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signed by Mr Jordi AYET PUIGARNAU, Director

date of receipt: 20 December 2017

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of  
the European Union

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Subject: COMMISSION STAFF WORKING DOCUMENT REFIT EVALUATION  
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

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Delegations will find attached document SWD(2017) 475 final.

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Brussels, 19.12.2017  
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**COMMISSION STAFF WORKING DOCUMENT**

**REFIT EVALUATION**

*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**

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## 1. CONTEXT

Obstacles to the free movement of goods within the single market can be eliminated by harmonising national legislation or through the principle of mutual recognition.

Mutual recognition is seminal for the 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 in the case law, and in 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<sup>1</sup> 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 interest, and those requirements are necessary and proportionate for achieving that objective. **This is the principle of mutual recognition in the field of goods.** Annex 4 contains an overview of the relevant case law on the basis of which the principle was elaborated.

The practicalities of how mutual recognition works in practice are defined by the **Mutual Recognition Regulation**. The Regulation 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.

In December 2013, the Conclusions on Single Market Policy, adopted by the Competitiveness Council, recalled 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<sup>2</sup>. 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 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 external evaluation<sup>3</sup>, part of the REFIT agenda in 2014<sup>4</sup>. Its objective was to assess the functioning of the principle, in terms of efficiency and effectiveness. Among the shortcomings identified the external evaluation pointed out the limitations of the Mutual Recognition Regulation and recommended several ways forward to improve its application. These conclusions triggered the need to evaluate the Mutual

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1 Applies also to EEA products

2 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](http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/intm/139846.pdf)

3 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](http://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/index_en.htm).

4 Scoreboard Regulatory Fitness and Performance Programme (REFIT): State of Play and Outlook, SWD(2014)192; [http://ec.europa.eu/smart-regulation/docs/com2014\\_368\\_en.pdf](http://ec.europa.eu/smart-regulation/docs/com2014_368_en.pdf)

Recognition Regulation, and to complement the evaluation of the mutual recognition principle.

This evaluation will assess the functioning of mutual recognition in the field of goods, i.e. the mutual recognition principle and the Mutual Recognition Regulation. According to the 'Better Regulation Guidelines'<sup>5</sup>, evaluations are an essential step to managing and revising the existing body of EU legislation and policies and should precede the impact assessment, in line with the "evaluate first" principle. This evaluation will assess to what extent mutual recognition has achieved its original objectives in term of effectiveness, efficiency, relevance, coherence, and EU value-added. Its findings should feed into the impact assessment of the planned initiative on achieving higher and better mutual recognition, called upon in the Single Market Strategy, Upgrading the Single Market: more opportunities for people and business, adopted on 28 October 2015<sup>6</sup>, and one of the main objectives of the 2017 Commission Work Programme<sup>7</sup>. This initiative, called "the Goods package", aims to give citizens and businesses the assurance that the Single Market protects and empowers them. People need to be confident that products available on the market can be trusted, their rights as consumers are not undercut, and businesses need to be confident that they can sell their products throughout the EU and that competition is fair. Therefore, the Commission is proposing, on the one hand, to strengthen the implementation of EU harmonisation legislation by supporting compliance and enforcement and on the other, to give a major boost to mutual recognition in the area of goods. The initiative has been linked to the REFIT programme<sup>8</sup> due to the impacts the malfunctioning of mutual recognition has on the functioning of the internal market. The evaluation will therefore examine the extent to which the legal framework for mutual recognition is fit for purpose and delivers its intended benefits while avoiding undue costs.

## **2. BACKGROUND TO THE MUTUAL RECOGNITION PRINCIPLE AND REGULATION**

### **1.1 Baseline**

The principle of mutual recognition, stemming from Articles 34-36 TFEU and elaborated on the basis of case law, requires that, notwithstanding technical differences between the national rules that apply throughout the EU, the Member State of destination may not prohibit the sale on its territory of products that are lawfully marketed in other Member States, even if those were manufactured in accordance with different technical rules. The only possibility for Member States to deny market access for products lawfully marketed in another Member States is on the basis of overriding interests linked to the protection of public interest such as protection of health, consumers, environment, etc. Therefore, the application of mutual recognition is not automatic. It can be lawfully denied if Member States demonstrate that, by not complying with its own national rules, a product lawfully marketed in another Member State would endanger the protection of a given the public interest. Mutual recognition aims to facilitate the free movement of goods, where there are no EU harmonised rules governing the marketing of products or parts thereof, while maintaining a high level of protection of public interests. It is particularly relevant for innovative products, where businesses need to rely on

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5 [http://ec.europa.eu/smart-regulation/guidelines/index\\_en.htm](http://ec.europa.eu/smart-regulation/guidelines/index_en.htm)

6 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

7 [http://ec.europa.eu/atwork/key-documents/index\\_en.htm](http://ec.europa.eu/atwork/key-documents/index_en.htm)

8 The aim of the REFIT programme is to ensure that EU laws are fit for purpose and deliver their intended benefits for citizens, businesses and society while removing red tape and lowering costs. It also aims to make EU laws simpler and easier to understand. REFIT pays particular attention to small businesses, which can be disproportionately affected by the burden of implementing EU rules.

existing national rules or deal with the absence of such rules in order to launch new products on the market.

Applying the mutual recognition principle also consists of scrutinising national technical rules, in order to identify those undermining free movement of goods. This was done mainly by:

- Requiring the insertion of a so called "mutual recognition clause" in the new national technical regulations, when those are notified to the Commission via Directive (EU) 2015/1535<sup>9</sup>
- Dealing with complaints and infringements of free movement of goods as guaranteed by Articles 34-36 TFEU

Yet, the application of the mutual recognition principle in practice was challenging since its introduction by the Court of Justice in 1979<sup>10</sup>. Already in 1996, the Commission highlighted in a communication to the Parliament and the Council<sup>11</sup> the difficulties of applying the mutual recognition principle in practice. These concerns were reiterated again in a Commission Working Document in 1998<sup>12</sup>, and in a communication from 1999<sup>13</sup>. Furthermore, the surveys carried out in 2002 for the second biennial report on the functioning of mutual recognition<sup>14</sup> indicated that about 35% of businesses reported problems with mutual recognition, and about 50% of them decided to adapt their products to the rules of the Member State of destination. Furthermore, about 25% of the complaints received in the area of free movement of (non -harmonised) goods related to mutual recognition, and market access for products constituted one of the most important problems registered by SOLVIT. The Commission analysed the reasons for this in 2007<sup>15</sup> and reached the following conclusion: The lack of awareness about the mutual recognition principle, the legal uncertainty about the scope of the principle and the burden of proof, the risk for enterprises that their products will not get access to the foreign market or that they will have to be withdrawn from the market of the destination Member State, and the absence of a dialogue between competent authorities in different Member States prevents the achievement of free movement of goods in the non-harmonised area<sup>16</sup>. Following this analysis, it was estimated that, depending on the product, the differences between technical rules in different national markets, combined with the need for multiple testing and certification, may constitute between 2% and 10% of overall production costs<sup>17</sup>. However, the 2007 analysis was based on a very theoretical methodology to estimate macroeconomic impacts, such as estimates as a percentage of increase in GDP. As these estimates could not be verified ex post, the findings of the 2007 analysis were not considered reliable enough to be used as a basis for the evaluation.

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9 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

10 C-120/78 "Cassis de Dijon"

11 The impact and effectiveness of the Single market, Communication from the Commission to the European Parliament and the Council, 30 October 1996 [http://ec.europa.eu/internal\\_market/economic-reports/docs/single\\_en.pdf](http://ec.europa.eu/internal_market/economic-reports/docs/single_en.pdf)

12 SWD on the application of the mutual recognition principle, SEC(1998) 242

13 Communication from the Commission to the Council and the European parliament, Mutual recognition in the context of the follow-up to the Action Plan for the Single Market, COM(1999)299 final

14 COM(2002)419final of 23.7.2002

15 Commission staff working document COM(2007) 36 Final of 2007

16 Communication on mutual recognition COM(1999)2999 Final, first and second biennial report on the application of the principle of mutual recognition, SEC(1999)1106 of 13 July 1999 and COM(2002)419 Final of 23 July 2002, Commission staff working document COM(2007) 36 Final of 2007

17 See footnote 15

The adoption of Regulation (EC) No 764/2008 ('the Mutual Recognition Regulation') was a response to the suboptimal application of the principle of mutual recognition in the field of goods, mainly aimed at addressing the issues identified and establishing a procedural framework to minimise the possibility that national technical rules create unlawful obstacles to the free movement of goods between Member States.

## 1.2 Objectives of the mutual recognition principle and Regulation

The objective of the mutual recognition principle is to guarantee free movement of goods in the internal market, in the absence of harmonised rules. The principle allows goods to move freely, despite the existence of different and potentially divergent national technical rules. As for the Mutual Recognition Regulation, it aimed to increase awareness of the mutual recognition principle, ensuring legal certainty for national authorities and businesses and improving administrative cooperation between national authorities.

## 1.3 Description of the mutual recognition principle and Regulation

This section describes the different components of mutual recognition.

### 1.3.1 *The mutual recognition principle and its tools*

The mutual recognition principle applies in the area of products that are not subject to EU common rules (non - harmonised products) or to aspects of products falling outside the scope of such legislation (partially harmonised products). It allows a product lawfully marketed in a Member State to be sold in other Member State, despite the fact that this product complies with different technical rules. Exceptions to this principle are justified on grounds of the protection of public morality or public security, the protection of health and life of humans, animals or plants, provided for under Article 36 TFEU or on the basis of overriding requirements of general public importance recognised by the case law of the Court of Justice, and also that they are proportionate to the aim pursued. The mutual recognition principle would apply in the area of childcare articles, textiles, decorative articles, furniture, lighters, cooking accessories, etc. The principle applies to the marketing of the whole product, or to aspects of it, if it is a partially harmonised product. For example, textiles: the content of chemicals that may be present in textiles is harmonised, but the lengths of the cords for children's textiles (to avoid strangulation risks) is left to national discretion (and thus subject to mutual recognition). Mutual recognition also applies to a number of non-consumer products. For example, while certain measuring instruments such as taximeters or water meters are subject to EU harmonisation legislation, others such as radars for speed measurement or breathalysers for estimating blood alcohol content are not.

- *The mutual recognition clause*

The clause is one of the tools allowing for the correct application of the mutual recognition principle. In its 2002 Communication on the application of the mutual recognition principle<sup>18</sup>, the Commission recommends<sup>19</sup> the insertion of a mutual recognition clause in national technical rules notified under Directive (EU) 2015/1535, to give the concerned economic operators a precise and clear understanding of their

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18 Commission interpretative communication on facilitating the access of products to the markets of other Member States: the practical application of mutual recognition, 2003/C 265/02

19 The insertion of the clause is not considered as mandatory for Member States

rights and obligations with regards to the application of that rule to their products lawfully marketed in other Member States. In practice, the clause refers to the mutual recognition principle and procedural guarantees of the regulation; it expressly mentions that products lawfully marketed in other Member States are allowed to enter the market despite not fully complying with this national technical regulation.

- *Complaints and infringements related to Articles 34-36 TFEU*

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 which cannot be justified.

### *1.3.2 The Mutual Recognition Regulation*

The Regulation lays down 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. Therefore, the Regulation only applies when national authorities intend to restrict market access, and not before. It applies when:

- a. national authorities intend to take an administrative decision,
- b. concerning a product lawfully marketed in another Member State,
- c. concerning a product or aspects of a product which are not subject to harmonised EU legislation,
- d. addressed to economic operators,
- e. based on a national technical rule, and
- f. has a restrictive effect on the product, namely that it will be:
  - i. prohibited from being placed on the market,
  - ii. modified or subject to additional testing before it can be placed or kept on the market, or
  - iii. withdrawn from the market

This means that 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<sup>20</sup>.

- *Assessment by Member States of the need to apply a technical rule and information to the economic operator*

The mutual recognition principle is not automatically applied. It is not an obligation on Member States, but a right which can be invoked by economic operators wishing to trade their products in the internal market. Member States may decide that the application of a national technical rule, to the detriment of mutual recognition, is necessary, based on the need to protect a given public interest. However, 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.

- *Product Contact Points*

Economic operators may wish to know about the applicable national rules before entering a market. The Regulation contains the obligation on Member States to establish Product Contact Points in their territories. The Product Contact Points 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.

- *The list of products which might be subject to mutual recognition*

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.

- *Reporting obligations*

Under the Regulation, every decision denying market access, as well as the grounds on which it is based, has to be individually notified by the Member States to the

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20 See recital 12 of the Mutual Recognition Regulation

Commission, in addition to notifying the economic operator. Additionally, Member States have to send the Commission on a yearly basis a report on the application of the Regulation.

**Table 2-1: Intervention logic mutual recognition**

| NEEDS   | ACTIONS   | OBJECTIVES  |  | IMPACTS                                    | EXTERNAL FACTORS   |
|---|---|---|--|--|--|
|   |   | GENERAL AND SPECIFIC                              | OUTCOMES   |  |  |
| <b>Remove barriers to trade of products lawfully marketed in one Member State</b> | Mutual recognition principle  | Free movement of goods in the non-harmonised area |  |  | Decentralized national administrations impeding the functioning of the product contact points network                        |
|   | <i>Mutual recognition clause</i>  |   |  |  |  |
|   | <i>Complaints and infringements</i>                                     |   | Products lawfully marketed in one Member States can be more easily sold in another | Better functioning of the internal market  |  |
|   | Regulation 764/2008   | <i>Awareness about mutual recognition</i>         |  |  | Perception of some national authorities that their own national rules are generally better than those of other Member States |
|   | <i>Procedures for assessing and denying / restricting market access</i> | <i>Legal certainty</i>                            | Reduction of information costs   | More choices for consumers at lower prices |  |
|   | <i>Product Contact Points</i>   | <i>Administrative cooperation</i>                 | Avoid duplication of tests/ additional testing                                     | More opportunities for businesses          | Perception of businesses that national rules must apply regardless of mutual recognition                                     |
|   | <i>List of products to which mutual recognition may apply</i>           |   |  |  |  |
|   | <i>Reporting</i>  |   |  |  | Tendency of businesses to avoid any problems by complying with national rules without questioning them                       |
|   | Complementary actions   |   |  |  |  |
|   | <i>Guidance documents on the application of</i>                         |   |  |  |  |

*the mutual  
recognition principle  
to specific sectors*

*Conferences,  
seminars and round  
tables on the  
application of the  
principle*

### 3. EVALUATION QUESTIONS

In order to assess the functioning of mutual recognition in the field of goods and to evaluate whether the mutual recognition principle and the Regulation are, in effect, on course to achieve their objectives, the following questions were used to guide the analysis:

- **Effectiveness**: To what extent have the mutual recognition principle and the Regulation been effective in meeting, or moving towards, the defined objectives (i.e. to what extent have they contributed to facilitating free movement of goods? To what extent has the Regulation contributed to achieving its objectives such as increasing awareness on the mutual recognition principle? To what extent has legal certainty been increased for businesses and authorities as a result of the Regulation? To what extent has the administrative cooperation been improved as a result of the Regulation? What are the factors that influenced the achievements and to what extent?)
- **Efficiency**: What are the costs of the mutual recognition principle and of the Regulation? What are the benefits of the mutual recognition principle and of the Regulation? To what extent are the regulatory costs (including administrative burden) proportionate to the benefits achieved?
- **Coherence with other policies**: To what extent is mutual recognition consistent with other policy actions at EU and national level?
- **Relevance**: To what extent is the mutual recognition principle and of the Regulation still relevant to its stakeholders? How well do the objectives (still) correspond to the current needs within the EU?
- **EU added value**: What is the additional value resulting from the Regulation, compared to what could be achieved by Member States at national and/or regional levels? To what extent do the issues addressed by the Regulation continue to require action at EU level? What would be the most likely consequences of repealing the Regulation?

### 4. METHOD

The approach was designed in several steps, in order to ensure collection of both qualitative and quantitative data from the relevant audience. First, a study on the functioning of the mutual recognition principle was carried out by an external consultant. On the basis of its results, an evaluation of the functioning of the mutual recognition principle and Regulation was conducted by the Commission's services, using the evidence from the above mentioned external evaluation and complemented by desk research, stakeholders consultation and a



study on the impacts of revising the Mutual Recognition Regulation. The evaluation covers the time period between the entry of the Regulation into force on 13 May 2009 and 31 December 2016. In terms of geographical coverage, the evaluation covers the EU Member States and the EFTA states that are contracting parties to the Agreement on the European Economic Area (EEA)<sup>21</sup>.

#### **1.4 External studies**

The application of the principle of mutual recognition was subject to an external evaluation<sup>22</sup>. 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. Thus, the study did not evaluate the Regulation specifically, but looked from a broader perspective at the impacts of an insufficient application of mutual recognition on economic operators and the internal market. Furthermore, the study focused on the effectiveness and efficiency aspects only, as these are the most relevant with regard to the mutual recognition principle, which stems directly from the Treaty and the jurisprudence. The 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.

Additionally, a study was launched in 2016 in order to estimate the market value of current intra-EU trade in non-harmonised products falling under the mutual recognition principle. Furthermore, the study looked into the magnitude of the problem triggered by the potentially suboptimal functioning of mutual recognition and its significance. This was done by analysing the intra-EU trade for harmonised goods compared to non-harmonised goods and their evolution over the last 10 years. The study was conducted between September 2016 and March 2017.

#### **1.5 Desk research**

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 4.1 and by the Commission's services. Available literature on the topic, annual reports from the Member States as well as all notifications<sup>23</sup> 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. The literature review comprised a review of existing business and academic literature on the non-harmonised areas in the EU internal market. Annex 4 contains a full overview of the assessed literature, and a summary of the notifications and annual reports received.

#### **1.6 Stakeholders consultation**

*Stakeholders consultation performed by the consultants*

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21 Iceland, Liechtenstein and Norway

22 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](http://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/index_en.htm).

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

In the framework of the external study mentioned under 4.1, 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 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). The interviews were conducted with the same person who responded to the survey, to the extent possible.

For the purposes of the second study mentioned under 4.1, an online survey was launched between December 2016 and January 2017. 100<sup>24</sup> respondents accessed the survey (40 businesses, 38 national authorities, and 22 business associations). In parallel with the launch of the survey, the research team started contacting selected stakeholders for in-depth interviews on the application of the mutual recognition principle across Europe. The team carried out 25 interviews in order to gather more fine-grained and detailed information about the implementation of mutual recognition.

Annex 2 provides a full overview of the stakeholders' consultation performed by the consultants.

#### *Stakeholders consultation performed by the Commission*

During the 8<sup>th</sup> meeting of the Consultative Committee on mutual recognition which took place on 25 October 2016, the preliminary findings on the functioning of mutual recognition were presented and discussed with Member States representatives.

An online public consultation was carried out from the 1<sup>st</sup> of June until the 30<sup>th</sup> of September 2016. 153 replies were received, representing 91 companies, 45 national authorities and 17 citizens. The consultation was made available to the general public, and aimed to gather data on how stakeholders perceive mutual recognition and its potential shortcomings, on the functioning of the Mutual Recognition Regulation (effectiveness, efficiency, coherence, relevance and EU added value), on the communication between mutual recognition users and on the possible options of achieving an increased and better mutual recognition. The results of the public consultation can be found in Annex 5.

A stakeholders' event was organised on 17 June 2016, to identify the main issues relating 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). The minutes of the event can be found in Annex 2.

## **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.

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24 However, only half of them answered the questionnaire to an extent that may be considered satisfactory

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 the full picture of the situation, as only 6 Member States are notifying decisions to deny market access<sup>25</sup>. 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 with 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 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<sup>26</sup>. 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.

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<sup>25</sup> See for more details section 7.1

<sup>26</sup> [http://ec.europa.eu/growth/smes\\_en](http://ec.europa.eu/growth/smes_en)

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<sup>27</sup>.

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 where a high regulatory activity at national level can be observed, and where the use of mutual recognition is more relevant<sup>28</sup>. 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, 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 exist or were introduced, in order to see if market access problems can be linked with 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 links 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 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 a strong indicative picture of the functioning of mutual recognition to be gathered, reliable enough to be used as a basis for further decision making.

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

28 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/>

Furthermore, it is necessary to draw lessons from the lack of reliable data on mutual recognition in order to be able, in the future, to better assess the impacts of the functioning of the principle on free movement of goods. In order to do so, is it appropriate to reflect on more reliable monitoring tools, such as a better information collection tool, preferably an IT tool, to facilitate the collection of data, as well as relying on existing surveys at EU level such on which the Commission could rely to collect data on how well the mutual recognition principle performs.

## 6. IMPLEMENTATION STATE OF PLAY

### 1.7 Implementation of the mutual recognition principle

In addition to the Regulation, two main tools were used for facilitating the implementation of the mutual recognition principle: the mutual recognition clause and the management of complaints.

#### *The mutual recognition clause*

It has been a longstanding Commission policy<sup>29</sup> to insist on the insertion of a mutual recognition clause in the technical rules of Member States<sup>30</sup>. During 2012 and 2014 for example, 2168 draft national rules were notified, and only 205 contained a mutual recognition clause. When inserted, the clause is often unclear or not very detailed. This shows that national authorities are reluctant towards mutual recognition, or that they lack awareness in particular regarding the benefits it could achieve. Therefore, they tend not to follow the Commission's recommendations in this area.

#### *Complaints*

Between 2009 and 2016, economic operators complained 195 times about a misapplication of the mutual recognition principle.

| Member State <sup>31</sup> | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | Total |
|----------------------------|------|------|------|------|------|------|------|-------|
| Austria                    |      |      |      |      | 1    | 1    | 1    | 3     |
| Belgium                    |      | 1    |      | 1    | 1    |      |      | 3     |
| Bulgaria                   |      |      | 2    |      |      |      |      | 2     |
| Czech Republic             |      |      |      | 1    |      |      |      | 1     |
| Denmark                    |      | 1    | 3    | 1    |      |      | 1    | 6     |
| Estonia                    |      |      | 1    |      |      |      |      | 1     |
| Finland                    |      | 1    | 1    |      |      | 1    | 1    | 4     |
| France                     | 1    | 6    | 7    | 4    | 7    |      | 3    | 28    |

29 Communications COM (1999) 299, COM (2002)419, COM (2003)200 and C (2003)3944

30 See section 2.3.1

31 Where the misapplication of the mutual recognition principle is reported

|                 |    |    |    |   |   |   |   |    |
|-----------------|----|----|----|---|---|---|---|----|
| Germany         |    |    | 1  | 2 | 1 |   | 1 | 5  |
| Greece          |    | 4  |    |   |   |   |   | 4  |
| Hungary         |    | 2  | 1  |   |   |   |   | 3  |
| Italy           | 7  | 7  | 3  | 2 | 1 | 3 | 2 | 25 |
| Latvia          |    |    |    |   |   |   | 1 | 1  |
| Lithuania       |    | 2  | 2  |   |   |   | 1 | 5  |
| Malta           | 1  |    | 1  |   |   |   |   | 2  |
| The Netherlands | 1  | 1  | 2  |   |   |   |   | 4  |
| Poland          | 16 | 10 | 10 |   | 1 | 1 |   | 38 |
| Portugal        |    |    | 3  |   | 1 |   |   | 4  |
| Romania         | 2  | 1  | 2  |   | 2 | 1 |   | 8  |
| Slovenia        |    |    |    | 1 |   |   | 1 | 2  |
| Slovakia        |    |    |    |   |   | 5 |   | 5  |
| Spain           | 4  |    | 1  | 4 | 3 | 2 | 3 | 17 |
| Sweden          | 2  | 1  | 2  | 1 |   | 1 | 1 | 8  |
| UK              |    | 1  | 1  | 1 | 6 | 5 | 3 | 17 |

The sectors where most of the complaints were registered are food, construction products, labelling and precious metals.

| Most concerned sectors                 |    |
|--|----|
| Food (e.g. food supplements, vitamins) | 30 |
| Construction products                  | 17 |
| Labelling (including food labelling)   | 21 |
| Precious metals                        | 6  |

## 1.8 Application of Regulation (EC) No 764/2008

This section describes the implementation of the different components of the Regulation, since its entry into force on 13 May 2009. The effects of the implementation are further assessed in section 7.

### *Establishing Product Contact Points (PCPs)*

PCPs have been established in all EU Member States. Their list was initially published in the OJ<sup>32</sup> and is regularly updated and available online on the Commission's website<sup>33</sup>.

The Regulation left the set-up of PCPs to the discretion of Member States, thus, their organisation and function vary significantly. Most Member States have a single PCP, responsible for all inquiries related to non-harmonised products. In a few Member States<sup>34</sup>, the PCP is split between a general one and a construction products specific one. Other Member States<sup>35</sup> have PCPs in 6-7 different ministries. In almost all Member States, the PCP (or the co-ordinator, where there are several PCPs) is located within the ministry responsible for industry/business and the internal market, often as part of a group or team dealing with internal market policy. Only in Slovenia the PCP is located in an independent institute (the Slovenian Institute for Standardisation). A few PCPs handle queries (or part of queries) themselves. In Malta, the PCP is responsible for all communication with companies. However, this setup is unique to Malta (and difficult, if not impossible, to handle in a larger Member State), and in most cases queries from economic operators are passed on to the responsible ministry, department or directorate or, occasionally, the relevant local authority. In Italy, there is an appointed PCP, however, economic operators must contact the relevant ministry in charge of their product and receive their answer from this authority – without the PCP being involved. The way replies are being provided to economic operators also varies from one Member State to another. Very often, the responsible authority replies directly to the company making the query. Thus, the PCP has little insight on the outcome of the queries. Sometimes, national authorities provide answers to companies via the PCP.

#### *Establishing the list of products to which mutual recognition may apply*

Article 12 (4) required the publication of a non-exhaustive list of products which are not subject to EU harmonisation legislation by the Commission. This task proved to be very challenging, as there is no correspondence between the nomenclature under which products are classified in the different existing databases and the scope of the different pieces of harmonised legislation. On the basis of the existing Commission's Export Helpdesk database<sup>36</sup> it was possible to extract an indicative, non-exhaustive list of products not covered by any piece of EU legislation. This list is available online on the Commission's website on mutual recognition<sup>37</sup>. However, the list was not regularly updated, thus does not take into account repealed or newly adopted legislation since 2009. Furthermore, it does not provide any information on those products which are only partially covered by harmonisation legislation, and where mutual recognition may apply with respect to those aspects not covered by the harmonisation legislation.

