within the EU most bicycles are sold in Germany (20% of the total volume), UK (18%) and France (16%).

Table 3: European bicycle sales (EU27) by country, 2011

Country	*Sales (1,000 units)*	*Country*	*Sales (1,000 units)*
Germany	4,050	Greece	325
UK	3,580	Portugal	320
France	3,200	Slovakia	300
Italy	1,750	Slovenia	250
The Netherlands	1,171	Hungary	240
Spain	780	Lithuania	115
Poland	610	Bulgaria	103
Denmark	550	Ireland	95
Sweden	520	Estonia	65
Belgium	468	Latvia	35
Austria	405	Cyprus	35
Romania	375	Malta	12
Czech Republic	345	Luxembourg	10

[169] EUROPEAN BICYCLE MARKET 2012 edition, Industry & Market Profile (2011 statistics), COLIBI and COLIPED. http://www.colibi.com/docs/issuu/European%20Bicycle%20Market%20&%20Industry%20Profile%20-%20Edition%202012.pdf

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Country	Sales (1,000 units)	Country	Sales (1,000 units)
Finland	330	**EU 27**	**20,039**

Source: EUROPEAN BICYCLE MARKET 2012 edition, Industry & Market Profile (2011 statistics), COLIBI and COLIPED.

Industry structure

In terms of industry structure (production), Eurostat data for the relevant NACE category 30.92 (*Manufacture of bicycles and invalid carriages*) indicate that 1,636 companies were active in the bicycle industry in 2010. The market is characterized by a combination of both large and small companies. Many bicycle producers are part of groups, which means that they produce several brands.

Table 4: Number of enterprises – bicycle and invalid carriages sector (NACE *30.92*)

Indicator	2008	2009	2010
Number of enterprises	1,654	1,555	1,636
Production value (in thousands)	€ 5,040	€ 4,794	€ 4,892

Source: Eurostat

In terms of production volume, according to the COLIBI/COLIPED report European production (EU27) has decreased from around 14.5 million bikes in 2000 to around 11.8 million in 2011.

Table 5: European bicycle production (EU27), 2000-2011

Year	Production (1,000 units)	Evolution (%)
2000	14,531	
2001	13,009	-10.47
2002	12,272	-5.67
2003	12,828	4.53
2004	13,232	3.15
2005	13,218	-0.11
2006	13,320	0.77
2007	13,086	-1.76
2008	13,246	1.22
2009	12,178	-8.06
2010	12,241	0.52
2011	11,758	-3.95

Source: EUROPEAN BICYCLE MARKET 2012 edition, Industry & Market Profile (2011 statistics), COLIBI and COLIPED.

According to the report of COLIBI/COLIPED, within the EU most bicycles are produced in Italy (20% of the total volume), Germany (19%) and the Netherlands (10%) which are traditionally the three main producers[170]. Production of parts and accessories also takes place in Italy (32%), Germany (16%) but also in Romania (15%). Still, at a global scale, over 60% of bicycles produced today are made in China[171].

[170] http://www.bike-eu.com/Sales-Trends/Market-Report/2013/3/European-Union-2012-Is-Cycling-Becoming-Hot-Again-in-Europe-1179947W/

[171] Source: Worldometer Stastics, http://www.worldometers.info/bicycles/

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Table 6: European bicycle production (EU27) by country (2011)

Country	*Production (1,000 units)*	*Country*	*Production (1,000 units)*
Italy	2,310	Greece	133
Germany	2,288	Sweden	129
The Netherlands	1,200	Belgium	109
France	900	Denmark	70
Poland	892	UK	40
Portugal	782	Finland	31
Bulgaria	642	Slovenia	5
Romania	422	Ireland	0
Hungary	387	Cyprus	0
Czech Republic	361	Estonia	0
Lithuania	326	Latvia	0
Slovakia	306	Luxembourg	0
Spain	275	Malta	0
Austria	150	**EU 27**	**11,758**

Source: COLIBI and COLIPED annual report (2011 statistics)

In terms of employment data from the Industry & Market Profile report produced by COLIBI and COLIPED shows that around 20.000 people work in the bicycle and the parts and accessories industry. In total are working in the industry. The report does not clarify if these numbers concern only production sector or also retailers[172].

Table 7: Total employment in the bicycle sector (COLIBI data)

Country	*Bicycle*	*Parts & Accessories*	*Total*
EU 27	**12,874**	**6,915**	**19,789**
Germany	2,450	1,200	3,650
Italy	1,574	1,600	3,174
The Netherlands	1,764	500	2,264
France	1,150	900	2,050
Poland	1,074	370	1,444
Romania	400	800	1,200
Portugal	690	500	1,190
Bulgaria	1,010	10	1,020
Czech Republic	460	480	940
Hungary	482	50	532
Austria	300	80	380
Slovakia	280	90	370
Belgium	220	150	370
Great Britain	250	70	320
Lithuania	190	0	190

[172] Please note that COLIBI and COLIPED do not give a definition in their report. It is therefore not possible to compare their findings one-on-one with the Eurostat data.

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Country	Bicycle	Parts & Accessories	Total
Spain	180	0	180
Greece	160	0	160
Finland	60	45	105
Sweden	90	0	90
Slovenia	10	70	80
Denmark	80	0	80
Cyprus	0	0	0
Estonia	0	0	0
Ireland	0	0	0
Latvia	0	0	0
Luxembourg	0	0	0
Malta	0	0	0

Source: COLIBI and COLIPED annual report (2011 statistics)

3. Analysis of applicable legislation

Bicycles are non-harmonised products and are not covered by a specific EU legislation (except Electrical Power Assisted Cycles). At the EU level the relevant piece of legislation is the mutual recognition which is presented in the section below. Additional information is provided on the development of the mutual recognition guideline, especially the impact assessment (case studies for bicycles). At the same time though, there are relevant EN standards, based on the General Product Safety Directive (GPSD 2001/95/EC). Furthermore, there are national pieces of legislation. In this study we examined the legislation of three Member States with a large bicycle tradition, namely (Germany, Netherlands and the UK).

As a separate part we also examined the legislation covering Electrical Power Assisted Cycles.

Relevant legislation: Mutual Recognition

Bicycles are covered by the Mutual Recognition Regulation (764/2008/EC). The principle of mutual recognition states that products lawfully sold and marketed in one Member state, should also be allowed to be marketed in another Member state. This statement holds, even when the product does not fully comply with the technical rules valid in the Member State. This guideline removes the need for harmonisation of all national technical rules. These rules state typically requirements for packaging, size, composition, weight and labelling. One exception to the mutual recognition guideline is when the Member State can show that this is necessary for the protection of for instance the consumer safety, public health or the environment and secondly that the required measures can be shown proportional.

The Mutual Recognition Regulation provides conditions and procedures which Member states have to follow when they want to introduce a national law (technical rule) which may disrupt the internal market[173].

[173] For examples from the UK for technical rules, please follow this link: https://www.gov.uk/mutual-recognition-regulation-across-the-eea

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General Product Safety Directive and EN standards

Except for the mutual recognition principle, bicycles are subject to the General Product Safety Directive (GPSD 2001/95/EC). Based on the GPSD the sector itself developed the standards. The EN standards provide safety standards for the bicycles. These are captured under CEN/TC 333. The European standards for bicycles are mandated by Commission Decision 2011/786/EC. This decision sets out the specific safety requirements for bicycles, bicycles for young children and luggage carriers for bicycles to be met by European standards pursuant to Article 4 of Directive 2001/95/EC.

An overview of the relevant standards is provided in the table below:

Table 8: Relevant EN Standards

Standards	Title
EN 14764:2005	City and trekking bicycles - Safety requirements and test methods
EN 14766:2005	Mountain-bicycles - Safety requirements and test methods
EN 14781:2005	Racing bicycles - Safety requirements and test methods
EN 14872:2006	Bicycles - Accessories for bicycles - Luggage carriers
EN 16054:2012	BMX bicycles - Safety requirements and test methods
EN 14765:2005+A1:2008	Bicycles for young children - Safety requirements and test methods

Source: European Committee for Standardization[174]

According to all interviewees the EN standards are used by all manufacturers inside Europe but also to a large extent also by manufacturers outside Europe. Even Chinese manufacturers of bicycles and components use the standards for their exports to Europe. Some interviewed European producers mentioned that they use their own standards which are often higher than the EN standards.

At the moment ISO standards are developed. These standards are based on the EN standards. When these ISO standards are ready, they will replace the EN standards.

Applicable national regulations

As stated above, the mutual recognition regulation does allow Member States to enforce different technical rules. These rules form exceptions on the Mutual Recognition principle and should be based on art. 36 TFEU. Examples include public health and the environment.

The **United Kingdom** has two specific regulations (technical rules) for bicycles. The first regulation (Pedal Bicycles (Safety) Regulations (SI 2010/198))[175] is concerned with safety and consumer protection. Examples from these regulations are that the bike should be equipped with a bell, right hand should operate the front brake and the incorporation of retro-reflected material in the design.

The second regulation (Pedal Cycles (Construction and Use) Regulations (SI 1983/1183))[176] is concerned with the construction of the bicycle as well as the use of these vehicles. Examples of

[174] See the following link: http://www.cen.eu/cen/Sectors/TechnicalCommitteesWorkshops/CENTechnicalCommittees/Pages/Standards.aspx?param=6314&title=Cycles

[175] For the full text of the regulation: http://www.legislation.gov.uk/uksi/2010/198/pdfs/uksi_20100198_en.pdf

[176] For the full text of the regulation: http://www.legislation.gov.uk/uksi/1983/1176/pdfs/uksi_19831176_en.pdf

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regulations include the name of the manufacturer on the bicycle, braking systems, and the presence of a gearing system between the pedals and the wheels.

