

Interim evaluation of the Low Voltage Directive 2014/35/EU

Final Report





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Interim evaluation of the Low Voltage Directive 2014/35/EU

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Abstract

The first Low Voltage Directive (LVD), Council Directive 73/23/EEC, was adopted in 1973 as one of the European Union's first product harmonisation directives. It introduced the obligation to ensure that electrical equipment placed on the market is safe, which is still the core of the Directive today.

No fundamental evaluation or impact assessment has been carried out prior to adopting the most recent version. The scope of this evaluation covers the functioning of the LVD including monitoring of the implementation as well as it will cover the operation of the conformity assessment. The primary objective is to evaluate the degree to which the LVD 2014/35/EU has achieved its original objectives as regards effectiveness, efficiency, coherence, relevance and EU added value.

Executive summary

Background of the Directive

The first Low Voltage Directive (LVD), Council Directive 73/23/EEC¹, was adopted in 1973 as one of the European Union's first product harmonisation directives. It introduced the obligation to ensure that equipment placed on the market is safe, which is still the core of the Directive today.

The LVD 2014/35/EU has two main objectives. Firstly, it provides that electrical equipment, within the scope of the LVD, must be compliant with the necessary requirements to ensure the health and safety of persons, domestic animals and property. Secondly, it aims to guarantee that compliant products can move freely within the internal market, for the aspects it covers (health and safety), thus ensuring functioning the internal market.

The LVD is applicable to electrical equipment with a rated voltage between 50 V and 1000 V (alternating current) or between 75 V and 1,500 V (direct current) that is introduced to or circulated on the internal market. According to Annex II of the Directive, the following types of equipment are excluded:

- electrical equipment for use in an explosive atmosphere
- electrical equipment for radiology and medical purposes
- electrical parts for goods and passenger lifts
- electricity meters
- plugs and socket outlets for domestic use
- electric fence controllers
- radio-electrical interference
- specialised electrical equipment for use on ships, aircraft or railways
- custom built evaluation kits destined for professionals to be used solely at research and development facilities

However, certain EU acts which cover also certain types of electrical equipment provide that the LVD is not applicable to these types of equipment. This is for instance the case with the Machinery Directive 2006/42/EC² (MD) and the Radio Equipment Directive 2014/53/EU³ (RED). While they refer to the safety objectives set out in the LVD and hence the safety objectives of the LVD are applicable via these other acts, at the same time they exclude these types of equipment from the scope of the LVD's application.⁴ In these cases, the LVD and these other directives are mutually exclusive.

Purpose and scope of the evaluation study

No fundamental evaluation or impact assessment has been carried out prior to adopting the most recent version. Thus, the legal substance of the LVD, other than the alignment with the New Legislative Framework and the Standardisation Regulation, has essentially been unchanged since the first version was adopted in 1973. The LVD has been assessed twice before, once in 1999⁵

¹ Council Directive <u>73/23/EEC</u> of 19 February 1973 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (Low-voltage Directive), available at: <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM%3Al21015b</u>.

² Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC, available at: <u>http://data.europa.eu/eli/dir/2006/42/oj</u>.

³ Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC, available at: <u>http://data.europa.eu/eli/dir/2014/53/oj</u>.

⁴ Annex I no. 1.5.1. Machinery Directive (2006/42/EC): "The safety objectives set out in Directive 73/23/EEC shall apply to machinery. However, the obligations concerning conformity assessment and the placing on the market and/or putting into service of machinery with regard to electrical hazards are governed solely by this Directive"; recital (7) Radio Equipment Directive (2014/53/EU): "The objectives with respect to safety requirements laid down in Directive 2014/35/EU are sufficient to cover radio equipment, and should therefore be the reference and made applicable by virtue of this Directive. In order to avoid unnecessary duplications of provisions other than those concerning such requirements, Directive 2014/35/EU should not apply to radio equipment".

⁵ ERA Technology, 1999, Study on the Implementation of the Low Voltage Directive.

and once in 2005⁶. In addition, it was covered in a 2014 horizontal study on product-related harmonisation legislation⁷.

The scope of this evaluation covers the functioning of the LVD including monitoring of the implementation as well as it will cover the operation of the conformity assessment. The primary objective is to evaluate the degree to which the LVD 2014/35/EU has achieved its original objectives as regards effectiveness, efficiency, coherence, relevance and EU added value.

The main conclusions of the evaluation study are presented hereafter.

Effectiveness

As regards its general objectives related to internal market and health and safety, the LVD itself can be considered as fairly effective, based on the data available in the context of this evaluation. Factors hindering the full achievement of its objectives are in fact mostly external to the Directive.

With regards to the internal market, the Directive is generally seen as contributing to an effectively operating internal market for electrical equipment in its scope, by removing regulatory and procedural barriers to trade, thereby facilitating intra-EU trade among economic operators. Indeed, the Directive contributes positively to the establishment of a set of harmonised rules and procedures for electric equipment throughout the EU (notably through the promotion of harmonised standards). No major cases of discrepancies have been detected across Member States in interpreting the requirements of the LVD for particular products.

As regards the extent to which the LVD effectively provides for a levelled playing field for economic operators, the affordability of international standards (which are revised more often than national standards) and the participation in standardisation activities as a whole, pose challenges for smaller players. Moreover, EU national authorities do not have powers to effectively act upon (un-)/compliant extra-EU competitors, which creates unfair competition between EU businesses and such competitors. This aspect, along with the issues relating to consistent market surveillance across EU Member States and the creation of 'markets within the internal market', should however be re-examined in the near future the light of current policy developments relating to Regulation (EU) 2019/1020.

With regards to health and safety, the limited quantitative data collected by Member States does not allow to firmly conclude on the overall level of safety in the EU low voltage market sector. RAPEX shows that the most commonly reported risk types are the risk of electric shock (65% of all alerts in 2005-2017), the risk of fire (5%), and the combination of the two (17%). Other types of risk reported include choking, cuts, burns, damage to sight, chemical, drowning, suffocation/asphyxiation, and unspecified injuries and health risks. Further, the most commonly reported RAPEX category is electrical appliances and equipment (55% of alerts over 2005-2018), which includes equipment such as small kitchen appliances and home electronics, cables, chargers and adapters, and hand tools.

Opinions of both national authorities and consumer organisations are rather positive regarding the contribution of the LVD on the safety of products, despite the identification of some improvement opportunities.

On the positive side, (harmonised) standards in particular play a key role in ensuring converging safety practices and are widely used by economic operators, who thereby benefit from both the presumption of conformity and the flexibility for product innovation. In addition, the Directive is overall considered to provide a fairly effective conformity assessment module, which in most cases allows to ensure the essential safety requirements are met.

Outstanding concerns remain on the extent to which the currents conformity procedures are effective enough for riskier products as well as for operators who may be less accustomed with

⁶ RPA, 2005, Impact Assessment of Various Policy Options for a Possible Amendment of the Low Voltage Directive 73/23/EEC.

⁷ CSES, Panteia, 2014, Evaluation of the Internal Market Legislation for Industrial Products, available at: See: http://ec.europa.eu/DocsRoom/documents/4225/attachments/1/translations/en/renditions/native.

conformity assessment duties. It should be further analysed whether including another module (B) into the Directive could increase the level of safety of low voltage products on the internal market. This module could provide additional support to smaller players in the conformity assessment process through the involvement of notified bodies, who, in parallel would certify the conformity of products that are considered as involving higher risks than average. Here it should be noted that the previous role of Notified Bodies within the framework of the LVD did not have a direct impact on the process of placing products on the internal market, but rather a role related to arbitration. On this specific change of the Directive, neither the EU-level and fieldwork interviews, nor the LVD Working Party Workshop did bring about any concerns.

Other improvement areas include: the requirements on the quality of technical documentation and safety instructions which could be strengthened to ensure they speak to end-users, and, the clarity of product labelling, which could be enhanced to ensure traceability.

In sum, limitations to the effectiveness of the LVD are mainly due to the intensity of market surveillance activities, which vary across the EU, and therefore leave room for uncompliant products not being intercepted. Indeed, as confirmed by the 2018 refit evaluation on the implementation of market surveillance Regulation (EC) No 765/2008, the extent to which Member States are able to identify uncompliant products is dependent on the Member States authorities' resources. While this is an element beyond the remit of the LVD, it negatively affects the enforcement of the Directive. As a consequence, the capacity to prevent uncompliant products from entering the internal market is impacted, similarly to the trade flows of electric equipment in the EU (avoidance of surveillance-intensive countries). Issues relating to market surveillance may also allow for the presence of uncompliant extra-EU economic operators selling products directly to EU consumers, notably via eCommerce who may influence the safety of products available on the internal market negatively.

Efficiency

The lack of data on costs and benefits of the LVD does not allow to conclude on the overall efficiency of the Directive with precision.

However, based on both, the qualitative and quantitative assessment of the costs and benefits of the Directive it appears that the benefits generated by the LVD outweigh its costs for each type of stakeholders – including national authorities, economic operators (irrespective of their size of place in the value chain) and tax payers, both individually and as a whole.

On the one hand, the costs for national authorities are composed of transposition, implementation and enforcement costs, which are deemed as rather low by stakeholders consulted. Costs borne by economic operators are composed of specific resources dedicated to LVD, technical compliance, procedural compliance and administrative compliance costs, which, while having a greater relative importance for SMEs, are considered as moderate to low by stakeholders consulted. As far as tax payers are concerned, the main costs related to LVD and other product legislation are taxes withheld for social security and public health. Consumer organisations consulted deem theses costs as proportionate to the benefits of the Directive.

On the other hand, benefits of the Directive for national authorities are related to cost-savings on regulatory activities, market surveillance and coordination, which are deemed as rather high to moderate. Economic operators benefit mainly from cost-savings on application of national safety compliance requirements, as well as facilitated intra-EU trade and increased competitiveness, which are both deemed as rather high to moderate. Finally, benefits for tax payers are related to increased safety and quality of products and availability of product choices and reduced prices thereof in the internal market. Consumer organisations consulted deem these benefits as outweighing the costs of the Directive.

Overall, based on the attempts of quantification proposed by the evaluation team, at the aggregated level, for each unit of cost, the Directive would generate indicatively 1.7 units of benefits, i.e. if taken in monetary terms, for every euro invested in the implementation of the LVD, the EU as a whole gains $1.7 \in$ worth benefits in return.

Therefore, the evaluation team has concluded that the Directive is both affordable for its stakeholders (including national authorities, economic operators and tax payers) as well as fairly cost-effective legislative instrument. Indeed, based on the rather positive assessment of the Directive's effectiveness (see section 5.1), it appears that the costs generated as part of the implementation of the LVD genuinely contribute to the achievement of the internal market and safety objectives.

In addition, following the discussion on the conformity assessment procedures currently included in the Directive and the possible inclusion of another, more costly procedure for the sake of increasing safety, the evaluation team concludes at this stage that the current achievement of the Directive's objectives could not be reached at a lower cost. However, it should be noted that further research is to be carried out in order to verify and define from a cost perspective the impacts of any discrepancies noted across Member States, which if verified as an actual and significant cost, could represent an alternative for decreasing the overall costs related to the implementation of the Directive.

Lastly, in light of the conclusions related to relevance and added-value, it can be concluded that the costs, which appear to be at the minimum possible and outweighed by benefits for all types of stakeholders involved, are borne for a justified cause. Indeed, the LVD is still considered as a relevant piece of legislation today, as its objectives are deemed to be corresponding both to the needs of taxpayers as well as those of economic operators. In the same vein, the added-value of the Directive lies notably in the capacity of the LVD, a piece of legislation preferred by EU economic operators over other EU Directives and international regulatory frameworks, to reduce disparities across national markets, raise safety standards, and create synergies across Member States.

Relevance

The objectives of the LVD are still relevant today. This is true for both objectives: 1) ensuring the health and safety of persons, domestic animals and property, and 2) ensuring free circulation of compliant products within the internal market. It addresses both the needs of consumers (which expect safety and benefit from a free circulation on the internal market) as well as those of economic operators (most of which consider safety as a key aspect of their competitiveness, and have the need for reducing barriers for intra-EU trade).

The Directive is generally considered quite clear, for example concerning the requirements to prove compliance, the conformity assessment procedures, etc.. However, in some cases it is not clear whether a product falls within the scope of the Directive. Indeed, "electronic equipment" is not defined and also the exceptions in Annex II lack clarity. In addition, the introduction of other Directives (notably the RED), together with technological changes (increased use of IoT), has effectively reduced the scope of the Directive in terms of number of products covered, and also created more grey areas (which directive covers a specific product?).. Increasing the clarity of scope of the LVD by including specific lists, notably of products or safety risks, both has its advantages and disadvantages. While it would help to increase clarity, an explicit list of LVD products and/or safety issues runs the risk of accidentally excluding products or safety issues, and the risk that with new technological developments, these lists have to be continuously updated.

With respect to products currently excluded from the LVD (as defined in Annex II), there are few strong opinions on the justification of their exclusion, as the majority of stakeholders did not have an opinion of the issue. "Plugs and socket outlets for domestic use" is the only category which a small majority of stakeholders indicate that it could be included within the scope of the LVD. The majority of stakeholders who expressed an opinion, is not in favour to include other categories currently in Annex II in the scope of the LVD.

With respect to the voltage limits of the LVD, the lower voltage limit seems no more justified from a safety perspective Indeed, the risk does not only depend on the voltage, but also on other factors (like the maximum current an electrical source can deliver) and therefore even products below the lower voltage limit can cause thermal burns or electrocution. In Norway, the LVD has already been implemented without the lower voltage limit. However, economic operators claim a

disproportionate increase in burden respect to benefits, in particular for low cost-products (e.g. birthday cards with music)

The provisions of the Directive related to safety are formulated in a technological-neutral way and can therefore be applied also on new products. Provisions that have been criticised by stakeholders (both economic operators and consumers) are the requirements relating to marking and documentation, which do not facilitate the use of internet-related solutions in combination with information on the product/in manuals. Moreover, based on the response to the OPC, there is room for improvement regarding the information provided to consumers with LVD products, as consumers are currently not always able to easily find and understand the information provided (e.g. related to safety instructions, contact details of manufacturer/importer).

Coherence

Regarding the internal coherence of the LVD, no significant issues were identified therein. Individual points suggested for improvement were the language of the Directive, which could be seen as outdated in some cases and using unnecessary "legal jargon" and providing a definition for "electrical device".

Regarding the external coherence with wider EU policy, the LVD was found to be well harmonised. Regarding the coherence with other legislative acts, issues were identified in particular relating to the Radio Equipment Directive 2014/53/EU. Due to the 'exclusion from LVD' referred to within the RED, all types of stakeholders experience issues in determining to what extent a product should fall under each Directive. This creates both confusion and additional administrative burden for the stakeholders, in particular for economic operators and market surveillance authorities. More specifically, the identified issues include:

Confusion particularly about the involvement of a notified body in the conformity assessment procedure (required under the RED, but not under the LVD).

Economic operators having to make the choice with Directive to apply in unclear situations, with no guarantee that all Member States will agree with the interpretation, creating additional costs.

Application of RED rather than LVD to all equipment with Wi-Fi connection, despite the fact that the potential health and safety risks of the product relate to their LVD related aspects rather than IoT aspects.

Related to the point above, a competency gap with respect to effective market surveillance, in Member States where national market authorities have to cope with the fact that traditionally LVD products are supervised by radio equipment experts.

Besides the coherence issues with RED, it was observed that there are some unclarities regarding the Machinery Directive 2006/42/EC, as for certain product categories the Machinery Directive does not provide a definition. This creates some confusion as to when to take the end use as domestic or industrial (e.g. with laundry machines or 3D printers), which would determine whether the LVD or the MD should be applied.

Also, where the General Product Safety Directive 2001/95/EC applies due to it containing different or more specific provisions, it was suggested by the consulted stakeholders that there might be similar competency gaps as with the RED.

However, most stakeholders considered that these issues stem from problems with the other Directives. Of all the EU legislative acts, stakeholders seem to consider the interaction with the RED as creating the most significant challenges. Some consumer associations and national authorities supported the merge by citing potential greater harmonisation and a better capability of taking into account technological developments: especially with the rise of Internet of Things. A comparative analysis of the relevant provisions of both Directives shows indeed that the obligations of economic operators with respect to radio equipment under the scope of the RED and electrical equipment under the scope of LVD are equivalent and symmetrical. For economic operators, a product falling under the RED would mean the involvement of a notified body within the conformity assessment procedure, which in principle should increase safety. Apart from this factor, whether a product falls within the LVD or RED has no significant impact on economic

operators but The majority of stakeholders consulted also do not support merging the LVD with RED. Several Member States also noted that a new unified Directive would potentially lead to additional administrative burden.

EU Added-value

By providing uniform safety requirements across the EU single market, the LVD facilitates the single market. In addition, it provides the consumers with reliably safe products on the internal market. The stakeholders consulted view positively both the Directive's relevance to its objectives and its effectiveness in meeting them.

Regarding its ability to offer better value to the stakeholders, the LVD brings added value to industry through generating a level playing field and clear rules for compliance, and to consumers by guaranteeing equal high level of safety of products across the EU. In addition, it provides methods of cooperation through the Working Party and AdCo.

By providing a common set of rules and standards, the LVD prevents fragmentation of safety rules across the Member States. The standards make it clearer for both the economic operators and national authorities to know what they need to do to ensure compliance and ensure the convergence of state-of-the-art practices for safety across the EU, by concretising the requirements of the Directive that may be considered as very generic and succinct.

1. INTRODUCTION

This chapter outlines the structure and the purpose of the present document.

1.1 Structure of the document

This deliverable constitutes the Final Report of the interim evaluation of the Low Voltage Directive 2014/35/EU (LVD) carried out by Ecorys, VVA and Deloitte for the European Commission, Directorate-General for Internal market, Industry, Entrepreneurship and SMEs (DG GROW). The report is structured as follows:

- Chapter 1 presents the synopsis of the different consultation activities conducted for the evaluation;
- Chapter 2 provides an overview of the context of the evaluation, including the policy background for the LVD as well as an analysis of the low voltage product market;
- Chapter 3 presents the findings related to each evaluation criteria as well as the answers to the evaluation questions;
- Chapter 4 concludes the report by summarising the key elements related to each evaluation criteria.

As Annexes we present (*in a separate volume*):

- A. LIST OF ABBREVIATIONS
- B. EVALUATION QUESTIONS
- C. DESK RESEARCH
- D. INTERVIEW QUESTIONNAIRES
- E. LIST OF INTERVIEWS
- F. STAKEHOLDER SURVEY QUESTIONNAIRE
- G. STAKEHOLDER SURVEY ANALYSIS
- H. OPEN PUBLIC CONSULTATION QUESTIONNAIRE
- I. OPEN PUBLIC CONSULTATION ANALYSIS
- J. WORKSHOP AGENDA AND ATTENDEES
- K. WORKSHOP REPORT
- L. SCORING CALCULATIONS FOR COSTS AND BENEFITS
- M. NATIONAL TRANSPOSITION MEASURES
- N. MARKET DATA
- O. MARKET SURVEILLANCE RESOURCES IN FIELDWORK COUNTRIES
- P. ELECTRICAL EQUIPMENT IN THIRD COUNTRIES

1.2 *Purpose and scope of the evaluation*

No fundamental evaluation or impact assessment has been carried out prior to adopting the most recent version. Thus, the legal substance of the LVD, other than the alignment with the NLF and the Standardisation Regulation as described above, has essentially been unchanged since the first version was adopted in 1973.

The LVD has been assessed twice before, once in 1999⁸ and once in 2005⁹. In addition, it was covered in a 2014 horizontal study on product-related harmonisation legislation¹⁰.

The scope of this evaluation covers the functioning of the LVD including monitoring of the implementation as well as it will cover the operation of the conformity assessment. The primary objective is to evaluate the degree to which the LVD 2014/35/EU has achieved its original objectives as regards effectiveness, efficiency, coherence, relevance and EU added value.

To do so, several evaluation questions were associated with each evaluation criteria, as presented in Annex B. These evaluation questions have guided this evaluation study, and replies to those questions are presented as conclusions on each evaluation criteria, at the very end of each section.

⁸ ERA Technology, 1999, Study on the Implementation of the Low Voltage Directive.

⁹ RPA, 2005, Impact Assessment of Various Policy Options for a Possible Amendment of the Low Voltage Directive 73/23/EEC.

¹⁰ CSES, Panteia, 2014, Evaluation of the Internal Market Legislation for Industrial Products, available at: See: http://ec.europa.eu/DocsRoom/documents/4225/attachments/1/translations/en/renditions/native.

2. METHOD

This chapter provides an overview of the methodology and different consultation activities carried out in the context of this evaluation.

2.1 Data collection and consultation strategy

The evaluation study was conducted from June 2018 to June 2019, with data collection activities running until April 2019, as presented in the figure below.

Figure 1 - Timeline of the evaluation study

| M1 | | M2 | МЗ | M4 | M5 | M6 | M7 | M8 | M9 | M10 | M11 | M12 |
|---------|-------------|---------------|--|----------------|---------------|---------------|---------------|--------------|-----------------|-------------|-----------------|----------------|
| June 2 | 018 | July 2018 | August 2018 | September 2018 | October 2018 | November 2018 | December 2018 | January 2019 | February 2019 | March 201 | .9 April 2019 | May 2019 |
| Phase | e 1: Inc | eption | | > | Phase | 2: Data coll | ection | | F | hase 3: | Analysis an | d reporting |
| Prelimi | nary desl | < research | | | | | | | | | | |
| | Strate | gic intervie | ws 🥲 | | | | | | | | | |
| | | Approach | refinement | | | | | | | | | |
| | | | | In-depth de | sk research | | | | | | | |
| | | | | EU-level sta | keholder inte | rviews 🔵 | | | | | | |
| | | | | | | Fieldwork in | 6 Member Sta | ates 💿 | | | | |
| | | | ean Commissior) and CEN-CENE | | | | Stakeholder | survey 📋 | | | | |
| | Managemer | nt Centre | | | | | | Open p | ublic consultat | ion | | |
| | | | ry, national auth consumer assoc | | | | | open p | | | | |
| | standardisa | ation bodies, | stry, national au consumer assoc 2 third country | ciations in | | | | | | ti-criteria | | |
| | | | ry, national auth consumer assoc | | | | | | ana | | Final report of | the evaluation |

2.1.1 Desk research

As presented in the figure above, desk research was a continuous activity during the whole study. The evaluation team analysed a series of insightful documents, recapped in Annex C, such as:

- Previous evaluations and impact assessments on the LVD as well as other EU instruments such as the market surveillance Regulation;
- Legislative and guidance documents on LVD and other legislation linked to the scope of this evaluation;
- LVD Working Party and AdCo (public and restricted CIRCAB) documents;
- Existing reports and studies on the electric equipment industry and related market trends,
- Database extracts from Eurostat, the Rapid Alert System for Dangerous Non-Food Products (RAPEX) and received from national authorities, etc.

The desk research allowed to gather inputs notably on:

- The functioning of the LVD, its strengths and weaknesses, as well as key topics on the agenda of related working groups.
- The functioning of other instruments applying to products in the scope of the LVD
- The low voltage product market, its economic operators and evolution over the years
- The number of uncompliant products reported over time in the EU.

2.1.2 Interviews

A significant number of interviews were carried out as part of the consultation activities. These were conducted with different types of stakeholders, at both EU and national level. Also stakeholders from third countries were interviewed in order to complement the evaluation team's understanding of legislative systems for low voltage products in other regions of the world, and possibly spot 'best practices' (presented in Annex P). The table below provides the overview of the types of stakeholders consulted throughout all interviews carried out in the context of this evaluation. Annex D presents the interview guides for each type of semi-structured conversations and Annex E contains the list of interviewees.

| Type of interviewee | Total number of interviews conducted | Strategic and EU- level | National- level | Third country |
|---|--|-------------------------------|--------------------|------------------|
| National authorities | 13 | 2 | 11 | |
| Businesses & industry representatives (incl. innovation hubs) | 39 | 4 | 35 | |
| Standardisation bodies | 8 | 2 | 6 | |
| Consumers | 3 | 1 | 2 | |
| Third country stakeholders | 2 | | | 2 |
| Total | 65 | 9 | 54 | 2 |

Table 1 - Types of stakeholders reached through interviews

2.1.2.1 Strategic and EU-level stakeholders interviews

Between July and November 2018, 9 EU-level stakeholders were interviewed, as presented in Table 1 above. These interviews contributed notably to the mapping of processes related to obligations set by the provisions of LVD to each type of stakeholder, as well as the identification of the type of costs and benefits associated with these processes.

Moreover, they provided more insights into the safety aspects as well as into the relations between the LVD and other Directives. They also allowed to raise these interviewees' attention to the stakeholder survey and subsequently requesting them to act as multipliers by sharing its link among their relevant contacts. Furthermore, some of these interviewees also provided the evaluation team with relevant documentation and potential interview contacts at Member State level for the fieldwork interviews.

In addition to the above activity, the evaluation team participated in the LVD Advisory Committee (AdCo) meeting that took place in Leuven on 5 December 2018. During the meeting, the evaluation team presented the objectives and focus of the evaluation, an overview of the methodology and the status to date of the assignment. Further, a set of questions and topics were discussed with the AdCo members. The participation to the meeting namely contributed to the better understanding of the views of the EU Member States.

2.1.2.2 National-level stakeholder interviews

Fieldwork was conducted in six selected Member States (Czech Republic, Germany, Finland, France, Italy and Poland) between end November 2018 and early February 2019. Interviews (up to 10 in each country) were organised in order to include the following types of stakeholders:

- **Businesses:** Businesses were chosen so as to ensure a mix across the value chain and business size (i.e. larger businesses and Small and Medium-sized Enterprises (SMEs) making sure to cover the five main product groups in the scope of the Directive. In particular, two product groups based on the second revision of the Statistical classification of economic activities in the European Community (NACE Rev.2, derived from the French *Nomenclature statistique des activités économiques dans la Communauté européenne*). NACE Rev.2 per Member State were selected as focus:
 - Czech Republic: C26.2 (Manufacture of computers and peripheral equipment),
 C27.1 (Electric motors, generators, transformers and electricity distribution and control apparatus)
 - Germany: C26.2 (Manufacture of computers and peripheral equipment), C27.1 (Electric motors, generators, transformers and electricity distribution and control apparatus);

- **Finland: C27.1** (Electric motors, generators, transformers and electricity distribution and control apparatus), **C27.5.1** (Electric domestic appliances);
- France: C27.4 (Electric lighting equipment), C27.5.1 (Electric domestic appliances)
- Italy: C27.4 (Electric lighting equipment), C27.9 (Other Electronic equipment)
- **Poland: C27.5.1** (Electric domestic appliances, **C27.9** (Other Electronic equipment)

First, the evaluation team mapped the stakeholders that included economic operators from relevant sectors and eventually shortlisted larger businesses and SMEs (at least 1 in each Member State), manufacturers, importers and distributors. The interviews themselves focused on gathering information on the compliance and administrative costs that firms face when complying with LVD-related provisions.

- **National authorities:** Similarly, the evaluation team conducted in-depth interviews with the relevant national authorities in charge of monitoring and enforcing the LVD on the national territory. In the case of the Federal State of Germany, where the enforcement of federal legislation and market surveillance is a competence of the subnational administrative units (16 federal states), the evaluation team interviewed in addition to the market surveillance central point of contact, an additional contact conveying the subnational priorities and tasks in the field of LVD.
- **European Committee for Electrotechnical Standardization (CENELEC) Committees:** the evaluation team also interviewed representatives of CENELEC Members of the National Electrotechnical Committees entrusted with electrotechnical standardisation.
- **National business and consumer associations**: of relevance to the study in order to further explore the effects of the LVD on companies and consumers (up to 1 in each Member State).

Overall, this activity allowed to collect information on issues regarding the implementation of the LVD, the current status of the market including any trends, international benchmarks or best practices that the interviewees considered relevant, and to collect additional sources of information. In order to best coordinate the additional data collection activities (e.g. open stakeholder's survey, fieldwork and phone interviews in six selected Member States), the evaluation team made sure to tap into the stakeholders' contacts in EU Member States.

The table below provides an overview of the fieldworks, per country and type of stakeholder:

| | Key stakeh | olders | | Additional st | Total nor | | |
|-------------------|------------|-------------------------|---------|---------------|--------------------------------------|-------|------------------------------|
| Member State | Rucineccec | National Authorities | CENELEC | Business | National Consumer Associations | Other | Total per Member State |
| Czech Republic | 2 | 1 | 1 | 1 | N/A | N/A | 5 |
| Finland | 5 | 2 | 1 | 1 | 1 | N/A | 10 |
| France | 5 | 2 | 1 | 3 | N/A | N/A | 11 |
| Germany | 5 | 2 | 1 | 2 | N/A | N/A | 10 |
| Italy | 5 | 2 | 1 | 1 | 1 | 1 | 11 |
| Poland | 3 | 2 | 1 | 1 | N/A | N/A | 7 |
| Total | 25 | 11 | 6 | 9 | 2 | 1 | 54 |

Table 2 – Fieldwork interviews per country and stakeholder type

2.1.2.3 Third country stakeholder interviews

In order to complement the information available through other data collection activities on the regulatory systems for electrical equipment in third countries the evaluation team carried out two interviews with third country stakeholders.

These interviewed allowed to:

- Finetune the understanding of regulatory systems in place for low voltage products in USA, Canada, China, South Korea, Japan, Argentina, thereby allowing to compare them with the LVD.
- Understand how third countries deal with aspects that are considered as the shortcomings of LVD, thereby possibly identifying best practices.

2.1.3 Surveys

Two online consultations were carried out as part of the evaluation: the targeted stakeholder survey, with differentiated questions per type of stakeholder, and the Open Public Consultation (OPC) with one set of questions available for all respondents.

2.1.3.1 Stakeholder survey

The stakeholder survey was set up on EU Survey and launched online on 4 December 2018. Its initial closure data was planned on 15 January 2019, however, it was extended until 31 January 2019 in order to maximise the response rate over the holiday period. The stakeholder survey targeted notably:

- **Businesses** (both larger businesses and SMEs) in all EU 28 Member States, including manufacturers, importers and distributors of electric products in the scope of the LVD;
- **Business and consumer associations** (including innovation hubs and incubators) in EU 28 Member States;
- **Standardisation bodies**: national standardisation committees for low voltage products in all Member States;
- **National authorities** in EU 28 Member States: e.g. national authorities that are responsible for the implementation of the LVD and related market surveillance;
- **Consumers** in all 28 EU Member States.

Dissemination was carried out through several channels, in order to maximise the outreach of the target population and thus the number of answers: the evaluation team shared the link with all interviewees (EU level stakeholders as well as fieldwork interviewees), asking them to disseminate the survey among their members/contacts, triggering all dissemination channels, including: social media pages (e.g. LinkedIn, Twitter account of those organisations), organisations' websites and newsletters, etc. DG GROW shared the link on its website, and on the respective intranets for the LVD Working Party and AdCo¹¹.

In total, 221 responses were received for this survey. Of these, 116 were manufacturers, 10 importers and distributors, 13 National Authorities including market surveillance authorities, 40 business associations, 4 consumer organisations, and 38 reported as belonging to "others" group. The last category included, among others, testing and standardisation organisations, present and former notification bodies, consultancies and academic and educational organisations. The highest number of stakeholders participating in the survey was from Germany (70), including German manufacturers.

The methodological note for the analysis of the stakeholder survey results is provided in section 2.2.1, while the Annexes F and G contain the survey questionnaires and results respectively.

2.1.3.2 Open public consultation

¹¹ See: <u>https://ec.europa.eu/growth/; https://www.facebook.com/EU.Growth/; https://twitter.com/eu_growth</u>

As per the Better Regulation Guidelines (BRG), the European Commission launched an OPC on 10 January 2019, which was online for the mandatory period of 12 weeks (closure on 4 April 2019). The OPC questionnaire (provided in Annex H) included general questions addressed to all EU citizens. It was aimed at gathering factual information, data, knowledge and perception by final consumers and citizens across the EU about the following aspects of the LVD:

- Relevance of the scope and the objectives of the LVD compared to the needs of the consumers;
- Effectiveness of the Directive in ensuring consumers' safety.

The open public consultation was mainly disseminated through a link on DG GROW's website. The OPC gathered a total of 93 replies across 17 Member States, with the highest number of replies from Germany and the UK.

Section 2.2.2 provides a methodological note on the assessment of the inputs collected via the OPC and Annex I presents the actual results.

2.1.4 Workshop

A validation workshop was organised on 8 February 2019 in Brussels. The purpose was to discuss the preliminary findings around the three topics outlined below with the LVD Working Party prior to their validation:

- **Understanding of the LVD**, i.e. regarding the clarity of the Directive, its objectives and requirements, scope, provisions, etc.;
- **Implementation of the LVD**, i.e. regarding the day to day functioning of the Directive and the way it is applied (e.g. use of standards, implementation of the conformity assessment procedure and CE marking, labelling requirements, etc.); and,
- **Enforcement of the LVD**, i.e. regarding the extent to which it is actually adhered to, market surveillance activities at national-level, (e.g. availability of resources, processes, results of market surveillance and safety, etc.).

Annex J contains the agenda and list of participants of the workshop and Annex K reports on the main conclusions of the workshop.

2.2 Data analysis strategy

Following the data collection activities, thorough data triangulation was conducted in order to map different inputs from different sources against each other, and deduct findings. Due to the lack of existing evidence, notably quantitative data, on the actual performance of the LVD as regards the evaluation criteria, the present report largely draws on the findings of the interviews and workshop carried out as part of the study. The opinions of the different stakeholder groups have been taken into account (including any under-represented stakeholder groups such as SMEs and consumers) and cross-checked against each other. Further, the targeted stakeholder survey as well as the OPC results – though not statistically representative, were leveraged to validate or challenge the trends identified through the previously mentioned data collection activities.

2.2.1 Methodological note for the stakeholder survey analysis

The methodological approach for the analysis of the stakeholder online survey consisted in the use of descriptive statistics. The answers have been analysed according to:

- **Type of organisation**: 116 manufacturers, 10 importers and distributors, 13 National Authorities including market surveillance authorities, 40 business associations, 4 consumer organisations, and 38 reported as belonging to "others" group. The last category included, among others, testing and standardisation organisations, present and former notification bodies, consultancies and academic and educational organisations.
- **Size of organisation**: 96 large enterprises (>250 employees) participated to the survey whilst micro, small and medium enterprises were 30 in total.

- **Country of origin of the respondents**: The types of organisation mentioned above represent 20 Member States: Estonia, Hungary, Lithuania, Latvia, Luxembourg, Malta, Romania and Slovenia did not have any stakeholder participating to the survey.
- **Evaluation criteria**: the results of the survey are presented broken down by the selected evaluation criteria of the LVD (effectiveness, efficiency, relevance and coherence).

All the figures presented are the result of the count of the number of answers for each option and calculating the respective percentages.

For all the questions, additional analyses had been made filtering the answers based on the size of the organisation (checking for consistency of the answers between SMEs and large companies) and the country of origin.

In particular, German respondents (70 stakeholders) represent 32% of the 221 respondents. This can be partially explained by the fact that Germany is the largest producer of low voltage products in the EU (see chapter 3.2 of the main report for a more detailed analysis of the low voltage market), and by the lower response rate from other countries. An ad hoc analysis excluding Germany had been performed to compare the answers without Germany in the sample with the ones including it. Looking at the most selected answers to each question, German interviewees account for 30%-34% of the respondents selecting those answers: e.g. at Q1:*"How relevant do you consider the Directive to ensure the safety of electrical products?"* the most popular answer is "Very relevant", selected by 182 respondents out of 221. The Germans answering "Very relevant" are 61, i.e. 33.5% out of the 182 who picked that option: this percentage is in line with the share of Germans participating to the survey, and the same pattern can be identified in each question. The analysis did not differ when German respondents were taken out from the sample of respondents.

Similar considerations can be made according to the difference in size. In very few questions (such as Question 9 and Question 12) of the manufacturer-specific set of questions) large companies showed higher satisfaction rates in terms of understanding of the LVD provisions or difficulties in application of LVD: for example, at Question 12, 85% of large manufacturers reported that LVD improves safety of products sold in the EU market, compared to a lower 69% reported by SMEs manufacturers., This difference in percentages reflects also the size of the sample. Notably, there were 90 large manufacturers , compared to 26 SMEs: an SME reply has therefore a higher impact on the final percentage of each answer. However, there are **no questions where the opinions are completely different** depending on the different size of the organisation.