#### *Notifications from Member States*

According to the Regulation, Member States shall notify the Commission every time they take an administrative decision denying or restricting market access. In the period between the entry of the Regulation into force on 13 May 2009 and 31 December of 2016, the Commission has received **3918** notifications, originating from **6 notifying Member States**.

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32 OJ C 185 of 7.08.2009, p. 6-12

33 [https://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/contacts-list\\_en](https://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/contacts-list_en)

34 Estonia, Latvia and Poland

35 Romania, Portugal and the Netherlands

36 <http://exporthelp.europa.eu/thdapp/index.htm>

37 [https://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/products-list\\_en](https://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/products-list_en)

The number of notifications received in 2015 amounts to 447, in line with the activity registered the year before (466 notifications in 2014). For 2016, the number of notifications increased: 646 notifications were registered. The measures notified relate mainly to precious metals. Some notifications concern food supplements, fertilisers, energy drinks and vitamins. Annex 7 contains an overview of all notifications received.

### *The yearly reports from Member States*

The Regulation requires Member States to submit a report every year on the application of the Regulation. However, despite the Commission's efforts to insist on the fulfilment of this obligation, not all Member States are communicating the reports as requested by the Regulation. For example, in 2016, only 23<sup>38</sup> Member States submitted annual reports, while 20 reports were received in 2015 and 21 in 2014.

Identifying recurrent problems and monitoring the application of the Mutual Recognition Regulation on the basis of the annual reports is not straightforward. This is because the data received is not homogeneous or comprehensive enough to be considered as usable input. The Regulation sets out minimum information to be provided in the annual reports, i.e. the number of decisions denying or restricting market access and the grounds on which they are based, and leaves to the discretion of Member States the additional information they might consider useful to report. This leads to considerable variations as regards the content of the reports received. The Commission suggested a template to be followed by Member States but this template is not widely used.

The reports highlight the main issues encountered by Member States when applying mutual recognition, in particular with regards to the lack of awareness, the poor administrative cooperation and the difficulties related to the concept of "lawfully marketed".

As regards awareness, almost all Member States highlighted in their annual reports the need for additional awareness raising campaigns and trainings, as many economic operators are not aware of mutual recognition and how it functions. Training and information campaigns are also considered useful and suggested for officials within Member States dealing directly with national technical rules, as this could have a positive impact on the way they apply mutual recognition with regard to products lawfully marketed in other Member States.

The lack of administrative cooperation is also a recurrent issue most Member States reported on. It is difficult to identify, within a Member State, the responsible authority responsible for a specific product. Difficulties are underlined also with regards to communication with authorities in other Member States. Some Member States report that they receive late and unclear answers<sup>39</sup>. Even when not reporting on specific problems encountered, Member States are calling for more administrative cooperation<sup>40</sup>. The reports also underline the limitations encountered by PCPs when exercising their activities. Often, they receive questions which are not within their remit, such as questions related to affixing the CE marking, which relates to the application of harmonisation legislation. They are also affected by the complexity of the questions they receive, the variety of products covered by mutual recognition and language limitations.

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38 Slovenia, the Netherlands, Malta, Italy and Luxembourg did not submit annual reports in 2016

39 e.g. Romania, Slovenia, annual report 2015

40 e.g. France, Sweden, annual reports 2015



The sectors where the application of mutual recognition is reported as being more problematic for both Member States and businesses are fertilisers, food labelling, food supplements (interpretation of various national authorisation procedures), construction products (role of autonomous certifying bodies, gold-plating, national quality marks and standards) and hallmarks (recognition of certificates).

Annex 7 contains an overview of all the annual reports received.

### *The telematic network*

Article 11 of the Regulation foresees that the Commission may establish a telematics network concerning the exchange of information between PCPs and/or the competent authorities of the Member States. The possibility of establishing this telematic network was discussed for the first time during the meeting of the Mutual Recognition Consultative Committee in 2014. The Commission suggested, for facilitating notifications and communication among PCPs, the use of the Internal Market Information tool (IMI)<sup>41</sup>. During the 2015 meeting of the Consultative Committee, they agreed on launching a pilot project for testing the use of IMI. However, this decision was postponed in the light of the adoption of the Single Market Strategy calling for higher and better mutual recognition by revisiting the Mutual Recognition Regulation. Member States considered that the choice of the IT tool for supporting notifications and communication should be made after the revision of the Regulation, and in line with the changes to be made, in order to be able to choose the most appropriate IT tool.

### *Meetings of the Consultative Committee on Mutual Recognition*

A Consultative Committee, established under the Regulation, assists the Commission. There is no obligation as regards how many times the Committee should meet. Usually, one meeting per year is organised. During the 8th meetings held, the Commission and the representative of the Member States and from EEA/EFTA (since 2011) have discussed matters relating to the application of this Regulation. The main topics discussed have been the guidance documents, the role of Product Contact Points, and ways forward in improving the application of the mutual recognition principle. Member States also raised the difficulties encountered during the application of the Regulation, such as the problematic concept of "lawfully marketed", the lack of awareness about mutual recognition and the lack of appropriate communication among PCPs.

Annex 12 provides an overview on the functioning of the Committee and issues discussed.

### *Guidelines, awareness raising campaigns and information*

A series of guidance documents offering practical information on the application of the Regulation to particular issues (e.g. the concept of "lawfully marketed", hallmarks, food supplements, etc.) have been prepared by the Commission with the input of the members of the consultative committee. These guidance documents are indicative, not legally binding, and have been made public on the Commission's website on mutual recognition<sup>42</sup>. Annex 4 contains an overview of all guidance documents published.

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41 [http://ec.europa.eu/internal\\_market/imi-net/index\\_en.htm](http://ec.europa.eu/internal_market/imi-net/index_en.htm)

42 <http://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/>

Since 2009, the Commission has organised or taken part in numerous seminars on mutual recognition in the internal market and the application of the mutual recognition principle. The main participants were businesses from areas most often impacted by mutual recognition and academia.

## 1.9 Compliance with the Regulation (EC) No 764/2008

During the period covered by this evaluation, no formal infringement procedures specifically related to the application of the Mutual Recognition Regulation were yet launched. Issues related to the lack of notifications or submission of annual reports were addressed with Member States during the meetings of the Consultative Committee<sup>43</sup>.

## 7. ANSWERS TO THE EVALUATION QUESTIONS

### 1.10 Effectiveness: Evaluating to what extent 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**. 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<sup>44</sup>. 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)<sup>45</sup>. In terms of turnover, non-harmonised sectors represent a significant contribution to the economy, i.e. enterprises operating within non-harmonised sectors contribute to around 20% of the total value of market sales of manufacturing sectors. Furthermore, the value on intra EU exports of non-harmonised products represented the 18% of the value of intra EU exports.

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

#### *1.10.1 Facilitating free movement of goods in the non-harmonised area through mutual recognition*

The results of the public consultation carried out between June and September 2016<sup>46</sup> show that the mutual recognition principle and the Regulation had limited effects in facilitating free movement of goods in the non-harmonised area.

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43 See annex 12

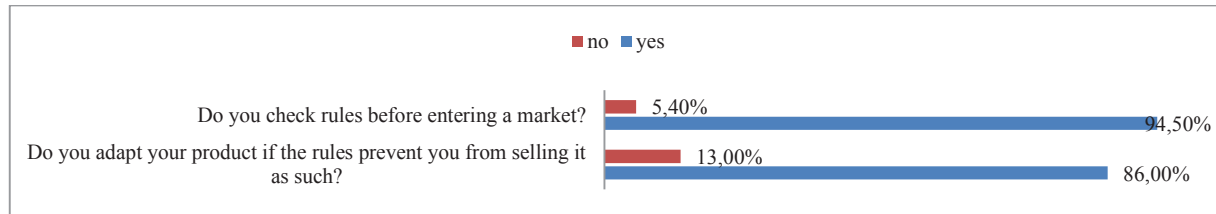
44 Around 2 million active enterprises are operating under Section C of NACE classification named Manufacturing. The correspondence between the list of NACE DIGIT-3 codes and the way they have been considered in the analysis (i.e. harmonised or non/partially harmonised) can be found in annex 5

45 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.

46 See annex 5

In general, the majority of companies wishing to sell products in another Member State check the applicable rules in that Member State. If these rules prevent them from selling their product as such, most of them adapt it.

**Figure 7-1: Public consultation 2016**

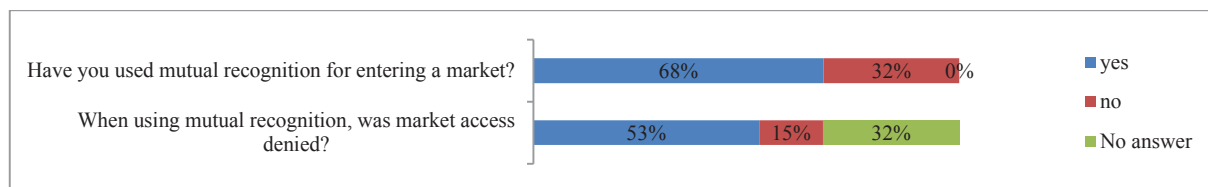


Several situations make businesses adapt their products. First, they can decide to do so immediately after the examination of the applicable national rules in the Member State where they want to sell their product, either because the business is not aware about the possibility of invoking mutual recognition to enter the market without adapting the product, or because the business don't trust mutual recognition, and prefer not to use it at all<sup>47</sup>. Secondly, they can decide to adapt the product after receiving an administrative decision denying market access, mainly because it's too long and costly to challenge such decision. Lastly, the choice of not using mutual recognition can also be solely based on strategic reasons, thus unrelated to awareness or trust in mutual recognition. For example, certain businesses prefer designing a product which fits all existing requirements in all Member States, and have the guarantee that they can penetrate any market without further modifications.

Furthermore, the 2016 public consultation shows that 68% of the respondents tried to use mutual recognition to enter a new market, but half of them faced market access denial. More specifically, 75% of micro enterprises, 80% of small enterprises and 71% of medium enterprises tried to use mutual recognition, and, respectively, 62%, 53% and 71% of them had their market access denied. In principle, national authorities can deny market access only when they have diverging product requirements whose mandatory imposition is justified by the need to protect a certain public interest, and those requirements are necessary and proportionate for achieving that objective. In practice, the stakeholders' feedback shows that market access denial is automatic, because national authorities are not aware of mutual recognition or they find that applying it to the detriment of their own rules results in legal uncertainty. Thus, they feel more confident in applying their national rules and ignore mutual recognition. Only 15% indicated that market access was not denied.

**Figure 7-2: Public consultation 2016**

47 31% had not used mutual recognition, mainly because they don't know about it (15%) or because they don't trust it (4%)



A recent study carried out by the Danish Business Association<sup>48</sup> also confirms the findings of the 2016 public consultations. This study shows that businesses are still experiencing barriers to free movement of products in the Single Market. 24 out of the 35 businesses interviewed by the association experienced problems with the application of the mutual recognition principle and Regulation, especially in certain sectors, such as construction products, food contact materials, products in contact with water and innovative products. According to this study, this is due to the fact that Member States apply national requirements<sup>49</sup> on products characteristics, including requirements relating to product testing and documentation, to the detriment of mutual recognition. This results in businesses having to retest or modify the products or giving up on marketing the products in certain cases.

### **Example: Upholstered furniture– a well-known obstacle for exports to the UK**

Special requirements in the UK for upholstered furniture – even for garden furniture – require that a special range of products have to be developed for the UK. Due to fire protection public interests, foam and textiles must be treated with flame resistant chemicals. These flame resistant chemicals, for environmental public protection reasons, are restricted in entering other markets.

The consequence for one specific company is that they need to have a double stock of furniture (binding capital of abt. 150,000 euro). There are extra initial costs for each product (abt. 50,000 euro per type), for which reason they have been forced to reduce the product range in the UK by abt. 25 p.c.

### **Example: Export of environmentally friendly, innovative product hindered by national regulation**

Some years ago, a small Danish manufacturer developed an intelligent solution for efficient pest control, completely without the use of poison. Since then, the products are in demand by an increasing number of countries around the world. The system monitors rodent activity and protects against rats entering the building or gaining a foothold in the area.

The product nevertheless meets many national obstacles in the form of national legislation

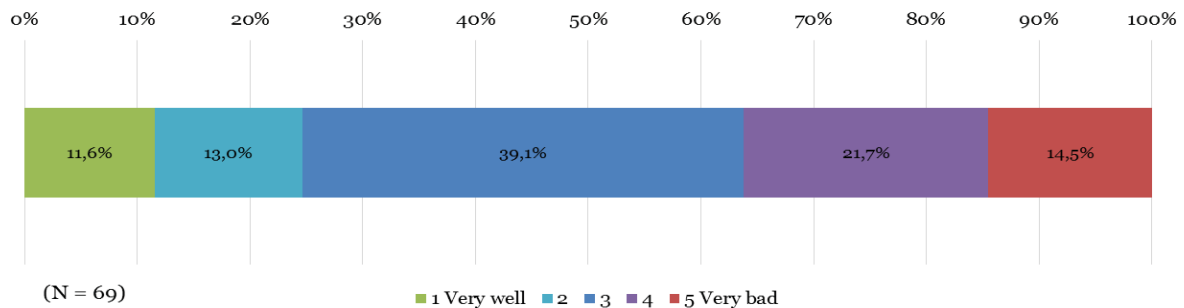
48 See annex 13 - based on qualitative telephone interviews with company executives and relevant technical managers from 35 member companies, covering many different sectors

49 Even if these national requirements are justified by the need to protect a given public interest, they may not always be necessary and proportionate.

aimed at animal protection (e.g. in Sweden and Germany). These national rules banning the use of electricity on animals de facto block the marketing of the products, even if they are proved to be both efficient and better than poison which remains in nature.

The findings of the surveys carried out during 2014-2015<sup>50</sup> are similar and point in the same direction. One third of the respondents among businesses believe that mutual recognition doesn't work well in practice. The reasons identified during the interviews are related to additional tests that national authorities require, to the detriment of mutual recognition. One of the examples provided relates to water taps<sup>51</sup>, where in 2014 several companies stated that additional different national tests are required, to the detriment of mutual recognition, in 17 Member States; the differences related not only to the testing required, but also to what needed precisely to be tested: in certain Member States components needed to be tested, while in others the testing referred to the whole product.

**Figure 7-3: Company survey: In your view, how well does the mutual recognition principle work in practice?**

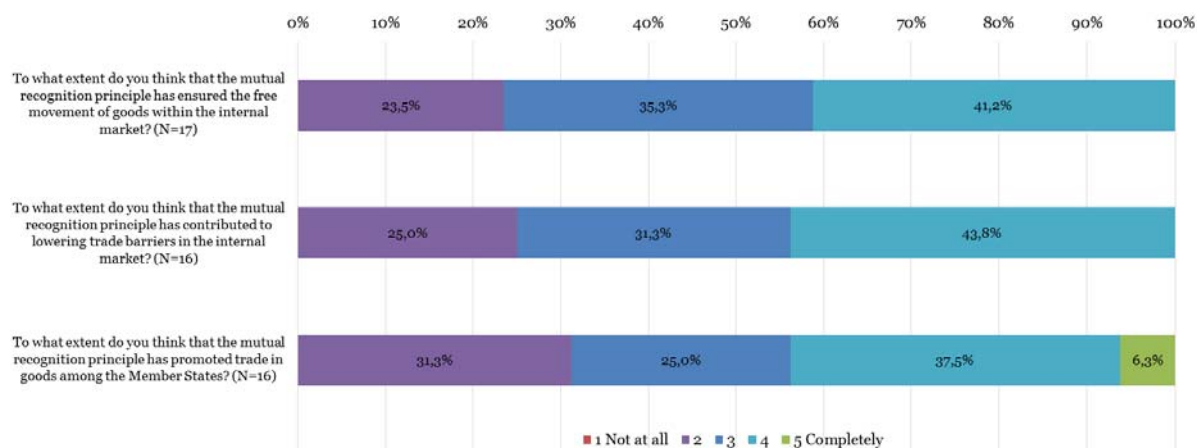


Source: Questionnaire survey among companies, running from 9 October 2014 to 5 January 2015, carried out by DTI

The survey among national business and sector associations showed that 25-35% of the respondents perceive the objectives to be partly reached (see Figure 7-4), because mutual recognition functions better in certain areas than in others. For example, a Belgian company with less than 10 employees in the precious metals sectors<sup>52</sup> explained that mutual recognition functions in an average way, and that it contributed to lowering trade barriers for certain categories of goods which can be sold without any further adaptations. A small company active in the construction area<sup>53</sup> (with 40% of its exports falling into the scope of mutual recognition) considered that mutual recognition works "badly" and that it did not lower trade barriers at all. This company gave up entering a market 3 times, due to the additional costs triggered by the request to modify or retest its products.

**Figure 7-4: Business and sector association survey: To what extent has the mutual recognition principle achieved its objectives?**

50 External evaluation of the mutual recognition principle 2014-2015  
 51 External evaluation of the mutual recognition principle 2014-2015, case studies, case study 2, 4, 8  
 52 External evaluation of the mutual recognition principle 2014-2015, case studies, case study 16  
 53 External evaluation of the mutual recognition principle 2014-2015, case studies, case study 12



Source: Questionnaire survey among national business and sector associations, running from 9 October 2014 to 5 January 2015, carried out by DTI

The perception of businesses that mutual recognition doesn't function properly is confirmed by the replies provided by national authorities during the 2016 public consultation. When national authorities check if products available on their market and coming from another Member State comply with the national rules they are enforcing, only **46%** verify if they are already lawfully marketed in the Member State of origin, meaning that they take into account the potential application of mutual recognition of these products<sup>54</sup>. The others directly conform to the applicable national rules, without looking into the potential application of the mutual recognition principle and Regulation. This can be because they are not well aware of the practicalities of applying mutual recognition, or because they simply prefer applying their own national rules, with whose cultural and historical backgrounds they are well acquainted.

The input submitted in the annual reports on the application of the mutual recognition Regulation goes in a similar direction: while Member States recognise the potential of the principle and Regulation in terms of achieving their objective, they also believe that in practice many difficulties stop these objectives being fulfilled. These difficulties, which mainly refer to the lack of awareness and understanding about how the principle should be applied and legal uncertainty, will be further assessed in the following sections.

The perception of PCPs<sup>55</sup> in the surveys carried out during 2014-2015 was more positive. Around half of them indicated in the survey that the objectives have been either completely reached or close to completely reached. The other half perceived the objectives as being partly reached, and a few PCPs said that there is quite a long way to go in terms of lowering trade barriers in the internal market. However, these results have to be treated with caution, as the PCPs, depending on how they are organised at national level, are mostly the interface between businesses invoking their right to mutual recognition and national authorities exercising their right to apply their own national rules. Most of them are only providing information to a specific request, and/or establish a contact between the business and the competent authority; they don't monitor the application of the mutual recognition principle, and don't have a lot of knowledge about the outcome of a case once it has left the remit of their competence<sup>56</sup>.

54 This doesn't mean that they allow market access automatically

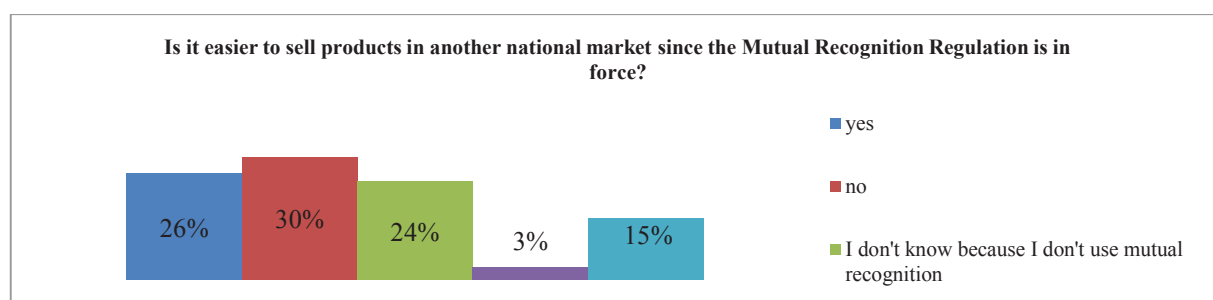
55 During this survey, only PCPs were interviewed. the survey did not reach national authorities granting or denying mutual recognition

56 See section 6.2 and 7 for a more detailed assessment of PCPs

This is also supported by the number of complaints received relating to the application of the mutual recognition principle. Since 2010, 195 complaints relating to a misapplication of the mutual recognition principle were registered.

With regards to the Regulation specifically, the results of the public consultation carried out in 2016<sup>57</sup> show that 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 in terms of facilitating free movement of goods, or don't know, either because they don't use mutual recognition or they don't sell products abroad<sup>58</sup>.

**Figure 7-5: Public consultation 2016**



The 2016 public consultation, the stakeholders' consultation performed in 2014 and the evidence submitted by the Danish business association all point to the same direction. Overall, stakeholders consider that despite the existence of the principle and the adoption of the Regulation, free movement of goods in the non-harmonised area still remains problematic. Businesses are still facing difficulties with regards to market access, despite the fact that their products are already lawfully marketed in other Member States. Thus, they often adapt their products or give up entering on a new market.

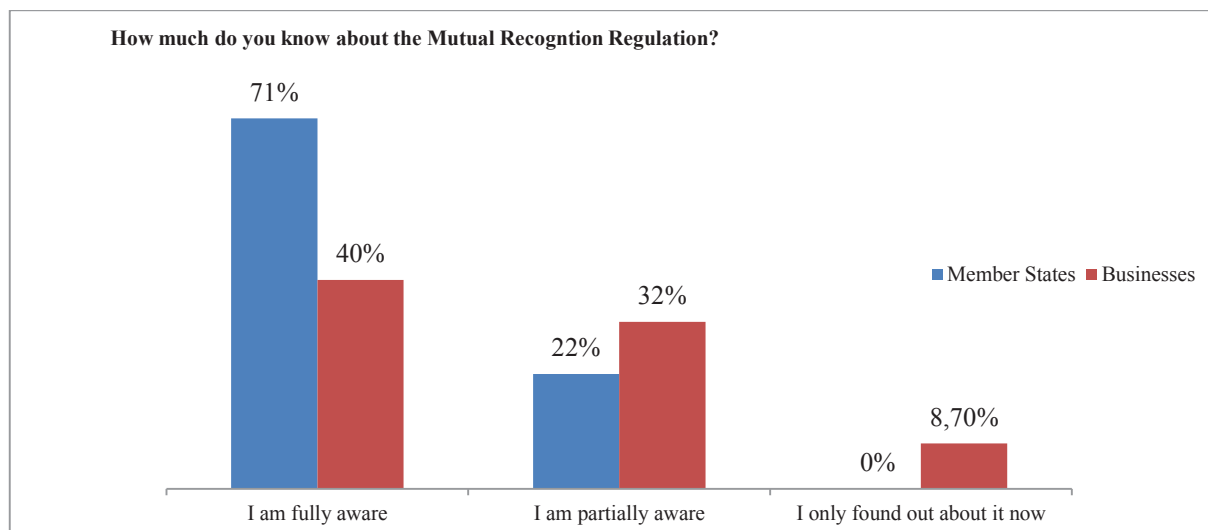
### 1.10.2 Increasing awareness of the mutual recognition principle

One of the specific objectives of the Regulation was to increase awareness about 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. It also triggers lack of awareness about the Regulation as well; as the Regulation enters into play once mutual recognition is denied, by issuing an administrative decision and notifying it to the economic operator and to the Commission.

**Figure 7-6: Public consultation 2016**

<sup>57</sup> See annex 5

<sup>58</sup> 15% replied other, but did not specify what they meant by it



Surveys carried out in 2004<sup>59</sup> and 2014<sup>60</sup> show a low level of awareness about mutual recognition among businesses. In 2004, 46% of the respondents declared awareness about 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<sup>61</sup> shows however a significantly higher level of awareness; 7% of the respondents declared being aware of mutual recognition. The 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. Thus, those not checking if products are already lawfully marketed elsewhere take for granted the fact that their national rules are applicable, and take measures against economic operators, asking them to align their products. Some Member States organised at national level such campaigns, mostly for authorities, and considered them very useful.

In order to increase awareness of the mutual recognition principle, the Regulation put in place Product Contact Points (PCPs)<sup>62</sup>. Most of the businesses (73%) replying to the 2016 public consultation declared that they have never contacted a PCP in order to obtain information about the applicable national rules and the mutual recognition principle, mostly (46%) because they are not aware of them.

In the period between the entry into force of the Regulation on 13 May 2009 and today<sup>63</sup>, the Product Contact Points received **8024** questions from economic operators.

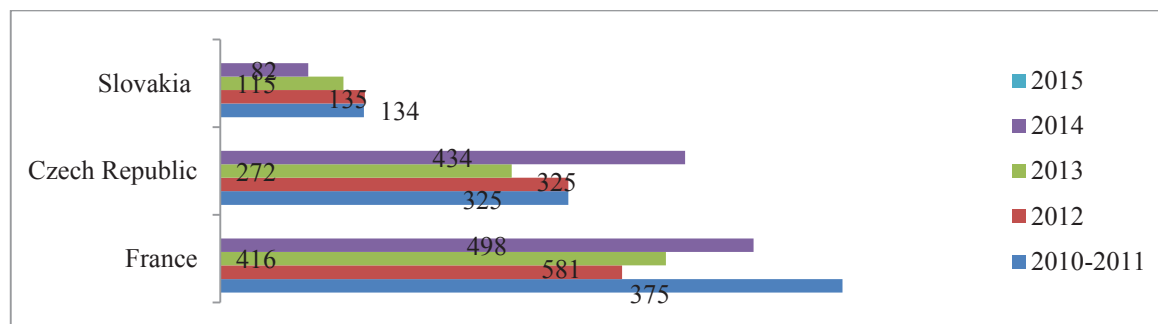
59 Survey carried out in the framework of the impact assessment supporting the proposal for the Mutual Recognition Regulation  
60 European Commission, Study commissioned to Technopolis Group (2015): 'Evaluation of the application of the principle of mutual recognition in the field of goods,' ENTR/172/PP/2012/FC – 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](http://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/index_en.htm).  
61 See annex 5  
62 See section 6.2  
63 Requests received in 2016 are not taken into account, as these will be reported by Member States in the 2017 reports



| 2010-2011 <sup>64</sup> | 2012 | 2013 | 2014 | 2015 |
|-------------------------|------|------|------|------|
| 1402                    | 1439 | 1826 | 1793 | 1564 |

The PCPs that were most contacted are France and the Czech Republic, followed by Slovakia.

