Lot VI - Interim, final and ex-post evaluations of policies, programmes and other activities

Evaluation of the Internal Market Legislation for Industrial Products

Executive Summary

13 January 2014
Executive Summary

The Evaluation of Internal Market Legislation for Industrial Products was carried out for the European Commission’s DG Enterprise and Industry by the Centre for Strategy & Evaluation Services (lead)\(^1\), Panteia and Oxford Research. This document sets out an executive summary of the study findings and recommendations. Reference should also be made to Section 7 of the final report which sets out the detailed rationale for each of the recommendations.

1.1 Evaluation aims and scope

This evaluation study provides an assessment of the relevance and coherence, efficiency, utility, effectiveness and impacts of Union harmonisation legislation and addresses a series of specific evaluation questions\(^2\). It provides an opportunity for a stock-taking exercise to assess the fitness for purpose of the body of Union harmonisation legislation that has evolved over a 30 year period.

The objectives were, in summary, to:

- Examine how far the body of internal market (“IM”) legislation for industrial products is fit for purpose and the extent to which they constitute an effective means of addressing barriers to the functioning of the internal market for industrial products;
- Evaluate the relevance and coherence, efficiency, utility, effectiveness and impact of Union harmonisation legislation and address a series of specific evaluation questions\(^3\);
- Identify and analyse any gaps, loopholes, inconsistencies and duplication in IM legislation for industrial products or in administrative requirements for economic operators;
- Assess the costs and benefits of Union harmonisation legislation for economic operators and the impact on strengthening industrial competitiveness;
- Assess the cumulative impacts of, and interaction between legislation and compliance requirements\(^4\).
- Make recommendations as to how the efficiency and effectiveness of IM legislation for industrial products (including structures and institutional actors to support its implementation) could be improved so as to strengthen industrial competitiveness and create more favourable conditions for growth and jobs;
- Identify possible future regulatory and administrative simplification measures and assess the appropriateness and feasibility of the different options to feed into a possible future impact assessment and carry out a preliminary analysis of the potential impacts.

The study’s scope was defined as Union harmonisation legislation for industrial products under Article 114 of the Treaty (TFEU), which allows for technical approximation measures to be adopted, while at the same time ensuring high levels of protection for safety and health, consumers and the environment. Since the adoption of the New Approach to legislating for products through the setting of essential requirements in the mid-1980s, there has been a gradual accretion of Union harmonisation legislation for industrial products. Today, there are more than 30 different internal market directives and regulations, with a distinction between legislation that covers specific areas of industrial products (e.g. pressure equipment, gas appliances) and horizontal directives that apply across many different product groups (e.g. RoHS, REACH).

---

\(^1\) The study is part of Lot VI of the Framework Contract for the Procurement of Studies and other Supporting Services on Commission Impact Assessments and Evaluations (2008/S146-195858).
\(^2\) A summary of the key evaluation questions specified in the specifications is provided in Section 2.1
\(^3\) A summary of the key evaluation questions specified in the specifications is provided in Section 2.1
\(^4\) A typology and conceptual framework showing how cumulative impacts have been assessed through the research is provided in Section 2.3.
Executive Summary

The study covered most though not all pieces of Union harmonisation legislation⁵, and also the workings of the regulatory regime, including European and national implementation structures. The focus was on harmonised products, although some research was undertaken in the non-harmonised domain. Industrial products are subject to both European internal market and environmental legislation. Although environmental legislation was formally outside the scope, the cumulative effects stemming from the interaction between different applicable legislation were taken into account.

1.2 Methodological approach

The methodology consisted of three phases and the use of a number of different research tools and methods for data collection and analysis. The study required a combination of desk research to review EU legislative texts and guidance documents, the carrying out of three online surveys, a major interview programme and the undertaking of product-based case studies across 10 selected product categories. In parallel, the Commission undertook an online consultation through Your Voice and integrated the results into our study. The following diagram shows the interconnection between the different phases and elements of the study.

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

The findings are strongly evidence-based since a broad spectrum of stakeholders took part in the evaluation, ranging from national competent authorities, market surveillance authorities, notified bodies and members of notified bodies groups, Administrative Cooperation groups (ADCOs), Product Contact Points, through to industry associations and firms. In total, 128 responses were received to the survey of notified bodies and accreditation bodies organised by CSES and 201 interviews were carried out across a broad spectrum of stakeholders. In addition, we analysed the results from a Your Voice online public consultation organised by the European Commission.

⁵ Specific pieces of IM legislation were excluded including the Construction Products Regulation and the Medical Devices Regulation (2012)⁶. Environmental legislation falling outside the scope of Article 114 (WEEE Directive, Energy Performance of Buildings Directive) were also formerly outside the scope, although the interaction with relevant IM legislation was considered.
Ten product-based case studies were carried out, eight in product groups subject to harmonised product legislation, and two in non-harmonised product groups. The harmonised cases selected were: electric motors, laptops, domestic refrigerators and freezers, lifts for persons, gardening equipment, instruments and appliances for measuring, testing and navigation, air conditioners and integrated circuits. The non-harmonised cases selected were ski and snow footwear and bicycles. The product case studies were supported by input from industry. A total of 62 firms and 20 industry associations took part. The aims were to: map out the applicable legislation for each product; analyse the business processes and procedures for managing compliance; develop an understanding of the different costs involved at particular stages in the compliance process (from familiarisation with the legislation and administrative requirements, through to conformity assessment and the preparation of technical documentation and a declaration of conformity (DoC). The possible scope for further administrative and regulatory simplification has also been examined.