In the **Netherlands**, bicycles are subject to the Warenwet in the Netherlands which covers general requirements for the safety of consumer products[177]. Secondly, bicycles are covered under the Regeling Voertuigen[178]. The former is based on the European directive for product safety. The latter is specifically for vehicles and gives specific (technical) rules to which bicycles should comply. The Netherlands does not have required approving each type of bicycle. The Regeling Voertuigen does only have several general requirements which bicycles have to fulfil if they want to enter the Dutch roads. One of the requirements are reflectors of a certain type on the side of the tires, pedals should have these as well. Also, the Dutch law knows the requirement of a bell.

Germany has a similar set-up to the Netherlands. Rules about the bicycles can be found in the Straßenverkehrszulassungsordnung (StVZO)[179]. From this legislation requirements are for instance the fact that bicycles should have two brakes which can be operated independent from each other. Also, bicycles should have a bell. In contrast to the Netherlands, Germany requires the bicycle it self to have lights, back and front. These lights should be operable at all time. The Netherlands only requires it during night and also allows the cyclist to have the lights on himself instead of the bike. Secondly, Germany requires a dynamo to operate the lights.

In the interviews some other requirements were mentioned. For example, in France bicycles have to be fully assembled and in Denmark a traceability code is required (in connection with theft) and in Spain bicycles have to be accompanied by test certificates.

From the countries discussed up to now, we see that the requirements seem to be quite similar. In general, safety standards are considered to be important which results in requirements for lights, reflectors as well as for brakes. In practice the different national requirements result in specific adjustments of bicycles per country.

In contrast to regular bicycles, Electrical Power Assisted Cycles (EPACs) are within the scope of by IM legislation. An overview of relevant directives is provided in the following table[180]:

Legislation	Obligations
Directive 2006/42/EC (Machinery)[181]	o Complete technical file o EC Declaration of Conformity o CE marking o Marking with ▪ The business name and full address of the manufacturer and, where applicable, his authorised representative ▪ Designation of the pedelec ▪ Designation of series or type, ▪ Serial number, if any, ▪ Year of construction, business name and full address of the manufacturer and, where

[177] See http://wetten.overheid.nl/BWBR0001969/geldigheidsdatum_23-05-2013 for the full text of this legislation.
[178] See http://wetten.overheid.nl/BWBR0025798/geldigheidsdatum_23-05-2013 for the full text of this legislation.
[179] http://www.gesetze-im-internet.de/stvzo_2012/BJNR067910012.html for the full text of the legislation.
[180] Source BIKE Europe EU Regulations for E-bikes & Pedelecs Series. See http://www.bike-eu.com/Laws-Regulations/Safety-standards/2010/8/EU-Regulations-for-e-Bikes-Part-1-Type-approval-legislation-and-CEN-standards--BIK004232W/

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Legislation	Obligations
	applicable, his authorised representative,
Directive 2004/108/EC (Electromagnetic Compatibility)[182]	o Complete technical file necessary to produce evidence of compliance. o EC Declaration of Conformity o CE marking o Fulfil requirements for traceability.
Directive 2011/65/EC (RoHS)[183]	o Complete technical file o EC Declaration of Conformity o CE marking
Battery transportation (dangerous good regulations for transport by road (ADR), class 9)	o Includes requirements for all transports of the battery. o Comply to UN3481 requirements o Follow handling procedures
Directive 2006/66/EC (Battery)	o Registration of the producers of batteries o Obligation to take back used batteries o Readily removable (or clear instructions on how to remove the bicycle) o Labelled with the correct symbols o Recycling of collected batteries

Source: BIKE EUROPE series on EU regulations for E-bikes and pedelecs.[184]

There is a technical standard for Electrical Power Assisted Cycles, EN15194:2009. In terms of technical standards a lot of the requirements are covered by technical standard EN15194:2009[185]. Only the requirements of the Machinery Directive are not fully included. Therefore following the standard does not mean that you meet all requirements of the directives. The fact that the standard does not fully cover the requirements of the directives makes it confusing for enterprises.

Also from the interviews the main conclusion is that the rules for EPAC are rather confusing. The main remarks from interviewees are:

- The EN standard for EPACs is a 'collage' of many single requirements from the applicable directives;
- It was already mentioned that EN 15194:2009 covers most of the requirements of the directives, but not all;
- EN 15194:2009 sometimes conflicts with national regulation on vehicles or traffic;
- The Machine Directive is applicable, but not all requirements of the MD are possible for EPACs. The interviewee mentioned for example that according to the Machine Directive rotating parts have to be covered, but if you do that with a bike, you cannot use the bike anymore. This

[181] http://www.bike-eu.com/Laws-Regulations/Safety-standards/2010/8/EU-Regulations-for-e-Bikes-Part-2-Machinery-Directive-BIK004233W/

[182] http://www.bike-eu.com/Laws-Regulations/Safety-standards/2010/8/EU-Regulations-for-e-Bikes-Part-3-Electromagnetic-Compatibility-BIK004234W/

[183] http://www.bike-eu.com/Laws-Regulations/Safety-standards/2013/3/EU-Regulations-for-E-bikes--Pedelecs-Part-6-RoHS-Directive-1258753W/

[184] Pedelecs stand for Pedal Electic Assisted Cycles or EPACS stand for Electronic Power Assisted Cycles.

[185] See http://www.vae-enov.com/fiches_2010/norme_en_15194.pdf

interviewee also mentioned that according to the Machine Directive the EPAC should have an emergency button. Although these are wrong interpretations of the interviewee, it shows that there is confusion.

- At the moment a working group is working on the revision of the EN 15194 standard to include the relevant requirements of the directives in the standard, including the requirements of the Machinery Directive. In the main time it is confusing for some enterprises that following the EN standard do not mean that you meet the requirements of IM legislation and that enterprises have to find out themselves which elements of the Machinery directive are relevant for Electrical Power Assisted Cycles.

4. Analysis of mutual recognition in non-harmonised product groups

Additional information on the role of mutual recognition in the case of bicycles was provided in the impact assessment study that took place in 2007[186]. A sectoral study that took place in 2002 found that 41% was unfamiliar with the principal of mutual recognition (2002)[187] while only about 50% of the companies familiar with the principle actually relied on it to access foreign markets.

The impact assessment (2007) illustrated three firm cases in the bicycle sector, with lack of mutual recognition and extra costs caused by national rules. The first case describes the technical barrier of lightning equipment used in bicycles. Different Member states have different requirements for these. The enterprise has to change these to meet the requirements in the different countries. Associated costs are estimated for the lack of mutual recognition of 98,000 and 148,000 EUR each year, which represents between 0.7% and 1% of the turnover of this company on the market of this (large) Member State.

The second case[188] of an SME importing indicated three specific requirements in his country:

- All bikes must be equipped with bells
- Particular stickers on the bikes.
- Need to have bikes type approved

All these requirements were reported to impose an extra cost to the firm of € 103,400 each year, representing 4.75% of its annual turnover for the specific company.
Finally, the third case indicated that the most important hurdle that each type of bicycle has to be previously tested in an accredited laboratory in the Member State in which the company wants to sell. If this test is successful, a code is provided which the company has to engrave in the frame of the bicycle. The specific costs could not be specified.

All above indicate that national requirements, which are allowed under the Mutual recognition principle, result in technical barriers and in extra costs for placing products on the market in other Member States.

From the interviews carried out there seems to be limited familiarity with the principle of mutual recognition. Still, the interviewees could not mention substantial problems with placing products on the market in other Member States. This is because nearly all manufacturers make use of the EN standards which facilitate the operation of the EU market. The only problems are the national

[186] See Impact Assessment, page 70.
[187] See Impact Assessment, page 15 and 16.
[188] See impact Assessment, page 71.

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requirements on especially lightning and retroflection which results in extra costs for especially designing of adjustments for specific countries or extra logistic costs (order and store different parts). These national requirements are allowed within the Mutual recognition principle and were already identified in the case studies in the impact assessment study mentioned before.

The impact of the national requirements on lights is limited. The European bicycle industry and market exist for a long time. They are used to the different requirements on lights. There are no problems with placing products on the market in another Member State. Furthermore, markets in the different countries are quite different because of differences in consumer preferences. There are some typical bicycle countries, like Germany, UK and the Netherlands. Producers in a country best know the national preferences. Therefore most producers produce especially for their home market and little for other countries.

At the same time the view of interviewees on imported bicycles (especially China) differs. Some suggest that they mostly meet the EN standards, but that they are generally of low quality. Others suggest that there are imported bicycles on the market that do no meet the EN standards, but that there is too little surveillance. Furthermore, there is a feeling that a certain level of dumping is taking place.

5. Analysis of management of regulatory compliance and administrative costs and burdens

Differences of national requirements mainly have to do with lighting and retroflection, and sometimes an extra brake. To comply with these national requirements some manufacturers have to make adjustments in their designs and they have to look for and buy the needed components. The interviewees have different views. One interviewee mentioned that there are extra costs to meet the national requirements of about 2 or 3 days per adjustment and that they have about 30 to 40 adjustments a year. Some interviewees estimated the extra costs on about 1% of turnover, because of extra inventory of different models or extra inventory of different kinds of lights. Some others mentioned that it is very easy and that there are hardly any extra costs. The suppliers of the lights know exactly the requirements of all countries and the bicycle producer only have to buy the right lights.