**Figure 7-7: Most contacted PCPs**



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. In 2010-2011, 2012 and 2014, 17 Member States indicated the number of questions received by the PCPs. 19 Member States supplied this information in 2013 and 16 Member States supplied this information in 2015. Also, with regard to the number of questions received, it is not certain that the number indicated covers questions related to mutual recognition only. Some Member States are reporting those questions related to mutual recognition only, while others are reporting all questions received, even when outside the remit of the PCPs. A few Member States<sup>65</sup> conducted national surveys on the usefulness of the PCPs, and the results show that economic operators are globally satisfied with the services provided by the network, which are considered useful.

In general, 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. These issues are also highlighted by the Member States in their annual reports. Some Member States indicated that the 15 day deadline set out by the Regulation is difficult to meet, although most of the time respected. According to the information submitted in the annual reports, these delays are caused by the wide range of products (or aspects of) falling under the scope of mutual recognition as well as the increasing number of applicable national rules, which makes it difficult to easily identify the responsible persons having the necessary expertise. The decentralisation of certain Member States administration and the fact that most often the necessary competences are distributed between different ministries add to these difficulties. Very often, the PCPs have to send the inquiry to the local responsible officer. Last but not least, language issues, especially when technical language is involved, add further delays and contributes to the sometimes low quality of the answers provided. Some good practices were also highlighted by Member States in their annual reports as regards the functioning of PCPs. Slovakia for example indicated that an expert network was put in place to support the work of the PCP. Furthermore, the PCP is located in the same department dealing with Directive (EU)

64 The reporting in annual since 2012

65 See annual reports from SE 2015, DE and FR 2013

2015/1535, thus aware of all national regulations notified to the Commission and subject to the application of the mutual recognition principle.

Overall, the PCPs network is considered by Member States in their annual reports as a useful tool, having the potential to help economic operators in obtaining information about the applicable national rules and the mutual recognition principle. Member States consider however that it needs to be further strengthened. In their annual reports, they call on enhancing administrative cooperation, and integrating the PCPs into a wider network, in order for them to gain the expertise and to reply more efficiently to the inquiries they received. This view is also shared by businesses, as 58% of the respondents indicated in the 2016 public consultation that PCPs are a useful tool, despite the fact that only 7% of them considered their experience with PCPs as satisfactory.

The Regulation had a limited effect in increasing awareness about 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 as regards their objectives.

Additionally, one of the objectives of the mutual recognition clause referred to in section 2.3.1 was to make authorities and economic operators aware of the mutual recognition principle. 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 rules<sup>66</sup>. The overview<sup>67</sup> of the draft national technical regulations notified between 2012 and 2014 shows a poor use of the mutual recognition clause:

| 2012  |                            | 2013  |              | 2014  |              |
|-------|----------------------------|-------|--------------|-------|--------------|
| Total | MRC <sup>68</sup> inserted | Total | MRC inserted | Total | MRC inserted |
| 755   | 69                         | 728   | 79           | 685   | 57           |

When inserted, the clause sometimes lacks clarity or is not properly implemented. Many of the comments and detailed opinions the Commission issued, when assessing draft national regulations in the framework of Directive (EU) 2015/1535, relate to a wrong wording of the mutual recognition clause:

**Table 7-1: Overview of comments and detailed opinions in the framework of Directive (EU) 2015/1535- 2015 and 2016**

| 2015 <sup>69</sup> | Total | Absence of MRC | MRC wrongly | Non |
|--------------------|-------|----------------|-------------|-----|
|--------------------|-------|----------------|-------------|-----|

66 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.

67 Carried out internally by the Commission services

68 Mutual recognition clause

|                          |       |                | worded             | related to the MRC <sup>70</sup> |
|--------------------------|-------|----------------|--------------------|----------------------------------|
| <b>Comments</b>          | 27    | 6              | 12                 | 9                                |
| <b>Detailed opinions</b> | 11    | 4              | 2                  | 5                                |
| 2016 <sup>71</sup>       | Total | Absence of MRC | MRC wrongly worded | Non related to the MRC           |
| <b>Comments</b>          | 35    | 18             | 11                 | 6                                |
| <b>Detailed opinions</b> | 14    | 3              | 8                  | 3                                |

Therefore, 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<sup>72</sup>, or to redraft it in order to ensure clarity, its use is still poor.

### *1.10.3 Ensuring legal certainty when using the mutual recognition principle*

Another specific objective of the Regulation is to ensure legal certainty when using the mutual recognition principle. The Regulation tried to address the lack of legal certainty by:

- (1) *Introducing the principle according to which the burden to demonstrate that the product does not meet the necessary requirements relies with the national authorities*
- (2) *Establishing a non-exhaustive list of products to which mutual recognition might apply*
- (3) *Introducing an obligation to notify administrative decisions denying market access*

### **Clarity of the concept "lawfully marketed"**

The main value of the Regulation was to place **the burden of proof** on the national authorities that intend to deny market access. This was justified by the uncertainties regarding who has to demonstrate that a product lawfully marketed in a Member State can be marketed in another Member State. The objective 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

69 776 notifications were received in 2015; 44 concerned Information services

70 Other issues related to incompatibility with EU law were raised, such as e.g. proportionality issues

71 756 notifications were received in 2016, the number of notifications on information services is unknown today

72 OJ L 241, 17.9.2015, p. 1–15

different requirements as regards the evidence to be submitted in order to demonstrate that a product is "lawfully marketed". The Commission has provided guidance<sup>73</sup> on this topic, explaining the meaning of the "lawfully marketed" concept and what type of evidence can be requested or accepted in order to demonstrate it. According to this guidance, any piece of evidence such as a product invoice, product label, catalogue with evidence of a date, sale or tax records, registrations, licences, notifications to/from the authorities, certifications, extracts from public records, etc. should be deemed suitable to demonstrate the actual marketing of the product in another Member State. Despite this guidance, Member States in their annual reports and businesses in their contributions report that the concept remains problematic. Economic operators declared for example that if a product invoice is sufficient in one Member State, very often it will not be considered as sufficient evidence in another Member State, who will require additional evidence. The first report on the application of the Regulation<sup>74</sup> underlines that the difficulty of demonstrating that a product has been lawfully marketed in another Member State is one of the issues where close and regular monitoring is necessary. National authorities need a stronger and clearer framework for being able to determine whether or not a product is lawfully marketed and to allow market access to products coming from other Member States despite the fact that they do not fully comply with their national technical rules.

The difficulties raised by the concept of "lawfully marketed" were also discussed during the stakeholders' event held in June 2016 "Single market for products: fresh ideas to unleash full potential"<sup>75</sup>. A specific workshop was dedicated to a more practical approach for proving and assessing lawful marketing of products in other Member States. During this workshop, business representatives described the problems they often encounter when trying to demonstrate that a product is lawfully marketed in a Member State, especially in terms of what is understood and accepted as evidence. In order to bring more clarity and facilitate market access, the participants focused on what is really needed as evidence to demonstrate the lawfulness of the marketing of a product and listed those elements considered necessary (e.g. name of the manufacturer and contact details, the market(s) where the product is marketed, and the regulations and standards it complies with. Participants concluded that standardising the type of information to be provided to national authorities in support of the demonstration of the lawfulness of the marketing of the product would have positive impacts on legal certainty when using mutual recognition.

Businesses replying to the 2016 public consultation identified the difficulty of demonstrating the lawfulness of a product as an obstacle to mutual recognition.

**Table 7-2: Public consultation 2016 – Ranking of obstacles –Businesses**

| Ranking of obstacles by order of importance  |            |
|--|------------|
| Difficult for businesses to challenge a national decision denying market access    | <b>62%</b> |
| Insufficient communication between national authorities of different Member States | 46%        |

73 <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013DC0592>

74 Communication from the Commission to the European Parliament and the Council, First report on the application of Regulation (EC) No 764/2008, OJEU C (2012) 292 final

75 See annex 2

|   |     |
|---|-----|
| Lack of awareness about mutual recognition  | 35% |
| Difficult to obtain information about whether mutual recognition applies to a specific product and thus to assess if mutual recognition can be used or not for a specific product | 32% |
| Other   | 29% |
| Slow/inefficient communication between businesses and national authorities  | 27% |
| Difficult to demonstrate to authorities in other Member States that a product is lawfully sold in a Member State  | 26% |
| Insufficient communication between national authorities within the same Member State  | 21% |

Stakeholders predominantly agreed<sup>76</sup> that standardising the type of information to be provided would facilitate demonstrating that a product is lawfully marketed in a Member State.

### **Clarity concerning the products to which mutual recognition apply**

Before the adoption of the Regulation, it was difficult for both economic operators and national authorities to know with certainty when a product falls into the scope of mutual recognition<sup>77</sup>. The Regulation required the Commission to publish a **non-exhaustive list of products which are not subject to EU harmonisation legislation and to which mutual recognition might apply**, as a mean to improve legal certainty when trying to use the mutual recognition principle. More information on the list is available in section 6.2. In 2015, for example, the web-page hosting the product list received 2655 visits, and 59% of them left the page immediately, without trying to use the list. However, during the public consultation carried out in 2016, 68% of Member States and 51% of businesses declared that the list is useful and necessary, but needs to be updated and made more user-friendly. These findings point to the fact that stakeholders agree with the usefulness of having such a list, but that the list in its current state is not reliable.

### **Transparency of administrative decisions**

**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. This doesn't mean that the precious metals area is the only area where the obligation to notify is respected by Member States. The fact that most of notifications relate to one category of products, i.e. precious metals, could be explained by the reluctance of Member States to apply the mutual recognition principle in an area where many of them have permanent and long-time established control bodies specifically devoted to assessing hallmarking and control of precious metals. This generated several infringement procedures, and the Court of Justice

<sup>76</sup> 75% of Member States and 80% of businesses

<sup>77</sup> See Impact assessment 2007

underlined in several rulings<sup>78</sup> that Member States have to respect the free movement of precious metals on the basis of the mutual recognition principle. Because of the abundant jurisprudence of the Court on these issues, national authorities became over time well acquainted with the application of the principle in this area, and with the obligation to notify contained in the Regulation.

Additionally, 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<sup>79</sup>. This points to the fact that Member States are not always notifying the Commission administrative decisions denying or restricting market access. This issue has been often addressed in the Mutual Recognition Consultative Committee<sup>80</sup>; representatives from Member States considered that the lack of notifications could be justified by the fact that inspectors performing controls on the market and taking these decisions lack awareness about the Regulation and its obligations and thus don't know that the decisions they are taking should be notified to the Commission. Some Member States reported<sup>81</sup> that information campaigns and trainings have been organised in order for their staff to get familiar with the Regulation; however these are more isolated cases, and don't allow drawing a conclusion of the effectiveness of these initiatives in terms of complying with the obligations of the Regulation.

### **Difficulty to challenge administrative decisions denying market access**

The Regulation foresees that when an administrative decision denying or restricting market access is notified to the economic operator, it shall mention the legal remedies available at national level allowing challenging this decision. Economic operators reported that national remedies usually consist in long and costly court proceedings. During the 2016 public consultation, they ranked this as the main obstacle to relying on mutual recognition:

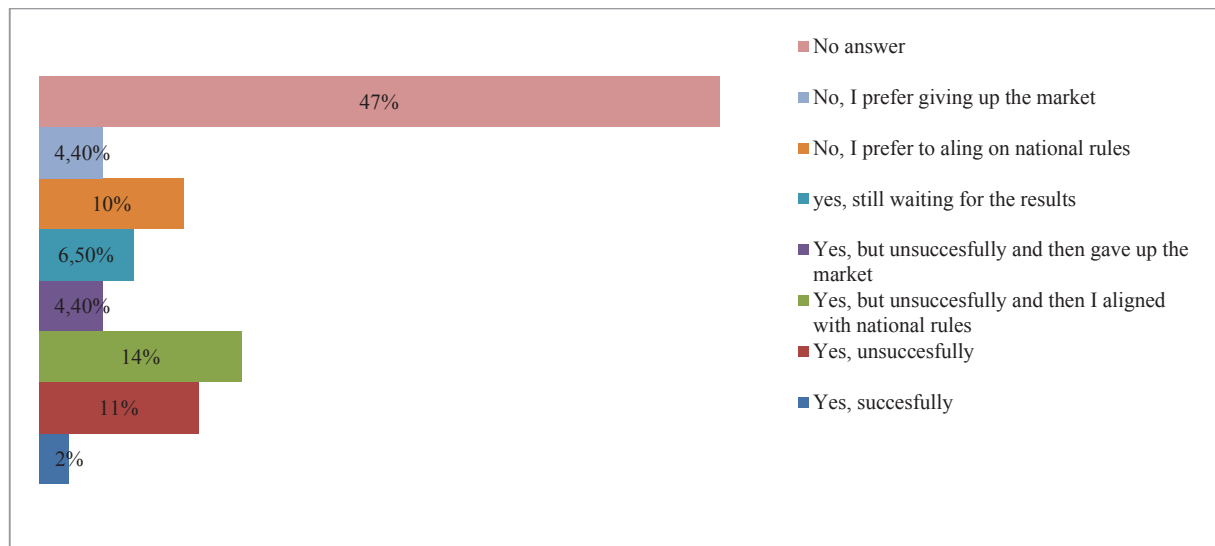
**Table 7-3: Public consultation 2016**

| Ranking of obstacles by order of importance                                     |                   |
|---|-------------------|
| Difficult for businesses to challenge a national decision denying market access | 62% <sup>82</sup> |

As court proceedings are very time consuming and expensive for businesses, they prefer adapting their products or renouncing to enter the market. This is supported by the 2016 public consultation, which shows that when market access (and mutual recognition) is denied, businesses rely rarely on the national remedies available to them:

78 The main cases being C-220/81 Criminal proceedings against Timothy Frederick Robertson and others, C-293/93 Criminal proceedings against Ludomira Neeltje Barbara Houtwipper, C-30/99 Commission v. Ireland  
 79 See annex 7  
 80 See annex 12  
 81 See annex 7  
 82 62% of respondents ranked this obstacle as being the most important one

**Figure 7-8: 2016 Public consultation: Did you challenge the decision denying market access?**



To further underline this issue, during the 2016 public consultation, one business association indicated that in the area of drinking water installations they are aware of more than 100 cases where national authorities denied market access and required the products to be adapted to the different national requirements; one company tried to challenge the administrative decisions denying market access, which resulted in a two years lawsuit (still ongoing); another indicated that because the only way to challenge these decisions is having a long and costly lawsuit in their national law, they prefer to adapt the product or give up entering the market.

Beyond the Regulation, the insertion of mutual recognition clauses<sup>83</sup> in the draft notified national regulations<sup>84</sup> also aimed to increase the level of legal certainty. However, the impacts of this policy in terms of legal certainty are limited.

The tools put in place by the Regulation had a 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.

#### *1.10.4 Improving administrative cooperation between national authorities (Mutual Recognition Regulation)*

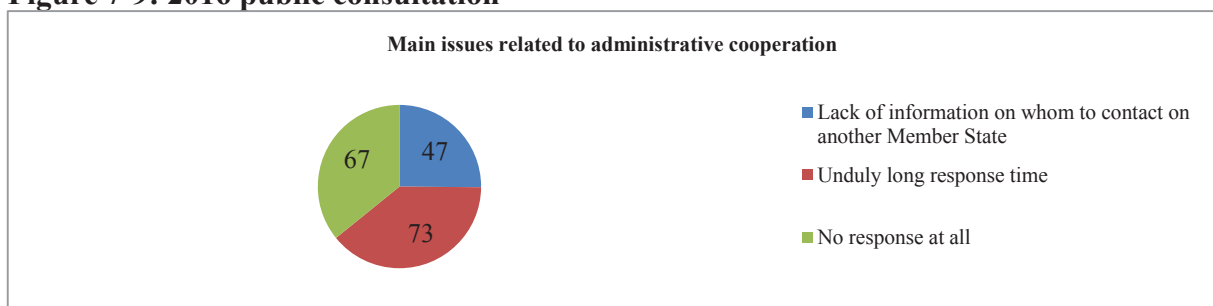
Before the adoption of the Regulation, dialogue between the national authorities of different Member States was very difficult, mostly due to the lack of a common address book /network. The Regulation tried to remedy to this problem by introducing the Product Contact Points and

83 See section 6.1  
84 See section 6.2.1

the telematic network<sup>85</sup>. Despite this, administrative cooperation remains suboptimal, for various reasons. Many Member States highlighted, in their annual report, the difficulties PCPs have to identify and contact 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<sup>86</sup>.

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

**Figure 7-9: 2016 public consultation**

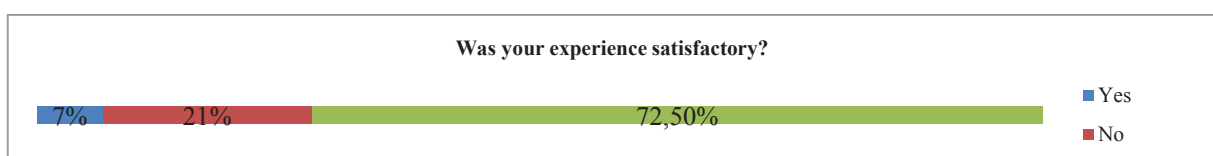


One PCP indicated that sometimes the delay for receiving a reply is **40-50** working days. Another indicated that the intervention of the Commission was necessary in order to obtain a reply.

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

The majority of those economic operators who contacted a PCP preferred not to assess if their experience was satisfactory or not.

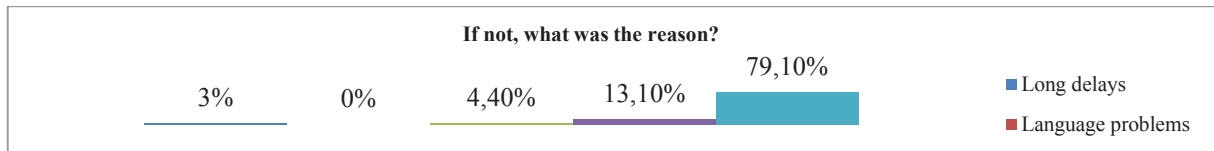
**Figure 7-10: Public consultation 2016**



85 Article 11 of the Regulation

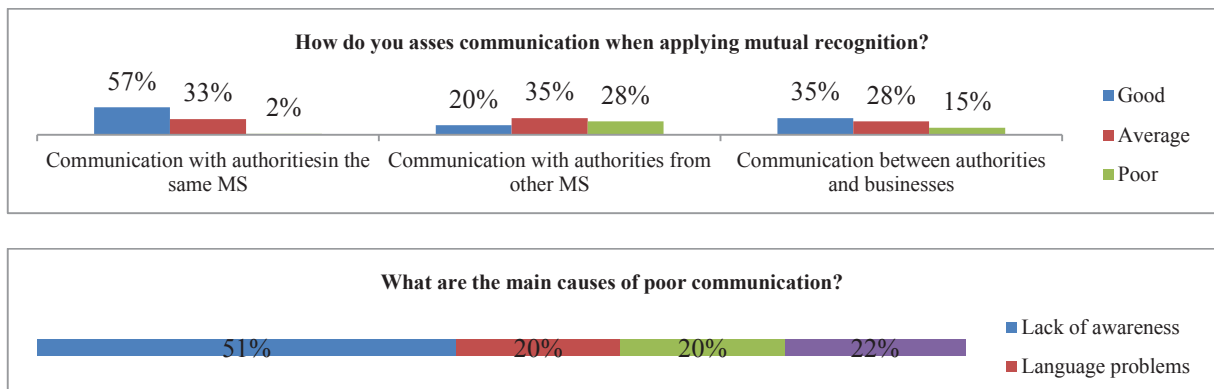
86 See annex 7





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

**Figure 7-11: Public consultation 2016**



As regards the telematic network foreseen by the Regulation, its creation was discussed several times with representatives from Member States during the meetings of the Mutual Recognition Consultative Committee without being finalised<sup>87</sup>.

### 1.10.5 Conclusion on effectiveness

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 States. During the 2016 public consultation, they ranked as the main obstacle in difficulty to challenge administrative decisions denying market access, followed by insufficient administrative cooperation and lack of awareness about mutual recognition.

The tools put in place by the Regulation in order to ensure awareness, i.e. the PCPs, 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<sup>88</sup>, or to redraft it in order to ensure clarity, its use is still poor.

<sup>87</sup> See section 6.2.2

<sup>88</sup> OJ L 241, 17.9.2015, p. 1–15

The tools put in place by the Regulation had also a 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 limited impacts the Regulation had in achieving the foreseen objectives of ensuring free movement of goods in the Single Market points to the fact 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<sup>89</sup> 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%**. A study done for the European Parliament<sup>90</sup> 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.

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 get a clearer picture of how the principle functions and its impacts on the free movement of goods.

**Table 7-4: 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 access are taken by national authorities                      | 65% |
| Increase effectiveness of mutual recognition to facilitate access to the internal market   | 64% |

89 Value of production-value of extra EU exports +value of intra EU imports

90 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](http://www.europarl.europa.eu/RegData/etudes/STUD/2014/510981/EPRS_STU(2014)510981_REV1_EN.pdf)

|  |     |
|--|-----|
| 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 7-5: 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 7-6: 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 access are taken by national authorities                      | 35% |
| Facilitate communication between all actors involved in mutual recognition (business, national authorities, European Commission)         | 23% |

## 1.11 Efficiency: Measuring the cost effectiveness of the mutual recognition principle and Regulation

One of the Commission's priorities is to make EU law simpler and to reduce administrative burdens. These objectives refer specifically to costs associated with reporting and administrative burdens, and costs related to the implementation of the mutual recognition principle and Regulation. Measuring the efficiency of the principle and Regulation means evaluating to what extent the costs generated by using the principle and the Regulation are proportionate to the benefits it achieved. Relevant stakeholders were consulted on this topic.

### 1.11.1 Costs for public authorities

The Regulation, by nature, is directly applicable; thus, no particular costs were incurred for transposing or integrating the requirements in national law. The PCPs generated specific costs for Member States. With regards to the principle, the main costs are generated by its incorrect application. The analysis below therefore looks into specific costs generated particularly by the PCPs, and at costs linked to the activity of national authorities other than PCPs, involved in the implementation of the principle and Regulation.

### Costs related to the implementation and functioning of the PCPs

National authorities 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<sup>91</sup>, one person on average is fulfilling the task of PCP. This is the case for example in France, Sweden, Ireland, Greece, the Netherlands, Bulgaria and Poland. In cases where the function of PCP is available in several ministries, such as in Romania or Portugal, several persons (5-8) have PCP related tasks among their portfolio. Estimates of labour costs for PCPs can be made by taking into account the costs of Full Time Equivalent (FTEs) necessary to perform the required tasks every year. As detailed information on the salary costs of administrative staff employed PCP is not available, an estimate has been made based on the Eurostat data (period 2010-2011) on the gross annual salaries for employees in national public administrations, as shown in the table below:

**Table 7-7: Gross annual salaries for employees in the public administration Eurostat**

| GEO/TIME       | N of staff      | 2010                             | 2011       |
|----------------|-----------------|----------------------------------|------------|
| Belgium        | 1               | 40124 Euro                       | 40921 Euro |
| Czech Republic | 5 <sup>92</sup> | 12786 Euro                       | 12850 Euro |
| Denmark        | 2               | <i>Information not available</i> |            |
| Germany        | 2               | <i>Information not available</i> |            |
| Estonia        | 1               | 11541 Euro                       | 11944 Euro |

91 See annex 7

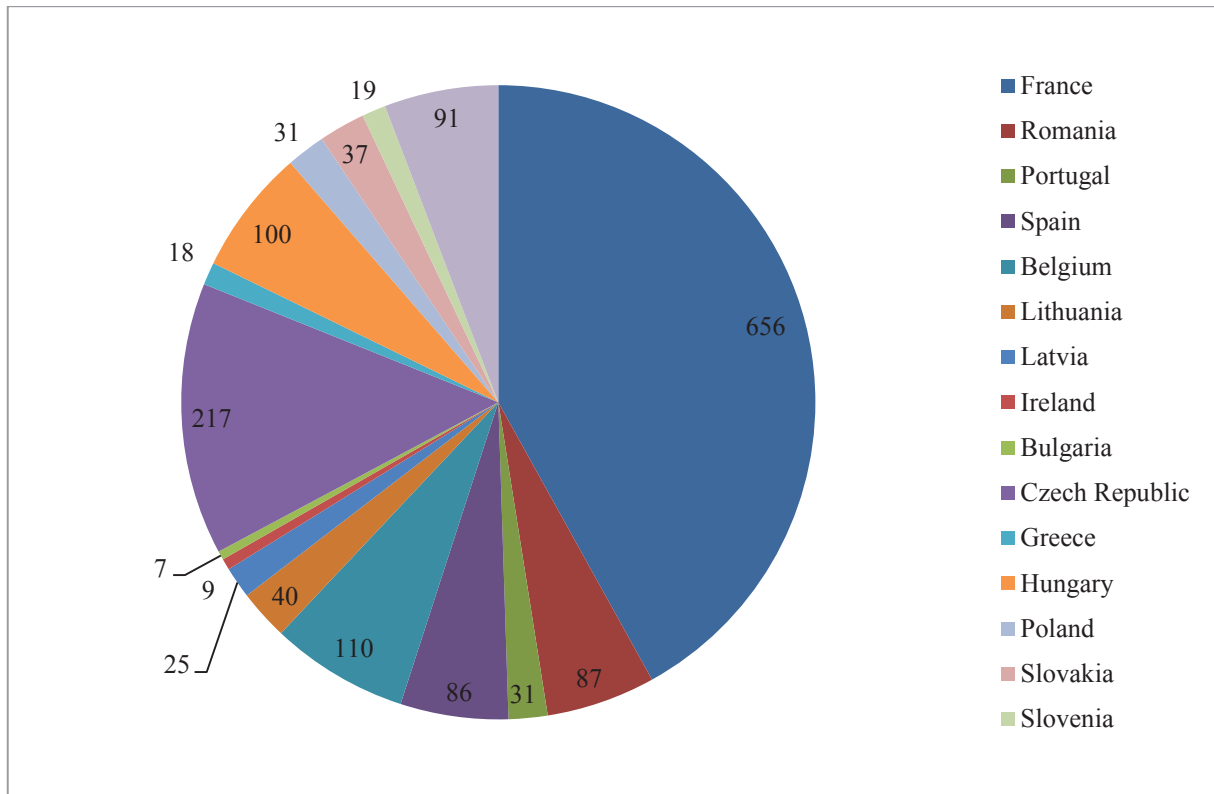
92 For all issues related to internal market information, so we can assume that one person fulfils the tasks of PCP

|             |     |                                  |            |
|-------------|-----|----------------------------------|------------|
| Ireland     | 1   | <i>Information not available</i> |            |
| Greece      | 2   | <i>Information not available</i> |            |
| Spain       | 0.5 | 29541 Euro                       | 29069 Euro |
| France      | 1   | <i>Information not available</i> |            |
| Netherlands | 1   | 46988                            | 47450      |
| Portugal    | 8   | <i>Information not available</i> |            |
| Romania     | 8   | 7675                             | 7417       |
| Slovakia    | 0.5 | 11648                            | 11060      |
| Sweden      | 1   | 38954                            | 41963      |

PCPs reply to inquiries from economic operators within the limits set out by the Regulation, and it is necessary, very often, to communicate in English. Most Member States (25)<sup>93</sup> have online portals providing information on the role of PCPs and mutual recognition. 18 Member States provide this information (sometimes partially) in English. The availability of online information generates costs related to creating the website and keeping it up-to-date; however, these are easily counterbalanced by the potential reduction of the number of "basic" inquiries PCPs would have to deal with in the absence of such online information. The number of inquiries received by PCPs varies from one Member State to another. Some Member States (France, Czech Republic, Belgium, Hungary and Sweden) registered a high number of requests, while others had very little. For example, in 2015, out of the 22 annual reports received, **16 only indicate the number of inquiries received**. The number of questions received amounted to **1645**. The most active Member States are France, Czech Republic and Belgium, followed closely by Hungary and Sweden.