2.1 Relevance and coherence

Among the issues examined relating to “relevance and coherence” were the extent to which Union harmonisation legislation is relevant to the problems and needs identified in the intervention logic, whether directives or regulations are a more effective instrument to achieve objectives, the extent to which the regulatory framework is coherent and consistent between different pieces of legislation and whether gaps, loopholes and inconsistencies could be identified.

The intervention logic underlying Union harmonisation legislation and the setting of minimum essential requirements for health and safety, supported by voluntary technical standards developed by European standards bodies in cooperation with industry, is fundamentally sound. Although there are differences of opinion as regards how burdensome IM legislation and the administrative requirements for economic operators are, industry stakeholders accept the need for such legislation.

The periodic recasting of IM directives and regulations has helped to ensure that Union harmonisation legislation remains coherent, and takes into account key developments in particular sectors and industries, as well as the views of stakeholders participating in expert working groups on particular directives and regulations wherever particular problems (such as inconsistencies or regulatory gaps) emerge. This has helped to keep the legislation up to date.

The New Legislative Framework (NLF) and Alignment Package of 9 Directives have begun to strengthen the coherence of the legislative framework for Union harmonisation legislation and promoted its modernisation. For instance, common definitions and obligations for different economic operators have been introduced. Although some minor regulatory gaps were identified and inconsistencies in administrative requirements, the problems identified are not that significant given the number of different pieces of internal market that have evolved over a 30 year timeframe. The NLF has however yet to be fully implemented, which means that minor inconsistencies will remain until 2015. The full and effective implementation of the NLF, the Alignment Package and further measures to align IM regulations and directives are necessary steps to ensure that there is a consistent and common underlying framework.

As regards the most appropriate regulatory instrument for Union harmonisation legislation, directives have been the main mechanism for regulating harmonised industrial products under the New Approach. However, the research has identified disadvantages with directives, such as the lack of synchronised timing in their implementation due to different national transposition timetables and minor divergence in interpretation.

Executive Summary

Regulations have become the preferred instrument in the past 5 years since they come into effect across all Member States simultaneously, thereby ensuring uniformity in application. However, the scope for deviations during the transposition was viewed as being limited, according to some national authorities and industry representatives. More consistent use of a single regulatory instrument would help to make the overall regulatory approach more coherent.

Although the legal framework underlying Union harmonisation legislation is generally clear and cogent, there are a number of areas where greater clarity would help to strengthen its coherence such as in relation to spare parts and components, where the research identified a divergence in approach between directives and regulations. This means that there are some inconsistencies as to whether spare parts and components are included within the scope of particular IM legislation.

There is already a common framework through Decision 768/2008/EC that sets out common elements that apply across Union harmonisation legislation. It would arguably be more coherent to set out these common aspects in a single horizontal regulation, rather than incorporating these in each and every piece of sectorial legislation, since this adds to the length and complexity of each piece of IM legislation.

2.2 Efficiency

Two sets of issues were considered under the “efficiency” criterion, firstly, the efficiency and effectiveness of mechanisms and structures to support the implementation of Union harmonisation legislation at national and European levels. Secondly, we examined the costs of compliance with IM legislation for manufacturers and other economic operators, how proportionate this is (taking into account the benefits – see effectiveness) and whether there is scope for further regulatory simplification.

2.2.1 Implementation mechanisms

There are a number of different mechanisms and structures at EU and national levels that facilitate the implementation of IM legislation. The extent to which these mechanisms and structures demonstrate efficiency and effectiveness was analysed and the main findings were that:

The Commission has played an effective role in the development of the legislative framework and in coordinating the periodic review and recasting of IM legislation in cooperation with industry. The Commission’s role in producing non-binding guidance to support manufacturers in complying with Union harmonisation legislation was viewed as important. However, there is a need to urgently update the current Blue Guide to reflect the changes that have been made through the New Legislative Framework and the Alignment Package. Although an updating process is ongoing, it was felt by some stakeholders that this should have taken place earlier.

Administrative Cooperation Groups (ADCOs) have been an effective mechanism for promoting detailed technical discussions on specific IM directives/regulations. ADCOs are seen as being knowledgeable about specific IM directives/regulations and play a useful role in informing the Commission about any particular problems and implementation-related issues.

Notified Bodies Groups have been found to be playing a positive role in strengthening cooperation between Notified Bodies across different Member States and the European Commission. There are however concerns regarding the differing levels of knowledge and experience among participants.

National Competent Authorities play an important role since they have strong technical knowledge about the specific IM directives/regulations for which they are responsible and are able to inform the Commission if there are any difficulties in implementation, such as economic operators experiencing difficulties in understanding or complying with particular administrative requirements.

7 Guide to the implementation of directives based on the New Approach and the Global Approach
Executive Summary

There are concerns among many stakeholders regarding the effectiveness of market surveillance, arising from: variations in the human and financial resources made available for market surveillance activities across different Member States, the low likelihood that more complex products such as industrial machinery will be checked and tested by Member State Authorities (MSAs) for technical compliance due to the lack of adequate technical capacity and practical challenges in testing products against the requirements set out in more complex IM legislation such as the Ecodesign Directive and its implementing regulations.