Significance of the answers

Although the opinions **do not notably differ** based on the country of origin of the respondent or on the size of the manufacturer, it must be stressed out that Germany and manufacturers account for a relevant share of the answers. On one hand, the limited number of distributors and importers (10) and consumer organisations (4) did not have opinions much differing from the majority of the respondents, on the other hand this small sample participating to the survey is an element that have an impact on the significance of the analysis.

2.2.2 Methodological note for the open public consultation analysis

The methodological approach for the analysis of the OPC consisted in the use of descriptive statistics. The OPC collected a total of 93 answers. However, it should be noted that not all the respondents provided a response to all the questions of the consultation, nor added comments where suggested. Therefore, the analysis might be based on a restricted sample.

In addition, in terms of geographical spread, respondents from 17 different Member States participated in the OPC, with the widest participation in Germany (32) and UK (9). Again, it should be noted that due to the absence of replies from some Member States, as well as the relative overrepresentation of Germany and the UK, the findings may not be representative of the EU as a whole. In any case, the findings presented in this report and its annexes are not to be regarded as statistically representative.

Further, it should be noted that the OPC questionnaire did not allow for further disaggregation of stakeholder groups. However, Q2 of the OPC required respondents to state their level of knowledge of the Directive. It appeared that the vast majority of the respondents (69 out of 93) deemed his/her level of knowledge of the Directive complete and detailed. Only 6 respondents did not really know about the Directive, while 18 positioned themselves as being aware of the Directive, but not throughout all details. When probed about the source of this knowledge, 66 out of 92 respondents to this question selected 'other sources' and specified notably the workplace (e.g.: working in a LVD-related industry, being responsible for monitoring the compliance of the products with LVD), delivering training on LVD, being part of the national CENELEC and reading the regulation itself. Respectively, 12 and 9 respondents selected the products users' manual and the media as the origin of them knowledge of the LVD.

In a nutshell, it seems the majority of the respondents to the OPC were professionals somehow related to the LVD rather than "citizen lambda" type of respondents, knowing the technicalities of the Directive to a lesser extent.

2.2.3 Methodological note for the market analysis

A challenge for the data collection and analysis is that low-voltage products are not a defined sector in the industry and are also not recorded as a separate group of products in statistical databases. As a result, assumptions need to be made to define the low voltage sector in relation to market data. This section presents the methodology and main assumptions made for data analysis.

The market analysis is based on a selection of nine NACE Rev.2 categories describing economic activities of the manufacture of electrical equipment. These nine categories are the ones defined in the 2005 Impact Assessment¹² (with the update to NACE Rev.2) and were reviewed by our technical experts to ensure these categories still cover the totality of the electrical equipment currently in the market. Section 4.2.1 introduces these specific categories.

The manufactured products described in the NACE categories contain products falling both within and outside the scope of the LVD. Therefore, as a next step, the more detailed Prodcom-level product list for each of these NACE categories were used to apply specific criteria to define whether each product category is likely to fall within the scope of the LVD. To fall within the scope of the Directive, a product category has to comply with the following criteria:

- Product refers to electrical equipment;
- Product falls within the voltage limits set by the Directive;
- Product is not part of the exceptions included in the Directive; and
- Product that is not excluded from the LVD because it falls under other relevant Directives (such as the Radio Equipment Directive or the Machinery Directive).¹³

Within the nine NACE categories, 188 product categories comply with the criteria set out. It should be noted that it is not possible to have a clear conclusion for each product category. This is because these categories consist of a mix of products, and these products can be within or outside the scope of the LVD, depending on the specific product characteristics. Therefore each product category was assessed for whether the products it contains are likely to be within or outside the scope of the LVD, or whether this depends

¹² Impact Assessment of Various Policy Options for a Possible Amendment of the LVD (2005)

¹³ Certain directives which cover equipment that also falls under the scope of the Low Voltage Directive explicitly state the Low Voltage Directive is not applicable for this equipment. For example, the LVD does not apply to products covered by the RED. Products which meet the definition of radio equipment and fall under the scope of the are explicitly excluded from the LVD. Therefore, where RED is applicable to radio equipment, the LVD does not apply.

on product characteristics not reflected in the code's label (mixed). This allows us to present a 'minimum' range of products that are within the scope of the LVD, and an 'additional' range of products that can be both within or outside the scope of the LVD. Together, these categories constitute the maximum range of products that are covered by the LVD. The full results of this exercise are presented in Annex N.

To give an example of how this was done: a code referring to washing machines could include washing machines with radio emissions (smart functionalities) and therefore fall under the RED, or be designed for use in an industrial setting and therefore fall under the Machinery Directive. This product would therefore be classified as a being "sometimes" under the scope of the LVD. This means that the 'mixed' category is overestimated, as not all products in the product category will be within the scope of the LVD. There can be variety between the sectors that are classified as mixed: in some product categories, the share of products falling outside the LVD may be much larger than in others. "More accurate estimates of the measures would require a more detailed analysis per product category. The difficulty in accurately quantifying the trends is illustrated in a box 1 in section 4.2.5 for lightning products with smart functionalities (and thus falling under RED).

It should be noted that the analysis of whether a product category classifies as within the scope or not is based on the current state of play (i.e. the situation at the time the study was conducted), both with respect to the product characteristics and the policy and regulatory setting. This assessment could therefore change over time, with developments in technologies and the policy landscape.

For trade data, products are grouped based on Harmonized System codes (the international nomenclature for the classification of product) on a level of six codes. HS6 codes are slightly more general than Prodcom codes but can be matched using conversion tables, with an equivalence of 150 HS codes to 188 Prodcom codes. It is important to highlight some issues related to the underlying data, that should be taken into account in the interpretation of the results. First, many product categories start recording values at different years, and the growth in trade may therefore be partly be due to better data availability in recent years. Secondly, data presented is for all current EU countries over time, to keep the number of countries constant and thus to separate trends in increased trade from EU enlargement. This means that trade with the countries that joined the EU after 2000 can therefore not be considered as intra-EU trade until their actual accession.

2.2.4 Methodological note for the analysis of RAPEX data

Data on dangerous products falling under the LVD was collected from the Rapid Alert System for dangerous non-food products (RAPEX) and visualised using Microsoft Excel.

RAPEX enables a quick exchange between 31 countries and the European Commission on measures taken against dangerous non-food products posing risks to the health and safety r environment or any other aspect of public interest protection of. The system contains all records of notifications since the creation of the system in 455.

While the public search functionality of RAPEX¹⁴ does notinclude a filter to select by Directive, the free text field was used to identify those products that were reported as not complying with the LVD (using the search term "Low Voltage Directive") Therefore, the list of alerts did not include any products that would have been reported to be in violation by a particular European standard only.

By 3 December 2018, alerts were submitted for 3,223 products covered by requirements of the LVD. The highest number of such alerts was submitted in 2013 (286 measures reported). It should be

¹⁴SearchtoolavailablefromSafetyGatewebsiteonhttps://ec.europa.eu/consumers/consumerssafety/safetyproducts/rapex/alerts/?event=main.search&lng=en. Note that this data concerns publicly available information only.

noted that the data submitted to RAPEX depend on surveillance and reporting practices and frequency, which vary between countries and also between years within a given country. Therefore, the data from year to year are not directly comparable.

RAPEX does not use a commonly recognised statistical categorisation of products. Therefore, it is not possible to link the products immediately to the product groups used in the economic analysis of this study. The RAPEX categories coinciding with LVD products for which there were alerts were the following:

- Communication and media equipment
- Electrical appliances and equipment
- Gadgets
- Kitchen/cooking accessories
- Laser pointers
- Lighting chains
- Lighting equipment
- Protective equipment
- Other

The most commonly reported RAPEX category for which reference to non-compliance with the LVD is made is electrical appliances and equipment (55% of such alerts over 2005-2018), which includes equipment such as small kitchen appliances and home electronics, cables, chargers and adapters, and hand tools. As the type of equipment is manually entered, doing precise calculations per equipment type is practically impossible due to different ways of entering the same type of equipment (e.g. different spellings and misspellings, inclusion or non-inclusion of the specific brand, plural or singular form, use of quotation marks, etc.).

It appears that 76% of the measures on products covered by the requirements of the LVD products reported originated from China across the years. From 2009 onwards, the share of such measures on Chinese products has remained in the range of 79% to 89% each year. As discussed in chapter 4.2.3, China is the EU's largest trade partner of LVD products, which partially explains the prevalence of unsafe faulty Chinese products reported in RAPEX. However, as RAPEX is not a statistical tool, these results cannot be extrapolated to the internal market in general.

2.2.5 Methodological note for the analysis of costs and benefits

It should be noted that very limited quantitative data on the costs and the benefits of the Directive was provided by stakeholders consulted in the context of this evaluation. This is mainly due to the following:

- The LVD sets few obligations directly for stakeholders apart from the generic reference to 'safety of low voltage equipment' and provides more of a framework for good conduct through the referral to other instruments, such as Regulation (EC) No 765/2008 (market surveillance and CE marking), Decision No 768/2008/EC (conformity assessment and CE marking) and Regulation (EU) No 1025/2012 (harmonised standards). It is therefore impossible to assess the costs of the Directive's provisions in isolation.
- In addition, the LVD has been in place since long time and is now fully integrated in the national regulatory framework. It is therefore challenging for them to assess (quantitatively) the costs and benefits that arise from the application of the Directive.

As a consequence, the findings presented in this report are mainly qualitative and descriptive, supported by examples of quantified data provided by stakeholders consulted whenever possible.

In order to reply to the evaluation questions and suggest conclusions on the overall efficiency of the LVD despite the lack of data, the evaluation team has proceeded with a system of relative weights and scores.

First, for each given stakeholder category, all possible types of costs and benefits related directly or indirectly (as discussed above, not all obligations emanate directly from the LVD) were identified. Then, each cost or benefit element were provided a relative weight (based on the findings of the stakeholder consultations) representing their importance with regards to the overall costs and/or

benefits of the Directive's application and/or effects. For example, on the cost side (see detailed justification in Annex L):

- For **national authorities**, transposition costs were mainly one-off costs, which in the overall lifetime of the LVD can be considered as minimal. These were attributed the relative weight of 0.05, while implementation and enforcement costs are considered to be more important activities with regards to LVD, and were attributed respectively the weights of 0.20 and 0.75
- For **economic operators** (i.e. manufacturers, distributors and importers), the allocation of specific resources was attributed the weight of (0.10), as seen as a marginal activity linked to the LVD. On the contrary, the manufacturing of (compliant) products following (harmonised) standards, the conformity assessment and the administrative compliance were all provided a weight of 0.30.
- For **tax payers**, the attempt to quantification was not carried out for the sake of robustness of the analysis.

Then, each element was be attributed a score ranging from [-3 to -1] and [+1 to +3] respectively, based on:

- **Stakeholder survey** replies (though not a statistically representative sample) whenever feasible, and as presented in the box below, or,
- **Judgment** following qualitative indications from **interviews** and overall from **findings** of the study, when the stakeholder survey does not allow to deduct a score (marked with *).

It should be noted that the caveat of this methodology is linked to the attribution of both the weights and scores, which were attributed to all types of costs using the same scale, despite the fact that in reality, the costs may not follow the same curves (This was done in order to avoid further assumptions in the model). While in these regards, the results of this assessment should be interpreted with caution, the evaluation team considers it still allows for a good indication of the distribution of costs and benefits across stakeholders.

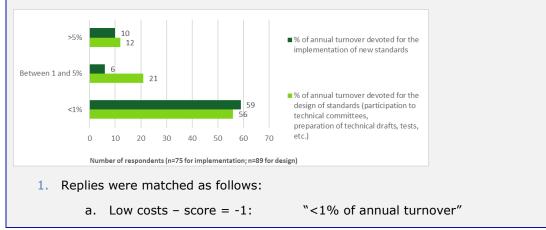
Box 1 – Example of score building based on stakeholder survey replies

For some types of costs and benefits, the stakeholder survey – though not statistically significant – allow to build a score by:

- 1. **Matching the stakeholder survey replies per score** i.e. +1, +2, +3 for low, medium, and high benefits, or -1, -2, -3 for low, medium and high costs;
- 2. **Calculating the score using a weighted average** of the number of replies per score category to the total amount of replies for the given benefit or cost;
- 3. If need be, **aggregating the scores by topic and/or stakeholder** using the mean of the scores obtained in step 2. for each individual benefit or cost.

For example, for the results of question 16 for manufacturers that provide a view on the costs related to the manufacturing of compliant products via standardisation:

Figure 2 – Stakeholder survey/manufacturers Q16: "Can you please estimate the overall annual average costs for activities linked to standardisation (as % of annual turnover)?"



| | b. | Medium costs – score = -2 : | "Between 1 and 5%" | | | | |
|--------------------|---|---------------------------------|--|--|--|--|--|
| | c. | High costs – score = -3 : | ">5%″ | | | | |
| 2. The | e sco | ores were calculated as follows | : | | | | |
| | a. | Design of standards: | -(1*56/89 + 2*21/89 + 3*12/89) = -1.505618 | | | | |
| | b. | Implementation of standards: | -(1*59/75 + 2*6/75 + 3*10/75) = -1.346667 | | | | |
| 1.4 to <u>c</u> | 3. The scores were aggregated by calculating the simple mean of both individual scores: - 1.43. This result, when compared with the results computed for other types of costs allow to gather insights on the significance of these costs for stakeholders. Based on the scale, these appear to be considered as moderate costs. | | | | | | |

Annex L presents the method and calculations for all findings reported in the Efficiency section.

3. BACKGROUD OF THE DIRECTIVE

This chapter presents the policy background of the study. It introduces the history and objectives of the LVD, the main features such as implementing bodies, roles of key stakeholders, as well as conformity assessment and market surveillance procedures.

3.1 Introduction to the Low Voltage Directive

The LVD has two main objectives. Firstly, it provides that electrical equipment, within the scope of the LVD, must be compliant with the necessary requirements to ensure the health and safety of persons, domestic animals and property. Secondly, it aims to guarantee that compliant products can move freely within the internal market, for the aspects it covers (health and safety), thus ensuring functioning the internal market.

The first Low Voltage Directive, Council Directive 73/23/EEC¹⁵, was adopted in 1973 as one of the European Union's first product harmonisation directives. It introduced the obligation to ensure that equipment placed on the market is safe, which is still the core of the Directive today. Although the CE marking did not yet exist at that point, the Directive already included provisions regarding conformity declaration and marking. In 1985, in the context of the Single Market, the EU developed the New Approach¹⁶ to standardisation in the internal market, resulting in Council Directive 93/68/EEC¹⁷ which harmonised the CE marking (introduced in 1985) and harmonisation directives adopted to that point. Thus, the LVD, as amended, included provisions on CE marking and conformity declaration procedure based on internal production control. The LVD Working Party (see below) commenced work on renewing the LVD in 2002, but the effort was terminated a year later, when it was decided that focus should be put on the implementation of the horizontal provisions of the New Approach. In 2006, Directive 73/23/EEC, as amended by Directive 93/68/EEC, but the contents of Directive 73/23/EEC, as amended by Directive 93/68/EEC, were not modified.

In 2008, the horizontal provisions of the New Approach were reviewed with the adoption of the New Legislative Framework (NLF) i.e. Regulation (EC) 765/2008¹⁹, Decision No 768/2008²⁰ and Regulation (EC) 764/2008²¹. The NLF aligns existing provisions regarding the placement of products on the market, to strengthen market surveillance, and to improve conformity assessment procedures and declarations. It introduces a set of harmonisation measures to apply

¹⁵ Council Directive <u>73/23/EEC</u> of 19 February 1973 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (Low-voltage Directive), available at: <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM%3Al21015b</u>.

¹⁶ Council Resolution 85/C 136/01 of 7 May 1985 on a new approach to technical harmonization and standards. ¹⁷ Council Directive 93/68/EEC of 22 July 1993 amending Directives 87/404/EEC (simple pressure vessels), 88/378/EEC (safety of toys), 89/106/EEC (construction products), 89/336/EEC (electromagnetic compatibility), 89/392/EEC (machinery), 89/686/EEC (personal protective equipment), 90/384/EEC (nonautomatic weighing instruments), 90/385/EEC (active implantable medicinal devices), 90/396/EEC (appliances burning gaseous fuels), 91/263/EEC (telecommunications terminal equipment), 92/42/EEC (new hot-water boilers fired with liquid or gaseous fuels) and 73/23/EEC (electrical equipment designed for use within certain voltage limits), available at: <u>http://data.europa.eu/eli/dir/1993/68/oj</u>.

¹⁸ Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits, available at: <u>http://data.europa.eu/eli/dir/2006/95/oj</u>.

¹⁹ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, available at: <u>http://data.europa.eu/eli/reg/2008/765/oj</u>.

²⁰ Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC, available at: http://data.europa.eu/eli/dec/2008/768(1)/oj.

²¹ Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC, available at: http://data.europa.eu/eli/reg/2008/764/oj.

to future product-related legislation, such as common definitions or streamlined procedures to ensure consistency across all relevant provisions, in order to reduce gaps and overlaps between different directives.

After the adoption of the NLF, an "Alignment Package" was introduced to align nine existing EU Directives to the NLF, including the LVD²². As a result, Directive 2006/95/EC was repealed and replaced by Directive 2014/35/EU, which has entered into force in April 2014 and became applicable as of 20 April 2016. In addition to this alignment package, twelve other directives and regulations have been aligned since the adoption of the New Legislative Framework²³. Directive 2014/35/EU (new LVD) restructured Directive 2006/95/EC (the previous LVD) and aligned it with the NLF as well as the procedures of Standardisation Regulation (EU) 1025/2012. Due to the alignment with the NLF, it clarifies the definitions and obligations of economic operators, it regulates the conformity assessment in further detail, it clarifies the meaning of CE marking and improves the procedures on market surveillance. The most significant changes are the removal, from the market surveillance provisions, of the references to notified bodies and the introduction of the rule that the references of the harmonised standards shall be published in the OJEU under LVD in order to grant presumption of conformity with the corresponding safety objectives. However, the new Directive does not amend or modify the Directive's legal substance with regard to its objectives (e.g. its safety essential requirements) and main scope (it has only inserted an exemption on 'Custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes').

3.2 Scope of the Low Voltage Directive

The LVD is applicable to electrical equipment with a rated voltage between 50 V and 1000 V (alternating current) or between 75 V and 1,500 V (direct current) that is introduced to or circulated on the internal market. According to Annex II of the Directive, the following types of equipment are excluded:

- electrical equipment for use in an explosive atmosphere
- electrical equipment for radiology and medical purposes
- electrical parts for goods and passenger lifts
- electricity meters
- plugs and socket outlets for domestic use
- electric fence controllers
- radio-electrical interference
- specialised electrical equipment for use on ships, aircraft or railways
- custom built evaluation kits destined for professionals to be used solely at research and development facilities

However, certain EU acts which cover also certain types of electrical equipment provide that the LVD is not applicable to these types of equipment. This is for instance the case with the Machinery

²² The other Directives were the Simple Pressure Vessels 2009/105/EC, Lifts and their safety components Directive 1995/16/EC, Equipment for use in Potentially Explosive Atmospheres 94/9/EC (ATEX), Electromagnetic Compatibility Directive 2004/108/EC, Measuring Instruments Directive 2004/22/EC, Non-Automatic Weighing Instruments Directive 2009/23/EC, Civil Explosives Directive 93/15/EC and Pressure Equipment Directive 97/23/EC.

²³ These are the Toy Safety Directive (2009/48/EU), the Transportable Pressure Equipment Directive (2010/35/EU), the Restriction of Hazardous Substances in Electrical and Electronic Equipment Directive (2011/65/EU), the Construction Products Regulation (No 305/2011 (EU)), the Pyrotechnic Articles Directive (2013/29/EU), the Recreational Craft and Personal Watercraft Directive (2013/53/EU), the Radio Equipment Directive (2014/53/EU), the Pressure Equipment Directive (2014/68/EU), the Marine Equipment Directive (2014/90/EU), the Cableway Installations Regulation (2016/424 (EU)), Personal Protective Equipment Regulation (2016/425 (EU)), the Gas Appliances Regulation (2016/426 (EU).

Directive 2006/42/EC²⁴ and the Radio Equipment Directive 2014/53/EU²⁵. While they refer to the safety objectives set out in the LVD and hence the safety objectives of the LVD are applicable via these other acts, at the same time they exclude these types of equipment from the scope of the LVD's application.²⁶ In these cases, the LVD and these other directives are mutually exclusive.

Generally, equipment that falls under the scope of several product harmonisation acts (directives and regulations) must comply with all requirements cumulated from these acts.

Electrical equipment within the scope of the LVD may also need to comply with other EU acts. A number of these acts also provide for CE Marking. The conformity assessment must therefore take the requirements from all relevant EU harmonisation legislation into account and the conformity declaration (EU Declaration of Conformity) must refer to all relevant EU harmonisation legislation.

The following acts, which provide for CE marking and apply to some types of electrical equipment covered also by the LVD, are mentioned as indicative examples:

- the "Gas Appliances" Regulation (EU) 2016/426, if the appliances covered by that Regulation include electrical components that fall also under the LVD.
- the Construction Products Regulation (EU) No 305/2011, if electrical equipment covered by the LVD is manufactured with a view to being permanently incorporated in construction works and falls also under Regulation 305/2011.
- the Electromagnetic Compatibility Directive 2014/30/EU which regulates the electromagnetic compatibility of equipment placed on the market (see section 5.4.3 for further discussion on these overlaps, if electrical equipment covered by the LVD is liable to generate electromagnetic disturbance or the performance of which is liable to be affected by such disturbance and falls also under Directive 2014/30/EU.

In addition, Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment²⁷ as well as the EU legislation on Ecodesign and energy labelling²⁸ relate to electrical equipment. Thus, if electrical equipment covered by the LVD falls under the scope of that EU legislation which relate to electrical equipment, shall also comply with that EU legislation. Moreover, electrical equipment within the scope of the LVD shall also comply Directive 2012/19/EU on waste electrical and electronic equipment (WEEE), which is not a CE Marking Directive but relates to electrical equipment, when it falls also under this act.

²⁴ Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC, available at: <u>http://data.europa.eu/eli/dir/2006/42/oi</u>.

²⁵ Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC, available at: <u>http://data.europa.eu/eli/dir/2014/53/oi</u>.

²⁶ Annex I no. 1.5.1. Machinery Directive (2006/42/EC): "The safety objectives set out in Directive 73/23/EEC shall apply to machinery. However, the obligations concerning conformity assessment and the placing on the market and/or putting into service of machinery with regard to electrical hazards are governed solely by this Directive"; recital (7) Radio Equipment Directive (2014/53/EU): "The objectives with respect to safety requirements laid down in Directive 2014/35/EU are sufficient to cover radio equipment, and should therefore be the reference and made applicable by virtue of this Directive. In order to avoid unnecessary duplications of provisions other than those concerning such requirements, Directive 2014/35/EU should not apply to radio equipment".

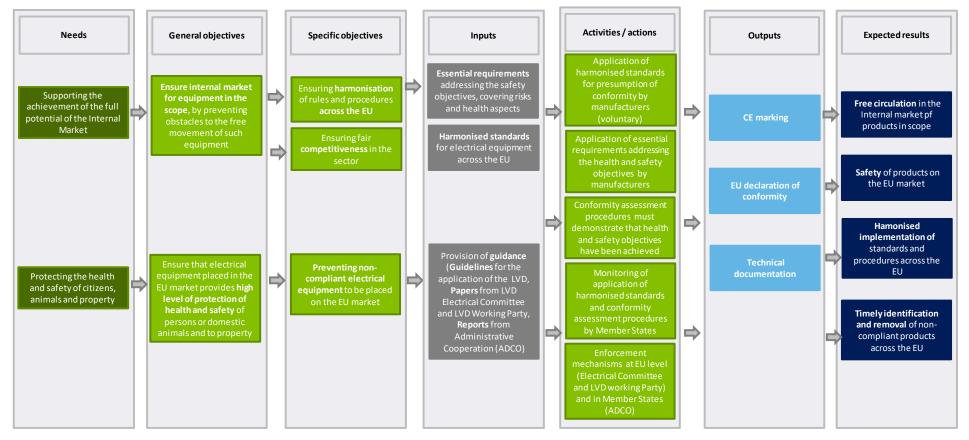
²⁷ Provides for CE marking.

²⁸ For details, see:

https://ec.europa.eu/info/energy-climate-change-environment/standards-tools-and-labels/products-labelling-rules-and-requirements/energy-label-and-ecodesign_en

Figure 3 presents the intervention logic of the LVD. The actions and outputs are further detailed in the next chapter.

Figure 3 – Intervention logic



Source: Consortium

4. IMPLEMENTATION AND STATE OF PLAY

This chapter provides an overview of the implementation of the Directive in practice, as well as an economic analysis of the low voltage product market.

4.1 Implementation of the Directive

This section presents the implementation of the LVD, including the roles of the implementing bodies and main stakeholders, as well as the functioning of the Directive.

4.1.1 Implementing bodies and key stakeholders

Several specific bodies assist the European Commission in managing, monitoring and enforcing the implementation of the LVD.

4.1.1.1 Committee on Electrical Equipment

The LVD has established a Committee on Electrical Equipment²⁹ which is a Committee within the meaning of Regulation (EU) No 182/2011³⁰ concerning mechanisms for control by Member States of the Commission's exercise of implementing powers. It consists of representatives from the Member States as members, as well as EEA countries, EFTA countries and Turkey, as observers, and is chaired by the European Commission (DG GROW). The European Commission is required to consult the committee on any questions where the opinion of sectoral experts is required by EU legislation (notably Regulation (EU) No 1025/2012³¹ on European standardisation). Moreover, the Committee may also initiate an ex officio examination on any matter regarding the implementation and application of the LVD.

4.1.1.2 LVD Working Party

In addition to the Committee on Electric Equipment, the European Commission has formed the LVD Working Party (LVD WP) which is registered on the 'Register of Commission Expert Groups' While the Committee assembles Member States and other States, the Working Party also includes non-state stakeholders such as standards makers, industry representatives, consumers, and laboratories. The Working Group is designed as a forum to discuss specific issues related to the implementation of the Directive, e.g. how to correctly affix the CE marking. As the Committee, the Working group is chaired by the European Commission (DG GROW).

4.1.1.3 LVD AdCo

The third body that assists the European Commission in the implementation of the Directive is the LVD Administrative Co-operation (LVD ADCO). This working group is composed of the national market surveillance authorities and it works independently from the European Commission. National market authorities use the working group for international co-operation and information exchange. Moreover, through the LVD AdCo the national market surveillance authorities publish recommendations on market surveillance practices, as well as reports on cross-border market surveillance activities. None of the LVD ADCO's publications are however legally binding.

²⁹ Article 23 Low Voltage Directive (2014/35/EU).

³⁰ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, available at: <u>http://data.europa.eu/eli/reg/2011/182/oj</u>. ³¹ Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on

³¹ Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the Parliament and of European the Council, available at: http://data.europa.eu/eli/reg/2012/1025/oj.

The national authorities are responsible for the implementation of the Directive, and its enforcement. Annex M provides details of the transposition acts in each Member State. No infringement cases are currently open; cases were closed without a Court judgment against Cyprus, Finland and Portugal in 2017.³² Market surveillance is discussed in further detail in the next chapter.

4.1.1.4 Economic operators

To achieve its objectives, the LVD sets a number of obligations for manufacturers, importers or distributors who place electrical equipment on the market. The primary obligation is to guarantee that the equipment is designed and manufactured in a way so that it does not pose a threat to health and safety of persons, domestic animals or property. To this end, the economic operator can rely on voluntary harmonised standards to which their references are published in the OJEU under the LVD and which, when fulfilled by the equipment, release a presumption of conformity with the directive's safety requirements.

Obligations of economic operators are set out in Chapter 2 of the Directive. Manufacturers (Art. 6) are obliged to ensure that electrical equipment they place on the market has been designed and manufactured in accordance with the safety objectives. They are also obliged to draw up the technical documentation and either carry out or have carried out the conformity assessment procedure referred to in Annex III of the Directive. Once compliance has been demonstrated, an EU declaration of conformity (DoC) must be drawn up and CE marking affixed. The DoC and the technical documentation must be stored for 10 years after placement on the market. In addition, the equipment or its packaging must bear identification of both the equipment and the manufacturer, including contact information, and be accompanied by instructions and safety information that are clear, understandable and intelligible, and in a language easily understood by end-users as determined by the concerned Member State.

The manufacturer is also obliged to ensure that procedures are in place for series production to remain in conformity, taking into account changes in product design, harmonised, international and national standards, and other relevant features. Corrective measures must be taken whenever there is a reason to believe that equipment the manufacturer has placed on the market is not in conformity. The manufacturer is also obliged to inform competent authorities where the equipment presents a risk, and in general provide the authority upon a reasoned request with any information and documentation to demonstrate the conformity of the equipment and cooperate with the authority on any actions taken to eliminate risks posed by the equipment.

The manufacturer may appoint an authorised representative by a written mandate (Art. 7), to keep the DoC and technical documentation at the disposal of national MSAs for 10 years, to provide the documentation and information to national authorities, and cooperate with them on risk elimination. However, the mandate may not include ensuring compliance or drawing up technical documentation.

Importers (Art 8) are obliged to ensure that the manufacturer has carried out the appropriate conformity assessment procedure, drawn up the technical documentation, affixed the CE marking and provided the required documents, and provided identification of the equipment and themselves as described in Art. 6. The importers shall also indicate their own name and contact information and ensure that instruction and safety information are provided in a language easily understood by end users, as determined by the Member State. To ensure product safety, the importers shall ensure that their storage or transport conditions do not jeopardise the equipment's compliance with the safety objectives. When deemed appropriate with regard to the risks, the importers shall carry out sample testing, and investigate and keep a register of complaints of non-conforming electrical equipment and recalls, as well as keep distributors informed of any such

³² COMMISSION STAFF WORKING DOCUMENT Part III: Member States Accompanying the document REPORT FROM THE COMMISSION Monitoring the application of European Union law 2017 Annual Report. SWD/2018/379 final.

monitoring. As the manufacturers, importers shall also take corrective measures in the event of potential non-conforming equipment, inform and cooperate with the competent national authorities. They shall also keep a copy of the DoC for 10 years after the equipment has been placed on the market and ensure that technical documentation can be made available to the authorities. On reasoned request, they shall provide the national authority with all the information and documentation to demonstrate the conformity of the equipment.

Art 10. States that an importer or distributor shall be considered a manufacturer, with all the manufacturer obligations applying, if they place electrical equipment on the market under their name or trademark, of modify the equipment already on the market in a way that may affect compliance with LVD.

4.1.2 Functioning of the Low Voltage Directive

This section outlines the functioning of the Directive in practice.

4.1.2.1 Safety objectives

Electrical equipment may be made available on the Union market only if, having been constructed in accordance with good engineering practice in safety matters in force in the Union, it does not endanger the health and safety of persons and domestic animals, or property, when properly installed and maintained and used in applications for which it was made. The principal elements of the safety objectives are listed in Annex I of the LVD.

These objectives cover all risks arising from the use of electrical equipment, not just electrical ones, but also mechanical, chemical (such as, in particular, emission of aggressive substances) and all other risks. They also cover health aspects of noise and vibrations, and ergonomic aspects as far as ergonomic requirements are necessary to protect against hazards in the sense of the LVD.

To this end, the economic operators can rely on harmonised standards (to which the references have been published in the Official Journal of the EU under the LVD) which, when fulfilled by the equipment, give a presumption of conformity with the corresponding safety objectives.

4.1.2.2 Standards

The Directive establishes a hierarchy between harmonised standards adopted by the EU, international standards published by the International Electrotechnical Commission (IEC), and national standards.

According to Article 12 of the LVD, electrical equipment in conformity with harmonised standards or parts thereof, adopted in accordance with Regulation (EU) No 1025/2012 on European standardisation and whose references are published on the Official Journal of the EU, shall be presumed to be in conformity with the safety objectives. As noted also in § 28 of the Guidelines to the LVD³³, manufacturers who apply harmonised standards can benefit from presumption of conformity with the safety objectives they cover, however the use of the standards remains voluntary.

Standardisation Regulation (EU) No 1025/2012 provides for a "formal objection" procedure for disputing a harmonised standard that is considered by a Member State or by the European Parliament that it does not entirely satisfy the safety objectives which it aims to cover.

Where EU harmonisation standards referred to in Article 12 of the LVD do not exist, equipment that complies with international standards referred to in Article 13 of the LVD is presumed to fulfil the necessary safety requirements. Where neither EU harmonisation standards nor international

standards exist, equipment that complies with national standards referred to in Article 14 of the LVD is presumed to fulfil the necessary safety requirements.

When market surveillance authorities take measures against non-compliant electrical equipment shall identify if the non-compliance is due to either of the following: (a) failure of the electrical equipment to meet the safety objectives referred to in Article 3 and set out in Annex I relating to the health or safety of persons or domestic animals, or to property; or (b) shortcomings in the harmonised standards referred to in Article 12 or in the international or national standards referred to in Articles 13 and 14 conferring a presumption of conformity.

If the product has not been manufactured in accordance with any harmonised, international or national standards, as defined in Articles 12-14 of the Directive, as their application remains voluntary, the manufacturer must provide a thorough documentation of the technical solutions that have been applied in order to fulfil the safety requirements of the LVD.

4.1.2.3 Conformity assessment procedure

In order to be placed on the EU market, electrical equipment must go through an internal conformity assessment procedure.

Article 6 and Annex III of the LVD describe the procedure by which the manufacturer ensures and declares conformity of the electrical equipment with the provisions of the LVD which includes three main elements: technical documentation, declaration of conformity and CE marking.

The conformity assessment is carried out by the manufacturer (without any obligation to involve a notified body or any other third party in the procedure. In fact the Directive does not include any provisions on notified bodies and the only conformity assessment procedure foreseen in the Directive is the internal production control ('Module A') which does not involve a notified body.

The technical documentation shall make it possible to assess the electrical equipment's conformity to the relevant requirements and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the electrical equipment.³⁴

Module A obliges the manufacturer to take all necessary means so that the manufacturing process and its monitoring ensure compliance with the technical documentation and the relevant requirements of the Directive. It also obliges the manufacturer to affix CE marking and draw up a written EU declaration of conformity (DoC),

The manufacturer then issues, with respect to the electrical equipment that satisfies the requirements of the LVD, a declaration of conformity in accordance with Annex IV of the Directive with which the manufacturer assumes responsibility that the equipment is compliant. The manufacturer assumes responsibility for the compliance of the electrical equipment with requirements of the LVD by drawing up the EU declaration of conformity (DoC). The DoC is drafted to state that the fulfilment of the safety objectives has been demonstrated (Art. 15). Annex IV provides the model structure. The DoC shall also contain the elements specified in Module A, shall be continuously updated, and shall be translated into language(s) required by the MS in which the equipment in question is placed or made available on the market. Where electrical equipment is subject to multiple acts requiring a declaration of conformity, a single DoC shall cover all of

³⁴ The technical documentation shall, where applicable, contain at least the following elements: (a) a general description of the electrical equipment; (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.; (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the electrical equipment; (d) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union or international or national standards referred to in Articles 13 and 14 and, where those harmonised standards or international or national standards have not been applied, descriptions of the solutions adopted to meet the safety objectives of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or international or national standards documentation shall specify the parts which have been applied; (e) results of design calculations made, examinations carried out, etc.; and (f) test reports.

these acts. In addition, the manufacturer shall affix the CE marking on the equipment. The general principles of the CE marking are set out in Article 16 of the LVD which refers to Article 30 of the New Legislative Framework Regulation (EC) No 765/2008 and the rules and conditions for affixing the CE marking are set out in Article 17 of the LVD. The marking must be visibly, legibly and indelibly affixed to the electrical equipment or its data plate, or if that is not possible or warranted on account of the nature of the equipment, it shall be affixed to the packaging and the accompanying documents. The CE marking shall be affixed prior to placing the equipment on the market. Member States are obliged to build upon existing mechanisms to ensure current application of the regime that governs the CE marking and take action in the event of improper use. The Guidelines to the LVD specify that LVD equipment that is not placed on the EU market but is incorporated into or attached to other equipment that is, only the latter needs to be CE marked. For two or more products supplied together on a package or combination, the application of CE marking needs to be considered on a case by case basis.

According to the mandate contractually agreed with the manufacturer, the authorised representative may fulfil the manufacturer's obligations related to the CE marking and the EU declaration of conformity.

The importer or distributor shall be considered as the manufacturer and shall undertake the responsibilities of the manufacturer when places the equipment on the market under his/her name or trademark or modifies electrical equipment already placed on the market in such a way that compliance with this Directive may be affected.

