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**PROPOSAL**

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| To: | Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union |
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**COMMISSION STAFF WORKING DOCUMENT**

**IMPACT ASSESSMENT**

***Accompanying the document***

**Proposal for a Regulation of the European Parliament and of the Council**

**on the mutual recognition on goods lawfully marketed in another Member State**

{COM(2017) 796 final} - {SWD(2017) 472 final} - {SWD(2017) 475 final} -
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## INTRODUCTION

Achieving a deeper and fairer single market, that builds on its strengths and fully exploits its potential in all its dimensions, represents one of the key political priorities of the European Commission.[1] The follow-up and the implementation of the Single Market Strategy, *Upgrading the Single Market: more opportunities for people and business,* adopted on 28 October 2015[2] constitute one of the main objectives of the 2017 Commission Work Programme.[3]

Within the Single Market, free movement of goods is the most developed of all four fundamental freedoms and generates around 25 % of EU GDP, 75 % of intra-EU trade. The EU accounts for around one sixth of the world's trade in goods. Trade in goods between EU Member States (intra-EU trade) was valued at EUR 3 063 billion in 2015[4]. However, there is still work to do to ensure a deep and fair European Single Market. The enforcement of common safety and environmental rules is still not functioning optimally and, where there are no common rules, the principle of mutual recognition is not being applied. The 'Goods Package' announced in the 2017 Commission Work Programme, intends to address both these fundamental problems, with proposals on compliance and enforcement of EU harmonisation legislation and on mutual recognition.

In the Single Market for goods, regulatory obstacles are prevented and removed through relevant EU legislation on specific products (i.e. through EU harmonisation legislation). This is for example in the case of toys, cosmetic products or pyrotechnical articles. Where no EU rules exist (non-harmonised areas), the Directive (EU) 2015/1535 on the notificaiton of national technical rules (the former Directive 98/34/EC) aims to prevent regulatory obstacles within the EU, at an earlier stage, and the principle of mutual recognition would be used to overcome them, at a later stage.

Mutual recognition is seminal for a proper functioning of the single market for goods, through the elimination of technical obstacles to genuine free movement. In areas where no specific EU legislation is in place, national rules that lay down requirements to be met by such products co-exist. In principle, national regulations may still create barriers to intra-EU trade if rules in different Member States diverge. The principle of mutual recognition requires however that a good that is lawfully marketed in one Member State should not be prohibited in another Member State, unless the latter has sound reasons for banning its sale. Mutual recognition applies to products that are not subject to EU harmonisation legislation or only partly covered by it; this is the case, for example, of a wide range of consumer products such as textile, footwear, childcare articles, jewellery, tableware or furniture, for example.

1 Jean-Claude Juncker, 'A New Start for Europe: My Agenda for Jobs, Growth, Fairness and Democratic Change', Political Guidelines for the next European Commission, Opening Statement in the European Parliament Plenary Session, 15 July 2014: http://ec.europa.eu/about/juncker-commission/priorities/index_en.htm.

2 Communication from Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Upgrading the Single Market: more opportunities for people and business, COM 2015 550/2.

3 COM(2016) 710 final: http://ec.europa.eu/atwork/key-documents/index_en.htm

4 Source Eurostat.

The adoption of Regulation (EC) No 764/2008 ('the Regulation')[5] was a partial[6] response to the weak application of the principle of mutual recognition in the field of goods, triggered by the lack of awareness about the mutual recognition principle, legal uncertainty when applying the principle and the lack of administrative cooperation among national authorities. The Regulation was aimed mainly at establishing a procedural framework to minimise the possibility of national technical rules creating unlawful obstacles to the free movement of goods between Member States[7].

In December 2013, the Conclusions on Single Market Policy, adopted by the Competitiveness Council, noted that to improve framework conditions for businesses and consumers in the Single Market, all relevant instruments should be appropriately employed, including harmonisation and mutual recognition.[8] The Commission was therefore requested to report to the Council on the sectors and markets where the application of the principle of mutual recognition is economically most advantageous, but where its functioning remains insufficient or problematic. In its Conclusions on Single Market Policy of February 2015, the Competitiveness Council urged the Commission to ensure that the principle of mutual recognition would function effectively and to bring forward proposals to that effect, as appropriate[9].

In response to the indications that the functioning of the principle might not be optimal, and taking into account the request of the Council, the application of the principle of mutual recognition was subject to an evaluation.[10] Building on the external evaluation, the Commission's Evaluation on the functioning of mutual recognition included an assessment of the functioning of the Regulation as well, in order to have a full picture of the obstacles impeding the optimal functioning of mutual recognition (hereafter, the Evaluation)[11].

This Evaluation has concluded that mutual recognition is not functioning well and that the principle and the Regulation had limited effects in meeting the foreseen objectives. With regards to supportive information and data, this impact assessment is also supported by the information contained in the Evaluation. The initiative has been linked to the REFIT programme due to the impacts the malfunctioning of mutual recognition have on the functioning of the internal market.

This initiative should be looked at along with other initiatives currently under preparation and in particular the initiative on enforcement and compliance with the EU harmonisation legislation on products, the Action Plan on SOLVIT and the proposal for a Single Digital Gateway to complement each other and contribute to reducing barriers to

5 COM(2014) 910 final: http://ec.europa.eu/atwork/pdf/cwp_2015_en.pdf.

6 Several other tools allow for the correct application of the mutual recognition principle, such as the mutual recognition clause and the complaints and infringements related to articles 34-36 TFEU. For more information, see the Evaluation

7 See the Evaluation.

8 Conclusions on Single Market Policy, Competitiveness Council meeting; Brussels 2 and 3 December 2013: http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/intm/139846.pdf.

9 Conclusions on Single Market Policy, Competitiveness Council meeting; Brussels 2-3 March 2015: http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%206197%202015%20INIT

10 European Commission, Study commissioned to Technopolis Group (2015): 'Evaluation of the application of the principle of mutual recognition in the field of goods,' ENTR/172/PP/2012/FC – LOT 4 carried out between April 2014 and May 2015: http://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/index_en.htm.

11 See annex 6 for a summary of the results of the Evaluation.

trade in the Single Market. Further and better compliance and enforcement will reduce unfair competition and ensure a more level playing field for businesses. An enhanced SOLVIT will facilitate informal problem resolution and the Single Digital Gateway will not only ensure visibility for the Product Contact Points established under the Regulation (PCPs) but also improve their functioning by subjecting them to the quality criteria in terms of online availability and quality of information and services provided to economic operators.

## 1. REGULATORY CONTEXT

Free movement of goods in the internal market and the principle of mutual recognition

As one of the four main fundamental freedoms, free movement of goods is a cornerstone of European integration and essential for European competitiveness. Free movement of goods in the internal market is ensured through EU common rules on products (EU harmonisation legislation) and the principle of mutual recognition.

EU harmonisation legislation sets out common requirements on how a product has to be manufactured, which includes rules on i.e. characteristics of the product, size, composition, etc. Its aim is not only the elimination of barriers and the free movement of goods in the single market, but also ensuring that only safe and otherwise compliant products find their way into the EU market, in such a way that honest economic operators can benefit from a level playing field, thus promoting at the same time an effective protection of EU consumers and professional users and a competitive single market. The adoption of EU common rules prevents Member State from regulating those technical aspects of products and products complying with such rules are guaranteed free movement across the single market.

However, EU harmonisation legislation covering every product and aspect of a product is neither a feasible nor a desirable objective [12]. Adopting EU common rules is a costly and time consuming process, where a balance needs to be struck between different approaches and should be reserved for those products and aspects of products where there are significant barriers to the free movement across the Single Market which cannot be addressed otherwise.

Where there are no EU common rules, or when only some aspects of the products are covered by EU common rules, Member States remain free to adopt national technical rules laying down requirements to be met by those products, such as rules relating to designation, form, size, weight, composition, presentation, labelling or packaging. These national technical regulations are however subject to the provisions of Articles 34 to 36 of the Treaty on the Functioning of the European Union (TFEU), which prohibit quantitative restrictions or measures having equivalent effect, and to the principle of mutual recognition. In addition, they also need to be notified under the Directive (EU)

12 See, for example, J. Pelkmans, Mutual Recognition: economic and regulatory logic in goods and services, Bruges European Economic Research Papers 24/2012, p 5 : "The lesson of four decades of EU harmonisation is that one has to find a suitable balance between, on the one hand, not suppressing the preferences of the (or some) Member States too much (as this may be welfare decreasing), and, on the other hand, avoiding overly costly common regulation by incorporating each and every specific element of national (often diverse) rules, prompting 'regulatory failure'".

2015/1535[13] in order to ensure that no unjustified barriers to the Single Market are allowed.

The principle of mutual recognition is embedded in Articles 34 and 36 of the TFEU and has been further elaborated on case law, especially the "Cassis de Dijon" case[14].

It means that in the absence of EU harmonised rules, if a business is lawfully selling a product in one Member State, in compliance with the applicable national technical rules of that Member State, it should be able to sell it in other Member States without having to adapt it to the national rules of that Member State where such products already meet equivalent levels of protection to those imposed by the importing Member State[15]. Barriers to free movement which result from differences in national legislation may only be accepted if the national measures:

- are necessary to satisfy mandatory requirements (those being public interests such as health, safety, consumer protection and environmental protection) which justified overriding the principle of free movement of goods, and
- can be justified with regard to the legitimate purpose and are proportionate with the aims.

Exceptions to the mutual recognition rule should be interpreted narrowly. Considering the exceptions, mutual recognition should not be viewed as entailing lower health and safety standards, or as limiting the market surveillance capabilities of national authorities; but rather as striking a careful balance between free movement and objectives of public interest.

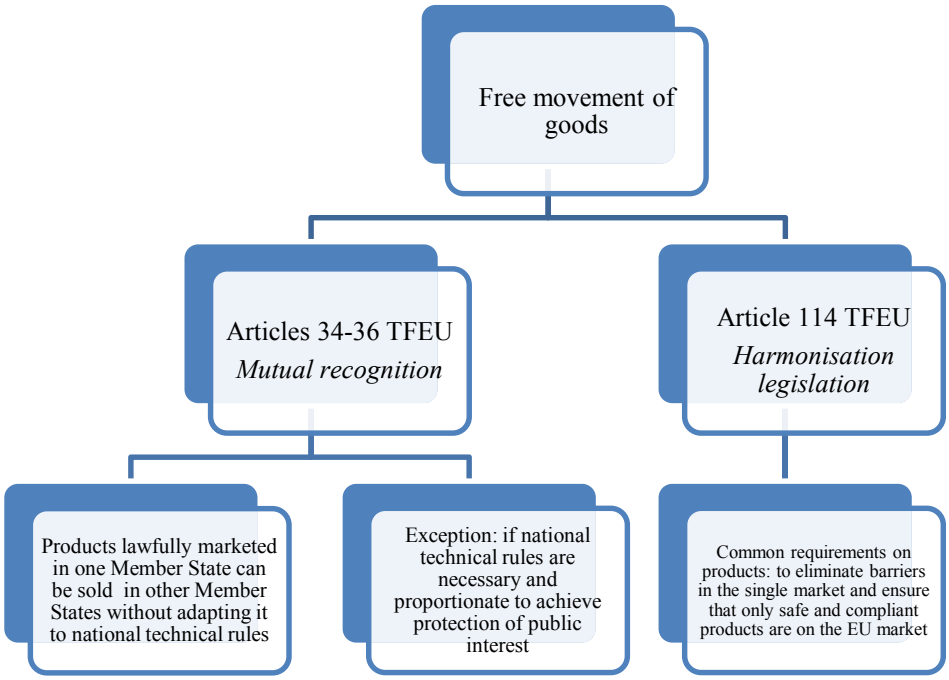
**Figure 1-1**[16]

13 Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (codification). OJ L 241, 17.9.2015, p. 1

14 Judgement of the Court of Justice of 20 February 1979 – Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein C 120/78.

15 For instance, ground 37 of the Judgment of the Court of 22 January 2002, Canal Satélite Digital SL v Administración General del Estado, in the presence of Distribuidora de Televisión Digital SA (DTS), case C-390/99, confirms this principle: 'It is well established in case law that a product which is lawfully marketed in one Member State must in principle be able to be marketed in any other Member States without being subject to additional control, save in the case of exceptions provided for or allowed by [EU] law.'

16 Source: Commission services




EU harmonisation legislation and mutual recognition are both necessary to achieve a fairer and deeper internal market. Mutual recognition is essential to guarantee the free movement of goods in the European Single Market where diverse and sometimes conflicting national technical rules can continue to coexist. When properly applied, mutual recognition guarantees the protection of the public interest whilst not creating excessive red tape.

The practical application of the principle of mutual recognition

The application of this general principle is, in practice, extremely complex. It requires, inter alia, an assessment of whether a product has been lawfully marketed in another Member State and an assessment of the equivalence of the rules in the Member State of origin to allow the non-application of the technical rules in the importing Member State. The latter should not be understood as a comparison of the theoretical intrinsic equivalence of the two Member States rules, but of the practical results produced by applying them in terms of how a particular product adequately protects the public interests at stake.

1. Some practical modalities on how mutual recognition should work in practice are defined by **the Regulation**.

   In particular, the Regulation introduced:

   - Product Contact Points: to provide, upon request, information on the technical rules applicable to a specific product, the contact details of the competent authorities in charge of supervising the implementation of the technical rule in question and the remedies available in case of dispute between the economic operator and the competent authority.

- Non-exhaustive list of products: Mutual recognition does not apply to products fully or to those aspects partially covered by EU harmonisation legislation. To facilitate the identification of products to which the mutual recognition principle may apply, the Regulation introduced an obligation for the Commission to put in place a non-exhaustive list of products which are not subject to EU harmonisation legislation.

  .

- Procedure for decisions denying market access: The Regulation lays down in particular the rules and procedures to be followed by the national authorities of a Member State when taking or intending to take a decision, in accordance with the national technical rules, which would hinder the free movement of a product lawfully marketed in another Member State and subject to Article 34 TFEU. In particular, the Regulation places the burden of proof on the national authorities intending to deny market access. A written notice has to be sent to the economic operator, informing him about their intention to deny market access, and specifying the technical rule on which the decision is based, and the supporting technical or scientific evidence which makes the decision justified and proportionate. The economic operator has the right to submit comments. Any decision denying market access taken after receiving comments from the economic operator shall be notified to him, and shall state the grounds on which it is based, the technical or scientific evidence supporting the decision and, when applicable, the reasons for rejecting the economic operator's arguments. The decision shall also indicate the remedies available under national law in order to challenge the decision.
- Reporting obligations: Member States have to submit yearly reports on the application of the Regulation. Furthermore, every decision denying market access, as well as the grounds on which it is based, has to be individually notified by Member States to the Commission, in addition to the notification of the economic operator.

2. The application of the principle of mutual recognition is also made possible by the inclusion of a **mutual recognition clause**[17] in national technical regulations. It provides legal certainty for economic operators, as they are informed about their rights, thereby actually putting the aforementioned principle into practice.

3. The Commission monitors whether Member States comply with the EU law and whether their national rules undermine the free movement of goods. To ensure that internal market rules are respected and applied correctly in the area of non-harmonised goods, the Commission follows up **complaints** based on alleged breaches of Article 34 TFEU and takes action, where necessary, to ensure that those restrictions which cannot be justified are eliminated.

## 2. ECONOMIC CONTEXT: NON-HARMONISED PRODUCTS IN THE EU

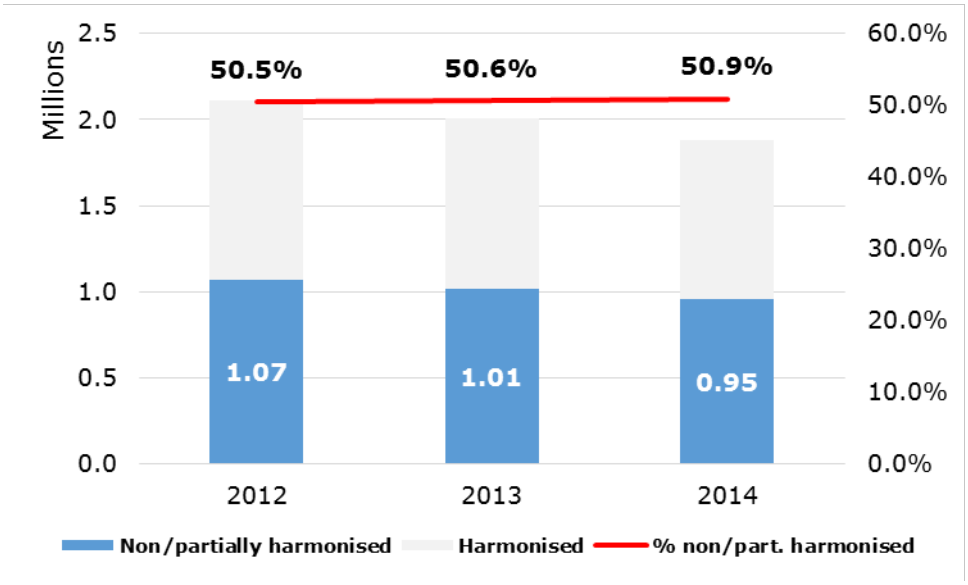
17 The mutual recognition clause, when inserted in national regulations, raises awareness about the application of the mutual recognition principle and the Mutual Recognition Regulation to products coming from other Member States and which are not in line with that particular technical rule.

Mutual recognition applies to non-harmonised products and to partially harmonised products, i.e. products which are in part covered by EU harmonisation legislation but which still have other aspects which are subject to national rules. It is difficult to have a strict separation between these two categories of products: while there are products which are subject to detailed EU rules (and considered as harmonised) such as toys, pyrotechnical articles or cosmetics, many products are however subject to EU harmonisation for at least specific aspects while the rest is left for national legislation and therefore subject to mutual recognition. Mutual recognition therefore applies to many consumer products where EU harmonisation measure is almost absent such as childcare articles, clothing, textile and footwear, furniture, jewellery, sports accessories. It also applies to products more heavily regulated by EU harmonisation measures regarding those elements not covered by these measures, for example, to food and food supplements, fertilising or construction products.

Whatever the scope for national rules (the totality of the product or many aspects of it), mutual recognition should apply to address any differences in technical requirements in the Member States. Therefore, for the purposes of this impact assessment, non-harmonised products should be understood as also including those products which are partially harmonised as they are still subject to national rules and thus, mutual recognition. More information on the economic relevance of products subject to mutual recognition can be found in Annexes 4 and 5.

Over the period from 2008 and 2014, around **0.89 million enterprises** were operating within non-harmonised sectors, representing more than **50% of the total number of active enterprises in the manufacturing economy**[18].

**Figure 2-1: Number of active enterprises: non-harmonised sectors vs overall manufacturing sectors (EU28, 2012-2014) NACE Digit-3 level**




18 Around 2 million active enterprises are operating under Section C of NACE classification named Manufacturing. The correspondence between the list of NACE DIGIT-3 codes and the way they have been considered in the analysis (i.e. harmonised or non/partially harmonised) can be found in annex 5

Source: Structural Business Statistics, Annual enterprise statistics by size class for special aggregates of activities (NACE Rev. 2) (sbs_sc_sca_r2), EUROSTAT (2016)

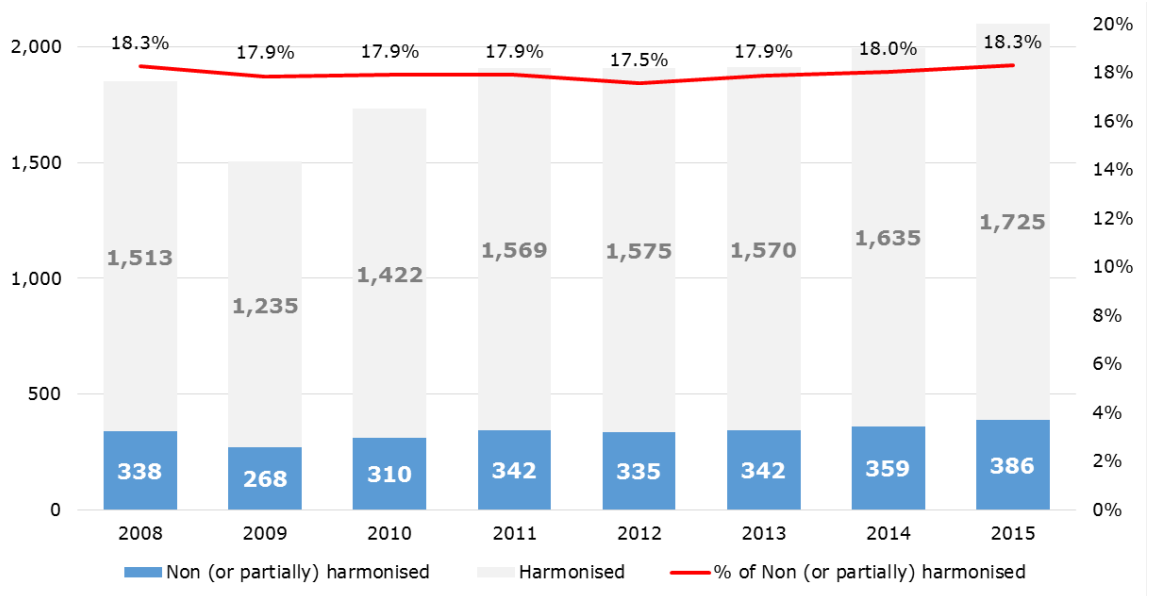
Around **87%** of the enterprises operating within the non-harmonised sectors **are micro enterprises** (i.e. with less than 9 employees) and around **11% are small and medium enterprises** (i.e. with a number of employees between 50 and 250)[19].

In terms of **turnover**, non-harmonised sectors represent a significant contribution to the economy. As shown in the figure below, enterprises operating within non-harmonised sectors contribute to around **20% of the total value of market sales of manufacturing sectors (€1,158 billion out of €5,690 billion,** corresponding to the overall turnover produced within the manufacturing sectors).

In addition, considering the period 2008 – 2015, the following was observed:

- The (average) annual value of intra EU exports of non (or partially) harmonised products has been equal to **€335 billion** ;
- The value on intra EU exports of non-harmonised products represented the **18%** of the value of intra EU exports.

**Figure 2-2: Value on non (or partially) harmonised products. Intra EU Exports, € billions, 2008 -2015**




## 3. PROBLEM DEFINITION

Mutual recognition is instrumental to removing barriers to intra-EU trade when harmonisation is either not desired or technically impossible. However, **mutual**

19 These figures have been computed for the period 2011 – 2013 since the enterprise statistics by size class for aggregates of activities (NACE rev.2) are only available for this period.

**recognition is not functioning well[20]. The weak use of the principle of mutual recognition and the limited impacts the Regulation had in achieving the foreseen objectives of ensuring free movement of goods in the Single Market** points that there is a lot of potential to be unleashed.

Businesses rarely rely on mutual recognition to sell their products in another Member State. Companies check the applicable rules in the Member State where they want to sell their products and if national rules prevent them from selling them, most of them adapt their product to those rules (87% adapt their products to national rules straight away or have tried to rely on mutual recognition but received a negative decision and after they adapted their product)[21]. For other companies, particularly SMEs, national technical rules act as barriers to enter those national markets, and they refrain from selling their products in those countries[22]. Where companies try to rely on the principle of mutual recognition, national authorities find it difficult to accept, on the basis of mutual recognition, products on their markets that do not conform to their national rules, to which technical, historical and cultural background they are well acquainted. Therefore, they deny market access to those products. 68% of companies which replied to the 2016 public consultation have tried to rely on mutual recognition, and for half of them, market access was denied. When market access is denied, it appears that companies find it extremely difficult to challenge these national decisions[23].

Stakeholders reported recurrent problems with the application of the principle of mutual recognition in certain specific sectors such as construction products, food and food supplements, food contact materials, fertilisers or childcare products; some of these sectors are of particular economic relevance[24].

Whilst the Regulation was adopted to facilitate the application of the principle of mutual recognition, it has not achieved its objectives. Generally, the 2016 public consultation shows that only half of the economic operators responding consider that it is easier to sell products in other Member States since the Regulation entered into force.[25]

### 3.1. Magnitude of the problem

Due to the complex nature of mutual recognition and the wide variety of products to which it applies, accurately estimating the magnitude of the problem triggered by its suboptimal functioning is not straightforward. Therefore, several elements were taken

20 For more information see the Evaluation.
21 Data from the public consultation carried out in 2016.
22 More than half of SMEs say that administrative procedures related to exporting to other Member States are too difficult to comply with and therefore deter many firms from exporting. Flash Eurobarometer 421: Internationalisation of Small and Medium-sized Enterprises https://data.europa.eu/euodp/en/data/dataset/S2090_421_ENG
23 Only 2% of companies challenged this decision successfully. Data from the 2016 public consultation
24 The construction sector is a major economic activity in the European Union, with a total value of production corresponding to over 9% of GDP, and a value added contributing for 3.1% to GDP formation in the EU28 countries in 2012. In 2014, there were over 3 million firms active in the construction of buildings, with a total turnover of about € 1,300 billion and a workforce of nearly 11 million persons. The EU fertilising product market is an economic sector that has between EUR 20 billion and EUR 25 billion in annual turnover and approximately 100 000 million jobs (see http://ec.europa.eu/enterprise/sectors/chemicals/files/fertilizers/final_report__23jan2012_en.pdf.). The food and drink industry stands as the largest manufacturing sector in the EU in terms of turnover (14.9%) and value added (12.9%) and the leading employer in the EU manufacturing sector (15% representing 4.25 million jobs) and generates 7% of GDP.
25 See annex 2

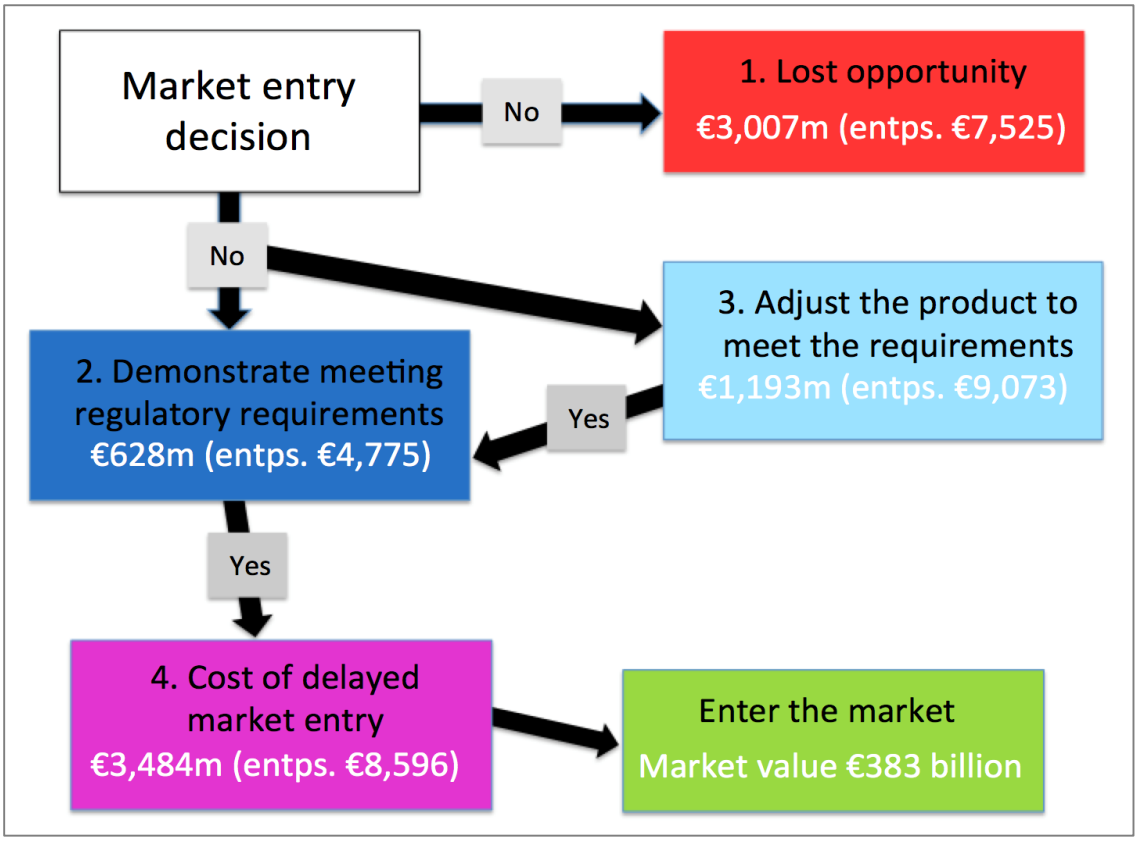
into account in the analysis, in order to illustrate the significance of the effects that a suboptimal mutual recognition may have.

First, the model[26] presented in figure 3-1 has been used to determine the costs that a company might incur when entering the market without fully benefiting from mutual recognition. The objective of the model is to distinguish the socio-economic costs of the malfunctioning of mutual recognition; the model contains seven components, and uses data about the value of intra-EU trade to calculate key costs. The model is underpinned by an enterprise decisions tree that considers routes to successful market entry and decisions not to export. By estimating the number of enterprises entering new markets with non-harmonised products, it is possible to apply an estimate of the number of days work required by enterprises to overcome sub-optimal functioning. This element of the model provides details of transactions costs. The second component of the model (cost of delayed market entry) estimates the cost per week of enterprises note being able to trade. These costs can then be treated separately, or combined to give a total estimate of costs associated with sub-optimal functioning of the Mutual Recognition principle.

**Figure 3-1: Decision tree diagram for export decisions associated with products not covered by the Mutual Recognition principle[27]**

26 The full description and methodology used for this model are described in Annex 4

27 Study on the costs and benefits of mutual recognition performed by E&Y and J. Pelkmans, Draft Final Report February 2017 (Service Request No 567/PP/GRO/IMA/16/1133/8852).

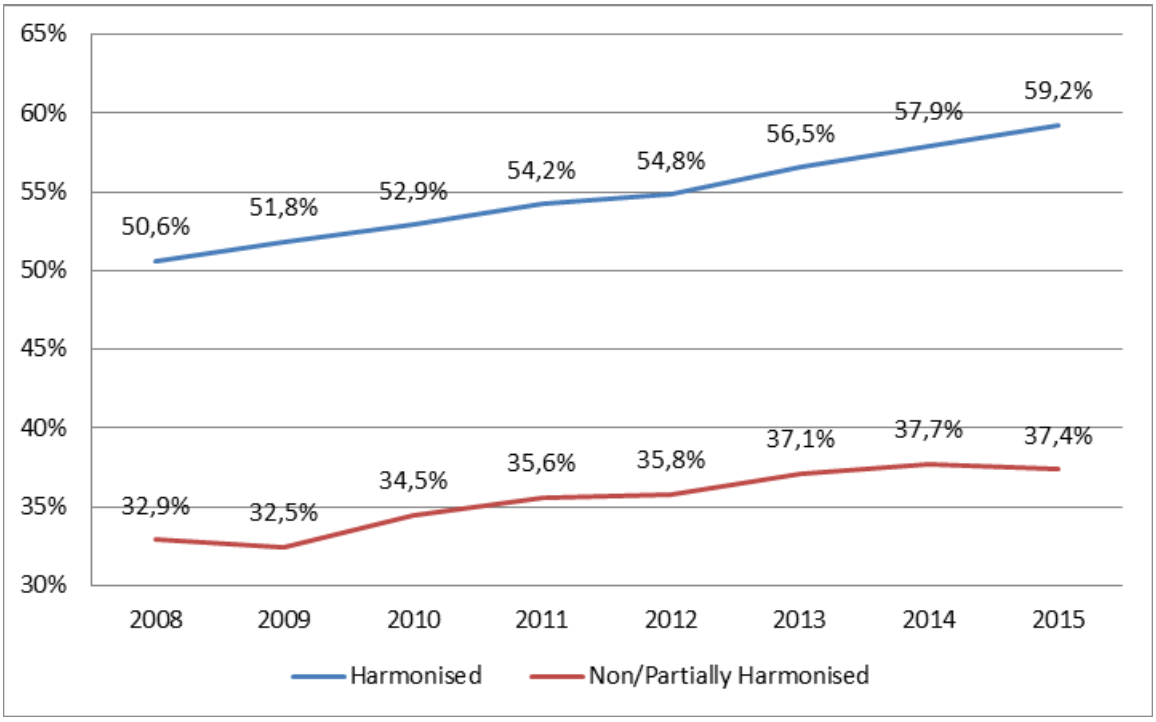



This diagram represents the route that enterprises can follow when deciding not to export or when entering another EU Member State market. The model provides a representation for an enterprise considering intra-EU exporting one product in one EU Member State. This model has been designed as a simplified framework to illustrate a complex process, and is a simplified representation of the reality of the market. A model where the values can be changed, based on the type of products, company and feedback received was preferred, as it allows an evolving estimation, reflecting the reality of the market. The values used for calculating the size of the problem based on this model are assumptions based on feedback from a very limited number of stakeholders and thus need to be treated with caution as they are not necessarily representative [28]. They vary substantially upon the number of products intended to be marketed and the number of markets targeted. Details can be found in Annex 4.

Second, the comparison of the value of the intra EU exports with domestic consumption[29] shows that for harmonised products the value of intra EU exports is **55%** of domestic consumption, while for the non-harmonised and partially harmonised goods it represents only **35%.** This might be also a sign of the effects that suboptimal functioning of mutual recognition has on trade, based on the assumption that in the harmonised area, due to uniform and standardised rules applicable in all EU Member State, there are no (or few) barriers to trade.

28 9 stakeholders interviewed on February 2017 , with very consistent results among them
29 Value of production-value of extra EU exports +value of intra EU imports

**Figure 3-2: Intra EU exports as % of the domestic consumption: harmonised vs non- harmonised or partially harmonised products, 2008-2015[30]**




Lastly, a global estimation of trade barriers in general can be used to compliment the previous findings. The fact that most companies feel compelled to adapt their products to national requirements constitutes a barrier to trade on the internal market. The magnitude of these barriers is also likely to be significant. A study done for the European Parliament[31] tried to estimate the magnitude of the impact that non-tariff barriers to trade have on the internal market. It concluded that a reduction of such barriers could lead to an increase in intra-EU trade of more than **100 billion EUR** per year. While the concept of non-tariff barriers in the paper is broader (including not only lack of mutual recognition or harmonisation but also discriminatory procedures and less favourable tax or subsidy treatment), it provides an indication that the problem of mutual recognition not working well in practice is economically significant.

## 3.2. The drivers of the problem

A number of factors explain the fact that mutual recognition is currently not functioning well, in particular, the lack of awareness about mutual recognition, the legal uncertainty with regards to its scope and the practical obstacles related to its application. According to the 2016 public consultations, businesses find that the difficulty to challenge a national decision denying market access is the main obstacle to the functioning of mutual recognition[32], followed by the insufficient communication between national authorities of

30 Source: PRODCOM statistics, EUROSTAT (2016)

31 The Cost of Non- Europe in the Single Market, 'Cecchini Revisited', An overview of the potential economic gains from further completion of the European Single Market, CoNE 1/2014 http://www.europarl.europa.eu/RegData/etudes/STUD/2014/510981/EPRS_STU(2014)510981_REV1_EN.pdf

32 62% of respondents ranked this obstacle as being the most important one.

different Member States, the lack of awareness and the legal uncertainty with regards to its scope.

There is still a significant lack of awareness and an important lack of legal certainty which hampers the effective functioning of mutual recognition. When businesses are aware of mutual recognition, the uncertainty with regards to its scope and application makes them reluctant to use the principle for entering new markets. First of all, it is difficult to know if mutual recognition applies to a particular product or not[33]. Secondly, when businesses rely on mutual recognition, the outcome is uncertain. In particular, the evidence that will be required to demonstrate that the product has been lawfully marketed in another Member State or the tests that will have to be completed vary among Member States. Furthermore, Member States are entitled to argue that mutual recognition does not apply where overriding public interests such as health, safety, consumer protection and environmental protection justify specific national requirements. Finally, if market access is denied, businesses can only challenge these decisions in the national courts which is a long and costly process.

### *3.2.1. Lack of awareness about the mutual recognition principle and Regulation*

The first condition for businesses and national authorities to use and apply mutual recognition is to be aware of it and what it means in practice for companies. However, there are still a significant number of businesses and national authorities unaware of mutual recognition. One of the specific objectives of the Regulation was to increase awareness of the mutual recognition principle. The stakeholders' consultation and the desk research performed by the Commission services show that there are businesses and national authorities still unaware about the mutual recognition principle and Regulation. Lack of awareness about the principle triggers lack of awareness about how this principle should be applied or the conditions under which mutual recognition could be denied. In many cases businesses simply assume that they need to adapt their products to the national rules if they want to sell them in another Member State. In other cases, this is required by the national authorities, to the detriment of mutual recognition[34].

Surveys carried out in 2004[35] and 2014[36]show a low level of awareness about mutual recognition among businesses. In 2004, 46% of the respondents declared being aware of mutual recognition; 54 % of the companies interviewed in 2014 declared not knowing about it or having heard of it but not being familiar with the details. The public consultation carried out in 2016[37] shows however a significantly higher level of awareness; 7% of the respondents declared being aware of mutual recognition. The

33 This issue was already highlighted in the First Report on the application of the Mutual Recognition Regulation, COM (2012)292 final: http://eur-lex.europa.eu/LexUriServ.do?uri=COM:2012:0292:FIN:EN:PDF

34 As indicated in the Evaluation, according to the 2014 survey, more than 40% of the companies simply assumed it was necessary to undertake steps to adapt their product to the requirements of the country of destination as they did not know if the mutual recognition principle applied to their product; more than 30% considered such steps because they were required for acceptance in the local market and did not check whether mutual recognition could apply, and nearly 30% relied on the principle, but it turned out it did not work in practice, as the national authorities still asked for testing or adaptation.

35 Survey carried out in the framework of the impact assessment supporting the proposal for the Mutual Recognition Regulation

36 European Commission, Study commissioned to Technopolis Group (2015): 'Evaluation of the application of the principle of mutual recognition in the field of goods,' ENTR/172/PP/2012/FC – LOT 4 carried out between April 2014 and May 2015: http://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/index_en.htm.

37 See annex 5

differences in the declared level of awareness can be explained by the fact that the consultation process was different (targeted surveys versus open consultation).

The level of awareness about mutual recognition among national authorities is mixed. The results of the public consultation carried out in 2016 shows that when national authorities check if products available on their market coming from another Member State comply with the national rules they are enforcing, 53% verify if they are already lawfully marketed in the Member State of origin while 46% don't.

Furthermore, confusion arises with regards to prior authorisation procedures; when such procedures are in place, economic operators cannot rely on the principle of mutual recognition to place their products on the national market. In fact, the Regulation does not apply to prior authorisation procedures, as the requirement that the placing of a product on the market is subject to prior authorisation is not a technical rule within the scope of the Regulation. However, the decision to deny prior authorisation merely because the product does not comply with the national rules in the Member States having the prior authorisation procedure is a decision within the scope of the Regulation[38].

Despite the fact that businesses indicated in the 2016 public consultation a high level of awareness, they still very much support the need for additional awareness raising campaigns**: 95%** of them replied[39] that awareness raising is still necessary, and ranked the lack of awareness as being the third main obstacle to a smooth functioning of mutual recognition. Also, Member States addressed the need for additional awareness campaigns. During the 2016 public consultation[40], 84% of national authorities consider that awareness-raising is still necessary. When asked to rank priorities for improving mutual recognition by order of importance, **awareness-raising was ranked as the first priority**, **with 52% of responding national authorities supporting it.** National authorities replying to this consultation are representing PCPs (31%) but also other authorities than PCPs (69%). The need for additional awareness raising campaigns is also highlighted by numerous Member States in their annual reports on the application of the Regulation. The outcome of the stakeholders' event held in June 2016 "Single market for products: fresh ideas to unleash full potential" [41] points into the same direction; national authorities participating stressed that awareness raising, for both economic operators and national authorities is essential for improving the functioning of mutual recognition.

The Regulation had a limited effect in increasing awareness of the mutual recognition principle, mainly due to the suboptimal functioning of the PCPs. This makes it difficult for businesses to know when mutual recognition can be used for entering a market and what their rights are. Most stakeholders agreed however that PCPs are a very useful tool, with a lot of potential. They need however to be strengthened in terms of administrative cooperation and network, in order to be efficient with regards to their objectives.

*3.2.2. Legal uncertainty as regards the scope of mutual recognition*

38 See recital 12 of the Mutual Recognition Regulation
39 See annex 5
40 See annex 5
41 See annex 2.

Determining if a product might benefit from the mutual recognition principle is not straightforward, as mutual recognition applies to a very wide range of products, i.e. products or aspects of products which are not covered, fully or partially, by EU harmonisation legislation. Therefore, clarifying whether mutual recognition should apply to a given product requires detailed knowledge of rules on products[42].

The main tools to guide economic operators to knowing if mutual recognition can be invoked for a product are:

1. The Product Contact Points (PCPs) established by the Regulation. However, there are problems with the functioning of PCPs. In the period between the entry into force of the Regulation on 13 May 2009 and today [43], the Product Contact Points received 8024 questions from economic operators.

| 2010-2011[44] | 2012 | 2013 | 2014 | 2015 |
|---|---|---|---|---|
| 1402 | 1439 | 1826 | 1793 | 1564 |

   The PCPs that were most contacted are France and the Czech Republic, followed by Slovakia. The low number of inquiries received shows that PCPs and the assistance they can offer are sub-optimally used45, the main issues underlined by economic operators in relation to PCPs are the long delays for receiving an answer, the quality of the answer or even the absence of it. The activity of PCPs is also undermined by the lack of administrative cooperation. They are also affected by the complexity of the questions they receive, the variety of products covered by mutual recognition and language limitations.

2. The list of products to which mutual recognition might apply put in place by the Regulation. This was done as a database, which is available online on the Commission's website on mutual recognition. The list of products contains goods classified according to the Combined Nomenclature[46] but it has not provided sufficient or reliable information to users. This is because the list lacks user-friendliness, it is extremely difficult to take into account products partially harmonised appropriately and it does not reflect harmonisation legislation newly adopted or repealed.

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42 See for instance Court judgment of 8 May 2003, ATRAL SA v État belge, (Case C-14/02) concerning alarm systems regulated by nothing less than three instruments of EU law (Low Voltage Directive 73/23/EEC, Electromagnetic Compatibility Directive 89/336/EEC, and Radio Equipment and Telecommunications Directive 1999/5/EEC). Still, the functionality testing, climatic tests and efficiency testing of these products are not covered by the mentioned EU common rules and, therefore, fall within the scope of the principle of mutual recognition.

43 Requests received in 2016 are not taken into account, as these will be reported by Member States in the 2017 reports

44 The reporting in annual since 2012. However, the number of questions indicated above is only indicative and does not constitute an accurate picture of all questions received or treated by the PCPs. This is because not all Member States are indicating in their annual reports the number of questions received and treated by the PCPs.

45 This is also supported by the 2016: 72% of economic operators declared that they have never contacted a PCP and 46% were not aware of them.

46 The Common Nomenclature is a method for designating goods and merchandise which was established to meet, at one and the same time, the requirements both of the Common Customs Tariff and of the external trade statistics of the Community. See http://ec.europa.eu/taxation_customs/business/calculation-customs-duties/what-is-common-customs-tariff/combined-nomenclature_en

3. The mutual recognition clause47, when inserted in national regulations, raises awareness (for businesses and relevant national authorities) about the application of the mutual recognition principle and the Mutual Recognition Regulation to products coming from other Member States and which are not in line with that particular technical rule. However, the use of the clause is still poor and it has not shed sufficient light on when mutual recognition is applicable. During the PCPs survey carried out in 2014, only 28% of the respondents indicated that a mutual recognition clause is included systematically in all relevant national rules48. The overview[49] of the draft national technical regulations notified between 2012 and 2014 shows poor use of the mutual recognition clause:

| 2012 | | 2013 | | 2014 | |
|---|---|---|---|---|---|
| **Total** | **MRC[50] inserted** | **Total** | **MRC inserted** | **Total** | **MRC inserted** |
| 755 | 69 | 728 | 79 | 685 | 57 |

### *3.2.3. Legal uncertainty as regards the application of mutual recognition and unreliability of the outcome*

The application of the principle of mutual recognition is also hindered by practical obstacles. Technical barriers may be intentionally adopted to protect national or regional markets or be the result of lack of trust that other national regulations offer an adequate protection of public interest. In addition, national authorities are entrusted with enforcing their national technical rules and it is difficult for them to accept a product which does not conform to such rules. This is for example the case for compulsory, nationally conducted tests; extra labelling requirements; stringent rules on the use of languages[51] or reference to mandatory national conformity marks. In other instances, , the application of the mutual recognition principle is sometimes knowingly disregarded because potential users find that the outcome when trying to invoke the principle is uncertain and unreliable.

In particular, the following elements that hinder in practice the application of mutual recognition were identified:

1. Evidence required by national authorities

   One of the main reasons is the lack of clarity in the **concept of "lawfully marketed",** as Member States have different requirements as regards the evidence to be submitted and are often very cautious towards products lawfully marketed in

47 The "Commission interpretative communication on facilitating the access of products to the markets of other Member States: the practical application of mutual recognition" (OJEU, 2003/C 265/2) provides a standard example of a mutual recognition clause.

48 8% replied that MRCs are not used at all, 20% replied that MRCs are included in few rules, and 44% replied that MRCs are included in more than half of the adopted national rules.

49 Carried out internally by the Commission services

50 Mutual recognition clause

51 Like those demanding for instance that solely the official language(s) of the country of destination be used in the labelling, barring the use of multilingual labels.

another Member State. The objective of the Regulation was to reduce the risk of seeing market access denied, by allowing communication between the businesses and the national authorities in order to prevent problems of free movement of goods. In practice, however, the outcome is not very positive. Placing the burden of proof on Member States did not have any added value as regards the lack of clarity in the concept of "lawfully marketed", which triggers the possibility for economic operators to invoke the mutual recognition principle to sell their products in other Member States. This is because the Regulation only indicates who has the burden of proof, without defining the concept of "lawfully marketed", nor the kind of evidence needed to demonstrate that a product was lawfully marketed. Furthermore, there is no jurisprudence from the Court of Justice on this concept. Thus, businesses report that Member States have different requirements with regards to the evidence to be submitted in order to demonstrate that a product is "lawfully marketed".

In the 2016 public consultation, businesses ranked the need to increase legal certainty when using mutual recognition as the second priority for the Commission.

Furthermore, the principle of mutual recognition excludes the unnecessary duplication of controls already carried out by another Member State and presumes recognition of tests carried out in another Member State especially where the results are available and may, at request, be given. In this respect, the Regulation sets out an obligation on Member States authorities to accept any test performed by conformity assessment bodies covered by an accreditation certificate in line with Regulation (EC) No 765/2008.