Overall the extra costs are limited. Furthermore, all interviewees mentioned that it is difficult to separate these costs for national requirements of light from costs for adjustments for national preferences. Bicycles are “cultural” products, meaning that every country has different consumer preferences. So, bicycles have to be adjusted for these consumer preferences in nearly every country anyway. Meeting the national requirements is incorporated in the processes.

From the analyses it can be concluded that while bicycles are non-harmonised products (except Electrical Power Assisted Cycles), the sector is to a large extent harmonised through the use of harmonised standards (for safety requirements under the General Product Safety Directive (GPSD 2001/95/EC)). The Mutual recognition principle does not play an important role in the bicycle sector.

6. Overall conclusions

The case study focused on bicycles covered by the Mutual Recognition Regulation (Regulation 764/2008/EC). Bicycles are not covered by Union harmonisation legislation (except Electrical Power Assisted Cycles) and the only relevant piece of legislation is the General Product Safety Regulation. In the context of the Regulation, a number of European EN Standards developed by CEN are key for the sector. They are used by all manufacturers inside Europe but to a large extent, also by manufacturers outside Europe.

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In 2011, the total European market for bicycles was close to €2.8 billion in size with a total of around 20 million bicycles sold on the European Market (EU-27). Production inside Europe was close to 11.8 million bicycles in 2011. Italy, Germany and the Netherlands are the three larger producers in Europe but 60% of the global production takes place in China.

The situation is different in the case of Electric Power Assisted Cycles, which are covered by IM legislation (Machinery, EMC, RoHS, Directive 2006/66/EC on batteries and accumulators). However, according to the input provided, the rules applying to Electric Power Assisted Cycles are confusing and the development of a new comprehensive technical standard is being developed.

Earlier studies on the costs of the different national pieces of legislation and our own analysis suggest that the additional costs may be up to 1% of firms' annual turnover as a result of different requirements concerning lighting and retroflection, the requirement to introduce additional breaks or bells, to apply specific stickers, but also the need to have bikes type approved in some EU countries. An important finding was that many firms are unaware about the concept of mutual recognition and its potential advantages, although since most firms follow the EN standards, this problem has been partly addressed by default.

7. Sources of information

Sources of information:

- COLIBI and COLIPED annual report (2011 statistics)
- European Committee for Standardization
- Eurostat PRODCOM
- http://www.worldometers.info/bicycles/
- http://www.colibi.com
- http://www.bike-eu.com
- Impact Assessment COM(2007) 36 FINAL SEC(2007) 113
- http://www.legislation.gov.uk/uksi/2010/198/pdfs/uksi_20100198_en.pdf
- http://www.legislation.gov.uk/uksi/1983/1176/pdfs/uksi_19831176_en.pdf
- http://wetten.overheid.nl/BWBR0001969/geldigheidsdatum_23-05-2013
- www.gesetze-im-internet.de/stvzo_2012/BJNR067910012.html
- www.cen.eu

Interviews:

- 3 interviews with a national industry association
- 6 interviews with producers of bicycles

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CASE STUDY ON ADDITIVE MANUFACTURING / 3D PRINTING

Introduction

Through this study, 10 product cases have been developed (8 harmonised and 2 non- harmonised). In addition, this case has been produced since the specifications posed questions as to how 'fit for purpose' the body of internal market legislation for industrial products is to accommodate new technologies and advanced manufacturing processes.

The main sources that have been used to carry out the case were: desk research to identify relevant studies and literature that provide information on the 3D printing sector and on regulatory issues raised by its rapid development. In addition, discussions with a small number of industry associations and manufacturers involved in the manufacture of laptops and printers have been interviewed. Lastly, the Your Voice consultation on possible reform of the Internal Market Legislation for Industrial Products included a question specifically on the issue of 3D printing. There were limited responses specifically relating to 3D printing, but some inputs were used.

Background on Additive Manufacturing (commonly known as 3-D printing)

Additive manufacturing is an advanced technology and an intermediate step in the production process. It can be used to develop prototype products for R&D and design purposes across a wide range of sectors. Additive manufacturing involves a process of making a three-dimensional solid object from a digital model. The manufacturing process involves making physical objects by depositing a material using a nozzle, print head, or another printer technology. A 3D object is made using an injector which during each pass deposits five or ten hundredths of a millimetre of an acrylic resin, a metal alloy, a wax or a nylon powder. This is consolidated with a laser, or left to cool, and then tested.

It is important to note that the terms '3D printing' and '3D printer' are misleading in that the process of additive manufacturing is more like a machine tool, except that instead of removing material, the machine adds materials in successive layers so as to produce a 3D object. Although 3D printing was initially used for the development of product prototypes, the different potential uses of 3D printing have evolved and become multifaceted.

Additive manufacturing is now used to produce highly customisable short-run manufacturing of industrial products and also for dental implants and medical devices. The purposes for which 3D printing are used are therefore becoming more diverse in terms of their potential applications across different markets. The 3D printing industry has grown markedly in the past 5 years, driven by growing consumer interest in 3D printers and the reduction in the cost of 3D printers and improvements in their technological capabilities. There are also an increasing number of industrial applications. For instance, a recent study in the US by GIS[189] estimated that the global 3D printing market will reach $2.99bn by 2018. The report states that the market for 3D Printing Products is projected to grow considerably in the near future as 3D printer systems become more affordable and easy to use.

[189] "3D Printing: A Global Strategic Business Report" announced by Global Industry Analysts

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3D Printing and Industrial Competitiveness

There is considerable potential to stimulate growth and competitiveness through this nascent industry. Customised products can be developed, developmental costs for new products reduced and this helps to level the playing field for SMEs through reduced lead times to market and the ability to carry out design and prototype development in-house rather than having to pay for external product prototype development.

Further advantages of additive manufacturing are that it can help to accelerate product development lead cycles considerably. Taking an example from Italy in the area of the design of customised parts for Formula 1 vehicles, 3D printing of prototypes dramatically reduces time to market. "In the 1970s, it used to take six years from the designer's first sketches to release to market. Today, we're looking at eighteen months, and even that's shrinking"[190].

Applicable IM legislation for additive manufacturing

- The legislation that is applicable to 3D printers includes:
- IM legislation applicable to the 3D printer itself e.g. the Machinery Directive
- IM regulations applicable depending on the products produced by the machines
- The products produced by the machines will also be subject to wider legislation beyond IM regulations e.g. intellectual property law, legislation to control dual-use potential and environmental legislation.

Since 3D printers are essentially machines, and are not like office printers, the current interpretation is that the Machinery Directive is always applicable[191]. Since the scope of the Machinery Directive is based on a broad definition of machinery and not on a list of product categories and since the essential health and safety requirements of the Directive cover all the potential risks, there is no need for new or amended legislation. On the other hand, effective application of the Machinery would be facilitated by the development of a specific harmonised standard or set of standards for this type of product.

There may be an outstanding question as to whether certain compact '3D printers' could not be considered as ordinary office machinery or IT equipment subject to the Low Voltage Directive. This issue could become more pertinent as 3D printers become ever-cheaper and the uses ever wider. There is evidence that the price point has been significantly reduced and that consumer-oriented 3D printers are becoming more common.

[190] http://www.corriere.it/english/13_maggio_14/formula-one_70300362-bc81-11e2-996b-28ba8ed4f514.shtml

[191] The demarcation between the MD and the LVD is based on the category of product, rather than its size or whether it is used in a consumer, office or industrial environment. All ordinary office machinery and IT equipment is excluded from the scope of the MD and is thus subject to the LVD.

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Since a central feature of Union harmonisation legislation is that it is technology-neutral, in principle, there are no specific legal barriers within current IM regulations that would hinder the development of additive manufacturing or of the products produced by 3D printers, which would follow existing IM legislation, depending on what type of product is being produced (and only if these products were placed on the market (not if they were basic prototypes). A respondent to the Your Voice consultation confirmed that *"3D printers can be covered through the existing CE-Marking directives. Similarly, products printed using 3D printers need to be compliant like any other manufactured good"*.

However, a distinction can evidently be made between the applicable legislation for the 3D printer as a piece of machinery and the products and prototypes it produces through additive manufacturing processes. No specific problems were identified in terms of gaps in internal market legislation. If products produced using such printers were placed on the market, they would be subject to whatever the applicable legislation is depending on the final product being produced.

There likewise do not therefore appear to be any problems relating to additive manufacturing being an intermediate stage in the production process, whereas IM regulations apply to products placed on the market. There is no evidence of specific gaps in IM legislation.

An interesting issue identified in relation to all types of printers (not only 3D) is that products can be modified through software updates post-placement on the market. Moreover, major manufacturers are increasingly designing hardware based on a single platform with some functions disabled so that different models can be sold using this platform simply through software updates and/ or the insertion of a configuration SIM card.