**Figure 7-12: PCPs activity 2015**

93 See "Screening Report on Member States Product Contact Points and Product Contact Points for Construction", Ecorys, 2016



The fact that some PCPs receive a higher number of inquiries can be explained by the fact that these are big attractive and / or more difficult markets, or that promotion of PCPs has been more efficient. The low numbers registered in certain Member States can be also explained by the fact that requests are not properly registered and monitored, or reported to the Commission. For example, some Member States are indicating in their annual reports an increase of the number of inquiries received by the PCPs, while the actual number of these inquiries was never communicated.<sup>94</sup>

### **Costs related to assessing products lawfully marketed in another Member State and notifying decisions restricting or denying market access**

Other costs supported by national authorities<sup>95</sup> are those related to assessing if a product lawfully marketed in a Member State can be placed on their market on the basis of the mutual recognition principle. This assessment is followed, depending on its outcome, by the obligation to notify economic operators and the Commission of their decisions restricting or denying market access. The assessment of the notifications and annual reports received by the Commission between 2009 and 2016 show that only a few Member States are notifying administrative decisions to the Commission. This makes it impossible to calculate the costs related to this obligation, as the Commission does not have any accurate knowledge about the actual number of administrative decisions taken over the last 6 years, as these were not notified. More precise information exists at sectorial level. For example, in the area of

<sup>94</sup> For a full overview of the number of inquiries received by the PCPs see annex 7  
<sup>95</sup> These costs are related to national authorities other than PCPs

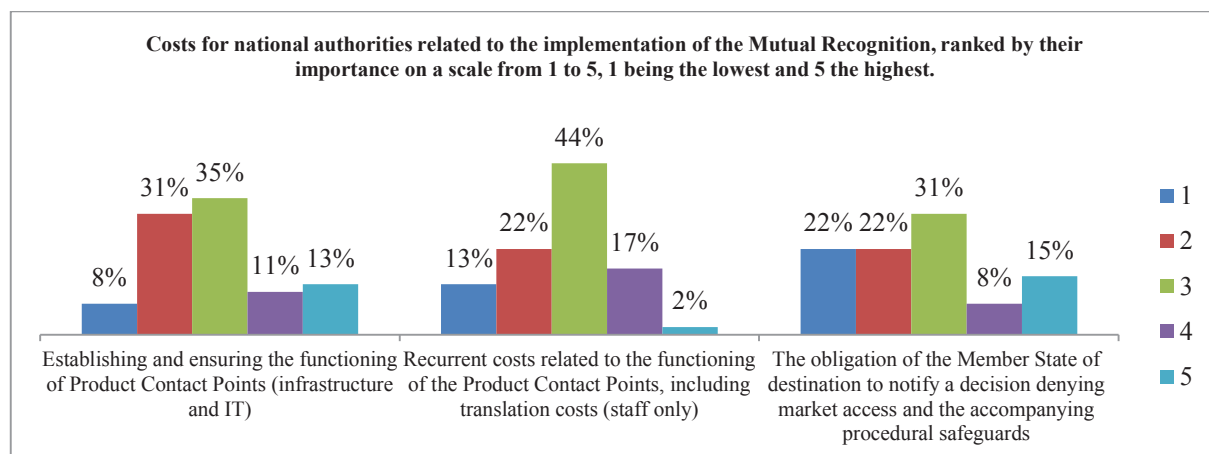
**fertilisers**, the costs on national authorities to assess if fertilisers lawfully marketed in a single Member State can be placed on their market has been estimated at EUR 420 000<sup>96</sup>.

Lastly, there are costs related to the obligation to send an annual report to the Commission on the application of the Regulation. This obligation did not incur any of the ordinary costs.

Some Member States promoted the Regulation via awareness raising campaigns and training activities. However, these costs appear marginal, and are not considered burdensome for the Member States.

Generally, during the public consultation, national authorities ranked the costs linked to the implementation of the regulation as average costs. Additionally to 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. This implies that they have to spend more time checking if a product is subject to harmonised rules or not. Some consider that additional costs are triggered by the administrative procedures, seen as long and time consuming.

**Figure 7-13: Public consultation 2016**



### 1.11.2 Costs for businesses

Generally, there are no major costs involved for businesses when applying the Regulation. Insignificant costs may relate to economic operators getting to know the Regulation and becoming familiar with the procedures it puts in place.

The main costs incurred (transaction and adaptation costs) are due to the **suboptimal application of the mutual recognition principle**. According to information provided during the 2016 public consultation, the following costs have been identified:

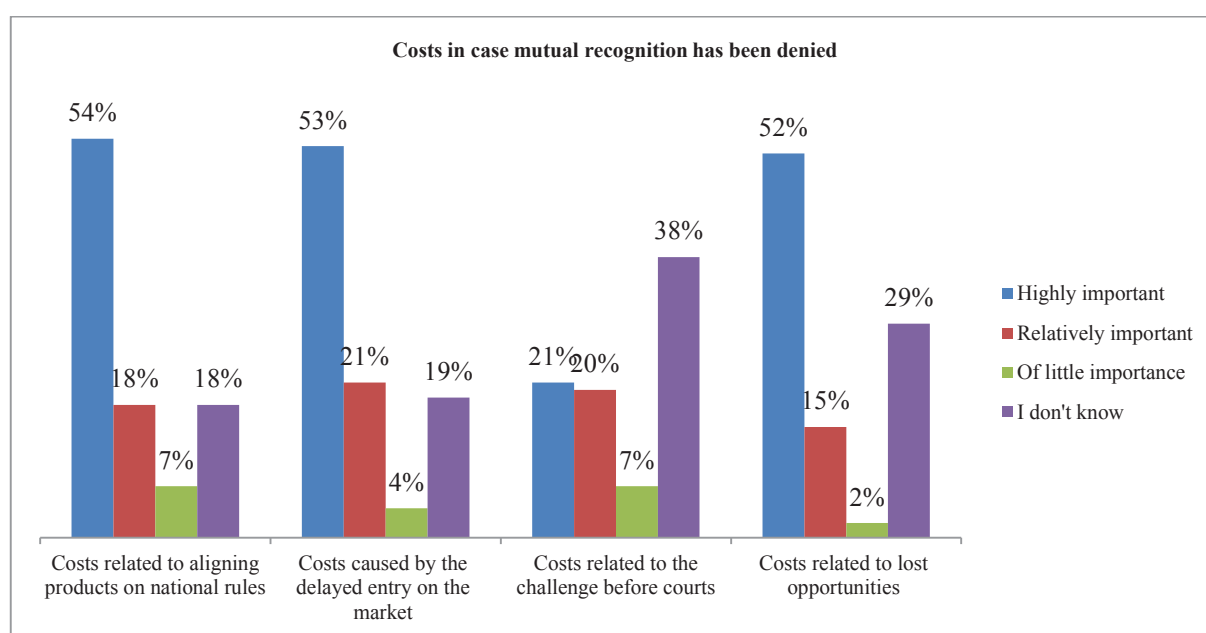
High costs are triggered by the need **to adapt the products** to the applicable national rules, when mutual recognition is either denied or not used for penetrating the market. These adaptation costs are estimated to be<sup>97</sup> between 1000 and 150 000 Euro per product and per

96 According to the survey on administrative costs carried out in the "Fertilisers Study", the costs for competent authorities to analyse requests for mutual recognition of national fertilising products have been estimated to be 0.2 FTEs x 28 x EUR 75 000 = EUR 420 000 (B.40) for the whole EU.

97 26% of respondents indicated an estimate of the costs incurred, the other choose not to reply or indicated that such estimation is impossible

market. High costs are also related to **delays in entering a market**, estimated<sup>98</sup> between 3000 and 500 000 Euro per product and per market, and to **lost opportunities**, when businesses renounce entering the market because of different national rules requiring the adaptation of the products. On average, the latest are estimated<sup>99</sup> at between 10 000 and 500 000 Euro per product and per market. The estimation of the adaptation costs appears to be lower than the estimation of costs linked to lost opportunities and delayed entry to the market. This may be due to the specific profile of the respondents to the public consultations that 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). Finally, the costs related to **challenging administrative decisions** denying market access are considered less important, mainly because few economic operators choose to do so. The estimate<sup>100</sup> is between 10 000 and 100 000 Euro per product and per market.

**Figure 7-14: Public consultation 2016**



Costs are also related in 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 an estimate of the actual costs incurred to be made when the assessment of whether or not mutual recognition can be used is outsourced. When done internally, economic operators spend on average 54 hours 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.

98 20% of respondents indicated an estimate of the costs incurred, the other choose not to reply or indicated that such estimation is impossible

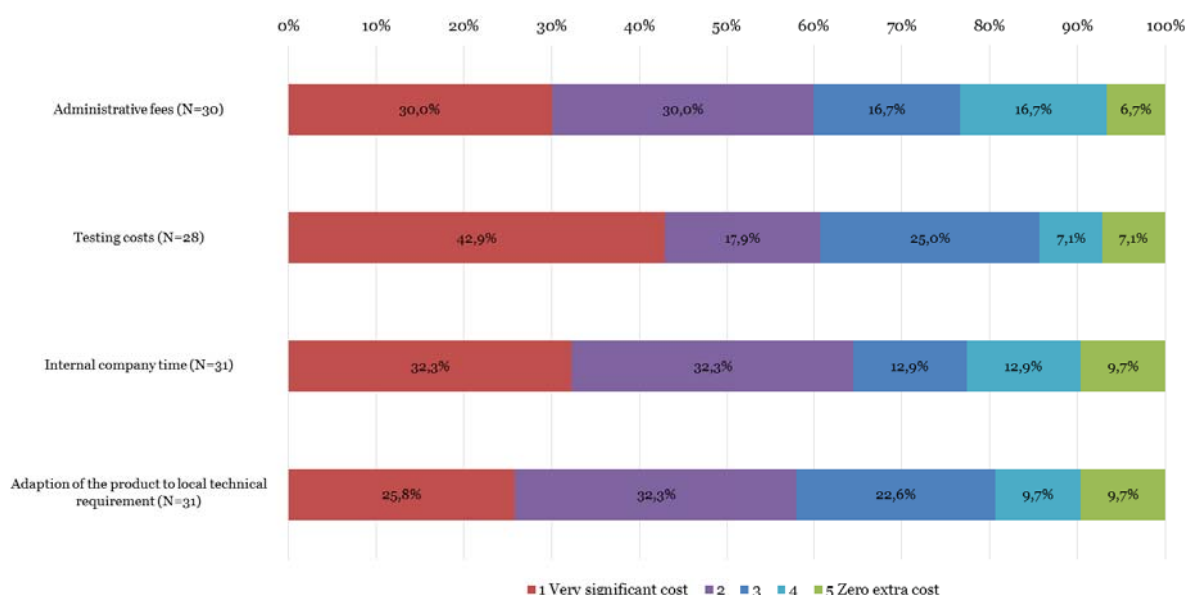
99 13% of respondents indicated an estimate of the costs incurred, the other choose not to reply or indicated that such estimation is impossible

100 11% of respondents indicated an estimate of the costs incurred, the other choose not to reply or indicated that such estimation is impossible



These results confirm the findings of the external study carried out in 2015<sup>101</sup>, 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 very significant cost. The testing costs vary considerably, depending on the sector and the product, but some examples from different sectors are provided in Figures 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 7-15: Company survey: What are the typical cost items involved and how significant are they?**<sup>102</sup>



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

With regards to the costs, the survey and the subsequent interviews carried out by the contractor revealed the same wide range of costs as during 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. Table 7-8 summarises some of the characteristics of the companies that provided cost estimates.

**Table 7-8: Overview of the businesses that provided estimates for the costs of adapting or retesting products**

101 See annex 6

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

| Sector                                       | Size of company | Knowledge of MR principle | Percentage of export goods falling under MR principle | Costs of adaptation or retest (percentage of yearly turnover or euros) |
|--|-----------------|---------------------------|---|--|
| Articles of precious metals                  | Small           | yes, but not in detail    | 100   | 10   |
| Childcare products                           | Small           | no                        | 10  | 50,000 EUR   |
| Childcare products                           | Large           | yes, but not in detail    | 90  | 1  |
| Childcare products                           | Micro           | no                        | 5   | 10   |
| Childcare Products                           | Small           | no                        | 50  | 0,3  |
| Childcare products                           | Medium          | yes, but not in detail    | 5   | Company originates from MS where national rules are stricter           |
| Construction products                        | Large           | yes                       | 70  | 0,5  |
| Construction products                        | Medium          | yes                       | 20  | 2  |
| Construction products                        | Small           | yes                       | 40  | 10   |
| Construction products                        | Large           | yes                       | 10  | Testing costs, see case  |
| Construction products                        | Medium          | yes, but not in detail    | 75  | 2,000-9,000 EUR/test   |
| Construction products                        | Small           | yes                       |   | Tailor-made products, agree on terms with client                       |
| Construction, retail                         | Large           | yes                       |   | 50,000- 100,000 EUR/test   |
| Electrical products                          | Medium          | no                        | 20  | 7  |
| Electrical products                          | Large           | yes, but not in detail    | 10  | 2  |
| Fertilisers                                  | Large           | yes                       | 5   | 20   |
| Fertilisers                                  | Small           | yes                       | 50  | 10   |
| Fertilisers and potting soil                 | Large           | yes                       | 60  | 1  |
| Food   | Large           | yes                       | 1-5   | 5  |
| Food   | Large           | yes                       | 80  | 0,1  |
| Food additives and food supplements          | Large           | yes, but not in detail    | 60  | 5  |
| Garments for children                        | Medium          | yes, but not in detail    | 10  | 0,2  |
| Medical devices and technical aids           | Large           | yes, but not in detail    | 50  | 20   |
| Paper industry, packaging for foodstuff etc. | Large           | yes                       | 100   | 0,0025   |
| Production of metal devices                  | Medium          | yes, but not in detail    | 5   | 1  |
| Sports equipment                             | Large           | yes                       |   | Document and testing costs, see also case                              |
|  | Large           | yes                       | 50  | 10   |
|  |                 | yes                       | 30  | 5  |

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

The variety of costs is mainly due to the fact that mutual recognition covers a wide range of products, with different characteristics and degrees of complexity. The two examples below show the diversity of costs that businesses may incur depending on the products they are selling:

### Example: water taps

In the area of **water taps**, migration of chemical substances, odour flavour and noise are regulated at national level, and thus subject to mutual recognition. National rules in this area

vary significantly, and one company indicated that for each product in the category of taps the certification and testing costs are up to €50,000. In addition, the cost of getting a new composition approved (to be used for the production of water taps) is between €50,000 and €100,000. Another company cited testing costs for a single component of approx. €2,000 and for the final product approx. €8000-9000. In addition, tests can be rather time-consuming. For instance, a test to determine whether the component or final product contains nickel takes up to 18 weeks.<sup>103</sup>

### **Example: Food contact materials**

In the area of food contact materials, a company producing paper that comes into contact with food had to re test the paper already lawfully marketed upon the request of the Italian authorities. The cost of the testing was 700 Euro (per test), considered by the company as not a major cost, but rather as an unnecessary cost.<sup>104</sup>

#### *1.11.3 Some practical illustrations at sectorial level*

### **Fertilisers**

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<sup>105</sup>. It is partly covered by harmonising legislation<sup>106</sup> 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 strong reluctance in accepting mutual recognition due to environmental and human health concerns, socio-economic aspects, and alleged administrative burden and introduced prior authorisation procedures<sup>107</sup>.

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<sup>108</sup> 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 about the legal situation in other Member States and are unsure whether they should adapt their products to the requirements of the Member State

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103 See external evaluation of the mutual recognition principle - case studies 2 and 4

104 See external evaluation of the mutual recognition principle - case study 1

105 See [http://ec.europa.eu/enterprise/sectors/chemicals/files/fertilizers/final\\_report\\_23jan2012\\_en.pdf](http://ec.europa.eu/enterprise/sectors/chemicals/files/fertilizers/final_report_23jan2012_en.pdf)

106 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

107 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](http://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/index_en.htm)

108 Available at: [http://ec.europa.eu/growth/sectors/chemicals/specific-chemicals/index\\_en.htm](http://ec.europa.eu/growth/sectors/chemicals/specific-chemicals/index_en.htm)

of destination by modifying the product (which means additional costs) or if they can rely on Mutual Recognition procedures (which may cause delay in accessing the market and create costs in the prior authorisation procedure in some Member States).<sup>109110</sup>

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<sup>111</sup> 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;*<sup>112</sup>
- *Other substances (e.g. amino acids).*

The three main issues linked to mutual recognition<sup>113</sup> are:

- *Maximum levels of vitamins and minerals*<sup>114</sup>
- *Substances other than Vitamins and Minerals*<sup>115</sup>
- *Botanicals and botanical preparation*<sup>116</sup>

Information collected from stakeholders shows 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. On 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 companies may have to deal with when trying to enter a new market and often culminating in having different products for different countries. On 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

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109 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)

110 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).

111 See annex 13 for the full case study on food supplements

112 Plant parts, concentrated sources of plants or their extracts or derivatives with a physiological effect.

113 Food Supplement Europe (2016), *Input into the REFIT of the Mutual Recognition Regulation 764/2008*.

114 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

115 Some Member States apply positive lists<sup>115</sup> with specific conditions to their use. In addition, some Member States may consider certain ingredients as for medicinal use only

116 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.

Member States, making it difficult to have a uniform and clear picture of the whole sector and the possible strategies to overcome barriers.<sup>117</sup>

### **Different countries, different rules**

Since the sector is not fully harmonised and limitedly regulated at EU level,<sup>118</sup> 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 medicines, therefore creating 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 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**: It may happen 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<sup>119</sup> 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 notify 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 to learn and cope with them, especially in countries with high levels of restrictions.<sup>120</sup> 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

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117 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.

118 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.

119 AT, NL, SE, SI and UK.

120 Such as AT, DE, FI, HR, SE.

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 the 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 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 a way. For instance, an Italian SME active in the area of food supplement suggested how, on average, costs for lawyers 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 light of these difficulties, stakeholders tend to:

- **Adapt the product** to the national requirements. Clearly this decision also 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 repay 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**<sup>121</sup>

Considering the available information, it is possible to estimate the total turnover of the sector as between **40 and 43 billion per annum**,<sup>122</sup> while the number of companies operating can be estimated at around **7,000 units**, with a heterogeneous distribution among small medium and large enterprises.<sup>123</sup>

Tests and certifications concerning the products in contact with drinking water come under several categories: mechanical, hygienic and audits. The cost-spread for these certifications as well as statutory audits are different among EU Member States. In Germany, for example, audit 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.<sup>124</sup>

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 the application of mutual recognition with regard to these products is seriously deficient currently, 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)<sup>125</sup> 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”.

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121 See annex 13 for the full case study on products in contact with drinking water

122 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

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

124 Figawa, *Member Survey*, 2016

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

The implementation and monitoring measures are left to the Member States, which have established their own national test and certification bodies<sup>126</sup> 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 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 does result 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 a few countries<sup>127</sup> at the same time in Europe, mainly due to additional testing and certifications that have to be done in each Member State requiring it. 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 aiming to sell 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.

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126 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), Ministero 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).

127 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.



The problem of double and additional testing is particularly acute in some countries. Stakeholders mentioned how Member States such as Spain, France, UK, and 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 in 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 to 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 about 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 with regards to 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**<sup>128</sup>

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

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128 See annex 13 for the full case study

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 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.<sup>129</sup> 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 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<sup>130</sup>, 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 a grey area for the systematic assurance of food safety. The level of non-compliance is not greater overall for non-harmonised materials, 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

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129 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>

130 European food and safety authority

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<sup>131</sup> 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<sup>132</sup>. Despite the existence of a number of EU harmonisation measures applying to mobile machinery<sup>133</sup>, 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 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 caused by the application of the different national requirements consist of both direct and indirect costs. Direct costs for the industry to comply 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 too challenging to enter new Member States markets and to comply with their specific rules, more than other firms.

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131 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

132 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>

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

#### 1.11.4 Costs for the Commission

The main costs incurred by the Commission are related to managing the implementation of the Mutual Recognition Regulation and to the handling of notifications, complaints and infringements in the area of Articles 34-36 TFEU. These costs can be estimated on the basis of Full Time Equivalents (FTEs), for which a yearly gross salary of kEUR 60 has been assumed, to which also 25% of overhead was added (75 000). It was assumed that one FTE corresponds to approximately 220 effective working days. Additionally, there are the costs of organising the Mutual Recognition consultative committee, estimated on the basis of the number of experts participating and the amounts of travelling fees reimbursed.

| Mutual Recognition Regulation (per year) | Notifications, complaints and infringements (per year) | Mutual Recognition consultative committee (per year) |
|--|--|--|
| 1 FTE – EURO 75 000                      | 3 FTEs – EURO 225 000                                  | EURO 9700  |

#### 1.11.5 Benefits for national authorities

There are several benefits of mutual recognition for the national authorities.

First, mutual recognition brings **regulatory benefits**<sup>134</sup>. These regulatory benefits are perceived in the sense of ‘better regulation’. The mutual recognition principle respects Member States' regulatory autonomy and diversity, as different coexisting national rules should be considered as equivalent while at the same time ensuring that in cases where consumer safety or health is at stake, derogations apply. Also, it avoids unnecessary harmonisation at EU level, by allowing free movement of goods for products which are not always designed and manufactured according to identical rules.

Second, **strategic benefits**<sup>135</sup> can be achieved, as the functioning of the internal market is enhanced without adding any new EU legislation. Economic operators are supposed to have access to new markets while this access was hindered /blocked before the existence of mutual recognition.

Finally, **economic welfare**<sup>136</sup> is another benefit, as mutual recognition aims to facilitate free movement of goods, thus enhancing competition, providing more and better choices to consumers and offering new opportunities to businesses.

Further to the benefits of mutual recognition mentioned above, the Regulation was expected to bring certain benefits, in terms of increased awareness of the mutual recognition principle, and better information on the applicable rules in the Member States where the products are lawfully marketed, allowing for a smoother application of the mutual recognition principle. The expected benefits deriving from the obligation to notify administrative decisions denying market access was supposed to discipline national authorities when applying the principle, as

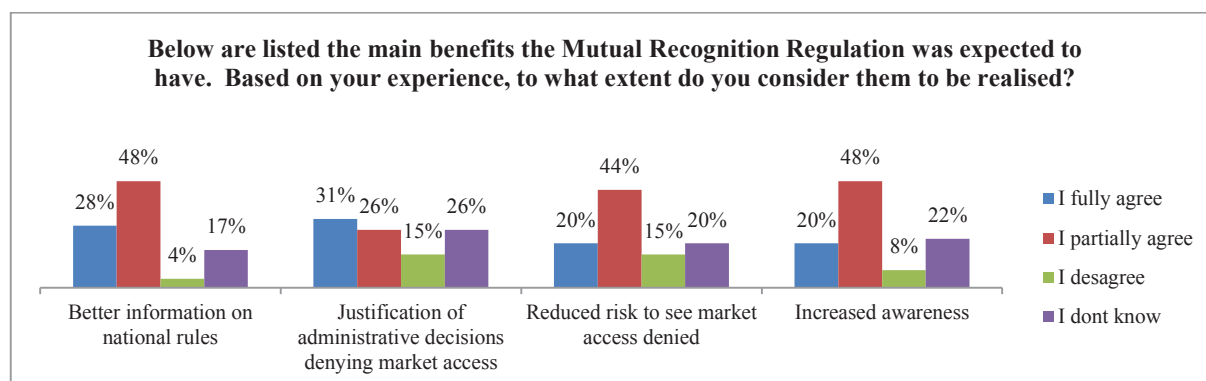
134 Pelkmans (2012): Mutual recognition: economic and regulatory logic in goods and services

135 Pelkmans (2012): Mutual recognition: economic and regulatory logic in goods and services

136 Pelkmans (2012): Mutual recognition: economic and regulatory logic in goods and services

they have to justify why market access is refused. National authorities agreed, fully or partially, with the benefits the Regulation brings.

**Figure 7-16: Public consultation 2016- Member States views**



### 1.11.6 Benefits for businesses

The main benefit that the mutual recognition principle and Regulation were expected to bring were **an easier access to the market of other Member States**; economic operators may exploit economies of scale by expanding into new geographical markets. Such changes should be reflected in gains in competitiveness and productive efficiency, and should thus contribute to the restoration of profit margins. In addition, it should foster innovation; the 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<sup>137</sup>. Furthermore, in order to launch innovative new products on the market, businesses need to rely on existing national rules or deal with the absence of such rules; a correct application of the mutual recognition principle would not only facilitate free movement of innovative/new products but could also increase a number of innovative products to be placed on the market<sup>138</sup>.