4.1.2.4 Market surveillance

The framework for market surveillance and controls of products entering the Union market are set in the New Legislative Framework Regulation (EC) No 765/2008. The LVD includes specific provisions to establish measures to monitor compliance with the Directive's objectives. The market surveillance authorities are authorised to carry out an evaluation of an equipment's conformity wherever they have reasonable indication that the equipment might pose a risk to health or safety of persons, domestic animals or property.

Market surveillance under LVD is addressed under Chapter 4 of the LVD. It sets a procedure for dealing with electrical equipment presenting a risk at national level (Art. 19), Union safeguard procedure (Art. 20), procedure for compliant electrical equipment which presents a risk (Art. 21) and a procedure for formal non-compliance (Art. 22).

The procedure for dealing with electrical equipment presenting a risk at national level includes as a first step an evaluation by the market surveillance authorities of the Member State, covering all relevant requirements laid down in the LVD. The relevant economic operators shall cooperate with the MSA as necessary. Where non-compliance is found, the MSA shall require the relevant economic operator to take appropriate corrective action (bringing the equipment into compliance, withdrawal from market or recall). Where the MSA considers that non-compliance is not restricted to the national territory, they shall inform the Commission and the other Member States of the results of the evaluation and the actions required from the economic operator. The economic operator is responsible for ensuring that all appropriate corrective action is taken of the equipment concerned that it has made available on the market throughout the Union. If the economic operator fails to take adequate corrective action within the timeframe specified, the MSA shall take appropriate provisional measures and inform the Commission and the other Member States of those. The other Member States, upon receiving any of the aforementioned information from the MSA, shall in turn inform the Commission and the other Member States of any measures they adopt and of any additional information relating to the non-compliance of the concerned equipment, as well as any objections they may have on the adopted national measure. Where no objection has been raised by the other Member States or the Commission within three months, the provisional measure shall be deemed justified. Member States shall ensure that appropriate restrictive measures are taken in all countries without delay.

The Union safeguard procedure provides for situations where objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to contradict Union legislation. In such an event, the Commission shall consult all Member States and the relevant economic operators to evaluate the national measure. On the basis of that evaluation, an implementing act shall be adopted to determine whether the national measure is justified or not. If the national measure is found justified, all Member States shall take the necessary measures to ensure the withdrawal of the non-compliant equipment. If the measure is found unjustified, the measure shall be withdrawn.

The procedure for compliant electrical equipment which presents a risk applies when a Member State finds after carrying out an evaluation under Art. 19 that the electrical equipment presents a risk despite being in compliance with the Directive. In such event, appropriate measures shall be taken as above. The Member State shall inform the Commission and the other Member States, with all available details including those required for the identification of the equipment, the origin and supply chain, the nature of risk, and the nature and duration of national measures taken. The Commission shall then launch an evaluation similar to that under the Union safeguard procedure, and where necessary, propose appropriate measures. On imperative grounds of urgency, the Commission shall adopt immediately applicable implementing acts to protect the health and safety of persons, domestic animals or property.

Formal non-compliance applies when the non-compliance is not directly related to health and safety risks, but could be an indicator of such, including the lack of CE marking, lack of DoC, incorrectly drawn up DoC, lacking or incomplete technical documentation, lack of complete and correct manufacturer/importer identification, or the lack of any other administrative requirement provided for in Articles 6 and 8. Where this kind of non-compliance occurs, the Member State shall require the relevant economic operator to correct the issue. Where the non-compliance persists, the Member State shall take appropriate measures to restrict or prohibit the equipment being made available on the market or ensure its recall or withdrawal.

4.2 Analysis of the low voltage market

This section presents the current economic importance of the sector in the EU, as well as the importance of the different industries that make up this sector. It looks at the extent to which it has evolved in the past 10 years as well as the trends in intra- and extra-EU trade. Finally, it looks into the latest relevant technological developments and how these could affect the relevance or coherence of the LVD.

4.2.1 Introduction of products

As explained in Section 2.2.3, the market analysis is based on data collected under to nine NACE categories and filtered through a set of criteria to define the LVD sector. These categories are shown in the table below.

| NACE code | Category name | | |
|-----------|--|--|--|
| C26.2 | Manufacture of computers and peripheral equipment | | |
| C26.3 | Manufacture of communication equipment | | |
| C26.4 | Manufacture of consumer electronics | | |
| C27.1 | Manufacture of electric motors, generators, transformers and | | |
| | electricity distribution and control apparatus | | |
| C27.3 | Manufacture of wiring and wiring devices | | |
| C27.4 | Manufacture of electric lighting equipment | | |
| C27.5.1 | Manufacture of electric domestic appliances | | |
| C27.9 | Manufacture of other electronic equipment | | |

Table 3 – NACE categories of products under the scope of the LVD

| NACE code | Category name |
|-----------|---|
| C29.3.1 | Manufacture of electrical and electronic equipment for motor vehicles |

The products in these categories were run through LVD-defining criteria, creating a group of products that are always under the scope of the LVD (minimum range) and an additional group of products that sometimes fall under the scope. The methodological note for the market analysis (Section 2.2.3) gives further information on the assumptions.

Most data presented in this section cover the maximum range of the low voltage market (minimum and additional products). Differentiations are only made when the trends differ for the minimum and additional range of product groups, which is not the case for the majority of data. Based on the limitations of the data and assumptions made, the data presented in this section should be interpreted with caution.

4.2.2 Economic importance in the EU

This section presents the Low Voltage market in the EU in terms of production, as producers are responsible for ensuring that their products comply with the LVD. It presents the relative importance of LV products (and the different categories) within the manufacturing sector as well as the structure of these industries in terms of companies and employees.

The minimum low voltage market represents approximately 1% of the European manufacturing sector. The additional low voltage market represents approximately 2.7%. This 3.7% maximum total amounted to EUR 206,067 million in 2017, with the most significant NACE industry categories being that of *motors, generators, transformers and electricity distribution and control apparatus* followed by *domestic appliances* and *equipment for motor vehicles*. With regards to low voltage production within each industry, those that have the highest percentage of products falling under the LVD are *electrical and electronic equipment for motor vehicles, electric domestic appliances* and *other electric equipment*.

| NACE code | Category name | | Total production | Min | imum LVD | Ado | ditional LVD |
|-----------|--|---|---------------------|-----|----------|-----|--------------|
| C26.2 | Manufacture of computers and peripheral equipment | € | 94,856 | € | - | € | 16,819 |
| C26.3 | Manufacture of communication equipment | € | 33,346 | € | 528 | € | 11,751 |
| C26.4 | Manufacture of consumer electronics | € | 20,847 | € | - | € | 12,143 |
| C27.1 | Manufacture of electric motors, generators, transformers and electricity distribution and control apparatus | € | 136,171 | € | 27,713 | € | 32,026 |
| C27.3 | Manufacture of wiring and wiring devices | € | 49,050 | € | 13,469 | € | 8,708 |
| C27.4 | Manufacture of electric lighting equipment | € | 30,247 | € | 358 | € | 12,518 |
| C27.5.1 | Manufacture of electric domestic appliances | € | 35,237* | € | 1,439 | € | 26,340 |
| C27.9 | Manufacture of other electronic equipment | € | 30,829 | € | 2,353 | € | 16,458 |
| C29.3.1 | Manufacture of electrical and electronic equipment for motor vehicles | € | 35,578* | € | 8,241 | € | 15,204 |

Table 4 - Production of low voltage products (million euro), 2017

Note: C27.5.1 and C29.3.1 information for total production from 2016.

Source: Own calculations based on Eurostat Manufacturing Statistics sbs_na_ind_r2

Figure 4 shows the average of the yearly production values over the past five years across different Member States.³⁵.

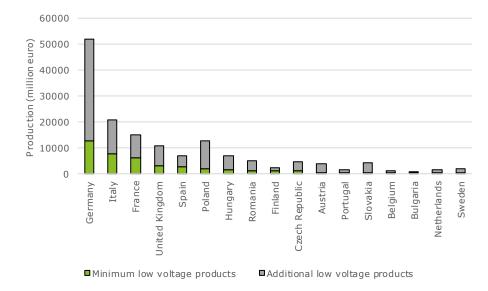


Figure 4 – Member State annual average production of low voltage product group (1)

Source: Own calculations based on Eurostat Manufacturing Statistics sbs_na_ind_r2

(1) Annual average calculated over the past five years (2012-2017)

It should be noted that product level data are not complete, as a large share of product-level data is reported as confidential.³⁶ Therefore, one should be careful in drawing strong conclusions from these data. Annex N includes the detailed production data at product level for the selected Member States in this study.

The largest producers in the EU (based on the maximum low voltage product list) are by far Germany, followed (by a large difference) by Italy, France, Poland and the UK.

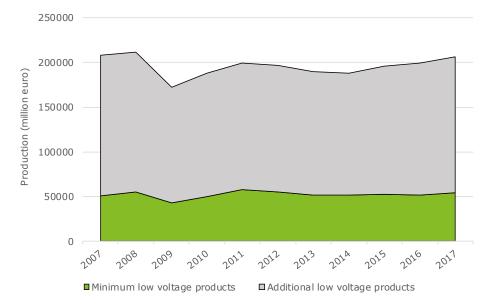
Figure 5 shows the production levels of the EU28 countries over time.³⁷ Given the data limitations, trends should be taken as an indication of overall changes, with small variations possible reflecting gaps in data. The production of low voltage products has grown steadily since the early 90s. However, the figure only shows data starting in 2007, due to the largest data gaps being before this year. Furthermore, there is a lot of variation in trends within the low voltage market — including variation within NACE product categories — when looking at production levels per product. Keeping this in mind, the EU28 appears to have had a dip in production after the crisis in 2008, after which production has slowly grown back to pre-crisis levels. In recent years (2014-2017) there has been somewhat higher growth in the production of the mixed category (products that can be both within or outside the scope of the LVD) as compared to production of the minimum range of low voltage products has remained the same.

³⁵ A five-year average is used, as annual data could give an inaccurate picture because there can be significant fluctuations in production values, largely due to data availability

³⁶ To illustrate, 63 of the 188 products of the low voltage products (maximum range) were reported as confidential for Germany in 2017.

³⁷ It should be noted EU membership has changed over the evaluation period, these data include all current EU Member States, so also before the accession of some of them.

Figure 5 – EU28 production of low voltage products, 2007-2017



Source: Own calculations based on Eurostat Manufacturing Statistics sbs_na_ind_r2

Low voltage product manufacturing has grown at a slightly lower rate that the overall EU28 manufacturing industry. The maximum low voltage production (minimum and additional) dropped from representing 5.0% of EU manufacturing in 1995 to approximately 3.8% in 2017. Part of this decrease can be attributed to offshoring, further described in the Trends and Development section of this chapter. Annex N includes a figure detailing this trend.

Market structure and concentration

Electric equipment is made across a variety of manufacturing industries, each with its own structure in terms of number of companies and company size. The number of active enterprises varies across industries, ranging from approximately 1,700 to 20,000. Even more variation is seen in the scale of these companies, with the average number of employees per enterprise ranging from approximately 19 to 148.

It should be noted that the numbers presented are for the overall electronics industries and not only for companies producing low voltage products. As most companies produce a variety of products —both within and outside the scope of the LVD —the numbers are shown are for the entirety of the relevant manufacturing categories. The numbers presented here are therefore an overestimation of the number of companies and employees but represent the sectors that are relevant for the low voltage market.

Taking this into account, based on the NACE level categories the highest number of both enterprises and persons employed is in the category of *electric motors, generators, transformers and electricity distribution and control apparatus* (which is also the category with the highest level of low voltage production).

Figure 6 provides additional information on company size per sector.³⁸ It shows that the majority of enterprises at NACE industry level are microenterprises, with 0 to 9 persons employed. The

³⁸ It should be noted that there are some difference in exact scope, as statistics on enterprise sizes only go down to group level, whereas some of our defined categories go down to class level, making a few of these categories slightly different in scope than the other sections of the market analysis. This is the case for C29.3.1 Manufacture of electrical and electronic equipment for motor vehicles which in this figure is replaced by C29.3 Parts and accessories for motor vehicles and for C27.5.1 Manufacture of electric domestic appliances, which is replaced by C27.5 Manufacture of domestic appliances.

share of micro enterprises is highest for the industry of manufacturing computers and peripheral equipment, and lowest for motor vehicles parts and wiring and wiring devices.

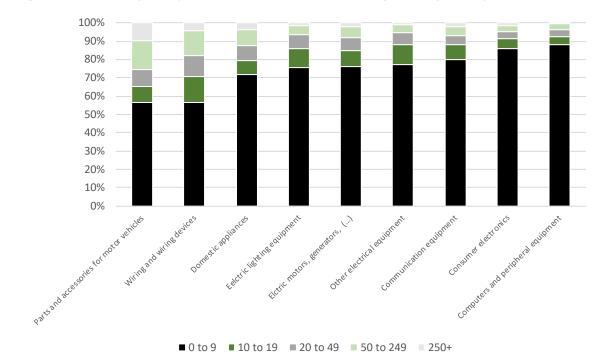


Figure 6 – Industry composition of selected NACE categories by enterprise size, 2017

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

Annex N includes more information on trends in enterprise numbers and number of people employed. The number of companies has decreased in all industries defined for the low voltage sector.³⁹ The largest changes were in the *electric motors industry, computers and peripherals, wiring and wiring devices* and *electric domestic appliances*. While it was the industry with the most companies in 2017, *electric motors* also had the largest decrease in number of companies, decreasing at a yearly average rate of 2% in the time period of 2011 to 2017.⁴⁰ The number of employees has decreased at a slower rate in the same period. Thus there are fewer, but on average bigger companies in terms of employees — resulting in increased market concentration.

The number of persons employed in the sectors decreased as a whole over this 5-year period, though not for every category. The largest decreases were in the *communication equipment* industry and in *consumer electronics*. The employment level in *electrical and electronic equipment for motor vehicles* has increased sharply in the past five years. The lighting equipment and other electrical equipment industries have also employed more people in the time period under consideration.

4.2.3 Intra- and extra-EU trade in low voltage products

This section presents trade levels of low voltage products, both within and outside the EU. It also combines the production data from the previous section with trade data to find an approximation of EU consumption of low voltage products.

³⁹ Except for electrical and electronic equipment for motor vehicles, for which there is no earlier data available. The selected indicators show data for the EU28 instead of the cumulative filter, so changes are not attributable to the 2013 enlargement of the EU.

⁴⁰ Time period chosen due to availability of data, none available at NACE Rev. 2 Group level before 2011.

Table 5 shows the levels of EU trade of low voltage products (using the maximum range of LVD products) with EU Member States and countries outside of the EU (for readability referred to as intra- and extra- EU). In 2017, intra-EU trade was larger than extra-EU trade and the EU imported more than it exported.

Table 5 – Intra and extra-EU trade maximum and minimum range (million euro), 2018

| | Intra | a-EU | Extra-EU | | |
|---------|------------------|------------------|------------------|------------------|--|
| | Minimum range of | Maximum range of | Minimum range of | Maximum range of | |
| | LVD | LVD | LVD | LVD | |
| Exports | 40.000 | | 33,972 | 101,825 | |
| Imports | 40,606 | 203,059 | 19,735 | 128,874 | |

Source: Own calculations based on Easy Comext

EU exports in low voltage products have always been higher in the intra-EU market (see Figure 7). The value of trade in low voltage products between the current EU Member States has fluctuated between 60% to 70% of total low voltage trade of the current EU Member States over the past decades.⁴¹ While both types of exports have been growing at similar rates, intra-EU exports have grown a bit more rapidly over the past 5 years, gaining in importance compared to exports to extra-EU countries.

The product category in trade with the highest values is that of machines for the reception and conversion of voice images or data (including switching and routing apparatus but excluding telephones for wireless networks) as well as apparatus for electric control or the distribution of electricity, electric conductors and switches.

Intra EU trade shows large values for electrical apparatus for switching or protecting electrical circuits, or for making connections to or in electrical circuits, e.g., switches, relays, fuses, surge suppressors.

Extra EU exports is strong on electric motors and generators (excl. generating sets) and electric transformers, whereas extra-EU imports have larger values for products with more domestic purposes, such as electric heaters, hairdryers, hand dryers and electric smoothing irons.

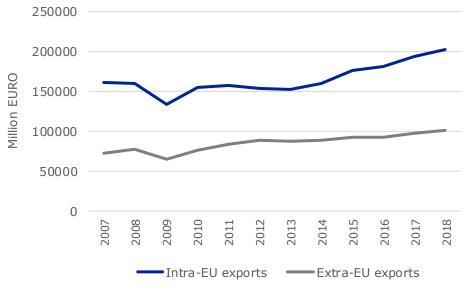


Figure 7 – Intra- and extra-EU exports of LVD products (maximum range), 2000-2018

Source: Own calculations based on Easy Comext.

⁴¹ As in the entire market analysis section, this is an estimation and based on a database with several gaps. The change in 2005 seen in the graph, for example, is due to previously unavailable trade data for some low voltage products becoming available, and not due to rapidly increasing exports.

For imports, the larger intra-EU flows also holds, though the difference in trends between intra and extra- EU imports in recent years has been less pronounced (Figure 8).

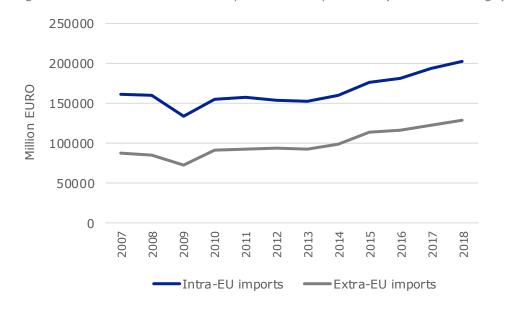


Figure 8 – Intra and extra-EU imports of LVD products (maximum range), 2000-2018

Source: Own calculations based on Easy Comext

The above figures show the trends for the maximum range of low voltage products. When disaggregating these values per product categories, the 'minimum' low voltage category is relatively more important in EU exports to the rest of the world than in its imports from other countries. Figures for these trends are included in Annex K. While low voltage imports have grown rapidly, this growth comes predominantly from the additional low voltage category, rather than the minimum one, which consists of LVD and non-LVD products. Whether the growth can be attributed to LVD products or not, can therefore not be assessed in the absence of more detailed data.

Figure 9 shows the low voltage trade deficit with the rest of the world. While it has always imported more than it has exported, the size of this difference fluctuated until 2013. Since then, imports into the EU have increased much faster than EU exports to the rest of the world, therefore increasing the trade deficit.

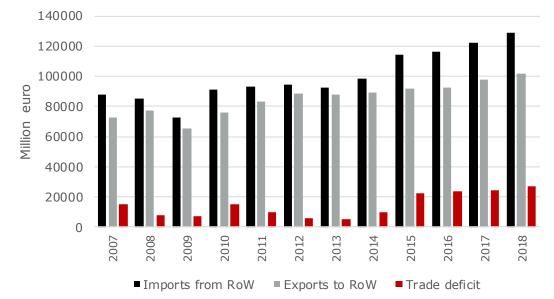


Figure 9 – EU trade with RoW in full (minimum and additional) category of low voltage products, 2007-2018

Source: Own calculations based on Easy Comext

Regarding trading partners outside the EU, China is by far the largest import partner. Export partners are more varied, with the US accounting for the largest share of exports (see Figure 10). Approximately 45% of extra-EU imports in 2018 came from China, which is the result of a significant growth in Chinese low voltage imports that started in the early 00s and have been growing exponentially since 2007 (see Figure 11).



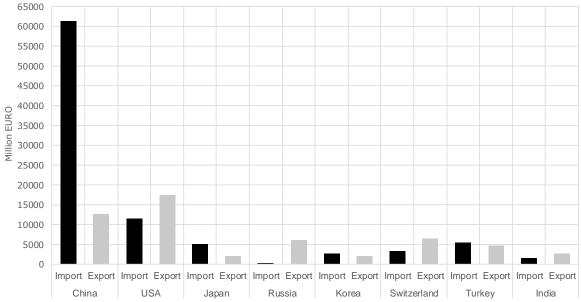
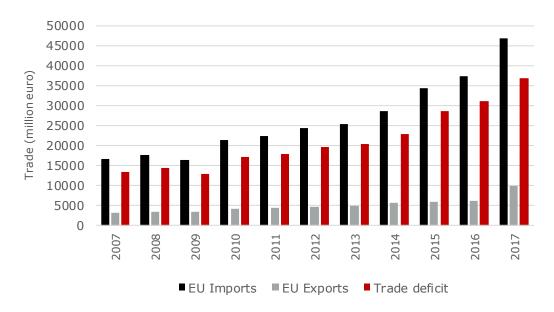




Figure 11 – EU trade with China in low voltage products (maximum range), 2007-2017



Source: Own calculations based on Easy Comext

4.2.4 Consumption of low voltage products

The European consumption⁴² of low voltage products (maximum product list) is interesting for the evaluation, as consumer safety is the ultimate objective of the Directive. An increase in consumption of the products under the scope of the LVD means the Directive is increasingly relevant. Over the last 20 years, consumption of electronic equipment has steadily increased. Although in 2008 consumption of LVD products showed a decrease as a result of the economic crisis, consumption has recovered after and was back on pre-crisis levels by 2016 (see Figure 12). Again, values should be taking as an approximation, both due to missing values for certain products and years and due to the combination of different statistical categories (Prodcom for production and HS for trade).

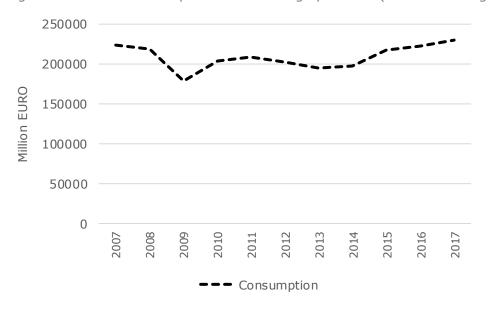


Figure 12 – EU28 consumption of low voltage products (maximum range), 2007-2017

⁴² Consumption levels calculated as Production level + (Extra-EU imports – Extra-EU exports).

4.2.5 Trends and developments within the low voltage market

This section outlines the various trends and developments identified within the low voltage market, including technological innovations, e-Commerce and production and consumer trends.

Technological innovations: connected systems and the internet of things

The scope of the LVD and the products it covers are very much affected by the increasing importance of the **Internet of Things (IoT)**, where everyday products are embedded with computing devices allowing them to send and receive data. Products that previously fell under the scope of the LVD start falling under the RED once they have radio emission functionalities.

IoT is an overarching development that affects many different technological applications and devices, ranging from consumer products (such as smart applications) to industry processes (such as smart automation) and large-scale urban solutions (such as smart energy).⁴³ Some of the largest potential application of the IoT in low voltage products are on home security, smart energy supply, smart applications, smart lighting and home automation.

Consumer electronics accounts for one of the largest segments of the IoT market. The surge of "smart homes" with multiple purposes (energy saving, replenishing, remote control, etc.) is expected to keep growing, with APPLiA⁴⁴ expecting average annual growth rate of smart appliance users in Europe to be 33% for the period of 2016-2022, and an EC study⁴⁵ estimating the market value of IoT in the EU to exceed one trillion euros in 2020. Statista estimated household penetration of smart homes in Europe at 10.9% for 2018, expecting this value to rise to 22.5% by 2023.⁴⁶ This means that almost a fourth of all European households is expected to have at least one type of home automation functionality in place – be that in appliances, entertainment systems, temperature control or lighting.

Box 2 – Growing importance of the IoT in lighting: quantification case study

A large number of products falling under the LVD are also potentially subject to the RED. Of the 188 products identified, 95 were marked as possibly falling under the scope of the RED (see Annex K), meaning that there are currently products of this type on the market with radio emission functionalities. These 95 products together represent approximately 56% of the identified product list production. The list classifies a product as a 'sometimes' if products with radio emission functionalities have been known to exist on the market, regardless of how commonplace they currently are.

The lighting sector is one in which the multiple IoT applications have been growing across products. This includes functionalities for smart homes, offices, industries as well as cities through lighting management that improves user experience and reduces costs. Europe's smart lighting sector growth has been accelerated through smart lighting solutions in residential, commercial and government sectors. Europe's smart lighting market was estimated as being worth over EUR 1.8 billion in 2017, and expected to experience a growth between 2018 and 2024 at a Compound Annual Growth Rate (CAGR) of around 20%.⁴⁷

Quantification of the trend

The 56% of products possible falling under the RED is by definition an overestimation, as not all products within the product categories have radio emission functionalities. To quantify this over estimation, it would be necessary to know how many of the products currently on the market actually have this functionality. However, this poses some difficulties. For the lighting sector, the product list for the market analysis of this evaluation includes the 19 products. These are under NACE category 24.7, Electric Lighting Equipment. This electric lighting equipment includes products such as filament, discharge and ultraviolet lamps,

⁴⁶ Statista, Smart Home

⁴³ CBI, What trends offer opportunities on the market for electronics and electrical engineering? (2017)

⁴⁴ APPLiA, The Home Appliance Industry in Europe 2017-2016 (2018)

⁴⁵ Definition of a Research and Innovation Policy Leveraging Cloud Computing and IoT Combination (2014)

⁴⁷ Graphical Research, Europe Smart Lighting Market Growth Forecast Report 2018-2024, 2018

illuminated lamps (such as road signs) and chandeliers and other electric ceiling or wall lighting fittings. All of these products can (and often do) include smart lighting solutions. So of the 19, 12 were identified as possibly falling under the RED.

It would be interesting to quantify how many of these products fall out of the LVD scope due to the RED. Estimates for smart lighting take-up give a house penetration rate of 5.0% for 2019, with an expected increase to 12.3% for 2023.⁴⁸ Applying the estimated 5.0% household penetration rate to the 12 products, gives 3.2% of the NACE category as falling under the RED. However, this is only for residential applications. Penetration rates for commercial and government sectors would also be required to further estimate this value. For example, one product under the category is for illuminated signs, components under smart street lighting. Further quantifying the trend would require identifying (i) the multiple applications for each potentially IoT product (be they commercial, industrial or governmental applications); (ii) whether these applications also fulfil the LVD criteria (e.g. are all these products within the voltage limits, or may some also fall under the machinery directive); and (ii) to what extent these have been replacing the traditional non-IoT versions; to what extent. Without accurate data on a product level, each applied percentage would generate additional assumptions and make values increasingly difficult to interpret accurately.

Furthermore, available values regarding IoT trends come in different forms – such as penetration rates, sales, production or revenue. Not having comparable values generate additional difficulties in the data analysis. The above example, relies on equating the penetration rate (consumption) to production, which is an assumption in itself, as trends could differ between the two, depending on the trade flows.

While the addition of radio emission functionalities does not interfere with the type of technical safety standards covered by the LVD -IoT safety concerns being primarily on privacy issues- they do push the products to be subject to another Directive (RED). More generally, it is also noted that innovation implies a continuous growth of new products entering the market, falling under the LVD or not (depending on the specifics of the products).

The rise of the IoT is also observed in other domains, like in industry. The term "Industry 4.0" is used to refer to developments in industry where machines are constantly being monitored by computer systems. Because those systems can also be responsible for the control of the machines, the collection of huge amounts of data, referred to as 'big data' allows computer systems to optimize production and maintenance systems in manufacturing lines. However, big data also creates data sharing uses because the manufacturing company is not necessarily the owner of the production line, and the owner of the production line is not necessarily the maintainer.

Similarly, the components of the civil infrastructure get more and more connected. Examples are transformers in the electricity supply, pumping stations for surface water management, and information signs of railway systems. With the upcoming introduction of the very fast 5G network, many of those components will be connected wirelessly, and thus be subject to the RED.

E-Commerce

The **growth in e-commerce** is another important development for the low voltage market. While this is not a new development, it continues to grow and is still far from reaching its full potential. – Seven in ten European online shoppers bought items from retailers outside their home country in 2017⁴⁹ and EU enterprises turnover from e-commerce reached an average of 18% of their total sales in the same year.⁵⁰

E-commerce changes the way consumers shop on a large scale, with 40% of consumers preferring to buy consumer electronics online via PC, tablets or smartphones.⁵¹ This was also confirmed by

⁴⁸ Statista, Smart Home

⁴⁹ UPS Pulse of the European Shopper - ComScore Survey

⁵⁰ Eurostat, Value of ecommerce sales [isoc_ec_evaln2].

⁵¹ PWC, Global Consumer Insight Survey (2018)

the OPC, which highlights that the most recurring channels for purchasing LVD products are online stores (response selected 95 times) and physical stores (response selected 93 times).

This changes how businesses market products, where products are sourced from and the distribution channels. The imported products must comply with Union harmonisation legislation on products, as products offered for sale online to EU consumers are considered as being placed on the EU market.

Challenges still remain related to all players in the process, including economic operators, surveillance authorities and consumers. Issues are:

- An increased number of non-EU economic operators active in the EU and the difficulty of tracing them;
- A lack of physical access to the products on the side of Market Authorities making it • difficult to sample products or conduct risk assessments (e.g. not all MS can purchase online items); and
- A lack of awareness on the side of consumers about product compliance online.

Steps are being taken for increased clarity (such as a new 2017 guidance for safe online shopping published within the Official Journal of the European Union) but challenges remain (c.f. section 5.1.2.4).

Production and consumer trends

One of the challenges faced by the EU manufacturing sector has been the relocation of production and product development. The outsourcing trend of EU production to lower cost countries began in the late 1970s, accelerated into the 1990s and is still ongoing today. ⁵² China became market leader in production in the late 90s, mostly at the expense of Japan and the United States but also taking over market shares of the EU.53 Relocation has also been a phenomena within the EU, with older Member States transferring electric and electronic manufacturing operations to newer Members States ('nearshoring' to Central and Eastern European countries) starting in the mid-00s.⁵⁴

Electrical manufacturing has always been one of the EU industries most sensitive to relocations. This was identified in an EP study in 200655 and has continued up to today. According to a 2016 ERM report⁵⁶ three manufacturing subsectors suffered around 60% of offshoring job losses: manufacture of motor vehicles, electronics (computers and mobile phones) and electrical products (domestic appliances). These are all significant industries in the low voltage production market. While absolute offshoring losses are largest in the larger Member States (France, Germany and the UK), the relative losses are higher for smaller Member States (Austria, Denmark, Ireland).

In 2016 Europe (including non-EU countries) accounted for over half of offshored jobs, while China accounted for about 26% of offshored job loss from EU13.

The DG GROW website for the electric and electronic industry⁵⁷ currently lists relocation to East Asia as one of the largest threats to the industry, creating a risk of a shortage of engineers and other labour skilled in advanced technologies. A 2013 study on the competitiveness of the electrical and electronic engineering industry found that the trend of relocation will continue until

⁵² EPRS, Reshoring of EU Manufacturing (2014)

⁵³ EPRS, Reshoring of EU Manufacturing (2014)

⁵⁴ Study on the Competitiveness of the Electrical and Electronic Engineering Industry (2013)

⁵⁵ European Parliament, Literature Overview: Relocation of EU Industries (2006)

⁵⁶ ERM annual report 2016: Globalisation slowdown? Recent evidence of offshoring and reshoring in Europe (2016) ⁵⁷ <u>https://ec.europa.eu/growth/sectors/electrical-engineering_en</u>

at least 2020, paired with a trend of declining domestic sales. However, new technologies and increasing automation in manufacturing could counter this long-standing trend in the future and bring more production back to the EU.

Consumer characteristics

Consumer characteristics and behaviour influence the sector structure and the development of new trends. While not all products falling under the scope of the LVD are consumer goods, the categories of electric domestic appliances and consumer electronics make up approximately 20% of the LVD product market in the EU.

Consumer are **sensitive to price differences** and strongly influenced by unusual prices in offers when making the decision to purchase an electric or electronic good ⁵⁸. **Higher visibility in prices** (such as through e-commerce or websites facilitating price comparison) only serve to make this sensitivity stronger. Furthermore, consumers find it easy to compare across electronic and decisions are often not need-dependent. This means that a consumer faced with similarly priced products will easily choose based on an outstanding characteristic. For example, when faced with televisions of different screen sizes, a consumer is almost always likely to choose the larger screen, regardless of the original need. In conclusion, when choosing a consumer electronic, consumers are likely to look firstly at price and be easily swayed by 'extra's' in a product that they were not originally looking for.

A global survey⁵⁹ found that the top priorities for consumers when choosing a tech product are product performance and reliability. Safety did not come out as a top priority for consumers, but based on the stakeholder consultations, it seems that product safety is assumed, and therefore not a conscious consideration when making purchasing decision. In the global survey, when asked about safety concerns for tech products, consumers expressed that they are firstly concerned about emissions, secondly about wireless radio waves and only after that about electric shock. The survey also found that there is not a lot of trust on manufacturers. Despite not putting safety as a main concern, 42% of consumers believe manufacturers of high-tech products value sales more than product safety.

Finally, **brand loyalty** is important for electronics, with the recognition of a brand being as large or larger of an influence on a consumer choice than descriptive information or information provided on a label.

⁵⁸ Real World Consumer Behaviour- Briefing Note 3: Consumer Behaviour and Electronics. EcoLogic (2009)

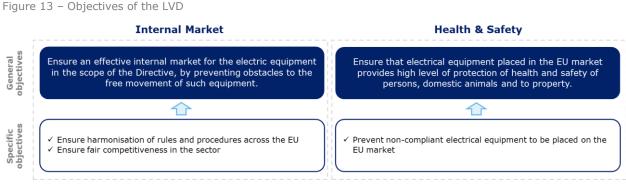
⁵⁹ The Product Mindset Survey (2013)

5. ANSWERS TO THE EVALUATION QUESTIONS

This chapter provides answers to the evaluation questions of each evaluation criteria: effectiveness, efficiency, relevance, coherence and EU added-value.

5.1 Effectiveness

This section presents the findings on the **effectiveness** of the LVD at the level of its core objectives, identified at strategic and specific level as presented in the figure below.



Source: European Commission – Terms of Reference

5.1.1 Objectives relating to the internal market

Heterogeneity in regulatory or procedural landscapes for specific goods across given countries are key barriers hindering the trade between these countries. In order to reap the full benefits of the internal market, the EU seeks to avoid discrepancies on technical product rules across Member States, thereby alleviating the costs for exporting economic operators and enhancing the potential for intra-EU trade. ⁶⁰ In this context, the general objective of the LVD is to ensure an effective internal market for electric equipment in the scope of the Directive. In other words, the overarching goal of LVD in this field is to ensure the free flow of such goods within the EU by preventing any barriers to their trade.

5.1.1.1 Harmonisation of rules and procedures across the EU

This section analyses the contribution of the Directive in harmonising the rules and procedures across the EU Single Market for the marketing and distribution of low voltage products.

Transposition and implementation of common rules and procedures

The LVD highlights a series of rules and procedures to be transposed by and implemented in all EU Member States, without exception, for the specific scope of products covered by the Directive⁶¹. These mandatory and common principles cover all aspects related to market access and are defined notably for:

- **The essential safety requirements:** all Member States are bound to align on the safety requirements for electric equipment described in the Directive, stricter or looser requirements are not permitted;
- **The free movement of electric equipment:** all Member States must allow economic operators to make available in their respective national market products that are compliant with the aforementioned requirements, their circulation may not be hindered;

⁶⁰ European Commission. (2019). Barriers to trade. Available at: <u>https://ec.europa.eu/growth/single-market/barriers-to-trade en</u>

⁶¹ See sections 3.2 for the definition of the Directive's scope and 1.1 for a discussion on its relevance.

- The obligations of economic operators: all Member States will impose the same obligations on economic operators making electric equipment available in their respective national market, fewer or additional obligations may not be considered;
- The presumption of conformity: all Member States have to regard as complying any products that have been manufactured against harmonised standards- thereby promoting the use of such standards⁶²; or in their absence, against international standards; or, in their absence, national standards. Similarly, all Member States will consider as lawful, and therefore, allow on their national market, any products with EU declarations of conformity and CE markings that are drawn up and apposed as specified in the Directive.
- The market surveillance: all Member States must carry out evaluations of products available on national markets whenever there is sufficient reason to believe they are uncompliant with the Directive.

As there are no infringement procedures⁶³ in relation with the Directive it can be concluded that it has been effectively transposed and implemented at Member State level, meaning that all 28 EU Member States have correctly translated these common rules and procedures into national legislation, and abide by these (Please refer to Annex M for the list of national transposition measures). This is also confirmed through the stakeholder consultation activities carried out as part of this study, as presented below.