Wider legal issues raised by 3D printing

Although a detailed examination of the legal implications of 3D printing is beyond study scope, having concluded that IM legislation is fit for purpose in accommodating new technologies and innovations, it is worth providing a short summary of the legal issues raised by the sector's development (and the practical challenges of ensuring that market surveillance is effective for the outputs produced by 3D printers. In summary, these were:

- The importance of addressing potential product abuse or misuse by carrying out of a thorough risk assessment procedure by manufacturers. There are risks that 3D printers could be used to produce products for nefarious purposes or that could potentially be misused. 3-D printers use computer-assisted design (CAD) blueprints as a template to print solid objects out of raw plastic polymers.
- Since these are downloadable over the Internet, there are clearly associated risks[192]. It is therefore essential that manufacturers carry out a thorough risk assessment at product design stage. However, the applicable conformity assessment modules under different IM legislation are already based on a risk-based approach and a manufacturer's risk assessment is already required under the MD. But there is as yet no specific mention in the guidance accompanying the LVD and MD respectively on 3D printers.

[192] For instance, the template for printing a fully functioning 3D gun in the US in 2013 attracted more than 100000 downloads before the technical blueprint was withdrawn.

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- A specific reference could be made when the guidance is next updated as to the need for "a manufacturer's risk assessments to take into due consideration possible product misuse, including dual use potential and any risks associated with changes to the product specifications resulting from software". In addition, guidelines could be introduced on a voluntary basis, drawn up between manufacturers, regulators and market surveillance authorities to ensure that there is a clearer understanding of the potential risks.
- 3D printing has implications for the legal framework in respect of intellectual property rights and these should be reviewed.

Under Decision 768/2008, manufacturers retain responsibility for updating product information for 10 years following their placement on the market. However, there is a question mark as to whether manufacturers should assume ongoing responsibility for potential product misuse. Technologies such as 3D printing may in future need to be included within IM product legislation, as such "disruptive technologies" are transformed towards more mainstream markets for consumer and industrial use.

There is also a need to ensure that the potential for misuse by consumers / end-users is appropriately regulated, for instance, to avoid consumers producing dangerous objects or weapons. However, there is already a robust regulatory regime in place to concern any products placed on the market, both for harmonised and non-harmonised products. 3-D printing does however raise wider legal issues such as disputes over copies of physical objects covered by patent law, since this tends to be less strict than copyright. There may also be grey areas and legal gaps in respect of intellectual property rights, for instance, patent law generally governs only complete assembled products. There may therefore be legal uncertainty as to whether creating replacement parts are legal.

A wider issue raised by 3-D printers and the use of advanced manufacturing equipment is how this should be addressed through IM legislation, which under the New Approach has historically focused on end-use following the placing on the market. An EC official commented that "there is a need to look at the entire value chain not just end product".

There are self-evident practical difficulties for market surveillance authorities in checking the safety of products if in future these can be produced directly by industry and consumers themselves. There is a need to ensure that any products placed on the market using 3D printers are subject to rigorous market surveillance and that there is adequate traceability. This is particularly the case given the issues mentioned above relating to the potential for the increased risk of product misuse or unintended use and the danger of or dual-use. Indeed, during the course of this study, there has been a. There is consequently a need to develop mechanisms to monitor product use following the placement on the market of 3D printers.

Stakeholder feedback on 3D printing.

A leading EU industry association representing the interests of manufacturers stated in response to the Your Voice consultation that *"Products and applications related to 3-D printing do not need to be regulated at EU level. However, there are some issues relating to their dual use (civil/military) and their potential for fraudulent use to counterfeit other goods. These issues need to be tackled under the existing regulatory framework, thereby avoiding establishing additional regulatory requirements for additive manufacturing"*.

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A major German industry association confirmed through the Your Voice consultation that although there was no need for 3D printing to be regulated at EU level, certain legal issues nevertheless arise in the context of 3D printing, such as possible violations of intellectual property, technology misuse (for military purposes, the risk of reduced quality of products produced on a decentralised basis), and the use of new materials through the development of new applications in the area of medical technology.

A further respondent to the Your Voice consultation confirmed that there are a wider set of legal issues beyond IM legislation and CE-Marking requirements. It was suggested that *"rules may need to be introduced or reviewed for products produced using 3D printers regarding possible copyright or IPR infringements and dual-use products"*.

Conclusions

- IM legislation is open to innovative products and techniques and existing IM legislation appears to adequately cover 3D printers. These should be considered as machines and therefore fall under the Machinery Directive.
- Since IM legislation is technology-neutral, there are no specific barriers under the applicable legislation to the development of new technologies, or to the use of additive manufacturing in production processes.
- However, since additive manufacturing is a relatively new and growing industry, and is changing rapidly, there is a need for a more thorough discussion with industry on the applicable EU legislation. Specifically, the Commission should clarify directly with industry whether all additive manufacturing machines and '3D printers' are subject to the MD or whether certain types maybe considered as ordinary office machinery or IT equipment subject to the LVD.
- Effective application of the Machinery Directive would be facilitated by the development of a specific harmonised standard or set of standards for this type of product.
- Where necessary, existing IM legislation can also cover the products produced by the machines when products are subsequently placed on the market.
- There may however be concerns with regard to intellectual property rights or certain abusive applications such as weapons but these do not relate to IM legislation itself and as such, are outside this study's scope.
- Additive manufacturing has strong potential to serve as an innovation catalyst and to level the playing field between SMEs and large industry in terms of R&D and product design costs.
- There is a need for vigilance by regulators so as to ensure that manufacturers' attention is drawn to the need to carry out adequate risk assessment, especially with regard to potential product misuse and/ or dual use.
- Likewise, the implications of micro enterprises and individuals being able to produce or "print" their own products in future, albeit on a limited production scale should be debated by Market Surveillance Authorities.

Literature sources:

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- Guidance on the application of the Machinery Directive and LVD
- Cross-sectoral Analysis of the Impact of International Industrial Policy on Key Enabling Technologies within the Framework Contract Sectoral Competitiveness ENTR/06/054, Final report - 28th March 2011
- Application of 3D Printing in the Manufacturing Process, Shimpei Kurokawa
- 3D printing and product lead times http://www.corriere.it/english/13_maggio_14/formula-one_70300362-bc81-11e2-996b-28ba8ed4f514.shtml
- 3D printing and product misuse/ dual use issues - http://www.guardian.co.uk/world/2012/sep/26/3d-printing-guns-legal-issues-us-law
- http://techcrunch.com/2013/01/18/like-it-or-not-i-think-3d-printing-is-about-to-get-legislated/

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This technical note sets out our approach to the case studies and to the quantification of costs. It sets out the more detailed methodological approach with regard to (i) the case study work (ii) the quantification of compliance costs and (iii) the quantification of the benefits of possible simplification measures. As such, it supports Section 5 of the main report.

E.1 Introduction – case study analyses

An important task in the specifications was to carry out ten case studies based on different product categories. The objectives were to:

- Identify which Union harmonisation legislation is applicable in eight selected harmonised product groups and to illustrate the interactions between different EU legislative texts;
- Identify and estimate the costs for firms of complying with Union harmonisation legislation;
- Assess the cumulative effects of IM legislation and the interaction between different pieces of legislation applicable to the same product;
- Assess the potential scope for any further regulatory and administrative simplification of IM legislation;
- Quantify (to the extent possible) the cost savings that might arise for firms at the level of the sector, and examine the possible impact on economic growth and employment creation from such measures.

It was agreed with the Commission that eight of the ten case studies would focus on harmonised products and two on non-harmonised products. In addition, a qualitative case study was carried out on 3D printing, which focuses on issues relating to fitness for purpose of the IM legal framework for accommodating innovation. The following table provides an overview of the case studies carried out, the number of interviews completed, the internal market legislation applicable to each product (environmental legislation was excluded from scope) and the selection criteria addressed through each case.

Table E.1: Product groups selected for case studies

No	Product	Applicable Legislation	Selection criteria covered	Interviews
Harmonised cases				
1	Electric motors	Core Directives - LVD, EMC, ATEX Other applicable IM legislation: REACH, RoHS, Ecodesign	• Professional users • High share of total manufacturing • High share of SMEs	• 2 national industry associations • 9 firms
2	Laptops	Core Directives - R&TTE, LVD and EMC Other applicable IM legislation: Ecodesign, RoHS, Packaging and Packaging	• Final consumers and professional users • Relative high share of e-commerce	• 1 EU industry association • 4 firms

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No	Product	Applicable Legislation	Selection criteria covered	Interviews
		Waste Directive	• Large firms dominant	
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	• Final consumers • Large firms dominant	• 1 EU association • 4 firms
4	Lifts for persons	Core Directives - Lifts[193], LVD and EMC	• Professional users • Large firms dominant	• 3 EU industry associations • 2 national industry association • 8 firms
5	Garden equipment	MD, EMC, Outdoor noise, Non-road mobile machinery Emissions, RoHS, REACH	• Professional users and final consumers • Large firms dominant	• 1 EU Association • 5 firms
6	Instruments & appliances for measuring, testing and navigation	LVD, EMC	• Professional users/intermediate products • Use of KETs • High share of SMEs	• 2 industry associations • 5 firms
7	Air conditioners	MD, EMC, LVD, CPR, RoHS, Energy labelling, PED[194], Ecodesign, the GAD, Regulation 2007/1494/EC on labelling requirements	• Final consumers and professional users • SMEs	• 1 EU and 1 national association • 8 firms
8	Integrated circuits	LVD, EMC, ATEX, RoHS	• Professional users/intermediate products • Use of KETs such as photonics	• 1 EU association • 8 firms

[193] Certain types of lifts are covered under other Directives. 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.