Still, in practice, tests already conducted in another Member State, also by accredited bodies, are often not recognized in other Member States[52]. This places a burden on the economic operator to duplicate tests in the Member State of destination. Duplication of testing comes at an economic cost – not only of the test but also for the delay of accessing a market.

2. Assessment of the need to apply national requirements to products lawfully marketed in another Member State

Member States can deny market access where the Member State of origin does not provide an adequate level of protection of the public interests in question; this requires national authorities to look at the practical effects that the application of their national rule would produce and the level of protection that would be achieved. The burden of proof that the restriction on the free movement of goods is justified[53] and necessary[54] to effectively protect the public interests invoked falls on the Member States and not on the economic operator. Such analysis is not

52 A recent study on the EU harmonisation of the requirements for the road circulation of mobile machinery (FWC ENTR/172/PP/2012/FC/Lot1) indicated that the fees of the national type approval and third party testing bodies are estimated to be of about €75 million across the EU. In total, type approval is estimated to generate costs of €78 million for the sector, representing 1.2% of their turnover.
http://ec.europa.eu/DocsRoom/documents/17786/attachments/1/translations/en/renditions/native

53 See for example the Judgments of the Court of 6 September 2012 in case C-150/11, Commission v Belgium, paragraph 54; and of 23 September 2003 in case C-192/01, Commission v Denmark.

54 See, to that effect, the Judgment of the Court of 28 January 2010 in case C-333/08 Commission v France, paragraph 87.

straightforward and national authorities tend to automatically apply the national rules at the cost of mutual recognition. The Regulation requires these decisions to be notified to the Commission, however in many instances, no notification is sent.

**The obligation to notify every administrative decision denying market access** was also intended to bring more legal certainty for economic operators when invoking their right to mutual recognition. In the period between the entry into force of the Regulation on 13 May 2009 and today, the Commission has received **3918 notifications**. All notifications received come from **6 Member States**, and one Member State, namely Portugal, accounts for around **80%** of the notifications received. Most of notifications refer to precious metals, and some relate to foodstuff, fertilisers, food additives and electrical equipment. There are discrepancies between the number of notifications received by the Commission and the number of administrative decisions indicated by Member States in the annual reports. For example, some Member States are indicating in their annual reports that a certain number of administrative decisions have been taken, while these have never been notified to the Commission. Other Member States are reporting that no administrative decisions have been taken, while complaints received show the contrary. This points to the fact that Member States are not always notifying administrative decisions denying or restricting market access to the Commission.

3. Difficulty challenging administrative decisions that deny or restrict market access.

The Regulation does not put in place any specific procedure to challenge administrative decisions denying market access; it only mentions the obligation on Member States to specify, in the administrative decision denying market access, the legal remedies available under the law in force in that Member State and the time limits applying to these remedies. The only option for challenging such decisions lies therefore in the legal means offered by national law (national courts, tribunals or other instances of appeal). Such proceedings are very long and costly for businesses, estimated between 5000 and 100 000 Euro per product and per market[55]. Other alternative non-judicial problem-solving mechanisms, such as SOLVIT, have not proved to be an effective solution for businesses up to now. Only a fraction of the cases submitted in SOLVIT are coming from businesses (107 out of 2414 in 2016). Within these 106 cases only 27 concerned goods and 5 mutual recognition related issues. Furthermore, the resolution rate of businesses cases is lower, especially for goods related cases. Most goods cases are about the justification of a national measure restricting the marketing of a good or the provision of a service. It is often very hard to analyze, prove and successfully argue before a national authority in an informal way that a given measure is disproportionate, especially where large sums are involved. Demonstrating that a particular national restrictive measure is unjustified would require technical expertise and formal powers that SOLVIT centers do not enjoy nowadays (for example in the area of mutual recognition and non-harmonised goods)[56].

55 Public consultation 1.06.2016-30.09.2016; 11% of respondents indicated an estimate of the costs incurred, the other choose not to reply or indicated that such estimation is impossible. There are considerable variations in the answers.

56 Source: SOLVIT database

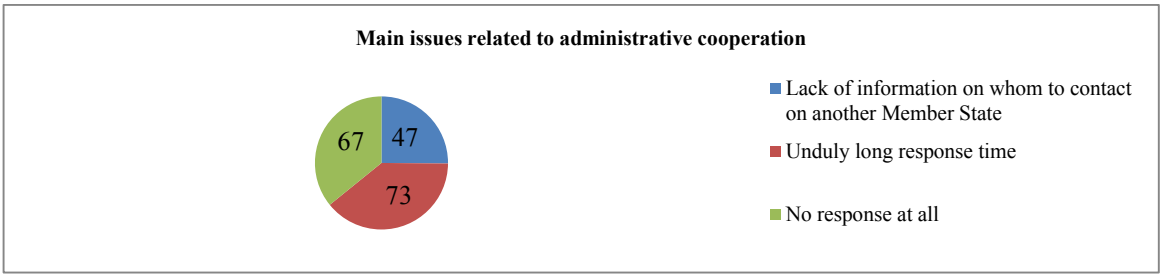
When asked to rank obstacles to mutual recognition by order of importance[57], the difficulty in challenging administrative decisions denying or restricting market access was considered as the main obstacle by businesses (62% of businesses responding to the 2016 public consultation), and 72% considered that ensuring effective remedies for taking action against such decisions should constitute the Commission's main priority.

### *3.2.4. Lack of trust and cooperation among authorities*

The lack of trust among authorities and the lack of efficient administrative cooperation, further contribute to these drivers. Before the adoption of the Regulation, dialogue between the national authorities of different Member States was very difficult, mostly due to the lack of a common address book /network. The Regulation tried to remedy to this problem by introducing the Product Contact Points and the telematic network[58]. Despite this, administrative cooperation remains suboptimal, for various reasons. Many Member States highlighted, in their annual report, the difficulties PCPs have in identifying and contacting the responsible authorities in their own administration in order to reply to requests received from economic operators. Some Member States managed over the years to put in place a network of experts, but the variety of products covered by mutual recognition and national legislation involved, as well as the different internal organisation in certain Member States make this task very difficult. Also, there is a lack of administrative cooperation between PCPs. The absence of a network, allowing rapid communication and exchange of information delays the work of the PCP when replying to a request from economic operators. Many are complaining about the absence of reply from their colleagues from other Member States, or about long delays to receiving an answer. Often, the answers received are of low quality as regards the information transmitted[59].

During the survey carried out in 2014, the interviewed PCPs indicated the main problems with regard to administrative cooperation:

**Figure 3-3: 2016 public consultation**




One PCP indicated that sometimes the delay for receiving a reply is **40-50** working days. Another indicated that the intervention of the Commission was necessary in order to obtain a reply.

57 Public consultation 1.06.2016-30.09.2016; the other obstacles and priorities indicated are listed in annex 2 and in the Evaluation
58 Article 11 of the Regulation
59 See the Evaluation.

Additionally, the administrative cooperation between PCPs is also undermined by the difficulty to communicate in a common language, especially when technical terms are involved. This issue is almost unanimous among PCPs, and was raised during the surveys, interviews, in the annual reports as well as during the meetings of the Consultative Committee on mutual recognition.

### 3.3. The consequences of the problem/ Who is affected and how

Due to the suboptimal use of mutual recognition, barriers to free movement of non-harmonised goods remain; thus, a single market for goods is far from being achieved. Those most affected by the problem are economic operators, who are not benefitting fully from the internal market and their existing rights. They face additional costs to enter a new market or even lose market opportunities. National authorities rely on their own national rules and this undermines the free movement of goods. Consumers and final users cannot fully benefit from more choices on the market and thus lower prices that the single market for goods should provide, while maintaining the level of protection of public interest they are entitled to.

The following consequences can be identified for economic operators, consumers and national authorities, resulting from the non-functioning of mutual recognition:

| Economic Operators | Consumers | National Authorities |
|---|---|---|
| 1. Lost opportunities<br>2. Transaction costs: tests and adaptations<br>3. Delays in accessing the national market<br>4. Information costs due to the lack of effective functioning of PCPs<br>5. Costs of challenging national decisions | 1. Less choice in terms of available products<br>2. Higher prices | 1. Information and assessment related costs to find out whether a product should benefit from mutual recognition, due to the lack of efficient administrative cooperation |

The financial costs caused by lack of mutual recognition are high for the **business operators**.

First of all, business need to **find out what the applicable national rules, requirements and administrative procedures are** in the Member State of destination and assess if mutual recognition can be used to sell products in another Member State without being able to rely effectively on PCPs in order to obtain this information. This is particularly challenging for SMEs; according to the public consultation on the start-up and scale-up initiative, resources required to navigate the regulatory complexity are the third-biggest

problem for SMEs.[60] Costs also related to assessing if mutual recognition can be used to sell products in another Member State. Very few economic operators (2%) are outsourcing this assessment, while 26% are doing it internally. 46% are doing both, depending on the product. The lack of additional information does not allow for an estimate of the actual costs incurred when the assessment of whether or not mutual recognition can be used is outsourced. When done internally, economic operators spend on average 54 hours on doing the assessment; however, the number of hours indicated varies from one company to another. Most indicated only a few hours (less than 10) while two indicated spending more than 500 hours on this. The average cost per hour is 78 Euro. When trying to demonstrate that a product is already lawfully marketed in a Member State, businesses indicate that the average number of hours spent is 16, and the average cost per hour is 76 Euro.

High costs are also triggered by the **need to adapt the products** to the applicable national rules, when mutual recognition is either denied or not used for penetrating the market. These adaptation costs are estimated to be [61] between 1000 and 150 000 Euro per product and per market.

**Other indirect costs** may be generated by the lack of well-functioning mutual recognition. There is a distortion of competition and of the level-playing field as cross-border operators face higher costs than local operators. Also, companies may be able to pass on these costs to the consumers, leading to higher prices. If the market is not big enough, or if the costs are too high, businesses may be discouraged and give up on entering that market. This is particularly relevant for SMEs. For example, more than half of SMEs say that administrative procedures related to exporting to other Member States are too difficult to comply with and therefore deter many firms from exporting.[62] According to the Commission's 2014 Competitiveness report, only 14% of SMEs are trading across borders in the EU compared to 85.4 % of large manufacturing firms[63]. This translates into **lost opportunities** for businesses as well as costs resulting from **delays for entering a market**. In addition, it also generates a loss of competitiveness and innovation. High costs are also relating to **delays for entering a market**, estimated[64] between 3000 and 500 000 Euro per product and per market, and to **lost opportunities**, when businesses renounce entering a market because of different national rules requiring adaptation of the products. On average, the latest are estimated to be[65] between 10 000 and 500 000 Euro per product and per market. The estimate of the adaptation costs appears to be lower than the estimation of costs linked to lost opportunities and delayed

60 Public consultation of the start-up and scale-up initiative available at http://ec.europa.eu/DocsRoom/documents/20222.

61 26% of respondents indicated an estimate of the costs incurred, the other choose not to reply or indicated that such estimation is impossible

62 Flash Eurobarometer 421: Internationalisation of Small and Medium-sized Enterprises https://data.europa.eu/euodp/en/data/dataset/S2090_421_ENG and Flash Eurobarometer 413: Companies engaged in online activities https://data.europa.eu/euodp/en/data/dataset/S2058_413_ENG

63 More specifically, the 2014 Competitiveness report indicates that among the roughly two million manufacturing SMEs (0-249 employees) in the EU-28, 14.3 % export goods to EU countries. One can observe that export participation increases strongly with firm size. Meanwhile, 7.9 % of micro enterprises, 37.5 % of small firms, and 67.0 % of medium-sized enterprises export to internal markets, compared to 85.4 % of large manufacturing firms. This indicates that the export participation of large firms is about 10 times higher than that of micro enterprises. SWD(2014)277 final: http://ec.europa.eu/DocsRoom/documents/6706/attachments/1/translations/en/renditions/native

64 20% of respondents indicated an estimate of the costs incurred, the other choose not to reply or indicated that such estimation is impossible

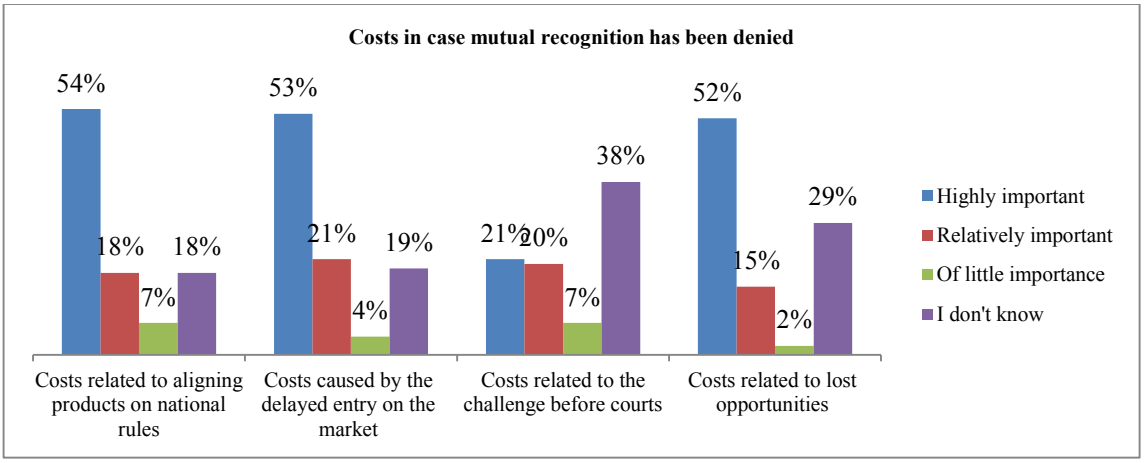
65 13% of respondents indicated an estimate of the costs incurred, the other choose not to reply or indicated that such estimation is impossible

entry on the market. This may be due to the specific profile of the respondents to the public consultation who were able to provide estimates, as testing costs can vary significantly from one product to another. The variety of products and how this translates in terms of costs is also highlighted later on (see table 7-8).

Economies of scale are crucially important for innovative firms that spend a large fixed cost in research and development (R&D) and need a large internal market to cover these costs[66].

Economic operators also face costs related to challenging administrative decisions denying market access; but they considered them as less important, mainly because few economic operators choose to do so. The estimates[67] are between 10 000 and 100 000 Euro per product and per market.

**Figure 3-4: Public consultation 2016**




These results confirm the findings of the external study carried out in 2015[68], where businesses underlined transaction and adaptation costs as being very significant. They perceived testing as being costly – more than 40% of them have rated testing as being a

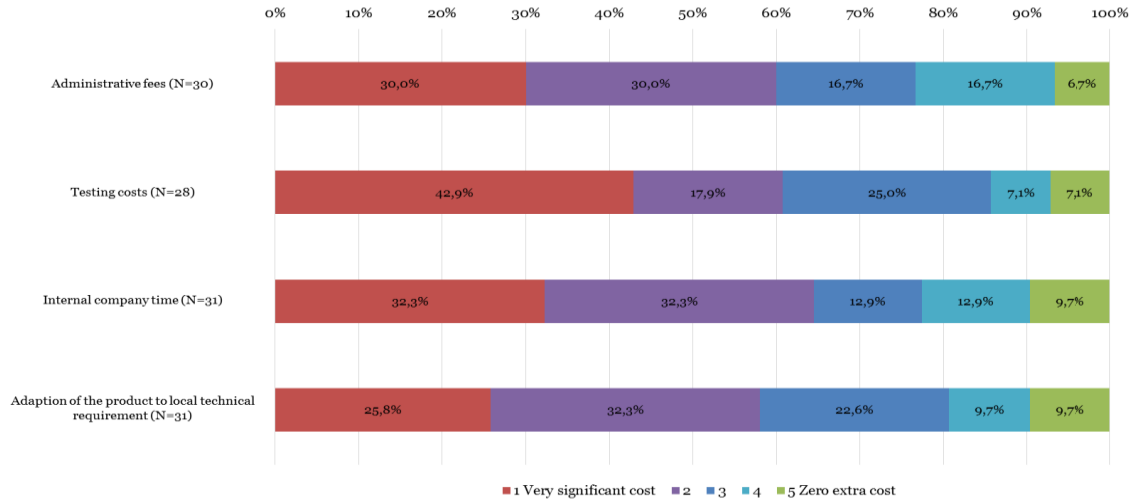
66 See OECD Economic Surveys: European Union 2014, Thematic Chapter Reinvigorating the EU single market: http://www.oecd-ilibrary.org/economics/reinvigorating-the-eu-single-market_5jxx3d3hk437-en. It is argued that the small size of firms in the EU relative to the United States is one indicator of costs of fragmentation. Van Ark et al. (2013) suggest substantial growth gains from further Single Market integration, in large part due to scale advantages. The correlation between the size of firms and their productivity in the manufacturing sector suggests that firms may have some potential to generate economies of scale.

67 11% of respondents indicated an estimate of the costs incurred, the other choose not to reply or indicated that such estimation is impossible

68 See the Evaluation.

very significant cost. The testing costs vary considerably, depending on the sector and the product, but some examples from different sectors are provided in Figure 7-18. Internal company staff time and administrative costs are perceived to be very significant by 32% and 30% of the companies, respectively. In the interviews carried out by the contractor, many companies mentioned that these types of costs naturally follow the testing costs and are therefore closely related to the issue of Member States demanding additional tests. Lastly, around 26% of businesses perceive the adaptation of products to local technical requirements to be a very significant cost. Furthermore, it is interesting that for all four categories, over half of the companies perceive the costs as either very significant or significant.

**Figure 3-5: Company survey: What are the typical cost items involved and how significant are they?[69]**




Note: N=28-31 (not all companies answered all questions)

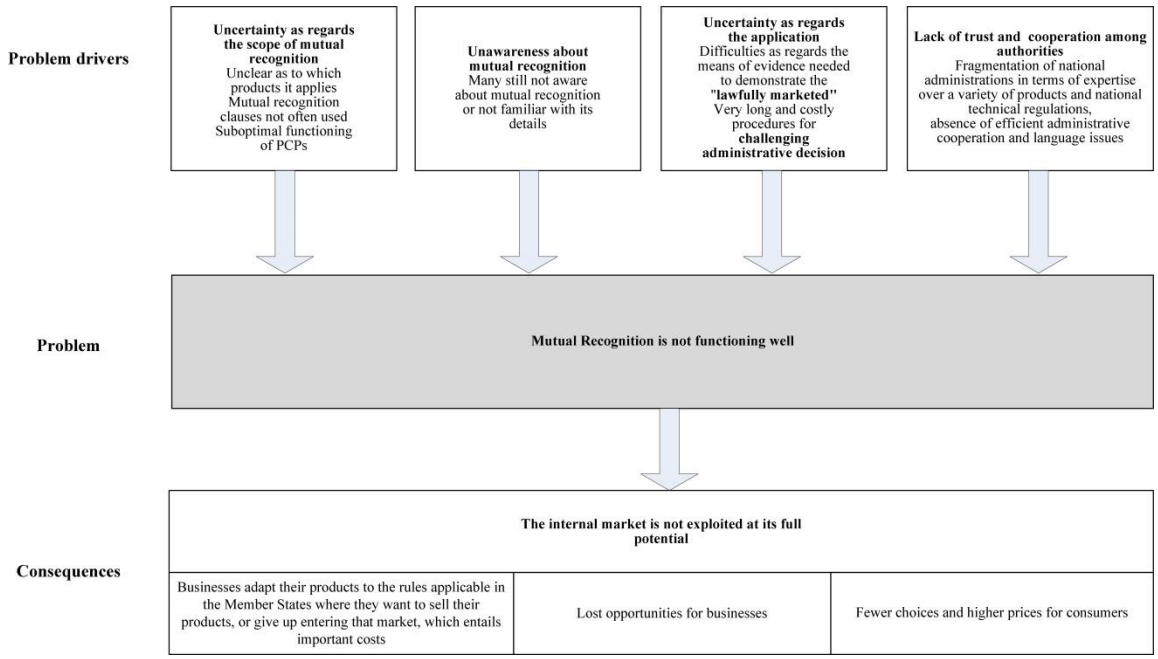
As regards the costs, the survey and the subsequent interviews carried out by the contractor revealed the same wide range of costs as those from the 2016 public consultation, depending on the different sectors. Similarly, few economic operators were able to put a figure on the costs faced due to the incorrect application of the mutual recognition principle. Of those that provided estimates, the costs ranged from 0.5% of the annual turnover, to 20% of the turnover. This is mainly due to the variety of products covered by mutual recognition.

The problem also affects **national authorities**, who are faced with lack of legal certainty regarding whether national rules should be applied to a product or not. Administrative costs are also incurred resulting mainly from the complexity of the legislations in place, which make it difficult to identify all rules applicable to a product and the scope for applying mutual recognition, and the difficulty of demonstrating that a product has been 'lawfully marketed' in another Member States (the latter being estimated for example EUR 420 000 in one sector such as fertilisers).

69 Source: Questionnaire survey among companies, running from 9 October 2014 to 5 January 2015, carried out by DTI

The lack of effective communication and cooperation further contributes to these indirect costs. The fact that PCPs don't efficiently exchange information, within their own administration and with PCPs from other Member States, delays the replies that they provide to businesses and impacts their quality. Furthermore, the assessment by national authorities of whether a product can be placed on their market based on mutual recognition is delayed and undermined by the fact that they don't properly cooperate and communicate with their colleagues in the Member State where the product under assessment has been lawfully marketed.

**Figure 3-6: Problem tree**




## 3.4. Foreseen evolution of the problem

Absent any action at EU level, it is foreseen that in the medium term, the problem of the lack of functioning of mutual recognition, and the underlying reasons, will remain.

The current procedures to support the use of mutual recognition would remain in place.

As such, obstacles to free movement of goods stemming from national rules will continue being addressed via existing tools: ex ante by the Directive (EU) 2015/1535, at the time of their adoption, and ex-post by the Regulation, at the time of their application to individual cases (national decisions denying market access). The clarification of legal uncertainties will be left to the case law of the Court of Justice of the European Union. Businesses and national authorities will continue to use the tools available (list of products to which mutual recognition may apply, guidelines, mutual recognition clause, Product Contact Points) to try to understand when mutual recognition applies in relation to a specific product.

The Product Contact Points network will continue functioning as up until now, and possibly benefit from being integrated into a wider network, which would act as a single entry point for all available business-related services. Under this wider network, the

provision of online information on products for economic operators would be facilitated through the 'Single Digital Gateway' (proposal forthcoming). The proposal for an EU Single Digital Gateway is expected to introduce a new obligation to provide information on national product rules online on a website, instead of upon request as now. Member States will need to provide a summary of the applicable rules for product categories, but may also refer to the assistance services for more detailed information tailored to specific products. This follows good practices already adopted by many Member States.[70] It is expected that having access to the information online will facilitate the accessibility and awareness of the role of PCPs and of national product rules by businesses. In addition, this initiative is expected to improve the functioning of PCPs by setting out quality criteria and the obligation to provide information online. However, the lack of awareness of the principle of mutual recognition, as well as the shortcomings in the functioning of PCPs, which have been constant despite the adoption of the Regulation, are expected to remain given that there are no current factors which could promote a higher awareness of the principle and its functioning.

Under the current provisions of the Regulation the Commission could undertake further work to update the list of products which may be subject to mutual recognition and make it more helpful and user friendly. The Commission will continue to ask for the inclusion of a mutual recognition clause for draft national technical rules notified under Directive (EU) 2015/1535, but its use is not expected to increase in the future given that the Commission has been encouraging the use of the clause in the past without it leading to significant results in terms of use or clarity.

Complexity and uncertainty around the application of the principle of mutual recognition will also remain. Businesses and national authorities will continue relying on guidance from the Commission in order to demonstrate that a product has been lawfully marketed; which however has not significantly solved the practical problems encountered while trying to rely on the application of mutual recognition. The outcome to be expected by businesses when trying to rely on the principle will remain uncertain. The burden of proof that a product should not be allowed market access remains on the national authorities. National authorities would remain obliged to notify both the economic operator and the Commission of all administrative decisions denying market access. Since its entry into force, the Commission services published several guidelines on the application of the principle of mutual recognition in various sectors and on what 'lawfully marketed' stands for. These elements do not appear as sufficient to address the problems described. These have not resulted in the expected improvement, in particular as regards the proof of lawful marketing of a product in a Member State. The Commission can use an existing IT system to support the notification process, however, the number of notifications of national decisions denying market access is also not expected to increase in the future.

The use of SOLVIT would remain an alternative for economic operators who wish to challenge administrative decisions denying market access. The foreseen Commission's action plan for improving SOLVIT aims to improve the awareness of its services to businesses, inter alia to increase the number of cases submitted against a national

70 For example, good practices on how to provide product information can be found in Austria, France, Denmark and the UK. See Annex 12 of the Evaluation.

decision denying market on mutual recognition grounds and the legal expertise of the SOLVIT centres in areas of interest to businesses such as the mutual recognition on goods. But it does not alter the informal character of SOLVIT and thus would still have limitations in offering efficient remedies for challenging unjustified decisions denying market access. Furthermore, without providing for the Commission technical assistance and further involvement for the goods cases, it is not expected that SOLVIT will produce better results for these cases as compared to the current situation.

It is not expected that Member States undertake any specific initiative to facilitate the functioning of mutual recognition. Furthermore, in problematic sectors where mutual recognition cannot facilitate free movement of goods, harmonisation of essential requirements can be used in order to ensure market assess for businesses. This is the case for example for fertilising products, for which a Commission proposal for an EU regulation was adopted on 17 March 2016[71]. This proposal will replace the current Regulation (EC) No 2003/2003 by, inter alia, extending it to currently non-harmonised products.

However, whilst harmonisation may take place where this is justified, necessary and proportionate, such measures cannot cover the totality of products and aspects of those products in the internal market, without there being any scope anymore for national rules. Whenever there are national technical rules, there will be a need to ensure the mutual recognition of those in order to guarantee the free movement of goods.

## 4. ANALYSIS OF SUBSIDIARITY

### 4.1. Legal Basis

The right to act is established on the basis of Article 114(1) TFEU dealing with the establishment and functioning of the internal market and specifying that measures can be adopted for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

### 4.2. Subsidiarity and Proportionality

Mutual recognition only applies in cross border situations where an economic operator would like to trade in a Member States a product already lawfully marketed in another Member State.

Action by Member States alone cannot solve problems associated with the application of the principle of mutual recognition across the single market. To be effective, the application of the principle needs to be based on common solutions to be applied equally

71 Proposal for a Regulation of the European Parliament and of the Council laying down rules on the making available on the market of CE marked fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 (COM(2016) 157 final)

by all national authorities. Only such common procedures can guarantee that national authorities will apply the principle in the same manner, thus allowing companies to benefit from an equal treatment regardless of the country where they try to market their product. Leaving the procedural aspects of the application of the mutual recognition principle to each Member State would weaken the principle by dismantling the modus operandi into 28 different and possibly contradictory procedures.

Therefore, EU action is both appropriate and justified to ensure the effective application of the principle.

The European added value of the mutual recognition rules was strongly underlined by the respondents to the 2016 public consultation. Most of them agreed that having a common set of rules guarantees equal treatment, and that relying on national rules only would undermine the internal market.

The EU has the right to act to ensure the functioning of the single market for goods. Pursuant to Article 26(2) of the Treaty on the Functioning of the European Union (TFEU), the internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of the Treaties. The prohibition, as between Member States, of measures having equivalent effect to quantitative restrictions on imports of goods is one of the main principles of the Treaty (Articles 34 to 36).

## 5. OBJECTIVES

Based on the problems described in section 4, the following objectives have been identified.

### 5.1. General Policy Objectives

The overall objective of the initiative is to achieve a fairer and deeper single market for goods through a higher level of and better mutual recognition.

### 5.2. Specific Policy Objectives

The specific objective will be to improve the functioning of mutual recognition by:

- Increasing awareness of mutual recognition.
- Increasing legal certainty for businesses and national authorities on when the mutual recognition principle can be used.
- Increasing legal certainty about the application of mutual recognition; both business and national authorities should know what they can reasonably expect when mutual recognition is, or ought to be, applied. This will reduce the risk for businesses that their products will not get access to, or will have to be unjustifiably withdrawn from the market.

- Enhancing communication, cooperation and trust among national authorities, so that they can act as a facilitating tool to ensure the functioning of mutual recognition.

## 6. POLICY OPTIONS

In order to address the problem identified in section 3 and its underlying drivers, a number of policy options have been identified. These options include a baseline scenario, soft law and legislative measures. The measures are presented from the softest to more far-reaching means to tackle the drivers and render mutual recognition fully effective. The soft law option 2 could be combined with any of the other legislative options (options 3, 4 or 5). Options 3, 4 and 5 would be mutually exclusive. Option 3a (free movement for products complying with European Standards) and 3b (transparency for administrative decisions) would be superseded by option 4. Option 4 provides for a voluntary declaration of compliance which would contain information on the compliance of the product with the applicable requirements. When European standards have been applied, the reference to such standards would be mentioned in the declaration and national authorities would now that compliance with those standards is ensured. In addition, option 4 provides for a fast-track appeal procedure where administrative decisions denying market access can be challenged, at last resort, by a binding opinion from of the Commission. This is in principle a more powerful incentive for Member States to apply correctly the principle of mutual recognition than the transparency of administrative decisions mentioned in option 3b.

Option 5 is construed as a self-standing option in that, providing for a pre-marketing authorisation procedure, intends to provide a different approach to offer a definitive answer on market access for the product and would not necessitate addressing the different drivers individually by additional means.

### 6.1. Discarded options

The option relating to repealing the Mutual Recognition Regulation has been discarded at an early stage. The Evaluation has concluded that, despite its current shortcomings, the Regulation remains relevant and that common procedures for the application of mutual recognition are still necessary. The lack of effectiveness was not triggered by the way the measures where designed but rather by their lack of ambition. The measures had the potential to achieve its objectives but were not strong enough to deliver the expected results. In particular, during the 2016 public consultation, there was overwhelming support from stakeholders in this respect even if their opinion on whether the objectives of the Regulation had been achieved was more mixed[72]. This is why repealing the Mutual Recognition Regulation altogether is discarded and other options have been envisaged building on the measures currently set out in the Regulation and enhancing them. However, if one of the options leading to a review of the Regulation is retained, this revision may also lead to removing certain provisions of the current Regulation which have not proved effective such as the obligation for Member States to report annually on

72 52% of businesses believe that the Regulation did not bring more legal certainty, whilst only 8% of Member States authorities share this view. Also, 60% of businesses responded that the Regulation did not reduce the risk of having market access denied whilst only 15% of Member States authorities share this view.

the functioning of the Regulation. The information provided by Member States in this context was limited in terms of content and usefulness.

Also, the option of proposing further harmonisation measures on specific basic requirements which would cover certain aspects of all products (such as traceability requirements, for example, since labelling requirements are often subject to national rules and have proved to be problematic for the application of mutual recognition) has been discarded. Adopting EU harmonisation legislation on specific products which appear particularly problematic, where this is justified, necessary and proportionate is always possible. Conversely, adopting horizontal harmonisation measures covering certain common aspects for all products is not likely to address the current problem drivers and the current situation is expected to be maintained, i.e. obstacles for companies in getting access to new markets, implying costs related to re-testing, lost markets and opportunities, etc. This is because these products will remain partly harmonised products, and for the elements not subject to the EU harmonisation legislation, they will still be subject to mutual recognition and to potentially conflicting national rules. This option would therefore not improve the functioning of mutual recognition.

The option of introducing a third party declaration of compliance has also been discarded at an early stage. This option looked into the possibility of introducing a declaration of compliance to be issued by a third party. Such a third party would be a body designated by the Member State in which the product is legally marketed, e.g. by the national Product Contact Point established in accordance with the Regulation. By issuing the declaration, this third party would take responsibility as regards the content of the declaration which would give more reassurance as to the compliance of the product; however, the responsibility as regards the compliance of the product would always remain with the economic operator. Such third party declaration of compliance could have been voluntary or mandatory. In both cases, such declaration would imply heavy costs for businesses as it would require the intervention of a third party in the drafting of the declaration.

Also, it would appear disproportionate, as it would apply to all types of products, contrary to the current situation for harmonised products. In the harmonised sectors, the type of conformity assessment procedure (requiring or not the intervention of a third party) is chosen by the legislator depending on the level of complexity and risk posed by a product. For example, electrical products (such an electrical kitchen appliance or a lamp)[73] do not require the intervention of a third party conformity assessment body, while other more complex products such as lifts[74] or fuel dispensers[75] do.

The intervention of third party certification also represents an important cost for business[76].

73 Subject to the Low Voltage Directive 2014/35/EU.
74 Subject to the Lifts Directive 2014/33/EU.
75 Subject to the Measuring Instruments Directive 2014/32/EU.
76 The Evaluation of the Internal Market Legislation for Industrial Products Accompanying the document the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee - A vision for the internal market for products (SWD (2014)23 final) indicated in its case studies that in the sector for gardening equipment the annual budget of firms for services of Notified Bodies is in the range of €30-80k, around €4,000 for certification of a single product and representing 20-25% of the total estimated costs for compliance. Similar figures were

### 6.2. Option 1: Baseline

The baseline scenario is the "no policy change" option. This implies that the Mutual Recognition Regulation in its current version remains the applicable legal framework. See more details in section 3.3.

### 6.3. Option 2: Soft law instruments to improve the functioning of mutual recognition

This option refers to the adoption of an action plan containing non-legislative measures to further boost the application of the mutual recognition principle. This option would not include a revision of the Regulation, and therefore the PCP network and the procedure to be followed by national authorities for denying market access would remain as they are today.

The action plan would contain, in particular, the following measures:

**a) Awareness raising and training**

*Increasing the general awareness of the mutual recognition principle was considered in the 2016 public consultation as the first priority for Member States (51%) and citizens (64%), and as the last priority for businesses, even if supported by 52% of economic operators responding to the consultation. Furthermore, 84% of Member States, 95% of businesses and 88% of citizens considered in this consultation that awareness-raising is still necessary.*

Awareness among economic operators and national authorities on mutual recognition and how it works in practice would have to be raised. Effective awareness-raising campaigns and specific sectorial training on the implementation of the mutual recognition principle would be provided at EU level.

The following tools could be included in the Action Plan:

a) **Training** at general and sectoral level. A training package to be adapted to targeted groups could be developed in all EU languages. The concept would be **"train the trainer"** whereby the Commission would develop the training package and would train the trainer. The targeted groups could include **national administrations**: PCP, national authorities responsible for product-related legislation in problematic areas, national courts/ judges, market surveillance authorities or SOLVIT staff. The same concept would be duplicated for **businesses**, where the trainer could be drawn from European Enterprise Network (EEN) staff.

b) As an outcome of the training courses, a comprehensive guidance document could be developed i.e. **a Mutual Recognition rule book**. This would include, for example, detailed guidance on the application of the principle, building on and updating the Commission interpretative Communication on facilitating access of products to the markets of other Member States: the practical application of mutual

provided by manufacturers of fuel dispensers. Manufacturers of fuel dispensers estimated that Notified Bodies fees represented 55% of the conformity assessment costs, 35% relating to initial inspections and 20% to periodic inspections.

recognition adopted in 2003[77], as well as identifying best practices.

c) The list of products to which mutual recognition would be reassessed to determine how it can be rendered more user friendly so that it can provide more meaningful information to stakeholders.

**b) A clearer mutual recognition clause**

The Commission would design a clearer mutual recognition clause as part of a guidance document to be included in national technical rules adopted by Member States.

The new mutual recognition clause would be further supported by guidance to Member States on how and when the clause should be included in the national legislation, and on the consequences of its inclusion.

**c) Exchange of officials in the area of mutual recognition**

Exchanges of officials from Member States working in the relevant national administrations would concern Product Contact Points but also national authorities working in problematic areas, such as construction products, food area, etc. The exchange would take place over a short period of time, for example 1 week.

### 6.4. Option 3: Minimum legislative changes to Regulation (EC) No 764/2008 to improve the functioning of mutual recognition

Under this option, containing several complementary sub-options, the Regulation would be revised; the changes to be introduced would address the drivers identified while allowing for more flexibility in the use of the mutual recognition principle.

In particular, the following changes would be introduced in the Regulation:

**a) Free movement of goods guaranteed by compliance with European standards**

*During the 2016 public consultation, 57% of Member States, 84% of businesses and 82% of citizens supported this option.*

A possible solution to address the differences in the technical requirements in national laws would be to guarantee that products lawfully marketed in one Member State and complying with specifically identified European standards would effectively enjoy the right of free movement in the EU. This option builds on the role that European standards already have in the harmonised sector. In particular, European standards the reference of which has been published in the Official Journal, provide presumption of conformity of a product with the specific requirements of a harmonisation legislation they covered. Such referenced European standards become thus "harmonised standards" and by applying them, the manufacturer enjoys the presumption of conformity with the applicable requirements and does not need to prove by other means the compliance of

77 2003/C 265/02

its product. In the current context of mutual recognition, this option refers only to already existing or future European standards but not to mandating the developments of specific European standards. The recognition of particular European standards would be done by the Commission via implementing acts, and after consultation of Member States. Compliance with these standards would give a presumption of compliance with the relevant technical rules applicable in any Member State, as the standards usually cover the design of the product and the testing methods, which are the core of technical rules. A product complying with the European standards would benefit from market access in the Member State of destination, unless the national authorities demonstrate that it does not offer adequate protection of the relevant public interests; thereby shifting the burden of proof to national authorities. Such presumption of compliance would facilitate the free movement of goods already lawfully manufactured in a Member State. It would provide legal certainty and reliability as to the outcome when businesses could invoke mutual recognition. Compliance with these standards would remain voluntary for economic operators, who would need to be aware and apply any particular European standards identified in the context of mutual recognition if they want to access other Member States markets. However, the limits of this option would be that currently, European standards do not exist for every product or aspect of product, and therefore it would not provide a solution for those other products or aspects of products. Also, the process for recognising them for the purposes of mutual recognition via implementing acts would be time consuming.

**b) Transparency for administrative decisions denying market access**

*During the 2016 public consultation, 46% of Member States, 81% of businesses and 64% of citizens agreed that dissuasive means are necessary to ensure the notification obligation is respected.*

The Regulation would reinforce the obligation to notify administrative decisions denying or restricting mutual recognition. Under this option, the notification obligations would be strengthened and administrative decisions which have not been notified to the Commission and the economic operator concerned would be considered as void and thus could not be enforced vis-à-vis the operator. More transparency for these decisions would be an incentive for Member States to apply the mutual recognition principle properly, as the lack of proper justification supporting the administrative decisions to be notified could be spotted easily by the Commission and any other Member State, including the Member State of origin. Using an IT tool for allowing Member States to notify would also give all notifications more visibility. The IT tool to be considered could be, e.g., the Internal Market Information tool (IMI) or ICSMS (i.e. the General Information Support System referred to in Article 23 of Regulation (EC) No 765/2008).

**c) Enlarging the role of Product Contact Points**

*During the 2016 public consultation, 64% of Member States, 64% of businesses and 70% of citizens agreed that PCPs need to be strengthened. Member States (31%) and citizens (23%) ranked this as the last priority for the Commission, while businesses ranked it second to last (54%).*

The efficiency of PCPs in raising awareness of mutual recognition and in providing

useful information to businesses was limited. However, the need to keep a network able to provide basic information and connect economic operators with the responsible authorities for more complex information remains. This is why it is proposed that PCPs remain as the main information points for mutual recognition, but that their role is enhanced. The role of PCPs would be enlarged in order to provide information on all applicable rules for all products, i.e. information on Union harmonisation legislation and on national technical rules adopted in the non-harmonised area. This would be particularly relevant for products where certain aspects are covered by harmonised legislation and others subject to national technical rules, since it would offer economic operators information on all rules applicable to their product and thus a more complete overview of the regulatory situation in the Member State of destination.

### 6.5. Option 4: Comprehensive legislative changes to Regulation (EC) No 764/2008 to improve the functioning of mutual recognition

Under this option, comprehensive regulatory changes would be made to the current legislation.

In particular, the following changes would be introduced in the Regulation:

**a) Clarifying the scope of mutual recognition**

*During the 2016 public consultation, 84% of Member States, 85% of businesses and 82% of citizens supported this option.*

The Regulation would be clarified and extended beyond its current scope of defining procedural guarantees for decisions denying market access. It would expressly mention that mutual recognition applies not only to products not subject to harmonisation legislation but also to products for which only certain aspects are covered by harmonisation legislation in whatever aspects are left for national rules. Clarifications would be provided also as regards the areas where measures restricting or denying market access can be taken on the basis of the mutual recognition principle and how these should be notified to the Commission and other concerned parties.

**b) Declaration of compliance**

*During the 2016 public consultation, 75% of Member States, 80% of businesses and 76% of citizens agreed that a declaration would simplify the demonstration of the lawful marketing of the products. Increasing legal certainty has been ranked by businesses (67%) and citizens (52%) as the 2nd priority for the Commission, while Member States (33%) ranked it second to last.*

The Regulation would introduce a declaration of compliance with the technical rules of the Member State where the product is being lawfully marketed, to facilitate the access of this product to the market of the other Member States. A similar declaration of compliance is already required for products within the scope of Union harmonisation legislation, giving Member States authorities the first information regarding the legislation the product complies with, and the conformity assessment procedure which has been followed, as appropriate. The aim of the declaration for mutual recognition is

to bring administrative simplification, as it will allow economic operators to show compliance with applicable national rules in the Member State where their products are lawfully marketed in a single standardised manner. It would replace the various and numerous existing means for requesting evidence to prove that a product is already lawfully marketed in a certain Member State by one single standardised document. It would bring legal certainty for both economic operators and national authorities, as it offers all the information necessary for carrying out the assessment of whether or not the product is allowed on the market. Moreover, it would facilitate the mutual recognition by the authorities of the Member State of destination of the requirements already met in the Member State of origin.

When entering a new market, economic operators would rely on the same declaration to attest that their product is already lawfully marketed. All national authorities would have to accept this declaration and, while they would be able to ask for evidence substantiating the information stated therein, they would not be able to require different means of evidence. The Regulation would define the **standardised content** this declaration of compliance would have. It would include at least the identification of the economic operator and of the product, the relevant legislation and /or standards the product complies with and, when applicable, the relevant conformity assessment procedure and specific tests carried out. It would be drafted in the language of the Member State where the economic operator intends to market his products, by making use of multilingual forms, which would be introduced as an Annex to the Regulation. It would be made available by the economic operator to national authorities upon request.

By signing the declaration, the economic operator takes full responsibility as regards the compliance of his product with the applicable rules in the Member State of origin and the lawfulness of what he is declaring. The limit of this option is that it will not guarantee absolute market access for the relevant products, given that the application of mutual recognition can be objected to by national authorities when this is justified and proportionate for the protection of legitimate public interests. This option contains the following sub-options:

**a)Voluntary self-declaration of compliance**

The declaration would be issued by the economic operator and would be voluntary for all those relying on mutual recognition to enter a new market.

**b) Mandatory self-declaration of compliance**

The declaration would be issued by the economic operator but would be mandatory for all relying on mutual recognition to enter a new market.

**c) Fast-track appeal procedure – effective remedies against national decisions denying market access**

*During the 2016 public consultation, 66% of Member States, 90% of businesses and 76% of citizens agreed that effective remedies to challenge administrative decisions denying market access are necessary. Businesses ranked this as the 1st priority for the Commission (72%), while Member States (40%) and citizens ranked it as the 3rd*

*priority.*

The Regulation would put in place a business friendly and non-intrusive mechanism, allowing for a fast and efficient resolution of problems triggered by a problematic national administrative decision denying or restricting market access. A similar system of objecting to national decisions denying market access exists in the harmonised area[78] which is called the Union safeguard procedure. By means of this procedure, Member States authorities taking a decision restricting market access to a particular product need to notify such decision to the Commission and other Member States who may object to the measure. If objections are raised, it is for the Commission to decide whether the measure is considered justified or not.

This mechanism would be a two-step procedure:

Firstly, it would built on existing problem resolutions tools, such as SOLVIT, in order to allow economic operators wishing to do so to challenge, in an informal way, an administrative decision allegedly incompatible with the mutual recognition principle. When faced with a decision denying market access, the economic operator would thus have the possibility to refer the case to SOLVIT to benefit from an informal problem resolution system. During this phase, the Commission would informally assist SOLVIT with the necessary technical expertise on demand. It would be expected that this assistance would increase the resolution rate of the goods related cases involving technical expertise which can be provided by the Commission on request.

Secondly, if the dialogue phase started by SOLVIT fails to achieve a suitable solution, a Commission binding opinion (fast track appeal procedure) can be required. The Commission, during this second phase, would have the choice of intervening or not, on opportunity grounds (strong case, systemic issues, multiplier effect in terms of impacts). The Commission binding opinion would be a powerful deterrent, particularly useful in the first step of the procedure and intervening only as a last resort tool. The Commission's assessment would be purely technical, as it would not concern the national rule as such and its merits, but only the practical results produced by applying a national rule to a specific product which has been lawfully marketed in another Member State. It would ensure a consistent and correct application of the mutual recognition principle.

**d) Strengthening the Product Contact Points and the cooperation between relevant authorities**

*During the 2016 public consultation, 64% of Member State, 64% of businesses and 70% of citizens agreed that PCPs needs to strengthen the PCPs. Member States (31%) and citizens (23%) ranked this as the last priority for the Commission, while businesses ranked it second to last (54%).*

The Regulation would strengthen the role of PCPs in order to provide information on all

78 See articles R31 and 32 of Decision No 768/2008/EC which has been incorporated into most pieces of Union harmonisation legislation, providing for a Union safeguard procedure.