While the way in which the LVD has been transposed into national law may differ, e.g. some countries (such as Finland) have incorporated these into existing law(s) while others (such as Germany) created new instrument(s), the evaluation team has found no evidence of discrepancies in the way Member States and related competent authorities have interpreted/ currently interpret the objectives and rules laid out by the LVD. In this respect, all types of stakeholders, including economic operators and standardisation bodies, Member States, and consumer organisations, highlight the rather generic but clear formulation of LVD's essential requirements, which leave no room for (mis-)interpretation, as they simply refer to 'safety'⁶⁴. Stakeholders interviewed explain these cannot be understood in any other way than: 'a piece of electric equipment falling under the scope of LVD has to be safe, i.e. no risks can be associated to the product or its use (under intended or predictable conditions of usage).

Based on the interviews conducted with all types of stakeholders at both EU and national level, there appears to be very limited to no excess norms, guidelines and procedures, or, in other words 'gold plating' in any of the 28 Member States (including at national, regional or local level): legislators at national-level seem to have integrated rules stemming strictly from the LVD - and only from LVD.

Regarding difficulties to apply the Directive in practice, 85 of the 116 manufacturers that responded to the stakeholder survey declare facing no or issues to a limited extent⁶⁵, this statement is valid irrespective of the size of the businesses as presented in the figure below. Similarly, the majority of manufacturers (90 out of 116) reported no issue related to the cross-border implementation of the Directive.

Out of those who mentioned having some issues, only three mentioned that some Member States lay down additional requirements for electronic products allowed in their market, hindering free market and competition. Examples include notably: acceptance of test reports carried out by specific third party certifiers only or Notified Bodies, acceptance of products manufactured according to certain national standards only.⁶⁶ Other comments provided with regards to issues across Member States related to a lack of convergence in market surveillance approaches and communication

⁶² The effects of harmonised standards on the effectiveness of LVD is discussed further down in the section. ⁶³ See online database of infringement decisions: <u>http://ec.europa.eu/atwork/applying-eu-law/infringements-</u>

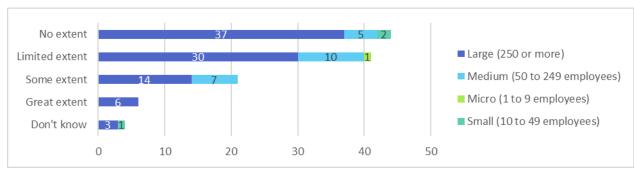
proceedings/infringement decisions/?lang code=en 64 EU-level and fieldwork interviews carried out for the study.

⁶⁵ Out of the 27 economic operators having reported facing issues to some or great extent, 18 provided further insights through comments. Overall, the main concerns are related to the overlaps with other legislation such as the Radio Equipment or Machinery Directive, which will be further discussed in section Error! Reference source not found.

⁶⁶ See section **Error! Reference source not found.** for more information on overall coherence of the Directive.

between market surveillance authorities across the EU. This is also in line with what emerged at the LVD Working Party Workshop: a trade association reported that, even with significant variances in approaches to surveillance in different Member States, the overall picture was clear enough to say that there are no major flaws that may harm the functioning of the Single Market. These elements will be discussed in more detail in section 5.1.2.4.

Figure 14 – Stakeholder survey/Manufacturers Q.9: "To what extent do you experience difficulties in applying the LVD?"



Source: Stakeholder survey

Finally, as presented hereafter, standards – harmonised, when available – appear to be the most used means to ensure the compliance for products, which also contributes positively to the harmonisation of rules and procedures across the EU.

Harmonised standards

By definition⁶⁷, harmonised standards allow to establish a code of conduct and good practice that is in line with the essential requirements of the Directive⁶⁸. In practice, economic operators following such standards in the manufacturing and/or marketing of low voltage products are thereby granted the presumption of conformity, as presented in section 4.1.2.2. In the case of LVD, 1018 harmonised standards have been listed in the Official Journal of the European Union (OJEU)⁶⁹.

The adoption of **harmonised European standards** is a key enabler with regards to the achievement of the internal market objectives. Similarly to European "EN" standards, harmonised "hEN" standards are to be implemented at national-level through corresponding national standards, and entail the withdrawal of any conflicting ones. This transposition at national level therefore clearly contributes to the removal of barriers to trade within the Single Market. This is also confirmed by the economic operators having replied to the survey who highlight the positive effects on the internal market as one of the main benefits of standardisation (c.f. section 5.1.2.2).

Though some criticism is encountered related to the speed of standardisation at EU-level in general – also beyond the evaluation at hand, the development of standards remains in fact a swifter and lighter procedure to harmonise rules and procedures than amending the Directive itself, which would require the launch of a full EU legislative process. In these respects, it is confirmed by all types of stakeholder groups consulted that standardisation is an effective means to ensure the adaptability of the Directive to market trends, including technological innovation and any related safety concerns.

⁶⁷ The International Organisation for Standardisation (ISO) and the International Electrotechnical Commission (IEC) define a standard as a "document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in given context". See: а https://www.cencenelec.eu/standards/DefEN/Pages/default.aspx

⁶⁸ Please note that the extent to which standards contribute to reaching the safety objectives of the Directive is discussed in section 5.1.2.2.

⁶⁹ European Commission Communication 2018/C 326/02. See: <u>https://eur-lex.europa.eu/legal-</u> content/EN/TXT/PDF/?uri=uriserv:OJ.C .2018.326.01.0004.01.ENG

As mentioned above, there are some discussions on the extent to which there is room to improve the overall speed of the standardisation process in the EU. These concerns are notably discussed in detail in the 2015 Review of the European Standardisation System (ESS).⁷⁰ When looking at standardisation activities for the LVD in particular, economic operators expressed the need for further procedural simplification and underlined the importance of fast publication of standards in the OJEU.⁷¹ These claimed inefficiencies would have negative impacts on both the functioning of the internal market and the safety of products: the current length of the procedure would delay the launch of new products for those manufacturers who aim to prioritise the use of standards, while simultaneously leaving *no other choice* to innovation leaders than to deviate from them. It should be noted that the crucial element for the latter case, is the sense of *obligation*. It will be discussed later that the *possibility* to deviate i.e. the voluntary characteristic of standards, is to be considered as a positive element guaranteeing the flexibility of the Directive and its applicability to new products/technologies.

While the 2015 report acknowledges that the ESS framework would in theory allow to enhance the timeliness of the overall standardisation procedure – which is one of its core objectives, it also highlights that the system's inclusiveness could suffer from increased rapidity: "*small players (SMEs or stakeholder representatives) may encounter more difficulties in participating in a faster process, as their involvement is limited by the time and the financial resources available. They would therefore not necessarily be able to cope with a faster standard development process and to participate with the required intensity in the development of standards. Increasing the speed of the process, in general, could therefore increase the risk of undermining the development of standards backed up by a high level of consensus."⁷²*

As referred to above, another element of discussion is the voluntary characteristic of standards, which was particularly put forward by standardisation bodies and business representatives as the pivotal element ensuring that the LVD does not hinder innovation.

With this regard, it was mentioned by the industry representatives during interviews, and acknowledged by Member States representatives during the workshop, that recent policy developments including European Court of Justice case law may question this element. Indeed, since the James Elliot judgment⁷³ some stakeholders feel the use of standards has implicitly become mandatory.

In such a context, a participative and consensus-based approach to standardisation at EU-level is ever more crucial. However, while in theory the delegation principle ensures that any stakeholder may participate in standardisation committees, it appears from interviews carried out as part of the study that in practice, this may be hindered by a lack of resources, notably for SMEs, as presented in the next subsection.

As a conclusion, voluntary harmonised standards appear as an effective tool to implement common rules and procedures for electrical equipment in the scope of the Directive throughout the EU, while ensuring the essential safety requirements are met and innovation is stimulated. Further research is

⁷⁰ These elements are discussed in-depth in the European Commission report "2015 Independent review of the European Standardisation System". See:

http://ec.europa.eu/DocsRoom/documents/10444/attachments/2/translations/en/renditions/pdf

⁷¹ One manufacturers stated that: "The standardisation work in Europe is mainly adoption of global standard to EU regulation. For 2 years, the time spent in committees is consumed purely on trying to answer the concern of the European Commission during the new approval process decided after the Elliott court case. It represents a high cost in term of human resources compared to the result. This process is inefficient and is counterproductive from a product safety perspective".

⁷² European Commission report "2015 Independent review of the European Standardisation System". See: <u>http://ec.europa.eu/DocsRoom/documents/10444/attachments/2/translations/en/renditions/pdf</u>, p.59

⁷³ The James Elliot Construction case C-613/14 referred to harmonised standards as part of EU law (See: http://curia.europa.eu/juris/liste.jsf?language=en&num=C-613/14)

required to determine whether in the specific context of the LVD, the aftermath of swifter standardisation activities at EU-level would bring about positive or negative results.

5.1.1.2 Functioning of the internal market for low voltage products

The stakeholder survey provides a positive feedback relating to LVD's contribution to a well-functioning internal market: 9 out of 12 national authorities having replied to the survey indicated that the facilitation of the functioning of the internal market, alongside the protection of health and safety are the Directive's main benefits, and rated these as 'high'⁷⁴. Similarly, the four consumer organisations also replied positively to a question about LVD's contribution to intra-EU exchanges. More specifically, 2 consumer organisations reported that intra-EU exchange of goods was facilitated to a "great extent", the other two to "some extent".

While these stakeholder groups i.e. national authorities and consumer organisations, were merely represented in the stakeholder survey, such views were also confirmed during the EU- and national level interviews. The Directive unanimously was referred to as a strong and stable act aimed at harmonising the landscape for the marketing of electric equipment in its scope. Specifically as regards its 'strength' it was underlined that the Directive allows to make available on the market or to recall/withdraw a given conform or non-conform product in one go throughout the EU, while still preserving the right for Member States to raise objections against a measure taken by another Member State⁷⁵.

As regards economic operators, the majority of manufacturers, importers and distributors having taken part to the survey share this opinion: when requested to list the main advantages of the LVD, "improved access to all EU markets" was often acknowledged by these types of stakeholders. Importers and distributors that replied to the survey also reported no significant issues related the LVD when importing/distributing products within the EU, with 8 out of 10 reporting "minor" or no problems at all. Further, 90 out of the 116 manufacturers reported that the LVD facilitates these exchanges to at least some extent, with the majority (69) being satisfied to a great extent; these opinions are aligned across SMEs and large corporations. Out of the 116 manufacturer respondents, only four considered that the LVD does not facilitate EU trade in any way⁷⁶. These overall positive findings are also confirmed by the low voltage product market analysis presented in section 4.1.1, which shows a stable but positive increase of intra-EU trade in low voltage products in the past 20 years.

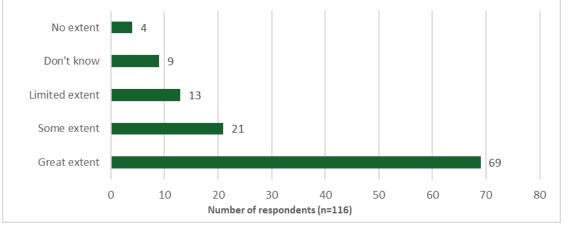


Figure 15 – Q10 manufacturers: "To what extent do you think that the LVD facilitates intra-EU exchange?"

Source: Stakeholder survey

⁷⁴ Two other authorities rated the benefits related to the internal market as 'moderate' and one did not provide any rating (Don't know).

⁷⁵ Art 20 §1 of the Directive.

⁷⁶ These replies were not substantiated further through comments.

It should be noted, however, that market surveillance is unanimously pointed out as a difficult issue for the LVD, as practices and intensity of market surveillance activities differ across the EU, notably due to budgetary reasons. Further, some national authorities interviewed believe this would lead to the creation of '*markets within the internal market'*. By this, it is meant that those Member States in which market surveillance activities are perceived as abundant and more stringent compared to other countries would deliberately be left aside by some economic operators – who may be doubtful about the compliance of their products. The marketing of those – possibly uncompliant – products would therefore be concentrated in certain countries only, thereby restricting the free flow of products throughout the EU and the potentially disrupting the safety landscape in certain countries.

An in-depth research into the low voltage product market, the types, origins and (non-)compliance of products and their distribution across the Single Market should be carried out to see whether any patterns arise, before being able to conclude on the actual existence of such biases in the market. These should also be cross-checked against the economic operators' pure business coverage/expansion strategies in place, which should be filtered out of the analysis.

The existence of such 'markets within the internal market' would definitely hamper the effectiveness of the LVD as regards its objectives. Nevertheless, as market surveillance is separately legislated outside of the LVD, the evaluation team does not consider this an element that can be directly attributable to the Directive as such. It should rather be regarded as an external issue related to the capacity of all EU Member States to ensure effective market surveillance, which consequently represents an external factor affecting the enforcement of the Directive in practice (more details will be provided in section 5.1.2.4 as this matter also influences the achievement of health and safety objectives). In this sense, the LVD itself can be concluded as an effective means to facilitate the functioning of the internal market, as further presented in the two subsections below that assess its performance as regards:

- Harmonisation of rules and procedures across the EU: on the one hand, the goal of the Directive is to align the regulatory and procedural organisation of all EU Member States for making electrical equipment in its scope available on the internal market. This is notably done through the adoption of harmonised standards entailing the presumption of conformity.
- Level playing field among economic operators: on the other hand, the goal of the Directive is to provide a level playing field for all economic operators willing to access and/or active within the EU low voltage market⁷⁷.

It should be noted that the first element provides a favourable ground for the latter. Indeed, harmonised rules facilitate the elimination of barriers for economic operators.

5.1.1.3 Level playing field among economic operators

A level playing field is characterised by fairness of competition among economic operators i.e. equal conditions and opportunities for all players, irrespective of their size⁷⁸. Besides EU competition rules, sector-specific instruments such as the LVD strive to enhance such features, notably by removing barriers to competition through the harmonisation rules and procedures as described above.

As discussed in the previous section, the Directive has been transposed at national level without discrepancies in interpretation or gold-plating: the common rules established by the LVD are therefore applicable to any economic operator in a consistent way across the EU. This is further confirmed by the fact that all 38 industry-related stakeholders interviewed as part of this study⁷⁹ are aware of the existence of the Directive imposing requirements in terms of safety and promoting the use of (harmonised) standards.

⁷⁷ The EU low voltage market as understood throughout the evaluation is defined in section 4.1.1.

⁷⁸ European Commission. (2019). Preserving and promoting fair competition practice. Available at: <u>https://europa.eu/european-union/topics/competition en</u>

⁷⁹ Including small and large businesses throughout the value chain, industry associations, Chambers of Commerce, etc. See section 2.1 for more details on the type of stakeholders consulted.

In addition, both national authorities and industry representatives interviewed agree on the fact that the freely available 'Low Voltage Directive 2014/35/EU Guidelines'⁸⁰ (LVD Guidelines) are providing useful material to further clarify the understanding of the Directive and its provisions. The aforementioned elements therefore suggest that there is no disadvantaged or privileged access to information that would render the application of the Directive more or less difficult for some economic operators (or national authorities).

The previous sections also presented the views of surveyed economic operators as regards the implementation of the LVD at national-level and in cross-border cases. When looking at the distribution of these findings by size, type and origin of economic operators⁸¹, no significant discrepancies are noted.

In practice however, while they are not mandatory as per the Directive, equal access to both the development and the use of (harmonised) standards should be further analysed in the case of smaller companies due notably to the overall cost they represent. Moreover, it should be noted that international standards – based on which harmonised standards are also usually developed – are updated more often than standards at national level, and that following the hierarchy induced by the Directive (c.f. section 4.1.2.2), the economic impact of the related product updates should also be accounted for. All other things being equal, a standard update for a given product will be relatively more costly for a small than a large player.

Indeed, beyond the activities related to their development, the utilisation of (harmonised) standards not only entails the financial cost⁸², but also investment in terms of time and human resources for their understanding and application. The affordability of (harmonised) standards is therefore relative and different across economic operators i.e. businesses may not all face the same opportunities in applying (harmonised) standards. In fact, overall resources being more abundant in large corporations than in SMEs, and, the cost of a given (harmonised) standard being fixed, its relative burden on resources will usually be higher for smaller corporations than larger ones, and vice versa.

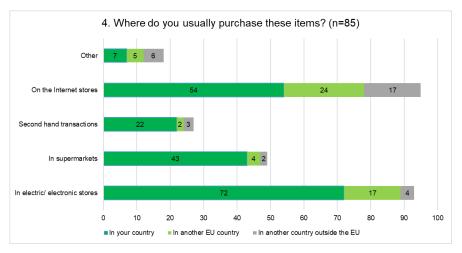
Similarly, the impact of extra-EU competitors reaching their consumers via online sales may also be considered as a factor undermining the achievements of the Directive related to fair competition. Indeed, through e-Commerce, consumers receive products directly (at home) meaning these do not transit by the shelves of stores within the internal market, and therefore, are not in the radar of the usual market surveillance inspections. The OPC confirms that online sales are considered as frequently (even slightly more) than physical store purchases, as presented in the figure below. Though overall, OPC respondents seem to prefer buying low voltage products in their countries or at least in the European Union, 17 out of 85 respondents stated buying these online in another country, outside the European Union.

Figure 16 – OPC Q5. Purchasing habits

⁸⁰ See : <u>https://ec.europa.eu/docsroom/documents/31221/attachments/1/translations/en/renditions/native</u>

⁸¹ The complete survey analysis is presented in Annex C.

⁸² Based on interviews with economic operators and standardisation bodies, it appears the price of one standard can vary from \leq 400 to \leq 1000. One product usually entails the use of multiple standards (actual number depends on the type of product and cannot be estimated), i.e. the purchasing of several standards.



Source: Open Public Consultation

The table below summarises the extra-European countries were low voltage items were purchased in the past two years. The most quoted countries were the Asian ones, China in particular, and the US.

Table 6 – OPC Q5. Foreign countries where low voltage products were purchased in the past two years

| 5. If you have ticked any option in 'in another country outside the EU' for the question above, please specify in which country/countries: | | | | |
|--|----|--|--|--|
| China | 14 | | | |
| Korea | 2 | | | |
| US | 7 | | | |
| India | 3 | | | |
| Switzerland | 2 | | | |
| Taiwan | 1 | | | |
| Japan | 1 | | | |
| New Zealand | 1 | | | |
| Norway | 1 | | | |
| Singapore | 1 | | | |
| Canada | 1 | | | |

Source: Open Public Consultation

In a nutshell, the LVD is considered to significantly contribute to the removal of trade barriers within the EU, thereby working towards levelling the playing field for all economic operators. The impact of two key elements, the accessibility of standards and the fairness of extra-EU competition should however further analysed in-depth, as these have the capacity to cast a shadow on the Directive's performance in this area. Both these aforementioned elements are also discussed in section 5.1.2, alongside concerns regarding the heterogeneity of market surveillance activities ('markets within the internal market') as external factors affecting the achievement of the Directive's health and safety objectives.

5.1.2 Objectives relating to health and safety

Alongside the establishment of an effective internal market for electric equipment in the scope of the Directive, the second general objective of the LVD is to provide a high level of protection of health and safety of persons, domestic animals and property. This section first provides an overview of the

evidence available on the level of safety in the EU. Then, it discusses the various elements of (or related to) the Directive having (in-) direct impacts on safety, namely: the compliance with essential safety requirements through standards, the conformity assessment procedure and market surveillance.

5.1.2.1 Safety analysis of the EU low voltage product market

RAPEX aims to enable a quick exchange between 31 countries and the European Commission on measures taken against dangerous non-food products posing risks for the health and safety or environment or any other aspect of public interest for protection of persons. It should be noted that the data submitted to RAPEX depends on surveillance and reporting practices as well as their frequency, which vary both between countries and between years for a given country. Therefore, RAPEX data is neither comparable across Member States, nor representative of the actual safety level in the EU. However, the data is used below to identify indications on equipment which tends to be most involved in cases of dangerous products, as well as on their most recurrent origin.

RAPEX includes more than 18 000 alerts overall⁸³. The database does not use a commonly recognised statistical categorisation of products. Therefore, it is not possible to link the alerts on products immediately to the product groups used in the market analysis presented in section 4.2.

Following a filtering of the RAPEX data based on a 'risk of non-compliance with the LVD', it appears that 3 223 alerts had been filed between 2005 and 2008. Among these products, 76% of the products reported originated from China across the years. From 2009 onwards, the share of reported LVD products originating from China has remained in the range of 79% to 89% each year. As discussed in section 4.2.3 China is the EU's largest trade partner of LVD products, which partially explains the prevalence of unsafe Chinese products reported in RAPEX.

The most commonly reported risk types in RAPEX are the risk of electric shock (65% of all alerts in 2005-2017), the risk of fire (5%), and the combination of the two (17%). Other types of risk reported include choking, cuts, burns, damage to sight, chemical, drowning, suffocation/asphyxiation, and unspecified injuries and health risks.

The most commonly reported RAPEX category is *electrical appliances and equipment* (55% of alerts over 2005-2018), which includes equipment such as small kitchen appliances and home electronics, cables, chargers and adapters, and hand tools. As the type of equipment is manually entered, doing precise calculations per equipment type is practically impossible due to different ways of entering the same type of equipment (e.g. different spellings and misspellings, inclusion or non-inclusion of the specific brand, plural or singular form, use of quotation marks, etc.).

However, the most commonly appearing equipment include *chargers* (including 'battery chargers', 'USB chargers' and others), power supplies/power supply units, extension leads, and travel plug adaptors. The second most common category is *lighting equipment* (26% of the alerts in 2005-2018). Among the most common types of equipment in this category are 'LED floodlights', 'table lamps' and 'LED lamps'. The third most common category is *lighting chains*⁸⁴ (13% in 2005-2018).

According to the market surveillance reports, in the period 2014-2016, in Belgium, Bulgaria, Croatia, Cyprus, Norway and Sweden the majority of cases where a non-conforming equipment was found were solved by voluntary corrective measures by the economic operator. On the contrary, in Estonia,

⁸³ Referenced on 16 March 2019.

⁸⁴ This category covers equipment simply labelled as 'lighting chain' as well as 'Christmas lighting chain', 'LED lighting chain', 'lighting decoration', 'LED strip light', 'rope light', 'string lights', twinkle net lights', 'LED tape', 'lighting tube' and 'flexible light tube'.

Hungary, Poland and Romania, compulsory measures by market surveillance authorities were taken in the majority of cases. For Denmark and Spain this varied by the year⁸⁵.

As the RAPEX system is not designed to provide information on the actual level of safety in the EU (but to facilitate the exchange of information between the Member States), the evaluation team investigated product-related injury data too⁸⁶. In view of the limitations on the usability of the data provided by RAPEX for the purpose of this evaluation, the safety analysis is further complemented by the perception of stakeholders consulted as part of the evaluation. Overall, all stakeholder categories consulted (including both national authorities and consumer organisations) consider that electric equipment bought within the EU internal market is rather safe, and that the LVD has improved the safety of electrical products in the EU to a significant extent⁸⁷. The Directive is regarded as 'best practice' product legislation thanks to its clarity and long term stability.

In the same vein, the majority of all respondent groups, including 9 out of 12 authorities, considered the main benefits deriving from the LVD related to health and safety protection to be 'high' (on a four-point scale from low to high). Similarly, 3 out of 4 consumer associations having replied to the survey reported that the Directive had improved the safety of the low voltage products available on the market at least to 'some extent'. Regarding economic operators, 18 out of 26 SMEs reported an improvement in the safety of electrical products thanks to the LVD to a "great" or at least to "some" extent. The figure is even higher for large companies (77 out of 90) but the overall trend is confirmed and not significantly affected by the size of the company. Unfortunately, stakeholders not sharing this opinion did not provide comments to substantiate their thoughts, apart from some medium-sized manufacturers as presented below:

- Manufacturer, medium-sized: 'Don't know': "We always applied Good engineering practice"
- Manufacturer, medium-sized: 'Limited extent': "The LVD is poorly enforced. There is an increasing number of mail-order products from non-EU countries that are unsafe."
- Manufacturer, medium-sized: `Don't know': "I'm not sure what was in place previously so can't say it has been improved"

Importers and distributors appear to agree on the high guarantee of safety ensured by the LVD provisions with manufacturers though to a lesser extent, as most replies were gathered in the 'some extent' category (4 out of 10 versus 3 out of 10 for 'great extent'). Only one importer reported that the LVD contributes to safety only to a limited extent. However, it should be noted that 10 cable manufacturers' associations reported LVD limited success in improving health and safety of electrical products sold in the EU market advocating for a better compliance to product standards. Also, another industry organisation highlighted again the problems of safety compliance of goods imported from third markets.

The analysis of the OPC highlights somewhat more concerning results in terms of LVD's effectiveness in ensuring the safety of products: 24 out of 93 respondents⁸⁸ affirm they have been involved in a risky situation with an LVD product. The dangerous products were various, such as toys, electric kitchen utensils, adaptors, etc. Situations in which instructions were not included or the CE marking was missing were also described.

National authorities participating in the stakeholder survey⁸⁹ were also asked to provide some information from their perspective on the numbers of non-conforming equipment. According to them, 'electric lighting equipment' is the category most commonly found to be non-compliant, followed by electric domestic appliances and consumer electronics. Figure 17 below displays the numbers in more

⁸⁵ Country reports on the functioning of market surveillance activities, available at: <u>http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation_en</u>.

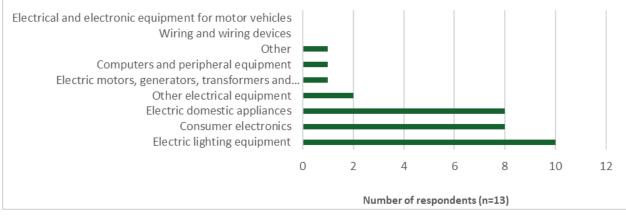
⁸⁶ A description of the regulatory systems in place in third countries for electrical equipment in the scope of the LVD is provided in Annex P.

⁸⁷ EU-level and fieldwork interviews warried out in the context of this evaluation; LVD Working Party workshop. ⁸⁸ The OPC did not allow to differentiate the respondents per type of stakeholder.

⁸⁹ Only 13 national authorities took part to the stakeholder survey.

detail. It should also be noted that in RAPEX the most commonly reported category of equipment is *electrical appliances and equipment* (55% of alerts over 2005-2018), which includes equipment such as small kitchen appliances and home electronics, cables, chargers and adapters, and hand tools.⁹⁰ In the same vein, according to the authorities having replied to the survey, electric lighting equipment, electric domestic appliances and consumer electrics are also the items most commonly recalled from the market.





Source: Stakeholder survey

National authorities were also probed with regards to the annual number of fatal incidents related to the products in the scope of LVD in their respective countries. It should be noted that the lack of data is an issue for public authorities, in particular as regards the number of fatalities registered: indeed, 6 out of the 9 respondents to this question reported not having such data.⁹¹ However, while two out of 13 authorities reported between 0 to 5 fatal incidents, only one public authority reported more than 5 fatalities linked to the LVD products.

As a matter of conclusion, the evaluation team notes that while the perception of both Member States authorities and consumer organisations is rather positive about the level of safety of low voltage products in the EU, there is still quite some room for improvement in this area.

5.1.2.2 Compliance with essential safety requirements through standards

Standards have been widely reported as being the preferred method for ensuring the compliance of electrical equipment, both in quantitative (i.e. it is the most used) and qualitative (i.e. it is the most preferable) terms. This was unanimously underlined by types of stakeholders consulted as part of this study, including consumer organisations, national authorities, business associations and economic operators, including standardisation bodies. All types of stakeholders highlight the capacity of standards to ensure the convergence, throughout the EU, of state-of-the-art practices guaranteeing the safety of low voltage products, notably by formalising the essential safety requirements of the Directive that may be considered very generic and succinct.

During the interviews carried out with the 38 business-related stakeholders consulted as part of this evaluation, standards (mostly harmonised and international) were unanimously mentioned as being the most leveraged means for economic operators to manufacture compliant products. The benefits linked to the presumption of conformity offered by the use of standards is considered to strongly outweigh their economic cost⁹². Indeed, it has been reported by economic operators, industry

⁹⁰ See section **Error! Reference source not found.** for analysis of RAPEX data comparability.

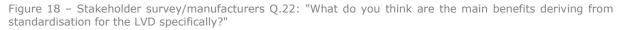
⁹¹ For example, the UK was unable to provide disaggregated data for fatalities and incidents.

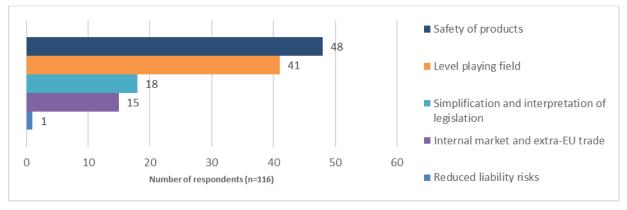
⁹² The overall costs (and benefits) of the Directive will be discussed in detail in section 5.2.

associations and standardisation bodies that deviations from standards occur very rarely. Industry associations actually mention there is an implicit rule in the sector: 'if there is a standard, use it'.

Generally, deviation from standards happens only when a standard does not exist (yet), which in turn is usually due to the fact that a product is very specific or new to the market. In such cases, manufacturers interviewed report that existing standards are used as 'inspiration' to the extent possible in order to leverage 'best practices'. This again underlines the importance of the voluntary characteristic of standards with regards to innovation and new product development.

In the same vein, the 116 manufacturers having replied to the stakeholder survey, highlight a number of benefits related to the use of standards. These include namely: ensuring the safety of products (48x⁹³), providing a level playing field in the EU (41x), allowing for the simplification and easier interpretation of the legislation (18x), enhancing the Internal Market and extra-EU trade (15x) and reducing liability risks (1x). Some manufacturers commented that the LVD is "*Defining clear & detailed rules for certain product categories to enable a level play[ing field] in the common market"* and also "*A simple directive and well-designed standards, drafted by experts, creates safe products and a level playing field"*.





Source: Stakeholder survey

Though standardisation activities are mostly industry-driven, dedicated organisations represent the interests of European consumers during technical committee meetings. In relation to this, consumer organisations positively welcome the 2014 version of the Directive, going from considering only the *intended* use of products⁹⁴ to also including their *reasonably foreseen* utilisation by end-users. In essence, this modification within the Directive improves the capacity of standardisation committees to develop standards that effectively mitigate the risks induced by low voltage products, by covering a wider range of possible (mis-)uses of the products in scope.

The consumer organisations having replied to the survey indicate as one of the highly-ranked benefits the opportunity to play an active role in setting standards, as well as to timely modify standards to ensure the safety levels required by the Directive are reached. One comment received from a consumer organisation included notably the following: "We can influence the standards. Standards affect us all every day and everywhere, contribute to economic growth and address societal needs. For consumers, standards are important as, when they are properly developed and applied, they can make our lives easier; the products we buy safer, interoperable and accessible to people of all ages and abilities. They can also improve product performance and help reduce environmental impacts. Moreover, standards can aid the quality and safety of services."

⁹³ Number of times a reply corresponding to the benefit was provided by the responding manufacturer.

⁹⁴ Directive 2006/95/EC refers to "[electrical equipment] installed and maintained and used in applications for which it was made"

Nevertheless, without effective consumer representation in the writing of standards, products need not be as safe, as interoperable, as accessible or as green as they might be. Knowingly or not, the position of business interests in the development of standards (industry dominates the standardisation process for LVD products) can undermine the broader consumer interest. However, consumer expertise at national level is scarce or non-existent in many countries and the role of [X], as the collective voice of European consumers in standardisation, is therefore also crucial in influencing the content of standards so that all consumers can benefit from their use. [X] ensures the consumer voice is heard in the setting of standards for products (and services), as well as in the shaping of laws and public policies."

Market surveillance authorities also underline the utility of standards as providing a benchmark and/or guiding principles to assess the conformity of a product in the context of product audits.

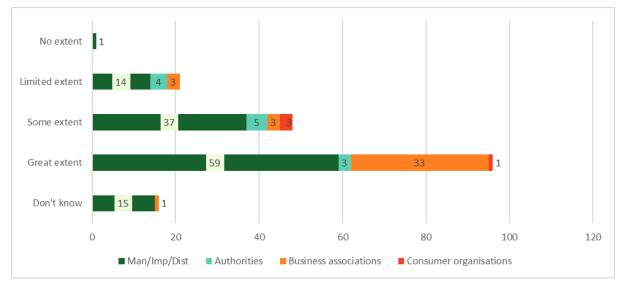
5.1.2.3 Conformity assessment procedure: Module A and absence of Notified Bodies

Based on the national-level interviews, the stakeholder survey and the LVD Working Party Workshop, it appears that overall, the current conformity assessment procedure (Module A, as provided by Annex III of the Directive) is rather positively regarded and considered to fulfil expectations related to ensuring safety of LVD products in a flexible and cost-effective way. Manufacturers consider themselves to be best placed to assess the risks related to their electric equipment; for them their . internal production control is effective and sufficient to ensure the safety Opinions by national authorities and consumer organisations are more nuanced. In particular 3 out of 4 consumers' organisation stated that conformity assessment procedures guarantee safety of electrical products only to "some extent".

8 out of 11 market surveillance authorities having replied to the survey consider Module A as safetyenabling to some or to a great extent. Comments received included notably the following notes from market surveillance authorities:

- MSA: `limited extent': ``Manufacturers (China!) do not always follow these procedures. Too complex? Too expensive?"
- MSA: `limited extent': `Conformity assessment could be according to the risks the products presents similar to Personal Protective Equipment legislation"
- MSA: 'limited extent': "Model B and H of the conformity assessment procedures should be included in the LVD Directive, because there are safety aspects involved wich come with a higher risk profile."

Figure 19 – Stakeholder survey: "To what extent do you think that the tool of the conformity assessment procedures, as provided by the LVD 2014/35/EU, is sufficient and appropriate to guarantee the safety of electrical products?"



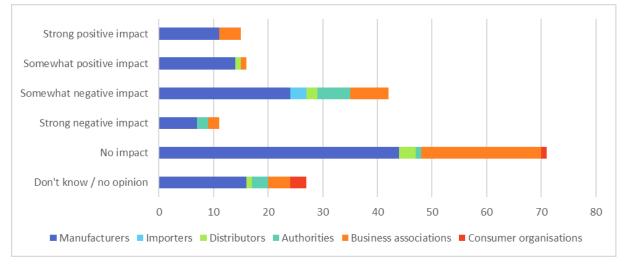
The effectiveness of Module A, as well as the absence/removal of Notified bodies was also one of the major topics specifically addressed during the LVD Working Party Workshop.

Before going over the different viewpoints on these matters, it should be reminded that Notified Bodies were indeed included in the original version of the Directive, though not in the 'traditional' way i.e. to carry out conformity assessments before placing the product in the market. They acted as third party 'referees' in the context of evaluations, recalls or withdrawals of (un)compliant products by market surveillance authorities, when economic operators would disagree with the actions of Member States. Thus, the previous role of Notified Bodies within the framework of the LVD did not have a direct impact on the process of placing products on the internal market, but rather a role related to arbitration.

On this specific change of the Directive, neither the EU-level and fieldwork interviews, nor the LVD Working Party Workshop did bring about any concerns.

However, more diverging views are presented in the stakeholder survey as highlighted in the figure below: one consumer organisation stated that the removal of Notified Bodies has a strong negative impact on safety (whereas the other three having replied to the survey did not have any opinion on this). Similarly, national authorities having replied to the survey have the most negative view of all stakeholder categories: none of them reported a "somewhat positive" or "positive impact" related to the absence of Notified Bodies, whereas eight out of twelve consider their removal as having at least a 'somewhat negative' impact. Unfortunately, none of the stakeholders expressing negative opinions in the stakeholder survey provided a comment to better explain their perspectives.

Figure 20 – Stakeholder survey Q14 "Since the LVD 2014/35/EU, the notified bodies are not anymore part of the procedure. What do you think is the effect of the current absence of notified bodies?: Concerning safety of products"



Coming back to the discussion on the adequacy of Module A during the LVD Working Party workshop, from the point of view of authorities, there was a consensus on the fact that re-integrating Notified Bodies into the conformity assessment procedure should not be an goal in itself, but done as a means to increase low voltage product safety within the EU. In turn, it was underlined by national authorities present at the workshop that the latter should be demonstrated by a thorough cost-benefit analysis.

Consumer organisations present at the workshop (and interviewed as part of other data collection efforts) welcomed the current conformity assessment procedure highlighting, however, that in order to further enhance the current level of safety in the EU market, Module B, involving a Notified Body, could be made available and/or in certain instances mandatory under the Directive, as for example proposed in the box below. This is also in line with the comments received from national authorities outlined above.