A further challenge is that there are differences in approach to market surveillance between MSAs as to the degree of emphasis they place on checking products for technical compliance and administrative requirements respectively. There is a perception among economic operators that there remain unacceptably high levels of non-compliance, which undermines the level playing field and serves as a disincentive for firms to invest in meeting European compliance requirements. With regard to e-commerce, from a market surveillance perspective, there are practical difficulties in preventing non-compliant products from entering the EU from third countries purchased on-line.

The Commission has already recognised the importance of strengthening the effectiveness of market surveillance and is seeking to take action in this area through the NLF and the PSMSP. For instance, coordination mechanisms at European level such as RAPEX have had their role expanded so as to promote information exchange about dangerous products between MSAs and through the ICSMS system to allow for greater coordination. This is viewed as having been effective, and support for such mechanisms as RAPEX and ICSMS is viewed by interviewees as being crucial to ensuring adequate cooperation on market surveillance matters.

However, there was a broad consensus that more remains to be done to strengthen market surveillance (for instance, ensuring that MSAs have the technical capacity to test more complex machinery and compliance with the eco-design requirements). One possibility is to extend the current practice in some Member States more widely, whereby some countries routinely publish the results of testing on web sites. This would make the process more transparent. The proposal for a Regulation on the Market Surveillance of Products (COM(2013)75) is seen as a step in the right direction, but there are concerns among stakeholders that the practical feasibility of some proposals has not - as yet - been fully thought through (e.g. no longer making a distinction between harmonised and non-harmonised approaches, and between consumer and industrial products). It was argued that these areas call for a differentiated approach to market surveillance.

**Notified bodies** were found to be playing an important role in supporting the implementation of Union harmonisation legislation. The services provided by testing, certification and inspection bodies continue to be in high demand, even though third party conformity assessment is not mandatory for the majority of IM directives and regulations. Manufacturers need to reassure their customers that products are safe and third party observation of internal testing may be imperative as part of quality management and production audit procedures. Less positively, however, there were concerns that the quality and consistency of the services provided by notified bodies varies. This problem could potentially be tackled through more rigorous accreditation.

---

9. Rapid Exchange of Information System, EU rapid alert system for dangerous consumer products
10. Information and Communication System on Market Surveillance (ICSMS)
Executive Summary

Accreditation was recognised as playing a useful role in strengthening the consistency and quality of conformity assessment services provided by notified bodies, an area of future priority given that there is perceived to be wide divergence in the quality of services being offered. Progress has been made by the Commission in promoting the implementation of a more common approach to accreditation through Regulation 765/2008 and uniformity in institutional structures (e.g. a single national accreditation body under the responsibility of national government).

However, there were concerns that there remain wide differences between national accreditation systems and procedures between different Member States, for instance in terms of their duration, cost and the level of rigour. However, there was only mixed support for compulsory accreditation, since there were concerns that this may be financially prohibitive and inappropriate for smaller notified bodies. Some of the problems identified could be overcome through work to develop common standards for accreditation at European level, and through the adaptation of existing ISO standards developed in the area of accreditation customised to European needs.

Product Contact Points (PCPs) were set up in 2008 to ensure the efficient and effective implementation of the Mutual Recognition Regulation (764/2008) covering non-harmonised products. PCPs were found to play an important role in providing an Alternative Dispute Resolution (ADR) mechanism to provide a point of contact and initial means of problem resolution for economic operators in case of incorrect treatment of non-harmonised products.

2.2.2 Costs of compliance with Union harmonisation legislation

A further aspect of efficiency was to assess the administrative and substantive costs of complying with Union harmonisation legislation for economic operators. It has not been possible to establish a baseline in respect of the costs of compliance prior to the internal market coming into being given that was no baseline data (and many firms find it difficult to compare the current situation with that of 25 years ago before the New Approach to Union harmonisation legislation. Nevertheless, it is broadly accepted that compliance with Union harmonisation legislation across different industry sectors is less costly than would have been the case if there were 28 different sets of national legislation and technical standards (the “counterfactual”).

In the absence of a historical baseline, the study instead has sought to quantify the current costs of compliance with IM legislation, and to use this as a baseline against which to compare the possible benefits of further simplifications. However, whilst most manufacturers interviewed were able to identify the level of human resources devoted to regulatory compliance and the most costly and administratively burdensome pieces of IM legislation, few firms were able to quantify the costs incurred at each of the five steps identified in the compliance process accurately. The most common reasons cited by manufacturers why they could not provide accurate data were commercial sensitivities, and a lack of data on compliance costs internally, either because these were spread across different business divisions located in different continents of because the costs are absorbed by ODM and OEM suppliers and manufacturers are not able to obtain a disaggregated breakdown of costs.

---

11 Regulation 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93
12 ISO/IEC 17011:2004 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies
13 The five steps were: (1) familiarisation with applicable/relevant obligations, (2) the introduction of processes or changes to product design and production processes, (3) conformity assessment procedures and relevant documentation (4) DOCS or other statement of compliance and (5) CE marking and other activities.
14 ODM (Original design manufacturer) and OEM (Original equipment manufacturer)
Executive Summary

There were sometimes difficulties in establishing the share of “Business as Usual” costs (BAU), the costs that would have been incurred by manufacturers regardless of whether or not there was a European regulatory framework in place (since industry wants to produce safe products to maintain their reputation). However, where possible, these were taken into account. Since many manufacturers incorporate product safety and testing into their internal quality assurance and risk management procedures, a discount was made for BAU costs, which were found to vary between industrial product groups.