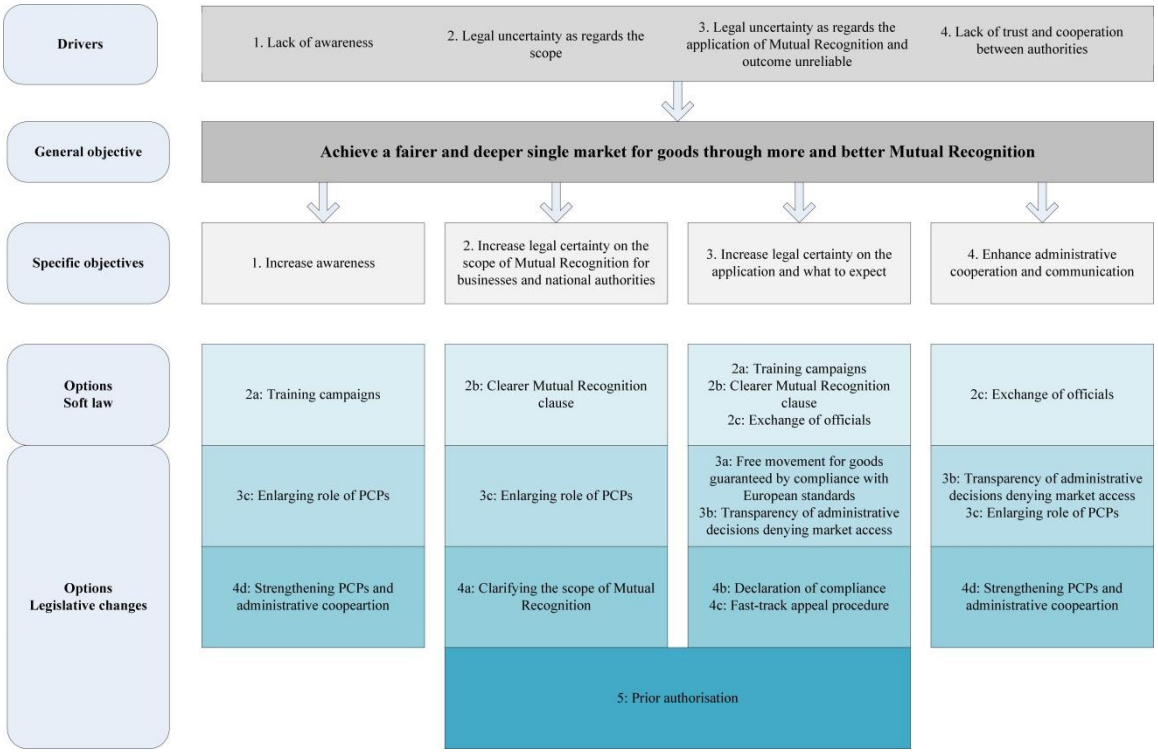
applicable rules for all products, i.e. information on Union harmonisation legislation and on national technical rules adopted in the non-harmonised area, as in option 3 c). In addition, mandatory administrative cooperation among Member States would be put in place to ensure communication and exchanges among the national authorities responsible for the application of the principle. This network would, for example, discuss difficult cases, identify problematic sectors, make recommendations for standardisation mandates, etc.

### 6.6. Option 5: Legislative changes to the Regulation to introduce a voluntary prior authorisation to placing on the market

Under this option, the suboptimal functioning of the mutual recognition principle would be addressed by intervening in a pre-marketing phase to prevent obstacles to free movement of goods rather than in a post-marketing phase as it is the case today. By introducing a system of prior authorisation to placing products on the market, economic operators would have confirmation that their products can have market access in the Member State of destination before actually entering that market. This voluntary procedure is currently not available at the moment. The Regulation would be amended to reflect the introduction of such a pre-marketing procedure.

| **Voluntary prior authorisation to placing on the market**<br><br>*Increasing legal certainty has been ranked by businesses (67%) and citizens (52%) as the 2nd priority for the Commission, while Member States (33%) ranked it second to last.* |
|---|
| This option is inspired from existing systems at national level, where the marketing of certain specific goods is subject to a mandatory prior authorisation system. Products lawfully marketed in the market of one Member State would be placed on the market of another Member State only after a prior examination and authorisation of the product by the receiving Member State. Such examination would consist in assessing if the product can be accepted in the Member State or not, i.e. the Member State would confirm (or disallow in certain specified cases) that a product, although not compliant with its own national legislation, can be marketed in its territory. This option would remove all uncertainties economic operators currently face when relying on the principle of mutual recognition to enter new national markets. Such a procedure would be voluntary for economic operators but if market access is denied, remedies under national law should be made available to the economic operator. |

**Figure 6-1: Table with options in relation to the objectives and problem drivers**




# 7. ANALYSIS OF IMPACTS

## 7.1. Assessment of the impacts

### Policy option 1- Baseline

The impacts of this option can be found in sections 3.1, 3.3 and 3.4.

### Policy option 2- Soft law instruments

| Economic Impacts |
|---|
| Economic impacts for businesses<br><br>It is expected that those economic operators who were not aware of mutual recognition or not very familiar with the details will try to use it in order to penetrate new markets. This assumption is limited by the fact that the decision to market products in other Member States is influenced by many other factors; economic operators behaviour and organisation do not necessarily occur in sequence but are rather continuous and dynamic[79]. Furthermore, as this option addresses effectively only the lack of awareness, |

79 See: Adriaan Dierx, Fabienne Ilzkovitz and Khalid Sekkat (Ed.), European Integration and the Functioning of Product Markets, Edward Elgar Publshing Ltd, 2004

without touching upon the substantial issues related to the lack of legal certainty in particular in the application of mutual recognition, it is also expected that these economic operators will face the same problems as those already using mutual recognition (e.g. high information costs, unjustified market access denial, adaptation costs, etc.).

This option will not entail additional costs for businesses; the trainings for businesses (sub-option 2a) would be organised by the European Enterprise Network and they would have the possibility to attend these or access information made available online. The mutual recognition clause (sub-option 2b) and the exchange of officials (sub-option 2c) would not entail any costs for businesses either.

Costs currently faced by economic operators due to the suboptimal functioning of mutual recognition are expected to be reduced but to a limited extent. While the exchange of officials (2c) would not have any direct impact on businesses, the trainings (2a) are expected to lead to certain cost savings for businesses, albeit not significant, in finding out the applicable rules in the Member State of destination. This is because, on the one hand, they would be aware that they can access the Member State of destination without having to comply with the applicable rules in that Member State and, on the other, because they would be made more aware of the role of PCPs which can facilitate any further information as appropriate. However, since this option only addresses effectively one of the policy objectives, but not the others related to the legal uncertainty, the economic benefits for businesses in particular in terms of reduced adaptation costs, lost opportunities, or costs related to challenging administrative decisions denying market access are not expected to be substantial by this option alone. The benefits that a clearer mutual recognition clause would bring (2b) would also be limited since these would only impact new national rules which will be adopted as from now on, and not all those existing rules.

Since SMEs need to allocate proportionately higher resources in finding out the applicable rules and are the most discouraged to internationalisation by the regulatory complexity; this option (particularly the awareness raising (2a)) is likely to benefit these companies particularly.

Given that this option (including all sub-options) does not address all problem drivers but only the awareness, it is not likely to lead, alone, to a significant increase in trade across Member States in non-harmonised sectors due to a better functioning of mutual recognition.

<u>Economic impacts for Member States</u>

National authorities would bear some costs related to the organisation of trainings and awareness campaigns (2a); however these costs are not expected to be substantial. The training campaigns would take the form of a "train the trainer" and in that regard, national administrations would be required to organise trainings to other national officials (such as specific administrations in problematic sectors, national judges…). However, part of the training would be developed and available as an online package. Furthermore, for national officials, these trainings could also be integrated into more comprehensive trainings that national officials receive (for example, when taking up their duties) so that it is put in the context of the overall tasks they have to perform, which would also limit the costs.

There are no costs associated with the introduction of a clearer mutual recognition clause (2b). The exchange of officials (2c) would have an impact for national administrations insofar as during a very short period of time (1 week), a salary would be paid to an official who would be in another Member State and, therefore, not actively performing his or her duties. However, given the short period envisaged, these costs related to the absence of the officials are not considered significant and this short absence can be assimilated to the attendance of training by the official. Other travel and accommodation costs would not be borne by the Member State but by the EU budget.

Economic impacts for the EU budget

Developing the training packages and coordinating the awareness raising campaigns (sub-option 2a) would imply costs for the Commission. These costs are considered to be normal costs related to the implementation of new legislation and should not have major impacts in terms of resources. As for the organisation of events in the Member States, if the Commission would organise events in all Member States for a wide audience, this would entail costs. For example, in similar campaigns organised by the Commission, the organisation of 28 national events over a period of 2 years with an average audience of 75 people per event was carried out with an external consultant with a budget of €1 million[80]. The Commission would however envisage that this training is structured with a "train the trainer" concept together with an online training package, for which a lower budget of €500.000 could be established.

A clearer mutual recognition clause (sub-option 2b) does not imply any costs for the EU budget.

The exchange of officials (sub-option 2c) would be financed by the EU budget as regards travel and accommodation costs. Similar schemes implemented at EU level in the area of product safety can be used to give an estimate for these costs. Such schemes required an annual budget of €170 000, covering for the travel and subsistence allowances for the officials participating in the scheme. This budget covered around 100 exchanges, involving 23 Member States[81]. On the basis of this estimate if the number of exchanges would be raised to 300, this could be realised with a budget of around €510 000.

| Social Impacts |
|---|
| This option is not expected to have social impacts to the extent that these can be assessed and quantified. |
| Environmental impacts |
| This option is not expected to have environmental impacts to the extent that these can be assessed and quantified. |
| Administrative simplifications |

80 The Late Payment Information Campaign was organised from October 2012 to November 2014to support the transposition of the new Late Payment Directive 2011/7/EU. See https://ec.europa.eu/growth/smes/support/late-payment/campaign/

81 http://ec.europa.eu/chafea/consumers/exchange-of-officials-index_en.html

No major administrative simplifications are expected under this option.

## Stakeholders views on the option

During the last meeting of the Consultative Committee on mutual recognition (25 October 2016), there was a consensus among Member States representatives on the fact that this option will be extremely effective in increasing awareness of the mutual recognition principle and therefore Member States representatives highly supported it.

During the additional survey and interviews conducted by an external contractor during 2016-2017[82], stakeholders shared the following views on this option:

| Sub-options | Effectiveness for raising awareness (Policy objective 1) | | Effectiveness for legal certainty on the scope (Policy objective 2) | | Effectiveness for legal certainty on the application of MR (Policy objective 3) | | Effects on reducing costs for economic operators | | |
|---|---|---|---|---|---|---|---|---|---|
| | MS | EO[83] | MS | EO | MS | EO | Transaction costs | Appeals | Delayed market access |
| Awareness raising and training | 58% | 50% | 42% | 42% | 42% | 33% | 42% | 25% | 25% |
| Clearer mutual recognition clause | 68% | 50% | 63% | 42% | 69% | 33% | 42% | 25% | 25% |
| Exchange of officials | 32% | 33% | 27% | 33% | 37% | 58% | 34% | 25% | 33% |

## Assessment of the option

Effectiveness in achieving the policy objectives

| | |
|---|---|
| *Increase awareness about mutual recognition* | +++ |
| *Increase legal certainty on the scope of mutual recognition* | + |
| *Increase legal certainty on the application of mutual recognition* | + |
| *Enhance administrative cooperation and communication* | ++ |

82 See Annex 2
83 Economic operators

| | |
|---|---|
| Economic impacts for economic operators | 0 |
| Economic impacts for Member States | - |
| Economic impacts on the EU budget | - |
| Administrative simplification | 0 |
| *Magnitude of impact as compared with the baseline scenario (the baseline is indicated as 0): +++ very positive; ++moderately positive, + positive; - - - strongly negative; - - moderately negative, - negative; neutral 0.* | |

**Policy option 3 – Minimum legislative changes to regulation (EC) No 764/2008 to improve the functioning of mutual recognition**

| Economic impacts |
|---|
| Economic impacts for businesses<br><br>Due to the complexity of mutual recognition and the variety of products involved, it is very difficult to provide a quantitative assessment of the reduction of costs that this option would trigger. It is expected that information costs would be partially reduced, as economic operators will receive more accurate information in light of the enlargement of PCPs (sub-option 3c); this will impact mostly those products which are considered to be partially harmonised.<br><br>As a result of sub-option 3a (free movement for products complying with European standards) information costs, adaptation costs as well as costs linked to delays in accessing markets and lost opportunities are expected to be reduced; this view is supported by businesses. However, this sub-option would only lead to cost-savings in those sectors and for those products where economic operators would be able to rely on European standards. Such sectors are relatively limited (e.g. childcare articles). Furthermore, this option would only apply to products for which the Commission, after consultation of Member States and via implementing acts, has also recognised the European standard in the context of mutual recognition; which may be a time-consuming process. For those products in the area of which European standards do not exist, or have not been formally recognised by the Commission, including in the area of new, innovative products, this would not lead to benefits. This is supported by views at sector level, where this sub-option is considered to have a lot of potential, but no practical application, due to the lack of existing EU standards in particular sectors84.<br><br>Denial of market access and associated costs are also expected to be partially reduced, due to the modification of national authorities' behaviour triggered by the transparency of administrative decisions (sub-option 3b).<br><br>This option (in particular sub-option 3a) would also entail a number of costs for businesses. Companies wanting to benefit from free movement by complying with certain |

84 See case study on Food supplements, annex to the Evaluation.

European standards would need to purchase these standards. The costs of the purchase and/or update of standards for a specific product group have been estimated in the harmonised sector to account for less than €2,000 on an annual basis, and in many cases less than €1,000[85]. This option would remain voluntary for companies even in those sectors where European standards exist and have been recognised by the Commission in the context of facilitating mutual recognition.

Furthermore, large firms participate much more actively in EU standardisation processes and they are often involved in drafting standards, ensuring that SMEs are sufficiently represented in the standardisation process and that their concerns are taken into account is one of the concerns of the Commission86. Therefore, large firms are more likely to benefit from this option than SMEs, and the impact on the functioning of mutual recognition may be less substantial in particular in view of the fact that 87% of companies involved in the non-harmonised sector are micro enterprises.

This option, in particular by ensuring the free movement of goods is complying with European standards (sub-option 3a) and the transparency of administrative decisions denying market access (sub-option 3b), is expected to have an impact, albeit limited, in increasing trade flows among Member States and thus, a positive impact on the competitiveness of European industry.

Economic impacts for Member States

Sub-option 3a (free movement for goods complying with European standards) would not trigger any costs for Member States; this would only require national authorities to stay informed of all the European standards which are recognised by the Commission for the purposes of mutual recognition and the products it affects. The transparency of administrative decisions denying market access (sub-option 3b) would also not entail any costs for Member States, given that they would submit a copy of such decisions via a supporting IT system and that an obligation to notify already exists under the baseline.

Member States are expected to bear certain costs as regards enlarging the role of PCPs (3c). National authorities have already incurred costs related to implementing their obligation to establish PCP (putting them in place and having them functioning on an annual basis). Most of the time, the PCP has been integrated in an already existing department dealing with internal market issues. Based on the annual reports[87], one person on average is fulfilling the task of PCP. Since PCPs would be required to provide information on harmonised sectors as well, they would need to be enlarged. It is likely that the number of information requests will increase quite sharply by including the provision of information on EU harmonised rules as well so that, under this option, it would require between 1 and 3 supplementary FTE per PCP[88].

85 Evaluation of the internal market for products, see footnote 76.

86 See the Joint Initiative for Standardisation; while the presence of SMEs and their associations is already improving at European level, more should be done to ensure appropriate representation and effective participation in international standardisation processes. http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8852

87 See the Evaluation

88 This assumption is based on the current number of FTEs employed in the PCP network in the different Member States (see the Evaluation, section 7).

Economic impacts for the EU budget

In case of ensuring transparency of decisions denying market access (sub-option 3b), the Commission would have to invest certain resources in the making available of an IT tool to support the notification system. However, this option would not imply setting up a new IT tool but it would rather rely on existing IT tools (such as ICSMS[89] or IMI[90]).
Accordingly, the impact on resources would be minor, as it would require only certain (internal) technical work and adaptations in order to put in place the necessary procedures and functionalities necessary for the purposes of these notifications.
Sub- options 3a (European standards) and 3c (enlarging the role of PCPs) would not trigger any costs on the EU budget.

Social impacts

Since this option, in particular by ensuring free movement of goods complying with European standards (sub-option 3a) and the transparency of administrative decisions denying market access (sub-option 3b), is expected to have a limited impact in increasing trade and thus, a positive impact on competitiveness of European industry; it would also have limited positive social impacts on the creation of employment. However, these impacts cannot be quantified.

Environmental impacts

Environmental impacts of this option cannot be quantified. Yet, an increase in trade flows between Member States may lead to some additional transport emissions, although they are not considered to be significant.

Administrative simplifications

The free movement for products complying with European standards would bring administrative simplification for companies when ensuring market access but it would only be for those products where a European standard exists and it has been recognised by the Commission for the purposes of mutual recognition. This is because for such products, companies would be able to rely on the compliance with the European standard and would not be required to further document that the product should be allowed market access on the basis of mutual recognition. If the Member State of destination would consider that the product does not adequately protect the public interests at stake despite complying with the European standard, it would be for the authorities to prove this.

The use of an IT tool to notify administrative decisions denying market access is seen as an administrative simplification. It would replace the many divergent notification channels used until now, would streamline the coordination and overview of the notifications, and would facilitate their assessment.

89 The Information and Communication System on Market Surveillance (ICSMS) is an IT platform to facilitate communication between market surveillance bodies in the EU and in EFTA countries.
90 Internal Market Information Tool.

| Stakeholders views on the option |
|---|
| During the 2016 public consultation, 46% of national authorities, 81% of businesses and 64% of citizens agreed with the need to introduce dissuasive measures to ensure that the obligation for national authorities to notify administrative decisions denying or restricting mutual recognition is respected. In addition, 57% of national authorities, 84% of businesses and 82%.<br><br>During the additional survey and interviews conducted by an external contractor during 2016-2017[91], stakeholders shared the following views on this option: |

| Sub-options | Effectiveness for raising awareness (Policy objective 1) | | Effectiveness for legal certainty on the scope (Policy objective 2) | | Effectiveness for legal certainty on the application of MR (Policy objective 3) | | Effects on reducing costs for economic operators | | |
|---|---|---|---|---|---|---|---|---|---|
| | MS | EO[92] | MS | EO | MS | EO | Transaction costs | Appeals | Delayed market access |
| European Standards | 48% | 75% | 48% | 75% | 53% | 58% | 66% | 42% | 42% |
| Transparency of national decisions | 58% | 58% | 58% | 58% | 74% | 50% | 50% | 50% | 50% |
| PCPs | 42% | 33% | 37% | 33% | 37% | 58% | 42% | 34% | 34% |

| Assessment of the option | |
|---|---|
| Effectiveness in achieving the policy objectives | |
| *Increase awareness about mutual recognition* | + |
| *Increase legal certainty on the scope of mutual recognition* | + |
| *Increase legal certainty on the application of mutual recognition* | ++ |
| *Enhance administrative cooperation and communication* | + |
| Economic impacts for economic operators | + |
| Economic impacts for Member States | - |

91 See Annex 2
92 Economic operators

| | |
|---|---|
| Economic impacts on the EU budget | 0 |
| Administrative simplification | + |
| *Magnitude of impact as compared with the baseline scenario (the baseline is indicated as 0): +++ very positive; ++moderately positive, + positive; - - - strongly negative; - - moderately negative, - negative; neutral 0.* | |

**Policy option 4- Comprehensive legislative changes to Regulation to improve the functioning of mutual recognition**

| Economic impacts |
|---|
| <u>Economic impacts for businesses</u><br><br>Under this option and its related sub-options, costs related to demonstrating that a product has been lawfully marketed in another Member State would be reduced, as well as costs related to a delayed entry on the market due to extensive discussions with national authorities as whether or not the product is lawfully marketed in another Member State.<br><br>Sub option 4b (Declaration of Compliance)[93], if voluntary, would not trigger any out of the ordinary costs for economic operators; economic operators would need to fill it in and keep it updated whenever necessary, such as when legislation or standards are revised. The Declaration of Compliance is only a summary of the conformity assessment procedures already carried out, and does not require any additional testing. It would be used only when judged necessary by economic operators, in situations involving products heavily regulated at national level and therefore where the Declaration of Compliance would really have a real added value in terms of streamlining and framing the discussions between economic operators and national authorities. A similar declaration is also used in the harmonised area, and had positive effects in terms of reducing costs and facilitating trade[94]. The study supporting the evaluation of the internal market for goods[95] shows that generally, drafting the declaration of conformity used in the harmonised area is not viewed as problematic or costly. Economic operators[96] see it rather as a minor step, not very costly and not very complex, which involves minimal administrative work for drafting the declaration. Similarly to the current situation in the harmonised area, it is expected that this declaration will be straightforward to complete, taking not more than 30 minutes. Given the diversity of the means of evidence that economic operators may be asked to provide at present to demonstrate that a product is lawfully marketed in a Member State, the time spent in completing the declaration is expected to constitute an improvement to the current situation.<br><br>On the contrary, a mandatory Declaration of Compliance in the non-harmonised area would be an administrative burden for economic operators, as economic operators would |

93 See annex 8for detailed information on this option.
94 See Annex 8.
95 See footnote 76.
96 As estimated based on case studies performed in sectors such as lifts, air conditioning, domestic refrigerators and freezers, electric motors, see study supporting the evaluation of the internal market for goods quoted above. For example, for electric motors it was estimated that the average costs for declaration of conformity or other statement of compliance and CE marking of the interviewed companies amount to approximately 0.1% of turnover. More than 90% of these costs are costs of human resources.

have to draft it and present it no matter what, even for simple products where there are no (or few) applicable national rules and therefore no real need for such a declaration and no real added value in terms of facilitating dialogue and market access.

The Fast Track Appeal Procedure (sub-option 4c) would avoid costs related to court proceedings, and reduce significantly costs linked to adaptation of products, delayed market access and lost opportunities[97]. Furthermore, the use of SOLVIT is particularly useful and adapted for SMEs, who, contrary to large companies, don't have the internal resources (e.g. a legal department) or the financial means to afford long and costly court procedures. The use of SOLVIT is free of charge, and the average duration of the procedure is 12 weeks. During 2016, 83% of economic operators who introduced a case in SOLVIT were SMEs.

Economic impacts for Member States

Costs on Member States relate to sub option 4d (Strengthen PCPs and administrative cooperation), as PCPs would need to be integrated in a wider network and cover harmonised products as well. National authorities already incurred costs related to implementing their obligation to establish PCP (putting them in place and having them functioning on an annual basis). Most of the time, the PCP has been integrated in an already existing department dealing with internal market issues. Based on the annual reports[98], one person on average is fulfilling the task of PCP. It is likely that the number of information requests will increase quite sharply by including the provision of information on EU harmonised rules as well so that, under this option, it would require between 1 and 3 supplementary Full Time Equivalent (FTE) per PCP. As regards mandatory administrative cooperation, some estimation can be drawn based with on a comparison with the harmonised area, where the annual costs of administrative cooperation amount to approximately 1 200 000 EURO[99]. The costs in the non-harmonised area are expected to be lower, as the harmonised sector represents a higher proportion of the total manufacturing sector[100].
Other costs are linked to option 4c (Fast-track appeal). The use of SOLVIT by economic operators is expected to increase, because this tool would become more business friendly due to the informal assistance and technical expertise offered by the Commission services and the possibility of having a Commission binding opinion. Currently, the number of cases relating to the application of mutual recognition in SOLVIT is very low[101], and accounts to 5 cases in 2016. While it is impossible to estimate with accuracy the number of cases that would be submitted to SOLVIT following the implementation of this procedure, an estimation can be made on the basis of the number of cases registered in SOLVIT in (1) the most successful areas and (2) and the less successful areas. In (1), the number of cases submitted in the area of social security accounted in 2015 to

97 Following the 2016 public consultation (see annex 2), adaptation costs were estimated between 1000 and 150 000 Euro per product and per market. Delays for entering a market were estimated between 3000 and 500 000 Euro per product and per market, and lost opportunities, were estimated between 10 000 and 500 000 Euro per product and per market.
98 See annex 7 to the Evaluation.
99 This covers the organisation of the networking meetings, the refund of travel fees for the participants and for the person in charge of the administrative secretariat (e.g. preparation of the agenda of the meetings and relevant documents).
100 Annex 5 offers an overview of harmonised and non-harmonised sectors
101 The reasons for this low number of cases are provided in section 3.2.3

approximately 1400, representing more than 50% of the total number of cases submitted to SOLVIT. In (2), the number of cases submitted in the area of goods (other than the application of the mutual recognition principle) accounted in 2015 to 102, representing less than 5% of the total number of cases submitted to SOLVIT. It is considered that, in order to deal with 16 to 50 cases, a SOVLIT centre needs to have 1 FTE[102]. Therefore, in (1) the increase in terms of SOLVIT centres staffing accounts for 28 FTEs, while in (2) it accounts to 2 FTEs. However, the costs triggered by the implementation of this option are expected to be limited, as one of the objectives of the Action Plan[103] for reinforcing SOLVIT is to increase the number of business cases. Furthermore, the action plan already foresees that Member States will ensure adequate and stable staffing and continuity of service for their centres.

The other sub options (4a-clarify scope, 4b Declaration of Compliance) are not expected to involve any other costs for Member States. On the contrary, sub- option 4a (clarify the scope) is expected to reduce costs for Member States, as the functioning of PCPs would be more efficient due to the clarity as regards the instances where mutual recognition applies or not. Sub-option 4b (Declaration of Compliance) would also reduce costs for public authorities assessing whether or not a products can be placed on the market based on mutual recognition, because the Declaration of Compliance would frame and streamline the dialogue and the assessment of the product intended to be marketed.

Economic impacts for the EU budget

Sub option 4a (clarify scope) and 4b (Declaration of Compliance) are not expected to cost the Commission anything.

Sub option 4c (Fast-track appeal) would have impacts on the Commission, in terms work load. The number of cases to be submitted to SOLVIT, as explained above, is expected to increase. Also, staff will need to deal with the appeals following the Fast Track Appeal procedure. While it is impossible to estimate with accuracy the increase of cases and related workload, an analogy can be made with the resources necessary to deal with complaints and infringements following Articles 34-36 TFEU. These costs can be estimated on the basis of FTEs, for which a yearly gross salary of kEUR 60 has been assumed, to which also 25% of overhead was added (75 000). Currently, 4 FTEs deal with complains and infringements pursuant to Articles 34-36. It is estimated that a maximum 3 additional FTEs will be needed to deal with the appeals, representing EUR 225 000 per year.

Social impacts

This option would facilitate trade for businesses in the non-harmonised area. Therefore it is expected that more economic operators will engage in cross border trade and will expand to new markets. This is expected to create more wealth, i.e. value added and turnover, and to have indirect positive impacts on the employment trend in those sectors.

102 See SWD Assessment of the performance of SOLVIT and SOLVIT database.
103 [Communication on an action plan on the reinforcing of SOLVIT]

Currently, more than 8 million persons are employed in the non-harmonised area of goods, representing 31% of all persons employed in the manufacturing sector[104]. Moreover, more trade means more products on the market, and therefore more choices at lower prices for consumers. They are thus likely to benefit from this option.

Environmental impacts

The potential use of digital means for supplying the Declaration of Compliance (sub-option 4b) is likely to ensure a higher level of protection of the environment (less paper). Yet, an increase in trade flows between Member States may lead to some additional transport emissions, although not considered to be significant.

Administrative simplifications

Sub-option 4b would bring significant administrative simplifications for businesses; it would replace the various and numerous means of proving that a product is already lawfully marketed in a certain Member State by one single standardised document which is expected to be filled in in around 30 minutes. One of the main drivers of suboptimal mutual recognition is the difficulty that economic operators have in terms of showing that their product is already lawfully marketed elsewhere, due mainly to the diversity of approaches at national level as regards the type of documents to be submitted.

Sub-options 4a (clarify scope) 4c (fast-track appeal) and 4 d (strengthened PCPs) are not expected to have significant impacts in terms of administrative burdens.

Stakeholders views on the option

During the 2016 public consultation[105], the sub-options assessed above received a lot of support from stakeholders. 84% of member States, 85% of businesses and 82% of citizens supported sub-option 4a (clarify scope), while 75% of Member States, 80% of businesses and 76% of citizens agreed that sub-option 4b (Declaration of compliance) would simplify the demonstration of the lawfulness of the marketing of a product. Furthermore, 66% of Member States, 90% of businesses and 76% of citizens agreed that efficient remedies for challenging administrative decisions denying market access (sub-option 4c-fast-track appeal) are necessary. Strengthening PCPs (sub-option 4d) was supported by 64% of Member States, 64% of businesses and 70% of citizens.

During the additional survey and interviews conducted by an external contractor during 2016-2017[106], stakeholders shared the following views on this option:

| Sub-options | Effectiveness for raising awareness (Policy objective 1) | Effectiveness for legal certainty on the scope (Policy objective 2) | Effectiveness for legal certainty on the application of MR (Policy objective 3) | Effects on reducing costs for economic operators |
|---|---|---|---|---|

104 See section 2 and Annex 4
105 See Annex 2
106 See Annex 2

| | MS | EO[107] | MS | EO | MS | EO | Transaction costs | Appeals | Delayed market access |
|---|---|---|---|---|---|---|---|---|---|
| Clarify scope | 68% | 84% | 68% | 75% | 63% | 50% | 58% | 50% | 50% |
| DoC | 58% | 83% | 52% | 67% | 48% | 59% | 58% | 50% | 50% |
| Fast-track appeal | 16% | 75% | 37% | 75% | 32% | 58% | 58% | 59% | 59% |
| PCPs | 37% | 83% | 37% | 33% | 32% | 42% | 59% | 59% | 49% |

| Assessment of the option | |
|---|---|
| Effectiveness in achieving the policy objectives | |
| *Increase awareness about mutual recognition* | + |
| *Increase legal certainty on the scope of mutual recognition* | +++ |
| *Increase legal certainty on the application of mutual recognition* | +++ |
| *Enhance administrative cooperation and communication* | +++ |
| Economic impacts for economic operators | +++ |
| Economic impacts for Member States | - |
| Economic impacts on the EU budget | - |
| Administrative simplification | ++ |
| *Magnitude of impact as compared with the baseline scenario (the baseline is indicated as 0): +++ very positive; ++moderately positive, + positive; - - - strongly negative; - - moderately negative, - negative; neutral 0.* | |

**Policy option 5- Voluntary prior authorization to placing on the market**

| Economic impacts |
|---|
| Economic impacts for businesses<br><br>This option is supposed to reduce to a certain extent some of the costs incurred by businesses, such as costs related to court proceedings and lost opportunities, due to the lack of legal certainty when using mutual recognition. Those who are not aware or very familiar with mutual recognition in the first place are not likely to benefit from this option. However, certain costs, such as adaptation costs, are expected to remain unchanged, as there is no guarantee that Member States will modify their behaviour |

107 Economic operators

towards mutual recognition solely because they will have to assess its application in a pre-marketing phase. Moreover, costs related to delayed entry on the market would remain unchanged, as the economic operator would have to wait for the reply from the authorities in the prior authorisation procedure which is expected to be long.

Economic impacts for Member States

This option would create excessive costs on the Member States. They would have to put in place the infrastructure and make available the necessary national resources in order to perform the assessment of the demands requiring prior authorisation.

Even if this option is voluntary, given its important impacts in terms of legal certainty, it is expected to become a market driven demand, and required by almost all economic operators wishing to have legal certainty when placing their products on new markets.

The value of the non-harmonised goods area has been estimated at 18% of the total value of intra EU exports, and mutual recognition potentially applies to a huge variety or products in the food and non-food area (Annex 5 provides an overview of the categories of products falling under the scope of mutual recognition, by NACE codes). For each category of products, national authorities would have to put in place the necessary structures and human resources with the necessary technical and scientific expertise in order to deal with the request. While it is impossible to assess with accuracy the magnitude of the costs Member States would have to bear in order to implement this procedure, estimates are possible based on the costs of prior authorisations in a specific (biocides) sector and on the number of economic operators active in the non-harmonised areas. There are 10 major sectors subject to the application of the mutual recognition principle[108], accounting for 770 430 active enterprises[109]. One scenario would be to assume that, because of the positive impacts in terms of legal certainty, 80% of the economic operators active in the non-harmonised area will ask for a prior authorisation, accounting for 616 344 enterprises; another scenario would be to assume that despite the positive impacts in terms of legal certainty, a reasonable number of economic operators, (in complex problematic sectors) i.e. 30%, accounting for 231 129 enterprises, will ask for this authorisation. In the specific sector of biocides, is was assessed that 100-150 FTEs would be needed to run a central prior authorisation such a system, and that the administrative costs related to this procedure would be between 18 and 20 million Euro per year[110].

Therefore, this option would rather create more barriers in the single market for goods, and would result in a new generation of administrative procedures very burdensome and long for economic operators. It also contradicts the general EU policy favouring the reduction of administrative burdens, and the jurisprudence of the Court of Justice which

108 See section 2 and Annex 5
109 See Annex 4
110 See SWD Accompanying document to the Proposal for a Regulation Of The European Parliament And Of The Council concerning the placing on the market and use of biocidal products, SEC(2009) 773 Final

considers prior authorisations to placing on the market as de facto infringing the free movement of goods fundamental principle[111].

Economic impacts on the EU budget

No costs for the EU budget have been identified.

**Social impacts**

As this option would have some impacts in terms of increasing legal certainty for economic operators when using mutual recognition, it is expected that it would generate an increase in trade of non-harmonised or partially harmonised goods. This increase would translate into more products on the market, thus a wider variety for consumer at lower prices. However, it is expected for these impacts to be limited, as the procedure described above is quite heavy and long for Member States.

**Environmental impacts**

No environmental impacts have been identified.

**Administrative simplifications**

This option is not expected to bring any administrative simplification; it is rather an important administrative burden for Member States and for economic operators.

**Stakeholders views on the option**

During the last meeting of the Consultative Committee on mutual recognition (25 October 2016), there was a consensus among Member States representatives on the fact that this option constitutes a major administrative burden and therefore Member States representatives advocated against it.

During the additional survey and interviews conducted by an external contractor during 2016-2017[112], stakeholders shared the following views on this option:

| Sub-options | Effectiveness for raising awareness (Policy objective 1) | | Effectiveness for legal certainty on the scope (Policy objective 2) | | Effectiveness for legal certainty on the application of MR (Policy objective 3) | | Effects on reducing costs for economic operators | | |
|---|---|---|---|---|---|---|---|---|---|
| | MS | EO[113] | MS | EO | MS | EO | Transaction costs | Appeals | Delayed market access |

111 See C-390/99 Canal Satelite Digital, where the Court sets very strict conditions for prior authorisations procedures, which are measures having an effect equivalent to a quantitative restriction on imports.
112 See Annex 2
113 Economic operators

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Voluntary prior authorisation | 16% | 58% | 32% | 59% | 27% | 33% | 58% | 58% | 33% |

| Assessment of the option | |
|---|---|
| Effectiveness in achieving the policy objectives | |
| *Increase awareness about mutual recognition* | 0 |
| *Increase legal certainty on the scope of mutual recognition* | 0 |
| *Increase legal certainty on the application of mutual recognition* | ++ |
| *Enhance administrative cooperation and communication* | 0 |
| Economic impacts for economic operators | + |
| Economic impacts for Member States | --- |
| Economic impacts on the EU budget | 0 |
| Administrative simplification | 0 |
| *Magnitude of impact as compared with the baseline scenario (the baseline is indicated as 0): +++ very positive; ++moderately positive, + positive; - - - strongly negative; - - moderately negative, - negative; neutral 0.* | |

## 8. COMPARISON OF OPTIONS

### 8.1. Effectiveness

As regards the effectiveness of the different options to achieve the policy objectives identified it is considered that option 2 (soft law) is the most effective to increase awareness on mutual recognition, since it will consist of training and awareness raising campaigns targeting not only national authorities but also stakeholders. This is why a score of +++ was given. However, this option alone will only have a limited impact in addressing the policy objectives for ensuring legal certainty on the scope of mutual recognition and on the outcome that can be expected, and thus ensuring the free movement of goods based on mutual recognition; this is why a score of + was given for these policy objectives. Since this option will also provide for a system of exchange of officials, it is expected to address the need for better trust and cooperation among authorities. However, in view of the fact that it will necessarily apply to a limited number of officials, a score of ++ has been given. Option 3 (European standards, transparency of decisions and enlarged role of PCPs) will address all policy objectives but only to a limited extent. Increased awareness of the principle of mutual recognition will be ensured via the PCPs; this is why it is expected to only have a limited effectiveness and a score of + has been given. Similarly, it is expected to be only slightly efficient in ensuring more legal certainty on the scope of the principle. This option will be very effective in providing legal certainty on the outcome to be expected when relying on European standards, but only for those products or aspects of products for which European

standards exist and have been identified for the purposes of mutual recognition; this is why a score of ++ has been given. Option 4 (declaration of compliance, fast track appeal and strengthened PCPs) is expected to achieve all policy objectives in the most effective manner. Option 5 (voluntary prior authorisation) will bring more legal certainty on the application of mutual recognition for those economic operators requesting it who will know in a definite manner whether they can have market access for a specific product, but for the rest of products and/or economic operators it will not address the policy objectives in a sufficient manner. This is why a score of ++ has been given for the efficiency for achieving the policy objective of ensuring legal certainty on the application of mutual recognition. However, by providing for a pre-marketing assessment of the product, this option will not be addressing the awareness or the legal certainty on the scope, nor the cooperation among authorities and this is why a neutral score (0) against those policy objectives has been given.

### 8.2. Efficiency

When comparing the costs and benefits of each option, Option 2 (soft law) will entail costs for the EU budget and minimum costs for the Member States, while it will not lead to costs for economic operators; but it will have the most benefits in terms of raising awareness of mutual recognition. However, since it will not be sufficiently effective for the other policy objectives, a score of ++ has been given. Option 3 (European standards, transparency of decisions and enlarged role of PCPs) does not trigger an important economic burden for any of the stakeholders but it is also not expected to lead to substantial benefits in the context of the policy objectives. The process for referencing European standards in the context of mutual recognition will be time consuming and burdensome, involving a committee of Member States representatives and the adoption of implementing acts. This is why a score of + has been given. Option 4 (declaration of compliance, fast track appeal and strengthened PCPs) will lead to costs for economic operators (in terms of drafting the declaration of compliance) which have not been deemed as very high and for Member States (for enlarging the PCPs) but will also lead to cost-saving for businesses when demonstrating that their products are lawfully marketed in the Member State of origin and when appealing national decisions denying market access. It is also expected to produce the highest benefits in terms of better functioning of mutual recognition and increasing intra-EU trade flows and thus, competitiveness of EU companies including SMEs. This is why a score of +++ has been given. Finally, while option 5 (voluntary prior authorisation) will lead to certain benefits for those economic operators requesting it, it will trigger the highest identified administrative burden and costs for both Member States and businesses. This is why a score of -- has been given.

### 8.3. Coherence

Option 2 (soft law) consists of training and information campaigns and as such is not considered inconsistent with any other EU policies. This is why a score of ++ has been given. Option 3 (European standards, transparency of decisions and enlarged role of PCPs) is coherent with the European standardisation policy and by enlarging the role of PCPs, it will also help in facilitating a joint assessment of EU harmonisation rules and the application of mutual recognition for economic operators. In addition, this will also be consistent with the current initiatives to ensure that economic operators have better access to information to benefit from the Single Market, in particular online (the Single

Digital Gateway). This is why a score of ++ has been given. Option 4 (declaration of compliance, fast track appeal and strengthened PCPs) will also be consistent with current initiatives such as the Single Digital Gateway and facilitate a joint assessment of all rules applicable to the product (harmonisation rules and mutual recognition). This is not only due to the strengthened role of PCPs, but also because of the fact that the Declaration of Conformity is a document required by all EU harmonised rules. Setting up a similar documentary form of evidence for mutual recognition will be particularly useful for those products which are partially covered by EU harmonisation rules and for which this Declaration of Conformity has to be prepared in any case in accordance with those rules. Also, the fast-track appeal procedure would be supported by current initiatives which aim to improve SOLVIT[114] so that it becomes a useful tool for businesses. This is why a score of +++ has been given. Option 5 (voluntary prior authorisation) contradicts the EU policy for free movement of goods in general, favouring a post market approach in controlling the compliance of the products and will represent in this respect a step back on what has been achieved for the Single Market for goods to date. This is why this option is considered very incoherent with other EU policies, and a score of -- has been given.

**Table 8-1: Comparison of the options**

| | **Policy option 2** | **Policy option 3** | **Policy option 4** | **Policy option 5** |
|---|---|---|---|---|
| *Effectiveness* | | | | |
| Policy objective 1<br>Increase awareness about mutual recognition | +++ | + | + | 0 |
| Policy objective 2<br>Increase legal certainty on the scope of mutual recognition for businesses and authorities | + | + | +++ | 0 |
| Policy objective 3<br>Increase legal certainty on the application of mutual recognition and what to expect | + | ++ | +++ | ++ |
| Policy objective 4<br>Enhance administrative cooperation and communication | ++ | + | +++ | 0 |
| *Efficiency* | ++ | + | +++ | - |
| *Coherence* | ++ | ++ | +++ | -- |

The scores are given on the basis of Commission expected results against the specific policy objectives as explained above; +++ being very positive, ++ positive, + slightly positive, 0 neutral, - negative and – very negative.

114 See the current work towards an Action Plan for Reinforcing SOLVIT.

Accordingly, the **preferred option** would be a **combination of Option 2** (soft law instruments) **and Option 4** (clarification of the scope of the regulation, introduction of a declaration of compliance and of a fast-track appeal procedure for businesses and strengthening the role of PCPs). This combination will address in the most effective and efficient manner all policy objectives to lead to a better functioning of the Single Market for non-harmonised products through more and better mutual recognition.

The Action Plan on mutual recognition is expected to raise awareness and understanding on the rights and obligations that all stakeholders involved (national authorities and businesses alike) have when relying on mutual recognition. This is expected to facilitate acceptance of products lawfully marketed in one Member State in other national markets without requiring it to follow technical adaptations. Economic operators will be able to gather more reliable and complete information from PCPs. When Member States authorities want to assess a product relying on mutual recognition, the voluntary declaration of compliance is expected to simplify the dialogue between businesses and national authorities, and provide more legal certainty on what to expect. Finally, when market access is denied, businesses will have the possibility to seek a solution via a fast track appeal procedure, which will ensure that market access is denied only where legitimate and proportionate public interests need to be protected. Administrative cooperation and better communication channels will increase trust among national authorities; all of this contributing to creating a favourable environment for mutual recognition and to ensure that companies can rely on this principle to reap the benefits of the Single Market.

As mentioned previously, a study done for the European Parliament[115] shows that a reduction of barriers to trade could lead to an increase in intra-EU trade of more than 100 billion EUR per year. The fact that mutual recognition does not function well is, de facto, a regulatory burden triggering barriers to trade. Therefore, the actions described in the preferred option will improve the functioning of mutual recognition and thus result in simplifications for businesses, e.g. easier access to markets.

### 8.4. Potential for reduction of administrative burdens for companies

The mutual recognition principle and the supporting measures currently set out in the Regulation were designed to facilitate free movement of goods in those areas where marketing conditions for products are not harmonised at EU level. Therefore, the sub-optimal functioning of mutual recognition is as such a burden for businesses and any efforts in improving the functioning of the principle and adapting the regulatory measures to the reality of the market should be considered as a simplification and a reduction of administrative burdens.

## 9. MONITORING AND EVALUATION

Monitoring and evaluation have traditionally been a major problem for mutual recognition. The monitoring and evaluation system to be put in place must avoid the

115 The Cost of Non- Europe in the Single Market, 'Cecchini Revisited', An overview of the potential economic gains from further completion of the European Single Market, CoNE 1/2014
http://www.europarl.europa.eu/RegData/etudes/STUD/2014/510981/EPRS_STU(2014)510981_REV1_EN.pdf

shortcomings identified in the Evaluation. The proposal will therefore specify that the reporting of activities and of the administrative decisions taken will be enhanced, and reported via an IT tool (this will be implemented via existing tools, such as ICSMS or IMI), to ensure full transparency and follow-up.

Furthermore, traditional tools such as the monitoring of complain and infringements, the SOLVIT and TRIS mechanisms will remain monitoring tools to be used. The Single Digital Gateway (SDG) can also be used to monitor the actives of PCPs, as they will be integrated into this network and access to their services will be facilitated by the single entry point offered by the SDG. Additionally, the lack of accurate quantitative data on mutual recognition (size of the market, number of products, costs and benefits) will be addressed by a systematic survey intended to gather the missing data and to prepare and service future evaluations. For this purpose, existing survey tools at EU level, such as the Commission's Innobarometer[116], could be used.

## 9.1. Operational Objectives

- Enhance awareness of mutual recognition, inter alia through regular training sessions for businesses and national authorities and the exchange of officials in national authorities. The Commission expects that, after the train the trainer has been ensured where it is expected that around 20 to 40 trainers be trained, at least 2-5 national events will be organised per year. Also, the Commission expects that around 5 to 15 exchanges of officials will take place each year.

- Ensure that Member States introduce a clear mutual recognition clause in all relevant national technical rules which are notified under Directive (EU) 2015/1535. The Commission expects that with a clearer clause, easier to integrate in notified drafts, the use of the clause would increase by 50%.

- Introduce a voluntary declaration of compliance facilitating the effective right to free movement within the internal market for products lawfully marketed in another Member States. The Commission expects that the declaration would be used by 60% of businesses operating in the non-harmonised area.

- Ensure that businesses can appeal national decisions denying market access through a fast-track procedure. This will be based on SOLVIT and, where appropriate, by the Commission intervention. The Commission expects that the resolution rate of goods related cases by SOLVIT would increase by 200%.

- Streamline the notification procedure for administrative decisions denying mutual recognition via an IT tool. The Commission expects that the IT tool would increase the number of notifications, reaching a level of at least 90% of decisions being notified.

- Strengthen the role of PCPs to become a central point for information on all products (including harmonized ones). The Commission expects that the number of requests and that the level of awareness and satisfaction would increase by 50%.

116 http://ec.europa.eu/growth/industry/innovation/facts-figures/innobarometer_fr

- Set up an administrative cooperation forum which would meet at least once a year where all national authorities would participate and discuss issues related to the application of mutual recognition. The Commission expects to have at least one meeting per year, reaching participation from at least 25 Member States.

### 9.2. Indicators for the monitoring

- Number of events organised (awareness campaigns and trainings), and number of persons participating in the events or receiving the training, as well as their level of satisfaction
- Number of officials participating in the exchange of officials' scheme
- Number of notifications of draft national rules containing a mutual recognition clause
- Number of economic operators using the declaration, their level of satisfaction and their input in terms of costs reduction
- Number of notifications of administrative decisions denying or restricting market access
- Number of cases introduced by business in SOLVIT and resolution rate
- Number of appeals to the Commission and number of binding decisions adopted by the Commission
- Number of complaints received on the misapplication of the mutual recognition principle
- Number of requests received by PCPs, deadlines for responding and level of satisfaction of economic operators
- Number of administrative cooperation meetings organised and number of participants

## ANNEX 1 PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

### 1. IDENTIFICATION

Lead Directorate General: Internal Market, Industry, Entrepreneurship and SMEs (DG GROW).

This initiative is identified in the Agenda Planning with the reference 2017/GROW/005.

### 2. ORGANISATION AND TIMING

Work on the Impact Assessment started after the adoption of the Commission's Single Market Strategy in October 2015. The Inception Impact Assessment was published on 13 May 2016.

An Inter-Service Steering Group (ISSG) chaired by DG GROW was set up in October 2015 and with the participation of the following Directorates General: Legal Service of the Commission (LS), Secretariat General (SG), DG Agriculture and Rural Development (AGRI), DG Economic and Financial Affairs (ECFIN), DG Energy (ENER), DG Environment (ENV), DG Justice and Consumers (JUST), DG For Mobility and Transport (MOVE), DG Health and Food Safety (SANTE), DG Taxation and Customs Union (TAXUD), DG Trade (TRADE), DG Maritime Affairs and Fisheries (MARE).