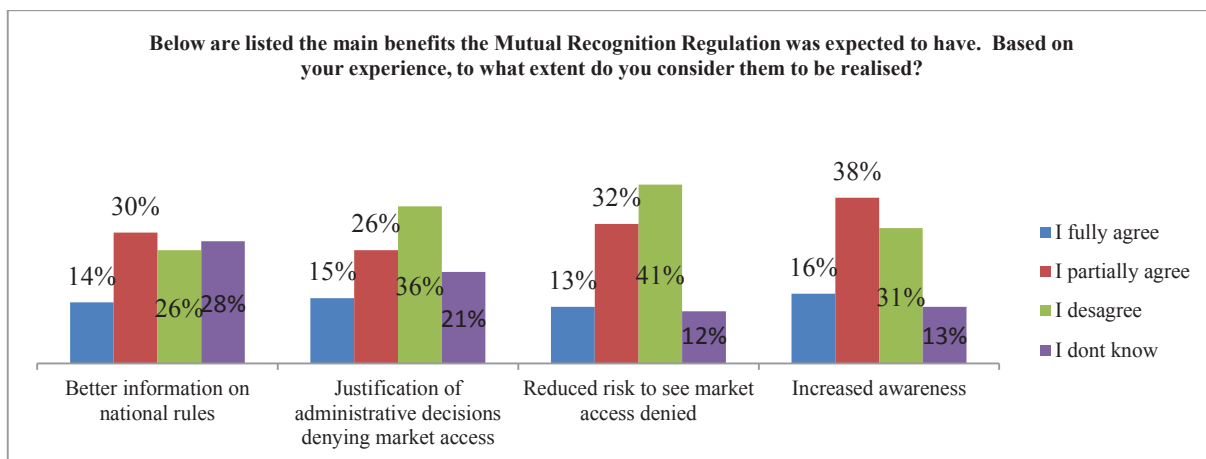
Following a proper application of the mutual recognition principle, the risk for enterprises that their products will not gain access to - or will have to be withdrawn from - the market of the Member State of destination would in many cases be reduced. A proper application of the mutual recognition principle would also imply less need for multiple testing and certification, and Member States would recognise products lawfully marketed in another member State and therefore not require additional testing. Additionally, the Regulation has additional potential benefits, as it is supposed to increase awareness of the principle and to facilitate access to information about the applicable national rules.

In terms of benefits that the Regulation brings, the perceptions of businesses are quite mixed:

**Figure 7-17: Public consultation 2016**

137 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](http://www.oecd-ilibrary.org/economics/reinvigorating-the-eu-single-market_5jxx3d3hk437-en).

138 The Innobarometer 2016 shows that the main barriers to commercialisation identified by business (including regulatory barriers) confirm in particular the relevance of the Single Market Strategy to give a boost to innovation performance



### 1.11.7 Benefits for consumers

In the case of an optimal functioning of mutual recognition, consumers would have access to a wider variety of products, and would enjoy lower prices, due to the economies of scale made by the manufacturers. Furthermore it can be assumed that consumers would also benefit in terms of public interest protection, as a product lawfully marketed in another Member State would be allowed in their own Member State only if it satisfactorily fulfils the same public interest protection requirements<sup>139</sup>.

This is also supported by a recent study carried out by the European Parliament<sup>140</sup>, where the benefits of removing remaining barriers to intra EU trade are evaluated. Although the study does not directly estimate the effects on consumers, the study points out that it is expected that EU consumers will benefit from a wider variety of supplies available for their consumption in line with increased bilateral trade flows. Furthermore, rising trade flows increases competitive pressure on domestic producers of goods and leads to lower prices for given products. The study estimates that a reduction in barriers to intra-EU trade could lead to increases in trade between Member States of a magnitude of more than 100 billion EUR annually.

### 1.11.8 Comparing costs and benefits

There are certain administrative costs resulting directly from the Regulation. For national authorities, the main costs relate to implementing the PCPs network and deciding if mutual recognition can be applied or not. For businesses, these relate to getting familiar with the Regulation.

The main costs involved are rather due to the suboptimal application of mutual recognition than to the application of the Regulation as such.

| Member States     |              | Businesses       |                    | Consumers     | Commission         |
|-------------------|--------------|------------------|--------------------|---------------|--------------------|
| BENEFITS          | COSTS        | BENEFITS         | COSTS              | BENEFITS      | COSTS              |
| <b>Regulatory</b> | Implementing | Easier access to | <b>Information</b> | Wider variety | Mutual Recognition |

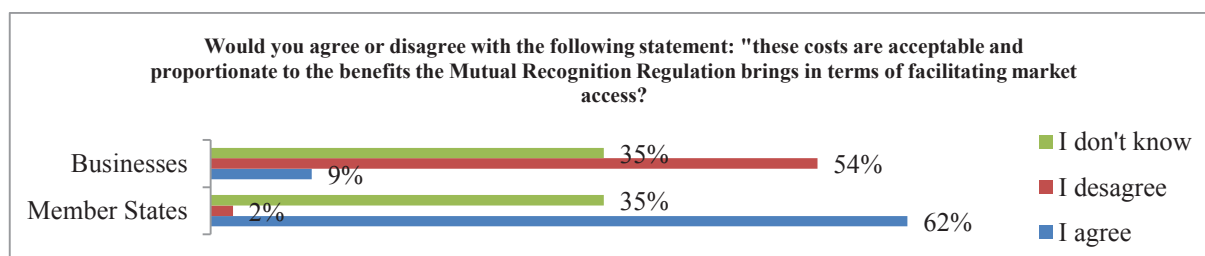
139 BIS publication (2014) Measuring the benefits to UK consumers from the creation of the European Single Market, How theory suggests the Single Market should create consumer benefits, mentions that "One main goal of the Single Market is the delivery of benefits to consumers, including access to goods and services at lower prices and higher quality and larger product variety." These are expected to be delivered via: "trade liberation (...), stronger competition (...), faster product innovation (...) and costs reductions from legal and regulatory harmonisation."

140 See "The costs of non- Europe", study of the European parliamentary research service: [http://www.europarl.europa.eu/EPRS/EPRS\\_STUDY\\_536353\\_CoNE\\_Single\\_Market\\_Lpdf](http://www.europarl.europa.eu/EPRS/EPRS_STUDY_536353_CoNE_Single_Market_Lpdf)

|  |  |  |   |                     |  |
|--|--|--|---|---------------------|--|
| (better regulation, regulatory autonomy and diversity, no unnecessary harmonisation) | and functioning of Product Contact Points EURO 7417-47450 <sup>141</sup>   | new markets (opportunities)                      | (on the applicable rules in the Member State of destination) 10-500 hours   | of supply available | Regulation (per year) 1 FTE – EURO 75 000                                    |
| <b>Strategic</b> (enhanced functioning of the Single Market)                         | Assessment of products and notification of decisions denying market access EURO 420 000 e.g. fertilisers sector) | Lower production costs (no need to retest/adapt) | <b>Adaptation</b> EURO 1000-150 000 <sup>142</sup><br><b>Delayed entry on the market</b> EURO 3000-500 000 <sup>143</sup> |                     | Notifications, complaints and infringements (per year) 3 FTEs – EURO 225 000 |
| <b>Economic welfare</b> (enhanced competition and more opportunities)                | Reporting on the implementation if the Regulation  | Better access to information on applicable rules | <b>Lost opportunities</b> EURO 40 000-500 000 <sup>144</sup>  | Lower prices        | Mutual Recognition consultative committee (per year) EURO 9700               |

It is not possible to compare costs and benefits in a reliable way. The costs observed cannot be estimated globally, because of the variety of products and sectors involved, and because of the lack of precise data related to the occurrence of market denial. The 2016 public consultation provides the perception of stakeholders as to whether or not costs are proportionate to the benefits. The results show that while Member States tend to consider that the costs of the Regulation (which include the costs of the suboptimal functioning of mutual recognition) are proportionate with the benefits it generates, businesses mostly disagree.

**Figure 7-18: Public consultation 2016**



This perception can be justified by the fact that businesses reported important/ significant costs while they did not really observe the expected benefits, due to the suboptimal functioning of mutual recognition. As the 2016 public consultation shows, 87% of businesses adapt their products instead of relying on mutual recognition. The costs incurred by national authorities were considered normal costs that are usually incurred in enforcing legislation, and thus proportionate with the benefits expected.

141 Based on Gross annual salaries for employees in public administration Eurostat  
142 Per product and per market  
143 Per product and per market  
144 Per product and per market

### 1.11.9 Conclusion on efficiency

Overall, it can be concluded that the suboptimal use of mutual recognition creates additional costs on 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 sectorial evidence and the results of the different surveys and consultations carried out, although not representative show that the costs are significant.

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<sup>145</sup> 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.

### 1.12 Coherence: how mutual recognition fits in the other EU policies

Several initiatives relevant for mutual recognition have been identified:

**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**<sup>146</sup>. The Directive contributes to ensuring higher and better mutual recognition by requiring Member States to notify the Commission and each other of any draft ‘technical regulations’ for products before they are adopted in national law, with a view to boosting transparency and control with regard to those regulations. Since national technical regulations might create unjustified barriers to trade between Member States, notification in draft form and subsequent evaluation of their content in the light of the mutual recognition principle help to diminish this risk. As for the relationship between the Directive and the Regulation, they have differing objectives. The Directive seeks to prevent trade barriers in the form of ‘technical regulations’ before they are adopted, by enabling the Commission and Member States to verify that the technical rule is compatible with EU law. The Regulation applies after a ‘technical rule’ has been adopted; it seeks to ensure that any authorities taking decisions based on such rules apply the principle of mutual recognition correctly in individual cases. The two acts are applied at different stages in the life cycle of a technical rule. While the Directive is a preventive mechanism which precedes the adoption of a technical rule, the Regulation is a corrective measure once the rule is in force, ensuring on a case by case basis that the rule is being applied correctly. On the basis of the above, it appears that there is no incoherence or duplication between the mutual recognition principle / Regulation and the Directive. Rather, the analysis carried out shows several synergies. The main synergy which can be highlighted relates to the inclusion of a mutual recognition clause in the draft technical regulations notified to the Commission. Other synergies relate to flagging sectors and areas where

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145 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

146 [http://www.europarl.europa.eu/RegData/etudes/STUD/2014/510981/EPRS\\_STU\(2014\)510981\\_REV1\\_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/STUD/2014/510981/EPRS_STU(2014)510981_REV1_EN.pdf)  
OJ L 241, 17.9.2015, p. 1–15



Member States tend to regulate intensively, and where challenges may arise in terms of applying the mutual recognition principle.

**Directive 2001/95/EC on General Product Safety**<sup>147</sup> (including the RAPEX<sup>148</sup> mechanism) ensures that products placed on the EU market are safe. The directive applies to non-harmonised consumer products. The Regulation also operates in the non-harmonised area, but do not apply to measures taken under Directive 2001/95 and concerning products posing a risk to the health and safety of consumers. The Regulation applies where the competent authorities of a Member State intend to prohibit the marketing or use of a non-harmonised consumer product, lawfully marketed in another Member State, on the basis of a technical rule and for reasons other than a risk to the health and safety of consumers. This is the case, for example, when a product is not allowed to be marketed for reasons based on the denomination, size, composition or packaging, or for environmental reasons. The analysis carried out on the coherence between these two legal instruments suggests that certain specific administrative decisions are excluded from the scope of the Regulation, while others are covered. Furthermore the analysis did not result in finding any clear explanation of the rationale for the differentiation and that this differentiation could generate a risk of confusion among national authorities and economic operators.

The relationship between the Directive and the Regulation is addressed in article 3.2 a) of the Regulation, on the basis of which it appears that the Regulation does not apply to the following administrative decisions:

- *temporary ban on the supply, the offer to supply or the display for however long is needed for the various safety evaluations, checks and controls for any product that could be dangerous (article 8(1)(d) of the GPSD);*
- *ban on the marketing and introduction of the accompanying measures required to ensure the ban is complied with for dangerous product: (article 8(1)(e) of the GPSD);*
- *order for or organisation of the actual and immediate withdrawal, and alert to consumers of the risks presented; order for or coordination – or, if appropriate, organisation together with producers and distributors – of the recall from consumers and the destruction of any dangerous product already on the market (article 8(1)(f) of the GPSD);*
- *any of the measures mentioned above as well as the requirement to mark with clearly worded and easily comprehensible warnings on the risks, to make the marketing subject to prior conditions to make the product safe and to order that persons to whom the product could pose risks are given warning in good time and in an appropriate form including the publication of special warnings, for products posing a serious risk (article 8(3) of the GPSD).*

Furthermore, the Regulation does not apply to certain measures, such as the organisation of appropriate safety checks on the safety properties of any product, the request of all necessary information from the parties concerned and the decision to take samples of products and

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147 OJ L 11, 15.1.2002, pp. 4-17

148 Rapid Alert System established under Directive 2001/95 on General Product Safety

subject them to safety checks (Article 8(1)(a) of the GPSD), as these are not administrative decisions taken on the basis of a technical rule in the sense of article 2 of the Regulation.

A contrario, the Regulation would apply to the following administrative decisions:

- *the requirement to mark with clearly worded and easily comprehensible warnings on the risks, to make the marketing subject to prior conditions to make the product safe and to order that persons to whom the product could pose risks are given warning in good time and in an appropriate form including the publication of special warnings, for products that could pose a risk in certain conditions and for products that could pose risks for certain persons (article 8(1) (b) and (c) of the GPSD).*

**Regulation (EU) No 305/2011 on construction products**<sup>149</sup> sets up Products Contact Points for Construction (PCPCs). Article 10 of The Regulation requires each Member State to nominate a Product Contact Point for Construction in order to "*provide information, using transparent and easily understandable terms, on the provisions within its territory aimed at fulfilling basic requirements for construction works applicable for the intended use of each construction product*". The Mutual Recognition Regulation, and in particular the requirements related to Product Contact Points (PCPs) complements coherently the PCPCs. The objective of the PCPCs is very similar with the objective of the PCPs under mutual recognition; furthermore, many construction products belong to the non-harmonised area. The importance of the construction sector both in terms of variety and complexity of products covered and number of active economic operators justify the existence of a specific PCP for construction products. Nevertheless, in numerous Member States, the PCPC and the PCP have been merged, in order to offer a "one single entry point" for businesses. Thus, it appears that there is no incoherence or duplication between the mutual recognition principle / Regulation and the Construction Products Regulation. Rather, the analysis carried out shows synergies between the two and guidelines<sup>150</sup> have been published for maintaining consistency between PCPs and CPCPs.

**The SOLVIT network**<sup>151</sup> is a service provided by the national administration in each EU Member State, and in Iceland, Liechtenstein and Norway. It helps business when their rights are breached by public authorities in another EU Member State, by aiming to find a solution within 10 weeks. Thus, SOLVIT may be used, as an alternative, by businesses when facing a national decision denying or restricting market access on the basis of the mutual recognition principle.

The proposal for an **EU Single Digital Gateway**<sup>152</sup> is expected to introduce a new obligation to provide information on national product rules online on a website, instead of upon request like currently. 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.<sup>153</sup> 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

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149 OJ L 88, 4.4.2011, p. 5–43

150 Study performed by Ecorys (final version and link not available)

151 [http://ec.europa.eu/solvit/what-is-solvit/index\\_en.htm](http://ec.europa.eu/solvit/what-is-solvit/index_en.htm)

152 <http://ec.europa.eu/DocsRoom/documents/22761>

153 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.

addition, this initiative is expected to improve the functioning of PCPs by setting out quality criteria and the obligation to provide information online.

**EU harmonisation legislation** and mutual recognition are fully complementary. 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 to eliminate barriers to the free movement of goods in the single market, but also to ensure that only safe and otherwise compliant products find their way onto 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 product is neither a feasible nor a desirable objective. 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 products are only partially 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.

The results of the 2016 public consultation confirm the analysis carried out above. There is a consensus among stakeholders as regards the coherence of the Regulation with regard to other EU pieces of legislation. Most of the respondents are not aware about any overlaps between the Regulation and other initiatives/legislation/policies. A minor part of respondents indicated that there are some overlaps linked to SOLVIT<sup>154</sup>, RAPEX<sup>155</sup>, ICSMS<sup>156</sup> and Regulation 765/2008 on market surveillance<sup>157</sup>. 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.

#### **Figure 7-19: Public consultation 2016**

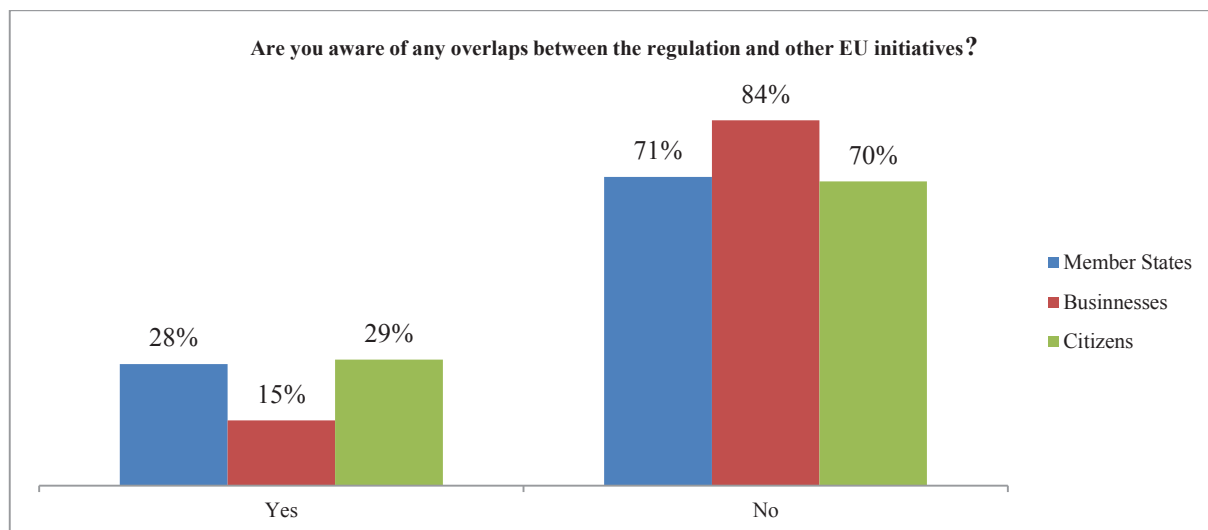
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154 [http://ec.europa.eu/solvit/index\\_en.ht](http://ec.europa.eu/solvit/index_en.ht)

155 See above 139

156 Internet-supported information and communication system for the pan-European market surveillance

157 OJ L 218/30, 13.08.2008



### 7.3.1 Conclusion on coherence

Overall, the internal analysis carried out, confirmed by the results of the 2016 public consultation show 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. Rather, the mutual recognition principle and the Regulation complement and are coherent with a number of initiatives in this area, as described above.

### 1.13 Relevance: assessing the continuous need for mutual recognition

Mutual recognition is "one of the most appreciated innovations of the EU"<sup>158</sup>, 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. However, the application of the mutual recognition principle in practice proved to be very challenging. The adoption of the Mutual Recognition Regulation aimed to enhance and improve the application of the mutual recognition principle and thus reduced some of the costs incurred by businesses.

*To what extent is mutual recognition still relevant to its stakeholders?*

Businesses still encounter problems when trying to sell in Member State products lawfully marketed in another Member State. Member States need to retain their regulatory autonomy and diversity while supporting the competitiveness of their economic operators and allowing them easy access to markets. 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. A recent study<sup>159</sup> shows that around 0.99 million enterprises<sup>160</sup> were operating within the non-harmonised area, representing more than 50% of the total number of active enterprises in the manufacturing economy. At EU28 level, more than 8 million persons are employed in the non-harmonised area, representing around 31% of all persons employed in the manufacturing sector). Furthermore, the (average) annual value of intra EU exports<sup>161</sup> of non-harmonised (or

158 "Mutual recognition: economic and regulatory logic in goods and services", Bruges European Economic Research Papers, 2012, Jacques Pelkmans

159 Study on the cost and benefits of the revision of the Mutual recognition Regulation (EC) No 764/2008, February 2017

160 Over the period 2012-2014

161 Over the period 2008-2015

partially harmonised) goods has been equal to €335 billion, while the contribution of enterprises in the non-harmonised (or partially harmonised) area is around 20% of the total value of market sales of manufacturing sectors (€1, 158 billion out of €5, 690 billion).

Furthermore, mutual recognition is particularly relevant for supporting innovation. In the area of new innovative products, there are no European harmonised rules, and businesses need to rely on existing rules/standards at national level, or even to deal with the absence of such rules. Mutual recognition is the only alternative for businesses wishing to market their new/innovative products in other Member States. Recent data<sup>162</sup> shows that more than two thirds of EU companies have introduced at least one innovation since 2013, and four in ten EU companies have introduced new or significantly improved products. For the majority of companies, innovative goods accounts for between 1% and 25% of their turnover (67%) while a further 17% say that they account for more than 26% of their turnover. The relevance of mutual recognition in this area is also supported by the fact that 57% of EU companies consider that the cost and complexity of meeting regulations or standards is a problem for the marketing of innovative goods, and for 48% this is one of the reasons why they have not introduced innovative goods on the market since 2013. Furthermore, 18% of those that have not introduced innovative products on the market believe that further support in relation to how to meet regulations and standards is needed.

Lastly, mutual recognition is an alternative to harmonisation. In order to be cost effective, harmonisation can be used only in sectors where the divergence of technical rules poses too many problems to permit a proper application of the mutual recognition principle. Furthermore, mutual recognition can achieve similar results to harmonisation with the advantage of not triggering transition costs (as harmonisation does, which forces companies to comply with new harmonised requirements that are likely to be different from the prior national requirements).

Thus, mutual recognition remains a very relevant issue for stakeholders across the EU, as the solutions it brings have the potential to address the needs of businesses and Member States. This is also supported by the fact that during the consultation process<sup>163</sup>, stakeholders showed a high interest in mutual recognition.

*How well do the objectives set out in the Regulation (still) correspond to the current needs within the EU?*

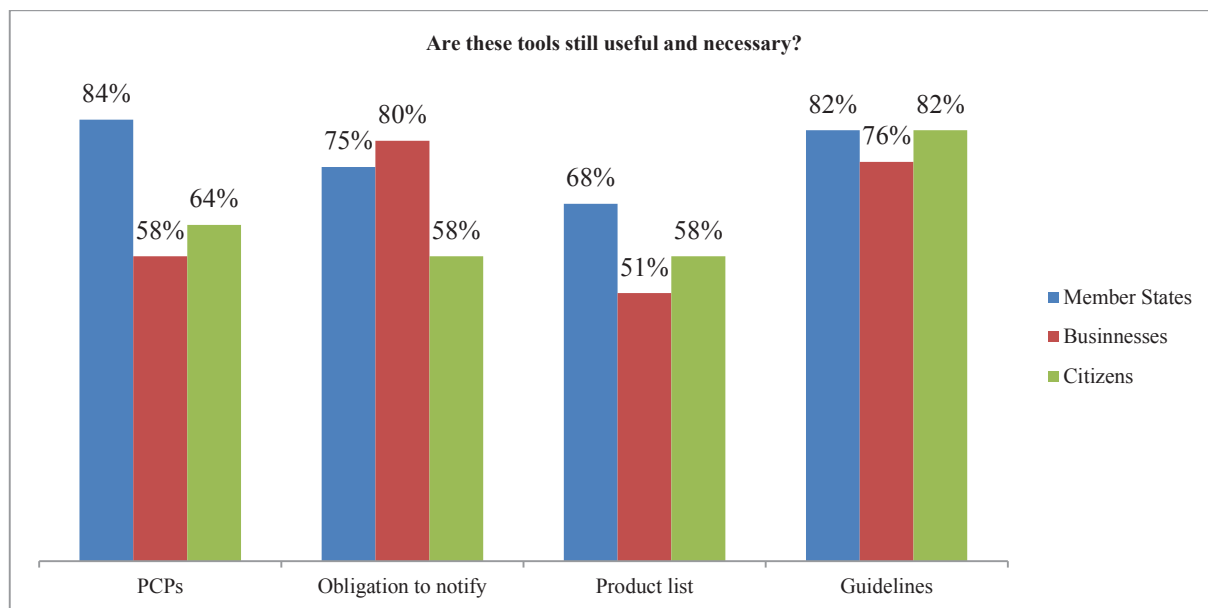
Mutual recognition remains a much appreciated tool for achieving free movement of goods while respecting Member States regulatory autonomy and diversity. The Regulation captured well the practical difficulties of the application of the mutual recognition principle; these difficulties remain valid and improving the application of the principle is still an objective which corresponds to the current need of stakeholders to rely on a smooth functioning of the internal market. This is confirmed by the results of the 2016 public consultation which shows that most of the tools put in place by the Regulation are still useful and necessary.

**Figure 7-20: Public consultation 2016: are the tools put in place by the Regulation still useful and necessary?**

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162 Innobarometer 2016 – EU business innovation trends

163 See annex 2



Since the introduction of the principle and the entry into force of the Regulation, the traditional way goods are being sold changed. Data<sup>164</sup> shows that more and more products are being sold online; in the future, more and more products will be sold online, and the number of online cross border transactions will increase. However, the way products are being made available to consumers (in shops or online) has no impact on the fact that these products should comply with the applicable rules and benefit from the free movement principle. Economic operators are entitled to invoke their right to mutual recognition regardless of how they intend to sell their products, provided that they are lawfully marketing them in one Member State. What might be impacted is the Member States capacity to conduct market controls and check those products which are sold online. Currently, market control procedures are more adapted to the classic selling methods (shops), but it is expected that, due to the increase of online sales, market control procedures will evolve in order to better capture those products sold online.

#### 7.4.1 Conclusion on relevance

The evaluation shows, that, overall, mutual recognition remains particularly relevant for businesses, which still encounter obstacles to free movement of goods, and for Member States, who still need to retain their regulatory autonomy. Mutual recognition remains also relevant for innovative products, where there is a need to rely on existing national rules or to deal with their absence. Furthermore, mutual recognition remains an alternative to harmonisation, which can be used only where it is cost efficient, due to a very important divergence of technical rules. 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.