The underlying idea is that (1) some (new/innovative) products may still pose a significant threat to end-users and the product should therefore be cleared by a third party organisation rather than the

manufacturer itself, and (2) that some economic operators, including SMEs (also supported by two national authorities present at the workshop), may be willing to *de facto* have recourse to Module B for all types of products, regardless of the risks they may represent, as they would rather rely on the expertise of a Notified Body in conducting the actual conformity assessment. In this second case, Notified Bodies are seen as a source of support and guidance for SMEs struggling with the conformity assessment procedure, or in cases of conflicts with Market Surveillance Authorities.

Such supportive role was also confirmed as beneficial through the stakeholder survey by manufacturing SMEs, importers and distributors. In particular, it was mentioned that for certain SMEs, it might be difficult to have the required technical expertise to demonstrate compliance, especially when developing innovative products which require a mix of different technical requirements. Further, even though there is not much information and consensus on the real impact of the provision (and how much it is strictly perceived as a "collateral effect" of the LVD), importers and distributors seem to be more worried about the impact that the absence of notified bodies might have had on the safety of products than the manufacturers, with 5 respondents reporting a "somewhat negative impact". On the other hand, this provision is seen as a possibility for the industry to reduce costs.

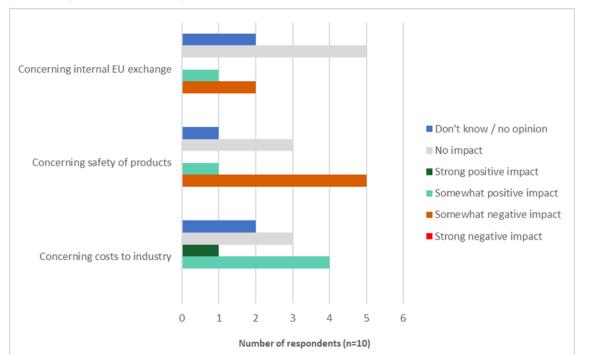


Figure 21 – Q15 Importers and distributors: "Since the LVD 2014/35/EU, the notified bodies are not anymore part of the procedure. What do you think is the effect of the current absence of notified bodies?"

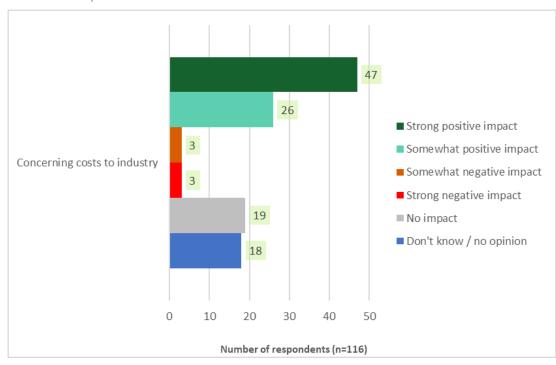


Figure 22 – Q14 manufacturers: "Since the LVD 2014/35/EU, the notified bodies are not anymore part of the procedure. What do you think is the effect of the current absence of notified bodies?"

The box below summarises the main elements of criticism reported as regards the clarity of economic operators' duties in ensuring the safety of products, including the current conformity assessment procedure. These emanate from all types of stakeholders consulted as part of this study, i.e. from economic operators themselves, as well as national authorities and consumer associations.

Box 3 – Shortcomings of current LVD provisions with regards to safety

For all stakeholder groups consulted (including national authorities, consumer organisations and economic operators) the majority of respondents and/or interviewees presented positive feelings as regards the LVD's contribution to safety of electric equipment in the EU market. However, some improvement opportunities regarding practical features of the Directive were mentioned across all stakeholder groups, which would allow to further improve the safety of low voltage products made available in the internal market:

- **Conformity assessment procedure:** all types of stakeholders noted that within the conformity assessment procedure (Module A), it may not always be clear for economic operators when there is a need for risk assessment and how to carry it out, which can compromise its implementation. In addition, some stakeholders, notably consumer organisations, may wonder whether all products should have the same procedure, or whether a distinction between risk-levels (e.g. the current self-certification for low-risk products and third-party certification for products with higher risks) would be more appropriate to prevent accidents. The evaluation team provides an illustrative example of such approach below:
 - For products with low to medium risk levels, economic operators would be left with the choice of module A or B, as products in this category would not pose a serious and/or life threatening risk for consumers in any of their intended or reasonably foreseeable use.
 - For products with high risk levels, economic operators would have to use Module B only, as products in this category may pose a serious and/or life threatening risk for consumers in some of their intended or reasonably foreseeable use.
- **Quality of technical documentation and safety instructions:** national authorities observed that translations may be of insufficient quality to be fully understandable for

consumers. It was suggested that in some of such cases, inaccuracies and incorrect wording may lead to products being recalled or withdrawn from the market. It was also explained by national market surveillance authorities that incidents may often be related to the misuse or mis-maintenance of the products by the end-users, thereby underlining the importance of clear and understandable safety instructions.⁹⁵

In this vein the OPC (see Annex I) also highlights that in particular, the combination of one page paper on safety aspect and the digital format for the entire manual of instructions were deemed the more useful and complete (43 out of 93 respondents), while the electronic/digital format and the paper format alone were considered enough to provide information on safety issues by 23 and 25 out of 93 respondents respectively.

• Labelling of products: both national authorities and consumer organisations mentioned that labelling of products, including those originating from extra-EU countries, may be unclear, especially in terms of manufacturer identification. This is confirmed by the OPC results (it should however be noted that only 41 out of 93 respondents replied to this question, further restricting the sample and therefore limiting the room for assumptions): even though the level of information provided by the manuals was generally deemed sufficient by the majority of respondents, it appears that often specific information are difficult to find or understand. As stated above, nearly 27 respondents were not able to find the contact details of the manufacturer, 22 could not identify the contact details of the importer, 16 did not find the serial number of the products and 15 the CE marking. In particular, it often emerged that safety information of instruction manuals are missing or incomplete, especially the ones related to products coming from extra European countries.

Economic operators interviewed state that including any other conformity assessment module than Module A, in other words, forcing the involvement of Notified Bodies, would increase the compliance cost on their end⁹⁶, without increasing the safety of products made available on the internal market. They argue that due to reputation and liability aspects, it would be in their own interest to place on the market only products that comply with the Directive's essential safety requirements: one could not expect to engage in prosperous business with products that bear the risk endanger their end-users, especially with the free flow of information enhanced by internet and social media. Businesses would therefore have sufficient incentives to strive for the safest products possible, without a mandatory involvement of Notified Bodies in the conformity assessment system.

In addition, it was mentioned that the involvement of Notified Bodies would in any case not improve compliance, as manufacturers willing to comply will do so in any case (following the reasoning presented above), while others – also referred to as '*black sheeps'* will always find their ways around the system. This point was also acknowledged by Member States' authorities present at the LVD Working Party Workshop: unlawful actors cannot be restricted on the "input" side, they should be caught up on the "output" end of the process, i.e. by market surveillance authorities themselves.

As underlined by Member States authorities, further analysis of the actual *need* to include Notified Bodies in the conformity assessment process as well as of the actual *impacts* of such inclusion should be carried out in order to be able to conclude with precision on this matter.

⁹⁵ For example in Finland, a series of incidents are commonly caused by the drying of textiles on electric-sauna stoves.

⁹⁶ Manufacturers interviewed at Member State level reported this would result in increasing the cost of the endproduct, which would be directly transferred to the customer due to the intensity of competition within the low voltage product market that already pushes the supplier surplus to the minimum. Further research should be conducted in order to identify evidence to substantiate this statement.

5.1.2.4 Market surveillance

Market surveillance for LVD has been highlighted as a key issue regarding the implementation and enforcement of the LVD, having impacts on both core objectives. It was noted that while in some countries the process works very well, and in good cooperation with economic operators, inconsistency across the EU is a challenge.

As the available budget for product audits within the national market depends on national political priorities, authorities in some Member States do not seem to have adequate resources to do sufficient testing (see table in Annex O for resources available in the countries covered during the fieldworks), especially as budgets have decreased in recent years in several countries. There are also clear differences between Member States, for the organisation of the market surveillance and in the intensity of market surveillance activities, but also, for example, in the punishment for violating safety requirements⁹⁷.

There was an overall consensus across all categories of stakeholders participating in the LVD Workshop that national budget constraints are a widespread issue across the EU (with the remarkable exceptions of Finland – see box below – and Denmark). This prevents national market surveillance authorities from performing sufficient in-depth product testing on a large scale, potentially highlighting a gap between formal compliance with the LVD and actual effectiveness of the safety provisions included in the Directive.

Because of these reasons, the safety of the products sold within the internal market thus can be compromised, as not all non-conforming products can be intercepted on time on the "output" end of the process. Further, it was mentioned by some national authorities that such discrepancies may create 'markets within the internal market' (c.f. section 5.1.1.1), thereby impacting negatively the effectiveness of the internal market of electrical equipment in the scope.

Another relevant issue which arose from the conversation about the varying levels of abundance of market surveillance activities with both economic operators and market surveillance authorities present at the LVD workshop, is the lack of cooperation and communication at intra-EU borders, also with customs authorities. Several stakeholders suggested there is a lack of efforts by market surveillance authorities in repressing fraudulent manufacturers of trying to sell non-compliant items at different national borders, after having already been rejected by the customs in one Member State. In this regard, it was also mentioned by both national authorities and economic operators that the absence of e-labelling and of an electronic registry for non-compliant products could possibly be favouring this phenomena. Lastly, the competition represented by extra-EU manufacturers been underlined as another aspect having possible negative impacts on both objectives of the LVD.

Market surveillance authorities interviewed and present at the LVD Working Party Workshop highlighted the risk that uncompliant products originating from outside the EU could not effectively be intercepted at before entering the internal market for multiple reasons: customs officers do not always have the relevant knowledge/training, their focus is on stopping undeclared, illegal and unlabelled rather than non-compliant products, and they do not have the capacity to examine the content of every shipment. Moreover, the pressure that EU Member States' authorities may apply on extra-EU manufacturers to address any incompliance on the product-safety side is limited due to their administrative and legal capacity.

- Administrative capacity: Member States authorities' limited resources would already restrict their actions as regards EU economic operators, therefore, contacting and following up with an extra-EU operator, in a foreign language and via postal mail, becomes rather ineffective and inefficient.
- Legal capacity: EU national authorities have no powers to legally penalise operators in extra-EU countries.

⁹⁷ European Commission and Member States : Review and assessment of market surveillance activities 2014-2016. Country reports available at: <u>https://ec.europa.eu/growth/single-market/goods/building-blocks/market-</u> <u>surveillance/organisation_en</u>

As previously mentioned, this also affects the fairness of LVD with regards to EU enterprises within the internal market. It was mentioned by both companies and national authorities interviewed that at the moment, (compliant) EU enterprises do not compete on a level playing field with extra-EU competitors, especially those active on e-Commerce platforms. Indeed, due to the shortcomings mentioned above, extra-EU competitors face fewer deterrents to incompliance that (compliant) EU enterprises, and therefore, are able to offer similar products at cheaper prices on the EU market.

Box 4 – Market surveillance activities in Finland

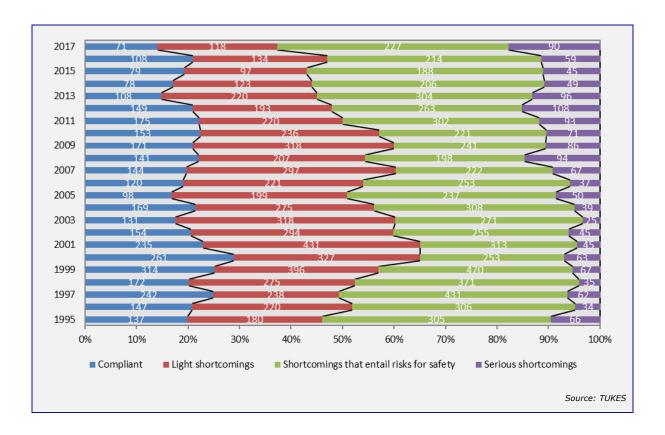
Regarding the Finnish system (generally considered to be well-functioning by all types of stakeholders consulted as part of this evaluation), it was observed during the fieldwork in Finland that the responsible authority TUKES scans the market actively and continuously reports at national level. In Finland, it has been historically compulsory at the national level to conduct testing and certification of electrical devices. This obligation was the result of a partnership in the domain of all Nordic countries, NCS certification, which allowed for the free circulation of NCS certified products in the Nordic countries. In Finland, the assessment is risk-based. Some of the evaluations are carried out internally by national authorities, some by external laboratories. Finnish stakeholders considered that there is good cooperation with economic operators and market surveillance authorities; yet the separate roles prevent conflict of interest.

Regarding the results of market surveillance audits in Finland, approximately 50% of products tested are concluded as presenting non-compliant features that could endanger their user as presented in the figure below. Though a bit below, this is in line with the overall results of market surveillance activities within the EU Single Market, where 58% of products evaluated are found uncompliant⁹⁸. In light of these rather worrying results, it should however be noted that, in order to make most efficient use of their limited resources, products actually tested by market surveillance authorities are those that are already suspected as being dangerous. Market surveillance authorities interviewed as part of this evaluation underline that this percentage is not representative of the products that are currently available on the shelves of retailers within the EU, which can be considered as safe to a great extent.

According to market surveillance authorities interviewed, the trend in accidents has decreased in Finland since the 1960s, and the very few yearly accidents that occur are mainly due to (unexpected) misuses of devices. On occasion, as presented by consumer organisations, the accident can also be due to an animal managing to turn a device on, or damaging the cords. It was considered that fire-linked risks in connection of misuse could to some extent be dealt with by national level legislation. It was also noted there is a lack of communication around the "normal lifespan" of the products to the consumers, as after that the risk for certain hazards will increase, even for originally LVD compliant products.

Figure 23 – Results of product tests by Finnish market surveillance authorities (TUKES) 1995-2017

⁹⁸ European Commission. (2017). Safe products in the EU Single Market: Commission acts to reinforce trust. Available at: <u>https://ec.europa.eu/growth/content/safe-products-eu-single-market-commission-acts-reinforce-trust-0 en</u>



The concerns above are largely confirmed by the European Commission's Refit evaluation on the implementation of market surveillance Regulation (EC) No 765/2008 carried out in 2018^{99} . Indeed, the results of this evaluation indicate notably that in terms of:

- Effectiveness:
 - It confirms the concerns highlighted above on the coordination and cooperation of national authorities in the EU, including with customs authorities. It also underlines the lack of use by Member States of the available tools for cross-border cooperation.
 - It confirms the expected level of uniformity and rigorousness of market surveillance in the EU with respect to its organisation, availability of resources, powers of inspections/sanctions, and systems of monitoring/reporting, has not been reached.
 - It confirms the lack of effectiveness of market surveillance on extra-EU imported products due to a lack of jurisdiction of Member States' authorities.
- Efficiency:
 - While the information costs to economic operators arising from the Regulation have been reported as insignificant, the evaluation confirms the lack of effectiveness of the Regulation might lead to additional and more significant costs for economic operators due to lower product compliance, unfair competition (including with extra-EU operators) as well as lower safety and consumer trust.
 - It confirms the current enforcement of the Regulation does not create a level playing field for economic operators in the internal market, which creates additional costs especially for SMEs.

In this context, and following an impact assessment, a new Regulation on market surveillance and compliance¹⁰⁰ was published with the purpose of enhancing and modernising market surveillance in the EU. The Regulation will apply to 70 legislative acts, including the LVD, and repeal Regulation

⁹⁹ Commission Staff Working Document SWD(2017)469 final. See: <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=SWD:2017:0470:FIN</u>

¹⁰⁰ Regulation (EU) 2019/1020 on market surveillance and compliance of products. See: <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1562683986925&uri=CELEX:32019R1020</u>

765/2008 as from 16 July 2021. In particular, the new Regulation includes the following elements, which should be addressing some of the pain-points presented earlier:

- The Regulation calls for more information to be provided to economic operators, notably SMEs,
- The Regulation allows for market surveillance authorities and economic operators to carry out some joint actions to promote compliance, identify non-compliance, raise awareness and provide guidance in implementing relevant product-harmonisation rules.
- The Regulation ensures that Member States will allocate sufficient resources to cater to the inspection of both online and offline products,
- The Regulation provides to the Commission the right to issue implementing acts specifying the type/frequency of activities to be carried out for certain product categories. Union testing facilities are also created in order to enhance laboratory testing capacity in the EU.
- The Regulation sets enhanced communication/coordination rules among Member States market surveillance authorities and customs authorities for 'mutual assistance' and products entering the EU respectively.

In sum, it is thus clear that market surveillance as currently implemented within the EU, is an external factor affecting negatively the full achievement of both the health and safety and the internal market objectives of the LVD. However, in light of the upcoming legislative changes, the situation should be reassessed in the near future, following the implementation of all rules stemming from Regulation 2019/1020.

5.1.3 Conclusions with regards to effectiveness of the LVD Directive

The table below provides the replies of the evaluation team to the evaluation questions highlighted in Annex B. These replies build upon the findings described throughout that entire section.

Table 7 – Replies to the evaluation questions: effectiveness

Conclusions

Regarding the achievement of the objectives of the LVD related to the internal market the evaluation team concludes that:

- The objectives of the Directive relating to the establishment of a fully-functioning internal market have been partly achieved:
 - The Directive contributes positively to the functioning of the internal market by providing favourable grounds for the harmonisation of rules and procedures across the EU. No major cases of discrepancies have been detected across Member States in interpreting the requirements of the LVD for particular products.
 - Through harmonisation, notably the referral to harmonised standards at EU-level, the Directive aims to ensuring a level playing field for market access to all economic operators. Its provisions do not create (un-)favourable situations to any economic operators as such.
- The two main shortcomings are attributable to factors that are external to the LVD directive, namely the affordability of standards for SMEs and the effectiveness of market surveillance:
 - As operators appear to be *de facto* obliged to follow international standards to demonstrate their compliance, and as their relative affordability is strongly depend of the size of the companies, the current situation may represent more advantages to larger corporations.
 - Similarly, as the effectiveness of market surveillance activities are currently uneven throughout the EU, the extent to which uncompliant low voltage products/economic operators are intercepted is diverging across Member States. This creates unfair competition (1) among (un-)/compliant EU businesses themselves e.g. certain countries may be considered as more 'lenient' markets than others, and (2) between EU businesses and (un-)/compliant extra-EU competitors upon which EU national authorities do not have powers to effectively act on. These aspects should however

be re-examined in the near future the light of current policy developments relating to Regulation (EU) 2019/1020.

Regarding the achievement of the objectives of the LVD related to health and safety the evaluation team concludes that:

- The objectives of the Directive relating to ensuring the safety of low voltage products available in the internal market have been partly achieved:
 - While no specific targets have been set (e.g. maximum number of non-compliant products found within the internal market), the Directive provides more often than not an effective framework for preventing that non-compliant electrical equipment is placed on the EU market.
- The two main shortcomings are attributed to one internal factor related to the conformity assessment procedure, and one external factor related to the effectiveness of market surveillance (capacity of national authorities to intercept uncompliant products):
 - The present analysis could not confirm/infirm that Module A is effective in providing for the safety of products in all cases. Further research is required to determine the extent to which additional benefits (in terms of product safety) would be generated with the inclusion of another conformity assessment module (Module B) into the Directive, notably (1) through the *mandatory* conformity assessment by third parties for certain high risk products, (2) through the *optional* conformity assessment by third parties for certain products.
 - The extent to which Member States are able to identify uncompliant products is dependent on their authorities' resources, which in turn, vary across the EU. While this is an element beyond the remit of the LVD, it negatively affects the enforcement of the Directive in terms of its health and safety provisions. Similarly to internal market objectives, the varying intensity of market surveillance activities carried out by national authorities, the lack of cooperation/coordination between Member States (including with national customs authorities) as well as the lack of jurisdiction of national EU authorities, leaves room for uncompliant products sold by extra-EU competitors in the internal market.

Regarding the extent to which the progressing towards the objectives can be credited to the LVD or external factors, the evaluation team concludes that:

• The progress towards the objectives can be attributed to the 'framework of good conduct' offered by LVD to a large extent, as widely confirmed by all types of stakeholders. Other drivers include (harmonised) standards and the presumption of conformity they entail as well as possibly the liability and reputational concerns of economic operators.

Regarding the extent to which the development and use of European harmonised standards contributed to the effectiveness of the LVD, the evaluation team concludes that:

- Harmonised standards play a key role in achieving both core objectives of the Directive, thanks to the presumption of conformity they entail. They allow to align practices ensuring safety of products across all Member States and to specify some unclarified aspects of the Directive.
- A shortcoming in this regard is the financial accessibility of the standards and the resource-intensive participation in standardisation activities (including the length thereof), which may be considered as bringing up inequalities notably across larger and smaller economic operators.

Regarding the aspects/means/actors that render certain elements of the LVD more or less effective than other, the evaluation team concludes that:

- While the generic and succinct formulation of the provisions of the LVD are welcome, they may in some instances lead to less effective practices, notably in terms of risk-assessment within the conformity assessment procedure.
- Market surveillance authorities render the impact of LVD on product safety less effective, due to diverging practices across the EU.
- Extra-EU economic operators may influence the safety of products available on the internal market negatively, thereby also negatively impacting the fairness of competition with compliant EU economic operators.

Regarding the possible obstacles hindering the achievement of expectations relating to the LVD, the evaluation team concludes that:

- As no specific targets have been set for the achievement of the objectives of the LVD, it
 is not possible to conclude specifically on the extent of their achievement. However, the
 evaluation team considers that overall, the progress of LVD towards its objectives is
 positive.
- The most significant obstacle hindering the pursuing of its objectives is the effectiveness of market surveillance, which is beyond the scope of the LVD.

5.2 Efficiency

This section assesses the **efficiency** of the LVD, i.e. the extent to which the contribution to the objectives as discussed in the previous section is 'good value for money' in terms of the resources used to obtain the actual effects.

5.2.1 Costs related to the implementation of the Directive

This section provides both a qualitative and a quantitative review of the costs associated with the implementation of the Directive as borne by the key stakeholders i.e. economic operators, national authorities and tax payers.

5.2.1.1 Mapping of costs and their perception by stakeholders

This sub-section identifies, per stakeholder, the types of costs associated with the implementation of the Directive, and provides an assessment of their magnitude based on stakeholder perceptions (collected via EU and national level interviews and the stakeholder survey).

Economic operators

The figure below maps the different costs borne by economic operators (including manufacturers, distributors and importers) along the process of making low voltage products available on the internal market.

Figure 24 – Mapping of costs borne by economic operators



The **first type of costs** that should be considered are those related to **any specific resources** allocated to dealing with the compliance and follow-up of the LVD. It appears from the interviews carried out at national level that these costs are in fact non-significant. Indeed, regulatory compliance in general, appears to be treated for smaller entities, directly at the production-level, or for bigger entities, within a quality assurance-related department, which therefore covers all sorts of legislation. In addition, companies irrespective of their size agree on the fact that LVD is to be considered effective and fairly easy to apply as it provides rather for an overall framework of 'good conduct' than specific obligations.

The **second type of costs** when considering the process of making low voltage product available on the internal market are **compliance costs**. These have been divided in two sub-categories, and pertain mainly to manufacturers duties.

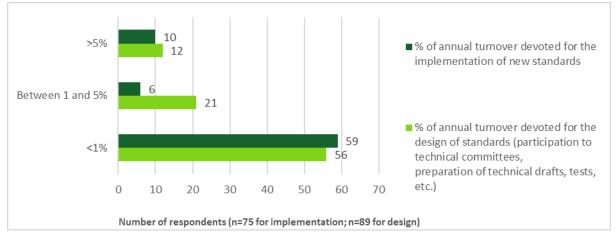
On the one hand, the **technical compliance costs**, which are related to the manufacturing of compliant products from the technical safety perspective. Here, as per the LVD, the manufacturer has the choice to (1) opt for the presumption of conformity through the use of (harmonised) standards, or (2) opt out from the utilisation of standards and ensure compliance through other means.

As previously discussed, it appears from the consultation activities that (harmonised) standards are the preferred option for all types of economic operators, irrespective of their size, whenever they are available. The technical compliance costs of the Directive can thus be associated to the purchase of (harmonised) standards, whose cost usually ranges between \leq 400 to \leq 1000 per piece. It is to be

noted that one product usually if not always involves multiple standards estimations vary from one to ten pieces, depending on the product and its technical complexity/safety risks posed. These wide estimations would bring the costs of acquiring standards from \in 400 in average per product in the best-case scenario to \in 10000 in average per product in a worst-case scenario. Considering the number of the low voltage product types (see section 4.2) and the fact that the number of products in a manufacturers' portfolio will vary from one to many, the costs of standards in indeed significant, and even more so for smaller players as previously discussed. In addition to these, some operators are active in the standardisation activities by attending committee meetings and participating in the actual development of standards.

The stakeholder survey provides interesting inputs as regards the perception of economic operators on the affordability of standards and related activities. From the manufacturers' perspective, it appears that these costs amount to less than 1% of annual turnover for the majority of respondents: 59 out of 75 for the implementation of new standards and 56 out of 89 for the design of new standards (see Figure 25). It should also be noted that as regards the implementation of new standards, proportionally more manufacturers consider these costs as exceeding 5% of annual turnover than it being between 1% and 5%. On the contrary, for the design of standards, more manufacturers tend to think that costs range between 1% and 5%, than over 5%. In relative terms, the cost associated with the development of new standards i.e. participation to technical committees, technical drafts, tests, etc., is perceived as higher than the actual use of standards. The findings are not sensitive to the size of the responding manufacturer.

Figure 25 – Q16 manufacturers: "Can you please estimate the overall annual average costs for activities linked to standardisation (as % of annual turnover)?"



However, an important element to note is that a non-negligible community of manufacturers (45 out of 116) and mostly SMEs, rate these costs related to standardisation activities as 'high' (see

Figure 26), which indicates that whether or not these costs are lower or higher than 1% or 5% of annual turnover, they are still considered to have a significant impact on businesses' resources. Again, while these trends are observed in the survey results for all manufacturers irrespective of their size, as previously discussed, the impact could be expected to be relatively higher for a smaller player than a large corporation.

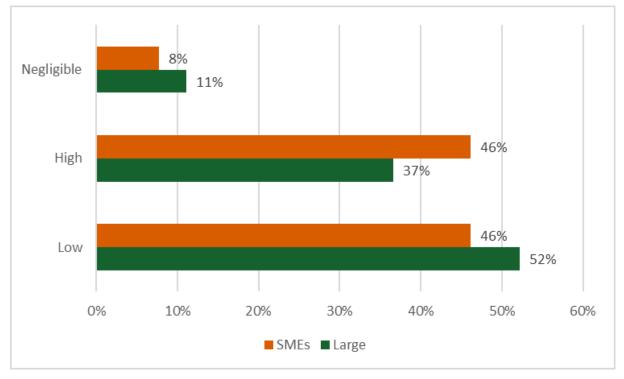
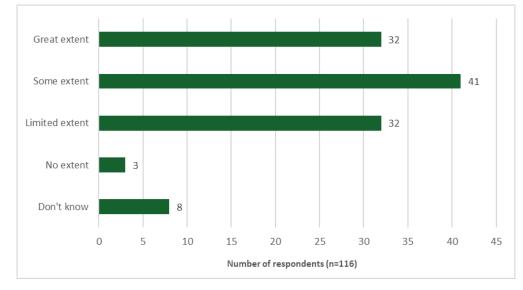


Figure 26 – Q17 manufacturers: "Overall, how would you rate the cost for activities linked to standardisation indicated [in the previous question]?"

Lastly, when manufacturers are probed about the extent to which the aforementioned costs are proportionate to the benefits, the landscape is divided, as presented in the figure below: while 41 out of 116 respondents assess the costs as proportionate to 'some extent', the same number of manufacturers (32 out of 116), consider the costs as proportionate to a 'great' and 'limited' extent. The additional comments received largely point out to a lengthy publication process of harmonised standards at EU-level, as discussed in section 5.1.1.1.

In light of the findings above, it can be fairly concluded about the technical compliance costs that while the benefits of standardisation (c.f. sections 5.1.1.1 and 5.1.2.2) are clearly acknowledged by all types of stakeholders, there appears to be a perception of lack of efficiency attributed to high costs in proportion to benefits.

Figure 27 – Q18 manufacturers: "To what extent do you consider the costs proportionate to the benefits for activities linked to standardisation?"



On the other hand, as explained earlier in this sub-section, there are the **procedural compliance costs**, which are related to the conformity assessment procedure, and the affixing of the CE marking following a positive evaluation. Here, as explained in section 4.1.2.3, the manufacturer has to apply the internal production control procedure (Module A), which, in theory, does not involve any third parties.

Indeed, it appears from the interviews carried out at national level that economic operators still involve third party laboratories in the conformity assessment procedure in order to:

- Guide the process and ensure accuracy of results
- Shift the responsibility to a recognised third party laboratory/certifier

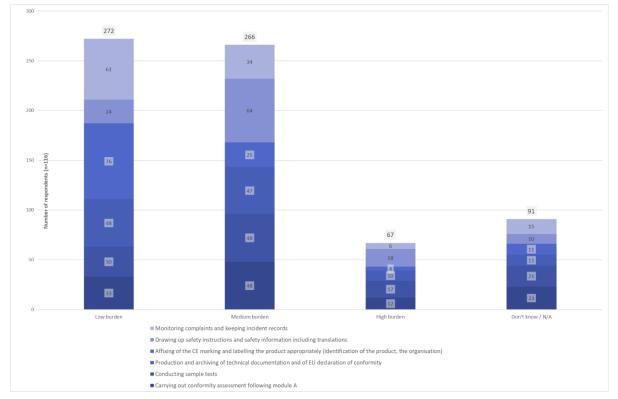
Similarly to standardisation, the stakeholder survey provides insights about economic operators' perception on the magnitude of the burden associated with the conformity assessment procedure prescribed by the Directive, as well as other economic operators' compliance duties such as conducting sample tests, production of the technical documentation and EU Declaration of Conformity (DoC), affixing of labels, including CE marking, drawing safety instructions (in national languages). It also describes the burden related to **administrative costs** such as monitoring and reporting of complaints. These pertain to all types of economic operators including manufacturers, distributors and importers.

The survey asked stakeholders to provide the opinion of the burden of a list of provisions in the LVD. It appears that overall, manufacturers consider the burden arising from LVD's provisions as rather low (the response was selected 272 times in total across all provisions surveyed) or moderate (the response was selected 266 times in total across all provisions surveyed). Based on the majority of responses for each provision surveyed, the burden they represent can be summarised as presented in the following table. 'Primary' perception is represented by the answer having being selected the most by respondents, while 'secondary' perception is represented by the answer having being selected the second most times by respondents.

| Provision | Primary answer for SMEs (Secondary answer) | Primary answer for large companies (Secondary answer) |
|--|---|---|
| Carrying out conformity assessment following module A | Medium ("Low" and "High" received the same number of answers) | Medium (Low) |
| Conducting sample tests | Medium (Low) | Medium (Low) |
| Production and archiving of technical documentation and of EU DoC | Medium (Low) | Low (Medium) |
| Affixing of the CE marking and labelling the product appropriately (identification of the product, the organisation) | Low (Medium) | Low (Medium) |
| Drawing up safety instructions and safety information including translations | Medium ("Low" and "High" received the same number of answers) | Medium (Low) |
| Monitoring complaints and keeping incident records | Low (Medium) | Low (Medium) |

Table 8 - Manufacturer's perception on the burden associated with LVD provisions (based on majority of replies)

While none of the provisions were rated as high based on the majority of replies, the high burden category was selected 67 times in total across all provisions surveyed, with the highest scores for: the drawing of safety instructions and information in national language (selected 18 times in total), the conduction of sample tests (selected 17 times in total) and the conformity assessment procedure through Module A (selected 12 times in total).





Importers and distributors participating in the survey provided very limited information about costs linked to the LVD provisions¹⁰¹. One distributor reported less than 0.01% of costs for compliance to LVD provisions. Two importers reported "medium/low burden", whereas one indicated high burden for drawing up safety instructions and information.

All in all, from the economic operators' perspective it appears that costs related to the implementation of LVD can be ranked as follows (highest to lowest):

- 1. Technical compliance costs
- 2. Procedural compliance costs
- 3. Administrative costs
- 4. Specific resources costs.

While some costs are perceived as being more justified/proportional to benefits than others (c.f. section 5.2.3, the overall landscape for the LVD is rather positive in terms of costs in entails for economic operators, irrespective of their size.

National authorities

The costs related to the implementation of the LVD borne by national authorities are three-fold. The perception of stakeholders regarding their magnitude is mainly constituted of the information collected during EU and national level interviews, and presented here below. All in all, these are considered as being rather low.

The first type of costs to consider are **transposition costs**: indeed, all Member States had to transpose the Directive into national law, either by integrating it into existing legislation or by creating new instrument(s). Further, these instruments at national level had to updated and/or

 $^{^{101}}$ Q12: "Please provide your best estimate for the costs borne on a yearly basis, on average, by your organisation for the following LVD provisions"

modified following the harmonisation package and related modifications of the LVD in 2014. Similarly, should any further changes be made to the Directive be made in the future, Member States would have to account for those as well. While the national authorities interviewed were not able to provide estimations of the costs these activities represent(ed), the overall understanding is that these costs are rather are/were rather low and negligible on the long run, as no specific difficulties were highlighted by national authorities. Here again, the generic formulation of the safety requirements were highlighted as facilitating elements.

Secondly, national authorities are faced with **implementation costs** i.e. those related to the dayto-day operations linked with the Directive such as the resources allocated to the national implementing bodies, the participation and follow-up with the LVD Working Party and the Committee on Electrical Equipment as well as keep up with standardisation activities. Here again, no specific difficulties were highlighted by national authorities consulted during interviews, and related costs are assessed as rather low.

The last and third type of costs faced by national authorities are those related to the **enforcement** of the Directive, i.e. market surveillance, which also includes the participation to the LVD AdCo. As previously discussed, the resources allocated to this activity vary across all Member States as it depends on political priorities. However, the understanding is that currently the means invested in market surveillance are rather low – at least in comparison with the actual needs for effective enforcement – across the EU, with notable exceptions in certain Member States (c.f. section 5.1.2.4). In addition, some Member States' authorities note some difficulties creating additional burden related to the undefined risk assessment methods prescribed under Module A (see section 5.1.2.3), as well as the overlaps with other legislation (see section 5.4.3).

Tax payers

As far as tax payers are concerned, the main costs related to LVD and other product legislation are taxes withheld for social security and public health. However, for the sake of robustness of the analysis, the attempt to quantifying such costs has not been carried out.

5.2.1.2 Attempt to quantification of costs

The table below presents an attempt to quantify the various costs identified per stakeholder in the previous sub-section, using the method described in section 2.2.5 and detailed in Annex L.

Table 9 – Assessment of the costs related to the Directive

| Stakeholder | Cost (Weight) | Description/assessment | Score (*based on qualitative stakeholder inputs) | |
|-------------------------|--------------------------------------|--|--|------------|
| category | | | Individual costs | Aggregated |
| | Transposition cost (0.05) | All EU Member States had to transpose the Directive into national law, either by integrating it into existing legislation or by creating new instrument(s). These national laws had to be updated following the harmonisation package in 2014. No specific difficulties were highlighted by national authorities. | -0.5* | |
| National authorities | Implementation cost (0.20) | Participation to the EU-level working groups on LVD (Committee on Electrical Equipment and Working Party). Follow-up on key issues (including standardisation). No specific difficulties were highlighted by national authorities. | -1* | - 1.35* |
| | Enforcement costs (0.75) | All EU Member States are required to carry out market surveillance. In addition to cost of the resources devoted to monitor the electric equipment made available in the national market, as presented above, some elements of the LVD may render this task more complicated: Undefined risk assessment procedures Overlap with other legislation | - 1.5* | |
| Economic operators | Specific resources cost (0.10) | None of the economic operators consulted reported specific resources allocated to the implementation of LVD. This is an integrated part of the overall quality and regulatory | 0 | -1.56 |

| | Technical compliance costs (via standardisation) (0.30) | compliance function of companies, which would exist irrespectively of the LVD Manufacturers bear the costs of related to the production of compliant products, which in most cases is liked to (harmonised) standards Costs of standards: €400-€1000/standard Some economic operators also bear the costs related to standardisation activities | - 1.79 | |
|------------|--|--|-----------|--|
| | Procedural compliance costs (Conformity assessment costs) (0.30) | Manufacturers bear the costs of the conformity assessment procedure (including third party costs for tests and certification) Duration of assessment period before launch: 3 to 12 months/product Costs of third party testing: €5000-€15000/test Economic operators bear the costs related to overlaps with other Directives (including involvement of notified bodies) Affixing CE marking and labelling of the product | - 1.67 | |
| | Administrative compliance costs (0.30) | Drawing up technical documentation and EU declaration of conformity Drawing up safety instructions (including translations) Archiving required documentation Monitoring complains and keeping incident records | - 1.76 | |
| Tax payers | Taxes for public health and social security | For the sector of extension of the exclusion the extension to exceed the exclusion of the e | | |

5.2.2 Benefits related to the implementation of the Directive

This section provides both a qualitative and a quantitative (when possible) review of the benefits associated with the implementation of the Directive as generated for the key stakeholders i.e. economic operators, national authorities and tax payers.