Overall, IM legislation does not appear to pose excessive cost burdens, although some pieces of legislation were regarded as costly (especially those with environmental and energy efficiency objectives rather than product safety). In several harmonised product groups under review, such as electric motors, domestic refrigerators/freezers, lifts, petrol pumps and air conditioners, annualised compliance costs (which include a combination of one-off and recurring costs, and administrative and substantive costs) for the sector do not exceed 1% of annual turnover. However, it should be stressed that there were difficulties in getting firms to estimate substantive compliance costs at the design and R&D phase for many of the harmonised product groups examined, so the true costs of compliance may be somewhat higher. There was moreover some divergence in estimated compliance costs between different product groups, which does not easily facilitate cross-product comparisons.

There were only two exceptions where compliance costs were higher than 1%, laptops (2%) and gardening equipment (3.9%). In the laptops sector, the estimates provided tended to over-estimate the total costs of compliance associated with Union harmonisation legislation alone since the industry is dominated by a small number of global manufacturers and it is difficult for them to disaggregate compliance costs fully by geographic region. Indeed, it was acknowledged that there are cost synergies for manufacturers from investment in compliance with IM legislation when exporting to other global jurisdictions, therefore costs can be lumped together. In the case of gardening equipment, the higher level of compliance costs is mainly because the costs associated with compliance with IM legislation that has an environmental focus (e.g. on outdoor noise, non-road mobile emissions) are relatively high. Furthermore, IM legislation with environmental objectives were found to have lower “business as usual” costs compared with those with product safety objectives. Administrative costs are still no more than 0.3% of annual sectoral turnover.

The requirement to strengthen the traceability of products in the value chain by requiring detailed addressee information to be provided about manufacturers and importers, were viewed as being insufficiently flexible and/ or disproportionate by some industry representatives. These affect all industrial product sectors since traceability requirements were strengthened through the NLF. However, there were particular concerns about how product packaging might be impacted for electrical products such as laptops. Since the adoption of Decision 768/2008/EC, a further uncertainty for manufacturers is that there is ambiguity as to the translation requirements for DoCs.

Compliance costs vary between different pieces of IM legislation. The costs of meeting the requirements of long-established product safety legislation are viewed as being less costly in comparison to more recent IM legislation with a focus on environmental protection and/ or on energy efficiency. Familiarisation with the legislation and with the applicable administrative requirements and technical standards for new legislation requires significant time and financial resource commitment. Incorporating energy efficiency and eco-design and broader environmental requirements into the R&D and design stage is especially cost-intensive.\(^{15}\)

\(^{15}\) The Ecodesign implementing regulations were seen as being among the most costly legislative requirements by manufacturers, particularly at the R&D and design stage because they set more demanding energy-efficient requirements that need to be incorporated in product configurations and to change motors and fans, etc. There may also be costs for to modifications of existing platforms for new models.
Evaluation of Internal Market Legislation for Industrial Products

Executive Summary

As a general rule, there was found to be an initial spike in compliance costs in the period following the introduction of new IM legislation, but this falls off over time, in the medium-long term, and there may be other benefits once the legislation is well-embedded (e.g. spurring innovation and R&D by promoting the take-up of new technologies, environmental benefits through the replacement of less energy-efficient products, the replacement of dangerous chemicals with less harmful substitutions, etc.).

The research also found evidence of differences in relative compliance costs by firm size. A considerable share of administrative costs (e.g. fees to notified bodies,) are fixed irrespective of the firm and production size and SMEs therefore experience higher costs per unit in comparison to large firms that can spread costs across a high number of units. Large firms are also more likely to participate in EU legislative-making and standardisation processes so will be aware about detailed changes to legislation well in advance of these coming into effect.

This reduces familiarisation time and minimises the level of substantive compliance costs, since regulatory requirements can be factored into the R&D/design stage from the outset. SMEs often do not have in-house testing facilities and are not therefore able to take advantage of the possible cost savings (through the use of the Supplier’s Declaration of Conformity (SDoC) conformity assessment procedure). Another difficulty for micro and small firms is that they are often only present in national markets, yet must fulfil CE marking and other compliance requirements. In other words, they have to bear the costs of IM legislation without the benefits that their larger counterparts have of accessing different national markets within the internal market.

There were only two examples of internal market legislation being adapted to alleviate some of the burden on SMEs (the Construction Products Regulation and REACH). However, with the exception of some SME associations, most stakeholders were unanimous in their opposition to introducing a differentiated approach for SMEs, with less demanding rules or procedures because of the risk of undermining the legislation’s objectives in relation to product safety.

2.2.3 Cumulative regulatory effects

The research identified a number of examples of the cumulative effects of Union harmonisation legislation, which arise from the high combined frequency of changes and updates to legislation across the body of Union harmonisation legislation. For instance, in the air conditioning sector, the introduction of eco-design requirements was regarded as burdensome especially since over a similar time period, several pieces of new environmental legislation were introduced.