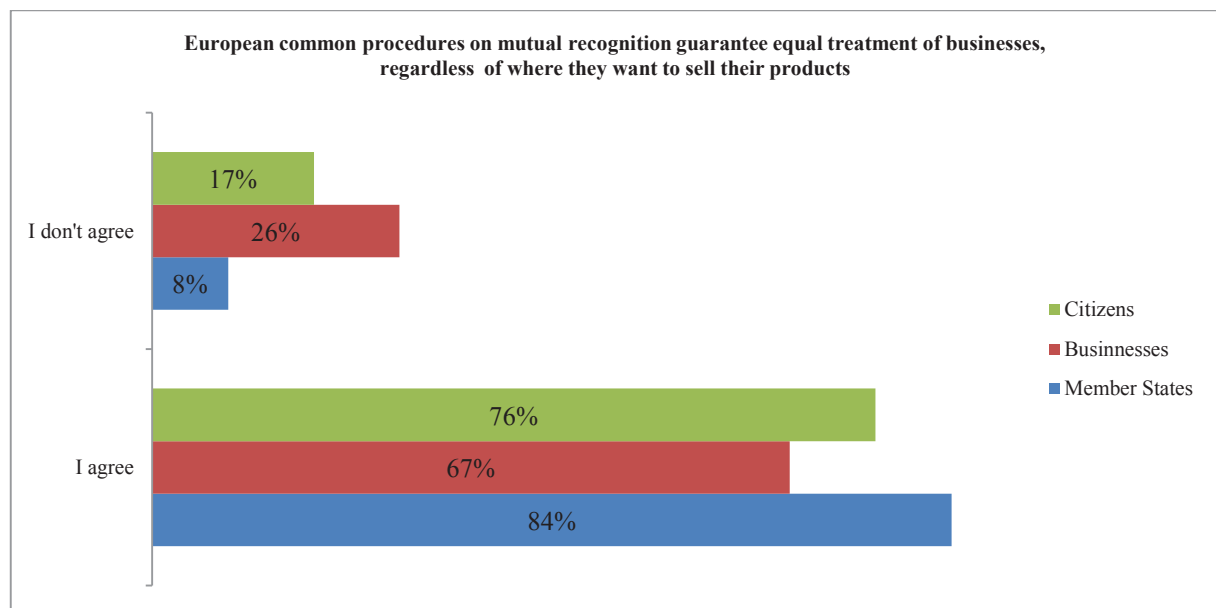
### 1.14 EU added value: Evaluating what mutual recognition brings to the EU

*What is the EU added value of mutual recognition for stakeholders? To what extent do the issues addressed by the mutual recognition provisions continue to require action at EU level?*

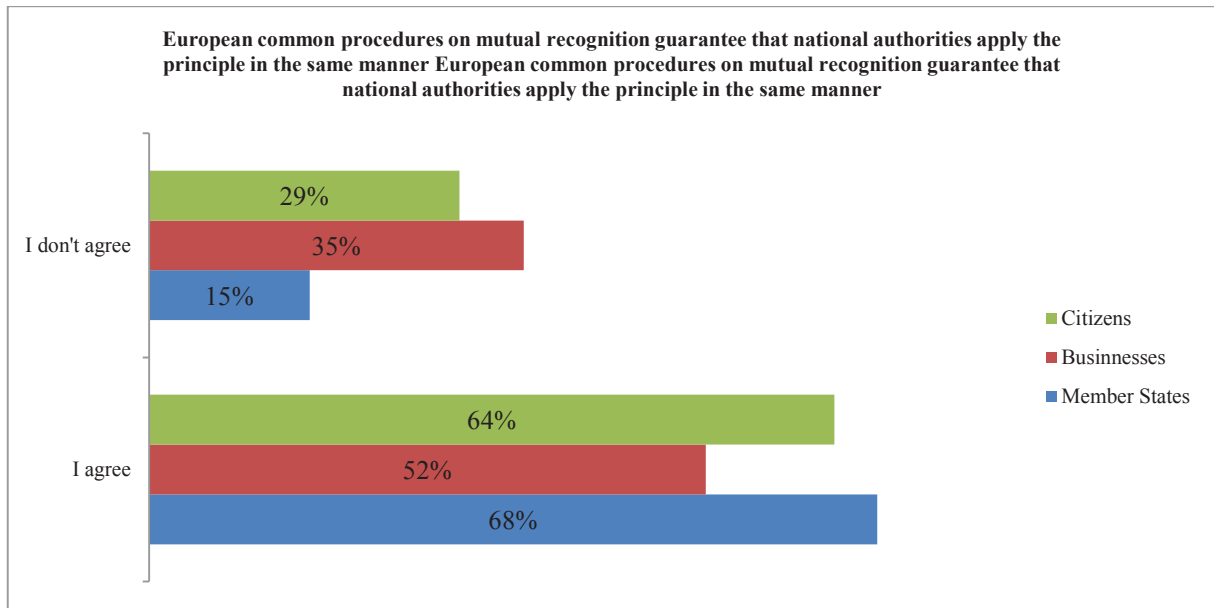
164 [http://ec.europa.eu/eurostat/statistics-explained/index.php/E-commerce\\_statistics](http://ec.europa.eu/eurostat/statistics-explained/index.php/E-commerce_statistics)

Following the stakeholders' consultation<sup>165</sup>, there is a general consensus among stakeholders that mutual recognition brings added value to the EU. It gives the possibility to market in other Member States products already lawfully marketed elsewhere, while maintaining 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. This is because mutual recognition only applies in cross border situations where an economic operator would like to trade in other Member States a product already lawfully marketed in a 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 harmonised procedures to be applied equally by all national authorities. Only such harmonised 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.

**Figure 7-21: Public consultation 2016 – EU added value of mutual recognition**



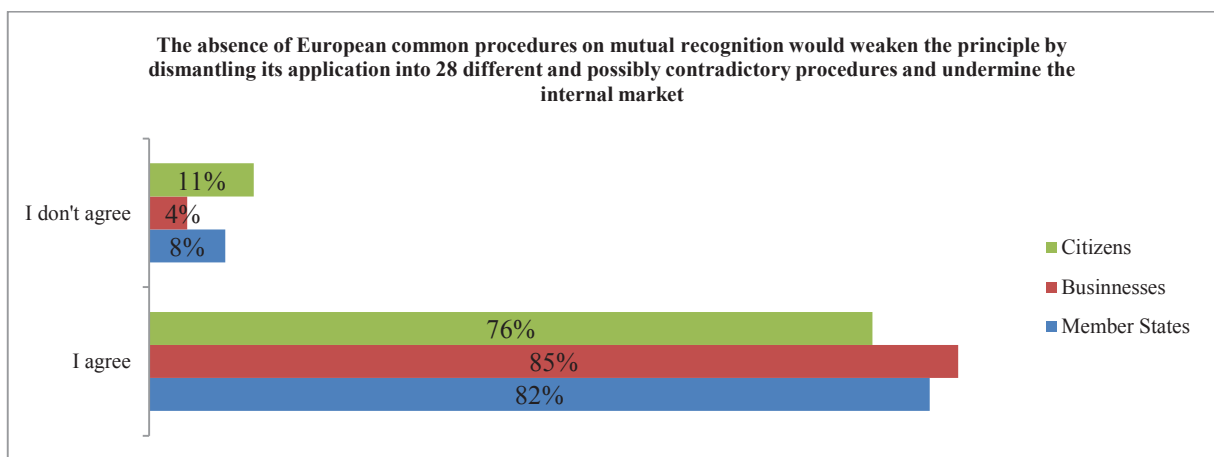
165 See annex 2



*What would be the most likely consequences of repealing the mutual recognition provisions?*

The mutual recognition principle arises from articles 34-36 TFEU and has been further developed on the basis of the Court's jurisprudence. It cannot be repealed as such. In case of repealing the Regulation, the mutual recognition principle would continue to apply. This means that economic operators would no longer have any procedural guarantees in case market access is denied. They would no longer have access to PCPs, when information on the applicable national rules is needed. Generally, businesses and national authorities would be reluctant to apply the mutual recognition principle alone, as they were before the adoption of the Regulation, in the absence of harmonised procedural guarantees. They would follow, de facto, the applicable national rules. In principle, this would mean going back to the baseline as it existed before the adoption of the Regulation.

**Figure 7-22: Public consultation 2016**



*7.5.1 Conclusion on EU added value*



The evaluation shows that there is a high consensus among stakeholders that mutual recognition brings added value to the EU, as it allows free movement of goods already lawfully marketed in one Member State while respecting Member States regulatory autonomy. Repealing the Regulation would mean depriving businesses of any procedural guarantees when invoking the mutual recognition principle.

## **8. CONCLUSION**

There is a general consensus among stakeholders that mutual recognition in the fields of goods has the potential to bring added value to the EU. It gives the possibility to market in other Member States products already lawfully marketed elsewhere. However, the evaluation of the mutual recognition principle shows that it is not functioning as it should. The majority of businesses wishing to sell products in another Member State declare that they check the applicable rules in that Member State, and, if these rules prevent them from selling the product, they don't rely on the principle of mutual recognition but most of them adapt the product to those rules. Where businesses try to rely on the principle of mutual recognition, national authorities often deny market access to those products.

Whilst the Regulation was adopted to facilitate the application of the principle of mutual recognition, generally, the evaluation shows that only few economic operators consider that it is easier to sell products in other Member States since the Regulation entered into force.

The Regulation had a very moderate effect with regards to the objectives settled, mainly because the procedural requirements it put in place proved to be insufficient to ensure an easy, reliable and user-friendly application of the mutual recognition principle. It had limited effects in raising awareness of the mutual recognition principle; still many economic operators and national authorities are not fully aware of the principle and its practical implications, and stakeholders, throughout the consultation process, were unanimous with regards to the necessity to continue efforts in raising awareness. Member States and citizens consider that this should be the Commission's first priority, while businesses ranked fourth.

Legal certainty remains an issue and makes users reluctant towards mutual recognition. Businesses ranked the need to increase legal certainty when using mutual recognition as the second priority for the Commission. The evaluation shows that the lack of knowledge as regards the scope of mutual recognition makes economic operators reluctant to use the principle for entering new markets. 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. Also, there are many uncertainties when it comes to demonstrating that products have been lawfully marketed in a given Member States. Furthermore, the difficulty to challenge administrative decisions that deny or restrict market access has been pointed out as a reason for not relying on mutual recognition. Businesses ranked this as being the main obstacle to using mutual recognition, and the first priority for the Commission; they were supported by Member States, who ranked this as the third priority. Although the actual number of administrative decisions denying or restricting market access is unknown, the evaluation of the functioning of mutual recognition shows that economic operators are often faced with such administrative decisions. Administrative cooperation remains limited, despite the fact that the PCPs network, even if not used at its full capacity, is judged useful by most stakeholders. Member States called on improving the current system,

by integrating PCPs in a wider network in order to gain expertise and by enhancing administrative cooperation.

Stakeholders consulted throughout the evaluation were unable to quantify the cost-saving brought by the principle and Regulation. A study done for the European Parliament<sup>166</sup> 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. Due to the ineffective application of the principle of mutual recognition, goods lawfully marketed in one Member State are generally not being sold in another Member State without adaptations to national rules. This leads to barriers to free movement of goods; in the absence of harmonisation legislation, a single market for goods is thus far from being achieved. Economic operators are not benefitting fully from the internal market and their existing rights. National authorities rely on their own national rules which may undermine the free movement of goods. The qualitative input received during the consultation process also points into the direction that mutual recognition, when working optimally, has the potential to reduce costs and generate benefits.

Throughout the consultation process, stakeholders were almost unanimous with regards to the necessity of enhancing the existing tools for achieving higher and better mutual recognition.

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166 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](http://www.europarl.europa.eu/RegData/etudes/STUD/2014/510981/EPRS_STU(2014)510981_REV1_EN.pdf)

## ANNEX 1: PROCEDURAL INFORMATION

In December 2013, the Conclusions on Single Market Policy, adopted by the Competitiveness Council, recalled that to improve the framework conditions for businesses and consumers in the Single Market, all relevant instruments should be appropriately employed, including harmonisation and mutual recognition. 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 response to the Council request and the indications that the functioning of the principle might not be optimal, the application of the principle of mutual recognition was subject to an external evaluation<sup>167</sup>. Its objective was to assess the functioning of the application of the principle and identify the shortcomings and on this basis, to identify possible ways to improve its application. The evaluation of the principle of mutual recognition was part of the REFIT agenda in 2014. This exercise did not include a full ex-post evaluation of the Mutual Recognition Regulation but provided some indications on its current performance.

Thus, the purpose of this exercise is to have a full ex-post evaluation of the Mutual Recognition Regulation, in order to assess the main difficulties encountered and follow-up on the implementation of the Single Market Strategy with respect to mutual recognition, and in particular on the proposal to revisit the application of the principle of mutual recognition and the implementation of the Mutual Recognition Regulation with a view to ensuring higher and better mutual recognition. This initiative is part of the Commission's 2017 Working Programme<sup>168</sup>.

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 Regulatory Scrutiny Board (RSB) of the European Commission assessed a draft version of the present evaluation and issued its positive opinion on 07/04/2017. The Board made several recommendations to further improve the report. Those were addressed in the revised report as follows:

RSB recommendations

Modification of the report

### **(B) Main considerations**

The Board gives a positive opinion, but considers that the report should be improved with respect to the following key aspects:

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167 <http://ec.europa.eu/DocsRoom/documents/13381>  
168 COM(2017)710 Final

(1) There is scope to improve the description and the relative importance of the main problems encountered in the application of the mutual recognition principle and the corresponding Regulation. Why do the key instruments put in place by the Regulation not deliver?

This recommendation has been addressed thorough the text, by adding relevant data collected during the study supporting the impact assessment on the revision of the Mutual Recognition Regulation.

(2) While being a REFIT evaluation, it does not clearly estimate existing regulatory burdens on companies or public administrations, or the potential for cost savings.

Clarifications on the REFIT aspects have been added in sections 7.1.5 and 7.2.9 of the SWD.

(3) The report does not provide clear conclusions on whether the Mutual Recognition Regulation remains relevant or not, or on the extent to which there is scope to remedy its ineffectiveness.

The conclusions have been amended accordingly; see more specifically sections 7.1.4, 7.1.5, 7.2.9, 7.3.1, 7.4.1, 7.5.1 and 8 of the SWD.

### **(C) Further considerations and recommendations for improvement**

(1) Effectiveness and magnitude of the problem

The report gives indications that the application of the mutual recognition principle and the related Regulation do not work properly. However, it does not provide robust evidence to show the extent of the problem. It should use information from the parallel draft impact assessment to estimate the magnitude of the problem (with the necessary caveats). In particular, it should further assess bottlenecks of the main delivery mechanisms: Contact Points in the national administrations, Commission database, mutual recognition clause in technical specifications. The report should differentiate between technical difficulties, lack of resources for

The problems have been completed with useful data collected during the study supporting the impact assessment on the revision of the Mutual Recognition Regulation (more specifically, see section 7.1 of the SDW). Explanations on the robustness of the data collected during the public consultations have been added in section 5 and 7.1.4 of the SWD.

enforcement, lack of awareness and political reluctance.

The presentation of the results of the open public consultation should mention that they are not statistically representative. The report should better explain why it considers that the replies provide a reliable basis to substantiate the assessment.

#### (2) Baseline

The baseline should analyse how the situation would have evolved without the Regulation.

It should show to what extent the observed evolution correspond to the estimates foreseen in the 2007 impact assessment accompanying the Regulation. It should also show to what extent the objectives of the Regulation were attained or not.

Information on the 2007 impact assessment was added in section 2.1 of the SWD.

#### (3) Efficiency

The report should quantify costs and benefits as much as possible and identify the unnecessary regulatory burden. This is particularly important given the REFIT dimension.

The report should clearly indicate the efforts made to obtain quantified data. The evaluation should compare figures against other estimates available (from statistics, studies, etc.) to show their robustness.

#### (4) Relevance

The report should discuss in this section how the lack of effectiveness of mutual recognition (both the principle and the Regulation) has no apparent major negative effects on the goods markets. In particular, the report should assess the relevance of the main measures of the Regulation, given their lack of effectiveness. The report should

This recommendation has been addressed by amending sections 7.1.5 and 7.2.9 of the SWD.

This recommendation has been addressed by amending sections 7.4 and 7.4.1 of the SWD.

better analyse how new developments in e-commerce affect mutual recognition and its application.

#### (5) Conclusions

The evaluation should present clear conclusions and underpin the statements with evidence. It should elaborate on the applicability of the mutual recognition principle, on whether the related Regulation remains relevant and to what extent there is scope to improve its effectiveness. It should also assess the usefulness and functioning of the main elements of the Regulation, for instance of the Product Contact Points or of the mutual recognition clause.

The overall conclusions (e.g. on effectiveness and efficiency) should be consistent with the findings of previous sections. The report should present the limitations of the available evidence more transparently.

The report should draw lessons from the suboptimal functioning of the monitoring and reporting framework. It should further explain how the DG would collect more reliable data for monitoring purposes.

The conclusions have been amended accordingly; see more specifically sections 7.14, 7.1.5, 7.2.9 and 8 of the SWD. The collection of data for improving monitoring has been addressed in section 5 of the SWD.

## ANNEX 2: STAKEHOLDER'S CONSULTATION

### 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 of free movement, despite a lack of compliance with the 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 to be taken 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**<sup>169</sup> were asked to provide their feedback during their latest 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 a correct application of the mutual recognition principle. The Commission presented also a 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

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<sup>169</sup> 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 specific topic, on a case by case basis.

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 also supported 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 be tasked with proving 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 that 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 a proper justification in supporting the administrative decisions to be notified. Using an IT tool for 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 to potentially breaching EU law. The fast track appeal procedure would be very quick (no longer than 3 months), and free of charge for businesses, as 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 the Member States' opinions 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 be 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 of 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 relating 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 of this conference 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 innovations.

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<sup>170</sup> 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 derive 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 are fully aware of the mutual recognition principle. More than half of the businesses responding tried to use mutual recognition to enter 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 to enter 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.

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<sup>170</sup> 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.

With regards to 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.

With regards to 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<sup>171</sup> on average at 23 000 Euro per product and per market. High costs are also related to delays in entering a market, estimated<sup>172</sup> 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 adapting the products. On average, the latest are estimated<sup>173</sup> 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<sup>174</sup> 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 perception of responding businesses is 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.

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171 26% of respondents indicated an estimate of the costs incurred, the other choose not to reply or indicated that such estimation is impossible

172 20% of respondents indicated an estimate of the costs incurred, the other choose not to reply or indicated that such estimation is impossible

173 13% of respondents indicated an estimate of the costs incurred, the other choose not to reply or indicated that such estimation is impossible

174 11% of respondents indicated an estimate of the costs incurred, the other choose not to reply or indicated that such estimation is impossible

## 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 relate to the lack of knowledge about 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 with regards to the Commission's priorities as regards 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 of mutual recognition.

### *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 respondents.

As to what would be the most appropriate alternative to mutual recognition, the majority of respondents agree that harmonisation is the most appropriate tool to use when mutual recognition does not 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<sup>175</sup>, 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

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175 <http://ec.europa.eu/DocsRoom/documents/13381>

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 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 to be 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 the stakeholders' point of view about the Policy Options. With respect to 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. The time required to receive a response from the 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 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 to redeem trust and strengthen 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 in 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 for 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**

Mutual recognition is essential to the Single Market for goods. Nevertheless, its use is suboptimal, generating lost business opportunities, less competition and higher prices for consumers. It needs to be further improved to reduce barriers to the free movement of products lawfully marketed in one or several Member States.

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. These findings will underpin the forthcoming Action Plan to raise

awareness on the mutual recognition principle and to create a "mutual recognition culture", and the revision of the Regulation.

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: Awareness raising and training; A clearer mutual recognition clause and Exchange of officials in the area of mutual recognition.

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 all the drivers identified while allowing for more flexibility on the use of the mutual recognition principle. In particular, the following changes would be introduced in the Regulation: Free movement of goods guaranteed by compliance with European standards; Transparency for administrative decisions denying market access and Enlarging the Product Contact Points.

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: Clarifying the scope of mutual recognition; Declaration of compliance; Fast track appeal procedure and Strengthening the Product Contact Points and the cooperation between relevant authorities.

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 on the basis of the mutual recognition principle before actually entering that market.

The soft law option could be combined with any of the other legislative options (options 3, 4 or 5). Options 3, 4 and 5 would be mutually exclusive.

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. Also, the option of proposing further harmonisation measures on specific basic requirements of products has been discarded. Adopting EU harmonisation legislation on specific products or aspects of products which appear particularly problematic, where this is justified, necessary and proportionate is always possible. However, adopting harmonisation measures which would cover certain aspects of all products (such as traceability requirements) 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.

### ANNEX 3: METHODS AND ANALYTICAL TOOLS USED IN PREPARING THE EVALUATION

This section sets out the methodological approach that has been applied to the evaluation objectives and the corresponding task requirements.

The methodology has combined desk research, focusing on existing textual and statistical sources, with a survey and qualitative interviews. This mix has allowed the team to triangulate the results of the different analytical steps. The figure below presents an overview of the work carried out in the project.

#### Overview of work



Source: DTI, Technopolis, EY and VVA Consulting

#### 1. LITERATURE REVIEW AND ANALYSIS OF PUBLICLY AVAILABLE STATISTICS

The literature review comprised a review of existing business and academic literature on the non-harmonised areas in the EU internal market. Annex A contains a full overview of the assessed literature. In addition, the evaluation team has assessed and analysed publicly available statistics from e.g. Eurostat and the OECD. This review aimed at gaining an initial overview of possible barriers and issues involved in the application of the mutual recognition principle as well as providing a good understanding of the available types of data, which were discussed in further detail during the surveys and qualitative interviews.

##### 1.1 The macro context

The Eurostat database provided data on the macroeconomic context, including:

- increases or decreases in intra-EU trade in terms of sectors and markets;
- unemployment rate;
- inflation;
- EU exports by sector; and
- EU imports by sector.

By using the above-mentioned quantitative context measures as a point of departure, it was investigated if Member States with a high share of cases/issues relating to the application of the mutual recognition principle shared a similar macroeconomic context. Clearly, the crisis



dynamics were unleashed by factors that had nothing to do with mutual recognition (or the application thereof), but the macroeconomic factors will be used to investigate if authorities in countries hit particularly hard by the crisis behave in a different way with regards to the application of the mutual recognition principle for certain product categories. Among the questions posed were, ‘Do some of the Member States that were hit particularly hard by the financial crisis tend to find it harder to apply the principle?’ ‘Do high levels of e.g. unemployment affect the application of the principle among Member States?’ By integrating the quantitative Eurostat indicators into the evaluation, the team seeks to shed light on these kinds of questions.

## **2. EXPLORATORY INTERVIEWS WITH COMMISSION OFFICIALS AND REPRESENTATIVES OF EUROPEAN BUSINESS ASSOCIATIONS**

The evaluation team has conducted ten exploratory interviews with or received written feedback from Commission officials and representatives of European business associations. The aim of these exploratory interviews was to gather information on the application of the mutual recognition principle and cross-European information on the challenges regarding the application of the mutual recognition principle and the areas where the problems are most pronounced. The interviews took place between August 2014 and December 2014.

## **3. SURVEYS TARGETING DIFFERENT STAKEHOLDERS AFFECTED BY THE MUTUAL RECOGNITION PRINCIPLE**

The objective of the questionnaire surveys was to collect quantitative information on the application of the mutual recognition principle in the Member States. 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<sup>176</sup>, a survey of national sector associations, and a product contact point survey. The surveys for the business and sector associations contained almost identical questions. In the subsequent analysis, these are grouped together.

The company survey and the survey of national business organisations and national sector organisations were conducted in English, French, German and Spanish.

### **3.1 National business and sector organisations (umbrella organisations targeting a broad range of sectors)**

This survey aimed to gain a broad picture of the burdens and costs that enterprises may experience and identifying areas where problems may exist. The team contacted one business association per Member State. The business associations have generally not put a high priority on responding to the survey, which is interpreted as a) the associations are not monitoring the subject, or b) that enterprises rarely approach their business associations with these kinds of issues. However, the business associations that have answered the survey and many of those that have participated in an interview have provided us with valuable input and company examples. The same impression applies to the national sector organisations. In addition, Business Europe has approached numerous business associations for their input to the evaluation, and some associations may have felt that this input was sufficient.

The national sector organisations represent the sectors in which the majority of decisions, requests for information and complaints arise (as indicated in the Terms of Reference). Some

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176 “National business associations” are cross-sector associations, typically functioning as national umbrella organisations for sector-specific associations etc.

of these sectors were covered by the national business organisations. The sector associations that received the survey represented food, construction, fertilisers, automobiles, and electrical products in the Member States. The questionnaire used here closely resembles the one used for the above-mentioned business organisations.

For both national business and sector organisations, only a minority of sectors and Member States are represented in the surveys. All received weekly reminders to participate in the survey and the business associations were also contacted by telephone. The participating organisations are represented by 10 national business associations, five sector associations in the food industry and three sector organisations representing the railway sector (the latter are all at the EU Level).

### **3.2 Companies**

The company survey was requested by the client during the inception phase of the evaluation. Due to budget and time constraints, the outreach of the survey was limited. In order to carry out the company survey with only a limited budget, the national business and sector organisations were asked to disseminate the survey questionnaire to their individual member companies to the extent possible. Thus, it has not been possible to control any bias in the sample with respect to:

- country representation;
- sector representation; and
- company size.

Because business associations sent out the questionnaires, it was not possible for the contractor to follow up with companies to ensure a greater response rate. It should be noted, however, that many business associations have been very cooperative in sending out the survey to their individual members.

As expected, the survey did not result in a representative sample, and all results should be interpreted with this in mind. Nevertheless, the responses do provide some indication of how companies perceive the application of the mutual recognition principle and of the potential costs for companies in Member State that do not comply with the mutual recognition principle.

In total, 447 companies have accessed the online survey. Of these, 199 companies completed the survey, either fully or partially. The majority of participating companies only completed the survey partially.

With respect to geographical coverage, there is significant geographical bias, which was unavoidable due to the constraints described above. Companies from Portugal (36), the UK (22) and Lithuania (21) are significantly overrepresented in the survey, while there were no responses from nine EU Member States or from any of the four EFTA countries (cf. above for details).

Large companies are overrepresented in the survey, while small companies are underrepresented. Large companies only make up around 1% of the EU's company

population.<sup>177</sup>. However, in this survey, 29% of the participating companies were large companies with more than 250 employees, 26% were medium-sized companies with 50 to 250 employees and 27% were small companies with 10 to 49 employees. Micro companies with less than 10 employees accounted for 18%.