[194] The SPVD is also applicable but only to certain types of air conditioners

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No	Product	Applicable Legislation	Selection criteria covered	Interviews
			• Large firms dominant	
Non-harmonised cases				
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	• Final consumers • High Share of SMEs	• 1 EU association • 5 firms
10	Bicycles	Mutual Recognition Regulation 764/2008	• Non-harmonised • High Share of SMEs	• 3 national industry associations • 6 firms
	Total			**62 firms** **19 industry associations**

Overall, the product groups selected for the case study work have achieved broad coverage across different types of industrial products addressed through Union harmonisation legislation.

A number of selection criteria were agreed with the Commission during Phase 1, such as: a mix of different industrial product sectors in terms of their market size and importance within the European economy, the need to include innovative product groups that integrate Key Enabling Technologies (KETs) and the use of advanced manufacturing in production processes; product groups in which SMEs have a strong market share, and products aimed at professional / industrial users and at final consumers. Although most harmonised product legislation relates to final products, a further criterion was to ensure that intermediate products were included in the selection of products, such as electric motors and integrated circuits.

The target was to carry out between 6-8 firms per case study. This was achieved for some case studies, but not others. In total, 62 firms and 19 industry associations contributed to the case study work out of a total of more than 220 firms contacted. There were challenges in getting cooperation from firms across all product groups. For instance, in the case of laptops and domestic refrigerators, the relevant industry associations (CECED and Digital Europe) were contacted and in turn encouraged their members to participate in our study. However, many were unwilling to be interviewed due to commercial sensitivity concerns, difficulties for firms in collecting the necessary data internally. In parallel with the efforts of industry associations to encourage participation in the case study research, manufacturers were contacted directly by our study team. The main challenges

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in data collection and in quantification – and how we have sought to overcome difficulties in so far as possible – are set out later in this technical note.

E.2 Methodological approach to case studies

The methodology for the case study research

Our approach to the quantification of administrative and substantive compliance costs for economic operators (mainly manufacturers) was informed by the Standard Cost Model (SCM) approach. A simplified version of SCM, which followed the main principles, was used in the eight harmonised product cases to get estimates of the costs of complying with Union harmonisation legislation.

The quantification exercise was initially meant to focus on the compliance costs associated with gaps, loopholes, inconsistencies and duplication, by measuring the current costs of compliance with IM legislation so as to establish a baseline and then assessing the possible benefits of regulatory and administrative simplification in future. The practical difficulties in applying SCM to the broader scope of all (relevant) IM legislation – and the need to adapt the model accordingly - are outlined in the next section.

The case studies have been prepared using a combination of research tools. These are:

- **Data analysis –** a review of sectoral data on market size and structure from Eurostat (SBS and Prodcom data), industry associations and information from other data sources, such as the Orbis database[195]. Where available, data from market studies were also analysed.
- **Desk research –** a review of relevant applicable Union harmonisation legislation, Commission non-binding guidance documents on specific legislation and a review of forthcoming simplifications set out through the NLF (764/2008, 765/2008 and 768/2008) and the Alignment Package.
- **Interviews -** 62 interviews were carried out with firms[196] and a further 19 with national and EU industry associations. Interviews with firms provided both quantitative and qualitative information on the costs of compliance with IM legislation.
- **Verification of case study findings and quantitative estimates –** checking with industry associations that the findings from the case studies and the quantitative estimates of compliance costs are realistic and reflect broader feedback on the experiences of manufacturers in complying with IM legislation.

The interview programme was carried out using a structured framework, which followed the SCM approach but which was adapted to reflect the complexity of applying SCM to multiple pieces of legislation in parallel. Economic operators interviewed were asked questions with regard to:

- How they manage regulatory compliance internally (whether they use third party Notified

[195] In order to obtain better information on the numbers of firms, CSES made use of the Orbis database which allowed the number of active firms or groups of firms in Europe for a number of sectors to be identified. This was considered preferable to the number of enterprises provided by Eurostat this is based on NACE two digit level classifications. NACE 2 digit product groups were usually broader in scope than the sectors we were examining and, critically, the number of enterprises provided refers to separate legal units, irrespective if these are subsidiaries of larger groups. In relation to compliance with IM legislation this is particularly important since more firms tend to perform most, if not all, relevant activities in one central location. Local subsidiaries usually have very limited, if any, role in the process.

[196] The firms were mainly manufacturers but some importers and distributors were also interviewed.

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Bodies);
- Views on the most costly and administratively burdensome pieces of IM legislation;
- The costs involved in regulatory compliance (one-off and recurring), both staffing and cash costs;
- Views on possible regulatory and administrative simplification measures; and
- Opinions about what the counterfactual - what would have been the situation in the absence of Union harmonisation legislation

Having carried out the interviews, the following steps were then undertaken to analyse the results:

- Step 1 - Analyse the current costs of compliance with Union harmonisation legislation based on information provided by firms. Aggregate these costs at a sectoral level ("baseline scenario").
- Step 2 – Identify and analyse possible simplification measures and quantify the potential benefits of implementing these.
- Step 3 – Consider the benefits of possible simplifications at macroeconomic level in terms of GDP and job creation - for the EU economy.

The first step was to estimate **the current costs of compliance with Union harmonisation legislation** based on information provided by firms and industry representatives. The intention was to aggregate these costs at sectoral level in order to develop a "baseline scenario" against which to compare the benefits of simplification. On the basis of data available on compliance costs, we then made an assessment of the costs for a "typical firm" of complying with IM legislation for each harmonised product group. This was then used to extrapolate and estimate the costs at the sector level, and to assess their significance in relation to market size and firm turnover.

The second step was to **identify, analyse and estimate the potential cost savings from simplification options** identified. The typology of simplification measures was used (see Section 2.3 of the main report) to distinguish between regulatory and administrative simplification measures. Two different methods were used to identify simplification measures. Through the eight harmonised product cases, manufacturers were asked for their views on possible simplifications. Secondly, the study team sought to identify through the wider research further generic simplifications that could be applied across multiple or all industrial product groups. A further distinction was made between simplifications already taking place through the NLF and additional possibilities identified through this study.

Quantification was not always possible however. Whilst some simplifications can be quantified relatively easily (e.g. putting in place a common template for a Declaration of Conformity to eliminate inconsistencies in the requirements) in other cases, such as merging different pieces of IM legislation, quantifying the benefits is difficult until the precise way in which the legislation will be combined can be set out. For instance, it may not yet be clear which conformity assessment procedures will apply post-merger if there are currently different requirements (e.g. combining the Machinery Directive and the Outdoor Noise Directive – would the SDoC be applicable or would a third party be required to check environmental noise levels?).

Since manufacturers themselves were often unable to estimate the savings, the estimates were often based on assumptions based on qualitative feedback. Taking an example, manufacturers were not generally able to quantify how much time they would save were there to be a common DoC with no divergence in requirements between IM legislation. But based on information gathered, assumptions

can be made with regard to time savings and the cost-savings that this would translate into[197]. In some cases, we assessed what part of the compliance process the specific simplifications would affect, and provided illustrations as to what could be considered as a realistic cost saving.

The third and final step was to estimate the potential for **cost savings from possible future simplification measures and to assess the macroeconomic impacts** on growth and job creation (see Section 5.6 of the main report). Here, PANTEIA's PRISMA and WIOM models were used to estimate the impacts of possible future administrative and regulatory simplification measures. Estimates were made in respect of potential cost savings for all sectors covered by IM legislation. A macroeconomic modelling analysis would have given an indication of the total possible economic impacts in terms of GDP and job creation for the EU economy. However, given the high level of uncertainty in relation to compliance cost estimates from some of the product groups selected and even greater uncertainty as to the savings from simplification measures, such an extrapolation from the 8 cases to the whole of the EU economy was not deemed to be appropriate.

Rather, the cases provide illustrations as to the potential cost savings from administrative and regulatory simplifications in specific product areas. It should be stressed that the data comes with caveats attached in terms of the comparability of compliance costs. It is therefore difficult to know how representative the estimated cost savings are in terms of the total picture for all industrial products covered by IM legislation, since there are different situations between product groups in terms of the number of different pieces of IM legislation applicable. We have therefore limited the exercise to providing an estimate of the macroeconomic effects across the eight sectors under review.

E.3 Challenges in the quantification of compliance costs

The challenges encountered in the quantification of the costs for economic operators of complying with Union harmonisation legislation are now presented. It is important to spell these out. Although useful data on compliance costs was collected, data at the level of individual product groups on compliance costs was sometimes partial with gaps in relation to some variables. Assumptions sometimes therefore had to be made in order to arrive at estimates for the sector as a whole.

E.3.1 Establishing the "baseline"

There were difficulties in establishing a baseline against which the current costs of compliance for economic operators could be compared. It has not been possible to get data on the costs incurred prior to the introduction of Union harmonisation legislation so that we could compare actual costs against a hypothetical case examining how the situation would have developed in the absence of the internal market and Union harmonisation legislation for industrial products. Whilst it was broadly accepted by firms and industry associations that compliance costs were higher prior to the introduction of IM legislation for industrial products, since there was considerable regulatory fragmentation and a need to comply with different national technical regulations and standards. However, in most cases it was not possible to provide specific cost figures or estimates.