The ISSG met in total nine times (29/01/2016, 07/03/2016, 21/04/2016, 29/09/2016, 28/11/2016, 27/01/2017, 13/02/2017, 27/02/2017 and 06/03/2017). The minutes of the last ISSG meeting were submitted to the RSB together with the draft IA report.

### 3. CONSULTATION OF THE REGULATORY SCRUTINY BOARD

The Regulatory Scrutiny Board of the European Commission assessed a draft version of the present impact assessment and issued its opinion on 7 April2017. The Regulatory Scrutiny Board gave a positive opinion on the Impact Assessment report. It considered that the report had an overall good presentation and recommended, as further improvement, to better explain the choice of options and how these would work in practice. The report should also draw clearer conclusions on how far the expected outcome of the revision will have an impact on the functioning of the mutual recognition on the ground and contribute to a well-functioning internal market. Finally, it should better assess the potential to simplify administration and reduce burdens (REFIT). The Impact Assessment has been amended to address the comments made by the Regulatory Scrutiny Board in its opinion.

| RSB opinion | Follow-up |
|---|---|
| **(B) Main considerations**<br>The Board notes the overall good presentation of this impact assessment report.<br>The Board gives a positive opinion, with a recommendation to further improve the report with respect to the key aspects | |

mentioned hereafter.

| | |
|---|---|
| (1) The report does not clearly explain the choice of the options and how these would work in practice. | 1) Section 6 on the Options has been amended to better explain the different options and the interaction between them, as well as how the options would work in practice. |
| (2) The report does not draw clear conclusions on how far the expected outcome of the revision will have an impact on the functioning of the mutual recognition on the ground and contribute to a well-functioning internal market. | 2) The conclusion of section 8 has been amended to explain the expected consequences on the market of the preferred option. |
| (3) The report has not assessed the potential to simplify administration and reduce burdens (REFIT). | 3) A new dedicated section 8.4 explains that the current regulatory burdens are due to the non-functioning of mutual recognition and indicates the effects of the preferred option is expected to have in reducing those. |
| **(C) Further considerations and adjustment recommendations** | |
| **(1) Problem definition** | |
| Based on available evidence, the report should more clearly explain the most problematic aspects of mutual recognition. It should explain to what extent the Mutual Recognition Regulation has been ineffective. It should elaborate on the issue of lack of trust between national administrations: the evaluation identifies this as one of the factors for the non-functioning of the mutual recognition. Moreover, the report should better assess why mutual recognition is not working in the Member States by presenting additional evidence. | The Impact Assessment report has been made a stand-alone document separated from the Evaluation. A summary of the results of the Evaluation has been added as a new annex 6, and evidence that was included only in the Evaluation has been incorporated throughout the problem definition.<br><br>The lack of trust among national administrations has been further elaborated and is now presented as a problem driver in section 3.2.4. |
| The IA report should be a self-standing document. Therefore, it should summarize the findings of the evaluation. In particular, the report should present in more detail the problems encountered with the current Regulation, including why Product Contact Points are not functioning. | The report includes further evidence on the problem definition on the problems encountered with the current Regulation and also more detailed information on Product Contact Points. |
| **(2) Options** | |
| In view of the acknowledged ineffectiveness of the current Regulation, the report should explain whether certain | In Section 6.1 on discarded options, it is explained in more detail while, despite its ineffectiveness, the Regulation is not |

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|---|---|
| provisions of the current Regulation could be removed or amended. | repealed but that certain of its provisions can be removed. |
| For instance, it should clarify why it is necessary to preserve the Product Contact Points despite their suboptimal functioning. | The advantages of preserving Product contact Points has been further explained in the description of option 3 in section 6.4. |
| The report should clarify the construction of the options and how they would work in practice. For instance, it should explain the design of options 3 and 4. The report should clarify the limits of options 3a (compliance with European standards) to better demonstrate the benefits of option 4 (in particular 4b: declaration of compliance). For both options, it should clearly mention the risks and responsibilities for stakeholders. In particular, the report should clarify that the burden on proof will shift from companies to national administrations. In short, it should explain how the more ambitious alternatives in option 4 would supersede options 3a and 3b. | The introduction to section 6 on the Options explains more clearly the construction of the options. Further explanations have also been added on options 3 and 4 to clarify how they relate to each other. |
| The report should make clear how the fast-track provision would work in practice and what will happen to the list of products. | Option 4 has been further elaborated to clarify the fast-track appeal procedure.<br>The possibility to review and make more user friendly the list of product is now specifically included in option 2, in section 6.3. |
| **(3) Impacts** | |
| The analysis of impacts should refer to experience from existing single market tools (in particular from the harmonised field) and the risks involved. The report should outline the existing Commission and Member State commitments, in particular in terms of resources. | Section 7 on the Impacts has been amended to address these remarks and explanations on the experience from the harmonised field have also been added to Section 6 on the description of the options. |
| It should explain the changes which the initiative would make for them. | An estimation of the burden that the declaration of compliance will represent for companies and the expected benefits which are expected to result from it has been included in the analysis of the impacts of option 4. |
| Given the likely increase in burden for national administrations, the report should make realistic (quantified) estimates of resource implications. It should further justify that the legal certainty provided by the declaration of compliance (option 4b) would outweigh the corresponding administrative burden. | The conclusion on the comparison of the options in section 8 has been revised to indicate more clearly the expected benefits of the preferred options for the free movement of goods ant the functioning of the single market. |
| Given the initiative's REFIT dimension, | |

| | |
|---|---|
| the report should more clearly identify the potential for simplification. It should also estimate the potential reduction of administrative burden for companies (identified in the related evaluation).<br>The report should explain to what extent this initiative and others under revision (e.g. market surveillance, Solvit, Single Digital Gateway) would have a meaningful impact on the functioning of the internal market for goods. | A new section 8.4 has been included to address the potential for reduction of administrative burden in the context of the REFIT initiative.<br>The Introduction has also been amended to reflect how this initiative links with others under revision to have an impact on the internal market. |
| **(4) Comparison of options**<br>In the absence of solid evidence, the report should better substantiate the high scores given to some of the options. For instance, what evidence is there to show that the action plan (option 2) would have a very positive impact ('++') on the increase of awareness? | The report now includes explanations on the scores given to the different options against each of the policy drivers. |
| **(5) Future monitoring and evaluation**<br>The report should outline more clearly operational monitoring and evaluation arrangements. It should indicate benchmarks against which the Commission will assess the success of the initiative. | Section 9 on monitoring and evaluation has been amended to include more specific benchmarks. |
| *Some more technical comments have been transmitted directly to the author DG* | *The report also includes a number of other changes to address the more detailed comments received ahead of the meeting of the RSB.* |

## 4. CONSULTATION AND EXPERTISE

The application of the principle of mutual recognition, including the functioning of the Regulation has been subject to an evaluation[117]. As part of that process, an external evaluation on the application of the principle of mutual recognition was conducted[118]. Its aim was to evaluate the application of the mutual recognition principle by Member States, in order to identify shortcomings and to present possible ways of enhancing the application of the principle. The external evaluation was based on a combination of data sources and data collection tools, which included a literature review, statistical data, web-based surveys among different target groups and in-depth interviews with Member States and relevant stakeholders. The study was conducted between 2014 and 2015, over the course of 9 months.

117 Commission Staff Working Document "Evaluation of the functioning of mutual recognition in the area of goods".

118 European Commission, Study commissioned to Technopolis Group (2015): 'Evaluation of the application of the principle of mutual recognition in the field of goods,' ENTR/172/PP/2012/FC – LOT 4 carried out between April 2014 and May 2015: http://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/index_en.htm.

In the framework of the external study for the evaluation mentioned above, four different surveys were launched on 9 October 2014 and completed on 5 January 2015. These were a company survey, a survey of national business associations, a survey of national sector associations, and a product contact point survey. Following the survey, qualitative interviews with national business associations and Product Contact Points in each Member State were also carried out. The objective of the qualitative interviews was to shed more light on the implementation of the mutual recognition principle in the Member States, in particular with respect to 'sensitive' areas such as notification practices (or lack thereof).

In addition, a stakeholders' event titled "Single Market for Products: Fresh ideas to unleash the full potential" was organised on 17 June 2016 and dealt with, amongst other things, the application of mutual recognition, to identify the main issues related to its functioning and to identify possible ways forward. 144 participants attended the event, representing businesses (62), national authorities (60) and others (22).

Following the delimitation of the scope of this Impact Assessment, an online public consultation was carried on from the 1st of June until the 30 of September 2016 (17 weeks) accessible via the *Your voice in Europe* website. The consultation was made available to the general public, and aimed to gather data on the functioning of mutual recognition, the current problems as well as possible options for improvement. **153** replies were received during the public consultation, representing 91 companies, 45 national authorities and 17 citizens.

Simultaneously with the online public consultation, or shortly thereafter, the Commission received position papers from a number of stakeholders, including consumer organisations, business associations, Member States, individual economic operators etc. The summary of opinions of these stakeholders is set out in Annex 2.

Stakeholders' views were also discussed in bilateral meetings that took place during 2016.

During the 8th meeting of the Consultative Committee on mutual recognition which took place on 25 October 2016, the problem definition and drivers as well as the envisaged options were presented and discussed with Member States representatives.

The Commission presented the initiative and sought the views of SMEs at the Small Business Act regular meeting with European SME associations on 7 December 2016.

To provide input for this Impact Assessment, a study on the costs and benefits of the revision of the Mutual Recognition Regulation was carried out between September 2016 and March 2017 in order to estimate the magnitude of the problem triggered by a suboptimal functioning of mutual recognition and to analyse the impacts of the different options envisaged for addressing this problem. In the context of this study, a survey was conducted in December 2016 and January 2017, addressing different categories of stakeholders. In parallel, the contractor carried out 25 targeted interviews, addressing different categories of stakeholders such as Member States and business associations. Five case studies were also further investigated, in order to corroborate the findings and ensure their robustness, while illustrating in practical terms the implication and impacts of the specific issues at stake.

Desk research was conducted for the purpose of the evaluation of the mutual recognition principle and Regulation, by the contractors in the framework of the external studies mentioned under 2.1 and by the Commission's services. Available literature on the topic, annual reports from the Member States as well as all notifications119 received between 2009 and 2016 were scrutinised. Also, the Commission services examined the complaints received from economic operators concerning a malfunctioning of mutual recognition and the draft national regulations notified on the basis of Directive (EU) 2015/1535. The desk research involved case studies in sectors where the application of mutual recognition is problematic and cases from the SOLVIT database. The literature review comprised a review of existing business and academic literature on the non-harmonised areas in the EU internal market. Annex 7 contains a full overview of the assessed literature, and a summary of the notifications and annual reports received.

## 5. LIMITATIONS AND ASSESSMENT OF ROBUSTNESS OF FINDINGS

Assessing the magnitude of the difficulties linked to the functioning of mutual recognition and its actual and potential impacts on stakeholders is not straightforward. Indeed, several factors are making the evaluation of the application of mutual recognition a difficult exercise.

First, mutual recognition, when it is working properly, is invisible; this is because it is impossible to monitor when and how many times goods are allowed to enter a market on the basis of the mutual recognition principle. Only the number of products for which market access has been denied can be estimated, on the basis of the monitoring tools in place by the Regulation (notification of administrative decisions denying market access and annual reports). However, this doesn't represent a full picture of the situation, as only 6 Member States are notifying decisions to deny market access[120]. The complaints received and the divergences noticed between the annual reports and notifications show that not all decisions taken are being notified to the Commission.

It is possible to estimate, based on intra EU trade statistics, the number of non-harmonised products lawfully marketed in one Member State and placed on the market of other Member States. However, this doesn't show how many products were marketed on the basis of the mutual recognition principle. This is because businesses may decide, on commercial grounds, not to use mutual recognition, and to align their products on the existing national rules in the Member States where they want to market their products. Some large companies choose to design and produce products fitting the highest requirements, and thus complying with all national technical rules.

Second, the results of the stakeholders' consultation might need to be treated with caution, as the consultations, targeted or opened, were not representative of different sectors, Member States and company types.

The surveys carried out in 2014-2015 by the external consultant registered a low rate of responses. 199 businesses and 20 national or sectoral associations participated in the survey. The businesses survey did not result in a representative sample. There was a

119 Notifications of national administrative decisions denying or restricting market access, on the basis of article 6 of the Regulation

120 See for more details section 7.1

significant geographical bias with respect to the geographical coverage. Companies from Portugal (36), the UK (22) and Lithuania (21) were significantly overrepresented, while there were no responses from 9 EU Member States or from any of the EEA countries. Also, large companies were overrepresented in the survey, while small companies were underrepresented. 29% of the participating companies were large companies with more than 250 employees, while they represent around 1% of the EU's company population[121]. 26% were medium-sized companies with 50 to 250 employees and 27% are small companies with 10 to 49 employees. Micro companies with less than 10 employees accounted for 18%. Also, the business associations had generally not put a high priority on responding to the survey, which can be either because they don't monitor issues related to mutual recognition, or because their members don't approach them in relation to these issues. Only a minority of sectors and Member States were represented in the survey. As regards the survey targeting PCPs, its main limitation came from the fact that PCPs are only the interface between business and national authorities in charge of applying the mutual recognition principle. Thus, they are not always familiar with the practicalities of the application of the mutual recognition principle, and they don't always have insight as regards the denial of market access for certain products. Furthermore, not all PCPs across the EU participated in the survey. PCPs from Austria, Bulgaria, France, Germany, Italy and Spain did not submit any responses to the survey, but, with the exception of Italy, they were subsequently interviewed. PCPS from Portugal and Romania were represented twice (as they have several PCPs), and out of the EEA/EFTA countries, Liechtenstein and Norway participated. More details are provided in the synopsis report.

As regards the public consultation carried out by the Commission, it gathered 153 replies only. Businesses actively participated (91) but without reaching a representative sample; large companies were overrepresented (19%), while, as mentioned previously, they only represent 1% of the EU's company population. Also, when asked to quantify the costs and benefits of the Regulation, most businesses indicated that such estimation is impossible. Only a few replied (between 11% and 26% depending on the questions), and the replies contain considerable variations. This is why case studies were used in order to complement the lack of accurate information on costs and benefits. Member States were represented in the consultation by both PCPs (13) and other authorities (32), but without reaching a good geographical balance: no replies were received from Cyprus, Denmark, Finland, France, Greece, Ireland, Luxembourg, Malta and UK[122].

The overview of the notifications of draft national technical rules for the assessment of their compatibility with EU law by the Commission under Directive 2015/1535 provides some insight on the sectors were a high regulatory activity at national level can be observed, and where the use of mutual recognition is more relevant[123]. From 2011 to 2013, **2114** notifications were received (675 in 2011, 734 in 2012 and 705 in 2013). The **construction sector** saw the highest number of notifications, with many measures related to energy efficiency of buildings and concrete structures, road pavements and constituent materials, fire safety of buildings. Construction was followed by **agricultural products,**

121 http://ec.europa.eu/growth/smes_en

122 Some of these Member States choose sending a position paper instead of participating in the public consultation, e.g. Denmark and France

123 Latest report available: http://ec.europa.eu/growth/tools-databases/tris/en/the-20151535-and-you/being-informed/reports/report-to-the-european-parliament-2011-2013/

**foodstuffs and beverages** (food hygiene, the composition and labelling of foodstuffs and beverages, food packaging, minimum price for alcoholic beverages, composition and marketing of alcoholic and non-alcoholic beverages). Notifications were also received in the **telecommunications sector** (radio equipment and telecommunications terminal equipment, radio interfaces, hardware and software for the collection, management and use of data gathered by electronic mechanisms installed on board vehicles (black box)) and in the **environment sector** (packaging and packaging waste, recyclable products, processing of biodegradable waste). This information was used in order to identify sectors where numerous national technical rules exists or were introduced, in order to see if market access problems can be linked to important regulatory activity. However, the use of this information is limited and should be treated with caution, as many issues related to compatibility with EU law are solved before the adoption of the national rule, during the stand still period. Furthermore, the assessment performed under this Directive is linked to the compatibility of the national rule with EU law, while the Mutual Recognition Regulation covers the application of a national rule to a specific individual case. Thus, while the national rule is compatible with EU law, its application in a specific individual case may be incompatible. Therefore, the notifications alone cannot be used as a good proxy for estimating the number of market access denials in specific sectors.

All these factors make the precise measuring of the mutual recognition principle and Regulation's effect quite challenging. The contributions received following the various surveys and consultations carried out did not allow to a statistically representative result to be reached. However, the stakeholders' consultation was very wide, and, together with the multitude of information sources used, it allows the gathering of a strong indicative picture of the functioning of mutual recognition, reliable enough to be used as a basis for further decision making.

# 1. OBJECTIVES OF THE CONSULTATION

The 'Single Market Strategy' (COM(2015)550 of 28.10.2015) highlights the need to strengthen the single market for goods in the field of mutual recognition. This principle allows products lawfully marketed in a Member State and not subject to European harmonisation legislation to enjoy the right to free movement, despite lack of compliance with national technical rules of the Member State of destination. However, the principle is not yet used at its full potential as shown in a recent evaluation of the mutual recognition principle.

To improve the application of the mutual recognition principle, the Commission will present an EU-wide Action Plan to raise awareness of the principle of mutual recognition. The plan will also include specific actions for sectors in which mutual recognition could achieve the greatest increase in EU competitiveness (e.g. construction). The Commission will also investigate the need for a revision of Regulation (EC) No 764/2008 to ensure a better application among businesses and national authorities. The objective of the consultation was therefore to seek stakeholders' views on the current and future application of Mutual Recognition.

## 1.1. Consultation methods and tools

The **members of the Mutual Recognition Consultative Committee**[124] were asked to provide their feedback on the previous meetings on **2 December 2015** and **25 October 2016**.

A **public consultation in all EU official languages** has been published on a consultation website hosted on *Europa.* The consultation has run from June to September 2016.

The public consultation has been supplemented by a **stakeholder conference** organised by the Commission on **17 June 2016**.

# 2. RESULTS OF THE CONSULTATION ACTIVITIES

## 2.1. Meetings of the Mutual Recognition Consultative Committee

The consultative "Mutual Recognition Committee" held its seventh and eighth meetings on 2 December 2015 and 25 October 2016 respectively. The Committee's members are representatives of Member States dealing with mutual recognition issues. The Commission presented the envisaged actions for raising awareness of mutual recognition and asked for feedback and input on these actions. Member States welcomed the activities presented and stressed the importance of awareness raising in relation to the correct application of the mutual recognition principle. The Commission presented also a

124 The members of this Committee are the national authorities responsible for mutual recognition in the 28 Member States and in Iceland, Liechtenstein, Norway, Switzerland and Turkey. Representatives of other third parties or other experts may be invited to participate on a specifc topic, on a case by case basis.

preliminary analysis of the main problems generated by the suboptimal functioning of mutual recognition, as identified in the framework of the ongoing evaluation. The delegates agreed that mutual recognition should not be only a right that economic operators may invoke, but also a principle that national authorities should apply. Furthermore, the Commission presented the preliminary options for improving mutual recognition and asked for feedback from the delegations. Some representatives were not convinced that there are benefits in fully revising the Regulation, whilst all of them agreed that some adjustments are necessary and that many of the problems can be solved with the actions foreseen in the Action Plan.

The participants supported also the option to clarify the scope of the Regulation, and mainly the mutual recognition principle, thus articles 34-36 TFEU, where guidelines are more appropriate to achieve this objective. The Commission also proposed having a clearer mutual recognition clause, such as a standard model, which could be adapted to particular cases, would be proposed, for systematic integration in new national technical rules. Another point discussed was the need for an updated and user friendly product database.

The Commission presented then the possible introduction of a declaration of compliance with the technical rules of the Member State where the product is being lawfully marketed, to facilitate the access of this product to the market of the other Member States. The declaration would offer a presumption of compliance for the economic operator; this presumption could be rebutted by national authorities, who would have the duty to prove the non-compliance. Some Member States considered that this option would introduce a significant administrative burden on economic operators but market surveillance authorities would welcome such declaration, as it would facilitate their tasks.

Another point discussed was the introduction of incentives for national authorities to ensure they comply with the obligation to notify administrative decisions denying or restricting mutual recognition. More transparency for these decisions would be an incentive for Member States to apply the mutual recognition principle, as it would render less acceptable the absence of notifications or the lack of proper justification supporting the administrative decisions to be notified. Using an IT tool allowing Member States to notify would also give all notifications more visibility. Furthermore, the Commission examines the possibility of creating a new fast track mechanism which would be an alternative to the costly and lengthy court procedures currently available. It would be inspired by the "safeguard procedure" operating in the area of products covered by Union harmonisation legislation, which allows a Member State or the Commission to intervene in order to challenge a national decision which is considered as potentially breaching EU law. The fast track appeal procedure would be very quick (no longer than 3 months), and free of charge for businesses and any other complaint they may address to the Commission. The option of a system of prior authorisation to placing products on the market was presented afterwards. Products lawfully marketed in the market of one Member State would be placed on the market of another Member State only after a prior examination of the product by the receiving Member State. Many Member States expressed their opposition to this option, as it would hinder the free movement of goods.

Another point of discussion was the option of ensuring free movement of goods guaranteed by compliance with European standards. This implies the recognition, by the

Commission, and after consultation of Member States, of certain European standards in the area of non-harmonised goods via implementing acts. This option refers only to already existing European standards and not to mandating the developments of new ones. Member States considered that focusing on essential requirements is more beneficial than using standards.

Additionally, the Commission sought Member States' opinion on the option of strengthening of the role of the Product Contact Points in order to provide information on all applicable rules for all products. Member States supported this option as the Product Contact Points lack resources and staff. The Commission proposed also the integration of the Product Contact Points in a wider network, e.g. the Single Digital Gateway. Delegations consider that the Single Digital Gateway initiative is not advanced enough in order to able to provide input on this option.

Another option presented was the harmonisation of certain basis requirements. Member States were strongly against this option, since partial harmonisation only for the sake of free movement does not bring benefits proportionate to the level red tape it adds.

## 2.2. Stakeholder conference of 17 June 2016

A stakeholders' event was organised on 17 June 2016, to identify the main issues related to the functioning of mutual recognition and to identify possible ways forward. 144 participants attended the event, representing businesses (62), national authorities (60) and others (22), such as consumer organisations, representatives of trade unions. The detailed minutes can be found at: http://ec.europa.eu/DocsRoom/documents/17963.

### *2.2.1. Main meeting*

**Knut Sauerbier**, responsible for product compliance and IP at BRITA, explained how mutual recognition functions for businesses by providing the example of drinking water treatment.

**Camilla Hjermind**, Head of Division of International Relations of the Danish Business Authority of the Ministry of Business and Growth presented the practical difficulties encountered while applying the principle of mutual recognition.

**Jacques Pelkmans**, Senior Fellow at CEPS in Brussels and visiting Professor at the College of Europe, outlined the main problems faced with mutual recognition, one of the EU's greatest innovation.

Following the three presentations, the floor was given to the participants at the conference to discuss the topics.

### *2.2.2. Workshops*

Workshop 1: Proving and assessing lawful marketing of products in other Member States: a more practical approach

The first workshop was held on the topic of proving and assessing the lawful marketing of products in another Member State. The participants were to discuss a more practical

approach on this issue. The workshop gathered around 30 participants and had a balanced representation of national authorities, businesses and associations.

Workshop 2: How to make mutual recognition a practical tool for businesses

The second workshop discussed how to make mutual recognition a practical tool for businesses. The workshop involved 46 stakeholders. Participation was well balanced among national authorities, businesses, associations and Commission services. The workshop was moderated by Annette Dragsdahl, Senior Adviser at the Confederation of Danish Industry.

## 2.3. Public Consultation

**153** replies were received during the public consultation. Businesses were strongly represented (91), followed by Member States authorities (45), and citizens (17). This includes respondents that did not want their replies published: 16 businesses, 9 authorities and one citizen. The remainder of the respondents agreed to have their response published either fully or anonymously. All replies are included in the statistics.

**45 authorities** from Member States replied to the public consultation. 31% are Product Contact Points, the rest are other authorities involved in this area. Among the group of citizens there are two consumer organisations. Individual companies (44) and business organisations (44) were equally represented, while only 3 chambers of commerce replied to the consultation. In terms of company size, the responses are roughly balanced between small and large[125] companies.

In terms of activity sectors, **manufacturing is the most represented sector (46%), followed by wholesale and retail trade (13%), agriculture, forestry and fishing (8%) and water supply (6%).**

The geographical representation is quite well balanced for businesses. As for national authorities, 18 Member States and Norway participated in the public consultation. No replies were received from Cyprus, Denmark, Finland, France, Greece, Ireland, Luxembourg, Malta and UK. The majority of consumers chose not to indicate their country of establishment.

The numbers and percentages used to describe the distribution of the responses to the public consultation come from the answers provided under the EU-Survey tool.

### *2.3.1. How stakeholders see mutual recognition and its potential shortcomings*

The majority of responding companies wishing to sell products in another Member State check the applicable rules in that Member State, and, if these rules prevent them from selling the product, most of them adapt it. This happens despite the fact that 70% of them

125 Enterprises can be classified in different categories according to their size; for this purpose different criteria may be used (e.g. number of persons employed, employees, balance sheet total, investments, ...), but the one most common in a statistical context is number of persons employed : small and medium-sized enterprises, abbreviated as SMEs: fewer than 250 persons employed ( SMEs are further subdivided into: micro enterprises: fewer than 10 persons employed; small enterprises: 10 to 49 persons employed; medium-sized enterprises: 50 to 249 persons employed); large enterprises: 250 or more persons employed.

are fully aware of the mutual recognition principle. More than half of the businesses responding tried to use mutual recognition for entering a new market. Among them, half had their market access denied, and only 2% challenged this decision successfully.

35% replied that they do not rely on mutual recognition for entering a new market, mainly because they do not know about it (15%) or because they do not trust it (4%).

When national authorities check if products available on their market and coming from another Member State comply with the national rules they are enforcing, **53% verify if they are already lawfully marketed in the Member State of origin while 46% do not.**

Despite the indicated high level of awareness about mutual recognition, the majority of respondents consider that awareness-raising remains necessary.

As regards the obstacles to the functioning of mutual recognition, businesses identified the lack of quick remedies for challenging national decisions denying market access as the highest one, followed by insufficient communication among authorities. **52%** of the respondents faced such obstacles themselves.

*2.3.2. Functioning of the Mutual Recognition Regulation*

**Effectiveness: to what extent has the Regulation achieved its objectives?**

The majority of respondents are aware of the Regulation, and consider that most of the tools put in place are useful and still necessary. As regards whether or not the Regulation has met its objective, the feeling is mixed among businesses and national authorities. Generally, very few economic operators consider that it is easier to sell products in other Member States since the Regulation entered into force. The majority consider that the Regulation has not improved the situation, or do not know, either because they do not use mutual recognition or they do not sell products abroad.

**Efficiency: costs and benefits of the Regulation**

As regards the costs of implementing the Regulation, national authorities ranked them as average. On top of the choices provided by the consultation, authorities also indicated additional costs linked to the absence of an updated list of products to which mutual recognition may apply**.** Some consider that additional costs are triggered by the administrative procedures, seen as long and time-consuming. Despite the costs, national authorities agree, fully or partially, that the Regulation brings benefits in terms of facilitating market access.

As regards businesses, the main costs incurred are triggered by the need to adapt the products to the applicable national rules, when mutual recognition is either denied or not used for penetrating the market. These costs are estimated[126] on average at 23 000 Euro per product and per market. High costs are also related to delays in entering a market,

126 26% of respondents indicated an estimate of the costs incurred, the other choose not to reply or indicated that such estimation is impossible

estimated[127] at 115 000 Euro per product and per market, and to lost opportunities, when businesses relinquish entering a market because of different national rules that require their products to be adapted. On average, the latest are estimated[128] at 136 000 Euro per product and per market. The costs related to challenging administrative decisions denying market access are considered as less important, mainly because few economic operators choose to do so. The estimates[129] are around 32 000 Euro per product and per market. There are however considerable variations in the answers.

Costs were also related to assessing if mutual recognition can be used to sell products in another Member State. Very few economic operators (2%) are outsourcing this assessment, while 26% are doing it internally. 46% are doing both, depending on the product.

In terms of benefits that the regulation brings, the perceptions of responding businesses are quite mixed. While Member States tend to consider that the costs of the Regulation are proportionate to the benefits it generates, businesses mostly disagree with only 9% agreeing.

**Coherence**

There is a consensus among respondents as regards the coherence of the Regulation. Most of the respondents are not aware of any overlaps between the Regulation and other initiatives/legislation/policies. The overlaps indicated by those replying positively are linked to Solvit, RAPEX, ICSMS and Regulation 765/2008 on market surveillance.

**EU added value**

The European added value of the mutual recognition rules is also strongly underlined by the respondents. Most of them agree that having a common set of rules guarantees equal treatment, and that relying on national rules only would undermine the internal market.

*2.3.3. Assessment of communication when using Mutual Recognition*

Most of the responding businesses have never contacted a Product Contact Point to obtain information on the applicable product rules, mainly because they are not aware of their existence. Among those having contacted Product Contact Points, it is quite difficult to identify their level of satisfaction or the reasons behind it.

Responding Member States consider the communication with authorities within their own country as good, while communication with authorities from other Member States is rather average or poor. As regards communication between national administrations and businesses, the assessment by authorities is quite mixed between good, average and poor. The main reasons for poor communication are related to the lack of knowledge about

127 20% of respondents indicated an estimate of the costs incurred, the other choose not to reply or indicated that such estimation is impossible

128 13% of respondents indicated an estimate of the costs incurred, the other choose not to reply or indicated that such estimation is impossible

129 11% of respondents indicated an estimate of the costs incurred, the other choose not to reply or indicated that such estimation is impossible

mutual recognition, language issues and the absence of an appropriate IT tool to facilitate communication.

*2.3.4. Priorities to improve Mutual Recognition*

Stakeholders have different views as regards the possible priorities with regard to mutual recognition. If businesses rank the need for effective remedies as being the highest priority, Member States and citizens opt in favour of increasing awareness about mutual recognition.

| **Ranking of priorities by businesses** | |
|---|---|
| Ensure that businesses have effective remedies at their disposal to take action against decisions denying mutual recognition when needed | 72% |
| Increase legal certainty for businesses when using mutual recognition to sell products abroad | 67% |
| Ensure that the procedures are duly followed when decisions denying market access are taken by national authorities | 65% |
| Increase effectiveness of mutual recognition to facilitate access to the internal market | 64% |
| Facilitate communication between all actors involved in mutual recognition (business, national authorities, European Commission) | 54% |
| Increase general awareness of the mutual recognition principle | 52% |

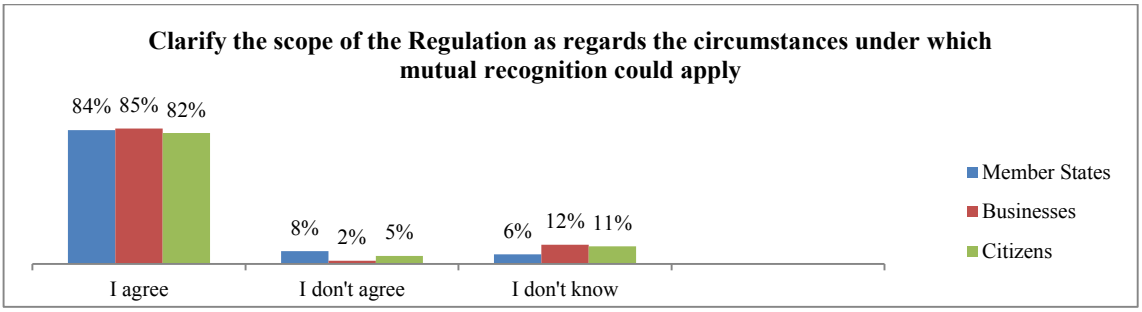
| **Ranking of priorities by Member States** | |
|---|---|
| Increase general awareness of the mutual recognition principle | 51% |
| Ensure that the procedures are duly followed when decisions denying market access are taken by national authorities | 42% |
| Ensure that businesses have effective remedies at their disposal to take action against decisions denying mutual recognition when needed | 40% |
| Increase effectiveness of mutual recognition to facilitate access to the internal market | 35% |
| Increase legal certainty for businesses when using mutual recognition to sell products abroad | 33% |
| Facilitate communication between all actors involved in mutual recognition (business, national authorities, European Commission) | 31% |

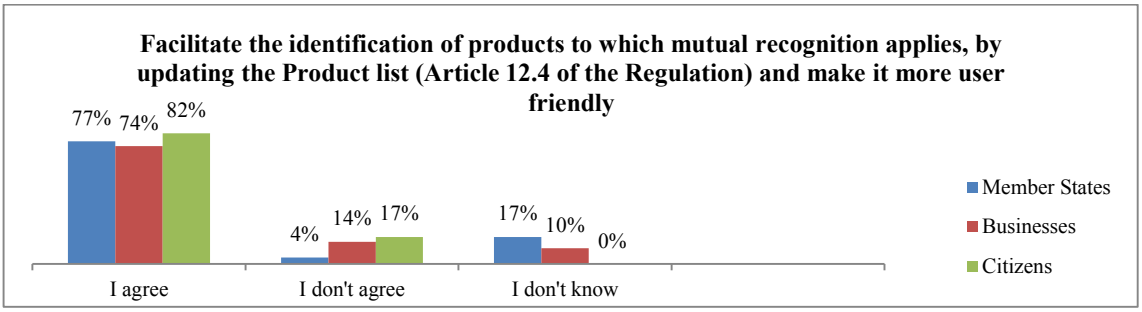
| **Ranking of priorities by citizens** | |
|---|---|
| Increase general awareness on the mutual recognition principle | 64% |
| Increase legal certainty for businesses when using mutual recognition to sell products abroad | 52% |

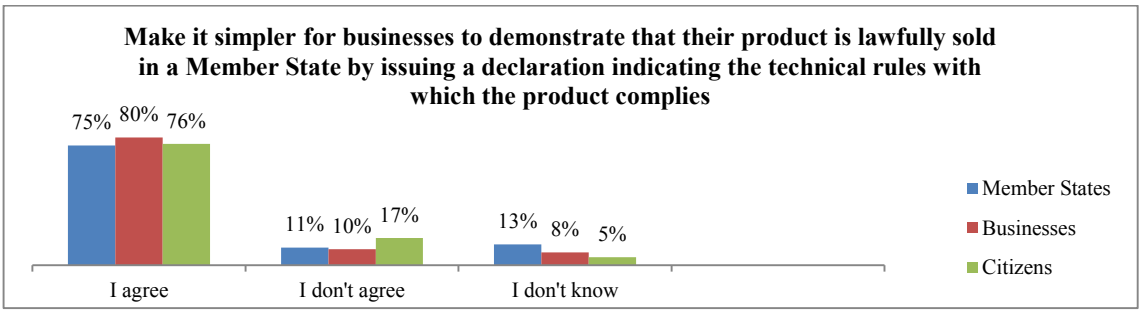
| | |
|---|---|
| Ensure that businesses have effective remedies at their disposal to take action against decisions denying mutual recognition when needed | 47% |
| Increase effectiveness of mutual recognition to facilitate access to the internal market | 41% |
| Ensure that the procedures are duly followed when decisions denying market access are taken by national authorities | 35% |
| Facilitate communication between all actors involved in mutual recognition (business, national authorities, European Commission) | 23% |

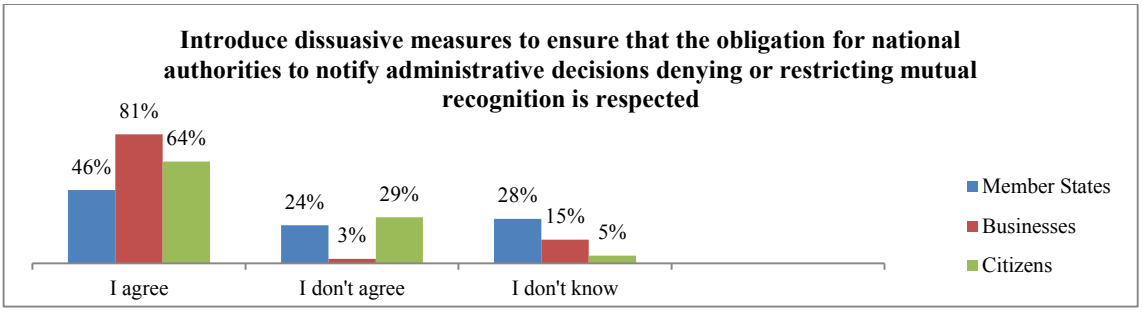
### *2.3.5. Options*

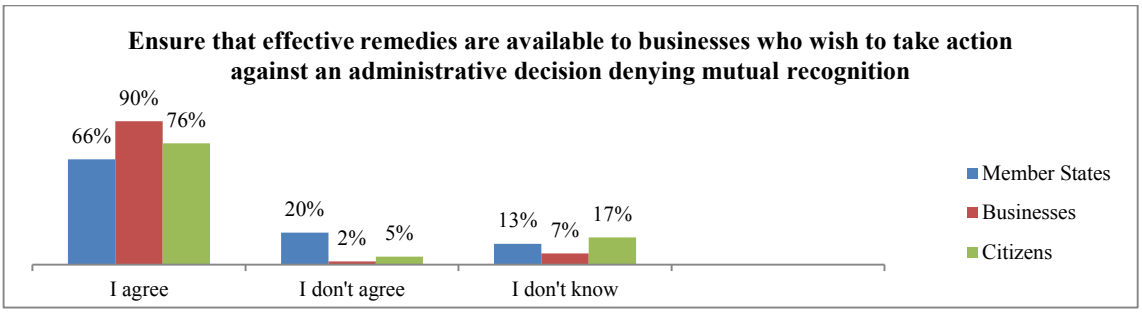
All options put forward for making mutual recognition easier to apply and more reliable received a high level of support among stakeholders.

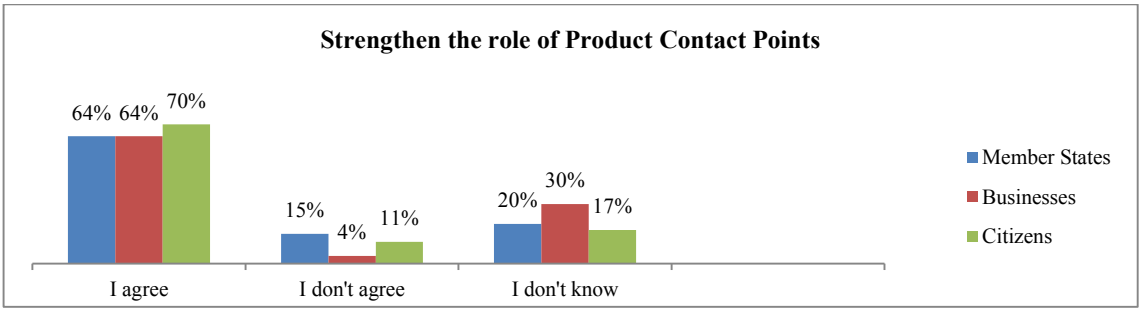


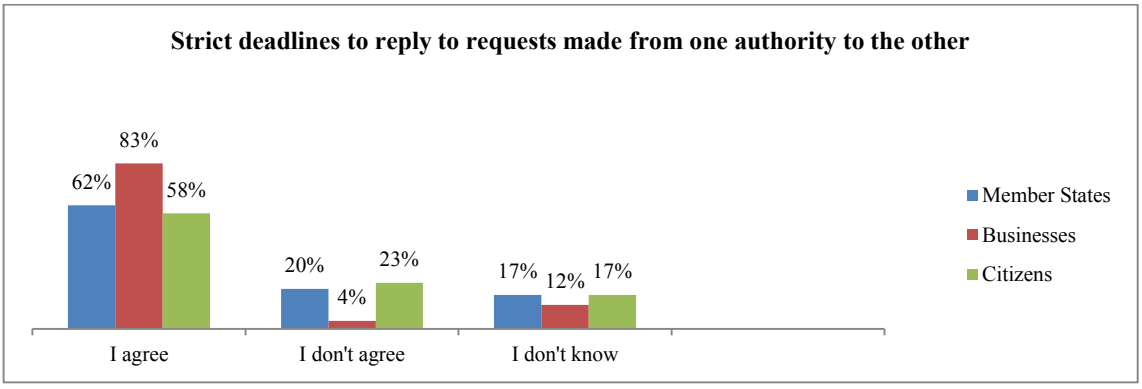



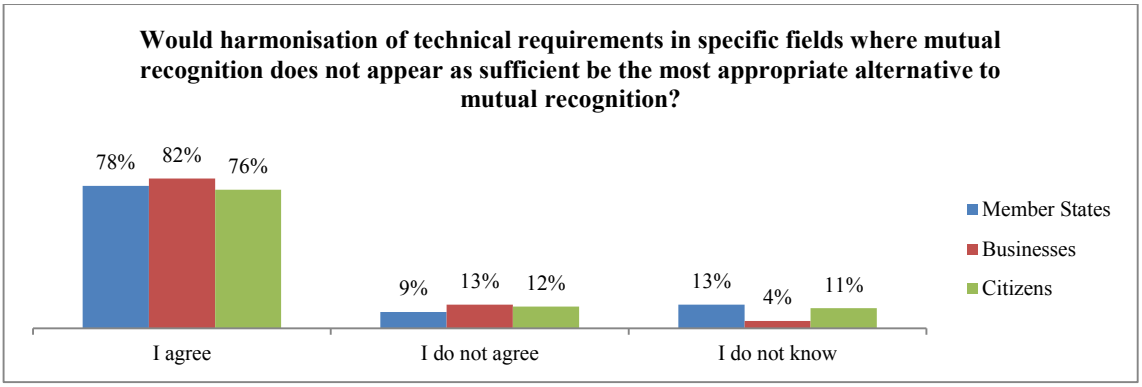


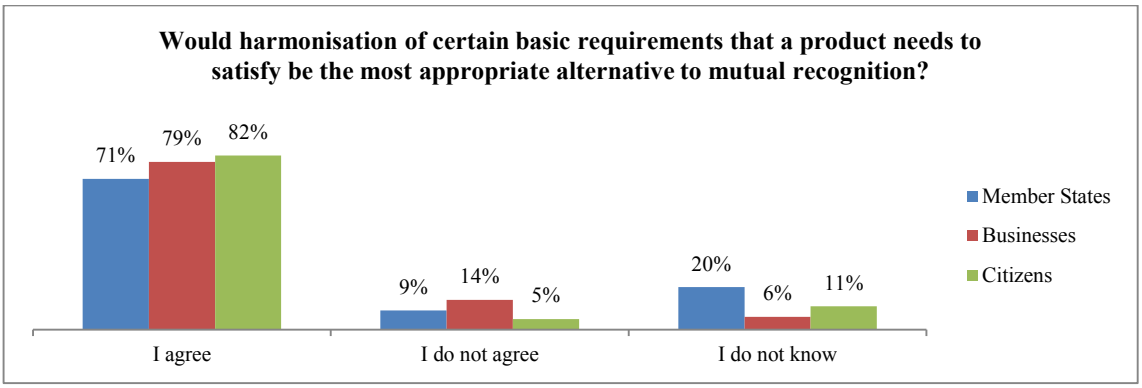



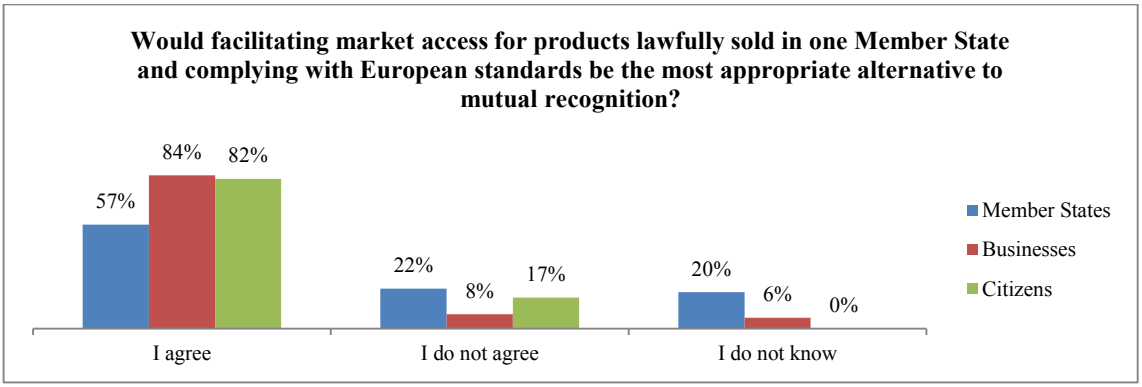




As to what would be the most appropriate alternative to mutual recognition, the majority of stakeholders agree that harmonisation is the most appropriate tool to use when mutual recognition doesn't work properly.




## 2.4. Surveys carried out by the external contractors

In the framework of the external study evaluating the functioning of the mutual recognition principle[130] , four different surveys were launched on 9 October 2014 and completed on 5 January 2015. These were a company survey (199 participants), a survey of national business associations and of national sector associations (20 participants), and a product contact point survey (26 participants). Following the survey, qualitative interviews with national business associations and Product Contact Points in each Member State were also carried out.

The findings of the surveys and interviews show that the application of the mutual recognition principle is challenging. Stakeholders outlined that there are still barriers to free movement of lawfully marketed goods due to additional requirements and tests

130 http://ec.europa.eu/DocsRoom/documents/13381

existing in certain Member States. The lack of knowledge and awareness about mutual recognition was also pointed out as being problematic, as companies and national authorities do not know when and how the principle should be applied, in particular with regard to the type of products falling under the scope of mutual recognition and to the type of documentation required for demonstrating that a product has been already lawfully marketed. Poor communication and cooperation among national authorities has also been pointed out as a weakness, contributing to the poor functioning of mutual recognition. In terms of efficiency, many businesses declared having to carry out additional tests at the request of the Member States on the territory of which they are trying to sell their products.