5.2.2.1 Mapping of benefits and their perception of stakeholders

This sub-section provides, per stakeholder category, an overview of types of benefits associated with the implementation of the Directive, which are strongly related with the objectives of the LVD discussed in the previous chapter.

Economic operators

The two main benefit areas of the Directive for economic operators are aligned with the objectives of LVD: some are related to the functioning of the internal market, and others are related to the harmonisation of health and safety compliance criteria.

On the one hand, regarding the internal market, economic operators benefit from:

- Access to markets: harmonised rules and procedures across the EU allowing for free access to all national markets within the EU. The effectiveness chapter above indeed confirmed the positive contribution of the Directive in this regard.
- Access to innovation: the voluntary use of standards allow economic operators to freely tap into innovation opportunities and set the scene for updated state-of-the-art safety requirements.

As presented in section 5.1.1 and Annex G, these two points are further confirmed by the results of the stakeholder survey for manufacturers which points out that 69 out of 116 respondents (irrespective of their size) report that the LVD facilitates intra-EU exchanges to at least some extent, with the majority being satisfied to a great extent. In the same vein, a similar proportion of manufacturers having replied to the survey highlighted facing no issue with the implementation of the Directive in different Member States. Distributers and importers appear to share these views and report no significant issues in the flows of goods within the Single Market, with 8 out of 10 reporting "minor" or no problems at all.

Further, as also presented in section 5.1.1, the voluntary characteristic of standards was particularly put forward by standardisation bodies and business representatives as the pivotal element ensuring that the LVD does not hinder innovation. This point was also validated during the expert workshop: the Directive's generic formulation of objectives allows to be flexible towards all types of innovation (possibly including new safety risks).

On the other hand, regarding safety related elements, economic operators benefit from:

- **Compliance savings:** harmonised rules and procedures across the EU also allowing for regulatory certainty and savings in technical/procedural compliance that would be required if systems were not aligned across the EU.
- **Reputational benefits:** economic operators having completed a positive conformity assessment procedure and affixed the CE marking benefit from the image of quality products associated with the label.

During the expert workshop, it was also discussed that the CE marking represents the achievement of a successful conformity assessment procedure for industry stakeholders, and that though it is not meant to be a token of quality (but safety!), it is most often than not perceived in that way by consumers. Consumer organisations interviewed also highlight that the CE marking is a reassuring label for end-users, who in doubt would rather buy a product with the marking than without.

Finally, the stakeholder survey allows to further shed light on the assessment of the main benefits related to the LVD by economic operators. It should be noted that, in the figures below, as presented in Annex G, the option "Internal Market" is the aggregate of "Guaranteeing the same level playing field for the different involved actors", "Cost savings deriving from simplified conformity assessment

procedures" and "Easier intra-EU exchange". It appears that benefits emanating from the LVD are mainly high, or to the least moderate from the perspective of manufacturers, distributers, importers and business associations.

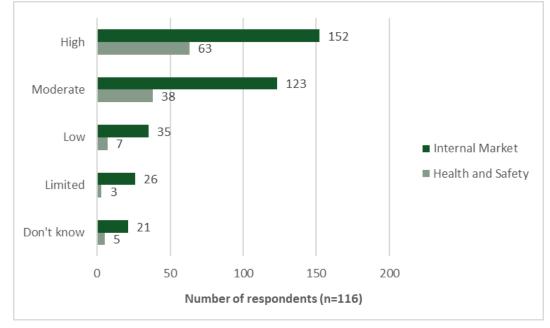


Figure 29 – Q21 manufacturers: "Overall, how do you rate the main benefits deriving from the LVD?"

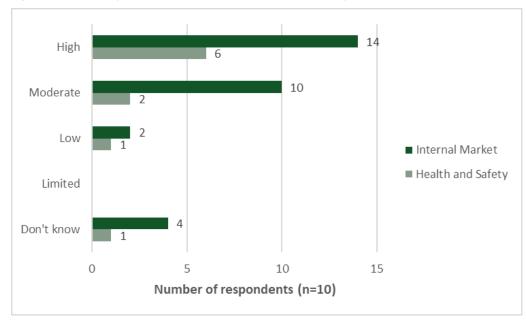


Figure 30 – Q16 Importers and distributors: "Overall, how do you rate the main benefits deriving from the LVD?"

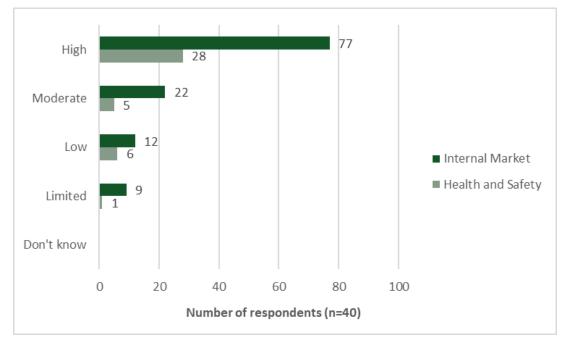


Figure 31 – Q17 (for business organisations):" Overall, how do you rate the main benefits deriving from the LVD?"

National authorities

As far as national authorities are concerned, the main benefits appear to be the following:

- **Regulatory cost-savings:** as the legislation is now dealt with at EU-level and as the use of (harmonised) standards is promoted, the costs of regulatory updates and follow-up are relatively decreased for Member States.
- **Savings on market surveillance and coordination:** as the actions taken by one national authority directly applies to all EU Member States, national authorities benefit from decreased costs related to the identification/sanctioning of uncompliant products.
- **Synergies in topical expertise:** through the collaboration in LVD related working groups (e.g. Committee on Electrical Equipment, LVD Working Party, LVD AdCo) Member States benefit from each other's expertise and best practices as regards the implementation of the Directive.

These findings are based on the interviews carried out at national-level during the fieldwork exercises, as well as the AdCo meeting in which the study team took part. They were finally validated during the expert workshop. These are also confirmed by the stakeholder survey results. Indeed, when assessing LVD benefits, **authorities'** views are consistent with manufacturers, distributors and importers as displayed in the figure below. This underlines positive results especially in terms of easier intra-EU exchange and health and safety protection: 9 authorities out of 12 reported "high" benefits.

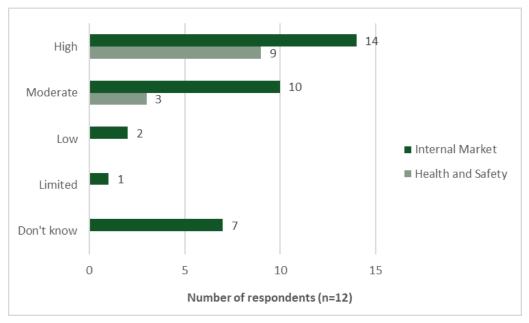


Figure 32 – Q16 Authorities: "Overall, how do you rate the main benefits deriving from the LVD?"

Tax payers

Lastly, as regards tax payers, the lower barrier to trade induced by the LVD, following economic theories, would allow for lower prices for products in scope along with higher quality. Further, as related to safety, the LVD contributes positively to safer products in the internal market, which consequently decrease the costs for tax payers related to social security and public health functions.

However, for the sake of robustness of the analysis, the attempt to quantifying such benefits has not been carried out.

In a nutshell, the main benefits noted are the following:

- Wider choice of low voltage products: as economic operators are granted market access more easily, tax payers are faced with a higher number of product choices, which consequently induces some pressure on the pricing of such products and their overall quality.
- **Increased safety of products throughout the EU**: while there is some room for progress in this area, tax payers appear to benefit from access to safe products throughout the EU, thereby diminishing the costs related to social security and public health.

5.2.2.2 Attempt to quantification of benefits

The table below presents an attempt to quantify the various benefits identified per stakeholder in the previous sub-section, using the method described in section 2.2.5 and in Annex L.

Table 10 – Assessment of the benefits related to the Directive

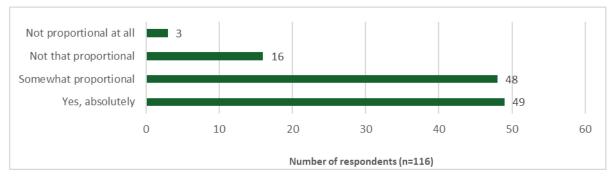
| Stakeholder category | Benefit (Weight) | Description/assessment | | Score (*based on qualitative stakeholder inputs) | |
|-------------------------|---|--|------|--|--|
| | | | | Aggregated | |
| National authorities | Regulatory cost-savings (0.10) | EU Member States' authorities benefit from decreased legislative updates at national- level thanks to the EU-level instrument and the promotion of the use of (harmonised) standards | 2.69 | | |
| | Cost-savings on market surveillance and coordination (0.90) | on marketcommon rules and (harmonised) standards across the EUsurveillanceEU Member States' authorities benefit from the ease of coordination on product recalls/withdrawalscoordinationEU Member States' benefit from synergies in key discussions and activities (including | | 2.65 | |
| | Compliance savings & CE marking (0.50) | Economic operators benefit from similar safety requirement, rules and procedures all over the EU & rules for launching products on the market Economic operators benefit from cost-savings related to mandatory Notified Bodies in (each) national market(s) Economic operators benefit from a generic framework to ensure the health and safety of their products | | | |
| Economic operators | Functioning of the internal market (market access) (0.50) | Economic operators benefit from a free access to national markets, i.e. a level playing field in all EU Member States for launching new products Economic operators benefit from a flexible self-certification leaving room for innovation thanks to voluntary standards | 2.29 | 2.32 | |

| Tax payers | Increased quality and safety of LVD products | For the sake of robustness of the analysis, the attempt to quantifying such benefits has not been carried o |
|------------|---|---|
| | Decreased price of LVD products | |

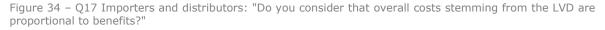
5.2.3 Comparison of costs and benefits of the LVD

Economic operators were requested to rate the proportionality of the costs with the benefits of the Directive. The majority of manufacturers reported that overall costs stemming from the LVD are 'absolutely' (49 out of 116) or 'somewhat' (48 out of 116) proportional. Only 3 respondents out of 116 deemed the costs as completely disproportional, and 16 somewhat disproportional. Comments received included notably references to duplication of work due to overlapping legislation such as the RED or the EMCD. It was also mentioned that "*The burden is disproportionately higher for the "good" manufacturers and suppliers"*, which also reinforces the findings presented in section 5.1.2.3 about '*black sheep'* economic operators. These opinions are aligned across SMEs and large companies.

Figure 33 – Q23 manufacturers: "Do you consider that overall costs stemming from the LVD are proportional to benefits?"



As regards distributors and importers, it appears that 8 out of 10 distributors and importers consider the costs absolutely or at least somewhat proportional to benefits, similarly to manufacturers. This was also confirmed by business organisations having replied to the survey, who rated the costs as absolutely proportional (24 out of 40) and somewhat proportional (16 out of 40).



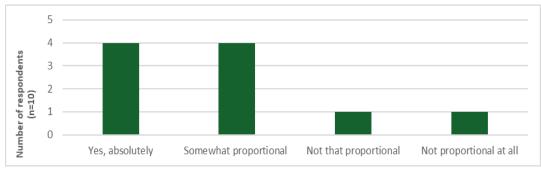
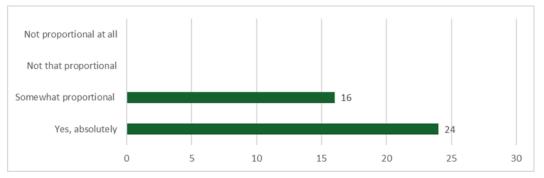
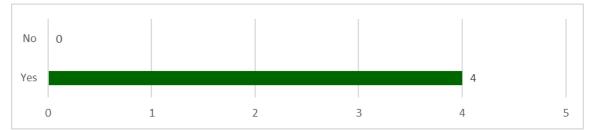


Figure 35 – Q18 (for business organisations): "Do you consider that costs stemming from the LVD are proportional to benefits?"



Consumer organisations answered in the same way: all the four surveyed organisations reported benefits proportionate to costs. This question was not raised to national authorities.

Figure 36 – Q17 Consumer organisations: "Are benefits of participating in standardisation committees/consultation bodies benefits proportionate to costs?"



Further, as explained in section 5.2.1.2 and 5.2.2.2, while the results of the quantitative assessment conducted above should be interpreted with caution, they still allow to provide an indicative overview of the costs and benefits of the Directive, as well as the distribution of these across stakeholders.

| Stakeholders | Costs | Benefits | Total |
|----------------------|-------|----------|-------|
| National authorities | -1.35 | +2.65 | +1.30 |
| Economic operators | -1.56 | +2.32 | +0.76 |
| Taxpayers | N/A | N/A | N/A |
| Total | -2.91 | +4.97 | +2.06 |

Table 11 – Comparison of the costs and benefits related to the Directive based on quantification attempts

In line with the findings emanating for individual survey replies and other consultation activities conducted, the table above suggests that:

- The benefits generated by the LVD would outweigh its costs for each type of stakeholders individually;
- The benefits generated by the LVD would significantly outweigh its costs when looked at from the aggregated level for all stakeholders;
- At the aggregated level, for 1 unit of cost, the Directive would generate 1.7 units of benefits, i.e. if taken in monetary terms, for every euro invested in the implementation of the LVD, the EU as a whole gains 1.7€ worth benefits in return.

Finally, as it is subsequently explained in section 5.3, the LVD is still considered as a relevant piece of legislation today. Indeed, its objectives are deemed to be corresponding both to the needs of taxpayers (which expect safety and benefit from a free circulation on the internal market) as well as those of economic operators (most of which consider safety as a key aspect of their competitiveness, and benefit from reduced barriers for intra-EU trade). In the same vein, section 5.5 presents that the added-value of the Directive lies notably in the capacity of the LVD to complement, stimulate, and leverage common action to reduce disparities across national markets, raise safety standards, and create synergies across Member States. In addition, it should also be noted that stakeholders view the LVD favourably also in comparison to other EU Directives, such as the RED, and regulatory product safety frameworks in other countries, such as in the USA and China.

Combined to the findings presented in sections 5.2.1 and 5.2.2, including the quantification attempts, these final elements relating to the relevance and added value of the Directive allow to conclude that the costs, which appear to be outweighed by benefits for all types of stakeholders involved, are borne for a justified cause.

5.2.4 Conclusions with regards to the efficiency of the LVD

The table below provides the replies of the evaluation team to the evaluation questions highlighted in Annex B. These replies build upon the findings described throughout that entire section.

Table 12 – Replies to the evaluation questions: efficiency

Conclusions

Regarding the type of regulatory costs borne by and benefits for various stakeholders, the evaluation team concludes that:

- As presented in section 5.2.1.1 and Table 9, the regulatory costs for
 - National authorities are composed of transposition, implementation and enforcement costs, which are deemed as rather low by stakeholders consulted.
 - Economic operators are composed of specific resources dedicated to LVD, technical compliance, procedural compliance and administrative compliance costs, which, while having a greater relative importance for SMEs, are considered as moderate to low by stakeholders consulted.
 - As far as tax payers are concerned, the main costs related to LVD and other product legislation are taxes withheld for social security and public health.
 Consumer organisations consulted deem theses costs as proportionate to the benefits of the Directive.
 - The evaluation team did not dispose of adequate data to conclude on the specific costs for standardisation bodies. Similarly, the evaluation team did not dispose of sufficient data on cases of discrepancies detected across Member States to conclude on their impacts in terms of costs.

• As presented in section 5.2.2.1 and Table 10, the regulatory benefits for

- National authorities are related to cost-savings on regulatory activities, market surveillance and coordination, which are deemed as rather high to moderate.
- Economic operators are related to cost-savings on application of national safety compliance requirements, as well as facilitated intra-EU trade and increased competitiveness, which are deemed as rather high to moderate.
- Tax payers are related to increased safety and quality of products and availability of product choices and reduced prices thereof in the internal market. Consumer organisations consulted deem these benefits as outweighing the costs of the Directive.
- The evaluation team did not dispose of adequate data to conclude on the specific benefits for standardisation bodies.

Regarding the affordability/proportionality of the above costs and the cost-effectiveness of the Directive, the evaluation team concludes that:

- The lack of data on costs and benefits does not allow to conclude on the affordability of the LVD with precision.
 - Based on both, the qualitative and quantitative assessment of the costs and benefits of the Directive it appears that the benefits generated by the LVD outweigh its costs for each type of stakeholders – including national authorities, economic operators (irrespective of their size of place in the value chain) and tax payers, both individually and as a whole.
 - At the aggregated level, for 1 unit of cost, the Directive would generate indicatively 1.7 units of benefits, i.e. if taken in monetary terms, for every euro invested in the implementation of the LVD, the EU as a whole gains 1.7€ worth benefits in return.
- However, despite the lack of robust quantitative proof, the evaluation team considers that the Directive is a fairly cost-effective legislative instrument.
 - Based on the rather positive assessment of the Directive's effectiveness (see section 5.1), it appears that the costs generated as part of the implementation of the LVD genuinely contribute to the achievement of the internal market and safety objectives.

 Based on the conclusions regarding the relevance and the added-value of the Directive, the costs, which appear to be outweighed by benefits for all types of stakeholders involved, are borne for a justified cause.

Regarding the potential for achieving the objectives of the LVD at a lower cost, the evaluation team concludes that:

- The lack of data on costs and benefits does not allow to conclude on this question with precision.
- However, the positive contribution of the LVD in the achievement of the objectives (see section 5.1.2.3) could not be achieved at a lower cost, without compromising the safety objective, as the current conformity assessment procedure is already the less costly alternative.

5.3 Relevance

This section presents the findings on the relevance of the LVD, i.e. to what extent the LVD still addresses current problems and needs.

Given the length of the evaluation period, it is especially important to take into account developments in technologies, markets and the regulatory landscape. This is reflected in the assessment in the next subsections, which focus on, respectively, the relevance of the objectives of the LVD, the scope of the LVD and the clarity of the LVD. The analysis is guided by the evaluation questions presented in Annex B.

5.3.1 Relevance of the objectives of the LVD

The main objectives of the LVD (ensuring the health and safety of persons, domestic animals and property, and ensuring free circulation of compliant products within the internal market) are considered still relevant today, 45 years after the introduction of the Directive. The LVD is relevant, because it addresses current needs as described below, and because there is no other legislation in place with the same scope and objectives. Respondents to the stakeholder survey also indicated that the LVD is relevant for achieving the main objectives.

We can break down the question of whether the objectives of the LVD (still) correspond to the needs of different stakeholders, with a focus on consumers and economic operators. Starting with the safety objective:

- for consumers, the Directive helps to reduce safety risks. Consumers assume that only
 products that are safe and compliant are put on the market. They trust that this is taken
 care off by the procedures.
- The interviews with business (associations) as well as the workshops showed that for most **economic operators (producers, traders)**, safety is considered a key issue for their competitiveness, as safety problems can damage their reputation, and therefore the LVD is seen to correspond to their needs.

The stakeholder survey response (response to question 1) confirms this finding: 82% of the 221 respondents consider the LVD to be "very relevant" for ensuring the safety of electrical products.

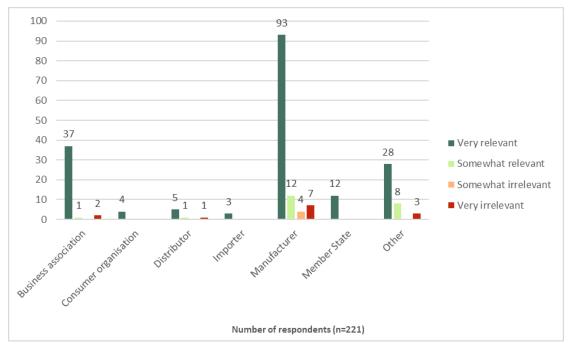


Figure 37 Survey question on relevance: *how relevant do you consider the Directive to ensure the safety of electrical products*

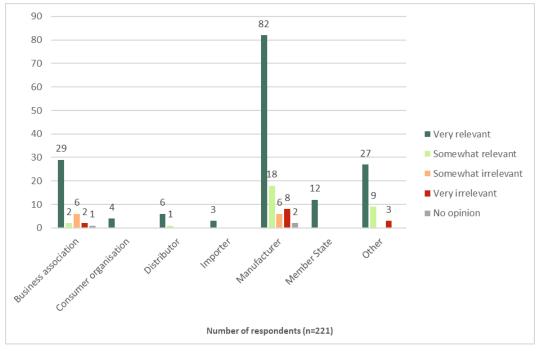
Source: Survey for the evaluation of the Low Voltage Directive

There is broad consensus on this among the different stakeholder groups: in each stakeholder group in the survey the majority shares this opinion.

With respect to the objective related to the free circulation of LVD products in the internal market:

- The Directive still responds to the needs of **economic operators** because it helps to prevent diverging regulations between Member States, thereby preventing trade costs and creating a level-playing field in the EU. As seen in section 2.2.3 on trade in LVD products, the majority of trade is still within the EU, and therefore this is an important aspect.¹⁰²
- The level-playing field that is created by the Directive is also beneficial for **consumers**, as the level –playing field also helps to prevent unnecessary costs of trade in the internal market. They are likely to be less aware of this, as also the OPC showed that most products are bought in the country itself, and they may not always be aware of the country of origin.¹⁰³

Figure 38 Survey question on relevance: *how relevant do you consider the Directive to ensure an internal market for LVD products?*



Source: Survey for the evaluation of the Low Voltage Directive

The stakeholder survey (response to question 2) again confirms the positive feedback relating to LVD's contribution to a well-functioning internal market: 74% of the respondents considered the Directive as 'very relevant' in achieving this objective. Also regarding this objective, the majority of all types of respondents (consumer, manufacturers, importers, etc.) shared this opinion.

5.3.2 Scope of the Directive

5.3.2.1 Developments in the scope over the evaluation period

The scope as defined in the Directive itself has been largely unchanged over the evaluation period. However, there have been other developments that have affected the scope of the Directive. First, the market for LVD has increased in size, because there is increasing supply and demand for electronic products, as presented in section 4.2. However, at the same time, as already noted in previous sections (and further elaborated in the next section), several other Directives have been

 ¹⁰² It should be noted that in the consultations many economic operators indicated that they work on the basis of international standards, as this this reduces their trade costs (for both intra-EU and extra-EU trade).
 ¹⁰³ See answers to OPC question 4.

introduced since the LVD came into force. These Directives cover products that could formerly be considered as within the scope of the LVD. This is especially true for products that now fall under the RED. Whereas in the past, for example, computers were considered LVD products, now that they almost all have Wi-Fi connections, they fall under the RED. And with technological developments, this is the case for an increasing number of different products (e.g. washing machines and refrigerators with Wi-Fi, see also the discussion in section 4.2 and the related Annex N). This implies the Directive applies to a decreasing number of products. There are other Directives which have similar effects, as highlighted in the coherence section. The net effect of these two developments on the scope of the Directive (i.e. the extent to which the decrease in products covered by the Directive is compensated by the increase in sales of remaining LVD products) cannot be assessed in the absence of detailed market data.¹⁰⁴

One of the implications of the introduction of RED and other Directives that may affect the scope of the LVD, is that the number of grey areas (whether a product falls under the LVD or another Directive) increases. In other words, it reduces the clarity of the scope of the LVD. Especially for economic operators and market surveillance authorities this can create uncertainty. For economic operators it could also have cost implications if Member States have a different interpretation, as each Directive has its own specific requirements that companies need to comply with (this is explained in more detail in the coherence section 1.1). Although the issue was brought up by many stakeholders, we note that at the same time the incidence of these problems seems to be relatively low: for almost all products it is clear which Directive is applicable.

Some stakeholders argued that it would be good to have a list of products that fall under the LVD, as it would reduce the uncertainty introduced by the emergence of new Directives. However, there are many others who warned that making an explicit list of LVD products runs the risk of accidentally excluding products, and the risk that with new technological developments, the list has to be continuously updated.

One change in the LVD is also worth highlighting here: whereas in previous versions of the LVD, economic operators had to ensure safety in relation to the *intended use* of products, this has been changed to *reasonable and foreseeable use*. This is considered important from a consumer perspective. Especially in domestic appliances there are child-appealing elements (e.g. toasters with pictures of unicorns), and economic operators have to ensure that the use of products by children is also safe. This change does not change the scope of the LVD in terms of type of products covered, but in the level of safety required. The new text therefore responds to the needs of the consumer.

5.3.2.2 Appropriateness of the voltage limit

The voltage limits of the LVD, especially the lower voltage limit, have been a point of discussion in the evaluation period. The possible lowering of this lower limit was one the scenarios investigated in an impact assessment study of 2005.¹⁰⁵ This study concluded that "because of the uncertainties surrounding the quantification of benefits and on-going costs, it has not proved possible to calculate the net efficiency effect [...]."Because of that assessment, the resulting Directive 2006/95/EC did not include a revisions in the overall scope.

The present evaluation has also investigated the appropriateness of the voltage limits of the LVD, with a focus on the lower voltage limit . Stakeholders have diverging views on this issue, as also reflected in the stakeholder survey (see figure below).

¹⁰⁴ As explained in the market analysis, many categories of products contain a mix of LVD and non-LVD products, but more detailed data are not available. An analysis of the scope over time would moreover require an analysis of when certain new technologies have been introduced, as well as an analysis of when other legislation affecting the scope of the LVD has been introduced, which goes beyond the scope of this study.

¹⁰⁵ Risk & Policy Analysts Limited (RPA) (2005) Impact Assessment of Various Policy Options for a Possible Amendment of the Low Voltage Directive 73/23/EEC, December 2005

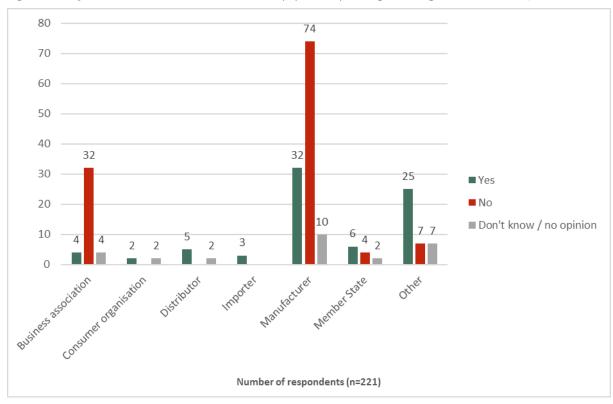


Figure 31 – Q6: "Should the Directive also cover equipment operating at voltages below 50V AC / 75 V DC?"

When looking at the total numbers, just over half of the respondents to the survey (53%) claimed that the lower bound for voltage should not be lowered, against a 35% of respondents stating the opposite. However, the figure shows that the response varies significantly across the respondent categories.

It is mainly business (the majority of manufacturers and business associations) who are of the opinion that the Directive should not cover the equipment operating at voltages below 50V AC / 75 V DC. These opinions are aligned across SMEs and large companies. Based on feedback received, they consider most of the products below the voltage limits as safe, also because the products still have to comply with the GDPS. In addition, including them in the LVD would increase the burden for economic operators. Especially where it involves very small, low costs products (e.g. birthday cards with music), the requirements of the LVD are considered too high in relation to their benefits.

The majority of other respondent categories with a view on this (i.e. consumer organisations, Member State authorities but also distributors and importers as well as others) indicate that the lower voltage limit should be removed. These stakeholders explained during the other stakeholder consultation activities that because of new product developments, and also because the LVD covers all types of safety, not only those related to electric shocks, they have doubts on the appropriateness of the lower voltage limits today. Many stakeholders gave the example of products that are below the lower voltage limit of the LVD (most cited products are those that operate on lithium batteries), and the increasing number of accidents with these products (e.g. fire)¹⁰⁶. These stakeholders therefore argue that the lower limit of the LVD should be removed. In Norway, this is already the case- in their transposition of the LVD in national legislation, the lower limit is not included. Also in the RED, which now covers many former LVD products, there is no lower voltage limit. While it is acknowledged that the extra-low voltage products are covered

¹⁰⁶ Although there are no hard data to confirm this trend (e.g. RAPEX does not provide information on the products' voltages, nor on the nature of the problem encountered), this trend has been confirmed by many stakeholders in the consultations.

by the GPSD, the LVD has more specific requirements and is therefore better able to ensure safety in their view.

According to the opinion of technical experts, and as confirmed in other stakeholder consultations, the fundamental problem is that the voltage limits that are used to categorize electrical equipment as LVD products, also suggest a categorization of risks. This is not necessarily correct because not all risks have a firm relation to the product's voltage. To summarise the main technical aspects:

- The safety requirements in the LVD are not specified and go beyond electrical safety. It is reasonable to state that the lower voltage limit unwarrantedly excludes electrical equipment that may also carry non-electrical safety risk.
- The risk of thermal burn is a factor that may not depend on the voltage but instead could solely depend on the current or involved chemical processes (e.g. batteries). Electrical equipment below the lower voltage limit could still contain the risk of thermal burns.
- The debate on what voltage level results in unacceptable risks to the human body as a result of electrocution is ongoing. This risk does not only depend on the voltage, but also on the maximum current an electrical source can deliver, the impedance of the medium and the time the electrocution takes place. There are several types of risks that can lead to injury or death. One of them is fibrillation of the heart, which already happens at relatively low current (100 milli Ampere). As an example, in case that a person's skin is very wet, a voltage below 50 V AC can already result in a current higher than 100 milli Ampere when a current path through the body is present.

5.3.2.3 Appropriateness of exceptions listed in Annex II

Next to the appropriateness of the voltage limits, respondents to the stakeholder survey could also indicate whether the products now excluded from the LVD based on Annex II should be included in the scope of the LVD. As the survey results show, many stakeholders did not have a specific opinion on the issue. Of the ones who had an opinion about the issue, the majority is not in favour of including equipment currently listed in Annex II in the scope of the LVD. There is only one category of electronic equipment for which there are slightly more stakeholders (80 against 70) encouraging their inclusion in the scope of the LVD, namely for "plugs and socket outlets for domestic use." Overall, the reason given is that these items are "One of the most common electrical products used by the consumers, and the safety of them is not regulated in the same way" and again "Safety is independent from voltage" (see above). For the other product categories, most respondents agree with their current exclusion.

5.3.3 Clarity of the Directive

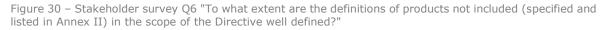
Based on the over 60 interviews carried out in the context of this evaluation , it appears that the overarching goal of the LVD as laid out in Article 1 , as well as the principal safety elements presented in Annex I of the Directive are clear to all types of key stakeholders . In particular, these provisions' succinct and generic formulation referring to 'safety' as outcome¹⁰⁷ is underlined as a key element allowing for no different or misinterpretation by stakeholders throughout the EU. This wording makes the objective technological-neutral, and thus still relevant despite all the technological developments that have taken place. Most stakeholders interviewed and present at the workshop see this as a positive aspect of the LVD. Some have argued for a more precise lists of safety risks, but others point to the risk of forgetting certain risks, or new, future, risks not being covered.

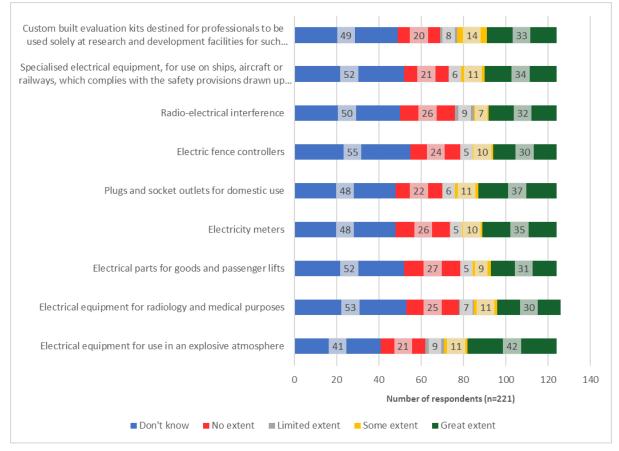
With respect to clarity of the scope of the LVD, this is defined as electrical equipment with a rated voltage between 50 V and 1000 V (alternating current) or between 75 V and 1500 V (direct current) that is introduced to or circulated on the internal market. In addition, Annex II of the Directive excludes some categories of electronic equipment.

¹⁰⁷ "it does not endanger the health and safety of persons and domestic animals, or property, when properly installed and maintained and used in applications for which it was made."

The Directive does not define what electrical equipment is. Some stakeholders (notably national authorities like standardization bodies or market surveillance authorities, but also some industry representatives) preferred more clarity on the definition. With the current definition, it is not clear what exactly is considered the product; does it go down to component level, full product level or beyond (systems that consist of different products)?

Annex II includes definitions for the exceptions of product categories from the LVD. This concerns electrical products that are within the voltage limits of the LVD, but still excluded from the scope. Based on the stakeholder survey response, the definitions of these exceptions are not considered clear. Looking at the respondents who have an opinion on the definitions ,¹⁰⁸ we note that in general less than half of the respondents indicate that the exceptions are well defined ("to a great extent"), while the majority indicates that this is not, to a limited, or to some extent, the case. The only exception is "electrical equipment for use in an explosive atmosphere", where a small majority indicates that this category is well defined "to a great extent".





A final point related to the clarity of the LVD with respect to the products covered has been identified earlier and concerns the emergence of new Directives, which can create confusion on which Directive is applicable for a specific product.

Despite these comments, the majority of stakeholders who had an opinion considered the scope of the Directive as it is presented in Article 1 as clear, also because the voltage limits help to define it. In addition, as mentioned earlier, all stakeholders interviewed seemed to agree on the fact that the 'Low Voltage Directive 2014/35/EU Guidelines' are providing useful material to

¹⁰⁸ The majority of the respondents had no opinion on the issue (e.g. due to a lack of expertise, given that it require detailed knowledge of the Directive). In the interviews and other meetings, we also received limited feedback on the issue.

further clarify the understanding of the Directive and its provisions, including the (complementary) applicability of other Directives.

With respect to conformity assessment, one national authority expressed the opinion that the articles of the LVD referring to the conformity assessment should be modified to only refer to harmonised standards. Referring to national/international standards was considered outdated, as "all economic operators seek the presumption of conformity".

In terms of the specific requirements to prove compliance with the LVD, clarity does not seem a problem to most economic operators, although they consider some provisions of the LVD outdated. This applies especially to the requirements with respect to marking and documentations. There have been technological trends that could be applied (e.g. QR codes, reference to websites), which with the current LVD provisions, is not possible yet (see also section 3.1). The related provisions are therefore considered as not responding to the current needs of economic operators that could be changed without significantly affecting the needs of other stakeholders (e.g. consumers). Based on the OPC results, consumers would also favour to have information (partially) provided in electronic/digital format. The OPC also shows that while the level of information provided by the manuals was generally deemed sufficient by the majority of respondents, the information is not always easy to understand (e.g. (part of) the safety instructions) or to find (e.g. contact details of manufacturers or importers).

5.3.4 Conclusions with regards to the relevance criteria

The table below provides the replies of the evaluation team to the evaluation questions highlighted in Annex B. These replies build upon the findings described throughout the entire section.

Table 13 – Replies to the evaluation questions: relevance

Conclusions

Regarding the relevance of the objectives of the LVD, the evaluation team concludes that:

The objectives of the LVD are still relevant today, as they correspond both to the needs
of consumers (which expect safety and benefit from a free circulation on the internal
market) as well as those of economic operators (most of which consider safety as a key
aspect of their competitiveness, and benefit from reducing barriers for intra-EU trade).

Regarding the scope of the LVD in terms of products covered, the evaluation team concludes that:

- In the course of the evaluation period the scope of the LVD has changed due to the introduction of other Directives (notably the RED), and technological changes (e.g. increased use of IoT), which can move products to other Directives. .
- With respect to products currently excluded from the LVD (as defined in Annex II), the majority of stakeholders who expressed an opinion on the issue is not in favour of including these in the scope of the LVD. The only exception is "Plugs and socket outlets for domestic use" for which a small majority of stakeholders indicate that it could be included within the scope of the LVD.