Firms were only able to provide a qualitative assessment as to how the current costs of compliance compare with the situation before the internal market came into effect. Since core "New Approach legislation" has been in place for 25 years, it is difficult for many interviewees to compare with how

[197] For example, less familiarisation time may be needed and there would be less chance of products being stopped by customs authorities because they do not have a paper copy of the DoC – which is currently required under the R&TTE-D and confusion about whether one must be placed together with the product.

the situation was prior to the internal market's establishment. Furthermore, it would have been difficult to make direct comparisons since there have been many changes affecting market size and structure during this period – e.g. globalisation, the expansion of the EU from 12 Member States when the single market came into effect to 28 Member States today. There is moreover an absence of data on compliance costs at the national level prior to its establishment. Nonetheless, the lack of such data did not however prevent us from considering the benefits of Union harmonisation legislation qualitatively (see main report, some case studies).

E.3.2 Data availability and reliability

Quantifying the costs of complying with EU legislation in general, and Union harmonisation legislation in particular, has been challenging for a number of reasons, such as the availability of data or the capacity to link specific activities with the applicable pieces of EU legislation and types of obligations. These are explained in more detailed in the following paragraphs. Interviewees were often not able or unwilling to provide with data to allow for a detailed analysis of compliance costs for a number of reasons:

- **Commercial sensitivity of data –** even having agreed to participate, some manufacturers were reluctant to provide cost estimates for commercial reasons. This was especially the case in terms of R&D, product design and testing costs, but less so in relation to human resources.
- Furthermore, **ODM and OEM suppliers are reluctant to provide information to manufacturers on the costs of compliance. Indeed, full testing data itself is often considered to be confidential.** Although ODMs and OEMs are required to provide their clients with basic test results for the technical file, such information is often partial. OEM suppliers are reluctant to provide full test information due to commercial sensitivity reasons. If they are asked for test data by an MSA, they often provide the requested information directly to the MSA and do not share this with manufacturers).
- **Data on some types of compliance costs was more readily available than for others.** It was straight forward to obtain data on the level of human resources working directly on compliance with IM legislation. However, there were challenges in respect of other data parameters, such as internal testing costs and the external costs of compliance. Firms were first more willing to provide data on human resources and secondly often lacked data on other types of costs.
- **Difficulty of disaggregating compliance costs when many different pieces of internal market legislation are applicable to a given product**. Interviewees often could not associate specific type costs with a specific piece of legislation since very often the activities to meet the relevant obligation consider the legal framework as a whole. For example, while fees to notified bodies can be more easily linked to specific piece of legislation, the same does not apply to familiarisation with legislation, preparation of technical files or other information collection obligations.
- **Difficulty of disaggregating data on compliance costs by specific product group.** Several harmonised product sectors covered through the cases are dominated by large firms. It was difficult for them to break down compliance costs by individual product group for the following reasons:
  - **There are difficulties in obtaining compliance data when they manufacture across multiple manufacturing sites.** Cost data is often fragmented and not collected or shared between business divisions involved in different aspects of compliance.

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- **Furthermore, manufacturers often outsource some parts or all of the manufacturing process so lack data.** There is a trend towards outsourcing manufacturing activities to Original Equipment Manufacturers (OEMs) and Original Design Manufacturers (ODMs). This means that manufacturers often do not have data on compliance costs themselves. Suppliers often provide a quotation for delivery of a final product or for parts and components, without any reference to compliance-related costs, such as testing.
- **Large manufacturers typically produce multiple product lines and do not collect data on compliance costs disaggregated by product platform**, especially for early stage testing as part of the R&D and product design phase. Within a given product group, they typically manufacture a number of different models/platforms and data on compliance costs is not kept on each of these even internally[198].
- **It was difficult for large firms developing products for global markets to separate the costs of complying with IM legislation in Europe with similar legislation that is applicable across multiple regulatory jurisdictions** - e.g. the US, Australia, Russia, BRICs. Although technical standards may differ, some test results and measures that firms take to comply with legislation in one part of the world can be used across a number of jurisdictions including the EU (although some adaptations and/ or retesting may be required). Examples are basic product safety requirements for electrical safety, compliance with RoHS, etc.[199]
- **The globalised nature of manufacturing – and the lack of a complete picture on costs since many manufacturers, ODMs and OEMs are located outside, or carry out at least some manufacturing activities outside the Union.** Regulatory compliance specialists within the European divisions of international firms interviewed often found it difficult to obtain data on compliance costs (especially for testing) from R&D laboratories and testing facilities within their firm located outside Europe. Where information was available, this is rarely disaggregated by individual product group.

Difficulties in associating costs with specific pieces of EU legislation and types of Information obligations

During the interviews it was often difficult to provide estimates of the resources and time allocated in relation to specific types of legislation or specific types of legal obligations. It was often the case that estimates were provided at only a rather generic level (e.g. over a period, or for a specific product group) with limited indication of their break down. More specifically, the main challenges were :

- **Difficulties in separating compliance costs resulting from IM legislation from other environmental legislation.** Environmental legislation such as the WEEE Directive and F-Gas Regulations are also applicable to industrial products. Although some firms have regulatory compliance specialists that deal with IM and environmental legislation separately, at the level of product groups, firms were not able to disaggregate compliance costs between different types of legislation, since compliance with EU legislation is sometimes dealt with horizontally.

[198] It was noted during the research by global manufacturers that a distinction can be made between a product model or basic platform for regulatory compliance purposes and a product model for marketing purposes, where there may be multiple variants, with only minor technical differences and upgrades, but based on the same regulatory model.

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- **Firms often could not identify the "substantive compliance costs".** This was mainly the case for long-established IM legislation where the requirements are well known and already integrated into their product design processes. Even when an estimate is available of the R&D costs during the product design phase specific to a particular product model, IM legislation is only one factor among others taken into consideration, making it difficult to disaggregate compliance costs..
- **More generally, the identification of the Business as Usual scenario (BaU) was often difficult.** Firms may find it difficult to accurately estimate the proportion of testing costs that they would be doing anyway as part of their internal quality assurance and quality management systems (which include product safety testing).
- **Some aspects of compliance are managed horizontally by firms** – especially preparatory steps such as participating in EU legislation-making and standardisation processes, and familiarisation with the relevant legislation and applicable Information Obligations ("IOs"). Whereas testing is product-specific, those working in regulatory affairs/ dealing with compliance are commonly employed by larger firms with a large product portfolio, work horizontally across many different products. Although a "best guesstimate" can be made as to the proportion of human resources spent working on specific product areas, given the horizontal role played by many regulatory compliance specialists working in industry, this is at best an approximation.

In summary, although for some case studies the target of 6-8 firms interviews was achieved, the data available from all firms often only covered some variables, while it was missing altogether for some others. In general, data estimates specific to the product group were more easily provided by SMEs but more difficult for large companies. As a result of the variability in the quality and quantity of data obtained, comparisons among the cases are problematic.

Overcoming data gaps

A number of steps were taken to overcome, to the extent possible, the difficulties and limitation described above. These were:

- **Ensuring that the firms that participated were broadly representative** - most firms that participated could be considered are rather typical of the relevant sectors even for those cases where more limited numbers of interviews were carried out, such as laptops and refrigerators. With the assistance of the relevant associations, the firms interviewed are established firms with long period of experience and, in those sectors where the market dominated by few large manufacturers (e.g. domestic refrigerators, laptops, air conditioners, lifts) firms relatively high market shares. In such cases, while not expecting to provide a picture covering all firms, we provide a rather "typical" case. In other cases, like the gardening equipment, the firms interviewed cover a range of sizes which helped identify the different practices between larger and smaller firms.
- **Developing assumptions about the costs of compliance –** where data was only partial in respect of particular parameters we used data from several firms, we were able to make imputations as to the average costs for a typical firm, which were then scaled up at the level of the product overall.
- **The aggregation of costs to the sector was either estimated by referring to the total number of firms in the sector or the total volume of production.** Certain types of costs (e.g. technical file preparation, purchase of data) were considered to be similar irrespective of the size of the firm. In that case we relied on the number of firms in the sector to reach an estimate of the total

costs. In other cases (e.g. ...) the proposed costs appeared to be linked with the volume of production or the number of models. In that case, the preferred approach was to use of market size data to estimate the total costs for the sector on an annual basis.

- In the case of data on market size and on the number of firms, we gave priority to data from industry associations or market reports and, only in their absence, to data from PRODCOM and Eurostat. Eurostat data on the number of enterprises was not considered to be an appropriate base for estimated cost data at the sectoral level. Eurostat data refer to individual legal units, which may be many more than one within a single enterprise, particularly among large multinational firms with presence across the EU market. Compliance related activities are often dealt centrally from a single unit. When possible, the data from market studies or associations were complemented by data from the the Orbis database providing information on active enterprises. In this case we considered the number of firms' headquarters as the most appropriate number to use.
- **Developing assumptions about the cost savings of simplifications** – In relation to the quantification of the of the savings from possible simplifications, the qualitative feedback about the type of cost savings, the main type of compliance cost affected and, in some cases, the order of magnitude allowed us to make some "reasonable" estimates of the possible cost savings. For example, in the case of savings related to the reduction of the use of notified bodies from the move to a self-regulatory approach it was possible to make some assumptions as to the maximum savings that could arise once the total costs of notified bodies was established. Even at a more aggregate level, simplifications of information obligations were assessed in relation to the overall weight of those obligations to the total administrative costs and what could be considered a reasonable (e.g. 10%, 20%, 50%) contribution to the costs reduction.