There are important familiarisation costs in keeping track of updates to directives and regulations and from the introduction of new legislation, changes to administrative requirements, the integration of requirements into the R&D and product design phase. There are also costs associated with the high frequency of updates to (voluntary) technical standards, which requires reviewing and updating DoCs. Another example of cumulative effects is the cumulative burden that stems from the overall volume of European legislation applicable to a given product, when both internal market and environmental legislation are taken into account.

Since a wide range of legislation is applicable to industrial products and most manufacturers have multiple product lines, there is an almost continual process of revision and updating. It has not been possible to quantify cumulative effects since manufacturers do not keep relevant data and methodologically, it is difficult to assess how far total administrative costs burdens are greater than the sum of the individual parts. Nevertheless, manufacturers that participated in the case studies have pointed to an increased volume of EU internal market and environmental legislation applicable to products overall.
2.2.4 Simplifications

A number of possible regulatory and administrative “simplification” measures were identified through the research. These include the possibility of merging specific directives and ensuring that there are common administrative requirements across different pieces of IM legislation. In identifying possible simplification measures, we took into consideration existing simplification initiatives that the Commission is either in the process of implementing, or has already implemented, through the NLF framework (see main report - Section 5.4). Further simplifications were also identified through the interview programme and desk research.

The amount of cost savings that can be derived through simplification measures is often difficult to estimate, since it is dependent on what form the proposed simplifications might take. The potential cost savings from mergers of IM directives and regulations depend on the nature and form of the proposed simplification and how the legislation will be integrated. For example, it is necessary to know which conformity assessment modules would be applicable post-merger and how this compares with what preceded e.g. whether mandatory third party conformity assessment will continue to apply, or the Supplier’s Declaration of Conformity (SDoC) can be applied. Although firms found it difficult to quantify potential cost savings until simplification measures were defined in detail, they were able to comment on the “order of magnitude” of cost savings.

Across the 8 harmonised product cases, the regulatory and administrative costs were estimated at €342 million annually. The potential cost reductions from simplification measures identified was 11%, equivalent to €38 million. The macro-economic analysis of the impact of those savings from only these 8 sectors indicated an increase in total GDP for EU28 of around of €48 million. In the 8 sectors under review, the GDP-increase for the metallurgical industry part amounts to almost €19 million. The macro level estimates of compliance costs and potential savings from regulatory simplification are set out in Section 5.6 of the report.

2.3 Effectiveness

Among the issues considered in relation to effectiveness were the extent to which the regulatory framework underlying Union harmonisation legislation is “fit for purpose” and how far the aims set out in Article 114 of TFEU are being achieved through Union harmonisation legislation.

2.3.1 Overall effectiveness

Overall, IM legislation for industrial products is regarded as having been an effective mechanism for achieving the harmonisation objectives set out in Article 114 of the TFEU. The regulatory framework demonstrates a high degree of “fitness for purpose” and has successfully addressed the need for the free circulation of industrial products within the internal market, while ensuring minimum levels of product safety, eliminating existing barriers to trade due to different national technical regulations and standards. This meant that industry formerly incurred significant additional costs in meeting different national administrative and regulatory compliance requirements.

16 The lack of reliable and comprehensive data on the comparative costs of SDoC as opposed to mandatory third party conformity assessment made it difficult to quantify the cost savings of mergers.

17 Art 114. of the TFEU concerns the functioning of the internal market through approximation measures.
The setting of essential requirements, while leaving industry to determine how conformity with these requirements might be met was seen as a highly effective and flexible mechanism for achieving these objectives. Industry was also positive about the role that the New Approach and subsequently the NLF have played in facilitating the free movement of industrial products within the internal market, although there were different stakeholder views as to steps that could be taken to strengthen effectiveness.

No evidence was found as regards the problem of national “gold-plating”. Although there was a perception that some Member States impose additional national regulatory requirements, this was not borne out by the research, which found that barriers identified by economic operators to accessing national markets in some Member States were non-regulatory in nature (e.g. requirements relating to product maintenance, “voluntary” national labelling and energy efficiency and labelling schemes). Even though such requirements are non-mandatory, it was not uncommon for industry to feel obliged to follow “voluntary” labelling and energy-efficiency schemes in order to compete in certain national markets. Although outside the scope of Union harmonisation legislation, this can in practice still undermine the effective functioning of the internal market, since this constitutes a de facto non-regulatory barrier to trade, and imposes additional costs on industry.

Union harmonisation legislation was considered to be sufficiently technology-neutral and does not impose particular restrictions or limitations on innovation for the majority of industry representatives. Although temporary regulatory gaps may emerge from time to time (as and when new technological developments arise), the main problem is the time-lag in the development of new technical standards that replace outdated standards.

The Mutual Recognition Regulation has strengthened the efficiency and effectiveness of the regulatory regime in the area of non-harmonised products. The discussions with national contact points and industry suggest that the Regulation has been helpful in promoting a strengthened approach in the non-harmonised sector.

2.3.2 Effectiveness – other issues (e-commerce, relation between products and services)

The research has identified few problems in respect of compliance with IM legislation related to industrial products sold through e-commerce channels. However, e-commerce can present practical challenges for market surveillance for products imported from 3rd countries into the EU. MSAs do not lack the legal authority to seize non-compliant products when the products concerned were sold through an e-commerce channel, as opposed to more conventional retail distribution. Rather, they face considerable practical difficulties in the identification and interception of goods purchased from third countries via the internet.