Regarding the scope of the LVD in terms of safety, the evaluation team concludes that:

- The LVD covers all risks, not only those related to electrical shocks. Because there can be safety problems with equipment below the lower voltage limit (e.g. thermal burns), this lower voltage limit is not justified from a safety perspective. On the other hand, economic operators claim a disproportionate increase in burden in relation to the benefits, in particular for low cost-products (e.g. birthday cards with music).
- The LVD is suited for technological innovation as the safety provisions are formulated in a broad and technological-neutral way and can therefore be applied also on new products and cover new types of risks.

Regarding the clarity of the LVD, the evaluation team concludes that:

- The Directive is generally perceived as quite clear by stakeholders. However, in some cases it is not clear whether a product is covered by the LVD or another Directive. This is because the Directive is not considered to use clear definitions and because the introduction of other Directives has changed the scope of the LVD.
- Increasing the clarity of scope of the LVD by including specific lists, notably of products
 or safety risks, has both advantages and disadvantages. While it would help to increase
 clarity, an explicit list of LVD products and/or safety issues runs the risk of accidentally
 excluding products or safety issues, and the risk that with new technological
 developments, these lists have to be continuously updated.
- Provisions that have been criticised by both economic operators and consumers are the requirements relating to marking and documentation, which do not facilitate the use of internet-related solutions in combination with information on the product/in manuals. Moreover, based on the response to the OPC, there is room for improvement regarding the information provided to consumers with LVD products, as consumers are currently not always able to easily find and understand the information provided (e.g. related to safety instructions, contact details of manufacturer/importer)..

5.4 Coherence

This section presents the findings on the coherence of the LVD, in terms of internal coherence as well as external coherence with both wider EU policy and with other legislative acts.

5.4.1 Internal coherence of the Directive

The majority of the stakeholders identified **no significant problems with the internal coherence** of the LVD. The LVD Guide is also considered very useful for clarification of any points that may be unclear in the text of the Directive itself. The only identified issues with the contents of the Directive relate to the scope, particularly the lower voltage limit and the definition of "electrical device". These issues were discussed in section 1.1.

5.4.2 External coherence of the Directive

5.4.2.1 Coherence with wider EU policy

This section presents the analysis of the coherence of the LVD with wider EU policy, including the Single Market Policy and the New Legislative Framework.

Single Market Policy

The main goal for the Single Market for Goods is providing both free movement of goods across the market and high safety standards for consumers and the environment. The LVD is one of the oldest Single Market Directives and, as described in section 3, these two aims of the Single Market match the two main objectives of the LVD. **No contradictions have been identified** between the objectives of the LVD and the wider EU Single Market policy, and as discussed above, stakeholders credit the Directive's longevity and stability as one of the reasons why it is so successful.

The coherence of LVD with the relevant environmental acts, the Eco-design legislation and the WEEE Directive (waste electrical and electronic equipment) are discussed in the next subchapter.

The New Legislative Framework (NLF) and the Alignment Package

The NLF, adopted in 2008, consists of three measures¹⁰⁹ that aim to improve the quality of market surveillance especially for what concerns importing from third countries and to build up a common legal framework for all the existing industrial products legislations and for the future one. It sets general principles for CE marking, with the aim to clarify its meaning, use and protection. It also introduces traceability requirements for all operators, with the goal of helping the competent authorities to trace the non-compliant products and take them out of market circulation. Further obligations for importers and distributors regarding product compliance will allow enforcement action to be taken at any level of the supply chain. These measures will further protect the competitiveness of compliant firms and thus support the level playing field. In addition, it sets transparent rules for the accreditation of notified bodies and provides for eight different modules for conformity assessment.

Against the NLF background, in February 2014 the Commission identified a specific set of product harmonisation Directives for which alignment with the NLF Decision 768/2008/EC could be dealt with as a package.

¹⁰⁹ Regulation (EC) 765/2008 setting out the requirements for accreditation and the market surveillance of products; Decision 768/2008 on a common framework for the marketing of products, which includes reference provisions to be incorporated whenever product legislation is revised. In effect, it is a template for future product harmonisation legislation; and Regulation (EC) 764/2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another EU country.

An "Alignment Package" was therefore introduced to align nine existing EU Directives to the NLF, including the LVD¹¹⁰, with the aim of reaching a legislation harmonization for industrial products and avoid problems of inconsistencies. Other Directives have been aligned with the NLF separately.

Definitions or entire provisions differed from one Directive to the other (e.g. manufacturer definition, notification requirements, safeguard clause, conformity assessment procedures), increasing complexity of legislation, interpretation and application of the several directives. The adoption of the abovementioned Alignment Package to the NLF therefore seeks to remedy these problems.

The Directives of the alignment package are in force since the 20th April 2016 and their essential requirements are not modified.

Regarding the alignment with the New Legislative Framework, the stakeholders' attitude is **largely positive**. The participants to the LVD Working Party Workshop considered that the new definitions integrated to LVD are clear and helpful – other aspects were not mentioned in this context. Some participants called for even further alignment with the NLF, although it was not specified what this would mean in practice.

One of the four EU-level industry representative interviewed during the study expressed disappointment with the New Legislative Framework alignment. This stakeholder considered that the alignment had introduced uncertainty to the sector as well as some additional administrative costs as "even slightly updating a label can have large costs". However, no further data was discovered to support this.

5.4.3 Interaction with and impact of other EU legislation

The products under the scope of LVD appear to interact with a series of other Directives. These are listed here below. For most of these Directives, the overlaps relate to the scope of the Directives and uncertainty of some definitions.

- Directive 2014/30/EU on Electromagnetic Compatibility (EMCD)¹¹¹
- Directive 2014/53/EU on Radio Equipment (RED)¹¹²
- Directive 2006/42/EC on Machinery (MD)¹¹³
- Directive 2011/65/EU on Hazardous Substances in Electrical and Electronic Equipment (RoHs)¹¹⁴
- Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE)¹¹⁵
- Directive 2001/95/EC on General Product Safety (GPSD)¹¹⁶

¹¹⁰ The other Directives were the Simple Pressure Vessels 2009/105/EC, Lifts and their safety components Directive 1995/16/EC, Equipment for use in Potentially Explosive Atmospheres 94/9/EC (ATEX), Electromagnetic Compatibility Directive 2004/108/EC, Measuring Instruments Directive 2004/22/EC, Non-Automatic Weighing Instruments Directive 2009/23/EC, Civil Explosives Directive 93/15/EC and Pressure Equipment Directive 97/23/EC.

¹¹¹ Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility, available at: <u>http://data.europa.eu/eli/dir/2014/30/oj</u>.

¹¹² Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC, available at: <u>http://data.europa.eu/eli/dir/2014/53/oj</u>.

¹¹³ Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC, available at: <u>http://data.europa.eu/eli/dir/2006/42/oj</u>.

¹¹⁴ Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, available at: http://data.europa.eu/eli/dir/2011/65/oj.

¹¹⁵ Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE), available at: <u>http://data.europa.eu/eli/dir/2012/19/oj</u>.

¹¹⁶ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, available at: <u>http://data.europa.eu/eli/dir/2001/95/oj</u>.

- Directive 2008/63/EC on competition in the markets in telecommunications terminal equipment¹¹⁷
- Directive 2014/34/EU on equipment and protective systems intended for use in potentially explosive atmospheres (ATEX)¹¹⁸
- Directive 2014/33/EU on Lifts¹¹⁹
- Directive 93/42/EEC on Medical Devices¹²⁰

This chapter discusses the interaction between LVD and the aforementioned Directives, including stakeholder opinion on the coherence where any were presented. The box below summarises the effect of the interaction with other legislation on safety.

Box 5 – Effect of the interaction with other legislation on safety

The products under the scope of LVD appear to fall under a series of other Directives. While this interplay is analysed in detail in this section, it should be mentioned that the interaction with Directive 2014/53/EU on Radio Equipment (RED) is perceived by all stakeholders consulted as creating significant challenges. Indeed, due to the 'exclusion from LVD' referred to within the RED, all types of stakeholders experience issues in determining to what extent a product should fall under one, the other or both directives.

For economic operators, a product falling under the RED would mean the involvement of a notified body within the conformity assessment procedure, which in principle should increase safety. Apart from this factor, whether a product falls within the LVD or RED has no significant impact on economic operators. A comparative analysis of the relevant provisions of both Directives shows indeed that the obligations of economic operators (Chapter 2 of both Directives) with respect to radio equipment under the scope of the RED and electrical equipment under the scope of LVD are equivalent and symmetrical.

However, in terms of market surveillance activities and detection of uncompliant products, the impact is more significant. Indeed, for national market authorities of some (larger) Member States, where surveillance for LVD and RED products are conducted by different bodies, this means that traditionally LVD products are supervised by radio equipment experts, thereby creating a competency gap with respect to effective market surveillance. Based on the market analysis, 56% of current EU low voltage production could be affected by this issue (see section 4.2.5)

5.4.3.1 Electromagnetic Compatibility Directive 2014/30/EU (EMCD)

The Electromagnetic Compatibility Directive 2014/30/EU (EMCD) ensures that electrical and electronic equipment does not generate, or is not affected by, electromagnetic disturbance.

All electric devices or installations influence each other when interconnected or close to each other, e.g. interference between TV sets, GSM handsets, radios and nearby washing machine or electrical power lines. The purpose of electromagnetic compatibility is to keep all those side effects under reasonable control. EMCD designates all the existing and future techniques and technologies for reducing disturbance and enhancing immunity.

¹¹⁷ Commission Directive 2008/63/EC of 20 June 2008 on competition in the markets in telecommunications terminal equipment , available at: <u>http://data.europa.eu/eli/dir/2008/63/oj</u>.

¹¹⁸ Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres, available at: <u>http://data.europa.eu/eli/dir/2014/34/oj</u>.

¹¹⁹ Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts, available at: http://data.europa.eu/eli/dir/2014/33/EU

¹²⁰ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, available at: http://data.europa.eu/eli/dir/1993/42/oj.

The majority of products within the scope of the LVD are also within the scope of the EMCD¹²¹. The EMCD does not apply to products covered by the RED. Indeed, products which meet the definition of radio equipment and fall under the scope of the RED (e.g. mobile radio transceivers, cell-phones, Wi-Fi and Bluetooth equipment, satellite transceivers including GPS receivers, domestic television and radio sets and radar equipment) are explicitly excluded from the EMCD. Therefore, where RED is applicable to radio equipment, the EMCD does not apply. While the revision of EMCD did not modify the scope of the previous EMCD (Directive 2004/108), the changes between the scopes of the Radio and Telecommunication Terminal Equipment Directive (R&TTED- 1999/5/EC¹²²) and RED had direct consequences with respect to the applicability of the EMCD.

Pure wired telecommunication terminal equipment, which was previously covered by the R&TTED, falls under the scope of the EMCD and depending on the voltage limits, the LVD. Television and sound broadcasting which were previously covered by the EMCD and, depending on the voltage limits the LVD, fall under the scope of Directive 2014/53/EU. The Radio Equipment Directive 2015/53/EU (see below) applies to products placed on the market on or after 13 June 2016 (not before). The LVD and EMCD apply to products placed on the market on or after 20 April 2016 (not before).

Table 14 compares the main features of both Directives. As both Directives are aligned to the NLF, they have similar rules for conformity assessment procedures and market surveillance. Besides the conformity assessment Module A included in the LVD, EMCD also includes Module B with Module C, and Module H, of which Modules B and H require the involvement of notified bodies. These modules must be used where the manufacturer has not applied or has applied only in part published harmonised standards (Art. 17(4)). As a similar requirement is not included in the LVD, it is possible to have different module requirements for the same equipment in the two Directives. However, **no issues were reported** regarding the coherence between LVD and EMCD by the consulted stakeholders.

| | LVD 2014/35/EU | EMCD 2014/30/EU |
|--------------------------------|---|--|
| Scope | Electrical equipment with a rated voltage between 50 V and 1000 V (alternating current) or between 75 V and 1,500 V (direct current) | all electrical equipment |
| NLF alignment | Yes | Yes |
| Notified bodies | Not involved | NLF criteria. Involved in the conformity assessment procedures according to Module B, Module H |
| Conformity assessment types | Module A | Module A, Module B, Module C, Module H |
| Market surveillance | Aligned to EC No 765/2008 Art. 15(3) and Art 16 to 29; Union safeguard procedure; Measures for compliant electrical equipment found to present a risk; Procedure for formal non-compliance | Aligned to EC No 765/2008 Art. 15(3) and Art 16 to 29; Union safeguard procedure; Procedure for formal non-compliance |

Table 14 - LVD and EMCD comparison table

¹²¹ With the exception of 'custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes'. The reasons of this exemption seem to be that such products are not intended to be placed on the market, but they are intended to be only used for development and research and, as such, will not need the cautions required for the ones destined to the market.

¹²² Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity, available at: <u>http://data.europa.eu/eli/dir/1999/5/oj</u>.

5.4.3.2 Radio Equipment Directive 2015/53/EU (RED)

The new Radio Equipment Directive 2015/53/EU (RED) entered into force on 11 June 2014 and is applicable as of 13 June 2016. It provided for a transitional period which ended on 12 June 2017. It replaced the R&TTED 1999/5/EC aligning it to the NLF. However, it was revised separately from the Alignment Package because, in addition to being aligned to the requirements of the NLF, it also introduces technical changes relating to the manufacture of radio equipment.

The RED scope is limited, subject to a number of exceptions to radio equipment, which is defined in Article 2.1(1) as "an electrical or electronic product, which intentionally emits and/or receives radio waves for the purpose of radio communication and/or radiodetermination, or an electrical or electronic product which must be completed with an accessory, such as antenna, so as to intentionally emit and/or receive radio waves for the purpose of radio communication and/or radiodetermination".

The LVD does not apply to products covered by the RED. Indeed, products which meet the definition of radio equipment and fall under the scope of the RED (e.g. mobile radio transceivers, cell-phones, Wi-Fi and Bluetooth equipment, satellite transceivers including GPS receivers, domestic television and radio sets and radar equipment) are explicitly excluded from the LVD. Therefore, where RED is applicable to radio equipment, the LVD does not apply.

While the revision of LVD did not modify the scope of the previous LVD (Directive 2006/95), the changes between the scopes of the Radio and Telecommunication Terminal Equipment Directive (R&TTED) and RED had direct consequences with respect to the applicability of the EMCD.

Pure wired telecommunication terminal equipment which was previously covered by the R&TTED¹²³, falls under the scope of the EMCD and depending on the voltage limits, the LVD. Television and sound broadcasting which were previously covered by the EMCD and, depending on the voltage limits, the LVD, fall under the scope of RED. Therefore, sound and TV receive-only equipment as well as radio equipment operating on frequencies below 9 kHz equipment are not covered by the LVD.

However, in order to avoid double coverage RED incorporates (Article 3.1) the essential requirements of EMCD and LVD (with no lower voltage limit).

A comparative analysis of the relevant provisions of both Directives shows that many provisions are equivalent and symmetrical, although there are some differences particularly concerning the obligations of economic operators (Chapter 2 of both Directives).

As to the general provisions of the Directives, equivalent provisions regulate the subject matter and scope, definitions, making available on the market and safety objectives, and free movement. A specific provision of the LVD on the supply of electricity is not reproduced in the RED, while only the RED contains provisions on the essential requirements of radio equipment (Art.3) and the information to be provided by the manufacturers to the Member States and the Commission on the compliance of combinations of radio equipment and software with such essential requirements (Art. 4). Another specific obligation under the RED requires manufacturers to register radio equipment types within categories of radio equipment affected by a low level of compliance with the essential requirements set out in Article 3 within a central system prior to place it on the market (Art. 5). Additionally, Articles 7 and 8 RED contain specific obligations for Member States on the putting into service and use of radio equipment that complies with the Directive and on the notification of radio interface specifications and assignment of radio equipment classes.

Concerning the obligations of economic operators, as far as the technical documentation required is concerned (Annex III, LVD and Annex V, RED), the content for products falling under the RED is slightly more detailed. Similarly, the declaration of conformity (Annex IV, LVD and VI, RED)

¹²³ Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity, available at: <u>http://data.europa.eu/eli/dir/1999/5/oj</u>.

under the RED requires, in addition to the requirement in the LVD, also the indication, where applicable, of "the notified body ... (name, number) ... performed ... (description of intervention) ... and issued the EU-type examination certificate" and the "description of accessories and components, including software, which allow the radio equipment to operate as intended and covered by the EU declaration of conformity". This difference can have consequences for the economic operators where there is unclarity over which Directive should be applied. A DoC produced under the LVD would not be sufficient under the requirements of the RED, leading to formal non-compliance of the equipment in question. According to RED Art. 43, any formal noncompliance needs to be corrected by the relevant economic operator, or the equipment shall be withdrawn or recalled from the market. In addition, the indication of software does have consequences for instances where the software is updated. In practice, particularly with internet connected equipment, the manufacturer or user can update the software to a version not mentioned in the DoC. This can be a safety issue and also cause difficulties for the market surveillance authorities. On the other hand, the software update can be done by the manufacturer in the event where the original software is discovered to contain safety or security issue after the DoC has been drawn.

Additionally, with regard to manufacturers' obligations specifically (Art. 6 LVD and Art. 10 RED), the content of the instructions and safety information which accompany the product is specified in more detail under the RED. Finally, under the latter, manufacturers are subject to a number of further obligations compared to the LVD (paragraphs 9 and 10 of Art. 10 RED are not reproduced in the LVD). These are, in particular, the obligation to ensure that each item of radio equipment is accompanied by a copy of the EU declaration of conformity or by a simplified EU declaration of conformity, and the obligation on packaging information allowing the identification of the Member States or the geographical area where restrictions on putting into service or requirements for authorisation of use exist. Reference to these further obligations is made also in the provision governing the responsibilities of the distributor, which is called to verify the manufacturer's obligations that the distributor is called to verify, the one relating to instructions and safety information is only recalled under the RED and not under the LVD.

The responsibilities of importers are instead completely identical under the two Directives, except for the specification, contained only in the RED, with reference to the duties of all economic operators, including importers, to the need to ensure that radio equipment is so constructed that it can be operated in at least one Member State without infringing applicable requirements on the use of radio spectrum.

Chapter 5 RED on union market surveillance, control of equipment entering the union market and union safeguard procedure corresponds almost *verbatim* to chapter 4 LVD.

One of the main difference with the RED, is the set of provisions on the "Notification of conformity assessment bodies" (Art. 22 to 38, under Chapter 4 RED), regulating the bodies authorised to carry out third party conformity assessment tasks (with specific requirements relating e.g. to the characteristics and duties of notifying authorities and notified bodies, the notification procedure, the decisions of notified bodies and appeals against them and the obligations on information and coordination).

Table 15 compares the main features of both Directives. As with the EMCD, the RED requires notified bodies to be involved for equipment for which published harmonised standards have not been applied or have been applied only in part. Both Directives are aligned to the New Legislative Framework and apply the NLF approach on market surveillance.

Table 15 - LVD and RED comparison table

| | LVD 2014/35/EU | RED 2014/53/EU | | | | |
|--|--|---|--|--|--|--|
| Scope | Electrical equipment with a rated voltage between 50 V and 1000 V (alternating current) or between 75 V and 1,500 V (direct current) | Radio equipment | | | | |
| NLF alignment | Yes | Yes | | | | |
| Notified bodies | Not involved | a rated 1000 V between urrent) Yes NLF criteria. Involved in the conformity assessment procedures according to Module B and Module H Module A, Module B, Module C, Module H Art. Aligned to EC No 765/2008 Art. 15(3) and Art 16 to 29; Union safeguard procedure; Measures for compliant radio equipment found to present a risk; Procedure for formal non- compliance Art 10 (1) Equipment needs to be designed and manufactured in accordance with essential requirements in Art 3. Art 10 (2) Equipment has to be constructed so that it can be operated in at least one MS without infringing applicable requirements on the use of radio spectrum. Art 10 (8) If the radio0 equipment is intentionally emitting radio waves, following | | | | |
| Conformity assessment types | Module A | Module H | | | | |
| Market surveillance | Aligned to EC No 765/2008 Art. 15(3) and Art 16 to 29; Union safeguard procedure; Measures for compliant electrical equipment found to present a risk; Procedure for formal non- compliance | 15(3) and Art 16 to 29; Union safeguard procedure; Measures for compliant radio equipment found to present a risk; Procedure for formal non- compliance | | | | |
| Differences in manufacturers' obligations ¹²⁴ | Art 6 (1) Equipment needs to be designed and manufactured in accordance with safety objectives in Art 3 and Annex I. | compliance Art 10 (1) Equipment needs to be designed and manufactured in accordance with essential requirements in Art 3. Art 10 (2) Equipment has to be constructed so that it can be operated in at least one MS without infringing applicable requirements on the use of radio spectrum. Art 10 (8) If the radio0 equipment is intentionally emitting radio waves, following information needs to be included: a) frequency band(s) in which the radio equipment operates; b) maximum radio- frequency power transmitted in the | | | | |

¹²⁴ The table aims to point out differences only. Besides the differences there are a number of common elements, such as: 1) Manufacturers are required to draw the technical documentation and perform the conformity assessment procedure in line with Annex III (LVD 2014/35/EU) and Art 21 (2014/53/EU) respectively; 2) Manufacturers need to keep the technical documentation and EU declaration of conformity for 10 years; 3) Having procedures in place for series production to remain in conformity with the applied Directive, including the harmonised standards and other technical specifications; 4) Identification of the equipment; 5) Single point of contact; 6) Display of instructions and safety information; 7) In case of (suspicion of) non-conformity of an equipment with the respective Directive take corrective measures necessary and inform the competent national authorities in the MS affected; 8) Upon request from a competent national authority demonstrate conformity through provision of information and documentation.

| | LVD 2014/35/EU | RED 2014/53/EU |
|--|-----------------|---|
| | | copy of the (simplified) EU declaration of conformity. Art 10 (10) Include information on packaging to allow identification of MS or geographical area within a MS where restrictions on putting into service or requirements for authorisation of use exist. |
| Differences in obligations of economic operators ¹²⁵ | Annex III NA | Annex V - a general description of the radio equipment including: (i) photographs or illustrations showing external features, marking and internal layout; (ii) versions of software or firmware affecting compliance with essential requirements; (iii) user information and installation instructions; copy of the EU declaration of conformity; where the conformity assessment module in Annex III has been applied, copy of the EU- type examination certificate and its annexes as delivered by the notified body involved; an explanation of the compliance with the requirement of Article 10(2) and of the inclusion or not of information on the packaging in accordance with Article 10(10). |

Of all the EU legislative acts, **stakeholders seem to consider the interaction with the RED as creating the most significant challenges**. Indeed, due to the 'exclusion from LVD' referred to within the RED, all types of stakeholders experience **issues in determining** to what extent a **product should fall under each Directive**. This creates both **confusion and additional administrative burden** for both economic operators and market surveillance authorities. For economic operators, there is confusion about the **involvement of a notified body** in the conformity assessment procedure (required under the RED, but not under the LVD).

The fieldwork interviewees as well as the Workshop participants also highlighted the difficulty of determining whether a product or a part of a product falls within the scope of LVD, RED or both. Economic operators in the Workshop predicted that the problem of RED overlap will only increase in the next decade, as "eventually all products will be RED products". It should be noted that this comment is somewhat hyperbolic - see section 4.2.5 for discussion on the actual increase of connected systems. Economic operators also raised the related issue that is it is not clear who

¹²⁵ The table aims to point out differences only. The technical documentation shall also contain at least the following elements: (a) a general description of the equipment; (b) conceptual design and manufacturing drawings and schemes etc.; (c) descriptions and explanations necessary for the understanding of those drawings and schemes; (d) a list of the harmonised standards (e) results of design calculations made, examinations carried out (f) test reports;

decides in case of grey area: there is no clear authority to give a final decision under which Directive the product should fall.

The participants to the workshop considered that the main difference between LVD and RED is **provision of the declaration of conformity** and the additional administrative steps linked to its provision. This creates problems for economic operators, as if it is not fully clear under which Directive a product falls, they have to make a choice, and it is not guaranteed that all Member States will agree with their interpretation. This may then create additional administrative costs.

National authorities and industry representatives, as well as standardisation bodies in several Member States and at the EU level, also noted there are some additional costs for the economic operators for having to operate with two compliance systems. In this context, one national standardisation body provided as an example lighting equipment which includes a radio device for long distance command will fall under RED, so the company should also include the conformity assessment for RED (including a notified body). As no standards are listed for RED, economic operators are required to go through notified bodies.

Fieldwork interviewees, EU level industry associations and the participants to the LVD Working Party workshop also observed that the LVD – RED interaction causes problems also due to the fact that, in many Member States, different **authorities are responsible for both Directives**. Thus, when a type of equipment moves from the scope of LVD to RED, traditionally LVD products are supervised by radio equipment experts, thereby creating a **competency gap** with respect to effective market surveillance. The experts newly in charge of the equipment may have a different focus and **lack the specific expertise and/or equipment required** to assess electricity-related safety issues. This could imply that safety risks are monitored less. In Germany, for example, the issue is further complicated by the fact that the responsible authorities are at different levels of government. The same problem can also apply to committees discussing formal objections.

Some stakeholders participating in the LVD workshop, as well as standardisation authorities interviewed, also expressed dissatisfaction with the fact that the introduction of Wi-Fi connection alone can impact whether an appliance falls under LVD or RED. **Potential safety risks of those products remain largely the same, relating to their LVD related aspects rather than IoT aspects.** It was suggested that the designation could be done based on their main function. For example, in the case of a smart fridge the main function would be to cool, which would keep it under the LVD, rather than to use radio communication, which would indicate belonging to the scope of RED.

Some of the workshop attendees suggested that the Directives should be geared at different types of risks rather than being product specific. Others suggested merging the Directives, however **there was no consensus on whether this would be a positive or negative change**. Particularly the business representatives expressed concerns towards decreased clarity for economic operators.

Correlating to the above, according to the respondents to the online survey the **overlaps in scope between the LVD and other legislation (notably RED) is a problematic issue for 42.5% of the stakeholders** ("great extent" or "some extent"). The opinions of different stakeholder groups responding to the stakeholder survey are illustrated in the figure below. In addition, this problem was observed at the LVD Working Party Workshop. Although for the 56% of the survey respondents this is not a problem at all, or just to a "limited extent", there is clear room for improvement in this area. Clarity about the scope of the LVD has an impact on several aspects, and as underlined by national authorities, one of these consequences is the variance in effectiveness of market surveillance activities across the different Member States.

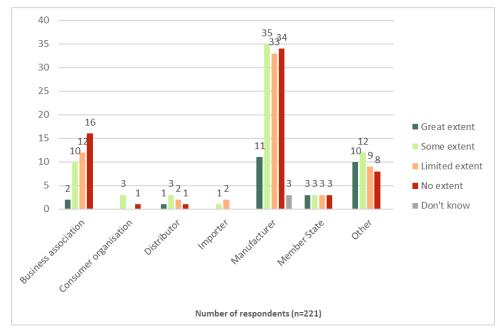
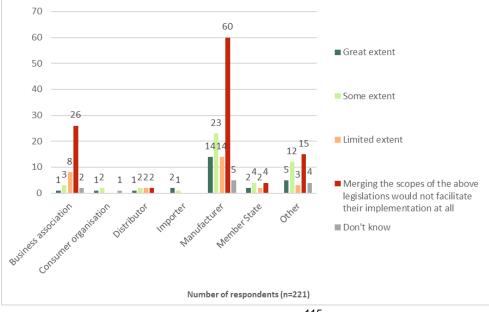


Figure 39 – Q3 all respondents: "A number of products falling under LVD scope also fall under other legislations. To what extent do you consider this is a problem?"

The opinion on a possible merge between RED and LVD are quite divided across type of stakeholders: manufacturers and business organisations are overwhelmingly against a merged legislative act. Indeed, they consider LVD as best practice example of a safety Directive and, on the contrary, RED was described very negatively due to for example additional costs deriving from notified bodies or provisions of additional documents such as a copy of the EU declaration of conformity or by a simplified EU declaration of conformity, and the obligation on packaging as disused above. On the other side, three consumers organisations and six national authorities see the merge more beneficial. Among cited possible benefits of a merged Directive are a greater harmonisation and a better capability of taking into account technological developments: with the rise of Internet of Things, the connected products need to be safe both at software and hardware level. Several Member States participating in the LVD Workshop also noted that a new unified Directive would potentially lead to additional administrative burden.

Figure 40 – Q4 all respondents: "To what extent merging the scope of the LVD with the Electromagnetic Compatibility Directive, the Radio Equipment Directive and the Terminal Equipment Competition Directive into one single act could facilitate implementation of these legislations?"



While stakeholders gave credit to the latest LVD guidance document on how to cope with the RED overlaps, industry and national representatives in one Member State suggested that besides the specific Directive guidelines, overall guidelines on the interaction of different Directives would be needed.

Text Box 1 - Stakeholder experience: RED

Changes in legal classification cause administrative burden to economic operators. For example, the manufacturer will be required to produce documentation compliant with LVD for a washing machine without Wi-fi, and documentation compliant with RED for washing-machine equipped with the Wi-Fi, even though certain aspects (such as door opening safety function) are in no way different between the two machines. This situation might result also in uncertainty in the market and problems of accountability.

5.4.3.3 Machinery Directive 2006/42/EC (MD)

The Machinery Directive 2006/42/EC (MD) is a total harmonisation Directive based on the New Approach to technical harmonisation and standards. It covers all hazards that come from machinery, including electrical hazards. However, according to the Machinery Directive, the safety objectives set out in LVD shall apply to machinery, while obligations concerning conformity assessment and the placing on the market and/or putting into service of machinery with regard to electrical hazards are governed by the Machinery Directive (Essential Health and Safety Requirement 1.5.1).

The MD has two overall objectives: ensuring a high level of safety and protection for users of machinery and other people exposed to it and securing the free movement of machinery in the internal market. An additional objective, protecting the environment, is limited to the machinery used in pesticide applications.

The products that it covers range from lawnmowers to 3D printers, from powered hand-tools to construction machinery, and from robots to complete automated industrial production lines. The Machinery Directive **clarifies the borderline between its scope and the LVD and** certain categories of electrical and electronic machinery products are hence excluded from the scope of the MD, namely household appliances intended for domestic use; audio and video equipment; information technology equipment; ordinary office machinery; low-voltage switchgear; and control gear; electric motors¹²⁶.

The first category "household appliances" designates equipment intended for typical housekeeping functions such as washing, cleaning, heating, cooling, cooking, etc. The appliances "intended for domestic use", (i.e. for use by private persons in the home environment) fall under the scope of LVD only¹²⁷; on the contrary, those household appliances intended specifically for commercial or industrial use are included in the scope of the MD only.

In general, electrical machinery that is not concerned by exclusions is in the scope of the MD. When such machinery has an electrical supply within the voltage limits of the LVD (between 50 and 1000 V for alternating current or between 75 and 1500 V for direct current), it also falls under the scope of LVD. In this case, the second paragraph of section 1.5.1 of Annex I of MD makes the safety requirements of the LVD applicable to machinery (the second sentence of this paragraph makes it clear that the procedures of the LVD relating to the placing on the market and putting

¹²⁶ Article 1(2)(k) of MD

¹²⁷ This is the case for: (i) appliances to be used in the home environment and appliances intended to be used by laymen in similar applications, such as: shops, offices and other working environments; in farm houses and by clients in hotels, motels and other residential type environment, in bed and breakfast type environments; (ii) appliances without moving parts are NOT considered as machines (according to Article 2 (a) of 2006/42/EC).

into service are not applicable to machinery subject to the MD only). This means that the manufacturer's Declaration of conformity for machinery subject to the MD shall not refer to the LVD.

The table below compares some main features of both Directives. As the Machinery Directive is not aligned to the NLF, its differences to the LVD are more obvious than those of EMCD and RED. Particularly, the market surveillance provision of the MD does not follow the NLF format and is much shorter. Like the EMCD and the RED, the MD also includes conformity assessment procedures involving notified bodies for certain types of machinery, aside from the self-assessment procedure.

| | LVD 2014/35/EU | MD 2006/42/EC | | | |
|---|---|--|--|--|--|
| Scope | Electrical equipment with a rated voltage between 50 V and 1000 V (alternating current) or between 75 V and 1,500 V (direct current) | Machinery, not intended for domestic use (with LVD exceptions) | | | |
| NLF alignment | Yes | No | | | |
| Notified bodies | Not involved | Involved in the conformity assessment procedures according to EC-type examination and full quality assurance | | | |
| Conformity assessment types | Module A Self-assessment; EC-type examination; full quality ass | | | | |
| Market surveillance Aligned to EC No 765/2008 Art. 15(3) and Art 16 to 29; Union safeguard procedure; Measures for compliant electrical equipment found to present a risk; Procedure for formal non-compliance app cor and app not | | Obliges Member States to take appropriate measures to ensure compliance and safety of machinery and partly completed machinery, to appoint competent authorities and to notify the Commission and other Member States thereof. | | | |

Table 16 - LVD and MD comparison table

The interaction with the Machinery Directive was mentioned by some stakeholders as a coherence issue. The fact that for **certain product categories the Machinery Directive does not provide a definition** creates some (incidental) confusion as to when to take the end use as domestic or industrial (e.g. with laundry machines or 3D printers). As in the case of RED, this was seen as less of a problem with LVD, but rather with the Machinery Directive, especially relating to the definitions or lack thereof of the latter. One national standardisation body also noted that the inclusion of a list of risks in the MD to solve the issue of determining which Directive applies for which risk does not fully clarify the issue. This stakeholder suggested using standards and guidance documents to solve the problem.

5.4.3.4 General Product Safety Directive 2001/95/EC (GPSD)

The General Product Safety Directive 2001/95/EC applies to consumer products in so far there are not specific provisions with the same objective in the EU sectorial legislation. The Directive aims to ensure that only safe consumer products are sold in the EU.

As noted in the LVD guidelines, the GPSD **only applies where it contains more specific provisions** compared to the LVD and to Regulation 765/2008/EC setting out the requirements for accreditation and the market surveillance of products (which applies at the same time with, and as a complement to the LVD). Following a detailed comparison of the provisions of the GPSD with the LVD as well as to the abovementioned Regulation, some measures of the GPSD have been identified as "more specific" and apply also to harmonised consumer products, including those in the scope of the LVD. These are the following:

• The measures provided for in Article 8(1)(b) of the GPSD, requiring Member States, for any product that could pose risks in certain conditions: (i) to require that it be marked with suitable, clearly worded and easily comprehensible warnings, in the official languages

of the Member State in which the product is marketed, on the risks it may present; (ii) to make its marketing subject to prior conditions so as to make it safe;

- The measures provided for in Article 8(1)(c) of the GPSD, requiring Member States, for any product that could pose risks for certain persons to order that they be given warning of the risk in good time and in an appropriate form, including the publication of special warnings;
- The measures provided for in Article 8(1)(d) of the GPSD, requiring member States for any product that could be dangerous for the period needed for the various safety evaluations, checks and controls, temporarily to ban its supply, the offer to supply it or its display;
- Any accompanying measures adopted to ensure that a marketing ban is complied with, as provided for in Article 8(1)(e) of the GPSD;
- Recalls and destruction of products, as provided for in Article 8(I)(f)(ii) of the GPSD, in relation to products that are dangerous without presenting a serious risk;
- Encouragement and promotion of voluntary action by producers and distributors, including where applicable by the development of codes of good practice, as provided for in Article 8(2), second subparagraph, of the GPSD;
- Active information of consumers and other interested parties on complaint procedures, as provided for in Article 9(2) of the GPSD;
- Giving the public access to information on product identification, the nature of the risk and the measures taken, as provided for in Article 16(1), first subparagraph, second sentence, of the GPSD.
- RAPEX notification of measures restricting or imposing specific conditions on the possible marketing or use of products by reason of serious risk (not amounting to a recall, withdrawal or prohibition of being made available on the market), as provided for in Article 12(1), first subparagraph, of the GPSD.

Therefore, the abovementioned provisions of GPSD apply also to products falling under the LVD. Stakeholders discussed the interaction between LVD and GPSD in the context of products below the LVD minimum voltage limit. It was observed by one national authority that as with RED, this can lead to market surveillance being carried out by people **without the right expertise on issues pertaining to the electrical aspect**. A consumer organisation also noted that the GPSD's safety requirements are not as specific as those of the LVD and suggested borrowing the RoHS definition of scope: "equipment dependent on electric currents/electromagnetic fields for range not exceeding 1000-1500V". Another national authority pointed out that the products currently under the GPSD would have to undergo the conformity assessment procedure under the LVD, which **could represent additional burden for the product currently outside the scope**.