In the framework of the study assessing the costs and benefits of the different options envisaged for improving mutual recognition, a survey and interviews were carried out by the external contactor. The stakeholder consultation focused not only on the current functioning of mutual recognition – and its main issues – but also on how to revise the Regulation, through the policy options proposed by the Commission. Targeted surveys and interviews allowed an understanding of stakeholders' point of view about the Policy Options. With respect the obstacles to the implementation of MR National authorities highlight that: the wide scope, size and fragmentation of the market falling under mutual recognition and the presence of many different national legislations may create difficulties in having clear, structured and smooth procedures to apply mutual recognition; products falling in areas where partial harmonisation and/or some EU standards exist create difficulties for authorities, since a mix of national and EU rules may apply, requiring more effort from their side to check and decide; a certain lack of communication exists also across Member States. This may result in difficulties for a national body to understand why a product was lawfully marketed in another Member State and what relevant rules apply, without investigating and asking for further information or clarification. Businesses highlighted several obstacles as well, in particular relating to the interaction with national authorities, especially in terms of obtaining easy access to information, concerning mainly relevant legislation and procedures in place especially because of language barriers, proving that the product is already lawfully marketed in another Member State since National Authorities require different information and evidence. Time required to receive a response from national authorities has a significant impact in delaying the entry into the market or even discouraging them to enter. Considering the issues highlighted by stakeholders both economic operators and national authorities agree that measures to improve the MR Regulation have to be taken. Within each category of stakeholder, preferences and opinions about the feasibility and priority of policy options (and sub-options) seem to be heterogeneous. While among National Authorities there is quite a spread consensus about the need for intervention, either through soft-law or hard-law instruments, economic operators appear to be more cautious on the effectiveness of the proposed options in avoiding delayed market access and reducing costs for them. However, economic operators and national authorities appear to be in favour of mixing different sub-options, rather than the adoption of a single, full policy option.

### 2.5. Other contributions received (position papers or e-mail)

Several interested parties submitted separate position papers, many of which revealed that indeed national technical rules are being used as a basis to deny mutual recognition

and that no effective mechanisms exist for businesses to question national decisions denying mutual recognition. For this reason, they consider that more ambition is needed to improve trust among Member States and the improvement of transparency of national decisions will alleviate this lack of trust.

Concerning the principle of mutual recognition, some stakeholders mentioned that it could further be strengthened by the introduction of a presumption of conformity to independently tested products. They argue that the Commission should provide for a conformity assessment by independent third parties as a precondition for a corresponding presumption of conformity with regard to the product marketed in another member state because they are not involved in the design, manufacture, supply, repair or maintenance of the item to be assessed.

The scope of the Mutual Recognition Regulation should be clarified, better structures for proportionality assessments should be put in place, and an informal set-up could ensure better sharing of best practices among Member States. Also, dissuasive means should be introduced to ensure that Member States notify according to their obligations in the Regulation. Moreover, effective remedies must be available to businesses in order for them to get quicker clarity on decisions taken against their products on the Single Market, including enhanced transparency to see the decisions. In addition, the Product Contact Points should be optimised and give businesses easy access to information about national decisions and technical rules. Also, there is an overall need for redeeming trust and strengthening cooperation among Member State authorities across the Single Market.

One proposal, made by some stakeholders, is that the notification of article 2.1 administrative decisions (Regulation (EC) No 764/2008) is brought together with the procedure used in the harmonised sectors. The Commission should also consider other measures in order to integrate the non-harmonised and harmonised goods sector not only at the practical level but also in the policy level still fully respecting the principle of mutual recognition.

The lack of trust between competent authorities should be overcome and national decisions should become more transparent. A Quick Assessment Procedure, allowing an evaluation of decisions denying market access without a binding decision, is a potential tool that can lead to better understanding of the Mutual Recognition principle and improve the functioning of the current Regulation.

## 3. FEEDBACK TO STAKEHOLDERS

The consultation processes provided a wide range of views regarding the implementation of the Regulation in terms of what has worked well and what has not worked so well, seen through the eyes of these stakeholders. The meetings with the stakeholders provided an early opportunity to promote the engagement of the national authorities, thus enhancing the chances of a good response rate.

The overall objective of this initiative is to achieve a deeper single market for goods through higher and better mutual recognition. This will be done by increasing awareness on mutual recognition, enhancing legal certainty for businesses and national authorities when using mutual recognition and improving administrative cooperation and trust

among authorities. This will result in unleashing the full potential of the internal market, by facilitating the use and application of mutual recognition, reducing the risk for businesses that their products will not get access to or will have to be unjustifiably withdrawn from the market and offering more choices at lower prices for consumers.

In line with the assessment carried out, and presented in Section 7 of the Impact Assessment, the preferred option would thus be a combination of Option 2 (soft law instruments) and Option 4 (clarification of the scope of the regulation, introduction of a declaration of compliance and of a fast-track appeal procedure for businesses and strengthening the role of PCPs). This combination will address in the most effective and efficient manner all policy objectives to lead to a better functioning of the Single market for non-harmonised products through more and better mutual recognition.

Option 2 (Soft law) was supported by all stakeholders, but considered effective only if complemented by other comprehensive tools. Furthermore, during the last meeting of the Consultative Committee on mutual recognition (25 October 2016), there was consensus among Member States representatives on the fact that this option will be extremely effective in increasing awareness of the mutual recognition principle and therefore Member States representatives highly supported it.

Option 3 (minimum legislative changes to the Regulation) was considered by Member States and economic operators as potentially effective, but to a lesser extent than other options. During the 2016 public consultation, 46% of national authorities, 81% of businesses and 64% of citizens agreed with the need to introduce dissuasive measures to ensure that the obligation for national authorities to notify administrative decisions denying or restricting mutual recognition is respected. This option was however not retained since it was considered that it would not address the problem in an effective and efficient manner.

Option 4 (clarification of the scope of the regulation, introduction of a declaration of compliance and of a fast-track appeal procedure for businesses and strengthening the role of PCPs) was considered as the most effective way to achieve the policy objectives and in reducing costs for business. During the 2016 public consultation, the sub-options assessed above received a lot of support from stakeholders and 74% of businesses considered ensuring effective remedies to challenge national decisions should be the Commission's first priority. This option has been assessed as the most effective and efficient to ensure legal certainty regarding the scope and the application of mutual recognition and this is why it has been retained.

There was a consensus among stakeholders that option 5 (voluntary prior authorisation) cannot remove the existing obstacles to mutual recognition. As demonstrated in the Impact Assessment this option will entail a high administrative burden and costs, both for Member States and companies, while not effectively addressing the problem, so it has not been retained.

The option related to repealing the Regulation and the option of proposing further harmonisation measures on specific basic requirements covering certain aspects of products have been discarded at an early stage, as well as the introduction of a third party declaration of compliance.

More information on how the different options have been assessed and the option retained, and on the views of the different stakeholders on each of these options can be found in Sections 7 and 8 of the Impact Assessment.

## ANNEX 3 WHO IS AFFECTED AND HOW

The preferred options are option 1- soft law, combined with option 4- comprehensive legislative changes.

| Affected stakeholders | How |
|---|---|
| **Member States** | Member States will have the obligation to organise the training and awareness campaigns foreseen in the soft law option and to contribute to more administrative cooperation foreseen in option 4d by gaining knowledge about mutual recognition and trust in other Member States regulatory systems.<br><br>When assessing whether or not a product lawfully marketed in another Member State can be placed on the market, Member States authorities will have to accept the voluntary declaration of compliance (option 4c) and only ask for additional evidence which supports what is indicated therein. Member States will have to provide for additional resources for the PCPs (option 4d), integrating them in a wider network and providing the necessary tools for a proper and efficient administrative cooperation. In case of doubt, Member States will be able to rely on the PCP network and on the reinforced administrative cooperation (option 4d) in order to ask for clarification.<br><br>National decisions denying market access will be subject to the fast track appeal procedure (option 4c). This will discipline national authorities for strongly encouraging a decision denying market access, and in thoroughly considering the application of the mutual recognition principle to products lawfully marketed in other Member States. This will result in a more consistent and correct application of the mutual recognition principle. |
| **Commission** | The Commission will ultimately have to adopt a binding opinion in the fast track appeal procedure (option 4c). This is expected to bring an increase of workload for the Commission services. This increased workload is expected to decrease over time, when the implementation of all the other options will trigger a smother application of the mutual recognition principle and therefore, less needs and grounds to challenge the administrative decisions denying market access. |
| **Economic operators** | Following the implementation of the soft law measures and of option 4d (PCPs), economic operators will gain in awareness and knowledge on mutual recognition and therefore use more the principle of mutual recognition in order to access new markets.<br><br>Economic operators will also gain in legal certainty as regards |

| | |
|---|---|
| | the scope of mutual recognition and also as regards its applicability. A clearer mutual recognition clause (soft law option) and the clarification of the scope of mutual recognition (option 4a) will allow them to know precisely when and how they can invoke mutual recognition in order to market their products in other Member States.<br><br>Economic operators will have the possibility to have recourse to the fast track appeal procedure (option 4c). This will allow them to fight against unjustified administrative decisions denying market access in a fast and business friendly way.<br><br>Economic operators will have the opportunity to demonstrate that their products have been lawfully marketed in another Member State by means of a voluntary declaration of compliance (option 4c). On top of legal certainty, the voluntary declaration of compliance will bring administrative simplifications, as it will replace many administrative documents with one single standardised document.<br><br>Following these changes, economic operators are expected to have an easier access to the markets of other Member States, to reduce information costs, as well as adaptation costs and costs linked to lost opportunities or delayed entry on the market. |
| **Consumers** | Consumers will benefit from an increased number of products and variety or products available on the market, and also from lower prices, resulting from the economies of scale made by economic operators. |

## ANNEX 4 ANALYTICAL MODELS USED IN PREPARING THE IMPACT ASSESSMENT

This section presents the methodology followed to estimate the market value and the magnitude of the problem, as well as to collect information among stakeholders about the current implementation of mutual recognition, its main obstacles and issues and sentiment about the proposed policy options.

### 1. METHODOLOGY FOR THE MARKET ANALYSIS

The approach for the market analysis has been based on the identification of non-harmonised and partially harmonised products in a "residual way" (e.g. excluding all sectors/products for which EU harmonised product rules exist, hereafter harmonised sectors). After that, we implemented a two-stage approach. Namely:

- An analysis at **sectorial level** oriented towards the macro dimension of the market for non (or partially) harmonised products, looking at:
    - The number of economic operators that are active within the economic sectors for which EU harmonised product rules do not exist (here after *non-harmonised sectors);*[131]
    - The current contribution of the non-harmonised sectors to the EU manufacturing economy.
- An analysis at **product level** focused on the value of non-harmonised products that are traded within the EU Single Market.

Results from the analysis at sectorial and product level have been combined to identify the sectors for which the value of trade of non (or partially) harmonised products is more relevant.

Furthermore, in order to identify the variables to be included in the analysis, we tried to identify the available statistics that are useful for the scope of the study. All data used within this study have been extracted from two databases:

- Structural business statistics (SBS)[132] provided by EUROSTAT have been used to describe the structure of non-harmonised and partially harmonised sectors and measure their economic performance;
- EU trade since 1988 by Standard International Trade Classification (SITC)[133] provided by EUROSTAT allowed us to estimate the value of intra EU trades of non-harmonised and partially harmonised products.

More in detail, the approach followed consisted of the following steps:

131 Each time we refer to non harmonised products/sectors we also include partially harmonised sectors/products.
132 http://ec.europa.eu/eurostat/web/structural-business-statistics
133 http://ec.europa.eu/eurostat/web/international-trade-in-goods/data/database

- **Step 1.** Identification of EU legislative acts introducing harmonised product rules (i.e. *harmonising legislation*)

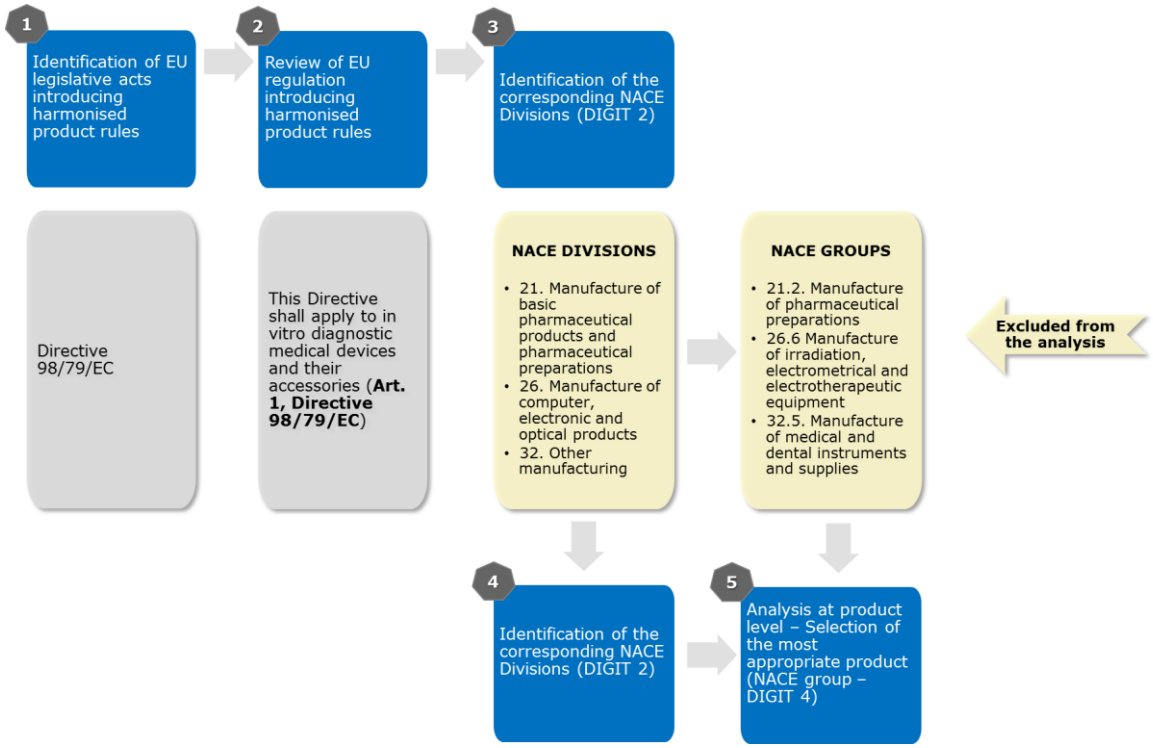
- **Step 2.** Review of EU legislation introducing harmonised product rules;

- **Step 3.** Identification of the corresponding NACE Divisions (DIGIT 2) and NACE group (DIGIT 3) that are impacted by the EU Regulation (i.e. *harmonised sector*) and that **should be excluded from the analysis**.

- **Step 5.** Identification of the NACE Divisions (DIGIT 2) and NACE group (DIGIT 3) for which harmonised product rules do not exist (i.e. *non or partially harmonised sectors*) and that **should be included in the analysis**

- **Step 6**. Selection of the most appropriate products (NACE group – DIGIT 4) for which no harmonised product rules exist and that **should be included in the analysis.**

**Figure A4-1: Methodological approach. Example for "medical devices"**




Results from this exercise are presented in annex 5. In particular:

- Annex 5.1. presents the list of **harmonised, non-harmonised and partially harmonised economic sectors** (as per NACE DIGIT-3 classification) that have been used for the analysis at sectorial level;

- Annex 5.2. presents the list of products (as per NACE DIGIT-4 classification) that have been considered as **non (or partially) harmonised** for the analysis at product level.

All the steps presented so far were needed to overcome the following issues:

- There is not an updated list of non-harmonised and partially harmonised products/sectors;
- Definitions of sectors/products in the regulation are usually different from nomenclatures used within statistics;
- Statistics at sectorial/product level use different nomenclatures (e.g. intra EU trade uses the Standard International Trade Classification [SITC], production values use the PRODuction COMmunautaire [Prodcom] nomenclature, business demographics uses the Statistical Classification of Economic Activities in the European Community [NACE]);
- Difficulties in identifying non (or partially) harmonised products within sectors that are highly harmonised. One of the most complicated cases is represented by the Food and Drink sector (see Box 1).

**Box 1: Food and drink products**

*The food and drink industry is the EU's biggest manufacturing sector in terms of jobs and value added. It is also an asset in trade with non-EU countries. The EU boasts an important trade surplus in trade in food and EU food specialities are well appreciated overseas. In the last 10 years, EU food and drink exports have doubled, reaching over €90 billion and contributing to a positive balance of almost €30 billion.*

*The EU food legislation is highly harmonised and the sector benefits significantly from the opportunities offered by the EU Single Market. At the same time, however, there are some EU legislative acts that imply the application of the Mutual Recognition principle such as:*

*Food contact materials (FCM) (Regulation (EC) No 1935/2004). Materials and articles intended to come in contact with food fall under a framework regulation that establishes the principles of safety assessment and management regarding the risk of transfer of chemicals from such materials into foods. While some materials are covered by EU-wide specific measures, others[134] remain overseen by national rules and depend on mutual recognition, raising concerns that inconsistencies can affect safety and trade.*

*Food supplements[135] (Directive 2002/46/EC) and labelling, presentation and advertising of foodstuffs (Directive 2000/13/E). Although the EU legislation harmonised various aspects (definition of food supplements, composition, specific labelling requirements, etc.) some non harmonised areas remained (for instance the maximum amounts of vitamins and minerals, other substances than vitamins and minerals,*

134 The materials covered only by national measures are adhesives, printing inks, coatings, glass, ion exchange resins, waxes, metals, cork, wood, paper and board, silicones, rubber, textiles and combinations of materials.

135 Food supplements are foodstuffs that are meant to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect. These can be found alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities. Moreover nutrients could be vitamins, minerals, herbal extracts and other ingredients.

*obligation for product registration at national level).*

*Thus in the scope of the analysis:*

- Concerning FCM some specific products have been identified within the following sectors
- Manufacture of paper and paper products;
- Manufacture of rubber and plastic product;
- Manufacture of other non-metallic mineral products.

*Concerning the food supplement and foodstuffs some specific products have been identifies within the sectors "Manufacture of other food products"*

*For the complete list of products that are considered as non (or partially harmonised) within the scope of this study please refer to 2.*

## 2. METHODOLOGY FOR THE ESTIMATION OF THE MAGNITUDE OF THE PROBLEM

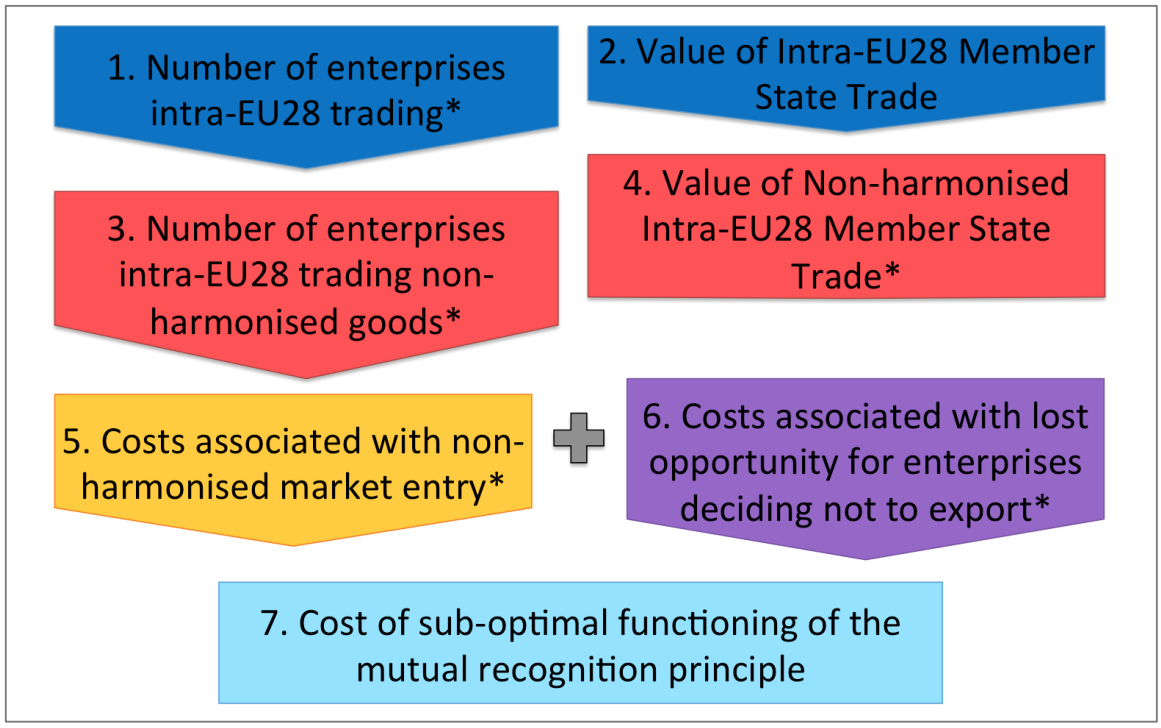
The objective of the model is to distinguish the socio-economic costs of a sub-optimal functioning of the mutual recognition principle by identifying and investigating relevant socio-economic costs. Figure A4-2 provides an overview of the key components of the model to estimate the impact of sub-optimal functioning of the Mutual Recognition principle, henceforth called the SFMR model. The model is underpinned by an enterprise decisions tree that considers routes to successful market entry and decisions not to export, further details are provided in chapter 4.

Figure A4-2 highlights that the model is comprised of seven components or stages. Calculations for components one, two and four were presented in the previous chapter. The model uses data from the value of intra-EU trade by EU Member States to calculate key cost elements associated with sub-optimal functioning of the Mutual Recognition principle. These include unnecessary compliance costs and adjustment costs.

By estimating the number of enterprises entering new cross-border markets with non-harmonised products (stage three of the model), it is possible to apply an estimate of the number of days work required by enterprises to overcome sub-optimal functioning (stage five). This element of the model provides details of transactions costs. The second component of the model (stage six - cost of delayed market entry) estimates the cost per week of enterprises note being able to trade.

Components five and six can then be treated separately, or combined to give a total estimate of costs associated with sub-optimal functioning of the Mutual Recognition principle.

**Figure A4-2: Key components of the model to estimate the cost of sub-optimal functioning of the Mutual Recognition principle**




*Note: Elements with asterisks can be changed in the model and/or updated when data from field research becomes available.*

As noted, the model is underpinned by clear and transparent assumptions that can be adjusted to enable sensitivity analysis in the model.

## 3. METHODOLOGY FOR CASE STUDIES

Five case studies were constructed and carried out in this project. Their objective is to allow us:

- To ensure a higher level of detail, which would not be feasible to obtain only through desk research and online survey, on specific topics emerged throughout the study that can help to better understand the impacts of the problems that emerged in the application of the mutual recognition principle and of the options envisioned;

- To provide enriched and more robust estimation of the cost and benefits of problems encountered in the application of the mutual recognition principle and of the options under analysis;

- To illustrate in practical terms the implication and impacts of specific issues in the application of mutual recognition.

Based on the results of the desk and field research, the team identified possible case studies, approved by the Commission, considering products or categories of products that appear relevant to be explored in a more detailed analysis.

Case studies were carried out through:

- Brief desk research that provides an overview of the product and collecting economic data and information;

- Interviews to collect information on the current actual implementation of mutual recognition in the sector – and in specific Member States, main costs and potential benefits of the proposed policy options, involving both:

    - **Relevant national authorities**, to understand the actual implementation of the Regulation, the main procedures in place and the possible revision that could be made in the light of the proposed options;

    - **Economic operators** – both businesses and business associations – active in the relevant sector, to collect information on the actual problems/obstacles faced and costs incurred by companies trying to enter the relevant market, as well as understanding the impact the proposed policy options would have in addressing them.

Each case study is presented below, providing both an overview of the case and relevant product/sector, as well as the issue and the details based on desk and field research.

## 4. ESTIMATION OF THE MARKET FOR NON-HARMONISED PRODUCTS

This section provides an estimate of the **market value of current intra-EU trade in non-harmonised products** falling under the mutual recognition principle, in order to understand the size of the EU market currently affected by the Regulation;

### 4.1. Estimate of the market value of current intra-EU trade in non-harmonised products falling under the mutual recognition principle

As described above, the market analysis follows a twofold approach.

- An analysis at **sectorial level** oriented towards the macro dimension of the market for non (or partially) harmonised products,

- An analysis at **product level** focused on the value of non-harmonised products that are traded within the EU Single Market.

The size of the market and of the value of traded goods for which the Mutual Recognition should apply to allow the research team to have figures for the estimate of

the magnitude of the problem and for the next steps, with the assessment of the policy options.

### *4.1.1. Analysis at the sectorial level*

For the analysis at **sectorial level,** we extracted from SBS data related to the following dimensions:

- Business Demographic;
- Input related;
- Output related.

The analysis has been undertaken on the **indicators** detailed in the following table.

**Table A4-1: List of indicators for the sector-level analysis**

| Dimension | Indicator | Definition |
|---|---|---|
| **Business demography** | *Number of enterprises* | Number of active enterprises |
| **Input** | *Number of persons employed* | Number of person aged 15 and over (or 16 and over in IE) who worked - even if just for one hour per week - for pay, profit or family gain. |
| **Output** | *Value added at factor cost* | The value added at factor cost is the gross income from operating activities after adjusting for operating subsidies and indirect taxes.<br><br>The value added at factor costs is calculated "gross" as value adjustments (such as depreciation) are not subtracted.[136] |
| | *Turnover* | "Turnover" comprises the totals invoiced and corresponds to market sales of goods supplied to third parties.[137] |

We identified the economic sectors (i.e. sectors identified with a 3-digit NACE code) that are potentially impacted by Regulation (EC) No 764/2008 and for which the Mutual Recognition principle should be applied (see annex5).

136 http://ec.europa.eu/eurostat/ramon/nomenclatures/index.cfm?TargetUrl=DSP_GLOSSARY_NOM_DTL_VIEW&StrNom=CODED2&StrLanguageCode=EN&IntKey=16619885&RdoSearch=BEGIN&TxtSearch=value%20added%20at%20factor%20cost&CboTheme=&IsTer=&IntCurrentPage=1&ter_valid=0

137 It includes all duties and taxes on the goods or services invoiced by the unit with the exception of the VAT invoiced by the unit vis-à-vis its customer and other similar deductible taxes directly linked to turnover.
It also includes all other charges (transport, packaging, etc.) passed on to the customer, even if these charges are listed separately in the invoice. Reduction in prices, rebates and discounts as well as the value of returned packing must be deducted.
Income classified as other operating income, financial income and extra-ordinary income in company accounts is excluded from turnover. Operating subsidies received from public authorities or the institutions of the European Union are also excluded.

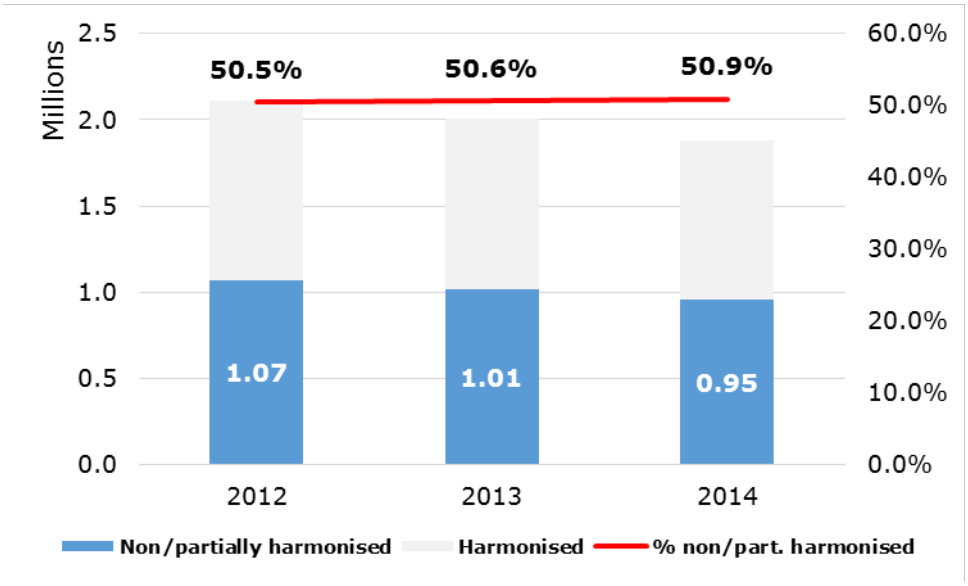
As regards this **sectorial analysis** it is important to underline that:

- Data is available at NACE Digit 3 – level only for the period 2012 – 2014. Thus it is almost difficult to identify some trends

- All **results should be considered as an upper estimate** because some economic sectors might contain one of more products for which harmonised product rules exist.

As shown in Figure A4-3, over the period from 2012 and 2014, **around 0.99 million enterprises were operating within non-harmonised sectors**, representing more than 50% of the total number of active enterprises in the manufacturing economy (around 2 million active enterprises are operating under Section C of NACE classification named Manufacturing). 1 presents the correspondence between the list of NACE DIGIT-3 codes and the way they have been considered in the analysis (i.e. harmonised or non/partially harmonised.

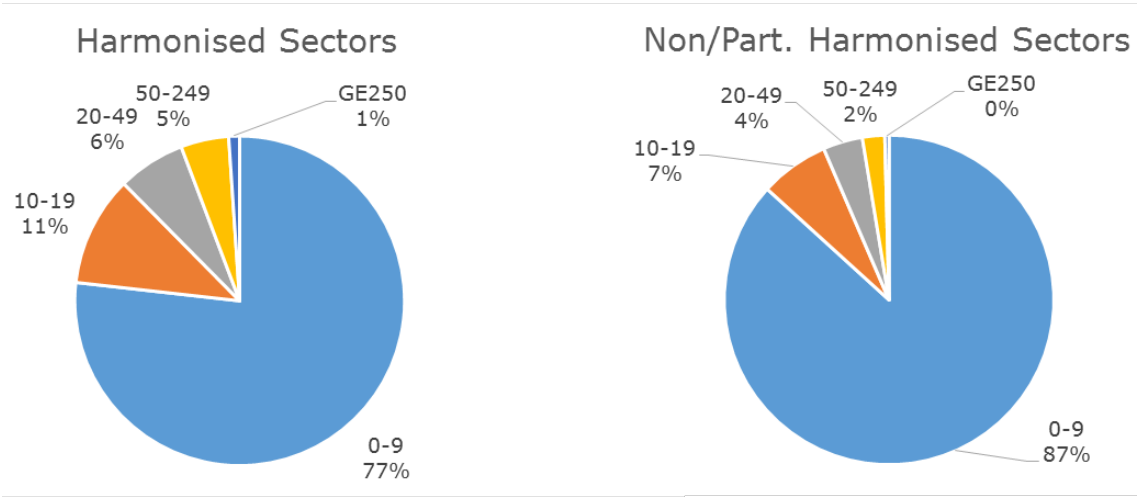
**Figure A4-3: Number of active enterprises: non-harmonised sectors vs overall manufacturing sectors (EU28, 2012 – 2014), NACE Digit-3 level**




Source: Structural Business Statistics, Annual enterprise statistics by size class for special aggregates of activities (NACE Rev. 2) (sbs_sc_sca_r2), EUROSTAT (2016)

It is very important to underline that around **87%** of the enterprises operating within the non (or partially) harmonised sectors **are micro enterprises** (i.e. with less than 9 employees) and around **11% are Small and Medium Enterprises** (i.e. with a number of employees between 10 and 250). If compared to harmonised sectors the relevance of micro enterprises is higher in non/partially harmonised sectors.

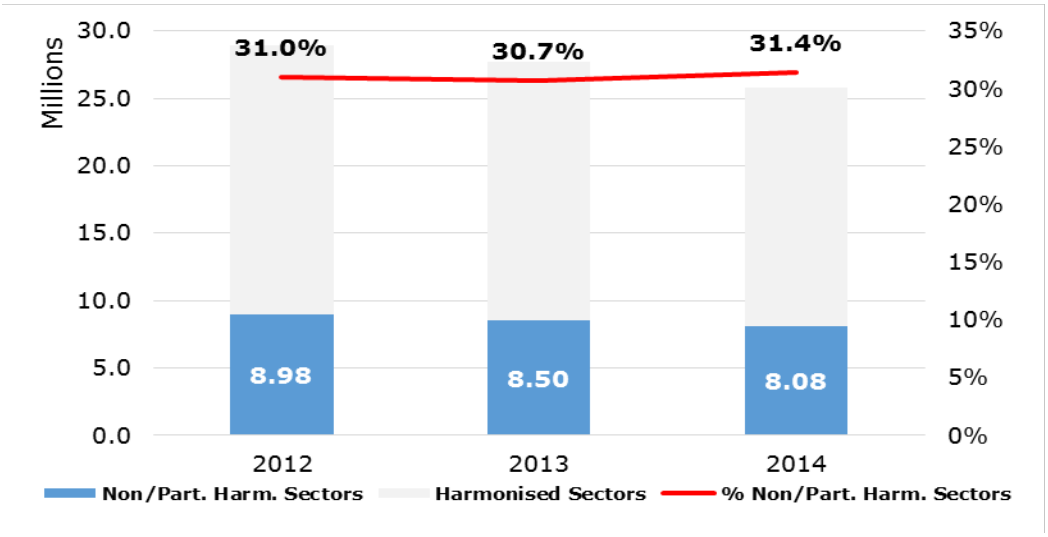
**Figure A4-4: Size of enterprises operating (2012 – 2014, EU 28), NACE Digit-3 level**




Source: Structural Business Statistics, Annual enterprise statistics by size class for special aggregates of activities (NACE Rev. 2) (sbs_sc_sca_r2), EUROSTAT (2016)

Furthermore, at EU28 level **more than 8 million person are employed** within the non (or partially) harmonised sectors (i.e. around 31% of all people employed in the manufacturing sectors), with no significant variation over the period considered.

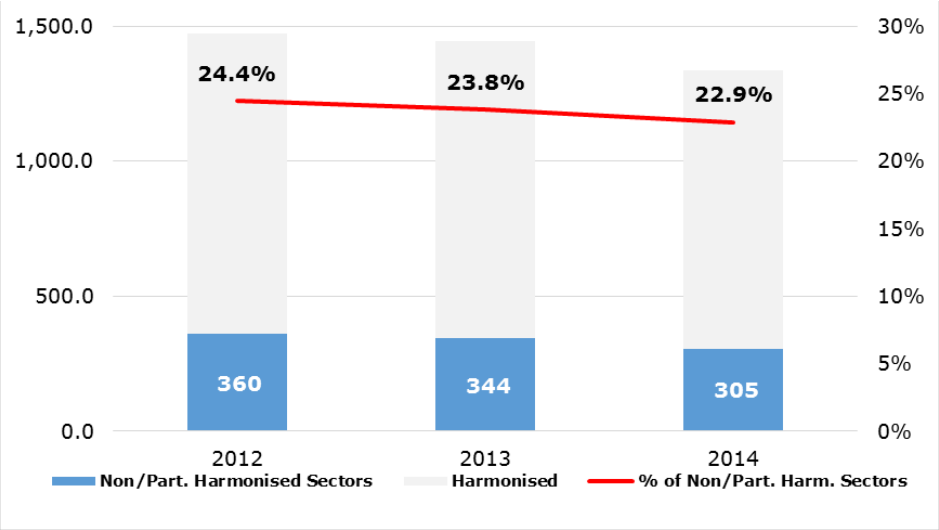
**Figure A4-5: Number of persons employed: non (or partially) harmonised sectors vs overall manufacturing sectors (2012 – 2014, EU28, millions)**




Source: Structural Business Statistics, Annual enterprise statistics by size class for special aggregates of activities (NACE Rev. 2) (sbs_sc_sca_r2), EUROSTAT (2016)

The magnitude of the non- (or partially) harmonised sectors can be also appreciated if wealth creation (i.e. added value and turnover) is considered. In particular, **the value added produced in non (or partially) harmonised sectors decreased by 15% during the period 2012-2014** (i.e. passing from €360 to €305 billion) and its contribution to the overall value added of the manufacturing sectors passed from 24.4% in 2012 to 22.9% in 2014.

**Figure A4-6: Value added at factor cost: non-harmonised sectors vs overall manufacturing sectors (2012 -2014, EU28), € billion**




Source: Structural Business Statistics, Annual enterprise statistics by size class for special aggregates of activities (NACE Rev. 2) (sbs_sc_sca_r2), EUROSTAT (2016)

Also in this case, within the period 2012–2014, **micro enterprises and SMEs contributed to the 59.5% of the value added produced operating in non-harmonised sectors** (i.e. €200.2 billion out of €336.5 billion) that corresponds to the 14.1% of the overall added value produced in the manufacturing sectors (€ 1,417.2 billion).

**Table A4-2: Value added at factor cost per size of enterprises: non-harmonised sectors vs overall manufacturing sectors (average 2012-2014, EU28), € billion**

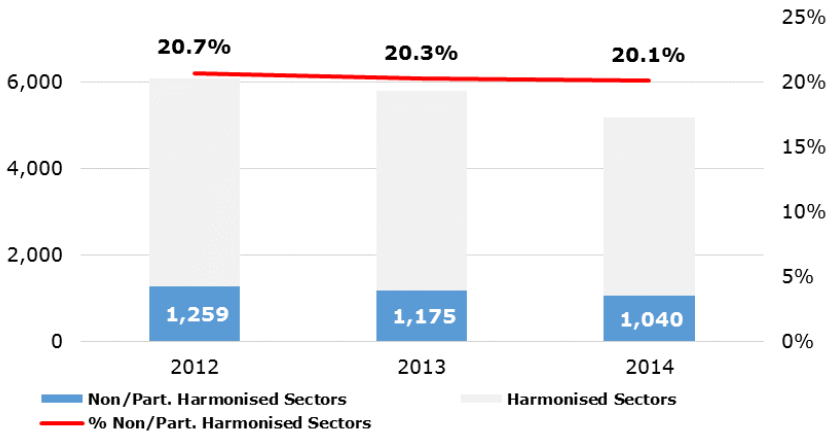
| Size of enterprises | Non-Harmonised Sectors | | Manufacturing | | Non-Harmonised S./ Manufacturing |
|---|---|---|---|---|---|
| | Total (€ Million) (a) | % | Total (€ Million) | % | (a)/(b) % |
| **Micro (< 9 employees)** | **43.158** | **12.8%** | 104.026 | 7.3% | **3.0%** |
| **Small (between 10 and 49 employees)** | **70.528** | **21.0%** | 219.824 | 15.5% | **5.0%** |
| **Medium (between 50 and 249 employees)** | **86.528** | **25.7%** | 339.206 | 23.9% | **6.1%** |
| **Large (>250 employees)** | 136.272 | 40.5% | 754.117 | 53.2% | 9.6% |

| Size of enterprises | Non-Harmonised Sectors | | Manufacturing | | Non-Harmonised S./ Manufacturing |
|---|---|---|---|---|---|
| **Total** | 336.485 | 100.0% | **1,417.17 (b)** | 100.0% | 23.7% |

Source: Structural Business Statistics, Annual enterprise statistics by size class for special aggregates of activities (NACE Rev. 2) (sbs_sc_sca_r2), EUROSTAT (2016)

Finally, relevant results emerged also considering the **turnover**. As shown in the figure below, enterprises operating within non (or partially) harmonised sectors contribute to around 20% of the total value of market sales of manufacturing sectors (€1,158 billion out of €5,690 billion, corresponding to the overall turnover produced within the manufacturing sectors).

**Figure A4-7: Turnover: Non-harmonised sectors vs overall manufacturing sectors (2012-2014, EU28), € billion**




Source: Structural Business Statistics, Annual enterprise statistics by size class for special aggregates of activities (NACE Rev. 2) (sbs_sc_sca_r2), EUROSTAT (2016)

If the size of enterprises is considered, **micro enterprises and SMEs** that are doing business in non (or partially) harmonised sectors **generated the 11.7% of the turnover generated within the entire manufacturing economy** (€662.2 billion out of €5,690 billion).

**Table A4-3: Turnover per size of enterprise: non-harmonised sectors vs overall manufacturing sectors (average 2012-2014, EU28), € Billion**

| Size of enterprises | Non-Harmonised Sectors | | Manufacturing | | Non-Harmonised S./ Manufacturing |
|---|---|---|---|---|---|
| | Total (€ Million) (a) | % | Total (€ Million) | % | (a)/(b) % |
| **Micro (< 9 employees)** | **128,872** | 11.1% | 319,955 | 5.6% | **2.3%** |
| **Small (between 10 and 49 employees)** | **222,107** | 19.2% | 725,176 | 12.7% | **3.9%** |
| **Medium (between 50 and 249 employees)** | **311,212** | 26.9% | 1,300,562 | 22.9% | **5.5%** |
| **Large (>250 employees)** | 495,825 | 42.8% | 3,344,326 | 58.8% | 8.7% |
| **Total** | 1,158,016 | 100.0% | 5,690,019 | 100.0% | 20.4% |

Source: Structural Business Statistics, Annual enterprise statistics by size class for special aggregates of activities (NACE Rev. 2) (sbs_sc_sca_r2), EUROSTAT (2016)

### *4.1.2. Analysis at product level*

The second type of analysis, at **product level**, is aimed at understanding the market value of all traded products for which EU harmonised product rules do not exist.[138]

The **indicators** considered in the analysis have been also extracted from Eurostat statistics currently available and are presented in the following table.

**Table A4-4: Indicators computed for the analysis at product level**

| Indicator | Definition | Geographical coverage | Timeframe | Source |
|---|---|---|---|---|
| **Value of intra EU exports for manufacturing products** | This indicator provides the monetary value of exported manufactured products from all | EU-28 | 2008 - 2015 | **EU trade since 1998 by SITC**[139] |

138 Only intra EU exports are considered for the analysis.
139 http://ec.europa.eu/eurostat/web/international-trade-in-goods/data/database

| Indicator | Definition | Geographical coverage | Timeframe | Source |
|---|---|---|---|---|
| | EU countries to other EU countries | | | |
| **Value of intra EU exports for non-harmonised and partially harmonised products** | This indicator provides the monetary value of non-harmonised and partially harmonised products from all EU countries to other EU countries | EU-28 | 2008 - 2015 | **EU trade since 1998 by SITC** |

**All EU-28 Member States** have been considered and the time period covered by data is 2008-2015. In terms of sectors, the manufacturing sectors listed in the following table have been included in the analysis. In particular the NACE codes used in the analysis have been grouped using the International Standard Industrial Classification of All Economic Activities (ISIC)[140]. Each sector contains both harmonised and non or partially harmonised products. **Annex 5 lists all non or partially harmonised products per each sector that have been used for the analysis at product level**.

**Table A4-5: Manufacturing Sectors included in the analysis at product level**

| Sectors | NACE DIVISION |
|---|---|
| Manufacture of food products, beverages and tobacco products | 10 to 12 |
| Manufacture of textiles, apparel, leather and related products | 13 to 15 |
| Manufacture of wood and paper products, and printing | 16 to 18 |
| Manufacture of coke, and refined petroleum products | 19 |
| Manufacture of chemicals and chemical products | 20 |
| Manufacture of pharmaceuticals, medicinal chemical and botanical products | 21 |
| Manufacture of rubber and plastics products, and other non-metallic mineral products | 22-23 |
| Manufacture of basic metals and fabricated metal products, except machinery and equipment | 24-25 |
| Manufacture of computer, electronic and optical products | 26 |
| Manufacture of electrical equipment | 27 |

140 http://ec.europa.eu/eurostat/documents/3859598/5902521/KS-RA-07-015-EN.PDF (pag. 44)

| Sectors | NACE DIVISION |
|---|---|
| Manufacture of machinery and equipment n.e.c. | 28 |
| Manufacture of transport equipment | 29-30 |
| Other manufacturing, and repair and installation of machinery and equipment | 31 to 33 |

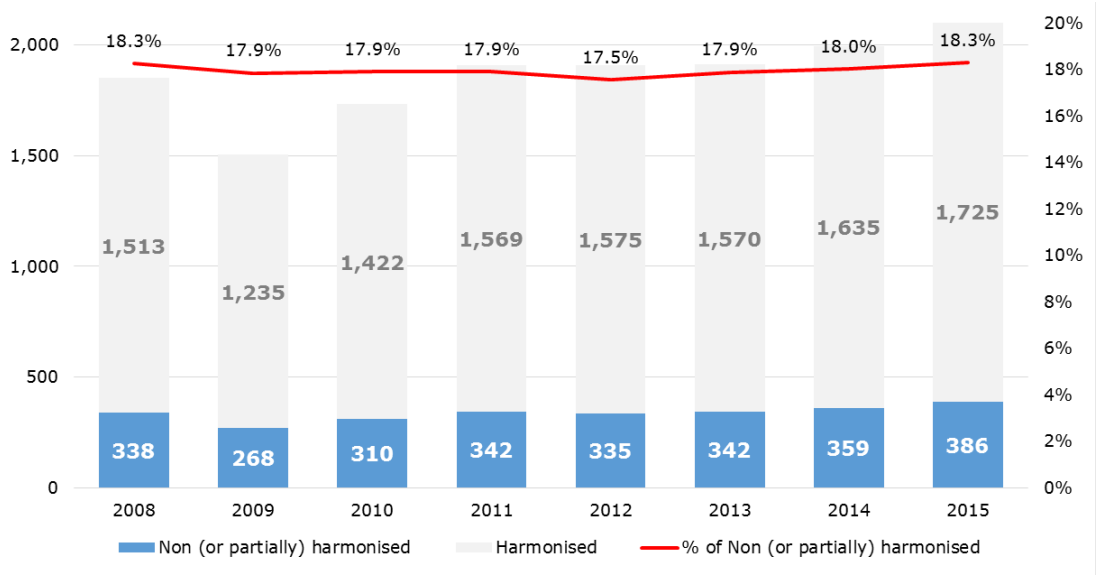
While the analysis at sectorial level provided an estimate of the number of economic operators that are potentially impacted by a sub optimal functioning of the Mutual Recognition and how they are contributing to the EU economy, the analysis at product level provides an assessment of the value of traded goods that should comply with the existing harmonised product rules.

The value of non (or partially) harmonised products has been estimated by considering the value of intra EU exports for these types of product. The 2 presents the list of products (as per NACE DIGIT-4 classification) that have been considered as being non (or partially) harmonised.

In particular, considering the period 2008 - 2015:

- The (average) annual value of intra EU exports of non (or partially) harmonised products has been equal to €335 billion (Figure A4-8);
- The value on intra EU exports of non-harmonised products represented the 18% of the value of intra EU exports (Figure A4-8);
- The value of intra EU exports of non or partially harmonised goods increased by 14.2% (i.e. passing from € 338 to € 386 billion), the same variation can be observed for harmonised good (i.e. the value passing from € 1,513 to € 1,725 billion).

**Figure A4-8: Value on non (or partially) harmonised products. Intra EU Exports, € billions, 2008 -2015**




The following table shows the average value of intra EU exports for non-harmonised and partially harmonised products for each sector, where the 83% (around €515 billion out of €681 billion) of products are manufactured by:

- Manufacture of basic metals and fabricated metal products, except machinery and equipment;
- Manufacture of textiles, apparel, leather and related products basic metals and fabricated metal products;
- Manufacture of transport equipment;
- Manufacture of wood and paper products, and printing.

Please refer to Annex 5 for the list of products that have been classified as non or partially harmonised for each sector.