E.4 Methodological approach to quantifying and assessing the costs of compliance with Union harmonisation legislation

In this section, a definition of administrative and substantive compliance costs is provided, together with an explanation of the difficulties in quantifying these separately in some instances. An overview of the methodology for estimating compliance costs is then provided. Reference should also be made to the full case studies set out in Appendix C since these spell out assumptions.

E.4.1 Definition of administrative and substantive compliance costs

Methodological guidance on SCM in the Secretary General's Impact Assessment guidelines and in international methodological documentation[200] makes clear that a distinction should be made between administrative and substantive compliance costs, which should be clearly distinguishable from one another.

- Administrative costs relate to the costs of preparing documentation and direct fees, while substantive compliance costs relate to any specific investments firms must make in order to comply with the law[201].
- The IA guidelines provide a definition of these terms and seek to clarify areas of possible nuance.

[200] International Standard Cost Model Manual - Measuring and reducing administrative burdens for businesses. SCM network, OECD - http://www.oecd.org/regreform/regulatory-policy/34227698.pdf

[201] See *inter alia - International Standard Cost Model Manual, Measuring and reducing administrative burdens for businesses.*

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For instance, the guidelines state in respect of testing costs that: "when businesses have to submit their products and processes to the test in order to get an authorisation or a certificate, these testing costs are not considered as administrative costs.

However, 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. Only the US requires product certification before products can be sold. 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.

Guidance on the application of the UK SCM model points to the difficulties in establishing BAU costs "dividing normal costs from burdens is difficult to achieve in practice as activities are embedded into business processes"[202]. There can still be challenges in breaking down the costs of compliance with IM legislation between administrative and substantive compliance costs.

If conformity assessment is accepted as being a substantive compliance cost, there are other aspects associated with conformity assessment procedures that are administrative, such as producing the technical file and preparing a Declaration of Conformity. This means that in practice, there may be nuances and an unclear demarcation between the two types of costs because such costs are **part of a continuum**. Although conformity assessment is a substantive compliance cost, it is equally an integral part of the process leading up to the production of administrative documentation.

The five steps represent how the various compliance steps can be seen conceptually. In practice some firms do manage compliance broadly according to these five steps. Other firms commented however that there is a lot of complexity and there is crossover between the different steps, with some compliance activities taking place in parallel, whereas others are sequential.

The way in which we have defined administrative and substantive compliance costs for the purposes of this study is summarised in the table on the following page:

Table E.2: Administrative and substantive compliance costs

Type of costs	*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
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 o The costs of temporary or permanent withdrawal from the market of products
Administrative and substantive costs	• Conformity assessment procedures under the applicable modules o Example of substantive cost - testing for conformity with the applicable modules defined in IM legislation[203] is

[202] Measuring Administrative Costs: UK Standard Cost Model Manual, Better Regulation Executive, 2005

[203] A common set of Conformity Assessment Modules is defined in Decision 768/2008

	• Example of administrative cost – preparation of a technical files in paralell with testing activities

Source: CSES and Panteia – assessment of different cost types

Testing carried out as part of conformity assessment procedures is arguably both an administrative and a substantive compliance cost since most firms say they that they carry out testing as part of internal quality assurance procedures (BAU costs) and for safety as part of the design stage. Products are designed, tested and then if legislative changes or changes to standards are introduced during the design phase, may also be redesigned in order to meets legal requirements (compliance with IM regulations and environmental legislation) and with the technical specifications set out in (voluntary) technical standards. In summary, while some compliance costs can clearly be defined as substantive, such as making modifications to products already on the market due to the introduction of new (or amendment of existing) IM legislation, others can be both administrative and substantive compliance costs, and there are "grey areas". A summary of the quantitative findings from is provided in the case studies. We have sought to quantify compliance costs.

E.4.2 Methodology for estimating compliance costs

Standard Cost Model

The quantitative analysis was carried out using a Standard Cost Model (SCM), the most widely applied methodology for measuring administrative costs. As noted earlier, there was a need to adapt SCM and to simplify and to customise the approach so that it was suitable for Union harmonisation legislation.

SCM is normally applied to measuring the costs of complying with a single piece of IM legislation (or at most a small number of different pieces of related legislation). Since multiple pieces of IM legislation are applicable to a given product (and in addition, to environmental legislation), there are practical difficulties for firms in disaggregating the costs of Information Obligations (IOs) for each piece of legislation separately. Moreover, the fact that multiple legislation and IOs are applicable makes SCM difficult to apply without spending a considerable amount of time with each enterprise (which with a few exceptions they were generally unwilling to do).

Another difference in the approach to this study is that whereas in a typical SCM exercise, a bottom-up approach alone is used, this was not feasible for this study, given the data difficulties encountered. Instead, a pragmatic and flexible approach was adopted that combined elements of bottom-up and–top-down. This was necessary given variations in the quality and extent of data availability between cases.

The quantification exercise was meant to focus only on the compliance costs associated with gaps, loopholes, inconsistencies and duplication, by measuring the current costs of establishing a baseline and assessing the possible benefits of regulatory simplification from eradicating these. Since less evidence of gaps, loopholes, inconsistencies and duplication was found than had been anticipated, during Phase 2, it was suggested that we should try to quantify the costs of compliance more generally. However, there are limitations in the extent of data availability and consequently its quality.

Development of assumptions

It was necessary to develop assumptions in order to produce the calculations set out in the case studies. The detailed assumptions that have been made in carrying out quantifications for each case

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are specified in the full case studies (Appendix C).

Assumptions can be developed under various circumstances so as to improve the quality of the data, such as when quantitative data is lacking and qualitative feedback is used to develop quantitative assumptions e.g. firms found it difficult to quantify internal testing costs themselves so data parameters for other firms were cited and the firm was asked if these were considered reasonable.

We have made had to develop various assumptions for different product groups, which are specified in the case studies. The nature of the assumptions and the extent to which we had to make assumptions varied between product groups depending on (i) how many firms were willing to participate (ii) the extent to which the issues raised earlier regarding data sensitivity were problematic (ii) the availability of data internally among firms themselves, which varied considerably between cases, and can depend on firm size (global manufacturers found it more difficult to quantify costs accurately and these dominate some of the product groups concerned.

Taking the counterfactual into account

Another way of obtaining a baseline would have been to assess how the situation would have developed in the absence of the internal market and of Union harmonisation legislation for industrial products ("the counterfactual"). Two main possibilities were considered as below:

- Counterfactual 1 – compliance costs pre-establishment of the internal market. However, here there was the difficulty that there was the absence of data on such costs and comparability issues.
- Counterfactual 2 - current costs of compliance with Union harmonisation legislation compared with possible future simplifications

We now explain why the second of these two approaches was adopted. If there were no regulatory framework and firms instead had to comply with 28 sets of different national legislation and technical standards, there would still be costs associated with complying with national regulations, since there would remain a need for national product safety regulations to protect consumers and users of industrial products.

Firms were only able to provide a qualitative assessment as to how the current costs of compliance compare with the situation before the internal market came into effect. Since core "New Approach legislation" has now been in place for 25 years, it is difficult for many interviewees to compare the situation prior to the internal market's establishment. It would more be difficult to make a direct comparison anyway for the following reasons:

- There have been many changes affecting market size and structure during this period e.g. globalisation, the expansion of the EU from 12 Member States when the single market came into effect to 28 Member States today.
- The absence of data on compliance costs at the national level prior to its establishment.
- The fact that a simple "before and after analysis" cannot be undertaken since the body of internal market legislation was introduced over a period of 25 years rather than three being a "big bang" when the internal market first came into being in 1993.

It was instead agreed with the Commission that the baseline would be based on the current costs of compliance with Union harmonisation legislation. A comparison was then made with what impact different simplification scenarios that could be implemented in future would have in terms of

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reducing current compliance costs. As noted in Section 5.2.2, there were challenges in obtaining data on the current costs of compliance, but data was obtained and assumptions developed across the 8 harmonised cases, presented later in this section.

Taking Business as usual scenario ("BAU") into account

As already indicated, in all sectors, parts of the costs incurred by firms in the process of ensuring compliance are costs that firms would incur even in the absence of the EU legislation. The estimated share of business as usual costs varies greatly though. In the case of garden equipment, around 10% and 35% of the total compliance would have been incurred even in the absence of IM legislation. In comparison, in the case of electric motors, 73% of the human resource costs and 87% of the testing equipment were considered as part of the BAU scenario.

Similar high shares of the BAU scenario apply in the case of lifts while in the other product categories around 50% of the cost incurred were considered as costs that would probably have happened even in the absence of IM legislation. The review of the data from the cases suggests that a key driver of high or low share of the business as usual costs is the level of costs for product design and testing linked to environmental legislation. Familiarisation with the legislation, fees for third party certification, preparation of technical files, DoC and CE marking is generally part of the compliance costs.

Where data on internal and external testing costs was available, establishing the costs specific to IM legislation as opposed to BAU costs was not always straight forward. While in some cases, the proportion of costs that were considered to be "BAU" was easy to estimate, for instance, a firm stating that 30% of the costs that it incurs as part of conformity assessment procedures would be incurred anyway (for instance, safety testing being carried out irrespective of whether there was IM legislation in place so as to ensure high levels of product safety, internal quality management systems and procedures to protect corporate reputation).

Average weightings to take into account firm size

The costs of regulatory compliance have taken firm size into account in different ways, depending on the mix of firms that have taken part in each case. Compliance costs were usually estimated as a percentage of the firm's turnover. Where not available, an alternative unit of measurement was used, such as the volume of units sold per year based on parameters for the regulatory costs per unit from other firms where turnover data was available. Some form of weighting was therefore included.