There is an increasingly blurred distinction between product and service markets (particularly installation and maintenance). Since Union harmonisation legislation applies to the placing on the market of products and that the national in-service inspection regime applies to many industrial products already on the market, this may pose some legal issues, since EU legislation covers the product itself, rather than after-services.

---

18 The majority of manufacturers choose to follow European harmonised technical standards, which are developed by the ESOs in conjunction with industry, but there is flexibility to choose their own means of achieving presumption of conformity.
19 Although national transposition was formerly outside the scope, it was necessary to look into this issue in general terms as part of the assessment as to whether regulations or directives were a more effective regulatory mechanism.
Examples of the difficulties that this may cause were identified in a number of areas, most notably: the extent to which original suppliers are liable for the on-going safety of products (particularly when “product use” may be changed post-placement on the market as a result of software updates) and, consequently, the actions that they must take at the point of sale; the difficulty in differentiating between the supply and installation of products such as lifts and some types of machinery; the supply of spare parts and components post-placement on the market (and the administrative burdens of updating technical files) as well as their use in after-sales service, e.g. whether a new component can be placed into an old product.

There is little support for a differentiated regulatory approach between industrial products intended for professional use and those used by final consumers. There is little evidence that products for professional users, as opposed to consumers should be subject to separate legislation or to any relaxation of the essential requirements. With limited exceptions (such as medical devices), it is difficult to determine that products, such as electric power tools, will not be sold or passed on to non-professional, untrained users without too much difficulty, creating considerable risks to safety.

2.3.3 Economic benefits of the internal market in industrial products

Eurostat intra-trade statistics show that there has been growth in intra-EU trade since Union harmonisation legislation was introduced. The available data for the period 1999-2011 show a strong increase in the general level of trade in goods as the share of EU GDP but also in terms of the intra-EU trade in almost all manufacturing sub-sectors. Over a 20 year period since the Single Market’s launch in 1992, intra-EU trade of goods has grown as a share of GDP by around 5%. Intra-EU trade represented around 17% of EU GDP in 1999 and close to 22% in 2011.

However, a limitation is that EU trade data are generally only available after 1999, whereas most IM directives and regulations under examination were already in force. Nonetheless, there are examples that serve to illustrate how intra-EU trade has grown during the period for which data is available. For instance, since the adoption of the Measuring Instruments Directive (2004/22/EC) (MID), there has been a gradual evolution in the value of gas analysers within the EU from 350m EUR in 2004 to 450m EUR in 2011.

A number of macro reasons underlie this trend such as globalisation and an increase in the level of international trade, EU enlargement and the introduction of the Euro - Union harmonisation legislation has contributed to boosting intra-EU trade by tackling existing barriers to cross-border trade by reducing regulatory and market fragmentation, and promoting a level playing field with fairer competition across the internal market During this same period, there has not only been marked growth in intra-EU trade, but also in imports to the EU, in part, due to manufacturing activities being shifted to non-EU countries for goods targeted at the EU.

The discussions with industry confirmed that there have been economic benefits from the removal of technical and regulatory barriers across different national markets. This has led to a process of industry consolidation in many harmonised sectors, and to changes in market size and structure, which in turn have allowed manufacturers to benefit from economies of scale and scope. Being able to access a single European market with a single set of harmonised technical legislation applicable to many industrial products has accelerated this process. It has also helped to expedite the adoption and increased the market size of more energy-efficient products, as a result of the Ecodesign and the Energy labelling Directives.

2.3.4 Impacts of IM legislation on innovation

The research examined how far IM legislation is “fit for purpose” in facilitating innovation. While the promotion of innovation is not the prime objective of the IM legislation, the technology neutral approach adopted under the New Approach (through the setting of essential requirements and leaving detailed technical implementation to harmonised technical standards) has created an environment in which innovation can flourish.
The only weakness identified is the important time-lag between the introduction of new technologies or the innovative use of new materials being integrated into products, and the development of the relevant technical standards. Technical standards often take a considerable period of time to develop, and this may create uncertainty in the interim period. Nonetheless, manufacturers are free to work together with notified bodies in order to demonstrate conformity with the essential requirements through alternatives other than harmonised standards.

There are also no problems identified in respect of the integration of Key Enabling Technologies (KETs) in those product categories already covered by harmonised product legislation. In contrast, in the case of non-harmonised products, there is some evidence that the absence of harmonised EU legislation risks creating a situation in which Member States may introduce their own legislation in order to address possible safety or ethical risks linked to the use of such technologies. An example identified in this regard was that of nano-registries, where a small number of Member States have already legislated (France, Belgium and Denmark), with a risk that divergent legislation emerges.

There is also the potential for some pieces of IM legislation to promote innovation. Some industry representatives and firms recognised that role of specific pieces of internal market legislation with an environmental focus – such as the Ecodesign or Outdoor Noise Directive. The contribution towards removing the worst performing products from the market and strengthen the market for better performing products but they also set requirements that seek to eliminate the worst-performing products from the market. Even stronger arguments have been made in respect of the REACH Regulation which promotes the substitution of substances of very high concern and, more general, the development of knowledge concerning the use of chemical substances. In both cases, it is too early to evaluate the full impacts on innovation for either REACH or Ecodesign.