**Table A4-6: Value of non-harmonised products per sector (Intra EU trade, average 2008 – 2015, € billions)**

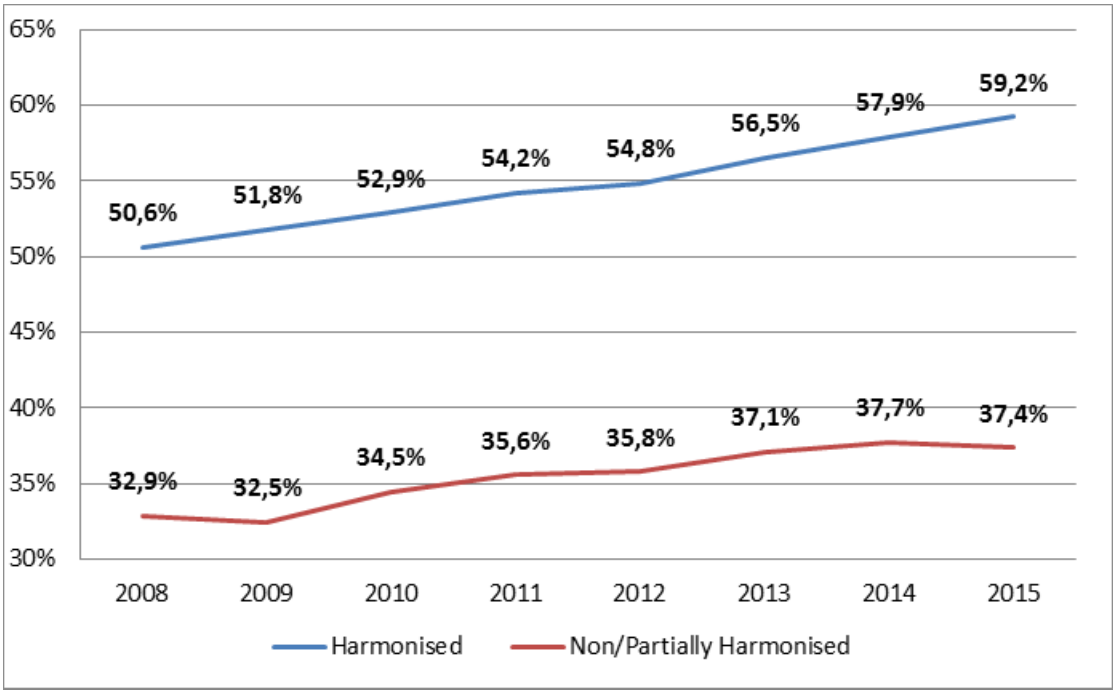
| | Average Annual value | % |
|---|---|---|
| Manufacture of basic metals and fabricated metal products, except machinery and equipment | 41.81 | 12% |
| Manufacture of coke, and refined petroleum products | 0.05 | 0% |
| Manufacture of computer, electronic and optical products | 15.69 | 5% |
| Manufacture of electrical equipment | 2.90 | 1% |

| | Average Annual value | % |
|---|---|---|
| Manufacture of food products, beverages and tobacco products | 3.37 | 1% |
| Manufacture of rubber and plastics products, and other non-metallic mineral products | 12.41 | 4% |
| Manufacture of textiles, apparel, leather and related products | 55.91 | 17% |
| Manufacture of transport equipment | 104.01 | 31% |
| Manufacture of wood and paper products, and printing | 76.40 | 23% |
| Other manufacturing, and repair and installation of machinery and equipment | 22.66 | 7% |
| **Total** | **335.22** | **100%** |

Source: EU trade since 1998 by SITC, EUROSTAT (2016)

Another interesting element emerged if the value of the intra EU Exports is compared with the domestic consumption (i.e. **value of production – value of extra EU exports + value of extra EU imports**): while for harmonised products the value of Intra EU exports is 55% of the domestic consumption, for non or partially harmonised products the Intra EU exports represent only 35% of the domestic consumption. This might be a sign of a suboptimal functioning of the Mutual Recognition that leads to potential barriers for intra EU trade in the case of non- or partially harmonised products.

**Figure A4-9: Intra EU trades (exports) as % of the domestic consumption: Harmonised vs non or partially harmonised products, 2008-2015**




Source: PRODCOM statistics, EUROSTAT (2016)

The results presented so far, as already mentioned, should be considered as an upper estimate of the market value for non-harmonised and partially harmonised products, due to the degree of sectoral aggregation. Even if, as showed in 2, we used up to 4 digits statistics, the estimated value cannot indicate itself if the MR is working or not. The implementation of the MR principle might be optimal in many subsectors, even if non-harmonised. This can be related to the fact that there is little regulation anyway or that, may be, countries rely on the same (European) standards, or that MR problems are more sector specific.

This chapter presents the revised model for the estimation of the magnitude of the problem arising from sub-optimal functioning of the Mutual Recognition principle.

## 4.2. Estimating the magnitude of the problem triggered by suboptimal functioning of the mutual recognition principle

### *4.2.1. Introduction and exporting decision tree*

This section presents a model for estimating the costs associated with the current sub-optimal functioning of the Mutual Recognition principle.

The approach adopted is innovative. No previous studies could be found that model or calculate costs arising from the current sub-optimal functioning of the Mutual Recognition principle [141]. In 2003 Pelkmans[142] identified three core costs – information,

141 Renda A et al. 2014. Towards indicators for measuring the performance of the Single Market. Briefing for the IMCO Committee. Directorate General for Internal Policy. A theoretical-economic approach is developed from the work of Ronald Coase from 1937 onwards on transaction costs and the nature of the firm and Oliver Williamson's work in the 1990's on transaction cost economics. These approaches employ a very different idea of 'transaction costs' and cannot be employed for this empirical study.

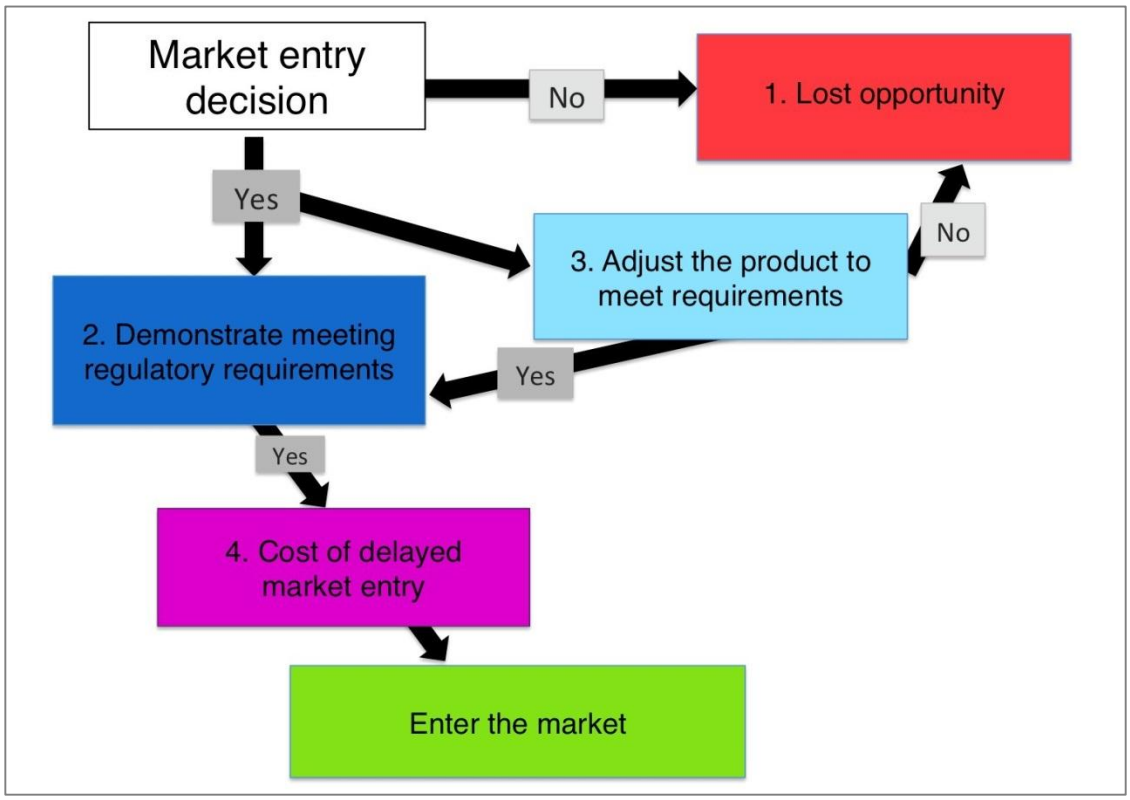
transaction and compliance. These elements are utilised and further developed in this study. Pelkmans also identified that there will also be waiting costs associated with the 'number of products waiting for EU regulation before free movement could become a reality for business'[143]. These are included in the model as 'Costs of delayed market entry'. Discussions with Pelkmans have identified that these elements are as relevant now as they were when his conceptual study was completed in 2003.

The previous section presented a number of options for enterprises to follow in order to export products. Figure A4-10 provides a decision tree diagram to represent the route that enterprises can follow when deciding not to export or when entering another EU Member State market with a product not covered by the Mutual Recognition principle.

**Figure A4-10. Decision tree diagram for export decisions associated with products not covered by the Mutual Recognition principle**

142 Pelkmans J. 2003. Mutual recognition in goods and services: An economic perspective. European Network of Economic Policy Research Institutes. Working Paper 16. p14.

143 Ibid Pelkmans. 2003. p8.




The decision tree captures the three main options (and subsequent steps) that an enterprise undertaking intra-EU exports of partial or non-harmonised products needs to consider. These key options are incorporated in the model developed within this section. The model provides a representation for an enterprise considering intra-EU exporting of one product in one EU Member State[144], this includes:

- **Market entry decision** – The starting point for figure A4-10 is the consideration by an enterprise to export. At that point they can decide to proceed and incur time and other costs before entering a market. Alternatively, they can decide not to attempt to export, these decisions will generally be underpinned by economic rationale (e.g. the perceived costs of exporting do not offer sufficient rewards) or enterprise staff may not welcome the risk or other pressures of exporting.

- If an enterprise decides to export they can follow one of two routes. Adjust their products to meet the requirements of the Member State markets they want to enter. Even if this strategy is followed the enterprise will have to demonstrate to national authorities that their product does meet the requirements of the Member State targeted for exporting.

- **Demonstrating meeting regulatory requirements** (action 2 in decision tree graphic) – Interviews are ongoing with enterprises to provide insight on how they meet regulatory requirements. As noted previously Pelkmans identified three

144 It is useful to highlight that Pelkmans' earlier work highlighted that Mutual Recognition, if implemented properly, also has costs. But these have rarely been considered in studies that generally examine benefits. Consideration of these is not within the scope of this study.

components to this action. A two-stage process is usually evident. Firstly, this option requires an assessment of information about Mutual Recognition principles for their product and the requirements for the target Market State (Pelkmans described these as 'information costs'). There was a relatively high level of agreement amongst those interviewed that this, on average, takes between 10 and 30 hours for a single product. However, some larger businesses with many products reported undertaking continual monitoring of relevant information.

The second step is demonstrating to relevant authorities that the product can be sold lawfully in another Member State – Pelkmans described these as 'transaction costs'. Interviewees suggested that this took between 30 and 50 hours. Pelkmans noted that undertaking these two activities should usually ensure that the third component identified – compliance costs; associated with judicial presentation or review – should be avoided. None of the businesses interviewed in connection with the decision tree model had incurred judicial costs. Since these judicial costs can usually be avoided by incurring 'information' and 'transaction' costs these are not included in the model.

At the average personnel costs quoted by enterprises (€60 per hour) the maximum time period of 80 hours (30 hours for information costs and 50 hours for transaction costs) equates to a cost of €4,800 per enterprise (per product per Member State). In the model this value can be adjusted, the default value is €4,800.

- **Adjusting the product to meet market requirements** (action 3 in decision tree graphic) – As noted above interviews are ongoing with enterprises to provide an insight to how many adjust products and the cost of adjusting products. Interviewees found it difficult to provide a precise cost for adjusting products due to different circumstances and the adjustments required. But the average estimate was two per cent of production costs. In the model this value can be adjusted, the default value is €16,800[145].

- After adjusting the product an enterprise would still need to demonstrate to relevant authorities that the product can be sold lawfully in another Member State (hence the arrow 'feeding back' to the preceding element (demonstrating meetings regulatory requirements) of the decision tree in figure A4-10.

However, it is possible that after undertaking product adjustments that the enterprise may decide not to continue. Hence the vertical 'no' arrow in figure A4-10 which indicates a 'lost opportunity'

- **Cost of delayed market entry** (action 4 in decision tree graphic) – The preceding elements take time and prevent immediate entry to the market. Enterprises suggest the average length of delay is about a month. They also report that the average cost

145 The average turnover of an intra-EU exporting enterprises is €215,000 per annum, see later research. Assuming production of a single product two per cent would represent €4,300. For the sake of simplicity, and to prevent making inaccurate assumptions about production costs in relation to turnover, it assumed that production costs of a single product could be equal to turnover (if margins on a product were small or the company was operating at break-even levels). This assumption could be a slight over-estimation, but users are able to adjust the model to reduce this assumption if this value is considered too high.

of delay is between one and ten per cent of turnover, the average value is four per cent. In the model this value can be adjusted, the default value is €8,600[146].

The preceding elements of the decision tree model have focused on the costs for businesses that decide to try and enter a market. Fairly robust insights to these costs have been obtained from businesses.

A further significant element that needs to be considered is the potential lost opportunity to those businesses that decide not to try and enter markets. These costs (from a lost opportunity) are independent from those of the business that do export and should regarded separately.

Lost opportunity costs are much harder to estimate. The majority of businesses in most sectors do not export for a wide variety of reasons. The proportion of businesses deciding not to export due to one reason - the sub-optimal functioning of the Mutual Recognition principle - is very difficult to estimate. Nonetheless, for completeness this study provides a transparent estimate of the possible number of businesses and the value of lost trade. These subjective assumptions are explicitly presented below and the spread sheet model enables relevant values to be adjusted to enable sensitivity analysis.

- **Lost opportunity** (action 1 in decision tree graphic) – Lost opportunity is difficult to investigate because it represents the outcome of a 'do nothing' option. However, logic would dictate that if rewards were high enough all enterprises would do something. Therefore the enterprises that 'do nothing' are probably those that predict that perceived costs of the preceding elements (actions 2 and 3) will be greater than the benefits they might receive, plus a small 'premium for the risk' of 'doing something'.

Enterprises suggest their estimate of lost opportunities was between one and ten per cent of turnover, with an average value of 3.5 per cent of turnover. This represents an average value for of intra-EU exporting enterprises of €7,525 per annum.

The other difficulty concerning 'lost opportunities' is the number of enterprises that might have seriously considered exporting. The average number of enterprises undertaking intra-EU exporting of non-harmonised products is 14.7 per cent (262,940 enterprises). Clearly it would not be reasonable to assume that the remaining 85.3 per cent (approx. 1,520,000) of enterprises producing non-harmonised products but not exporting should be included in 'lost opportunity' calculations. Interviews with enterprises did not provide an insight to their perceptions of lost opportunity because those willing to respond were all exporters. The model therefore assumes that the number of enterprises seriously considering intra-EU exporting, but deciding not to go ahead, will be twice the number that actually do export. In the model the number of enterprises that incur a 'lost opportunity' is set at 29 per cent (twice the 14.7 per cent that export; 441,000 enterprises) of non-harmonised producing enterprises that do not export, this value can be adjusted in the model.

146 See the above footnote for an explanation of turnover in relation to production costs.

The decision tree has been developed into a model that can be adjusted (for the key components documented above, in a manner similar to sensitivity analysis), to estimate the costs of sub-optimal functioning of the Mutual Recognition principle. The methodology is founded on the analysis of the value of intra EU exports (in non-harmonised products) presented in the preceding chapter. Previous analysis in this study focused on the Standard International Trade Classification (a classification of goods used to classify the exports and imports - SITC). Data related to this classification did not provide an accurate insight into the number of enterprises in the sectors or the proportion undertaking Intra-EU exporting.

The decision tree has been developed into a model that can be adjusted (for the key components documented above, in a manner similar to sensitivity analysis), to estimate the cost of sub-optimal functioning of the Mutual Recognition principle. The methodology is founded on analysis of the value of intra EU exports (in non-harmonised products) presented in the preceding chapter. Previous analysis in this study (submitted in December 2016) focused on the Standard International Trade Classification (a classification of goods used to classify the exports and imports - SITC). Data related to this classification did not provide an accurate insight into the number of enterprises in the sectors or the proportion undertaking Intra-EU exporting.

The current approach therefore uses the statistical classification of economic activities in the European Community, abbreviated as NACE[147]. This approach provides more granular insights and importantly detailed insights into the number of enterprises in sectors and exporting. Enterprise level data enables 'real-world' insights from interviews with enterprises, undertaken during the study, to be introduced into the model. This overcomes the shortcoming earlier in the study (due to a lack of information about the number of enterprises with SITC data) of making assumptions about enterprise exports and the number of companies undertaking intra-EU exports.

### *4.2.2. The Sub-optimal Functioning of the Mutual Recognition model*

Like any model the Sub-optimal Functioning of the Mutual Recognition model (henceforth called the SFMR model) is a simplified framework designed to illustrate complex processes, using mathematical techniques. The model establishes an argumentative framework for applying logic and mathematics that can be independently discussed and tested and that can be applied in various instances. The model does not pretend to be a theoretical representation (such theories do not exist). Instead, it builds on previous conceptual studies and provides the basis for discussing key parameters and drawing conclusions from a model that is an approximate representation of economic facts. Feedback from the Commission has been beneficial in further refining the model and its underlying assumptions.

As noted above the model is a representation of reality. However, the values presented in the various components of the new model are founded on feedback from enterprises[148]. The default values, described earlier, are based on input from nine enterprises that took

147 http://ec.europa.eu/eurostat/statistics-explained/index.php/Glossary:Statistical_classification_of_economic_activities_in_the_European_Community_(NACE).

148 The previous SITC model was not based on enterprises so assumptions were generally 'unfounded'.

part in the first round of interviews. As more interviews with enterprises are completed the values presented in the various components of the model can be further refined. But it is not expected that values will change very much.

The model provides estimates of costs. It will probably be most useful in providing an insight to the relative differences of costs in different parts of the model and the different non-harmonised sectors. This should help policymakers to focus activities in the areas or sectors that offer the highest level of returns.

### *4.2.3. Number of enterprises undertaking non-harmonised trade*

The research team have developed an approach that converts SITC Trade volume (€) to NACE codes whilst aligning non-harmonised NACE categories. This can then be reliably cross-tabulated with Eurostat data on the number of enterprises exporting. EC studies have also investigated worldwide exports and intra-EU exporting at enterprise level. We have thus found a method to robustly estimate (from Eurostat data) the number of enterprises at EU28 level undertaking intra-EU exports.

Table A-4-7 provides an overview of trade volumes and the number of enterprises producing and intra-EU exporting non-harmonised products. The average number of enterprises intra-EU exporting is 14.7 per cent of enterprises (262,940) in the non-harmonised sectors. However, as the table indicates there is considerable variation between sectors – ranging from 10.6 per cent of enterprises in the 'Other manufacturing, and repair and installation of machinery and equipment' (but this still represents 65,227 enterprises) to 35.2 per cent in the 'Manufacture of computer, electronic and optical products' sector, despite the relatively high percentage figure the number of enterprises intra-EU exporting is only 1,766.

If policymakers decided to focus improvements on the sectors with the highest number of enterprises they should select the 'Manufacture of wood and paper products, and printing' (71,706) intra-EU exporting enterprises) and 'Other manufacturing, and repair and installation of machinery and equipment' (65,227). These two sectors comprise 136,933 enterprises or 52 per cent of intra-EU exporting enterprises.

Interestingly these two sectors also comprise the enterprises with some of the lowest average turnover in the nine non-harmonised sectors examined in this analysis (wood €156,000 per enterprise per annum, other manufacturing €44,000). These relatively small sized/turnover enterprises are probably the least able to afford costs associated with meeting or demonstrating market requirements in other EU Member States (estimated at €9073 for enterprises adjusting products and demonstrating market compliance). It must be highlighted that these observations relate to average enterprises sizes, larger and smaller enterprises will obviously operate in the markets.

**Table A4-7: Trade volume and enterprises undertaking non-harmonised intra-EU exporting**

| | Non-harmonised intra-EU trade (€ million) | Non harmonised enterprises | % Intra-EU exporting enterprises | Intra-EU exporting enterprises | Avg, Non harmonised enterprise turnover (€m) |
|---|---|---|---|---|---|
| Manufacture of basic metals and fabricated metal products, except machinery and equipment | 46,370 | 105,361 | 16.6 | 17,490 | 0.440 |
| Manufacture of coke, and refined petroleum products | 17 | 101 | 33.0 | 33 | 0.168 |
| Manufacture of computer, electronic and optical products | 16,019 | 5,017 | 35.2 | 1,766 | 3.193 |
| Manufacture of food products, beverages and tobacco products | 4,187 | 42,976 | 12.0 | 5,157 | 0.097 |
| Manufacture of rubber and plastics products, and other non-metallic products | 13,834 | 110,615 | 32.5 | 35,950 | 0.125 |
| Manufacture of textiles, apparel, leather and related products | 66,094 | 368,439 | 17.0 | 62,635 | 0.179 |
| Manufacture of transport equipment | 127,466 | 8,728 | 34.1 | 2,976 | 14.604 |
| Manufacture of wood and paper products, and printing | 82,438 | 527,248 | 13.6 | 71,706 | 0.156 |
| Other manufacturing, and repair and installation of machinery and equipment | 26,927 | 615,353 | 10.6 | 65,227 | 0.044 |
| **Total** | **€383,352** | **1,783,838** | **14.7%** | **262,940** | **€0.215m** |

Source: Structural Business Statistics

Costs associated with the decision tree model

Table A4-8 uses the evidence based default values presented in section 4.2.1 to provide an overview of costs associated with market entry for non-harmonised products.

**Table A4-8: Enterprise costs associated with market entry for non-harmonised products**

| | Demonstrating regulatory requirements (Model Action 2) (€m) | Product adjustment and demonstrating requirements (Actions 2 & 3) (€m) | Cost of delayed market entry (Action 4) (€m) | **Total Cost (€m)** |
|---|---|---|---|---|
| Manufacture of basic metals and fabricated metal products, except machinery and equipment | 41.8 | 79.3 | 308 | **429** |
| Manufacture of coke, and refined petroleum products | 0.1 | 0.2 | 0.2 | **0.5** |
| Manufacture of computer, electronic and optical products | 4.2 | 8.0 | 226 | **238** |
| Manufacture of food products, beverages and tobacco products | 12.3 | 23.4 | 20 | **56** |
| Manufacture of rubber and plastics products, and other non-metallic products | 85.8 | 163.1 | 180 | **429** |
| Manufacture of textiles, apparel, leather and related products | 149.5 | 284.2 | 449 | **883** |
| Manufacture of transport equipment | 7.1 | 13.5 | 1,739 | **1,759** |
| Manufacture of wood and paper products, and printing | 171.2 | 325.3 | 448 | **945** |
| Other manufacturing, and repair and installation of machinery and equipment | 155.7 | 295.9 | 114 | **566** |
| **Total** | **€628m** | **€1,193m** | **€3,484m** | **€5,305m** |

| | Demonstrating regulatory requirements (Model Action 2) (€m) | Product adjustment and demonstrating requirements (Actions 2 & 3) (€m) | Cost of delayed market entry (Action 4) (€m) | **Total Cost (€m)** |
|---|---|---|---|---|
| **Average per enterprise** | **€4,775** | **€9,073** | **€8,596** | |

Table A4-8 provides an overview of the costs of getting one non-harmonised product into a single EU Member State. The table shows that in nearly all sectors the lowest proportion of costs (average €4,775 per enterprise) is associated with demonstrating meeting regulatory requirements. Section 4.2.1 noted that on average these represented only 80 hours of time per enterprise.

Costs are obviously increased for enterprises that incur this regulatory cost and undertake product adjustments, on average these costs are €9,073 per enterprise undertaking this route to intra-EU exporting.

The largest costs are associated with a delay in market entry, this was estimated to cost four per cent of turnover or approximately €8,596 per enterprise.

*4.2.4. Lost Opportunity*

The estimate presented in **Error! Not a valid bookmark self-reference.** uses a multiplicand of 441,000 enterprises (previously described in section 4.1 as the number suffering a lost opportunity at twice the number that actually do export, this equates to 29 per cent of non-harmonised non-exporting enterprises). This provides an average value for intra-EU exporting enterprises of €7,525 per annum.

Table A4-9 provides an overview of the level and cost of lost opportunities in the sectors examined. Section 4.2.1 noted that this element of the model is more subjective and enterprises choose not export for a wide variety of reasons. The proportion of enterprises not exporting due to the sub-optimal functioning of the Mutual Recognition principle is very difficult to estimate. The model assumes that the number of enterprises seriously considering intra-EU exporting, but deciding not to go ahead, will be twice the number that actually do export. The number of enterprises that incur a 'lost opportunity' is set at 27 per cent in the model (twice the 14.7 per cent that do export of non-harmonised products), this value can be adjusted in the model. Section 4.2.1 also highlighted that enterprises estimated lost opportunities averaged a value of 3.5 per cent of turnover. The estimate presented in **Error! Not a valid bookmark self-reference.** uses a multiplicand of 441,000 enterprises (previously described in section 4.1 as the number suffering a lost opportunity at twice the number that actually do export, this equates to 29 per cent of non-harmonised non-exporting enterprises). This provides an average value for intra-EU exporting enterprises of €7,525 per annum.

Table A4-9: Enterprise costs associated with lost opportunities for intra-EU exporting

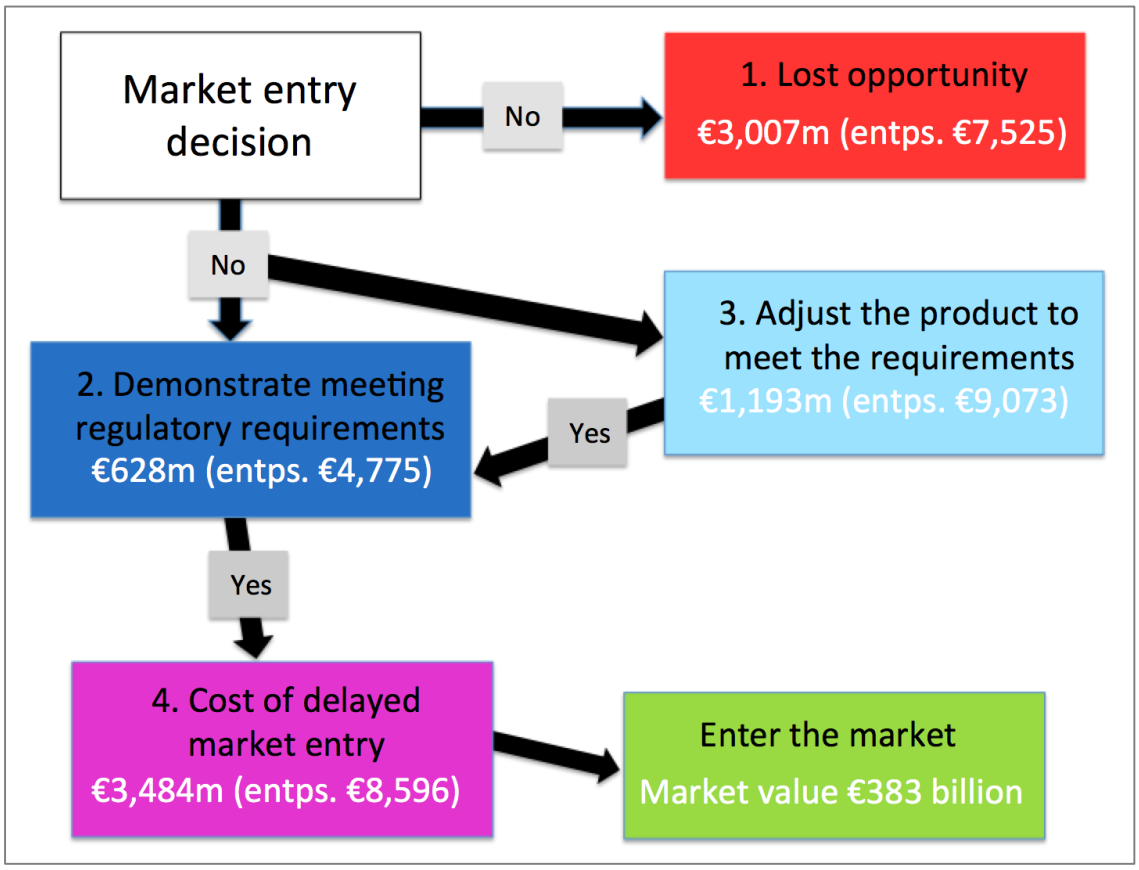
| | Estimate of lost opportunity (€m) |
|---|---|

| | Estimate of lost opportunity (€m) |
|---|---|
| Manufacture of basic metals and fabricated metal products, except machinery and equipment | 393 |
| Manufacture of coke, and refined petroleum products | 0.1 |
| Manufacture of computer, electronic and optical products | 105 |
| Manufacture of food products, beverages and tobacco products | 37 |
| Manufacture of rubber and plastics products, and other non-metallic products | 95 |
| Manufacture of textiles, apparel, leather and related products | 557 |
| Manufacture of transport equipment | 853 |
| Manufacture of wood and paper products, and printing | 723 |
| Other manufacturing, and repair and installation of machinery and equipment | 244 |
| **Total** | **€3,007m** |
| **Average per enterprise** | **€7,525** |

### *4.2.5. The Sub-optimal Functioning of the Mutual Recognition (SFMR) model*

Figure A4-11 provides an overview of the key components of the model to estimate the costs of sub-optimal functioning of the Mutual Recognition principle. Preceding sections have described each component of the model and the assumptions used in calculations. As noted earlier, it is important to stress that the model provides costs associated with an enterprise introducing one product into one EU Member State.

**Figure A4-11: Costs and lost opportunity calculations associated with the decision tree diagram for export decisions associated with products not covered by the Mutual Recognition principle**




As noted earlier The SFMR model has been developed as an MS excel spreadsheet. It enables users to change the values of all the key assumptions.

The final component of the model enables users to enter values for enterprises introducing more than one product into more than one EU Member States per annum. The model does not take account of whether exporting enterprises will continue to export in later years, nor does it examine any further costs associated with the sub-optimal functioning of the Mutual Recognition principle.

**Table A4-10: Results of sensitivity analysis examining different numbers of products and Member States targeted by exporters per annum**

| | Demonstrating regulatory requirements (€m) | Product adjustment and demonstrating requirements (€m) | Cost of delayed market entry (€m) | **Total Cost (€m)** | **Avg. per enterprise (€)** |
|---|---|---|---|---|---|
| One product in one EU Member State | 628 | 1,193 | 3,484 | **5,305** | **€20,175** |
| One product in 14 EU Member States | 8,789 | 16,700 | 48,780 | **74,270** | **€282,460** |
| One product in 28 EU Member States | 17,579 | 33,400 | 97,561 | **148,540** | **€564,919** |
| Five products in one EU Member State | 3,140 | 5,960 | 17,420 | **26,525** | **€100,879** |
| Five products in 14 EU Member State | 43,946 | 83,501 | 243,902 | **371,350** | **€1,412,299** |

| | Demonstrating regulatory requirements (€m) | Product adjustment and demonstrating requirements (€m) | Cost of delayed market entry (€m) | **Total Cost (€m)** | **Avg. per enterprise (€)** |
|---|---|---|---|---|---|
| Five products in 28 EU Member State | 87,900 | 167,000 | 487,800 | **742,700** | **€2,824,598** |

Table A4-10 provides an overview of costs associated with different numbers of products and different numbers of Member States targeted for exporting.

Table A4-7 highlighted that the value of intra-EU exporting is €383 billion and the average turnover per intra-EU exporting enterprise is €215,000. Many of the scenarios presented in Table A4-10 would therefore appear to be unrealistic. Most enterprises would not be able to afford the costs associated with multiple products or markets (for many of the scenarios in Table A4-10 costs per enterprise are above the average enterprise turnover). Equally, it is unrealistic to assume that costs associated with market entry would come close to or exceed the total size of the market (see the two final scenarios in Table A4-10; in relation to the value of intra-EU exporting [€383 billion].

This observation about the number of products being developed matches the results from the enterprises. Only one claimed to be developing more than one product a year for EU exports. This company, with 48 employees, was also the only one providing an insight to the number of EU countries targeted for new products – it was targeting only two Member States.

### *4.2.6. Conclusion*

The SFMR presents a model to estimate the magnitude of the problem. It should be possible to make revisions to the model when additional feedback from enterprises is derived from the case study component of the research.

Due to the nature of the problem and complexities and costs that would be associated with a detailed evaluation it is not possible to undertake a complete evaluation of the problem. The model therefore contains assumptions that have been fully explained in preceding sections. Assumptions in the model are based on feedback from exporting enterprises[149]. Commentators and observers might have different views concerning some of the assumptions. Without further evidence no single viewpoint should be regarded as 'correct'. For this reason values associated with assumptions in the model can be changed. And changes (to 'default' values) can be made when field research is complete.

Nonetheless, the model still has provided an estimate of costs associated with the sub-optimal functioning of the Mutual Recognition principle. Table A4-8 provides an overview of the assumptions (in brackets) and key results described in preceding sections.

149 Eight in total as at 24th February. But results are surprisingly consistent between enterprises. The decision tree and model have evolved as the product has developed (this has posed new areas to discuss with enterprises as the study has developed); so further information is being sought during case study interviews.

## ANNEX 5 HARMONISED NON-HARMONISED AND PARTIALLY HARMONISED PRODUCTS-SECTOR AND PRODUCT LEVEL ANALYSIS

### 1. HARMONISED, NON-HARMONISED AND PARTIALLY HARMONISED SECTORS - CLASSIFICATION USED IN THE MARKET ANALYSIS (SECTORIAL LEVEL)[150]

| NACE Group | Description | Harmonized |
|---|---|---|
| C101 | Processing and preserving of meat and production of meat products | harmonized |
| C102 | Processing and preserving of fish, crustaceans and molluscs | harmonized |
| C103 | Processing and preserving of fruit and vegetables | harmonized |
| C104 | Manufacture of vegetable and animal oils and fats | harmonized |
| C105 | Manufacture of dairy products | harmonized |
| C106 | Manufacture of grain mill products, starches and starch products | harmonized |
| C107 | Manufacture of bakery and farinaceous products | harmonized |
| C108 | Manufacture of other food products | no/partially |
| C109 | Manufacture of prepared animal feeds | no/partially |
| C110 | Manufacture of beverages | no/partially |
| C120 | Manufacture of tobacco products | no/partially |
| C131 | Preparation and spinning of textile fibres | no/partially |
| C132 | Weaving of textiles | no/partially |
| C133 | Finishing of textiles | no/partially |
| C139 | Manufacture of other textiles | harmonized |
| C141 | Manufacture of wearing apparel, except fur apparel | harmonized |
| C142 | Manufacture of articles of fur | no/partially |
| C143 | Manufacture of knitted and crocheted apparel | harmonized |

150 A level 3 (three-digit code) of the hierarchy of codes in NACE was used

| NACE Group | Description | Harmonized |
|---|---|---|
| C151 | Tanning and dressing of leather; manufacture of luggage, handbags, saddlery and harness; dressing and dyeing of fur | no/partially |
| C152 | Manufacture of footwear | harmonized |
| C161 | Sawmilling and planning of wood | no/partially |
| C162 | Manufacture of products of wood, cork, straw and plaiting materials | no/partially |
| C171 | Manufacture of pulp, paper and paperboard | no/partially |
| C172 | Manufacture of articles of paper and paperboard | no/partially |
| C181 | Printing and service activities related to printing | no/partially |
| C182 | Reproduction of recorded media | no/partially |
| C191 | Manufacture of coke oven products | no/partially |
| C192 | Manufacture of refined petroleum products | no/partially |
| C201 | Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms | harmonized |
| C202 | Manufacture of pesticides and other agrochemical products | harmonized |
| C203 | Manufacture of paints, varnishes and similar coatings, printing ink and mastics | harmonized |
| C204 | Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations | harmonized |
| C205 | Manufacture of other chemical products | harmonized |
| C206 | Manufacture of man-made fibres | no/partially |
| C211 | Manufacture of basic pharmaceutical products | no/partially |
| C212 | Manufacture of pharmaceutical preparations | harmonized |
| C221 | Manufacture of rubber products | harmonized |
| C222 | Manufacture of plastics products | harmonized |
| C231 | Manufacture of glass and glass products | harmonized |

| NACE Group | Description | Harmonized |
|---|---|---|
| C232 | Manufacture of refractory products | no/partially |
| C233 | Manufacture of clay building materials | harmonized |
| C234 | Manufacture of other porcelain and ceramic products | no/partially |
| C235 | Manufacture of cement, lime and plaster | harmonized |
| C236 | Manufacture of articles of concrete, cement and plaster | harmonized |
| C237 | Cutting, shaping and finishing of stone | no/partially |
| C239 | Manufacture of abrasive products and non-metallic mineral products n.e.c. | no/partially |
| C241 | Manufacture of basic iron and steel and of ferro-alloys | no/partially |
| C242 | Manufacture of tubes, pipes, hollow profiles and related fittings, of steel | harmonized |
| C243 | Manufacture of other products of first processing of steel | no/partially |
| C244 | Manufacture of basic precious and other non-ferrous metals | no/partially |
| C245 | Casting of metals | harmonized |
| C251 | Manufacture of structural metal products | harmonized |
| C252 | Manufacture of tanks, reservoirs and containers of metal | harmonized |
| C253 | Manufacture of steam generators, except central heating hot water boilers | harmonized |
| C254 | Manufacture of weapons and ammunition | no/partially |
| C255 | Forging, pressing, stamping and roll-forming of metal; powder metallurgy | no/partially |
| C256 | Treatment and coating of metals; machining | harmonized |
| C257 | Manufacture of cutlery, tools and general hardware | no/partially |
| C259 | Manufacture of other fabricated metal products | harmonized |
| C261 | Manufacture of electronic components and boards | harmonized |
| C262 | Manufacture of computers and peripheral equipment | harmonized |

| NACE Group | Description | Harmonized |
|---|---|---|
| C263 | Manufacture of communication equipment | harmonized |
| C264 | Manufacture of consumer electronics | harmonized |
| C265 | Manufacture of instruments and appliances for measuring, testing and navigation; watches and clocks | harmonized |
| C266 | Manufacture of irradiation, electromedical and electrotherapeutic equipment | harmonized |
| C267 | Manufacture of optical instruments and photographic equipment | no/partially |
| C268 | Manufacture of magnetic and optical media | no/partially |
| C271 | Manufacture of electric motors, generators, transformers and electricity distribution and control apparatus | harmonized |
| C272 | Manufacture of batteries and accumulators | harmonized |
| C273 | Manufacture of wiring and wiring devices | harmonized |
| C274 | Manufacture of electric lighting equipment | harmonized |
| C275 | Manufacture of domestic appliances | harmonized |
| C279 | Manufacture of other electrical equipment | harmonized |
| C281 | Manufacture of general-purpose machinery | harmonized |
| C282 | Manufacture of other general-purpose machinery | harmonized |
| C283 | Manufacture of agricultural and forestry machinery | harmonized |
| C284 | Manufacture of metal forming machinery and machine tools | harmonized |
| C289 | Manufacture of other special-purpose machinery | harmonized |
| C291 | Manufacture of motor vehicles | harmonized |
| C292 | Manufacture of bodies (coachwork) for motor vehicles; manufacture of trailers and semi-trailers | no/partially |
| C293 | Manufacture of parts and accessories for motor vehicles | no/partially |
| C301 | Building of ships and boats | harmonized |

| NACE Group | Description | Harmonized |
|---|---|---|
| C302 | Manufacture of railway locomotives and rolling stock | harmonized |
| C303 | Manufacture of air and spacecraft and related machinery | no/partially |
| C304 | Manufacture of military fighting vehicles | no/partially |
| C309 | Manufacture of transport equipment n.e.c. | no/partially |
| C310 | Manufacture of furniture | no/partially |
| C321 | Manufacture of jewellery, bijouterie and related articles | no/partially |
| C322 | Manufacture of musical instruments | no/partially |
| C323 | Manufacture of sports goods | harmonized |
| C324 | Manufacture of games and toys | harmonized |
| C325 | Manufacture of medical and dental instruments and supplies | harmonized |
| C329 | Manufacturing n.e.c. | harmonized |
| C331 | Repair of fabricated metal products, machinery and equipment | no/partially |
| C332 | Installation of industrial machinery and equipment | no/partially |

## 2. PRODUCTS CLASSIFIED AS NON OR PARTIALLY HARMONISED IN THE MARKET ANALYSIS (PRODUCT LEVEL) [151] BY SECTOR

| Nace code | Description |
|---|---|
| **Manufacture of food products, beverages and tobacco products** | |
| 10.89 | Manufacture of other food products n.e.c. |
| 12.00 | Manufacture of tobacco products |
| **Manufacture of textiles, apparel, leather and related products** | |
| 13.10 | Preparation and spinning of textile fibres |

151 All PRODCOM codes under the level 4 (four-digit code) NACE hierarchy included in the table **are considered as non or partially harmonised** in the Market Analysis at product level.

| | |
|---|---|
| 13.20 | Weaving of textiles |
| 13.30 | Finishing of textiles |
| 13.91 | Manufacture of knitted and crocheted fabrics |
| 13.93 | Manufacture of carpets and rugs |
| 13.94 | Manufacture of cordage, rope, twine and netting |
| 13.95 | Manufacture of non-wovens and articles made from non-wovens, except apparel |
| 13.96 | Manufacture of other technical and industrial textiles |
| 13.99 | Manufacture of other textiles n.e.c. |
| 14.11 | Manufacture of leather clothes |
| 14.20 | Manufacture of articles of fur |
| 15.11 | Tanning and dressing of leather; dressing and dyeing of fur |
| 15.12 | Manufacture of luggage, handbags and the like, saddlery and harness |
| 15.20 | Manufature of footware |
| **Manufacture of wood and paper products, and printing** | |
| 16.10 | Sawmilling and planing of wood |
| 16.21 | Manufacture of veneer sheets and wood-based panels |
| 16.22 | Manufacture of assembled parquet floors |
| 16.23 | Manufacture of other builders' carpentry and joinery |
| 16.24 | Manufacture of wooden containers |
| 16.29 | Manufacture of other products of wood; manufacture of articles of cork, straw and plaiting materials |
| 17.11 | Manufacture of pulp |
| 17.12 | Manufacture of paper and paperboard |
| 17.21 | Manufacture of corrugated paper and paperboard and of containers of paper and paperboard |
| 17.22 | Manufacture of household and sanitary goods and of toilet requisites |
| 17.23 | Manufacture of paper stationery |
| 17.24 | Manufacture of wallpaper |
| 17.29 | Manufacture of other articles of paper and paperboard |

| | |
|---|---|
| 18.11 | Printing of newspapers |
| 18.12 | Other printing |
| 18.13 | Pre-press and pre-media services |
| 18.14 | Binding and related services |
| 18.20 | Reproduction of recorded media |
| **Manufacture of coke, and refined petroleum products** | |
| 19.10 | Manufacture of coke oven products |

| | |
|---|---|
| **Manufacture of chemicals and chemical products** | |
| ***All products within this sector have been considered as harmonised*** | |
| **Manufacture of pharmaceuticals, medicinal chemical and botanical products** | |
| ***All products within this sector have been considered as harmonised*** | |
| **Manufacture of rubber and plastics products, and other non-metallic mineral products** | |
| 23.19 | Manufacture and processing of other glass, including technical glassware |
| 23.41 | Manufacture of ceramic household and ornamental articles |
| 23.44 | Manufacture of other technical ceramic products |
| 23.49 | Manufacture of other ceramic products |
| 23.69 | Manufacture of other articles of concrete, plaster and cement |
| 23.70 | Cutting, shaping and finishing of stone |
| 23.91 | Production of abrasive products |
| 23.99 | Manufacture of other non-metallic mineral products n.e.c. |
| **Manufacture of basic metals and fabricated metal products, except machinery and equipment** | |
| 24.31 | Cold drawing of bars |
| 24.32 | Cold rolling of narrow strip |
| 24.33 | Cold forming or folding |
| 24.34 | Cold drawing of wire |
| 25.12 | Manufacture of doors and windows of metal |
| 25.40 | Manufacture of weapons and ammunition |
| 25.50 | Forging, pressing, stamping and roll-forming of metal; powder metallurgy |
| 25.71 | Manufacture of cutlery |
| 25.72 | Manufacture of locks and hinges |
| 25.73 | Manufacture of tools |
| **Manufacture of computer, electronic and optical products** | |
| 26.52 | Manufacture of watches and clocks |
| 26.70 | Manufacture of optical instruments and photographic equipment |

| | |
|---|---|
| **Manufacture of electrical equipment** | |
| 27.52 | Manufacture of non-electric domestic appliances |
| **Manufacture of machinery and equipment n.e.c.** | |
| ***All products within this sector have been considered as harmonised*** | |
| **Manufacture of transport equipment** | |
| 29.20 | Manufacture of bodies (coachwork) for motor vehicles; manufacture of trailers and semi-trailers |
| 29.31 | Manufacture of electrical and electronic equipment for motor vehicles |
| 29.32 | Manufacture of other parts and accessories for motor vehicles |
| 30.99 | Manufacture of other transport equipment n.e.c. |
| **Other manufacturing, and repair and installation of machinery and equipment** | |
| 31.01 | Manufacture of office and shop furniture |
| 31.02 | Manufacture of kitchen furniture |
| 31.03 | Manufacture of mattresses |
| 31.09 | Manufacture of other furniture |
| 32.11 | Striking of coins |
| 32.12 | Manufacture of jewellery and related articles |
| 32.13 | Manufacture of imitation jewellery and related articles |
| 32.20 | Manufacture of musical instruments |
| 32.91 | Manufacture of brooms and brushes |
| 33.11 | Repair of fabricated metal products |
| 33.12 | Repair of machinery |
| 33.13 | Repair of electronic and optical equipment |
| 33.14 | Repair of electrical equipment |
| 33.15 | Repair and maintenance of ships and boats |
| 33.16 | Repair and maintenance of aircraft and spacecraft |
| 33.17 | Repair and maintenance of other transport equipment |
| 33.19 | Repair of other equipment |

| | |
|---|---|
| 33.20 | Installation of industrial machinery and equipment |

## ANNEX 6 – MAIN FINDINGS OF THE EVALUATION OF THE REFIT EVALUATION ON THE PRINCIPLE OF MUTUAL RECOGNITION AND THE MUTUAL RECOGNITION REGULATION NO (EC) 764/2008

Mutual recognition is seminal for a proper functioning of the single market for goods. It consists of a principle, embedded in Articles 34 and 36 of the Treaty on the Functioning of the European Union (TFEU), and further elaborated on case law, and of a legal act, Regulation (EC) No 764/2008 (the Mutual Recognition Regulation), defining the practical modalities of its implementation.