### **3.3 National product contact points**

The aim of the survey among product contact points was to help identify issues in the legal framework, to gain an understanding of whether there are some sectors that are particularly ‘problematic’ in the country in question, and areas where further dialogue with other product contact points and the Commission, etc., might be necessary.

The product contact points (or the co-ordinator, where there are several product contact points) are typically located within the ministry responsible for industry/business and the internal market. The product contact points have a coordinating function (at least with respect to notifications) and are thus in the best position to have an overview of the application of the mutual recognition principle in their country. Other Member State authorities responsible for applying the mutual recognition principle in their field have a narrower domain (e.g. sectoral, or regional). This means that none of these authorities will have a good overview of the general (cross-sectoral, national) situation pertaining to the application of the mutual recognition principle in the Member State.

Not all product contact points across Member States participated in the product contact point survey (cf. the footnote to). In general, the team put much effort into ensuring a high level of response from all survey target groups. The team followed up with phone calls to the product contact points and national business associations to gain a higher response rate and set up qualitative interviews. For the vast majority of product contact points, this approach was successful. However, for the business associations, the response rate in the survey remained rather low.

Explanations for the relatively low response may be:

- that business and sector organisations do not monitor mutual recognition closely;
- that companies do not approach the business and sector associations when they experience problems;
- that business associations have already given input to Business Europe;
- that companies are not concerned with the mutual recognition principle; or
- that companies experience problems with the free movement of goods in the internal market, but do not link these problems to the principle of mutual recognition and therefore do not know that their problem falls within this area.

## **4. QUALITATIVE INTERVIEWS**

Following the survey, the evaluation team carried out qualitative interviews with national business associations and product contact points in each Member State. The objective of the qualitative interviews was to shed more light on the implementation of the mutual recognition

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177 E.g. [http://ec.europa.eu/enterprise/policies/sme/facts-figures-analysis/index\\_en.htm](http://ec.europa.eu/enterprise/policies/sme/facts-figures-analysis/index_en.htm)

principle in the Member States, in particular with respect to ‘sensitive’ areas such as notification practices (or lack thereof). The interviews were conducted with the same person who responded to the survey, to the extent possible (in a few cases the interview was referred to a colleague).

The evaluator has been in contact with product contact points in all Member States except Italy. As for the Italian product contact point, the team was informed by the contacts at the Italian Ministry (provided by the Commission) that they do not deal with the mutual recognition topic, and that they were not aware of other authorities in Italy that we could contact.

The evaluator has repeatedly contacted business associations in all Member States and approached them for an interview. Some business associations monitor the application of the mutual recognition principle closely, and they have provided us with valuable insights into the problems and the benefits of the mutual recognition principle. Others do not monitor the application of the principle closely and/or have not heard about problems from their members, but agreed to an interview. The last (small) group of business associations did not monitor the application of the mutual recognition principle, had not heard about problems in the field from their members, and consequently did not feel that they were in a position to contribute. In these cases, we have attempted to contact sector associations that may provide insight into the field, but in some cases, it was not possible to identify a sector association either that could provide information, as the mutual recognition principle was not monitored.

The companies have been asked to put a figure on the cost of the incorrect application of the mutual recognition principle for their company. Very few companies have been able to do so. The main reason seems to be that companies adapt their products to the requirements from the Member State in question and test their products/withdraw from the particular market/do not enter the market. They do not spend time on calculating what the costs of the situation might be. Similarly, none of the business associations that we have interviewed have these cost figures, either because they have not asked the companies specifically about this, or because the companies cannot put a figure on it.

## ANNEX 4: OVERVIEW OF THE ASSESSED LITERATURE AND CASE LAW

### 1. LITERATURE

- BIS publication (2011): The economic consequences for the UK and the EU of completing the Single Market
- BIS publication (2013) : Optimal Integration in the Single market: A Synoptic Review
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- Commission report COM(2001)736 of 7 December 2001, “Economic Reform : Report on the functioning of Community product and capital markets”
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- Council resolution of 28 October 1999 on mutual recognition (2000/C 141/02)
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#### The Mutual Recognition Regulation

- Regulation (EC) No 764/2008 of the European Parliament and of the Council, of 9 July 2008, laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC

#### Communications and other Commission documents

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- European Commission (2010): Guidance Document: The application of Mutual Recognition Regulation to narcotic drugs and psychotropic substances  
  
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- European Commission (2010): Guidance Document: The application of Mutual Recognition Regulation to food supplements  
<http://ec.europa.eu/DocsRoom/documents/13481/attachments/1/translations>
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- European Commission (2010): Guidance Document: The application of Mutual Recognition Regulation to fertilisers and growing media  
<http://ec.europa.eu/DocsRoom/documents/5825/attachments/1/translations>
- European Commission (2010): Guidance Document: The application of Mutual Recognition Regulation to articles of precious metals  
<http://ec.europa.eu/DocsRoom/documents/5806/attachments/1/translations>
- European Commission (2010): Guidance Document: The application of Mutual Recognition Regulation to weapons and firearms  
<http://ec.europa.eu/DocsRoom/documents/5824/attachments/1/translations>

## 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*, ECLI:EU: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 requirements 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**

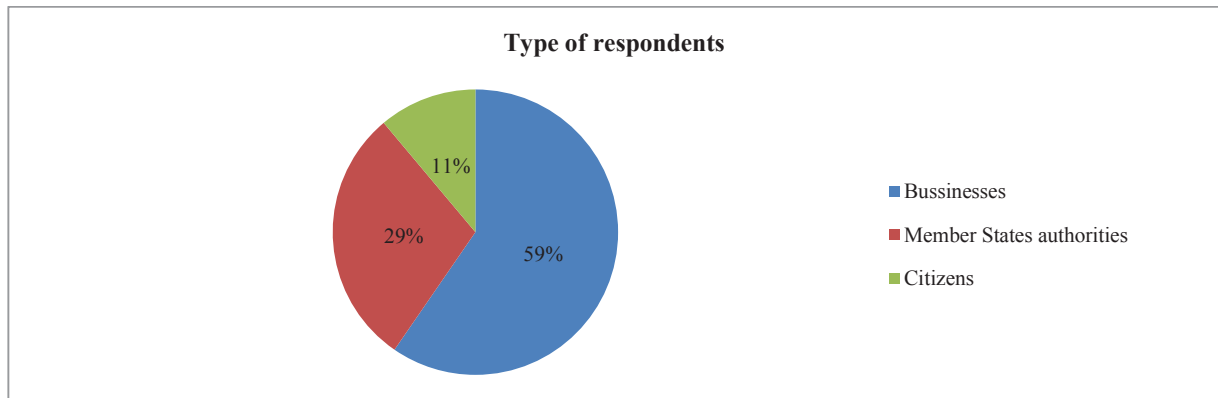
Article 34 TFEU and Article 31(1) and (12) of Directive 2007/46/EC of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive) must be interpreted as not precluding 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 5: RESULTS OF THE PUBLIC CONSULTATION

### 1. TYPE OF RESPONDENTS

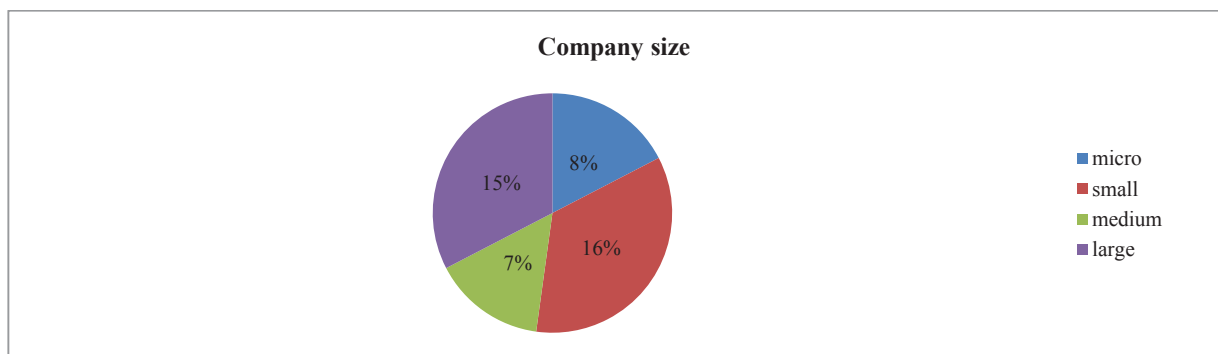
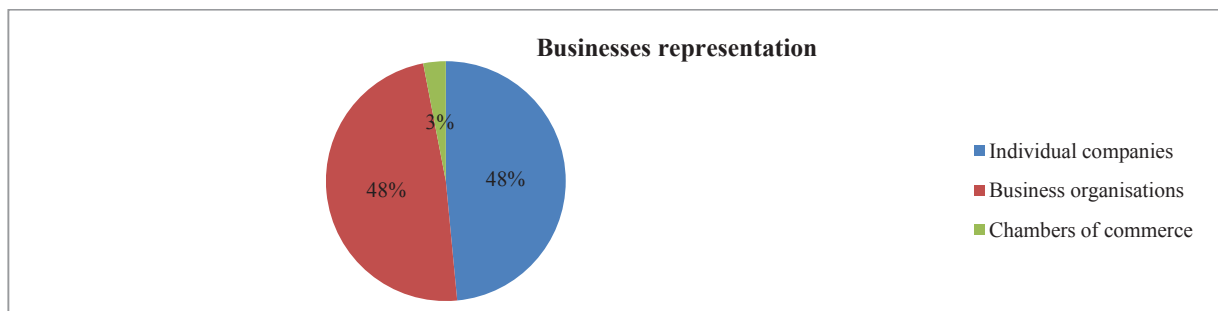
153 replies were received during the public consultation. Businesses were strongly represented (91), followed by Member States authorities (45), and citizens (17). This includes respondents that did not want their replies published: 16 businesses, 9 authorities and one citizen. The remainder of the respondents 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.

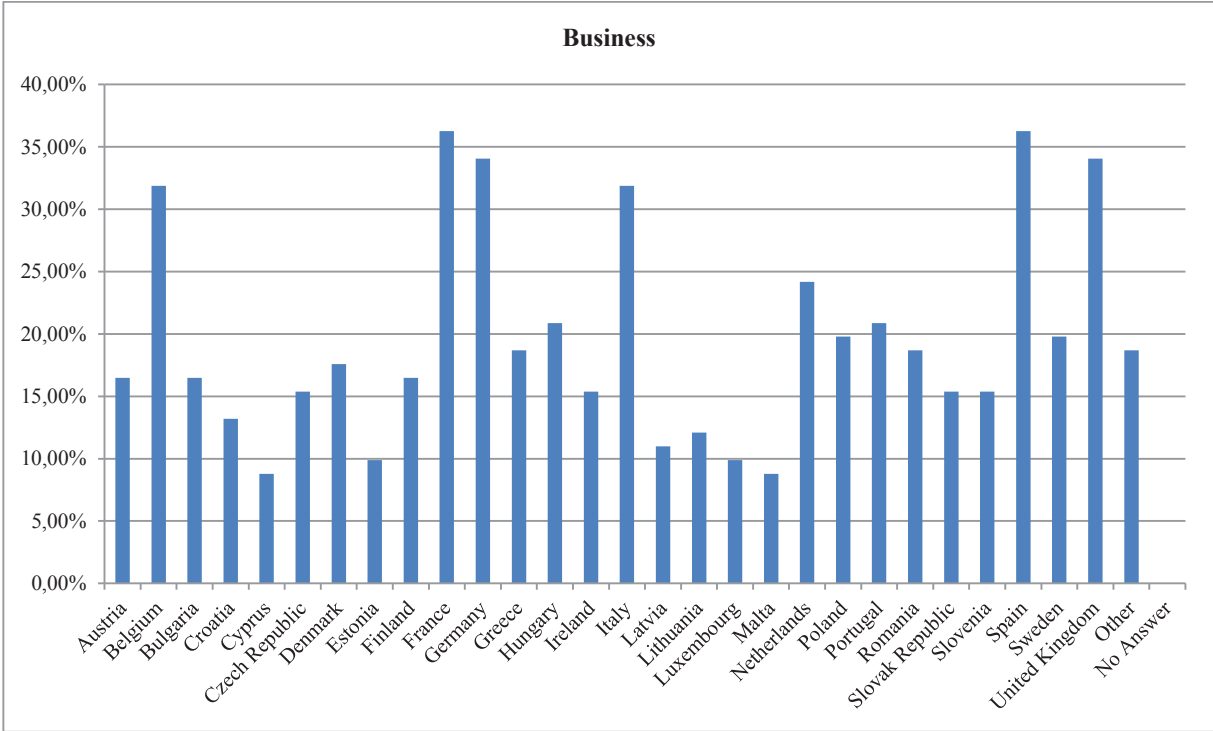
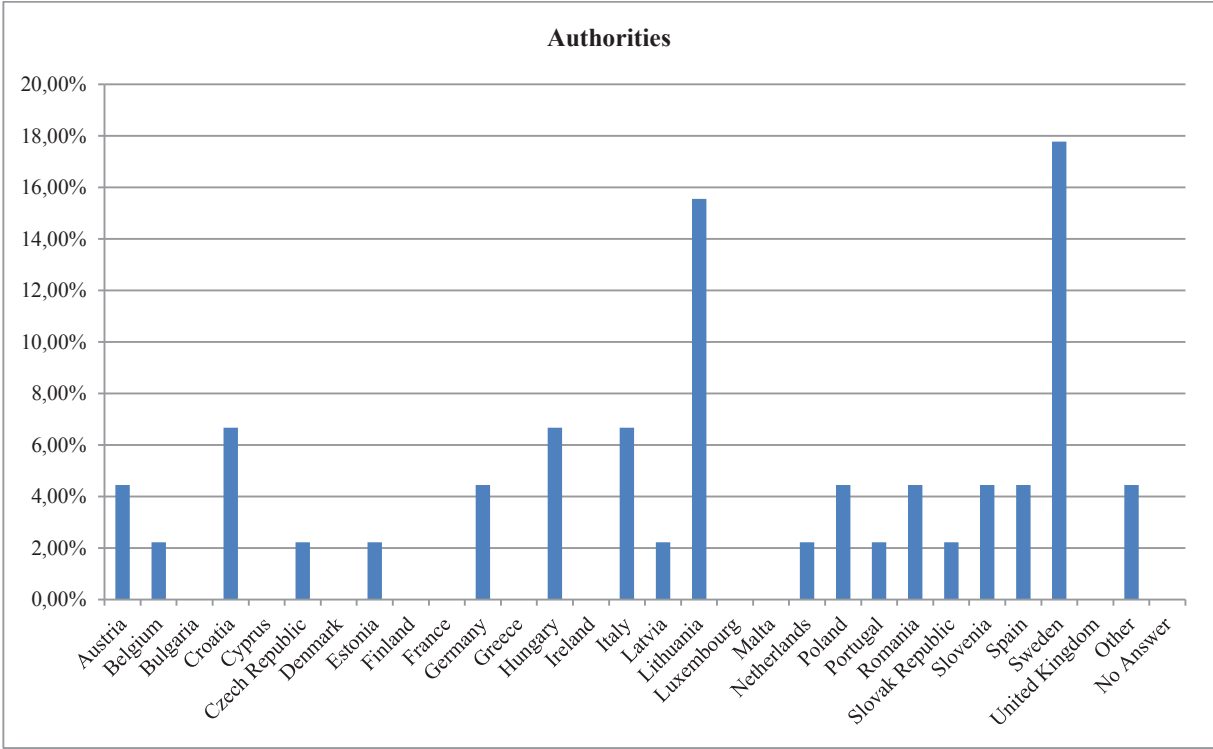
Among the group of citizens there are two consumer organisations.

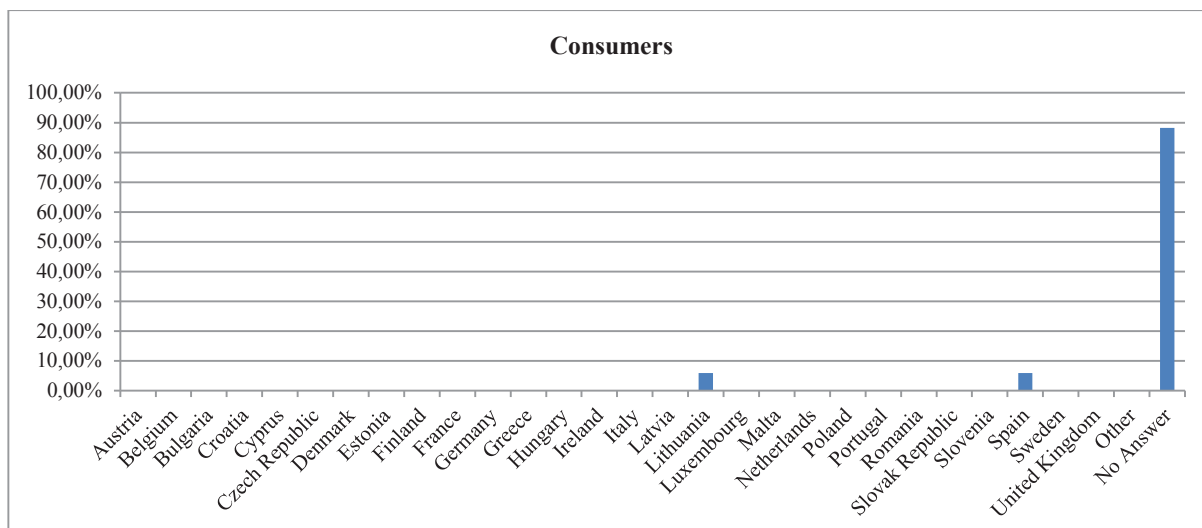
Individual companies (44) and business organisations (44) were equally represented, while only 3 chambers of commerce replied to the consultation. In terms of company size, the responses are roughly balanced between small and large companies.



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.



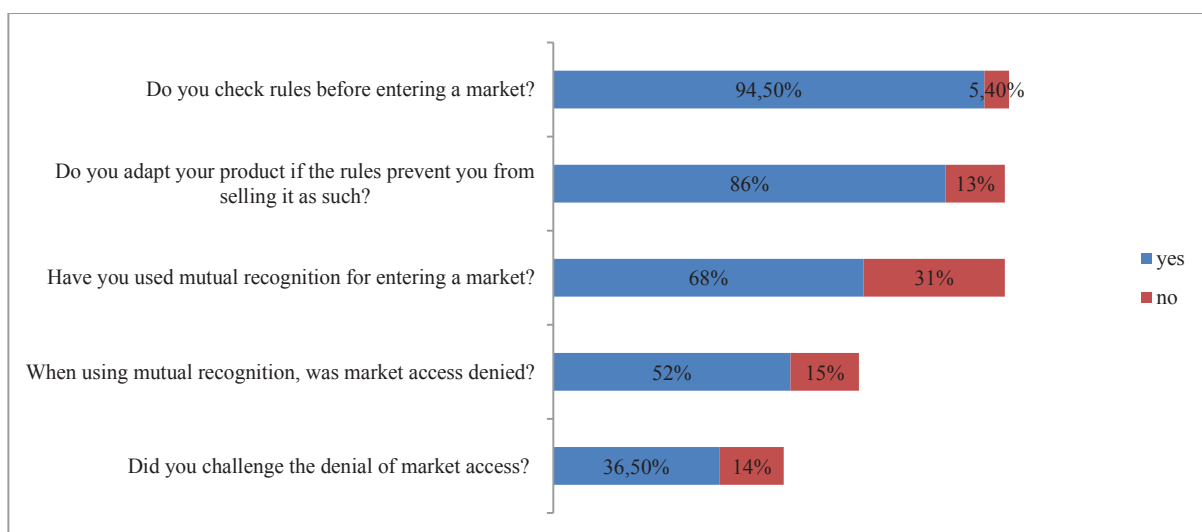


The numbers and percentages used to describe the distribution of the responses to the public consultation derive from the answers provided under the EU-Survey tool. Other submissions of stakeholders to the public consultation, such as position papers and contributions by email, have been taken into account when describing and analysing the views of stakeholders, but without being considered for the statistical representation.

## 2. HOW STAKEHOLDERS SEE MUTUAL RECOGNITION AND ITS POTENTIAL SHORTCOMINGS

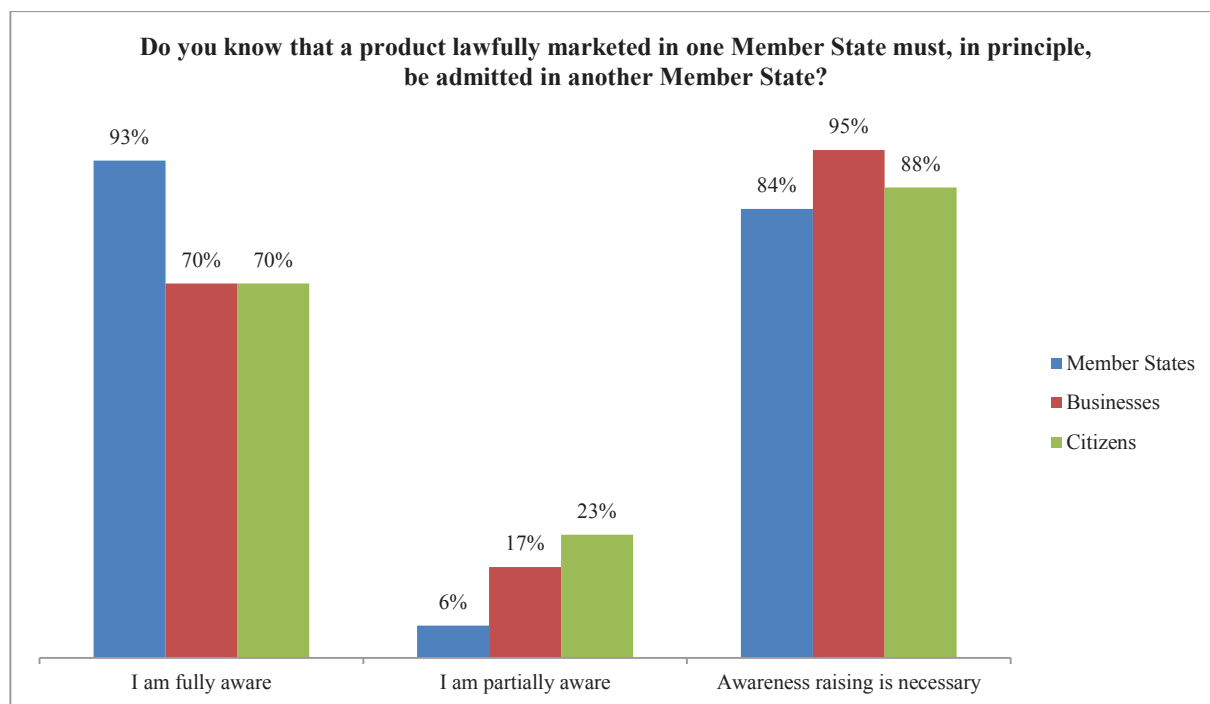
The majority of companies wishing to sell products in another Member State check the applicable rules in that Member State, and, if these rules prevent them from selling the product, most of them adapt it. This happens despite the fact that 70% of them are fully aware of the mutual recognition principle. More than half of the businesses responding tried to use mutual recognition to enter a new market. Among them, half had their market access denied, and only 2% challenged this decision successfully.