2.3.5 Impact of IM legislation on health & safety, consumer protection and environmental protection

Union harmonisation legislation has contributed towards the achievement of the key EU policy goals set out in Article 114 of TFEU, relating to ensuring the safety of products with high levels of safety and consumer protection. Union harmonisation legislation has contributed to strengthening product safety by providing a common framework across all Member States. European standards have brought about a more uniform approach to the testing and conformity assessment of products, which also has potential safety benefits. However, there is still a significant level of technical or administrative non-conformity identified by the various Market Surveillance Authorities (MSAs) that undermine the operation of the internal market and this may pose a threat to consumer safety and confidence in the effectiveness of the market surveillance system.

IM legislation has also made a useful contribution to strengthening environmental protection by setting minimum – although not always demanding - performance requirements. Through improvements in products’ energy efficiency, some IM legislation such as the Ecodesign requirements has contributed to tackling pressing European and global challenges such as climate change, although the order of magnitude of the contribution will need to be assessed by reference to evaluations of specific IM legislation.
Evaluation of Internal Market Legislation for Industrial Products

Executive Summary

Recommendations

3.1.1 Improving the architecture of Union harmonisation legislation

1. The Commission should give consideration on a case by case basis to whether to use regulations or directives as the most appropriate instrument for implementing Union harmonisation legislation as part of the impact assessment process.

2. Periodic reviews of IM legislation for industrial products should be undertaken so as to ensure that the regulatory framework is consistent, and that there are no gaps or loopholes in the legislation itself or inconsistencies or duplication between different pieces of IM legislation.

3. A horizontal regulation based on Decision 768/2008 should be considered in the medium-term, setting out common definitions and other common elements that apply across Union harmonisation legislation. Although not feasible in the near term, since a different approach has been adopted through the Alignment Package, a horizontal regulation would be more coherent and would reduce the length of legal texts in individual product regulations and directives.

4. Non-binding guidance on complying with Union harmonisation legislation should be updated by the Commission on a more regular basis, given its usefulness to manufacturers. Where possible, it should give insight into the rationale for particular requirements or standards.

5. In a number of areas within professional goods, the legislation applicable at the use phase (e.g. installations, maintenance) set at national level imposes additional barriers that reduce the benefits of harmonised legislation. While such aspects are outside the scope of IM legislation itself, the development and provisions of IM legislation should take such aspects into consideration aiming to minimize any obstacles (to the extent possible).

3.1.2 Strengthening the effectiveness of the regulatory framework and standards development

6. Legislative review processes leading to the recasting of existing IM legislation should be coordinated and synchronised so as to minimise administrative burdens for industry\(^\text{20}\). The research showed that there are cumulative effects in the form of increased administrative burdens for firms due to the high cumulative frequency of legislative changes and updates to technical standards.

7. Consideration should be given as to the feasibility (political/legal and practical) of introducing a specific date/year when new or amended pieces of IM legislation that have already been adopted come into force. This would also give SMEs more time to prepare.

8. The Commission should give further consideration as to ways of strengthening the participation of SMEs in EU legislative-making and standardisation processes. One possibility would be to ensure that SME representative associations are better represented in working groups on specific IM directives and regulations, with support provided for the costs of their participation where possible\(^\text{21}\).

9. There should be a faster transition towards “e-market surveillance” in which economic operators will be expected to make as much compliance information available online as possible. This would promote more efficient and effective provision of two-way compliance information and data between MSAs and economic operators. This would also be more efficient for economic

---

\(^{20}\) Since IM legislation has in the past been updated at different times, there has been high cumulative frequency of regulatory changes for industrial products. Industry stated that it would be beneficial if there were to be coordinated updating exercises.

\(^{21}\) There is already funding for NORMAPME which represents SMEs in standardisation but in an earlier study they reported that they still did not have enough resources to adequately follow standardisation processes.
operators from an internal organisational perspective, given the need for periodic review and updating of DoCs and other technical documentation.

10. Economic operators should be allowed to make general regulatory information about specific products / models/ platforms available in online format only (e.g. DoCs). More sensitive technical documentation and supporting test data requested by MSAs could be transferred electronically via secure data transmission.

11. The Commission should actively promote cultural change among MSAs to encourage them to accept compliance information electronically. Many MSAs prefer to have paper copies of compliance documentation (DoCs, technical files). One means to achieve this could be through the exchange of officials, as proposed in the Product Safety and Market Surveillance Package.

12. In order to facilitate the transition towards a paperless future for market surveillance, market surveillance authorities (and customs authorities where appropriate) should be equipped with scanning equipment or smart phone readers that would link through to the compliance section of the economic operators’ website or to a dedicated standalone website. This is subject to resources being identified and requires joint investment by industry and MSAs.

13. Economic operators should be given greater flexibility as to how they meet traceability requirements in order to promote greater use of e-labelling. This would help to alleviate the major concerns that economic operators have with regard to current traceability requirements for products and packaging to provide full addressee information. These are seen as unnecessary and detract from product aesthetics and industrial design. E-labelling provides a viable alternative route to meeting the same requirements.

14. When a currently non-harmonised product group becomes part of a harmonised product group, consideration should be given as to whether it is possible to integrate new product groups within existing pieces of IM of legislation, rather than proposing new legislation.