If a business is lawfully selling a product in one Member State, it should be able to sell it in other Member States without adapting it to the national rules of that Member State, even when there are no common European rules on how the product has to be manufactured (rules on i.e. characteristics of the product, size, composition, etc.). The right to sell a product lawfully marketed in another Member State[152] can be refused only when the Member State of destination has diverging product requirements whose mandatory imposition is justified by the need to protect a certain public interests, and those requirements are necessary and proportionate for achieving that objective. This is the principle of mutual recognition in the field of goods. The application of the principle proved to be problematic in practice. Therefore, in 2008, the Mutual Recognition Regulation was adopted. It introduces procedural guarantees to ensure on one hand that businesses can easily invoke their right to mutual recognition, and on the other hand that Member States use their right to deny mutual recognition in the light of the proportionality principle.

This evaluation assessed the functioning of mutual recognition in the field of goods, i.e. the mutual recognition principle and the Mutual Recognition Regulation. It looked to what extent mutual recognition has achieved its original objectives in term of effectiveness, efficiency, relevance, coherence, and EU value-added.

### Effectiveness

The evaluation assessed the extent to which mutual recognition achieved its objectives. The general objective of the mutual recognition principle and Regulation was **to facilitate free movement of goods in the non-harmonised area.** Additionally, the Regulation had the following specific objectives:

- *To increase awareness about the mutual recognition principle ,*
- *To ensure legal certainty when using the mutual recognition principle,*
- *To improve administrative cooperation among national authorities when applying the mutual recognition principle*

Overall, the findings of the evaluation show that the principle and the Regulation did not meet their objectives. Businesses are still encountering numerous obstacles to the free movement of products lawfully marketed in another Member State. During the 2016 public consultation, they were ranked as the main obstacle to challenging administrative decisions denying market access, followed by insufficient administrative cooperation and

152 Applies also to EEA products

lack of awareness about mutual recognition. The tools put in place by the Regulation in order to ensure awareness, i.e. the Product Contact Points, had a limited effect, mainly due to their suboptimal functioning. Businesses still don't know when mutual recognition can be used for entering a market and what their rights are. Furthermore, the mutual recognition clause has not shed sufficient light on when mutual recognition is applicable. Despite the regular recommendations by the Commission to insert the clause in draft national legislation notified following Directive (EU) 2015/1535[153], or to redraft it in order to ensure clarity, its use is still poor.

The tools put in place by the Regulation had also a very limited effect on increasing legal certainty when using the mutual recognition principle. The lack of legal certainty appears to remain a major obstacle to unleashing the full potential of the principle, and the main reason why Member States and businesses are reluctant towards mutual recognition.

As regards administrative cooperation, it still needs to be enhanced in order to facilitate the application of the mutual recognition principle.

The weak use of the principle of mutual recognition and the very limited impacts the Regulation had in achieving the foreseen objectives of ensuring free movement of goods in the Single Market points that there is a lot of potential to be unleashed. Estimating accurately the magnitude of this unleashed potential is not straightforward, due to the complex nature of mutual recognition and the wide variety of products to which it applies. However, several elements indicate that the suboptimal use of mutual recognition triggers significant costs and that improving its functioning would bring significant benefits. The comparison of the value of the intra EU exports with domestic consumption[154] shows that for harmonised products the value of intra EU exports is **110%** of domestic consumption, while for the non-harmonised and partially harmonised goods it represents only **39%.** Therefore, in terms of priorities for the Commission to remedy to the ineffectiveness of the regulation, national authorities and citizens ranked first the need to increase awareness of the mutual recognition principle, while businesses stressed their need for effective remedies to take action against decisions denying market access. If the consultation did not result in a representative sample of sectors, company type and Member States, it provides however a good indication of areas where the scope of mutual recognition can be improved. Furthermore, the difficulties in terms of gathering useful data on the functioning of mutual recognition needs to be addressed, in order to allow a clearer picture of how the principle functions and on its impacts on the free movement of goods.

**Table A6-1: 2016 public consultation**

| **Ranking of priorities by businesses** | |
|---|---|
| Ensure that businesses have effective remedies at their disposal to take action against decisions denying mutual recognition when needed | 72% |
| Increase legal certainty for businesses when using mutual recognition to sell products abroad | 67% |
| Ensure that the procedures are duly followed when decisions denying market | 65% |

153 OJ L 241, 17.9.2015, p. 1–15
154 Value of production-value of extra EU exports +value of intra EU imports

| | |
|---|---|
| access are taken by national authorities | |
| Increase effectiveness of mutual recognition to facilitate access to the internal market | 64% |
| Facilitate communication between all actors involved in mutual recognition (business, national authorities, European Commission) | 54% |
| Increase general awareness of the mutual recognition principle | 52% |

**Table A6-2: 2016 public consultation**

| Ranking of priorities by Member States | |
|---|---|
| Increase general awareness of the mutual recognition principle | 51% |
| Ensure that the procedures are duly followed when decisions denying market access are taken by national authorities | 42% |
| Ensure that businesses have effective remedies at their disposal to take action against decisions denying mutual recognition when needed | 40% |
| Increase effectiveness of mutual recognition to facilitate access to the internal market | 35% |
| Increase legal certainty for businesses when using mutual recognition to sell products abroad | 33% |
| Facilitate communication between all actors involved in mutual recognition (business, national authorities, European Commission) | 31% |

**Table A6-3: 2016 public consultation**

| Ranking of priorities by citizens | |
|---|---|
| Increase general awareness on the mutual recognition principle | 64% |
| Increase legal certainty for businesses when using mutual recognition to sell products abroad | 52% |
| Ensure that businesses have effective remedies at their disposal to take action against decisions denying mutual recognition when needed | 47% |
| Increase effectiveness of mutual recognition to facilitate access to the internal market | 41% |
| Ensure that the procedures are duly followed when decisions denying market | 35% |

| | |
|---|---|
| access are taken by national authorities | |
| Facilitate communication between all actors involved in mutual recognition (business, national authorities, European Commission) | 23% |

**Efficiency**

Overall, the evaluation concluded that the suboptimal use of mutual recognition creates additional costs for businesses and prevents them from taking advantage of the benefits that mutual recognition might bring. Due to the difficulty of gathering accurate data on mutual recognition, it was not possible to establish the global costs incurred by businesses. But sectoral evidence and the results of the different surveys and consultations carried out although not representative show that the costs are significant. Relevant stakeholders were consulted in order to evaluate to what extend the costs generated by using the principle and the Regulation are proportionate to the benefits it achieved. In terms of costs, the Regulation generated few costs for national authorities: the implementation and functioning of the PCPs (EURO 7417-47 450, based on 1 FTE) and the costs related to the assessment of products lawfully marketed in another Member State (EURO 420 000 in one sector such as fertilisers). They consider these costs to be average. The main costs incurred by businesses are rather due to the incorrect application of mutual recognition. They have to adapt their products, duplicate tests and procedures (EURO 1000-150 000 per product and market), or lose opportunities (EURO 40 000-500 000 per product and market) because they are obliged to renounce entering a new market. Most of these costs were considered to be important. In terms of costs-benefits, the perception is quite mixed. While national authorities tend to agree that the costs are proportionate to the benefits, businesses mostly disagree. They consider that the costs are significant, while the benefits were not achieved.

A better functioning mutual recognition would reduce the costs incurred by businesses when they are obliged to adapt their products or to give up entering a market, while allowing all of the benefits listed above. A study done for the European Parliament[155] shows that a reduction of barriers to trade could lead to an increase in intra-EU trade of more than 100 billion EUR per year. The fact that mutual recognition does not function well is, de facto, a regulatory burden triggering barriers to trade. Therefore, any efforts to improve the functioning of mutual recognition would result in simplifications for businesses, e.g. easier access to markets. The remaining costs (information costs and costs related to implementing the Regulation) would become negligible in the light of the full benefits achieved.

**Some practical illustrations at sectorial level**

Fertilisers

155 The Cost of Non- Europe in the Single Market, 'Cecchini Revisited', An overview of the potential economic gains from further completion of the European Single Market, CoNE 1/2014
http://www.europarl.europa.eu/RegData/etudes/STUD/2014/510981/EPRS_STU(2014)510981_REV1_EN.pdf

The EU fertiliser product market is an economic sector that has between EUR 20 billion and EUR 25 billion in annual turnover and approximately 100 000 jobs[156]. It is partly covered by the harmonised legislation[157] regulating inorganic fertilisers, leaving the other fertilising materials regulated at national level. Thus, intra-EU movement of national fertilisers should be covered by the principle of mutual recognition, but most Member States expressed a strong reluctance to accept mutual recognition due to environmental and human health concerns, socio-economic aspects, and alleged administrative burden and introduced prior authorisation procedures[158].

The ex-post evaluation of the Fertilisers Regulation and the implications of the entry into force of the Mutual Recognition Regulation for the fertilising products sector[159] found that in 2009, the year of entry into force of MRR, an annual average of no more than 5 to 10 fertilising products had been placed on the market under the application of the procedures for mutual recognition in most Member States. Since then, the yearly reports of the Member States on the implementation of the Regulation show that 20 Member States out of 27 specifically mentioned issues relating to fertilising products. They are reported as one of the product categories for which economic operators submit many information requests to PCPs, which means that there is a significant interest in intra-EU trade, but that economic operators are uncertain about the requirements applicable in different Member States.

National producers often lack knowledge of the legal situation in other Member States and are unsure whether they should adapt their products to the requirements of the Member State of destination by modifying the product (which means additional costs) or if they can rely on Mutual Recognition procedures (which may cause a delay for access to the market and costs of prior authorisation procedure in some Member States). [160][161]

In order to solve the recurrent issues faced by economic operators in the area of fertilisers, an optional harmonisation solution was preferred for fertilising products that have not been harmonised.

Food supplements

Food supplements[162] are concentrated sources of nutrients (or other substances) with nutritional and physiological effect, marketed by business operators in the food sector. Such goods can be sold in "dose" form, such as pills, tablets and capsules, and could contain:

- *Nutrients (vitamins and minerals);*
- *Botanicals;*[163]

156 See http://ec.europa.eu/enterprise/sectors/chemicals/files/fertilizers/final_report__23jan2012_en.pdf
157 Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers, OJ L 304, 21.11.2003, p. 1
158 See also the guidance document on the application of the Mutual Recognition Regulation to prior authorisation procedures, 2010: http://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/index_en.htm
159 Available at: http://ec.europa.eu/growth/sectors/chemicals/specific-chemicals/index_en.htmas
160 See the Commission Staff Working Document - Impact Assessment accompanying the Proposal for a Regulation of the European Parliament and of the Council laying down rules on the making available on the market of CE marked fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 (COM(2016) 157 final)
161 See the Commission Proposal for a Regulation of the European Parliament and of the Council laying down rules on the making available on the market of CE marked fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009, (COM(2016) 157 final).
162 See annex 13 of the Evaluation for the full case study on food supplements

- *Other substances (e.g. amino acids).*

The three main issues linked to mutual recognition[164] are:

- *Maximum levels of vitamins and minerals*[165]
- *Substances other than Vitamins and Minerals*[166]
- *Botanicals and botanical preparation*[167]

Information collected from stakeholders show a very heterogeneous picture of the application of mutual recognition in the sector, with many issues faced by companies, relating to both differences in national procedures/requirements and to the specific nature of the various products included in the sector. Regarding the former, different Member States follow different procedures and rules, in addition to a very dissimilar recognition and application of the principle, creating issues and obstacles that companies may have to deal with when trying to enter a new market and often culminating in having different products for different countries. Regarding the latter, stakeholders highlight the complexity of a sector with many different products, ingredients and their combinations, under different levels of controls and requirements among Member States, making it difficult to have a uniform and clear picture of the whole sector and the possible strategies to overcome barriers.[168]

**Different countries, different rules**

Since the sector is not fully harmonised and has limited regulation at EU level,[169] companies and their products are subject to national legislation and mutual recognition. The main issues for companies arise from:

- **Different classification** of ingredients or substances: as already mentioned, some products may be classified as food supplements by a Member State, while another country – sometimes the very neighbour – can consider them to be medicines, therefore with completely different requirements, rules and procedures to be followed for their marketing;
- **Different levels** of ingredients or substances allowed. One of the most (and most differently) regulated elements is the level of ingredients (e.g. vitamins, minerals and other substances) allowed in a specific products at national level. Member States tend to have

163 Plant parts, concentrated sources of plants or their extracts or derivatives with a physiological effect.
164 Food Supplement Europe (2016), *Input into the REFIT of the Mutual Recognition Regulation 764/2008*.
165 Many Member States established national maximum levels for the amounts of vitamins and minerals in food supplements, while others preferred not to have specific maximum levels. The existence of particularly low levels applied in certain Member States, together with the large differences between the levels applied for the same substances across the EU, make it extremely difficult for companies to manufacture one single product for whole of the EU
166 Some Member States apply positive lists166 with specific conditions to their use. In addition, some Member States may consider certain ingredients as for medicinal use only
167 Botanicals are used in a wide variety of food supplements. Many Member States have positive lists, including conditions of use. The content of these lists differ widely, and certain botanicals are banned in different Member States because of medicinal status, while they are widely marketed as food supplements in others.
168 This is particularly true for botanical products: while the use of botanicals and other derived preparations need to be compliant with requirements of Regulation (EC) No 178/2002, stakeholders underlined how no real steps forward seem to have been made to clarify the framework, without a centralised authorisation procedure – which would be extremely helpful – for the use of botanicals or to determine the classification of botanicals as either medicines or food supplements. This, as well as the large differences among Member States in the definition of botanicals and lists of products/ingredients which are allowed or not, create an uncertain and difficult environment for companies to operate.
169 Some exceptions include the Regulation (EC) No 1924/2006 on nutrition and health claims, or Directive 2002/46/EC, with a list of substances that can be used for food supplement production, but whose implementation and monitoring is entrusted to the individual Member States.

their own levels that apply to the same products, creating problems for companies which need to adapt their products and formulas to comply;

- **Terminology and labels**: there may occur that terms and labels are not uniformly accepted across Europe (e.g. probiotic). This requires companies to change and adapt labels and packaging if it is the case.

In addition, it appears that there is not full uniformity in the national systems in place, with few Member States[170] that, unlike the others, do not rely on a **notification-based system**, which, according to stakeholders, may tend to constitute a sort of pre-market authorisation instead of a procedure to simply notifying national authorities about the products to be marketed and register information on labels.

In the end, what emerges is that there is not a real issue of complexity of procedures, but rather the co-existence of many different rules, requirements and practices at national level that help companies investing time and resources learn and cope with them, especially in countries with high levels of restrictions.[171] However, since most of the companies present in this sector are SMEs, resources and time become crucial elements for their survival.

**The application of mutual recognition**

Stakeholders find the application of mutual recognition to be difficult in the complex environment described above. They underline how national authorities tend to focus on national legislation when deciding, without taking into account other EU Member States certifications or proof of the fact that the product is already lawfully marketed in another Member State.

In addition, existing instruments meant to favour the application of mutual recognition – such as Product Contact Points – are not really instrumental in helping companies, given their role of as information hubs, with no real consultative or assessing capabilities and tasks.

Companies emphasise how the main reason used by national authorities to delay or even block a product from being marketed in a Member State concerns the existence of potential safety issues and the need for the authorities to protect the consumers, which cannot be easily challenged by companies. Sometimes, however, companies report a lack of transparency in the reason for denial.

In this regard, stakeholders suggest how the fact the burden of proof is on companies – and not on national authorities – when demonstrating that a product is not dangerous, may limit their action and ability to challenge a decision, considering time and resources needed.

Companies may see also a potential effort of national authorities not to allow (or delay) foreign companies in entering the local market in order to reduce competition for national companies.

Considering the potential expenses and (considerable) use of time and resources to challenge a decision taken by national authorities through judicial procedures, sometimes such an option is not considered by companies. According to stakeholders, this can be due to:

- **Resources** needed, as mentioned. For a company – especially an SME – such resources needed can be high to discourage it from pursuing such action. For instance, an Italian SME active in the area of food supplement suggested how, on average, costs for lawyers

170 AT, NL, SE, SI and UK.
171 Such as AT, DE, FI, HR, SE.

and appealing procedures can amount to around EUR 20,000 per product, but other stakeholders provided more extreme examples;

- **Uncertainty** of the final outcome of the procedure, which can result in another and definite loss for the company;

- Preference not to **antagonise** national authorities, which will be crucial for the approval of the many other products that a company in this sector usually has and tries to market.

In the light of these difficulties, stakeholders tend to:

- **Adapt the product** to the national requirements. Clearly also this decision entails some costs.

    - An Italian SME indicated how adapting the product to sell it as a medicine could be virtually unbearable for an SME in terms of time and costs (with the need to develop a complete dossier, with testing, clinical tests and documentation), easily amounting to thousands of EUR.

    - Adapting a product to different limits of ingredients or substances can also require some effort from the company, since it requires a new technological development, with lab costs and feasibility studies. Such costs can be important for an SME (at least EUR30-50,000 in each case), not considering the potential impact on the production lines, which need to be differentiated even for a single ingredient. This strategy is not likely to result in regaining the amount spent when the targeted market is too small not to justify such investments.

- **Not entering the market** at all, when companies realise that costs and efforts will not lead to a positive solution or, even if it is the case, they will be too high to be sustained. In this case it can be very difficult to estimate the costs and potential losses for companies, but there is no doubt that this can result in losing money as well as possible damages to the company's image and reputation, especially after a judicial procedure;

- Trying to look for a "**least common denominator**" among a group of Member States, which can have similar rules and requirements and targeting this group with a single product that would easily comply with all different national regulations.

Products in contacts with drinking water[172]

Considering available information, it is possible to estimate the total turnover of the sector between **40** and **43 billion per annum,**[173] while the number of companies operating can be estimated at around **7,000 units**, with a heterogeneous distribution among small medium and large enterprises.[174]

Tests and certifications concerning the products in contact with drinking water fall mainly under several categories: mechanical, hygienic and audits. The cost-spread for these certifications as well as statutory audits is different among EU Member States. In Germany, for example, audit

172 See annex 13 of the Evaluation for the full case study on products in contact with drinking water

173 Eurostat data for product categories is not specific to drinking water contact products, some estimation based on expert evaluation are available thanks to data and document collection

174 Panteia, *Economic Effects of Article 10 of the Drinking Water Directive,* 2016

costs amount to a figure around 14% of the total costs for tests and certifications, while in other countries like U.K., Netherlands and France such a cost is around 1% of the total.[175]

Water taps are among the products whose commercialization is more problematic, according to stakeholders. Water taps segment covers about **35%** of the entire turnover of companies active in the area of products in contacts with drinking water.

Stakeholders revealed how currently the application of mutual recognition with regard to these products is seriously deficient, thus creating limitations to both competition among businesses and availability of products for consumers in the EU single market. The main issue stems from the absence of comprehensive EU harmonised requirements on such products. Article 10 of Directive 98/83/EC (Drinking Water Directive)[176] requires Member States to verify that the materials and substances used in the treatment and distribution systems are not present in drinking water "in concentrations higher than is necessary for the purpose of their use and do not, either directly or indirectly, reduce the protection of human health".

The implementation and monitoring measures are left to the Member States, which have established their own national test and certification bodies[177] to assure the quality of materials and to issue licences for the sale of products in contact with drinking water. Each body assesses the conformity of materials and products in contact with water for human consumption against specific requirements and criteria that vary at national level (for example as regards the compliance of products with a specific composition or the effects of the materials on the microbiological growth in the water).

This framework creates the conditions for double or multiple testing of products in contact with drinking water in the EU market. Companies willing to obtain a licence for marketing their product in a single Member State have to comply with all the national test criteria and requirements as defined by in the law and by the relevant test and certifications bodies in that Member State. However, when they want to market that same product in other Member State, they are typically required to repeat those same tests by the relevant bodies in each individual Member State they want to enter, as Member States not only have different test criteria, but also do not recognise each other's tests. This practice results in an expensive and time consuming reiteration of activities for businesses, which are forced to repeat tests and acquire certifications several times in the EU market, into higher final prices for consumers and – more importantly for our analysis – into the infraction of mutual recognition principle. As pointed out by a representative of one of the largest European manufacturer of hydraulic accessories and components, it is currently not possible for a business to market its products in more than few countries[178] at the same time in Europe, mainly due to additional testing and certifications that

175 Figawa, *Member Survey*, 2016

176 Concerning the quality assurance of treatment, equipment and materials in contact with drinking water.

177 FIGAWA reports the following list of national test and certification bodies: Österreichische Vereinigung für das Gas- und Wasserfach (AT), BELGAQUA (BE), Sekretariatet for byggevarer godkendt til drikkevand (DK), VTT Expert Services (FI), Centre Scientifique et Technique du Bâtiment (FR), Deutscher Verein des Gas- und Wasserfaches (DE), National Institute of Environmental Health (HU), Ministerio della Salute (IT), Kiwa NL (NL), Państwowy Zakład Higieny (PL), Instituto Nacional de Saude (PT), Institut Za Varovanje Zdravja Republike Slovenije (SI), Asociación Española de Normalización y Certificación (ES), Kiwa Swedcert (SE), Schweizerischer Verein des Gas- und Wasserfaches (CH), Water Regulations Advisory Scheme (UK).

178 The countries mentioned by the interviewee in these respect are AT, DE, and NL. Indeed, the interviewee stated that initial product certifications are sought and obtained in these MS, as the laboratories having the necessary technical instrumentation and know-how for complex (mechanical and hygiene) testing are mainly settled there. Moreover, the interviewee company has a preference for German speaking countries due to the absence of language barrier in interacting with test and certification bodies.

shall be taken in each Member State requiring so. In some instances, the cost of additional testing may even exceed the cost of initial testing and certification.

As an example, the interviewee reported that, in the context of EUR 2 million project aimed at selling a single hydraulic product in 15 EU Member States, the total cost for the initial certification of such product amounted to EUR 35,000, while cost the double testing in a single country (FR) was EUR 38,000. Similarly, for a large project worth EUR 60 million concerning the renewal of product present on the market for a long time, interviewed stakeholder expects the costs for initial certifications (estimated at around EUR 1 million) to double when trying to market the product in all the 28 Member State due to additional certification.

Moreover, companies have to deal with the auditors of the different national certification bodies who periodically conduct audit visits concerning the quality certifications already acquired. The current cost reported by the interviewed stakeholder for managing all these certifications (which are, for drinking water only, around 1,350) is around EUR 2.3 million per year. Remarkably, all of these costs faced by businesses are passed on to consumers via final prices.

The problem of double and additional testing is particularly acute in some countries. Stakeholders mentioned how Member States such as Spain, France, UK, and more in general the Scandinavian countries, can be seen as the most problematic in this respect. Businesses may find double testing not only expensive in terms of fees to be paid to repeat the same test in different Member States, but also extremely time consuming. The time that elapses between the registration for tests and the certification of approval typically can span from six up to 12 months, and may even reach 24 months in more complex circumstances. For companies, this obviously results into foregone profits due to the delayed market access.

Crucially, when businesses make the point of mutual recognition in dealing with national authorities in other MS, the latter typically refer to the application of the relevant national norms and legislation, rather than EU Legislation.

From the point of view of businesses, there is a generalized lack of awareness (if not deliberate disregard) of the mutual recognition principle by national test and certification bodies.

Moreover, interviewees reported “cherry picking” by national authorities, as some tests and certifications presented by businesses can be accepted by some MS, while other tests shall be repeated. Businesses are simply asked to comply with national requirements and test criteria, even though their products underwent the same testing in other countries.

However, businesses are reluctant to bring national authorities to court to see the principle of mutual recognition applied. There are two main reasons behind this. First, businesses do not want to see their long-lasting relationship with national authorities jeopardised just to seek the application of mutual recognition to a single product. In other words, they prefer avoiding confrontation with national authorities and complying with national requirements by repeating tests, mainly because they are concerned of being treated unfavourably in the future. Second, businesses are concerned that, in absence of harmonised rules at EU level on hygienic testing, the enforcement of mutual recognition with respect to materials and products in contact with drinking water may start a “race to the bottom” among producers as regards the quality of products, a fact which is expected to negatively impact the safety of consumers. Finally, interviewed business associations also reported how among its members there is a problem of awareness about mutual recognition. While companies dealing with products in contact with drinking water are aware of and well-versed in relevant legislation such as Regulation (EU) No 305/2011 (Construction Products Regulation) or Directive 98/83/EC (Drinking Water Directive), are less aware about the possibility of benefiting from mutual recognition.

Food contact material[179]

Food contact materials (FCM), including food packaging, are only partially harmonized at the EU level and subject both to extensive national regulation and to extended practical scrutiny by the competent authorities, which may be partially justified by the potential impact of these products on public safety and more precisely public health.

The food and drink industry in general is the EU's biggest manufacturing sector in terms of jobs and value added. The EU boasts an important trade surplus in trade in food and EU food specialities are well appreciated overseas. In the last 10 years, EU food and drink exports have doubled, reaching over €90 billion and contributing to a positive balance of almost 30 billion. The FCM sector in particular has an approximate annual turnover of €100 billion.

The range of the non-harmonised aspects of the FCM industry was recently examined through a 2016 JRC Study on the European regulatory and market situation of non-harmonised food contact materials.[180] The Study found that due to the lack of harmonisation of materials listed under the framework regulation the sector was subject to mutual recognition. Specifically, the study highlighted a lack of detail in relation to requirements and quality assurance towards the declaration of compliance and supporting documents, certification where applicable, basis for enforcement and sanctions. Tellingly, the Study argued that this was a hurdle for competent authorities as well, rather than only for economic operators. Indeed, FCM is an industry in which the Member States have a complementary authority, allowing them to exercise a certain margin of discretion, but only within the limitations permitted by the FCM Regulation, the procedural norms established in relation to EFSA[181], and the logic of the Mutual Recognition Regulation. From a Member State perspective, the mirror image of this competence is the need to be relatively specific in relation to the criteria and processes that they apply to make their decisions. This can be problematic in practice.

At the national level, requirements on declarations of conformity to be provided by economic operators and supporting documents lack guidance and associated quality criteria. Self-regulation can address this to some extent by providing additional sectorial guidelines, but it is unclear whether these are known and applied in particular by SMEs.

National measures on specific materials are mainly based on lists of authorised substances and corresponding restrictions. Close to 8,000 substances were found. Some materials are regulated by more than 10 Member States (metal, glass) and some only by a few (wood). National rules for ceramics, glass and metals/alloys cover about 15 heavy metals and ban substances such as barium and mercury. There are between 100 and over 5,000 substances authorised for each category of the other materials. Only 15-35 % of substances considered nationally are in the lists that EFSA reported as being adequately risk assessed.

There is a lack of concerted strategies for the monitoring of various FCMs among Member States. This can be perceived as grey area for the systematic assurance of food safety. The level of non-compliance is not greater overall for non-harmonised materials,

179 See annex 13 of the Evaluation for the full case study

180 Non-harmonised food contact materials in the EU: regulatory and market situation, 2016, JRC; see https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/non-harmonised-food-contact-materials-eu-regulatory-and-market-situation-baseline-study

181 European food and safety authority

but it is prevalent for their imports. Enforcement also suffers from lack of standards or test methods.

To economic operators, the lack of transparency and accessibility on applicable requirements, rules and procedures is the key challenge: when moving from one Member State to the next, it is challenging to identify (a) whether national rules exist; (b) who the competent authority is; (c) what the applicable requirements for their specific FCMs are; and (d) whether the MR Regulation is a satisfactory solution.

The interrelationship between the FCM Regulation and the Mutual Recognition Regulation is not clear to economic operators. In practice, there is significant familiarity with the FCM Regulation as such and with applicable rulesets in major markets, but economic operators are insufficiently aware of the principles and scope of application of the Mutual Recognition Regulation and its ability to facilitate compliance with specific national rules. As noted in the 2016 study, this lack of clarity "leads industries to seek external legal advice, which adds to costs and may result in lengthier authorisation processes and delayed market access. It can also result in a greater focus on certification and accreditation systems at industrial level".

Road circulation of mobile machinery

The mobile machinery industry[182] consists of a series of products across sectors (such as agricultural machinery (excl. tractors), construction machinery, garden equipment, municipal equipment). The total production value in the EU amounted to €10.3bn in 2013[183]. Despite the existence of a number of EU harmonisation measures applying to mobile machinery[184], the road approval aspect of mobile machinery is not subject to EU harmonisation and thus mutual recognition should apply. However, mobile machines are still facing a series of different requirements across EU Member States when requesting road approval causing costs for manufacturers, authorities, users and citizens.

The absence of harmonised requirements for the road circulation of mobile machinery in the EU has led to these specific problems:

- Different requirements for road circulation of mobile machinery are applicable in different Member States. Road approval is necessary as required by the relevant Member States. This procedure causes direct costs (administrative burdens for manufacturers and regulatory charges – such as third party testing and other inspection activities) and indirect costs to industry (time delays in the introduction

182 Mobile machinery refers to any self-propelled mobile machine or vehicle, with a maximum design speed higher than 6 km/h, running on tyres and that is not intended for carrying passengers or goods on public roads

183 Study on the EU harmonisation of the requirements for the road circulation of mobile machinery – FWC ENTR/172/PP/2012/FC/Lot1. http://ec.europa.eu/DocsRoom/documents/17786/attachments/1/translations/en/renditions/native

184 Amongst others: NRMM Directive 97/68/EC, Outdoor Noise Equipment Directive 2000/14/EC, Machinery Directive 2006/42/EC, Regulation (EU) No 167/2013

of new products, reduced product innovation etc.) as well as indirect costs to others (administrative costs for MS governments, administrative burdens for dealers, time delay in delivery etc.).

- Compliance costs related to non-harmonised requirements are causing direct industry costs (additional logistics, administrative translation, additional manufacturing & design costs) which cause indirect industry costs (higher product prices, barriers to market entry etc.). Based on the market power of the industry such costs may be further passed-on to downstream clients (in the form of increased prices or different prices across Member States, differentiated access to machines);

Costs created by the application of the different national requirements consist of both direct and indirect costs. Direct costs for the industry in complying with existing legislation add up to €90 m in the EU. This corresponds to 1.3% of their turnover. Indirect industry costs were also identified, such as time delays on the introduction of products, reduced innovation, higher product prices or barriers to entry as well as reduced choice for consumers and administrative burdens for national administrations. Barriers to market entry are impacting above all SMEs who consider it more than other firms too challenging to enter new Member States markets and to comply with their specific rules.

**Coherence**

Overall, the evaluation shows that there does not seem to be any contradiction between mutual recognition and other EU policies for achieving the internal market and facilitating the free movement of goods in the EU. This conclusion relies on the Commissions internal analysis and is confirmed by the results of the 2016 public consultation. There is a consensus among stakeholders as regards to the coherence of the Regulation with regard to other EU pieces of legislation. Most of the respondents are not aware of any overlaps between the Regulation and other initiatives/legislation/policies. The mutual recognition principle and the Regulation complement each other and are coherent with a number of initiatives for achieving the internal market and facilitating the free movement of goods in the EU, such as the "Transparency"[185], the Construction Products Regulation[186,] The SOLVIT network[187] and EU harmonisation legislation. A minor part of respondents to the 2016 public consultation indicated that there are some overlaps linked to SOLVIT, RAPEX[188], ICSMS[189] and Regulation 765/2008 on market surveillance[190.] However, the analysis of their individual replies shows that their perception is due to a misunderstanding of the EU legislation identified rather than to real overlaps.

**Relevance**

185 Directive (EU) 2015/1535 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services OJ L 241, 17.9.2015, p. 1–15
186 Regulation (EU) No 305/2011 on Construction products OJ L 88, 4.4.2011, p. 5–43
187 http://ec.europa.eu/solvit/what-is-solvit/index_en.htm
188 See above 139
189 Internet-supported information and communication system for the pan-European market surveillance
190 OJ L 218/30, 13.08.2008

Mutual recognition is "one of the most appreciated innovations of the EU"[191], as it aims to achieve a deep market integration while respecting diversity and regulatory autonomy among Member States. It is seen as an alternative to harmonisation, when the latest is not necessary, justified and proportionate. There are currently 0.99 million enterprises operating in the non-harmonised area. Furthermore, mutual recognition is particularly relevant for supporting innovation, where it represents the only alternative for businesses wishing to market their new/innovative products in other Member States. This conclusion justifies the need for a continued effort to refine and improve the functioning of mutual recognition and achieve full potential of the internal market.

**EU added value**

The evaluation shows a general consensus among stakeholders that mutual recognition brings added value to the EU. It creates the possibility to market products in other Member States that are already lawfully marketed elsewhere, while maintaining the Member States' regulatory autonomy and diversity. It is widely acknowledged that the objectives it sets out can be met only by acting at EU level. Throughout the consultation process, stakeholders were almost unanimous as regards the necessity of having an EU legal instrument for achieving more and better mutual recognition.

191 "Mutual recognition: economic and regulatory logic in goods and services", Bruges European Economic Research Papers, 2012, Jacques Pelkmans

## ANNEX 7 ASSESSED LITERATURE AND JURISPRUDENCE

### 1. LITERATURE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## 2. RECENT CASE LAW OF THE CJEU ON MUTUAL RECOGNITION

**CJEU, Case C-227/06 *Commission v Belgium*, ECLI:EU:C:2008:160**

By requiring economic operators wishing to market construction products, which have been lawfully manufactured and / or marketed in another Member State, in Belgium to obtain national conformity marks, Belgium has failed to fulfil its obligations under Articles 34 and 36 TFEU (ex 28 EC and 30 EC).

**CJEU, Case 88/07 *Commission v Spain*, ECLIEU:C:2009:123**

By withdrawing from the market products based on medicinal herbs lawfully produced and/or marketed in another Member State, under an administrative practice consisting in withdrawing from the market any product based on medicinal herbs not included either in the annex of the an Order on the creation of a special register of medicinal herb-based preparations or the annex of an Order establishing the list of plants sale of which to the public is prohibited or restricted because of their toxicity, other than a preparation the constituents of which are exclusively one or more medicinal herbs or whole parts of such herbs, or crushed or powdered parts of such herbs, on the ground that that product is deemed to be a medicinal product marketed without the requisite marketing authorisation, Spain has failed to fulfil its obligations under Articles 34 and 36 TFEU (ex 28 EC and 30 EC) and Articles 1 and 4 of Decision No 3052/95/EC of 13 December 1995 establishing a procedure for the exchange of information on national measures derogating from the principle of the free movement of goods within the Community.

**CJEU, Case C- 132/08 *Lidl,* ECLI:EU:C:2009:281**

Member States cannot, under Directive 1999/5/EC of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity, require a person who places radio equipment on the market to provide a declaration of conformity even though the producer of that equipment, whose head office is situated in another Member State, has affixed the 'CE' marking to that product and issued a declaration of conformity in its regard.

Where a matter is regulated in a harmonised manner at Community level, any national measure relating thereto must be assessed in the light of the provisions of that harmonising measure and not in that of Articles 34 and 36 TFEU (ex 28 EC and 30 EC).

**CJEU, Case C-100/08 *Commission v Belgium.* ECLI:EU:C:2009:537**

By making the import, possession and sale of birds born and bred in captivity that were legally marketed in another Member States subject to restrictive conditions requiring

economic operators to alter the specimen marking to respond to the specific requirements of Belgian law and by not allowing the marking accepted in other Member States or certificates issued (in accordance with Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade) and by denying traders the ability to obtain exemptions from the prohibition to hold European native birds legally marketed in other Member States, Belgium has failed to fulfil its obligations under Article 34 TFEU (ex 28 EC).

**CJEU, Case C-333/08 *Commission v France,* ECLI:EU:C:2010:44**

By laying down, for processing aids and foodstuffs whose preparation involved the use of processing aids from other Member States where they are lawfully manufactured and/or marketed, a prior authorisation scheme not complying with the principle of proportionality, France has failed to fulfil its obligations under Article 34 TFEU (ex 28 EC).

**CJEU, Case C-142/09 *Vincent Willy Lahousse*, ECLI:EU:C:2010:694**

Council Directive 92/61/EEC of 30 June 1992 relating to the type-approval of two or three-wheel motor vehicles, and Directive 2002/24/EC of 18 March 2002 relating to the type-approval of two or three-wheel motor vehicles and repealing Directive 92/61 are to be construed as meaning that, where a vehicle or a component or separate technical unit thereof does not qualify for the type-approval procedure established by those directives, on the ground that it does not come within their scope, the provisions of those directives do not prevent a Member State from introducing, in its domestic law and in relation to such vehicle, component or separate technical unit, a similar mechanism for recognising the checks carried out by other Member States. In any event, such legislation must comply with EU law, in particular Articles 34 TFEU and 36 TFEU.

**CJEU, Case C-484/10 *Ascafor and Asidac*, ECLI:EU:C:2012:113**

Articles 34 TFEU and 36 TFEU must be interpreted as meaning that the requirements laid down in Spanish legislation for official recognition of certificates demonstrating the quality level of reinforcing steel for concrete granted in a Member State other than Spain constitute a restriction on the free movement of goods. Such a restriction may be justified by the objective of the protection of human life and health, provided the requirements laid down are not higher than the minimum standards required for the use of reinforcing steel for concrete in Spain. In such a case, it is for the referring court to ascertain — where the entity granting the certificate of quality which must be officially recognised in Spain is an approved body within the meaning of Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations and administrative provisions

of the Member States relating to construction products, as amended by Council Directive 93/68/EEC of 22 July 1993 — which of those requirement go beyond what is necessary for the purposes of attaining the objective of the protection of human life and health.

**CJEU, Case, C-171/11 *Fra.bo*, ECLI:EU:C:2012:453**

Article 34 TFEU (ex 28 EC) must be interpreted as meaning that it applies to standardisation and certification activities of a private-law body, where the national legislation considers the products certified by that body to be compliant with national law and that has the effect of restricting the marketing of products which are not certified by that body.

**CJEU, Case C-150/11 *Commission v Belgium*, ECLI:EU:C:2012:539**

By requiring systematically the production of a vehicle's certificate of conformity for the purpose of a roadworthiness test prior to the registration of a vehicle previously registered in another Member State (in addition to production of a certificate of registration) and by making such vehicles subject to a roadworthiness test prior to their registration due to a change in ownership, without taking into account the results of the roadworthiness test carried out in another Member State, Belgium has failed to fulfil its obligations under Article 4 of Council Directive 1999/37/EC of 29 April 1999 on the registration documents for vehicles, as amended by Council Directive 2006/103/EC of 20 November 2006, and under Article 34 TFEU.

**CJEU, Case C-385/10 *Elenca*, ECLI:EU:C:2012:634**

Articles 34 TFEU to 37 TFEU must be interpreted as precluding national provisions which automatically make the marketing of construction products, originating from another Member State, subject to the affixing of CE marking.

**CJEU, Case C-481/12 *UAB Juvelta*, ECLI:EU:C:2014:11**

Article 34 TFEU must be interpreted as precluding national legislation under which, for it to be permissible for them to be sold on the market of a Member State, articles of precious metal imported from another Member State, in which they are authorised to be put on the market and which have been stamped with a hallmark in accordance with the legislation of that second Member State, must, where the information concerning the standard of fineness of those articles provided in that hallmark does not comply with the requirements of the legislation of that first Member State, be stamped again, by an independent assay office authorised by that first Member State, with a hallmark confirming that those articles have been inspected and showing their standard of fineness in accordance with those requirements.

**CJEU, Case C-423/13 *Vilniaus Energija*, ECLI:EU:C:2014:2186**

Article 34 TFEU and Directive 2004/22/EC of 31 March 2004 on measuring instruments must be interpreted as precluding national legislation and practice according to which a hot-water meter which satisfies all the requirements of that Directive and is connected to a remote (telemetric) data-transmission device is to be regarded as a measuring system and, as a result, cannot be used for its intended purpose so long as it has not been subject, together with that device, to a metrological verification as a measuring system.

Competent national authorities may not, in any event, unnecessarily require technical analyses where those analyses have already been carried out in another Member State and their results are available to those authorities or may, at their request, be placed at their disposal (see, to that effect, Commission v Portugal, ECLI:EU:C:2005:669, paragraph 46 and the case-law cited).

**CJEU, Case C-354/14 *Capods Import-Export*, ECLI:EU:C:2015:658**

Article 34 TFEU and Article 31(1) and (12) of Directive 2007/46/EC of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive) must be interpreted as not precluding national legislation, which makes the marketing in a Member State of new spare parts for road vehicles subject to the application of an approval or homologation procedure in that Member State, provided that that legislation also lays down exceptions such as to ensure that parts lawfully produced and marketed in other Member States are exempted or, failing this, that the parts in question are capable of posing a significant risk to the correct functioning of systems that are essential for the safety of the vehicle or its environmental performance and that that approval or homologation procedure is strictly necessary and proportionate in relation to the objectives of protection of road safety or of protection of the environment.

The conditions for proving that such parts have already been approved or homologated or constitute original parts or parts of matching quality are governed, in the absence of European Union rules on the matter, by the law of the Member States, subject to the principles of equivalence and of effectiveness.

## ANNEX 8 THE DECLARATION OF COMPLIANCE

The EU has a comprehensive policy geared to ensure that only safe and otherwise compliant products find their way on to the market, in such a way that honest economic operators can benefit from a level playing field, thus promoting at the same time an effective protection of EU consumers and professional users and a competitive single EU market. The 'New Approach' developed in 1985, restricted the content of legislation to 'essential requirements' leaving the technical details to European harmonised standards. The 'New Legislative Framework' adopted in July 2008, builds on the New Approach and completes the overall legislative framework with all the necessary elements for effective conformity assessment, accreditation and market surveillance including the control of products from outside the Union.

### 1. EU PRODUCT LEGISLATION UNDER THE 'NEW APPROACH'

The 'Cassis de Dijon' judgement played an immense role in modifying the EU approach to technical harmonisation on three fundamental counts:

(1) In stating that Member States could only justify forbidding or restricting the marketing of products from other Member States on the basis of non-conformity with 'essential requirements', the Court opened a reflection on the **content of future harmonisation legislation**: since non-respect of non-essential requirements could not justify restricting the marketing of a product, such non-essential requirements need no longer figure in EU harmonisation texts. This opened the door to the 'New Approach and the consequent reflection on what constitutes an essential requirement and how to formulate it in such a manner that conformity can be demonstrated,

(2) In stating this principle, the Court clearly placed the **onus on national authorities** to demonstrate where products did not conform to essential requirements but it also begged the question of the **appropriate means for demonstrating conformity in a proportionate manner**,

(3) By noting that Member States were obliged to accept products from other Member States except in circumscribed conditions, the Court identified a legal principle but did not produce the means to create the trust in the products that could help authorities to accept products they could not vouch for. This led to the need to develop a **policy on conformity assessment**.

The 'New Approach' legislative technique approved by the Council of Ministers on 7 May 1985 in its Resolution on a new approach to technical harmonisation and standards[192] was the logical legislative follow up to the Cassis de Dijon case. This regulatory technique established the following principles:

- **Legislative harmonisation should be limited to the essential requirements** (preferably performance or functional requirements) that products placed on the EU market must meet if they are to benefit from free movement within the EU;

192 OJ C 136, 4.6.1985, p. 1.

- The **technical specifications** for products meeting the essential requirements set out in legislation should be laid down in **harmonised standards** which can be applied alongside the legislation;

- Products manufactured in compliance with harmonised standards benefit from a **presumption of conformity** with the corresponding essential requirements of the applicable legislation, and, in some cases, the manufacturer may benefit from a **simplified conformity assessment procedure** (in many instances the **manufacturer's declaration of conformity**, made more easily acceptable to public authorities by the existence of the product liability legislation);

- The **application of harmonised or other standards remains voluntary**, and the manufacturer can always apply other technical specifications to meet the requirements (but will carry the burden of demonstrating that these technical specifications answer the needs of the essential requirements, more often than not, through a process involving a third party conformity assessment body).

As a general rule, **EU product legislation under the 'New Approach'** obliges the manufacturer, when placing a product on the market the manufacturer, to take all measures necessary to ensure that the manufacturing process assures compliance of the products and in particular:

(1) carry out the applicable conformity assessment or have it carried out, in accordance with the procedure(s) laid down by the relevant Union harmonisation legislation. Depending on the Union harmonisation act, the manufacturer may be required to submit the product to a third party (usually a notified body) to have the conformity assessment carried out, or to have a quality system approved by a notified body. In any case, the manufacturer bears full responsibility for product conformity;

(2) draw up the required technical documentation;

(3) draw up the EU declaration of conformity;

(4) accompany the product with instructions and safety information as required by the applicable Union harmonisation legislation, in a language easily understood by consumers and other end-users, as determined by the Member State concerned.

(5) satisfy the following traceability requirements:

  – keep the technical documentation and the EU declaration of conformity for 10 years after the product has been placed on the market or for the period specified in the relevant Union harmonisation act,

  – ensure that the product bears a type, batch or serial number or other element allowing its identification,

  – indicate the following three elements: his name, registered trade name or registered trade mark and a single contact postal address on the product or when not possible because of the size or physical characteristics of the products, on its packaging and/or on the accompanying documentation. The

single contact point may not necessarily be located in the Member State where the product is made available on the market;

(6) affix the conformity marking (CE marking and where relevant other markings to the product in accordance with the applicable legislation;

(7) ensure that procedures are in place for series production to remain in conformity. Changes in product design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which conformity of a product is declared must be adequately taken into account. The kind of action to be taken by the manufacturer depends on the nature of changes in the harmonised standards or other technical specifications, in particular whether these changes are material with regard to the coverage of the essential or other legal requirements and whether they concern the product in question. This might require for instance to update the EU Declaration of conformity, change the product design, contact the notified body, etc.;

(8) Where relevant, certify the product and/or the quality system.