Text Box 2 - Stakeholder experience: GPSD

Issues are reported to arise from battery-powered products that are below the LVD's lower limit. These products currently fall under the GPSD, which means that market surveillance in some (larger) countries may be carried out by people without the right (electrical) expertise, although no further evidence was found to support this view.

Table 17 compares some of the main features of both Directives. The GPSD is not aligned to the NLF, and it does not include provisions for conformity assessment procedures or notified bodies.

| | LVD 2014/35/EU | GPSD 2001/95/EC | | | |
|--------------------------------|--|--|--|--|--|
| Scope | Electrical equipment with a rated voltage between 50 V and 1000 V (alternating current) or between 75 V and 1,500 V (direct current) | Consumer products where not covered by sectorial legislation | | | |
| NLF alignment | Yes | No | | | |
| Notified bodies | Not involved | N/A | | | |
| Conformity assessment types | Module A | N/A | | | |

Table 17 - LVD and GPSD comparison table

| | LVD 2014/35/EU | GPSD 2001/95/EC |
|---------------------|---|---|
| Market surveillance | Aligned to EC No 765/2008 Art. 15(3) and Art 16 to 29; Union safeguard procedure; Measures for compliant electrical equipment found to present a risk; Procedure for formal non-compliance | Obliges Member States to put in place appropriate procedures, including for cooperation, to give opportunity for interested parties to submit complaints and ensure that these complaints are followed up as appropriate, and the Commission to promote and take part in the operation in a European network of the authorities of the Member States competent for product safety, developing in a coordinated manner with existing procedures such as RAPEX. |

5.4.3.5 ATEX Directive 2014/34/EU

The ATEX Directive 2014/34/EU covers *equipment and protective systems intended for use in potentially explosive atmospheres.* The Directive defines the essential health and safety requirements and conformity assessment procedures, to be applied before products are placed on the EU market. The Essential Health and Safety Requirements in Annex II provide for the requirements relating to the design and construction of the relevant equipment and protective systems, including specific requirements for specific equipment types. The ATEX Directive is aligned with the New Legislative Framework policy, and it is applicable from 20 April 2016, replacing the previous Directive 94/9/EC.

Products for use in potentially explosive atmospheres are explicitly excluded from the scope of the LVD. However, the devices which are intended for use outside potentially explosive atmospheres but *required for or contributing to the safe functioning of equipment and protective systems* are not excluded from the scope of the LVD. In such cases both Directives shall be applied. Table 18 provides further comparison of provisions. **No particular conflicts were identified** between LVD and ATEX.

5.4.3.6 Medical Devices Directive 93/42/EEC

The legal framework on medical devices has been recently revised to reflect progress over the last 20 years. Two new Regulations – on medical devices and on in vitro diagnostic medical devices – were adopted by the Council and the Parliament, and entered into force in May 2017. They will only fully apply after a transitional period replacing Council Directive 93/42/EEC on Medical Devices (MDD) as of 26 May 2020. LVD is not applicable to electrical equipment for radiology and medical purposes that are used for therapeutic use (in this case only Directive 93/42/EEC applies). However, medical devise for home use (i.e., a foetus-monitoring device) will fall under LVD.

Like LVD, the MDD is aligned to the NLF. Notified bodies are involved in all available conformity assessment procedures. In (EU) 2017/745, the conformity assessment procedures are conformity assessment based on a quality management system and on assessment of technical documentation, conformity assessment based on type-examination and conformity assessment based on product conformity verification. Table 18 provides further comparison of provisions. For the most part, the **interaction between LVD and MDD seems to be unproblematic**. However, it was pointed out by an AdCo member that there is a competency gap in market surveillance similar to that of with RED and GPSD, and MSA that cover the medical devices for home use MDD may not have the specific skills to test such an equipment.

5.4.3.7 Lifts Directive (2014/33/EU)

Article 1 of the Lifts Directive (2014/33/EU) establishes the scope of the Directive by means of a definition given in paragraph 1 and a limitation by the exclusions set out in paragraph 2. The provisions of the Directive apply to lifts (as defined in Article 1(1)) and safety components for lifts

(as listed in Annex III). The electrical parts of lifts are explicitly excluded by the scope of the $\rm LVD^{128}$.

The Lifts Directive refers to the health and safety requirements of the Machinery Directive (which, for electrical hazards, refers to the safety objectives of the LVD). Therefore, electrical parts for goods and passenger lifts, which fall within the scope of the Lifts Directive, must comply with the safety objectives of the Low Voltage Directive (set out in Annex I of the LVD) but not with the LVD as such.

Table 18 provides further comparison of provisions. Both Directives are aligned to the NLF, and **no notable conflicts were identified**.

5.4.3.8 The WEEE Directive 2012/19/EU and the RoHS Directive 2011/65/EU

The WEEE Directive 2012/19/EU (waste electrical and electronic equipment) and RoHS Directive 2011/65/EU (on the restriction of the use of certain hazardous substances), are the outcome of the 2011 recast of Directives 2002/95/EC and 2002/96/EC, aiming at ensuring coherency with the NLF for the marketing of products in the EU. In January 2017, the Commission adopted a legislative proposal to introduce further adjustments in the scope of the Directives.

The objectives of the WEEE Directive are concerned, they are the prevention of waste electrical and electronic equipment (WEEE); the reuse, recycling and other forms of recovery of such wastes so as to reduce the disposal of waste; the improvement of the environmental performance of all operators involved in the life cycle of electrical and electronic equipment, e.g. producers, distributors and consumers and operators directly involved in the treatment of waste electrical and electronic equipment. On the other hand, the purpose of the RoHs Directive is to approximate the laws of the Member States on the restrictions of the use of hazardous substances in electrical and electronic equipment and to contribute to the protection of human health and the environmentally sound recovery and disposal of waste electrical and electronic equipment.

The vast majority of products that fall within the scope of the LVD also fall within the scope of RoHS and WEEE Directives.

The categories of products covered by WEEE and RoHS in electrical and electronic equipment are:

- Large household appliances;
- Small household appliances;
- IT and telecommunications equipment;
- Consumer equipment;
- Lighting equipment;
- Electrical and electronic tools (with the exception of large-scale stationary industrial tools);
- Toys, leisure and sports equipment;
- Medical devices;
- Monitoring and control instruments including industrial monitoring and control instruments;
- Automatic dispensers;
- Other electrical and electronic equipment not covered by any of the categories above.

¹²⁸ These electrical products are not covered by the LVD because they are covered by the Lift Directive which is more specific and therefore mutually exclusive with the LVD.

In RoHS Directive 2011 several product groups are excluded from the scope. It is the responsibility of the manufacturer, importer, or any other economic operator involved to assess whether his tool or installation benefits from either exclusion. Where a combination of equipment, components and sub-assemblies is being brought together or combined and placed on the market as a single piece of equipment or a manufacturing process line, then consideration could be given to application of other directives such as the EMC, LVD and MD. Due to the nature of the definitions, assigning broad types or classes of equipment to products' category is not possible. Decisions are to be taken on a case-by-case basis considering all criteria in each definition. The Directive's Guidelines¹²⁹ provide non-exhaustive lists of examples and criteria with the aim to support those decisions.

Table 18 provides further comparison of provisions. While no significant issues or conflicts relating to the interaction with the other Directives has been explicitly reported, it appears the **definition of 'electrical equipment' offered by some of the other Directives** (such as RoHs) are sometimes used as substitutes for interpreting the LVD, which offers no such definition.

5.4.3.9 Directive 63/2008 on competition in the markets in telecommunications terminal equipment

Directive 63/2008 on Competition in the markets in telecommunications terminal equipment aims to open up telecommunications terminal equipment markets to competition. It also aims to improve the information available to consumers on different equipment to allow users to benefit from technological progress and make informed choices as consumers.

Directive 63/2008 does not lay down any safety requirements. As of 13 June 2016, the safety and electromagnetic compatibility requirements for radio terminal equipment are laid down in RED. The safety requirements for fixed-line (non-radio) terminal equipment, depending on the characteristics, are laid down in the LVD. If the equipment has a voltage rating of between 50 and 1000 V for alternating current or between 75 and 1500 V for direct current, the requirements for electromagnetic compatibility are laid down in the Electromagnetic Compatibility Directive. Table 18 provides further comparison of provisions. **No notable conflicts were identified** between LVD and Directive 63/2008.

5.4.3.10 Directive 2014/32/EU on Measuring Instruments

The Measuring Instruments Directive 2014/32/EU (MID) establishes the requirements that measuring instruments have to satisfy with a view to their being made available on the market and/or put into use. The definition of a measuring instrument is "any device or system with a measurement function which is covered by the above-mentioned measuring instruments".

The Directive applies to the following measuring instruments: water meters, gas meters and volume conversion devices, active electrical meters, thermal energy meters, measuring systems for the continuous and dynamic measurement of quantities of liquids other than water, automatic weighing systems, taximeters, material measures, dimensional measuring instruments and exhaust gas analysers. Annex II of LVD explicitly excludes active electrical meters from its application, and **no conflicts were identified between** the two Directives.

5.4.3.11 Ecodesign Directive 2009/125/EC

The Ecodesign Directive 2009/125/EC establishes a framework for the setting of eco design requirements on Energy related Products (ErP) addressing all environmental aspects from a life cycle perspective. The EU legislation on Ecodesign is an effective tool for improving the energy efficiency of products. It eliminates the least performing products from the market, significantly contributing to the EU's 2020 energy efficiency objective. It also supports industrial

¹²⁹ <u>http://ec.europa.eu/environment/waste/rohs_eee/pdf/faq.pdf</u>

competitiveness and innovation by promoting better environmental performance of products throughout the Internal Market.

Examples of the energy related products include lighting equipment, motors, pumps, refrigerators, computers, TVs, air conditioning and ventilation systems or machine tools. Some products within the scope of the LVD will, therefore, also be within the scope of the Ecodesign Directive.

However, there are **no conflicts identified between Eco-design and LVD**, due to their different purpose and scope. The Eco-design Directive is concerned with efficiency and sustainability of the products, while the LVD concerns their conformity to security and risks provisions.

It is possible to identify synergies between the applications of both directives: Eco-design Directive introduces further requisites about sustainability and efficiency without prejudice for LVD dispositions.

Table 18 – LVD and other interaction with other Directives

| | LVD 2014/35/EU | ATEX 2014/34/EU | MDD 2017/745 | Lifts Directive 2014/33/EU | WEEE 2012/19/EU | RoHS 2011/65/EU | Directive 63/2008 | MID 2014/32/EU | Ecodesign Directive 2009/125/EC |
|-----------------------------------|--|---|---|--|---|---|----------------------------------|---|---------------------------------------|
| Scope | Electrical equipment with a rated voltage between 50 V and 1000 V (alternating current) or between 75 V and 1,500 V (direct current) | Equipment and protective systems intended for use in potentially explosive atmospheres | Medical devices and their accessories | All lifting appliances whose speed is greater than 0,15m/s | Electrical and electronic equipment | Electrical and electronic equipment | Telecommunicati ons terminals | Measuring instruments | Energy-related products |
| NLF alignment | Yes | Yes | Yes, as of (EU) 2017/745 | Yes | No | Yes | No | Yes | No |
| Notified bodies | Not involved | NLF criteria. Involved in the conformity assessment procedures according to Module B, Module D | NLF criteria. Involved in all available conformity assessment procedures | NLF criteria. Involved in the conformity assessment procedures according to all available Modules | Not covered | Not covered | Not covered | NLF criteria. Involved in the conformity assessment procedures according to Modules B, C, C2, D, D1, E, E1, F, F1, G, H and H1 | Not covered |
| Conformity assessment types | Module A | Module B, Module D, Module F | (EU) 2017/745: Conformity assessment based on a quality management system and on assessment of technical documentation; conformity assessment based on type- examination; conformity assessment based on product | Module B, Module E, Module H, Module G, Module C2, Module H1, Module D | Not covered | Not covered | Not covered | Module A, Module A2, Module B, Module C, Module C2, Module D1, Module E, Module E1, Module F1, Module F1, Module G, Module H, Module H1 | Internal design control |

| | LVD 2014/35/EU | ATEX 2014/34/EU | MDD 2017/745 | Lifts Directive 2014/33/EU | WEEE 2012/19/EU | RoHS 2011/65/EU | Directive 63/2008 | MID 2014/32/EU | Ecodesign Directive 2009/125/EC |
|------------------------|--|---|--|---|--------------------|---|----------------------|---|---|
| Aligne 765/20 | Aligned to EC No 765/2008 Art. | Aligned to EC No 765/2008 Art. 15(3) and Art 16 | MDD 2017/745 conformity verification | Aligned to EC No 765/2008 Art. 15(3) and Art 16 | | 2011/65/EU | | 2014/32/EU Aligned to EC No 765/2008 Art. 15(3) and Art 16 | Directive 2009/125/EC |
| Market surveillance | 15(3) and Art 16 to 29; Union safeguard procedure; Measures for compliant electrical equipment found to present a risk; Procedure for formal non- compliance | to 29; Union safeguard procedure; Measures of compliant products in scope found to present a risk; Procedure for formal non- compliance | Measures for post-market surveillance by the manufacturer; | to 29; Union safeguard procedure; Measures for compliant lifts and safety components for lifts found to present a risk; Procedure for formal non- compliance | Not covered | Obliges Member States to carry out market surveillance in accordance with Articles 15 to 29 of Regulation (EC) No 765/2008. | Not covered | to 29; Union safeguard procedure; Measures for compliant measuring instruments found to present a risk; Procedure for formal non- compliance | to keep the Commission informed about the results of the market surveillance. The Commission shall pass the information to other Member States where appropriate. Interested parties shall be given an opportunity to submit observations to the authorities. |

5.4.4 Conclusion with regards to evaluation questions

The table below provides the replies of the evaluation team to the evaluation questions highlighted in Annex B. These replies build upon the findings described throughout the entire section.

Table 19 – Replies to the evaluation questions: coherence

Conclusions

Regarding the internal coherence of the LVD, we conclude that:

- No significant problems were identified with the internal coherence.
- Individual points were raised by stakeholders on the language of the Directive, which is seen by some as "legal jargon" and in some cases outdated, and the lack of definition for "electrical device".
- In addition, some stakeholders are of the opinion that especially considering the increase of battery-powered devices, the bottom voltage limit should be extended or removed.

Regarding the potential issues of coherence with other legislation, we conclude that:

- The LVD is one of the oldest Single Market Directives and one of the Directives included in the Alignment Package. In general, the LVD appears to be well harmonised with the wider EU policy.
- The LVD is well harmonised with the other NLF aligned Directives.
- The biggest issues regarding the interaction with other legislative acts are with the Radio Equipment Directive (RED). The unclarity of and changes in respective scopes of the Directive lead to both confusion and additional costs to stakeholders, and the changing of scope of specific equipment due to Wi-Fi connection causes competency gaps for the testing and market surveillance authorities.
- Issues were also identified with the Machinery Directive, where the scope is not entirely clear, and with the GPSD, which may lead to similar competency gaps as the RED connection.
- However, most stakeholders considered that these issues stem from problems with the other Directives. Of all the EU legislative acts, stakeholders seem to consider the interaction with the RED as creating the most significant challenges. Some consumer associations and national authorities supported the merge by citing potential greater harmonisation and a better capability of taking into account technological developments: especially with the rise of Internet of Things. A comparative analysis of the relevant provisions of both Directives shows indeed that the obligations of economic operators with respect to radio equipment under the scope of the RED and electrical equipment under the scope of LVD are equivalent and symmetrical. For economic operators, a product falling under the RED would mean the involvement of a notified body within the conformity assessment procedure, which in principle should increase safety. Apart from this factor, whether a product falls within the LVD or RED has no significant impact on economic operators but the majority of stakeholders consulted also do not support merging the LVD with, RED. Several Member States participating in the LVD Workshop also noted that a new unified Directive would potentially lead to additional administrative burden.

5.5 EU Added value

This section presents the findings on the **EU added value** of the LVD. Following the Better Regulation Tool #47, this section brings together the findings of the other evaluation criteria to assess the LVD based on the following three criteria:

- 1. Effectiveness: where EU action is the only way to get results to create missing links, avoid fragmentation, and realise the potential of a border-free Europe.
- 2. Efficiency: where the EU offers better value for money, because externalities can be addressed, resources or expertise can be pooled, an action can be better coordinated.
- 3. Synergy: where EU action is necessary to complement, stimulate, and leverage action to reduce disparities, raise standards, and create synergies.

5.5.1 Effectiveness

The LVD aims to eliminate barriers and ensure free movement of (compliant) products on the single market, as well as to ensure safety of those products. As such, its purpose is to avoid fragmentation of safety standards and to realise the internal market for products in its scope. As discussed in sections 5.4.2 and 5.4.3 the LVD is also coherent and well harmonised by the wider single market policy and other NLF aligned Directives.

As noted in section 5.3.1, the majority of all types of stakeholders consulted consider the LVD as "very relevant" in achieving the objective of free circulation of compliant products within the internal market. As discussed in section 5.1.1, the majority of stakeholders view positively the role of the LVD in facilitating the functioning of the internal market. Specifically mentioned were both placing products on the market and recalling/withdrawing non-compliant products in the internal market as one area, while still providing for an opportunity for the Member States to raise objections against measures taken by another Member State.

The voluntary harmonised standards are also identified as an effective tool for the implementation of common rules and procedures across the internal market, while ensuring that essential safety requirements are met and without hindering innovation. As discussed in section 5.1.1, stakeholders flagged some concerns regarding the slow speed of the standardisation process, as well as the fact that recent developments, particularly the James Elliot judgment¹³⁰, may bring the voluntary nature of the standards to question. It was also observed that due to the fixed cost of standards, their relative burden is higher for smaller businesses.

Regarding the objective of ensuring safety of electrical products in the internal market, the majority of all stakeholder groups consider that the LVD is "very relevant" for ensuring the safety of electrical products, as discussed in section 5.3.1. The majority of all stakeholder categories consulted also consider that the LVD has improved the safety of electrical products in the EU to a significant extent (see section 5.1.2). Standards are widely reported as the most widely used and also the most preferred method for ensuring the compliance of electrical equipment. According to the stakeholders, the standards ensure the convergence of state-of-the-art practices across the EU, as well as the safety of products by formalising the essential safety requirements.

No significant differences in transposition across Member States were identified. There are also very limited to no excess norms, procedures or procedures in the Member States. As discussed in section 5.1.2, all types of stakeholders highlight the LVD's essential requirements, which leave no room for interpretation, as they simply refer to "safety". Thus, also in terms of implementation the LVD functions well in facilitating the internal market.

Variances in market surveillance intensity and practices, resulting from budget and resource constraints, were highlighted as an issue negatively affecting the LVD's ability to realise the

¹³⁰ The James Elliot Construction case C-613/14 referred to harmonised standards as part of EU law (See: http://curia.europa.eu/juris/liste.jsf?language=en&num=C-613/14)

internal market, as it was considered by some national authorities to create '*markets within the internal market*', with some economic operators choosing to go for countries where market surveillance activities are considered less stringent. There is however no common perception among manufacturers that the single market is segmented in "easily accessible" markets (with lower safety standards) and markets "accessible only with difficulty".

The national budget constraints on market surveillance prevents responsible public authorities from performing sufficient in-depth product testing on a large scale, potentially highlighting a gap between formal compliance with the LVD and actual effectiveness of the safety provisions included in the Directive. As discussed in section 5.1.2, there are also issues with intercepting non-compliant products entering the market from outside the EU, as custom officers do not have the relevant knowledge or training, and their main focus is on stopping products that are illegal or unlabelled rather than non-compliant as such. In addition, there are no enough resources to examine the contents of every shipment. It was also noted that the Member State authorities have limitations on how much pressure they may apply on extra-EU manufacturers.

5.5.2 Efficiency

As discussed above, the LVD ensures the safety of products and eases the launch of products, particularly compared to the situation where 28 different national systems would be in place. It also does this in a way that the stakeholders consider to be of low to medium burden.

As discussed in section 5.2, the benefits generated by the LVD outweigh its costs for each type of stakeholder. As detailed in section 5.2.2, national authorities particularly benefit from:

- the LVD as an EU-level instrument and the use of (harmonised) standards, leading to decreased need of updates of national legislation
- ease of product evaluation based on common rules and standards
- ease of coordination on withdrawal/recall of non-compliant products
- the synergies in key discussions and activities, including standardisation.

For economic operators, there are particular benefits from:

- uniform framework for ensuring the health and safety of their products, and for lauching the products on the market
- the flexible self-certification and voluntary standards, allowing for innovation.

Tax payers also benefit from:

- the high level of safety of the electric equipment, including access to instructions and technical documentation
- higher number of products and innovative products on the internal market.

The stakeholders also credit the fact that LVD also facilitates cooperation through the AdCo and the Working Party, allowing for discussion and change of views between national authorities and economic operators, creating synergies, facilitating the exchange of best practices and sharing of experiences, allowing for refining and clarifying the common rules and practices. Such communication platforms with similar level of authority and geographical reach would be more difficult to create outside the framework of an EU level legislation.

5.5.3 Synergy

The flipside of the LVD facilitating the internal market and common rules on safety is that without EU-level action, it is possible that safety standards and/or procedures for addressing dangerous products could differ between Member States, although the extent of diversity of approaches is challenging to establish. In any case, this could hinder the cross-border market of products, and information on dangerous equipment spread in different countries would not automatically be shared as widely and comprehensively. In addition, consumers could not rely on uniform safety standards across the EU. As discussed in section 4.2, the intra-EU market is growing in volume, highlighting the importance of common regulation.

As discussed above and in section 5.3.3, the set of harmonised rules and procedures support fairness across the playing field, and the standards make it clearer for both the economic

operators and national authorities to know what they need to do to ensure compliance. The stakeholders also benefit from the standards ensuring the convergence of state-of-the-art practices for safety across the EU, by concretising the requirements of the Directive that may be considered as very generic and succinct.

Several stakeholders also favourably compared the LVD to other Directives, noting that its stability, clarity and accompanying guidance documents make it clearer and easier to comply with than other Directives it was compared to, such as RED and the Machinery Directive.

5.5.4 Conclusion with regards to evaluation questions

The table below provides the conclusions regarding the EU added value of the LVD. These replies build upon the findings described throughout the entire section.

Table 20 - Replies to the evaluation questions: EU added-value

Conclusions

Regarding the effectiveness of the LVD in creating missing links, avoiding fragmentation, and realising the potential of a border-free Europe:

- By providing uniform safety requirements across the EU single market, the LVD guarantees the free flow of products within its scope, and a level playing field for the economic operators.
- The stakeholders consulted consider the LVD to be relevant to both ensuring safety of products in its scope and ensuring their free movement in the single market. It is also considered effective in meeting these two objectives.
- The LVD has been consistently implemented across Member States.
- Issues identified mainly concern resource related variances in market surveillance intensity and practices.

Regarding the efficiency of the LVD in offering better value for money through addressing externalities, pooling resources or expertise and coordinating action:

- The LVD brings added value to the economic operators particularly through generating a level playing field for low voltage products on the internal market, and to consumers by ensuring the safety of products.
- The benefits generated by the LVD outweigh its costs for each type of stakeholder.
- The LVD also provides methods of cooperation through the Working Party and AdCo.

Regarding the capacity of the LVD to complement, stimulate, and leverage action to reduce disparities, raise standards, and create synergies:

- Without EU-level action, it is possible that safety standards and/or procedures for addressing dangerous products would differ between Member States.
- The set of harmonised rules and procedures support fairness prevent disparities and ensure high safety standards across the internal market.
- Stakeholders view the LVD favourably also in comparison to other EU Directives, such as the RED, and legal product safety frameworks in other countries, such as USA and China.

6. CONCLUSIONS

This chapter summarises the conclusions of the evaluation drawn on the basis of the findings presented throughout the previous chapters of this report. These should therefore be considered in parallel with the elements above, which further substantiate and/or nuance them, and not as 'standalone' messages.

6.1 Effectiveness

As regards its general objectives related to internal market and health and safety, the LVD itself can be considered as fairly effective, based on the data available in the context of this evaluation. Factors hindering the full achievement of its objectives are in fact mostly external to the Directive.

With regards to the internal market, the Directive is generally seen as contributing to an effectively operating internal market for electrical equipment in its scope, by removing regulatory and procedural barriers to trade, thereby facilitating intra-EU trade among economic operators. Indeed, the Directive contributes positively to the establishment of a set of harmonised rules and procedures for electric equipment throughout the EU (notably through the promotion of harmonised standards). No major cases of discrepancies have been detected across Member States in interpreting the requirements of the LVD for particular products.

As regards the extent to which the LVD effectively provides for a levelled playing field for economic operators, the affordability of international standards (which are revised more often than national standards) and the participation in standardisation activities as a whole, pose challenges for smaller players. Moreover, EU national authorities do not have powers to effectively act upon (un-)/compliant extra-EU competitors, which creates unfair competition between EU businesses and such competitors. This aspect, along with the issues relating to consistent market surveillance across EU Member States and the creation of '*markets within the internal market*', should however be re-examined in the near future the light of current policy developments relating to Regulation (EU) 2019/1020.

With regards to health and safety, the limited quantitative data collected by Member States does not allow to firmly conclude on the overall level of safety in the EU low voltage market sector. RAPEX shows that the most commonly reported risk types are the risk of electric shock (65% of all alerts in 2005-2017), the risk of fire (5%), and the combination of the two (17%). Other types of risk reported include choking, cuts, burns, damage to sight, chemical, drowning, suffocation/asphyxiation, and unspecified injuries and health risks. Further, the most commonly reported RAPEX category is electrical appliances and equipment (55% of alerts over 2005-2018), which includes equipment such as small kitchen appliances and home electronics, cables, chargers and adapters, and hand tools.

Opinions of both national authorities and consumer organisations are rather positive regarding the contribution of the LVD on the safety of products, despite the identification of some improvement opportunities.

On the positive side, (harmonised) standards in particular play a key role in ensuring converging safety practices and are widely used by economic operators, who thereby benefit from both the presumption of conformity and the flexibility for product innovation. In addition, the Directive is overall considered to provide a fairly effective conformity assessment module, which in most cases allows to ensure the essential safety requirements are met.

Outstanding concerns remain on the extent to which the currents conformity procedures are effective enough for riskier products as well as for operators who may be less accustomed with conformity assessment duties. It should be further analysed whether including another module (B) into the Directive could increase the level of safety of low voltage products on the internal market. This module could provide additional support to smaller players in the conformity assessment process through the involvement of notified bodies, who, in parallel would certify the

conformity of products that are considered as involving higher risks than average. Here it should be noted that the previous role of Notified Bodies within the framework of the LVD did not have a direct impact on the process of placing products on the internal market, but rather a role related to arbitration. On this specific change of the Directive, neither the EU-level and fieldwork interviews, nor the LVD Working Party Workshop did bring about any concerns.

Other improvement areas include: the requirements on the quality of technical documentation and safety instructions which could be strengthened to ensure they speak to end-users, and, the clarity of product labelling, which could be enhanced to ensure traceability.

In sum, limitations to the effectiveness of the LVD are mainly due to the intensity of market surveillance activities, which vary across the EU, and therefore leave room for uncompliant products not being intercepted. Indeed, as confirmed by the 2018 refit evaluation on the implementation of market surveillance Regulation (EC) No 765/2008, the extent to which Member States are able to identify uncompliant products is dependent on the Member States authorities' resources. While this is an element beyond the remit of the LVD, it negatively affects the enforcement of the Directive. As a consequence, the capacity to prevent uncompliant products from entering the internal market is impacted, similarly to the trade flows of electric equipment in the EU (avoidance of surveillance-intensive countries). Issues relating to market surveillance may also allow for the presence of uncompliant extra-EU economic operators selling products directly to EU consumers, notably via eCommerce who may influence the safety of products available on the internal market negatively.

6.2 Efficiency

The lack of data on costs and benefits of the LVD does not allow to conclude on the overall efficiency of the Directive with precision.

However, based on both, the qualitative and quantitative assessment of the costs and benefits of the Directive it appears that the benefits generated by the LVD outweigh its costs for each type of stakeholders – including national authorities, economic operators (irrespective of their size of place in the value chain) and tax payers, both individually and as a whole.

On the one hand, the costs for national authorities are composed of transposition, implementation and enforcement costs, which are deemed as rather low by stakeholders consulted. Costs borne by economic operators are composed of specific resources dedicated to LVD, technical compliance, procedural compliance and administrative compliance costs, which, while having a greater relative importance for SMEs, are considered as moderate to low by stakeholders consulted. As far as tax payers are concerned, the main costs related to LVD and other product legislation are taxes withheld for social security and public health. Consumer organisations consulted deem theses costs as proportionate to the benefits of the Directive.

On the other hand, benefits of the Directive for national authorities are related to cost-savings on regulatory activities, market surveillance and coordination, which are deemed as rather high to moderate. Economic operators benefit mainly from cost-savings on application of national safety compliance requirements, as well as facilitated intra-EU trade and increased competitiveness, which are both deemed as rather high to moderate. Finally, benefits for tax payers are related to increased safety and quality of products and availability of product choices and reduced prices thereof in the internal market. Consumer organisations consulted deem these benefits as outweighing the costs of the Directive.

Overall, based on the attempts of quantification proposed by the evaluation team, at the aggregated level, for each unit of cost, the Directive would generate indicatively 1.7 units of benefits, i.e. if taken in monetary terms, for every euro invested in the implementation of the LVD, the EU as a whole gains $1.7 \in$ worth benefits in return.

As a result, the evaluation team has concluded that the Directive is both affordable for its stakeholders (including national authorities, economic operators and tax payers) as well as fairly cost-effective legislative instrument. Indeed, based on the rather positive assessment of the

Directive's effectiveness (see section 5.1), it appears that the costs generated as part of the implementation of the LVD genuinely contribute to the achievement of the internal market and safety objectives.

In addition, following the discussion on the conformity assessment procedures currently included in the Directive and the possible inclusion of another, more costly procedure for the sake of increasing safety, the evaluation team concludes at this stage that the current achievement of the Directive's objectives could not be reached at a lower cost. However, it should be noted that further research is to be carried out in order to verify and define from a cost perspective the impacts of any discrepancies noted across Member States, which if verified as an actual and significant cost, could represent an alternative for decreasing the overall costs related to the implementation of the Directive.

Lastly, in light of the conclusions related to relevance and added-value, it can be concluded that the costs, which appear to be at the minimum possible and outweighed by benefits for all types of stakeholders involved, are borne for a justified cause. Indeed, the LVD is still considered as a relevant piece of legislation today, as its objectives are deemed to be corresponding both to the needs of taxpayers as well as those of economic operators. In the same vein, the added-value of the Directive lies notably in the capacity of the LVD, a piece of legislation preferred by EU economic operators over other EU Directives and international regulatory frameworks, to reduce disparities across national markets, raise safety standards, and create synergies across Member States.

6.3 Relevance

The objectives of the LVD are still relevant today. This is true for both objectives: 1) ensuring the health and safety of persons, domestic animals and property, and 2) ensuring free circulation of compliant products within the internal market. It addresses both the needs of consumers (which expect safety and benefit from a free circulation on the internal market) as well as those of economic operators (most of which consider safety as a key aspect of their competitiveness, and have the need for reducing barriers for intra-EU trade).

The Directive is generally considered quite clear, for example concerning the requirements to prove compliance, the conformity assessment procedures, etc.. However, in some cases it is not clear whether a product falls within the scope of the Directive. Indeed, "electronic equipment" is not defined and also the exceptions in Annex II lack clarity. In addition, the introduction of other Directives (notably the RED), together with technological changes (increased use of IoT), has effectively reduced the scope of the Directive in terms of number of products covered, and also created more grey areas (which directive covers a specific product?).. Increasing the clarity of scope of the LVD by including specific lists, notably of products or safety risks, both has its advantages and disadvantages. While it would help to increase clarity, an explicit list of LVD products and/or safety issues runs the risk of accidentally excluding products or safety issues, and the risk that with new technological developments, these lists have to be continuously updated.

With respect to products currently excluded from the LVD (as defined in Annex II), there are few strong opinions on the justification of their exclusion, as the majority of stakeholders did not have an opinion of the issue. "Plugs and socket outlets for domestic use" is the only category which a small majority of stakeholders indicate that it could be included within the scope of the LVD. The majority of stakeholders who expressed an opinion, is not in favour to include other categories currently in Annex II in the scope of the LVD.

With respect to the voltage limits of the LVD, the lower voltage limit seems no more justified from a safety perspective Indeed, the risk does not only depend on the voltage, but also on other factors (like the maximum current an electrical source can deliver) and therefore even products below the lower voltage limit can cause thermal burns or electrocution. In Norway, the LVD has already been implemented without the lower voltage limit. However, economic operators claim a disproportionate increase in burden respect to benefits, in particular for low cost-products (e.g. birthday cards with music)

The provisions of the Directive related to safety are formulated in a technological-neutral way and can therefore be applied also on new products. Provisions that have been criticised by stakeholders (both economic operators and consumers) are the requirements relating to marking and documentation, which do not facilitate the use of internet-related solutions in combination with information on the product/in manuals. Moreover, based on the response to the OPC, there is room for improvement regarding the information provided to consumers with LVD products, as consumers are currently not always able to easily find and understand the information provided (e.g. related to safety instructions, contact details of manufacturer/importer).

6.4 Coherence

Regarding the internal coherence of the LVD, no significant issues were identified therein. Individual points suggested for improvement were the language of the Directive, which could be seen as outdated in some cases and using unnecessary "legal jargon" and providing a definition for "electrical device".

Regarding the external coherence with wider EU policy, the LVD was found to be well harmonised. Regarding the coherence with other legislative acts, issues were identified in particular relating to the Radio Equipment Directive 2014/53/EU. Due to the 'exclusion from LVD' referred to within the RED, all types of stakeholders experience issues in determining to what extent a product should fall under each Directive. This creates both confusion and additional administrative burden for the stakeholders, in particular for economic operators and market surveillance authorities. More specifically, the identified issues include:

- **Confusion** particularly about the involvement of a notified body in the conformity assessment procedure (required under the RED, but not under the LVD).
- Economic operators having to make the choice with Directive to apply in unclear situations, with no guarantee that all Member States will agree with the interpretation, creating **additional costs**.
- Application of RED rather than LVD to all equipment with Wi-Fi connection, despite the fact that the potential **health and safety risks** of the product relate to their LVD related aspects rather than IoT aspects.
- Related to the point above, **a competency gap** with respect to effective market surveillance, in Member States where national market authorities have to cope with the fact that traditionally LVD products are supervised by radio equipment experts.

Besides the coherence issues with RED, it was observed that there are some unclarities regarding the Machinery Directive 2006/42/EC, as for certain product categories the Machinery Directive does not provide a definition. This creates some confusion as to when to take the end use as domestic or industrial (e.g. with laundry machines or 3D printers), which would determine whether the LVD or the MD should be applied.

Also, where the General Product Safety Directive 2001/95/EC applies due to it containing different or more specific provisions, it was suggested by the consulted stakeholders that there might be similar competency gaps as with the RED.

However, most stakeholders considered that these issues stem from problems with the other Directives. Of all the EU legislative acts, stakeholders seem to consider the interaction with the RED as creating the most significant challenges. Some consumer associations and national authorities supported the merge by citing potential greater harmonisation and a better capability of taking into account technological developments: especially with the rise of Internet of Things. A comparative analysis of the relevant provisions of both Directives shows indeed that the obligations of economic operators with respect to radio equipment under the scope of the RED and electrical equipment under the scope of LVD are equivalent and symmetrical. For economic operators, a product falling under the RED would mean the involvement of a notified body within the conformity assessment procedure, which in principle should increase safety. Apart from this factor, whether a product falls within the LVD or RED has no significant impact on economic operators but The majority of stakeholders consulted also do not support merging the LVD with RED. Several Member States also noted that a new unified Directive would potentially lead to additional administrative burden.

6.5 EU Added-value

By providing uniform safety requirements across the EU single market, the LVD facilitates the single market. In addition, it provides the consumers with reliably safe products on the internal market. The stakeholders consulted view positively both the Directive's relevance to its objectives and its effectiveness in meeting them.

Regarding its ability to offer better value to the stakeholders, the LVD brings added value to industry through generating a level playing field and clear rules for compliance, and to consumers by guaranteeing equal high level of safety of products across the EU. In addition, it provides methods of cooperation through the Working Party and AdCo.

By providing a common set of rules and standards, the LVD prevents fragmentation of safety rules across the Member States. The standards make it clearer for both the economic operators and national authorities to know what they need to do to ensure compliance and ensure the convergence of state-of-the-art practices for safety across the EU, by concretising the requirements of the Directive that may be considered as very generic and succinct.

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