3.1.3 Strengthening the implementation regime for Union harmonisation legislation

15. The mechanisms to facilitate cooperation and the exchange of information between MSAs should continue to be supported and given appropriate funding. EU funding for EU coordination and support actions relating to market surveillance through the PSMSP are critical and should be maintained if not further extended in coordination with MSAs aiming for the most efficient use of resources.

16. IT-driven systems such as the RAPEX and the ICSMS information system should continue to be supported. They serve different purposes/ functions and have proven vital to strengthening the effectiveness of market surveillance and regulatory enforcement.

17. Although data is already collected by MSAs on the incidence of non-compliance of products checked, this should be further disaggregated by type of non-compliance. At the minimum, comparable data should be available and this should be broken down according to whether instances of non-compliance are administrative or technical.

18. Accreditation should be further strengthened in order to fully implement Regulation 765/2008. A better coordinated approach to the choice of harmonised standards for the accreditation of notified bodies should be found. This would involve the help of the European Cooperation for Accreditation and coordination between Member States and the European Commission.

19. The operation of Notified Bodies Groups/Organisations could be strengthened and extended to all pieces of IM legislation, given their important role in promoting coordination and a more consistent approach among NBs. A requirement could be introduced for active participation by Notified Bodies Groups for all Notified Bodies, while taking into consideration the cost implications for the operation of smaller Notified Bodies. Extensive use of the appropriate information exchange systems (already in place among some of the existing Notified Bodies
Executive Summary

Groups) should help to keep the costs of participation low.

20. The possibility of making the accreditation of Notified Bodies mandatory should be further considered, with priority given to Internal Market legislation that concern high risk product categories or issues of higher safety and consumer protection concern.

21. In order for the above to happen in practice, there could be a compulsory accreditation requirement for non-European testing house granted Notified Body status. Concerns were expressed with regard to retaining confidence in the quality of the services provided by all Notified Bodies – European and non-European.

22. Synergies should be fully exploited between different structures in the IM implementation regime, for instance between SOLVIT (which solves general problems relating to the non-functioning of the internal market and Product Contact Points (PCPs), which have more specialised knowledge about non-harmonised product legislation. For instance, there could be referrals of cases from SOLVIT to PCPs, and staff working at SOLVIT contact points could be made better aware about coordination mechanisms and contact points for industry that specialise in issues relating to the implementation of internal market in industrial products.

23. The role of the Product Contact Points should be expanded to harmonised products so as to provide a first point of contact for and basic information about Union harmonisation legislation to firms. Many firms don’t know who to turn to and there is a low level of knowledge among some smaller firms and micro enterprises about internal market legislation.

3.1.4 Reducing administrative burdens for economic operators.

24. The SME Test should always be applied to internal market legislation so as to ensure that administrative requirements do not impose disproportionate burdens to SMEs. It should be reiterated however that there is only limited scope for SME exemptions from the legal provisions in IM legislation and for a lighter regime in terms of administrative requirements.

25. A single reference source could be developed at EU level for firms providing information as to what changes have been made to IM legislation and updates to standards and when these come into force. This could be funded by the Commission and delegated to an appropriate body (or operated through a technical service contract).

26. The Commission should ensure that the administrative simplifications proposed through the NLF’s Decision 768/2008 are fully implemented. For instance, inconsistencies in requirements for DoCs between directives should be eliminated. However, there remains a need for adequate consultation to ensure that these changes ensure sufficient flexibility for economic operators.

27. Economic operators should be allowed to continue to choose between producing a single DoC and a different DoC for each piece of applicable IM legislation. Some economic operators prefer the latter approach, since it means that there is less frequent updating of individual DoCs when technical standards are updated.

28. The current requirement for a DoC to be placed together with products in paper copy in the R&TTE Directive should be removed. The short form of the DoC currently used is not necessary given that electrical manufacturers already provide the full DoC online.

29. The Commission should provide clarity as to what constitutes a “reasoned request” for translating part of the technical file by an MSA (c.f. Decision 768/2008). Safeguards should be put in place to ensure that MSAs requesting the translation of part of a technical file is the exception rather than norm.

22 Technical files can vary in length from hundreds to thousands of pages.
Executive Summary

3.1.6 Regulatory simplification

30. Future simplification exercises should take into close account and give priority to previous and ongoing simplifications within the NLF framework, including through the Alignment Package. It is crucial that industry is not overburdened with too frequent legislative changes, since there have been many changes in the past decade, with others due to come into effect in the near future.

31. Regulatory simplifications identified through the research\textsuperscript{23} that involve the merger of different pieces of IM legislation should be subject to public consultation, and supported by technical studies. Careful consideration is needed to ensure that proposed simplification measures enjoy sufficiently broad stakeholder support.

3.1.7 Extending the reach of IM legislation

32. The Commission should promote international convergence in legislation on industrial products, since this could help to lower compliance costs for industry, thereby strengthening industrial competitiveness. The Trade and Investment Partnership (TTIP) being negotiated between the EU and the US is a step in the right direction, but further cooperation with regulators in other third countries that are key European export markets should be explored, such as China, Russia, Brazil, Mexico and Australia.

\textsuperscript{23} Examples are the possible merger of the Machinery Directive and the Outdoor Noise Equipment Directive and the possible merger of the PED and the SPVD.