## 2. THE EU DECLARATION OF CONFORMITY IN EU PRODUCT LEGISLATION

The EU Declaration of Conformity is obligatory in various sectors such as:

**SECTORS WITH DECLARATION OF CONFORMITY**

- **The restriction of the use of certain hazardous substances in electrical and electronic equipment (Directive 2011/65/EU)**
- **Appliances burning gaseous fuels (Directive 2009/142/EC)**
- **Ecodesign requirements for energy-related products (Directive 2009/125/EC)**
- **Simple pressure vessels (Directive 2009/105/EC and Directive 2014/29/EU)**
- **Toys' safety (Directive 2009/48/EC)**
- **Electrical equipment designed for use within certain voltage limits (Directive 2006/95/EC and Directive 2014/35/EU)**
- **Machinery (Directive 2006/42/EC)**
- **Electromagnetic compatibility (Directive 2004/108/EC and Directive 2014/30/EU)**
- **Measuring instruments (Directive 2004/22/EC and Directive 2014/32/EU)**
- **Non-automatic weighing instruments (Directive 2009/23/EC and Directive 2014/31/EU)**
- **Cableway installations designed to carry persons (Directive 2000/9/EC)**

- **Radio equipment and telecommunications terminal equipment (Directive 1999/5/EC and Directive 2014/53/EU)**
- **Active implantable medical devices (Directive 90/385/EEC)**
- **Medical devices (Directive 93/42/EEC)**
- **In vitro diagnostic medical devices (Directive 98/79/EC)**
- **Pressure equipment (Directive 97/23/EC and Directive 2014/68/EU)**
- **Transportable Pressure equipment (Directive 2010/35/EU)**
- **Aerosol Dispensers (Directive 75/324/EEC as amended)**
- **Lifts (Directive 95/16/EC and 2014/33/EU)**
- **Recreational craft (Directive 94/25/EC and Directive 2013/53/EU)**
- **Equipment and protective systems intended for use in potentially explosive atmospheres (Directive 94/9/EC and Directive 2014/34/EU)**
- **Explosives for civil uses (Directive 93/15/EEC and Directive 2014/28/EU)**
- **Pyrotechnics (Directive 2013/29/EU)**
- **Regulation on the Labelling of Tyres (Regulation (EC) No 1222/2009)**
- **Personal protective equipment (Directive 89/686/EEC)**
- **Marine equipment (Directive 96/98/EC and Directive 2014/90/EU)**
- **Noise emission in the environment by equipment for use outdoors (Directive 2000/14/EC)**
- **Emissions from non-road mobile machinery (Directive 97/68/EC as amended)**
- **Energy labelling (Directive 2010/30/EU)**

The Union harmonisation legislation referred to above imposes **an obligation on the manufacturer to draw up and sign an EU Declaration of Conformity before placing a product on the market**[193]. The manufacturer or his authorised representative established within the Union must draw up and sign an EU Declaration of Conformity as part of the conformity assessment procedure provided for in the Union harmonisation

193 Please note that the Machinery Directive 2006/42/EC foresees the placing on the market of "partly completed machinery" to be accompanied by a so- called declaration of incorporation which is different from the EU Declaration of conformity. According to Regulation (EC) No 552/2004, constituents of the European Air Traffic Management network are accompanied either by a declaration of conformity or a declaration of suitability for use.

legislation. The EU declaration of conformity is the document that states that that the product satisfies all the relevant requirements of the applicable legislation.

By drawing up and signing the EU Declaration of Conformity, the **manufacturer assumes responsibility** for the compliance of the product.

The EU Declaration of Conformity must be kept for ten years from the date of placing the product on the market, unless the legislation specifies any other duration[194]. This is the responsibility of the manufacturer or the authorised representative established within the Union. For imported products, the importer must take on this responsibility for the DoC[195].

The contents of the EU Declaration of Conformity either refer to the model declaration contained in Annex III of Decision No 768/2008/EC or a model declaration directly annexed to the sectoral Union harmonisation legislation at stake. The declaration may take the form of a document, a label or equivalent, and must contain sufficient information to enable all products covered by it to be traced back to it.

Where several pieces of Union harmonisation legislation apply to a product, the manufacturer or the authorised representative has to provide a single declaration of conformity in respect of all such Union acts[196]. In order to reduce the administrative burden on economic operators and facilitate its adaptation to the modification of one of the applicable Union acts, the single declaration may be a dossier made up of relevant individual Declarations of conformity[197].

The EU declaration of conformity must be made available to the surveillance authority upon request. Moreover, Union harmonisation legislation relating to machinery, equipment in potentially explosive atmospheres, radio and terminal telecommunication equipment, measuring instruments, recreational craft, lifts, high-speed and conventional rail systems and constituents of the European Air Traffic Management network require products to be accompanied by the EU declaration of conformity.

The EU declaration of conformity must be translated into the language or languages required by the Member State in which the product is placed or made available on the market[198]. Union harmonisation legislation does not necessarily specify who has the obligation to translate. Logically, this should be the manufacturer or another economic operator making the product available. The EU declaration of conformity must be signed by the manufacturer or his authorised representative. If a translation of the EU declaration of conformity has been produced by another economic operator and is not signed by the manufacturer, a copy of the original EU declaration of conformity signed by the manufacturer must also be provided together with the translated version.

194 According to the Directives relating to medical devices and in vitro diagnostic medical devices the EU Declaration of Conformity must be kept for 5 years and in the case of implantable medical devices for 15 years.
195 For responsibilities of the manufacturer, the authorised representative and the importer, see Chapter 3.
196 Article 5 from Decision No 768/2008/EC.
197 See for example recital 22 of Directive 2014/35/EU, or the similar recital 24 of Directive 2014/34/EU.
198 Article R10(2) of Annex I of Decision No 768/2008/EC.

The standard model of the DoC is annexed to Decision 768/2008[199], and to all relevant EU harmonisation legislation using it:

**EC DECLARATION OF CONFORMITY**

1. No … (unique identification of the product):

2. Name and address of the manufacturer or his authorised representative:

3. This declaration of conformity is issued under the sole responsibility of the manufacturer (or installer):

4. Object of the declaration (identification of product allowing traceability. It may include a photograph, where appropriate):

5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:

6. References to the relevant harmonised standards used or references to the specifications in relation to which conformity is declared:

7. Where applicable, the notified body ... (name, number) … performed … (description of intervention) … and issued the certificate: …

8. Additional information:

Signed for and on behalf of: ……

(place and date of issue):

(name, function) (signature):

### 3. COMPARISON BETWEEN THE ROLE OF THE MANUFACTURER IN EU HARMONISATION LEGISLATION AND IN THE MUTUAL RECOGNITION PROPOSAL

| Manufacturer's tasks | EU harmonisation legislation | Mutual Recognition proposal |
|---|---|---|
| (1) Conformity assessment | Obligatory | Requirement that product is lawfully marketed in another Member State |
| (2) Technical documentation | Obligatory | -- |
| (3) EU declaration of conformity | Obligatory | Voluntary |

199 eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0082:0128:en

| | | |
|---|---|---|
| (4) Accompany the product with instructions and safety information | Obligatory | -- |
| (5) Traceability requirements | Obligatory | -- |
| (6) Conformity marking | Obligatory | -- |
| (7) Ensure that procedures are in place for series production to remain in conformity. | Obligatory | -- |
| (8) Where relevant, certify the product and/or the quality system. | Obligatory | -- |

## 4. COMPARISON BETWEEN THE DECLARATIONS OF CONFORMITY

| International standard EN ISO/IEC 17050-1 | EU harmonisation legislation | Mutual Recognition proposal |
|---|---|---|
| Unique identification | 1. No … (unique identification of the product) | |
| Name, contact address and signature of the issuer; | 2. Name and address of the manufacturer or his authorised representative | |
| | 3. This declaration of conformity is issued under the sole responsibility of the manufacturer (or installer) | |
| An identification of what the declaration covers (for example, product description, type and extent of management system) | 4. Object of the declaration (identification of product allowing traceability. It may include a photograph, where appropriate) | |
| The complete list of specified requirements, including standards, that the declaration is based on | 5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation | |
| | 6. References to the relevant harmonised standards used or references to the specifications in relation to which conformity is declared: | |
| | 7. Where applicable, the notified body ... (name, number) … performed … | |

| | | |
|---|---|---|
| | (description of intervention) … and issued the certificate: … | |
| Any limitation related to the validity of the declaration. | 8. Additional information: | |
| Date and place of issue | Signed for and on behalf of:<br>……<br>(place and date of issue):<br>(name, function) (signature): | |

## 5. THE SUPPLIERS DECLARATION OF CONFORMITY IN INTERNATIONAL TRADE

### 5.1. The use of the suppliers' Declaration of Conformity in global trade

The suppliers' Declaration of Conformity is a widely used feature in global trade.

The preamble of the TBT Agreement recognizes the important contribution international standards and conformity assessment systems can make by improving efficiency of production and facilitating the conduct of international trade. That is also the reason why Members are encouraged to accept other Members' conformity assessment results.

The source of the obligation to recognize other Members' conformity assessment procedures and conformity assessment results can be found in Article 6 - Recognition of Conformity Assessment by Central Government Bodies - which states that:

*With respect to their central government bodies:*

*6.1 Without prejudice to the provisions of paragraphs 3 and 4, Members shall ensure, whenever possible, that results of conformity assessment procedures in other Members are accepted, even when those procedures differ from their own, provided they are satisfied that those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures. It is recognized that prior consultations may be necessary in order to arrive at a mutually satisfactory understanding regarding, in particular:*

*6.1.1 adequate and enduring technical competence of the relevant conformity assessment bodies in the exporting Member, so that confidence in the continued reliability of their conformity assessment results can exist; in this regard, verified compliance, for instance through accreditation, with relevant guides or recommendations issued by international standardizing bodies shall be taken into account as an indication of adequate technical competence;*

*6.1.2 limitation of the acceptance of conformity assessment results to those produced by designated bodies in the exporting Member.*

*6.2 Members shall ensure that their conformity assessment procedures permit, as far as practicable, the implementation of the provisions in paragraph 1.*

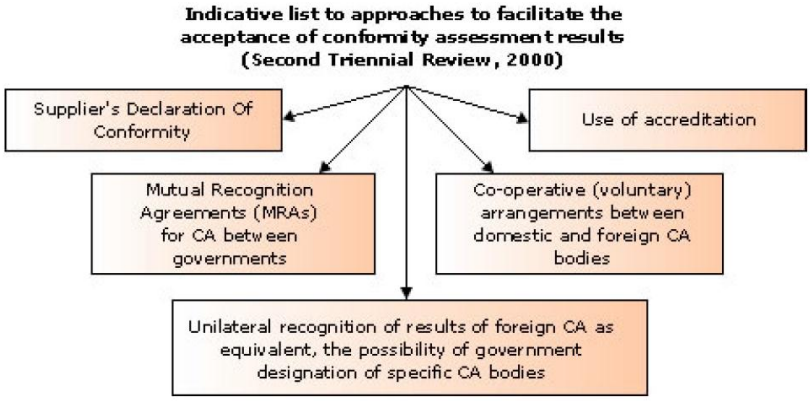
*6.3 Members are encouraged, at the request of other Members, to be willing to enter into negotiations for the conclusion of agreements for the mutual recognition of results of each other's conformity assessment procedures. Members may require that such agreements fulfil the criteria of paragraph 1 and give mutual satisfaction regarding their potential for facilitating trade in the products concerned.*

*6.4 Members are encouraged to permit participation of conformity assessment bodies located in the territories of other Members in their conformity assessment procedures under conditions no less favourable than those accorded to bodies located within their territory or the territory of any other country.*

The TBT Committee has identified five approaches to facilitate the acceptance of the conformity assessment procedures (G/TBT/9):

- accreditation;
- the unilateral recognition of results of foreign conformity assessment as equivalent, including the possibility of government designation of specific conformity assessment bodies;
- the negotiation and conclusion of Mutual Recognition Agreements (MRAs) for conformity assessment between governments;
- the conclusion of co-operative (voluntary) arrangements between domestic and foreign conformity assessment bodies; and
- the use of Supplier's Declaration of Conformity (SDoC).

Accreditation, unilateral recognition and mutual recognition agreements are expressly mentioned in the TBT Agreement. The other two approaches were proposed by the TBT Committee during the Second Triennial Review of the Agreement as part of an indicative list of existing mechanisms to facilitate the acceptance of conformity assessment results. This list was not intended to prescribe particular approaches that Members might choose to adopt, as it was recognized that the application of different approaches would depend on the situation of Members and the specific sectors involved.




*Source: WTO*[200]

The TBT Agreement does not contain a specific reference to SDoC. However, Members at the TBT Committee have recognized that SDoC is a trade-friendly approach to conformity assessment: it is a flexible approach that can reduce the costs of conformity assessment, since, while it may imply certain costs for administrations, in particular higher costs for market surveillance, it can involve lower costs for industries and importers, resulting in cheaper products for consumers and possibly, in the long run, higher levels of competitiveness.

As a minimum, an SDoC shall identify ("Development Manual 2: Conformity assessment", ISO, Second edition, 1998, page 47):

- the supplier making the declaration;
- the product(s) covered; and
- the relevant standard(s) or technical regulation(s).

SDoC may be used to declare the conformity of a product with a standard or a technical regulation, or with both. The declaration is usually a separate document. Alternatively, it may be made in a statement, catalogue, invoice, or users instructions relevant to the product.

The assessment of conformity may be undertaken either by the suppliers' own internal test and inspection facilities, or by third-party test laboratories and inspection bodies. In addition, the supplier may use an accredited laboratory or inspection body and indicate this on the declaration.

A regulatory authority may impose by law that suppliers follow certain steps in the conformity assessment process, or include certain elements in the declaration, such as the use of the proper form, the preparation of a technical file about the product and its test reports, the requirement of a follow-up, etc.

200 https://ecampus.wto.org/admin/files/Course_399/Module_608/ModuleDocuments/TBT_M5_E.pdf

Finally, the following elements have been mentioned by Members in relation to the decision to use SDoC[201]:

- Product Coverage: SDoC is mostly used for products and sectors which involve a low or medium risk to health, safety and the environment. In addition to the risk, consideration of the characteristics and infrastructure of the given sector; number of existing voluntary marking schemes for the product; types of production methods used; level of commercial confidence; and other economic and social factors are used.

- Liability Regime: When conformity assessment is based on SDoC, it is the supplier rather than the regulatory authority that is responsible for ensuring compliance with relevant technical regulations. SDoC as an approach has a better chance if a product's liability law is in place and ensures that anyone suffering injury from a defective product can claim damages from the supplier of the product at the importing country.

- Market Surveillance: Market surveillance consists of verifying in the market the current conformity of products with existing laws and regulations. The lesser the involvement by a third party during the conformity assessment process before a product is placed on the market, the greater the need for efficient market surveillance (through product samples, remedial actions, penalties for false declarations, "spot checks", etc).

- International Standards: the use of relevant international standards could help to make the SDoC process more transparent, and support its value and usability. In this context, the ISO/IEC Guide 22 on "General criteria for SDoC" developed by the ISO Committee on Conformity Assessment (CASCO) in 1996 may be relevant (nowadays, ISO/IEC 17050 standard on "Conformity assessment – SDoC").

- Combination of SDoC with other Conformity Assessment Procedures: The use of test/inspection reports or certification results from third parties or in-house laboratories, accredited on the basis of relevant international standards, could facilitate the use of SDoC. Members have hence suggested the possibility of combining SDoC with other approaches to conformity assessment, such as accreditation and certification.

## 5.2. International standard EN ISO/IEC 17050-1

The international standard **EN ISO/IEC 17050-1** has been drawn up with the objective of providing the general criteria for the declaration of conformity, and it can also be used as a guidance document provided it is in line with the applicable Union harmonisation legislation. ISO/IEC 17050-1:2004 specifies general requirements for a supplier's declaration of conformity in cases where it is desirable, or necessary, that conformity of an object to the specified requirements be attested, irrespective of the sector involved. For the purposes of ISO/IEC 17050-1:2004, the object of a declaration of conformity can be a product, process, management system, person or body.

201 https://ecampus.wto.org/admin/files/Course_399/Module_608/ModuleDocuments/TBT_M5_E.pdf

The international standard EN ISO/IEC 17050-1 addresses one of the three types of attestation of conformity, namely **attestation undertaken by the first party** (e.g. the supplier of a product). Other types are **second-party attestation** (e.g. where a user issues an attestation for the product the user is using) or **third-party attestation**. Each of these three types is used in the market in order to increase confidence in the conformity of an object.

| **Item** | **First party** (also known as supplier's declaration of conformity, or SDoC) | **Second Party** | **Third Party** |
|---|---|---|---|
| Conformity assessment party | Manufacturer, importer, or other supplier | Customer | Regulatory body or independent testing body |
| Description | Procedure by which the manufacturer, importer, or distributor provides written assurance of the conformity of its products to specified requirements | Buyer requires and certifies that the products it wishes to purchase from suppliers meet one or more standards.<br><br>Purchaser's own inspectors usually perform the assessment of the supplier's products. | Conformity assessment by technically competent body not under control of either buyer or seller. Assessment undertaken in government laboratories or by accredited third-party bodies. |

This part of ISO/IEC 17050 specifies requirements applicable when the individual or organization responsible for fulfilment of specified requirements (supplier) provides a declaration that a product (including service), process, management system, person or body is in conformity with specified requirements, which can include normative documents such as standards, guides, technical specifications, laws and regulations. Such a declaration of conformity can also make reference to the results of assessments by one or more first, second or third parties. Such references are not to be interpreted as reducing the responsibility of the supplier in any way. These general requirements are applicable to all sectors. However, these requirements might need to be supplemented for specific purposes, for example for use in connection with regulations.

The standard specifies that the content of a supplier's declaration of conformity should contain the following as a minimum:

- unique identification;
- name, contact address and signature of the issuer;
- an identification of what the declaration covers (for example, product description, type and extent of management system);

- the complete list of specified requirements, including standards, that the declaration is based on;
- date and place of issue;
- any limitation related to the validity of the declaration.

### 5.3. U.S. International Trade Commission

The Office of Industries of the U.S. International Trade Commission (USITC) analysed how conformity assessment measures impede trade and raise costs in specific industries and examines different approaches for addressing them. It looked at the impact of conformity assessment barriers on exporters. The paper discussed the relative advantages and disadvantages of several alternatives for reducing the impact of conformity assessment barriers to trade: mutual recognition agreements (MRAs) among trading partners, unilateral recognition by a country of another country's conformity assessment results, and increased acceptance of a supplier's declaration of conformity (SDoC). It found that when conformity assessment is mandatory, companies often favour SDoC over third-party conformity assessment as it provides them with greater flexibility, non-discriminatory treatment, and lower costs when entering overseas markets. The challenge for supporters of SDoC is convincing the regulatory authorities that it will not compromise regulators' obligations for reducing risks to human and animal health and safety, or to the environment[202].

### 5.4. The Use of Supplier's Declaration of Conformity in the U.S.

In the United States, some regulatory agencies promote the use of SDOC for certain, but not all, equipment. For example, the U.S. Federal Communications Commission (FCC) has adopted a rule that permits recognition of Supplier's Declaration of Conformity (SDOC; also sometimes called Self Declaration of Conformity) for certain digital devices. For other equipment, such as personal computers and attachments thereto, the FCC allows the equipment declared compliant by the supplier, under a process called Declaration of Conformity, provided supporting test results are obtained from an accredited laboratory.

Other U.S. regulatory agencies rely upon SDOC for technical regulations. The U.S. Department of Transportation, for example, accepts SDOC from manufacturers or importers of motor vehicles and motor vehicle equipment. Under U.S. law, manufacturers are required to certify that their products comply with all applicable Federal Motor Vehicle Safety Standards (FMVSS). This certification is in the form of a permanent label affixed to the product. This label is required for all vehicles and equipment covered by the FMVSS, and must be present if a vehicle or equipment covered by the FMVSS is to enter the United States. A manufacturer outside the United States who offers its product for importation into the U.S. must submit itself to the

202 Johnson C., 'Technical Barriers to Trade: Reducing the Impact of Conformity Assessment Measures', Office of Industries of the U.S. International Trade Commission (USITC), https://www.usitc.gov/publications/332/ca-dft-rev-final082008.pdf.

jurisdiction of Federal courts in the US by designating an agent in the United States who will receive legal papers on behalf of the manufacturer[203].

## 5.5. Case study: Australia[204]

### *5.5.1. Introduction*

In recent years regulation in Australia has been subject to significant scrutiny to determine its impact both in terms of effectiveness and the underlying costs to industry, government and consumers. The high profile of the European Union in developing a Declaration based approach as part of its overall efforts to create a single market has dominated thinking in terms of product compliance.

Recent regulatory and legislative changes have seen the introduction of the Supplier's Declaration in place of approval processes for telecommunications and radio communications. The introduction of electromagnetic compatibility (EMC) regulation was supported by industry on the basis that it was to be a minimum impact compliance system based on the SDoC.

The information technology and communications sector has been at the forefront of supporting regulatory agencies in the development of SDoC based compliance regimes because of its urgent need to have compliance requirements that are consistent with short product cycles and rapid technology development.

The use of SDoC currently has a limited application in the area of electrical safety in Australia but was considered further in the context of the development of a compliance regime based on a definition of 'essential safety' requirements and the means for demonstrating compliance with those requirements.

### *5.5.2. Supplier's Declaration: an Assessment*

Since the introduction of SDoC, regulators and industry have learnt a great deal about the nature of the changes that this type of regulatory system brings and the preconditions for its successful use, particularly from the point of view of the small economy.

Overall the SDoC is strongly supported by industry in Australia as a system of regulation which is:

- consistent with the needs of competitive industry
- compatible with the direction of technology development; and importantly
- able to meet public objectives as expressed in legitimate regulatory outcomes

The advantages that it offers are broadly:

203 https://www.nist.gov/standardsgov/use-suppliers-declaration-conformity
204 https://www.wto.org/english/tratop_e/inftec_e/gall.doc

- Lower Cost: direct costs associated with pre-market regulatory requirements are removed. There is much greater scope for the supplier to manage compliance costs.

- Manufacturer controls time and access to market: with product lifecycles getting shorter, this is the most significant benefit of SDoC. Pre-market approvals could take up to 90 days in some areas.

- Design changes easier to effect: SDoC offers a stimulus to product range development and innovation by eliminating requirements to re-submit design changes and variants for regulatory approval. Manufacturers are able to declare ranges of products and new features. Importers and those with less technical skill can utilise technical services of certification/inspection bodies and testing laboratories to develop an assessment plan.

- Flexibility over choice of suppliers of components and materials: Responsibility for compliance is focussed on the compliance of the end product. The performance of components and materials is to some extent not critical, provided the product represents a total solution.

- Permits an innovative approach to testing and assessment: Greater flexibility in use of testing and assessment services has emerged. Also, compliance documentation can be upgraded as products are enhanced.

In an environment of growing competition and accelerating technology development the advantages that supplier's declaration offers as a regulatory mechanism are significant. However, the SDoC is not a 'set and forget' solution. Nor is it de-regulation. It involves serious commitment on the part of suppliers and regulators to ensure that it does not:

- introduce imbalances between suppliers, or

- compromise legitimate end user protections.

To be successful in meeting regulatory objectives and industry needs SDoC requires the right regulatory environment and a constructive working relationship between industry and regulator.

### *5.5.3. Impact of SDoC on Stakeholders*

#### 5.5.3.1. Regulator

Compliance based on supplier responsibility has not eliminated the role of government and its regulatory agencies in conformity assessment; it has significantly changed the role of regulator from that of an approval body to a technical policy and audit enforcement body.

An adequate and visible audit enforcement mechanism has proved to be one of the most critical functions for managing SDoC. Although much responsibility for product conformity has swung to the industry, the regulator retains a significant role in policy and

also in ensuring that the system of compliance is not undermined. Post-market audit and surveillance become an essential requirement for ensuring integrity of the system.

It is widely accepted that without audit enforcement there are risks that imbalances between suppliers may emerge and regulatory objectives will not be met.

Audit enforcement has been essential to ensuring that competing suppliers have not sought to gain advantage by disregarding their obligations. In so doing it has reduced any loss in market confidence through exposure to sub-standard products.

This changed role for the regulator has required a different set of skills and outlook than those needed to successfully manage an approval-based system. In many respects the changing the role of regulatory staff has been one of the more difficult changes to make under the introductions of SDoC. A managed implementation plan has been essential.

5.5.3.2. Suppliers

SDoC relates to suppliers (in the case of electromagnetic interference (EMI) regulation SDoC is required from manufacturers, wholesalers or retailers) and not just to manufacturers. It applies the same level of obligation to any person/company responsible for placing a product on the Australian market.

Under the Supplier Declaration system as it has been introduced for telecommunications and EMC, the supplier is now expected to assume greater responsibility for regulatory outcomes. As a consequence the level of technical skill maintained by regulators for the purpose of managing an approvals-based system has diminished. There has been a corresponding need for suppliers to raise their level of technical skill. Where the supplier is a manufacturer it has not been difficult to respond to this need. However, import distributors and some retailers have also fallen under the scope of suppliers and have not always been in a position to readily meet their responsibilities.

This has been difficult for many suppliers to come to terms with, as the regulator is no longer always technically skilled or empowered to exercise discretionary powers in relation to compliance. Nor is the regulator able to provide the level of information and support that is often expected from past experience.

An equally acute problem for suppliers has been the increased administrative load that must be carried because of the need to support the declaration of conformity with compliance folders or technical construction files. The need for suppliers to determine for themselves what constitutes an adequate compliance folder also created a good deal of uncertainty as to what was expected by the regulator. Addressing these problems required both a lengthy phase-in period and a significant commitment by the regulator to information dissemination.

5.5.3.3. End User

In Australia SDoC is invisible to end-users. However, the introduction of SDoC has not reduced end user protections in any measurable way.

**Preconditions for SDoC**

Throughout the implementation process a number of issues have emerged as having a critical impact on the use of SDoC. These include:

- the quality and content of standards
- the capacity to provide high-quality plain-language information
- a clearly articulated regulatory objective
- conformity assessment tools; and
- appropriate regulatory framework.

**The Quality and Content of the Standards**

The quality of standards is critical to the smooth operation of SDoC. Standards are generally the means for setting the regulatory objectives required of products. Where standards are unclear or capable of more than one interpretation it becomes increasingly difficult to exercise a declaration, particularly where regulators' technical skills are reduced. Other remedies may be found through testing and certification bodies, but ideally the standards themselves should be capable of use under a SDoC regime. International standards developed by organisations such as the International Electrotechnical Commission (IEC) increasingly show awareness that they are likely to be used in conjunction with SDoC and aim for greater clarity and useability.

WTO ITA could consider issues affecting participation by a broader range of countries in international standards writing bodies.

**Quality of Information**

The change of role for regulators implied by SDoC may result in a reduction of service levels by regulators. SDoC is a system based on the responsibility of suppliers and under this arrangement resources within regulatory organisations have been reduced or redirected. Whereas once a regulator may have been able to provide interpretations of complex regulatory documents, under SDoC they may not always be resourced to provide such advice. One remedy to this is the publication of plain language information in the form of suppliers' guides.

When written in plain language rather than legal or technical jargon guides of this kind are indispensable for communicating to suppliers—whether they be local or foreign manufacturers, retailers or distribution agents—what the essential obligations are.

Our experience in working within the APEC Telecommunications Working Group on mutual recognition and related matters has highlighted the critical role that a common understanding of requirements in each member economy plays in creating mutual confidence and a base for action on trade facilitation initiatives.

The development and publication of accurate, detailed and accessible regulatory information would facilitate trade in IT products and provide a basis for considering further mutually beneficial outcomes. This may be something that ITA may wish to examine. Information and communications technologies make this an achievable task at very little cost.

**SDoC and Conformity Assessment Tools**

The use of Supplier's Declaration of Conformity alongside specific conformity assessment requirements is a matter of much debate. For some, SDoC is sufficient on its own; others regard it as essential that some reference is made to external third party assessment as the basis on which SDoC is made.

First and foremost the mandatory use of accredited testing as the basis for SDoC should always be a matter of risk assessment.

In some circumstances a supplier's declaration alone may well be sufficient to ensure that a given regulatory objective is met particularly where the risk of harm to third parties is low. But, as the risks posed by product failure become more serious it has become the case that suppliers are required to make a declaration based on the results of accredited testing, certification or inspection assessment.

The Australian system required the use of accredited testing (either third party or manufacturer's testing) for telecommunications network connection. Accredited testing is a benchmark for EMI testing, but is mandatory only for products deemed to be high risk.

This may appear to be contrary to the apparent intent of a SDoC system but in some cases the use of accredited testing has proven to be an essential requirement for maintaining a viable SDoC system. The use of accredited testing has been an important element is gaining acceptance for SDoC through:

- giving an initial degree of confidence to allow regulators to step back from pre-market approvals
- ensuring a common approach to testing amongst competing manufacturers
- providing regulators with a level of consistency in assessment on which to base audit enforcement
- maintaining confidence of end consumers that SDoC could assure expected protections
- providing technical confidence for sections of the supply sector that are not technically skilled.

Importantly, basing conformity assessment requirements on international arrangements such as IEC CB Scheme and agreements between accreditation systems have contributed to greater portability of conformity assessment.

Market conditions are also emerging as factors in determining whether SDoC should be tied to specific conformity assessment requirements. But it is by no means clear how this might be applied. For instance, in a situation where suppliers to a market are characterised by a small number of ethical suppliers then SDoC might be sufficient with no specific conformity assessment obligations, particularly where there are strong general consumer protection laws. Where the supply market is highly fragmented, setting a minimum level of acceptable testing or certification performance may be an acceptable and necessary constraint on SDoC.

A further point worth considering in relation to conformity assessment tools is the role of third party accredited certification services. It had been proposed that the introduction of SDoC in Australia would see a rapid decline in demand for certification services. This has not been the case. Many suppliers, particularly those without internal technical expertise, have chosen to buy in that expertise and manage their exposure to increased responsibility through the use of third party certifiers.

There is a need for greater risk-based assessment in setting regulation and achieving better decisions about conformity assessment requirements for regulated products.

WTO ITA could examine the application of risk-based assessment by regulators to the setting of conformity assessment requirements.

WTO ITA could conduct this examination with a view to supporting the work being undertaken by organisations such as the International Laboratory Accreditation Cooperation (ILAC) and IEC to implement systems of portable conformity assessment based on equivalent processes of peer assessment and accreditation.

**Appropriate Regulatory Framework**

As a system of regulation SDoC requires a different set of skills and functions from a regulator to those required in an approval system. The skills and functions necessary in a regulatory framework that utilises SDoC cannot be easily stated for all countries, but some important considerations are:

- The capacity and powers to conduct audit and market surveillance
- Ability to support multiple conformity assessment routes
- Applying risk factors to regulation
- Properly stated regulatory objectives
- Use of international standards
- Open communications of requirements
- Appropriately trained staff
- Capacity to conduct and maintain industry liaison and consultation

- Adequate checks and balances to support consumer confidence
- Referral to external experts in appointment of conformity assessment bodies.

WTO ITA could examine the principles for regulatory practice which maximise the benefits of greater trade facilitation while ensuring the integrity of legitimate regulatory protections.

## 6. EVALUATING THE TRADE EFFECTS OF SUPPLIERS' DECLARATION OF CONFORMITY

The OECD investigated the impact of Supplier's Declaration of Conformity (SDOC) on trade flows[205]. As under SDOC regimes suppliers themselves provide written assurance of conformity to applicable technical regulations of a market, the costs of compliance are assumed to be smaller than for CA regimes requiring certification by third parties.

The study focuses on three cases of SDOC introduction in the European Union covering eligible products from the medical devices, telecommunications equipment and machinery sectors. The paper explains the rationale for using SDOC, expected benefits and design characteristics of SDOC regimes. The quantitative analysis uses a gravity model and finds compelling evidence that the introduction of SDOC in the EU was a factor that influenced the evolution of import flows into EU markets positively. Intra-EU trade flows and imports from extra-EU OECD countries increased for SDOC-eligible radio and telecommunications equipment and low-risk medical devices, whereas the results for machinery are ambiguous. The most striking increases, visible in all three sectors, are found for exports to EU markets from non-OECD (developing) countries included in the sample. Analysis of the effect of SDOC for selected individual EU members furthermore suggest that the magnitude of effect depends on the nature of the CA regime that SDOC replaced.

The study concluded the following:

First, introduction of SDOC in the EU region was indeed one factor that influenced positively the evolution of imports during the time period studied. Results from the two-stage Heckman estimation show that replacement by SDOC of CA regimes that EU members applied to RTTE and Class I medical devices and that on average were stricter, made trade easier. For the products studied, the switch to SDOC enabled trade (imports) of SDOC products among country pairs that did not trade these products before, and it raised the level of trade that already existed. The situation for machinery is less clear; we have less confidence in the estimates obtained because of the peculiar behaviour of the machinery market, which renders the coefficients of the SDOC variables unstable across alternative equations.

Second, the regression analysis reveals an intriguing feature of the import behaviour observed. While the EU's SDOC policy applies without discrimination to all producers, regardless of where they are located, the impact varies across different groups of source countries. Imports from non-OECD (developing) countries have benefited most.

205 Fliess, B., F. Gonzales and R. Schonfeld (2008), "Technical Barriers to Trade: Evaluating the Trade Effects of Supplier's Declaration of Conformity", OECD Trade Policy Papers, No. 78, OECD Publishing, Paris.

Third, the regression analysis confirms that bilateral trade flows between EU markets and with extra-EU countries are influenced by a host of factors other than SDOC, some of which were explicitly taken into account in the specification of the gravity equations. These were however not the variables of prime interest to this study.

The results from both the first stage selection and second-stage regression of the Heckman model indicate that SDOC has facilitated non-EU countries' entry of EU markets for eligible RTTE and Class 1 medical devices, and that in particular firms located in non-OECD (developing) countries have rather consistently profited from the EU-wide switch to SDOC in all three sectors. This lends support to the notion that the testing and other requirements of the national CA regimes previously in place created important fixed costs that effectively acted as a barrier to exporting. Such costs do not vary with the volume exported to a foreign market, but they can deter firms from pursuing sales opportunities abroad. SDOC appears to have lowered firms' fixed costs.

The evidence in this paper furthermore suggests that SDOC affects firms' variable costs more than their fixed costs. This is because while new market entries occurred, this response is weaker than the positive change found for already existing imports. Results from second-stage OLIS regressions confirm that the introduction of SDOC created more export opportunities for countries with firms already supplying EU markets. Here again, there was a very favourable impact of SDOC on imports from non-OECD (developing) countries, which emerge as clear winners from the change of the CA system. For extra-EU OECD countries and for intra-EU trade, results tended to be positive and statistically significant, but less consistently so - e.g., SDOC facilitated imports from OECD countries of eligible medical devices, but not of RTTE, and it contributed to higher intra-EU imports of RTTE and medical devices, but not machinery. This observed stronger impact on the level of existing imports differs from what Baller (2007) found in her study of MRAs. SDOC apparently has only a modest influence on a firm's decision whether it should enter a market, but once a supplier has entered a market SDOC makes a difference and strengthens sales. In the case of MRAs Baller found the market entry effect to dominate.

The question whether firms actually adjust their practices of demonstrating conformity with given requirements in ways that would allow them to take advantage of the cost savings that the CA regime change offers is answered affirmatively by the results of this study. This clearly happened in the case of the EU's SDOC initiative, an additional incentive perhaps being that SDOC was introduced EU-wide so that potential gains were amplified by the prospect of further gains resulting from selling to a unified large market. Note also that the size of cost savings and hence the trade facilitation potential depends on the magnitude of the regime change. As this paper has explained, SDOC regimes can vary greatly in their complexity, and the EC opted for a relatively simple form of SDOC, which replaced national regulations that on average were more restrictive. The analysis of individual Member States' imports of medical devices and machinery represent the first attempt to formally estimate how variation in the magnitude of regime change affects the trade response.

That the estimation results of the Heckman model show that the trade effects vary depending on the different groups of exporters and that the difference is particularly strong for OECD and non-OECD countries does not appear to be consistent with a policy

measure (SDOC) that by design is non-preferential. Logic and non-statistical evidence may offer some help in understanding why the variations have emerged. It is widely accepted that in what is sometimes called the SQAM field (Standards, Quality, Accreditation, Metrology) the technical infrastructure in developing countries is weak, and that its poor quality constitutes a barrier to development. In many technical assistance programmes, the SQAM field is an identifiably separate field for aid. While SQAM infrastructure remains poor, complex processes of conformity assessment will be harder to master for local producers than for producers in more developed markets. The problem is compounded when mandatory third-party conformity assessment is coupled with the requirement to use a conformity assessment body (CAB) in the destination market: for suppliers from most OECD member countries at similar stages of development, it will be relatively easy to develop a relationship with a highly competent CAB in another country – not so for a developing country supplier. The removal of mandatory third-party CAB in a destination market will therefore be an even greater benefit to a developing country supplier who did not have the capability to master it in the first place.

That argument, however, does not explain why imports between EU countries would be affected differently by SDOC than imports coming from other OECD countries outside the region – i.e., why exporters located in OECD countries benefit less from SDOC than their counterparts in EU countries. A logical explanation for that might be simply that EU suppliers would generally be more keen to take advantage of significant new benefits offered in their home market, which in many cases will count for a higher proportion of total revenues than for suppliers outside.

One less palatable argument may also be mentioned – and indeed sometimes is mentioned – to explain the apparently disproportionate benefit to developing countries: that imports from non-OECD countries into the EU have increased because of widespread rogue practices of manufacturers operating in developing countries. They self-certify compliance with the standards in the EU but in practice may not verify. This way they save most of the costs associated with SDOC and can offer their products at very competitive prices. Concern about the dangers to public safety presented by the abandonment of ex ante technical checks by bodies under the direct authority of government in the import market is well known and understood, and is consistent with this fear of rogue practice. The authors have, however, not come across official records that would indicate that such practices are indeed common in the three sectors studied.

The authors made a special comment on the results for machinery, which are partly ambiguous and partly contradict the statistical conclusions from the other two sectors. Only for non-OECD (developing) countries are the results for machinery consistent with those for the other two sectors: SDOC can be demonstrated to have led to increased exports by developing countries to the EU. But for intra-EU trade and for imports from OECD countries, the results are ambiguous or negative. No statistical explanation for this exception emerges from the study, and a wider debate may be justified.

The authors do feel, however, that it is possible to offer a logical hypothesis to explain the difference. It is based on the complexity of the other changes to EU technical regulation introduced simultaneously by the same technical regulation which introduced SDOC in this sector: notably, the commissioning of an entire new generation of

European standards which may have led in some cases to radical changes in manufacturing processes or documentation even for established, domestic suppliers. The changes were far more complex than those involved in the other two cases in this study – remember notably that in the (admittedly often complex) medical devices sector, this study covered only the simple Class I medical devices, with a relatively limited number of standards. In machinery, on the other hand, several hundred new standards were involved, and the process of identifying the combination standards applicable to a specific product was initially complex, and complicated further by the fact that for many products, product specific standards took years to develop, forcing suppliers to determine for themselves – or with the help of external specialists – how to meet the – also new – essential requirements of the directive itself. The process of adaptation might have been more disruptive for producers in developed countries than for new suppliers in the developing world, who would have seen the simplification and uniformity across the entire EU as an opportunity rather than a burden.

There are two ways in which regulatory complexity affects measurement of the trade impact of SDOC in the case of the EU. First, when SDOC was introduced it replaced all previous national systems at the same time; i.e. SDOC was harmonised across the region for applicable product classes. Second, in two of our three sectors the Directives which introduce SDOC also introduce other changes unrelated to SDOC, such as the harmonisation of standards. This study's model specification has tried to separate SDOC introduction from its EU-wide harmonisation and from the Directives' other provisions by including a set of products in each sector that are not eligible for SDOC and taking into account also the imports of three countries that did not join the EU's SDOC initiative. In addition, the authors have worked with product fixed effects that should also cover effects such as those generated by SDOC harmonisation. These are first estimates, and while the authors think their model has been well specified, they think that it would be useful to replicate this study for individual countries that have adopted SDOC in the absence of other regulatory changes.

Factors such as economic growth and technological developments, have undoubtedly contributed to a significant expansion over the last decade of exports of RTTE and other manufactured products from such countries as Brazil, China and India, which are included in this study's sample of non-OECD countries. But exports from these countries driven by such factors have increased not only with respect to Europe but also with respect to the United States and other major markets of the world. By differentiating the EU from the control group countries and adding country and time fixed effects, the specifications of the gravity equation have controlled for the interference of these factors in the measurement of SDOC impact.

The authors argue that the econometric procedures used are appropriate and, with the exception of the machinery sector, the specifications have performed well enough to create confidence about the sign of the coefficients of the SDOC variable. The size of the effect (i.e., size of SDOC coefficients) is best taken as indicative, for two reasons:

– First, the effect of SDOC is for the set of (SDOC and non-SDOC) products included in the study, and the specific products covered could explain the big effects observed for SDOC in the estimations. Import behaviour in other sectors

could be different, although it would be reasonable to expect to find SDOC having a positive effect where the transition is from a more restrictive regime.

– Second, the gravity model is most widely used and has proven itself when modelling uses bilateral flows of trade at the aggregate level. Here, it was applied to trade in product segments in three sectors, making use of highly disaggregated trade data. Other empirical work has shown that the gravity model remains a useful analytical tool even at a disaggregated level of trade; however, disaggregation heightens the sensitivity of explanatory variables and this may lead to surprising results. This warrants caution not to take the magnitude of the coefficients of the SDOC variable at face value. At this time it is not possible to provide external tests for our estimates, as other studies assessing SDOC's trade effects are nonexistent to the authors' knowledge.

## ANNEX 9 THE SME TEST – SUMMARY OF RESULTS

| **(1) Preliminary assessment of businesses likely to be affected** | |
|---|---|
| Around **87%** of the enterprises operating within the non-harmonised sectors **are micro enterprises** (i.e. with less than 9 employees) and around **11% are small and medium enterprises** (i.e. with a number of employees between 50 and 250)[206].<br><br>Therefore, the problem is likely to particularly affect SMEs. | (See section 2 – Economic context and 3.2 - The consequences of the problem as well as Annex 3- Who is affected and how and Annex 4 – Analytical tools and economic context) |
| **(2) Consultation with SMEs representatives** | |
| An online public consultation was carried on from the 1st of June until the 30 of September 2016 (17 weeks) accessible via the *Your voice in Europe* website. The consultation was made available to the general public, and aimed at gathering data on the functioning of mutual recognition, the current problems as well as possible options for improvement. **153** replies were received during the public consultation.<br><br>Many business associations which replied to the consultation represented SMEs and, in addition, 22 SMEs and 8 micro enterprises submitted an individual reply to the consultation. The results show that the majority of SMEs, when faced with national rules preventing them from selling their products as such tend to adapt their products instead on relying on mutual recognition. This happen despite the fact that the majority of SMEs tried to rely on mutual recognition for entering the market. Market access denial also affected SMEs, as up to 71% of SMEs were faced with a market access denial decision after using mutual recognition for entering a market. As regards challenging these decisions, 7% of SMEs successfully challenging such decision (0% for micro and medium enterprises).<br><br>The Commission presented the initiative and sought the views of SMEs at the Small Business Act regular meeting with European SME associations on 7 December 2016. | (See Annex 1 - Procedural issues and Annex 2 – Synopsis report of the stakeholder consultation) |

206 These figures have been computed for the period 2011 – 2013 since the enterprise statistics by size class for aggregates of activities (NACE rev.2) are only available for this period.

| | |
|---|---|
| | |
| **(3) Measurement of the impact on SMEs** | |
| More than half of SMEs say that administrative procedures related to exporting to other Member States are too difficult to comply with and therefore deter many firms from exporting.[207] According to the Commission's 2014 Competitiveness report, only 14% of SMEs are trading across borders in the EU compared to 85.4 % of large manufacturing firms[208]. This translates into **lost opportunities** for businesses as well as costs resulting from **delays for entering a market**. In addition, it also generates a loss of competitiveness and innovation.<br><br>Furthermore, SMEs are more impacted by information costs, as they don't have the necessary internal resources to allocate to finding the applicable rules in the member State where they want to sell their products, nor the financial means to externalise this research. Alike, SMEs are heavily impacted by the lack of efficient means to challenge administrative decisions denying market access, because they don't have internal legal departments to deal with these long and costly procedures. For a fact, 83% of businesses using alternative disputes resolution systems such as SOLVIT are SMEs[209]. | (See section 7 – Analysis of the impacts and Annex 3 – Who is affected and how) |
| **4) Assess alternative options and mitigating measures** | |
| At the end of the impact assessment, the selected option shows that the initiative might have a very positive economic impact on the stakeholders in general, including SMEs. Consequently, there is no element showing the need for SME specific measures in order to ensure compliance with the proportionality principle. | (See section 7 – Analysis of the impacts and Annex 3 – Who is affected and how) |

207 Flash Eurobarometer 421: Internationalisation of Small and Medium-sized Enterprises https://data.europa.eu/euodp/en/data/dataset/S2090_421_ENG and Flash Eurobarometer 413: Companies engaged in online activities https://data.europa.eu/euodp/en/data/dataset/S2058_413_ENG

208 More specifically, the 2014 Competitiveness report indicates that among the roughly two million manufacturing SMEs (0-249 employees) in the EU-28, 14.3 % export goods to EU countries. One can observe that export participation increases strongly with firm size. Meanwhile, 7.9 % of micro enterprises, 37.5 % of small firms, and 67.0 % of medium-sized enterprises export to internal markets, compared to 85.4 % of large manufacturing firms. This indicates that the export participation of large firms is about 10 times higher than that of micro enterprises. SWD(2014)277 final: http://ec.europa.eu/DocsRoom/documents/6706/attachments/1/translations/en/renditions/native

209 Source: SOLVIT database

## ANNEX 10 GLOSSARY OF TECHNICAL TERMS AND ABBREVIATIONS

**List of acronyms and abbreviations**

| | |
|---|---|
| BIS | Business Innovation and skills |
| CBA | Cost benefits analysis |
| CBT | Computer based training |
| CE | Conformité Européenne |
| CPCP | Construction Products Contact Point |
| DG | Directorate General |
| EEA | European Economic Area |
| EC | European Commission |
| EEN | Enterprise Europe Network |
| ECJ | European Court of Justice |
| EFTA | European Free trade Association |
| ESO | European standardisation organisations |
| EU | European Union |
| IA | Impact assessment |
| ICSMS | Information and Communication System on Market Surveillance |
| IMI | Internal Market information System |
| IT | Information Technologies |
| MR | Mutual Recognition |
| MS | Member States |
| NLF | New legislative framework |
| OECD | Organisation for Economic Co-operation and development |
| PCP | Product Contact Point |
| RAMON | Reference and Management of Nomenclatures |
| SITC | Standard international Trade Classification |

| | |
|---|---|
| SME | Small And Medium Enterprises |
| SOLVIT | Service provided by national administrations offering assistance when your rights as a citizen or business are breached by public authorities in another Member State |
| SWOT | Strengths, Weaknesses, Opportunities, Threats |
| TFEU | Treaty on the Functioning of the European Union |
| TRIS | Technical regulations Information Systems |

**List of countries**

| | |
|---|---|
| AT | Austria |
| BE | Belgium |
| BG | Bulgaria |
| CY | Cyprus |
| CZ | Czech Republic |
| DE | Germany |
| DK | Denmark |
| EE | Estonia |
| EL | Greece |
| ES | Spain |
| FI | Finland |
| FR | France |
| HR | Croatia |
| HU | Hungary |
| IE | Ireland |
| IT | Italy |
| LT | Lithuania |
| LU | Luxemburg |

| | |
|---|---|
| LV | Latvia |
| MT | Malta |
| NL | The Netherlands |
| PL | Poland |
| PT | Portugal |
| RO | Romania |
| SE | Sweden |
| SI | Slovenia |
| SK | Slovakia |
| UK | United Kingdom |