There were limitations as to the extent to which a detailed quantitative analysis could be undertaken of compliance costs based on firm size. There was a lack of SMEs participating in the interview programme generally, although some SMEs took part in some of the cases. This partly depended on the product case, since some sectors such as laptops are dominated by large global manufacturers. Even when SMEs were interviewed, however, it was difficult to make a definitive judgement as regards compliance costs since for each case study, only a small number of firms were involved in the SCM exercise (e.g. 2 SMEs, 2 medium, 2 large firms). Although SMEs were well represented in sectors such as bicycles, this is a non-harmonised case.

Nevertheless, where possible, average costs were calculated so as to take into account any information obtained about differences in the level of compliance costs between SMEs and large firms. We asked firms to provide data on the volume of units sold in Europe annually and for their turnover and number of employees (this data was not always available). Establishing the regulatory cost per unit was possible for some cases, which allowed a weighting to be made.

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Other qualitative considerations with regard to how SMEs and large firms manage the compliance process were also taken into account, since this can influence the structure of compliance costs. Since SMEs are less likely to have their own in-house laboratories and expertise and capacity to carry out testing for all IM directives and regulations under the SDoC procedure, they are therefore more likely to have conformity assessment carried out in an external laboratory. Whilst even under the SDoC, large firms also commonly use the services of a third party at some point during the conformity assessment procedure, they will typically carry out some testing in-house and use third party observation to provide external validation and audit of internal testing. They may then also outsource some testing activities linked to conformity assessment for some directives, such as the LVD (electrical safety).

Salary costs

With regard to salary costs, the study team asked for actual cost estimates in the first instance. However, in some cases these differed markedly between firms. For instance, a firm in the air conditioning sector pointed out that the salary costs of those working on compliance within the company across different divisions in the EU and in Asia can vary by a factor of between 5 and 10. Even within the EU, the costs of staff involved in compliance can vary considerably between different countries in many cases. Since only a small number of firms took part in most case studies, so as to ensure greater consistency and comparability, standard parameters were applied to participant firms based on Eurostat average salaries.

E.4.3 Types of compliance costs for industry

Evaluation question 15 - What are the compliance costs with Union harmonisation legislation in eight selected harmonised product groups?

Two main types of costs were taken into account in our assessment: (i) the costs of compliance with Union harmonisation legislation and in meeting the essential requirements either through following voluntary harmonised technical standards[204] or alternative means and (ii) the administrative costs that economic operators have to fulfil in order to meet the essential requirements (e.g. development of a technical file, production of a DoC, CE marking). In so far as possible, we have distinguished between whether costs are one-off or recurring, but in many cases, there are elements of both. For instance, the main cost in preparing a technical file is in the period from the product design stage up to product launch but the file needs to be maintained and updated (as does the DoC) for up to 10 years following its placement on the market.

A distinction was also made in the case study quantification exercise between substantive and administrative compliance costs but given the continuum between some types of compliance activities, this was not always possible. The following table summarises the main types of compliance costs identified:

Table E.3: Types of costs incurred in complying with Union harmonisation legislation.

[204] Although harmonised technical standards are voluntary, most manufacturers follow these in order to meet the essential requirements. The costs of meeting standards to support the legislation's implementation were also included not only the administrative requirements and information obligations underlying these.

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Type of costs	*One-off or recurring?*
• **Human resources –** examples of the resources required to manage compliance are: o **Regulatory compliance managers -** participation in EU legislative-making and standardisation processes (mainly large firms), familiarisation with the applicable legislative and administrative requirements (all firms), keeping track of changes to legal requirements and updates to standards, briefing other business divisions about the legislation and forthcoming developments, ensuring that documentation (e.g. DoCs, technical files are kept up to date and made available online, responding to requests from market surveillance authorities). o **Product and testing engineers –** staff involved in R&D and new product development (early stage), engineers involved in testing and conformity assessment procedures prior to product launch.	Recurrent - global manufacturers employ small teams of permanent compliance specialists Some one-off costs – e.g. part of salaries of engineers prior to product launch can be attributed to IM legislation (discounting for BAU[205])
• **Investment in laboratories and testing equipment** - the cash costs of compliance (e.g. purchasing equipment). Although harmonised standards are voluntary, since the vast majority of manufacturers follow these standards, compliance with standards in order to meet the essential requirements has generally been considered as part of overall compliance costs.	One-off and recurrent
• **Third party conformity assessment –** typically a one-off cost prior to product launch. Although 3rd party CA is mandatory for a small number of IM directives and regulations, typically, the Suppliers' Declaration can be used and the use of a 3rd party is voluntary.	One-off – costs incurred prior to product launch

Section 5.4 of the main report provides an assessment of the compliance costs themselves and draws conclusions between product groups.

E.5 Methodological approach to estimating the broader impacts on growth and jobs from simplification measures

The analysis presented in the main report makes use of the estimated compliance costs and simplification savings potential calculated from the eight product groups examined in the context of the case studies.

[205] BAU - Business as usual costs – a term used under the Standard Cost Model

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The basic assumptions of the analysis are that any cost reductions from simplifications will be translated into savings of firms' operational costs that will, in turn, be translated into improved labour productivity which is then passed into lower prices of products. This improves (international) competitiveness, boosting exports and reducing imports relative to final demand; which, ultimately, should have a positive impact on Gross Domestic Product which should, in turn lead to increased employment. At the same time, increased labour productivity should be expected to reduce employment in the short term reducing disposable household income and as a result, private consumption demand. Thus, whereas the 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 are now outlined:

1. We developed a medium/long-term baseline scenario of economic development by defining a set of plausible values of the exogenous variables of the model.[206] These include the volumes of export, consumption (household and government), investment (enterprises and government), imports, GDP and depreciation and its prices as well as labour costs and employment numbers. This baseline scenario did not include simplification of IM regulation.[207]
2. Definition of the nature and size of the cost savings as a result of possible simplifications to the IM regulation on the basis of the results of the case studies.
3. Taking the original baseline scenario as point of departure, we prepared an alternative scenario of economic development including the estimated compliance cost reductions
4. Comparison of the alternative scenario to the baseline scenario to estimate the impact of the compliance cost reduction on economic development

Ideally the estimation of the possible impact would be based on a model of the EU economy as a whole or of each individual member state. As these were not available, the PRISMA model for the Netherlands has been used[208]. Thus, the relative costs reductions hypothesised for the EU economy were applied to the Dutch economy to determine the impact on growth and jobs. The results were then extrapolated at the EU level and the World Input-Output model was applied[209].

Ideally the estimation of the possible impact would be based on a model of the EU economy as a whole or of each individual member state. As these were not available, the PRISMA model for the Netherlands has been used[210]. Thus, the costs reductions hypothesised for the EU economy were applied to an economic baseline scenario to determine the impact on growth and jobs. The results

[206] It should be noted that in general macro-economic models tend to be log-linear; therefore 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.

[207] It should be noted that in general macro-economic models tend to be log-linear; therefore 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.

[208] 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.

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

[210] 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.

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were then extrapolated at the EU level and the World Input-Output model was applied[211]. This approach is sensible under the assumption that the core elasticities – mainly price elasticities– do not vary much between EU countries.

The model variables that are directly affected are domestic final demand by category (household and government consumption, investment), demand in the private sector and the labour productivity. Furthermore, exports should be expected to increase as a result of a reduction in prices. The impact on EU imports too has also been taken from the PRISMA model. Together final demand and imports determine GDP. On the basis of changes in GDP employment effects can be estimated making use of expected changes in labour productivity. These are taken from the PRISMA exercise. Further information about Panteia's PRISMA-model is provided in the following box:

Box: Panteia's PRISMA-model

PRISMA - an acronym of Policy Research Instrument for Size-aspects in Macro-economic Analysis - is an economic macro-sector model. It has been designed in such a way that it produces results that are consistent with those produced by the current macro model of the Netherlands Bureau for Economic Policy Analysis. PRISMA is used for forecasting, scenario building and what-if analyses with respect to government policies and exogenous shocks. Its time horizon is 3-25 years. PRISMA consists of a kernel and a number of modules. PRISMA's business sector is disaggregated into nineteen industries. Within each economic sector, a distinction is made between SMEs and large enterprises.

Hence, the following two types of model exercises become possible. First, economic effects derived by PRISMA's kernel - for example when forecasting, building a scenario, or evaluating the consequences of changes in policy or the economic environment - can be 'translated' into the prospects for SMEs. Second, when circumstances change differently for SMEs compared to large businesses - for example due to a policy measure that focuses particularly on SMEs – the consequences can be evaluated by using the size-class module. The relevant PRISMA-sector for the current application is business services (NACE Rev. 2 N+M), of which the services sectors under consideration make up 50% in terms of value added (EUROSTAT SBS, 2010)

References:

- General Introduction (http://www.ondernemerschap.nl/index.cfm/1,95,305,0,html/Prisma)
- PRISMA 2001, The Kernel (http://www.ondernemerschap.nl/index.cfm/12,html?nxt=ctm_publikatieandbestelnummer=H200104)

PRISMA, The Size-Class Module (http://www.ondernemerschap.nl/index.cfm/12,html?nxt=ctm_publikatieandbestelnummer=N200207)

Section 5.6 of the main report provides a quantitative assessment of the simplification benefits using the PRISMA model.

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