35% replied that they don't rely on mutual recognition to enter a new market, mainly because they don't know about it (15%) or because they don't 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% don't.**

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



With regards to 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. By order of importance, obstacles have been ranked as follows:

| Ranking of obstacles by order of importance   |     |
|---|-----|
| Difficult for businesses to challenge a national decision denying market access   | 62% |
| Insufficient communication between national authorities of different Member States  | 46% |
| Lack of awareness about mutual recognition  | 35% |
| Difficult to obtain information about whether mutual recognition applies to a specific product and thus to assess if mutual recognition can be used or not for a specific product | 32% |
| Other   | 29% |
| Slow/inefficient communication between businesses and national authorities  | 27% |
| Difficult to demonstrate to authorities in other Member States that a product is lawfully sold in a Member State  | 26% |
| Insufficient communication between national authorities within the same Member State  | 21% |

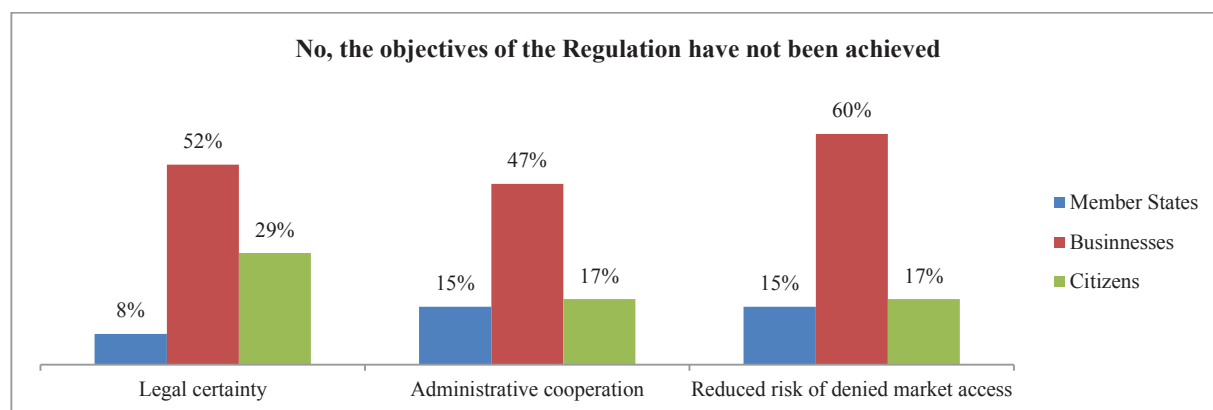
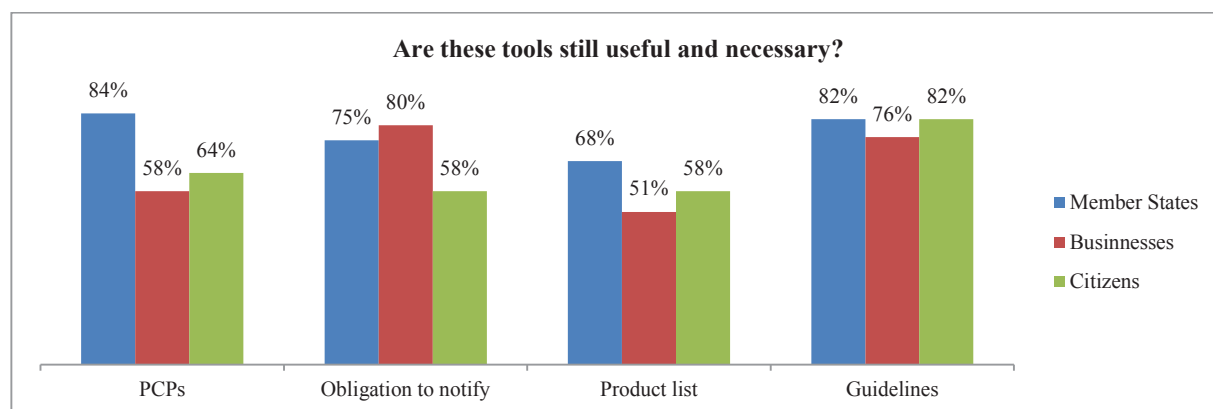
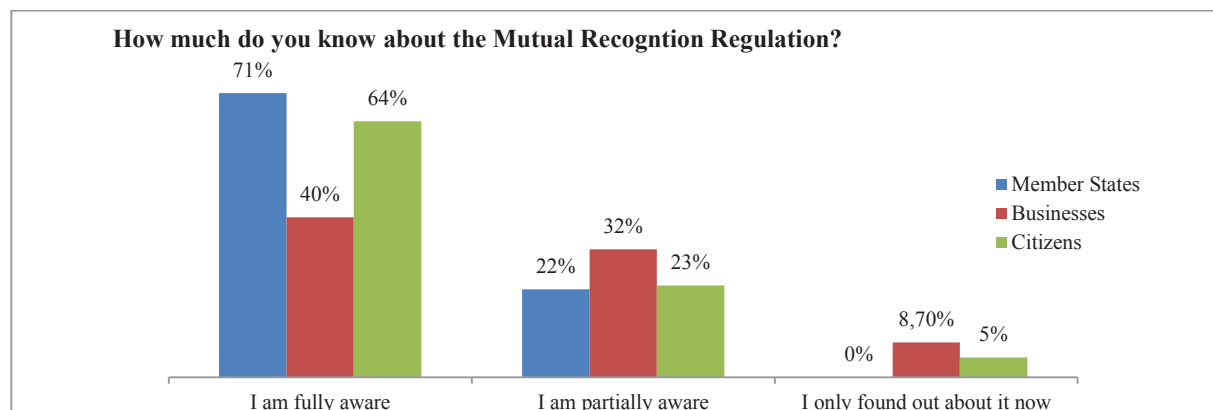


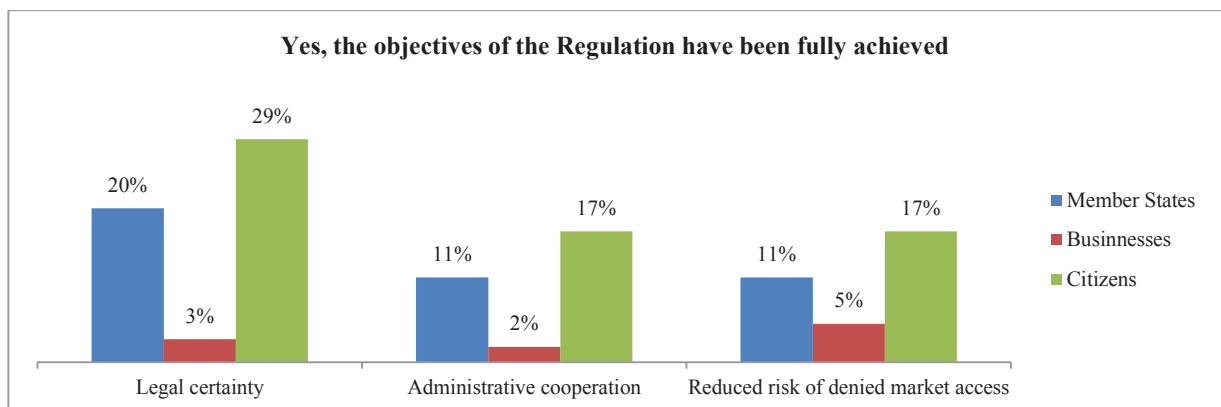
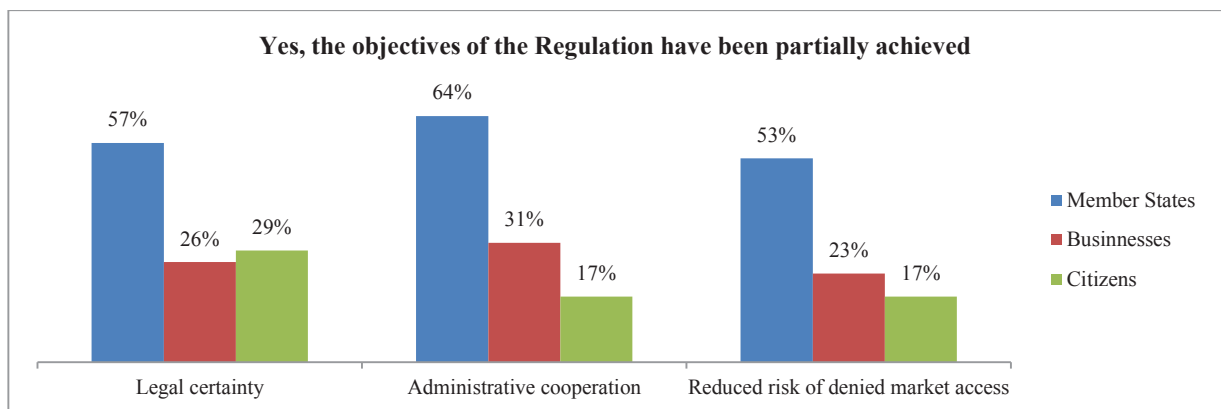
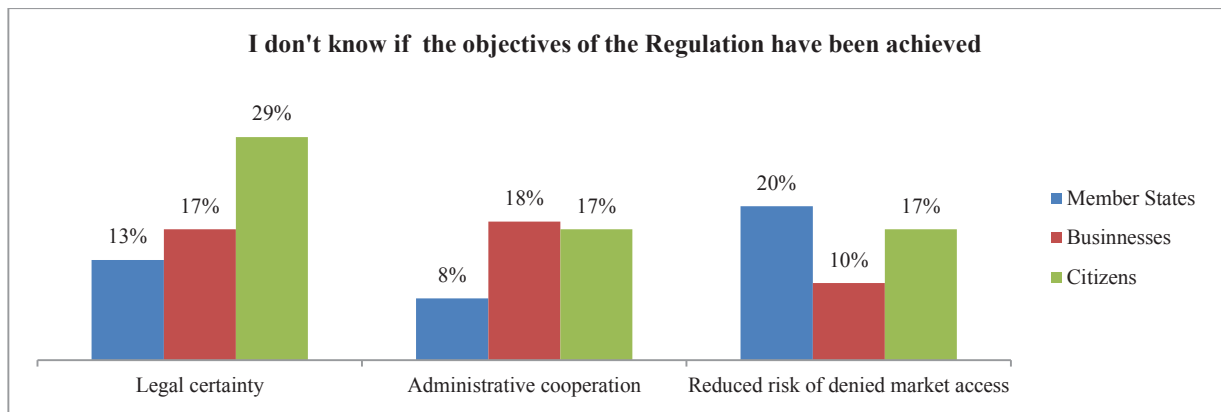
52% of the respondents faced such obstacles themselves. Most of the examples provided relate to national authorities insisting on applying the national rules at the cost of mutual recognition, very often in relation to food legislation or fertilisers.

### 3. FUNCTIONING OF THE MUTUAL RECOGNITION REGULATION

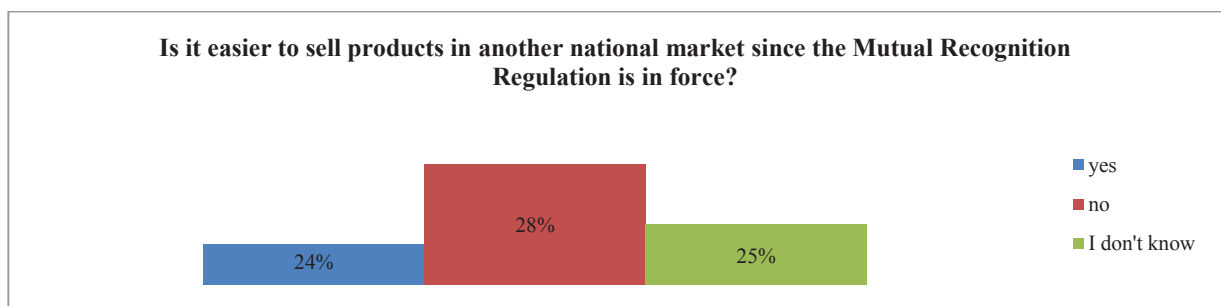
#### Effectiveness: to what extent has the Regulation achieved its objectives?

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.



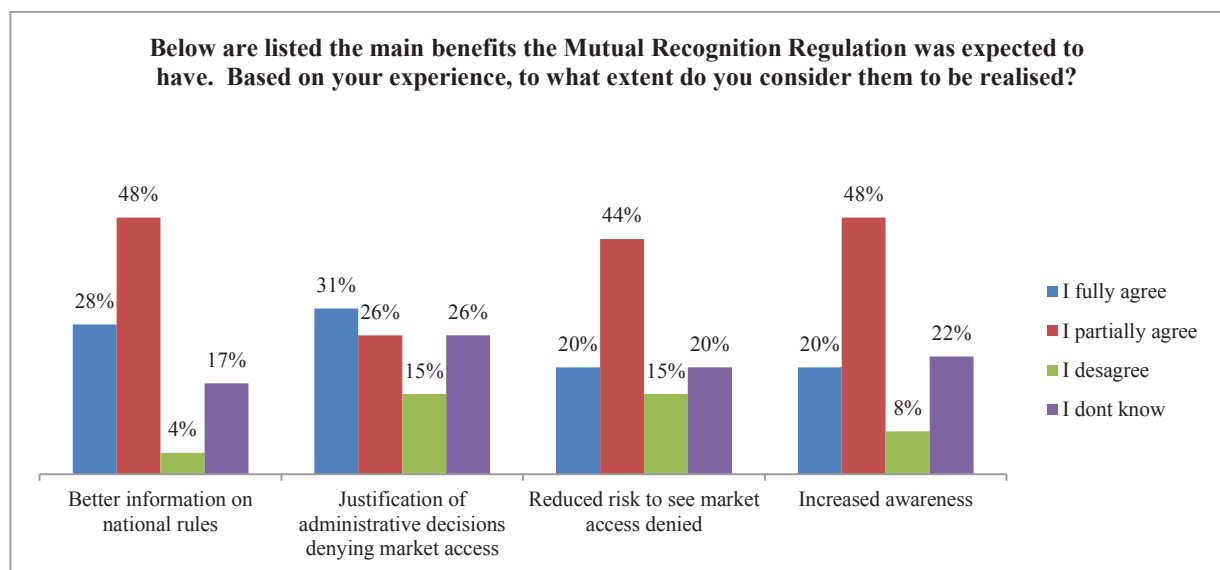
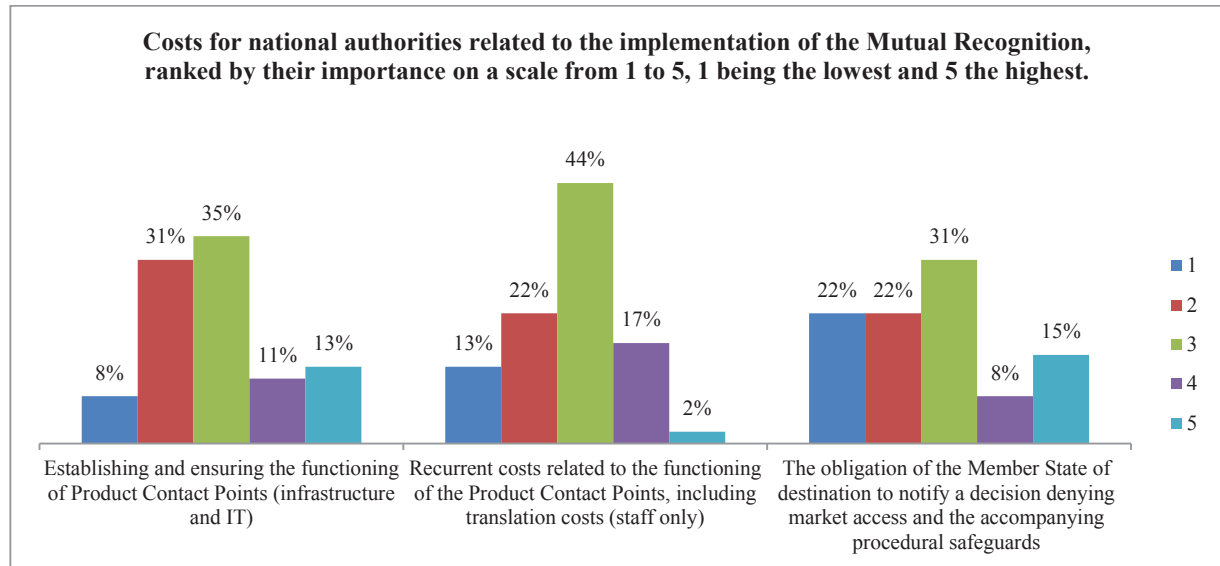


Generally, very few economic operators consider that it is easier to sell products in other Member States since the Regulation entered into force. The majority consider that the Regulation has not improved the situation, or don't know, either because they don't use mutual recognition or they don't sell 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.

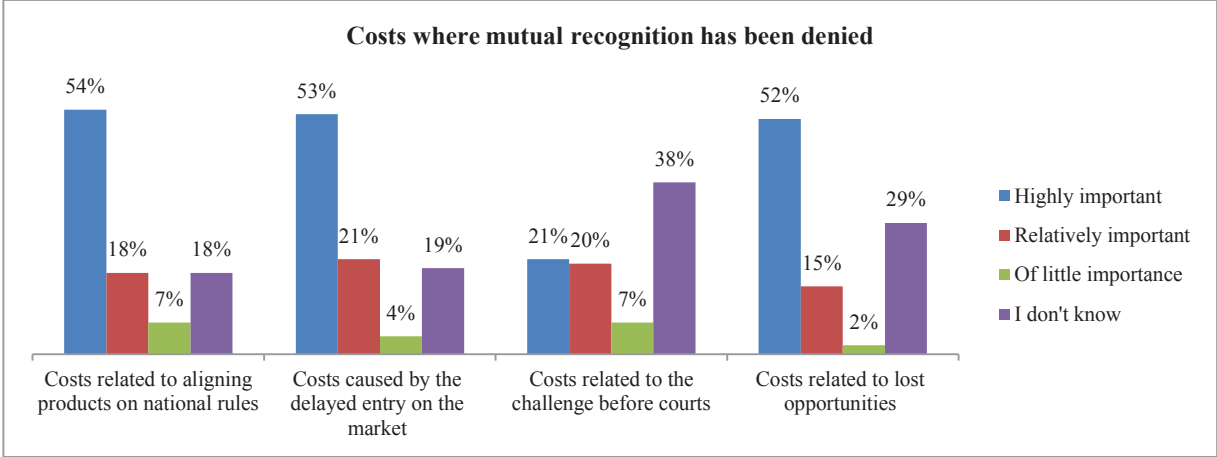


With regards to businesses, the main costs incurred are triggered by the need to adapt the products to the applicable national rules, when mutual recognition is either denied or not used for penetrating the market. These costs are estimated<sup>178</sup> on average to be 23 000 Euro per product and per market. High costs are also related to delays in entering a market, estimated<sup>179</sup> at 115 000 Euro per product and per market, and to lost opportunities, when

178 26% of respondents indicated an estimate of the costs incurred, the other choose not to reply or indicated that such estimation is impossible

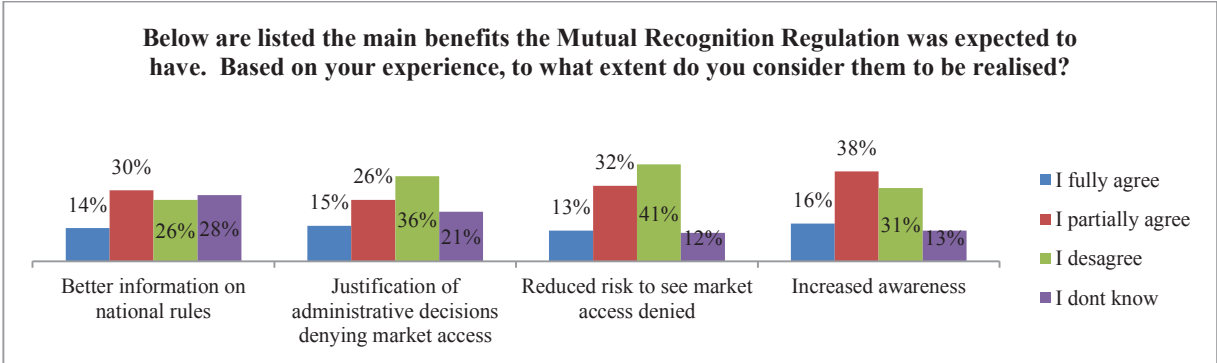
179 20% of respondents indicated an estimate of the costs incurred, the other choose not to reply or indicated that such estimation is impossible

businesses relinquish entering a market because of different national rules that require the products to be adapted. On average, the latest costs are estimated<sup>180</sup> at 136 000 Euro per product and per market. The costs related to challenging administrative decisions denying market access are considered to be less important, mainly because few economic operators choose to do so. The estimates<sup>181</sup> 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. The lack of additional information does not allow an estimate of the actual costs incurred when the assessment of whether or not mutual recognition can be used is outsourced to be made. When done internally, economic operators spend on average 54 hours 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 amount of hours spent is 16, and the average cost per hour is 76 Euro.

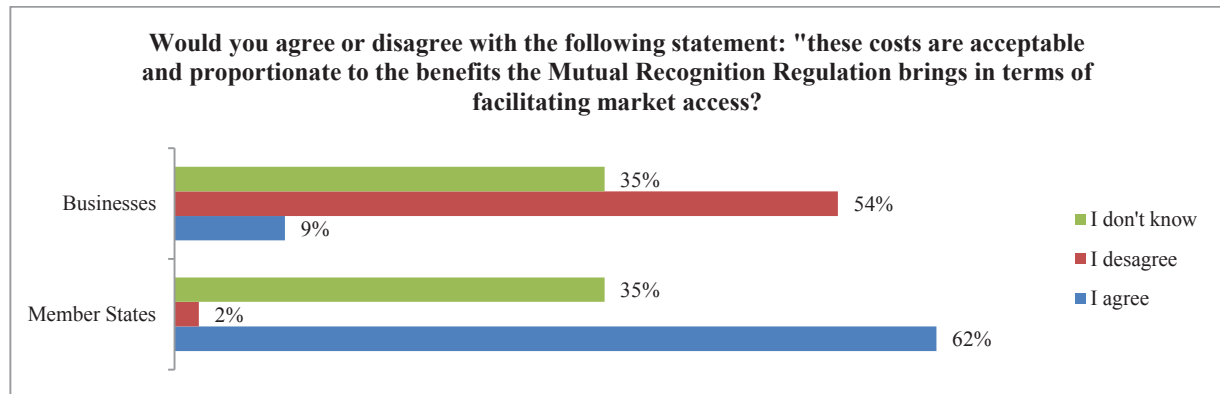
In terms of benefits that the regulation brings, the perception of businesses is quite mixed:



180 13% of respondents indicated an estimate of the costs incurred, the other choose not to reply or indicated that such estimation is impossible

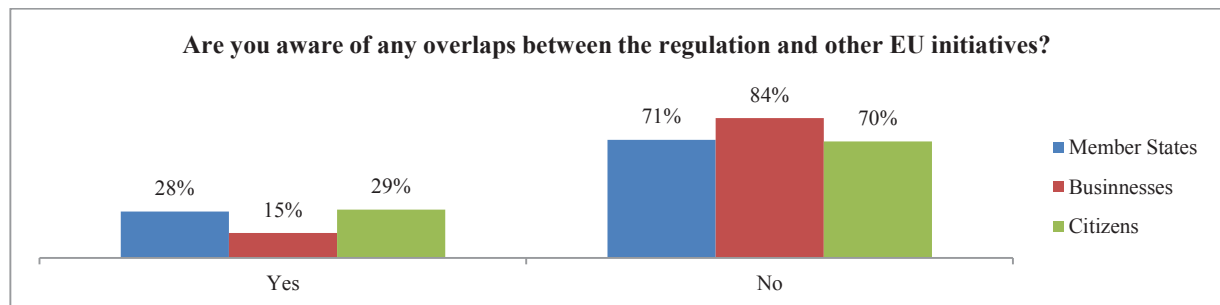
181 11% of respondents indicated an estimate of the costs incurred, the other choose not to reply or indicated that such estimation is impossible

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.



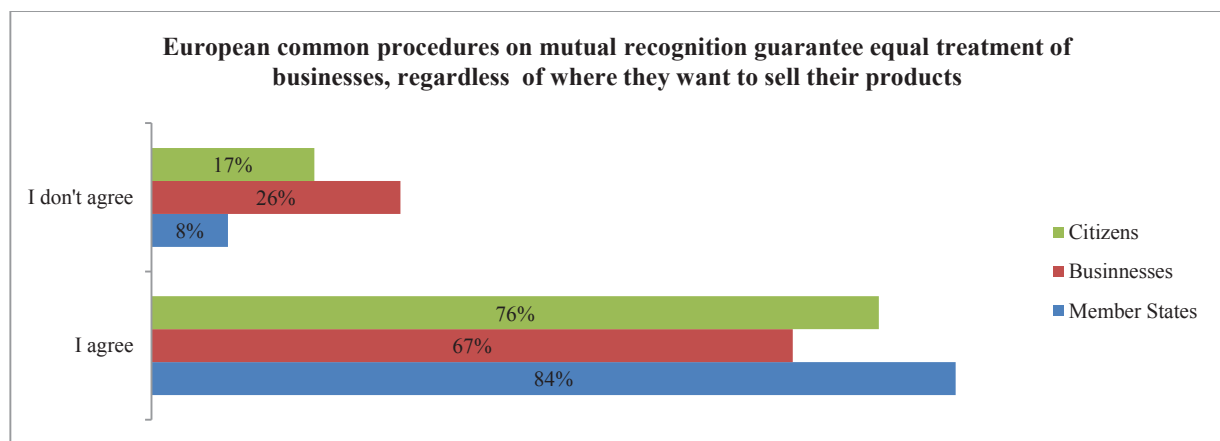
### Coherence

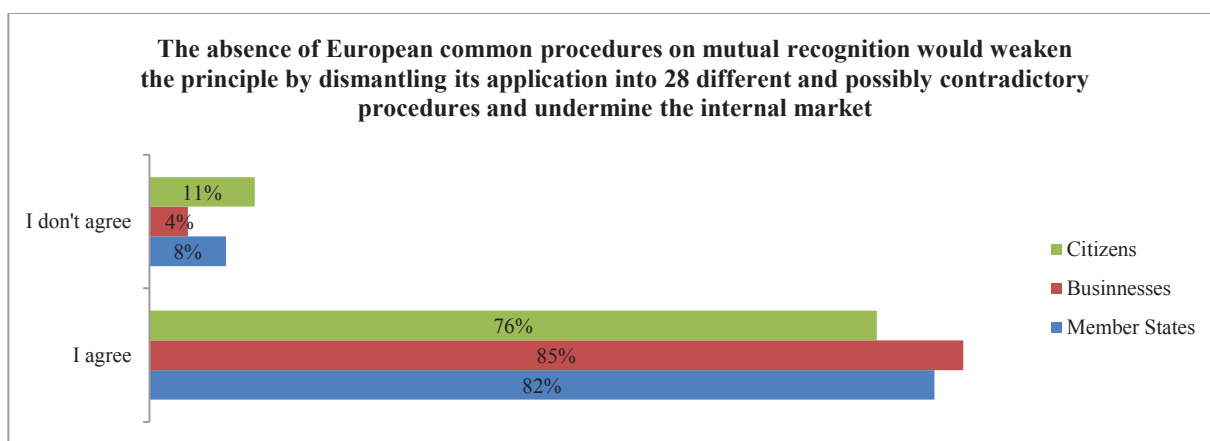
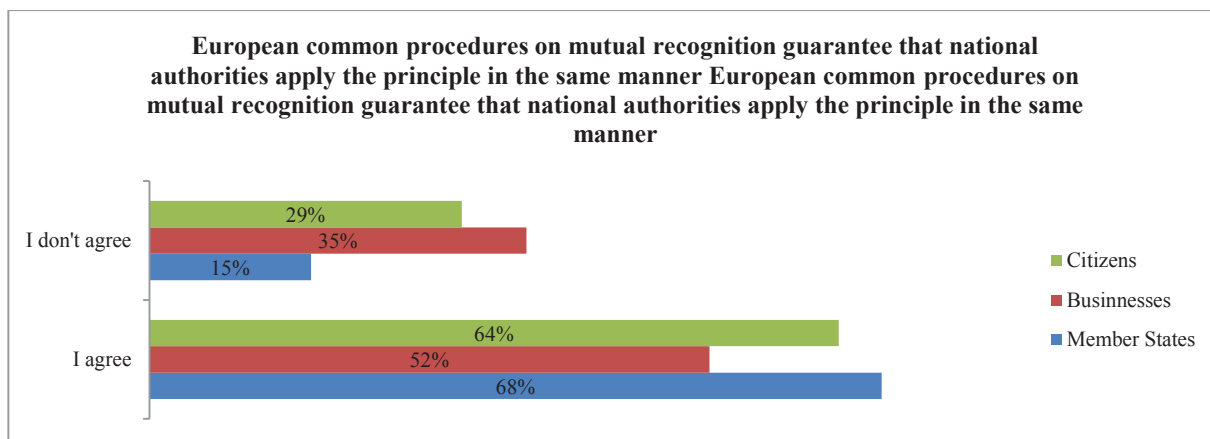
There is a consensus among stakeholders as regards the coherence of the Regulation. Most of the respondents are not aware of any overlaps between the Regulation and other initiatives/legislation/policies. The overlaps indicated by those replying yes are linked to Solvit, RAPEX, ICSMS and Regulation 765/2008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



### EU added value

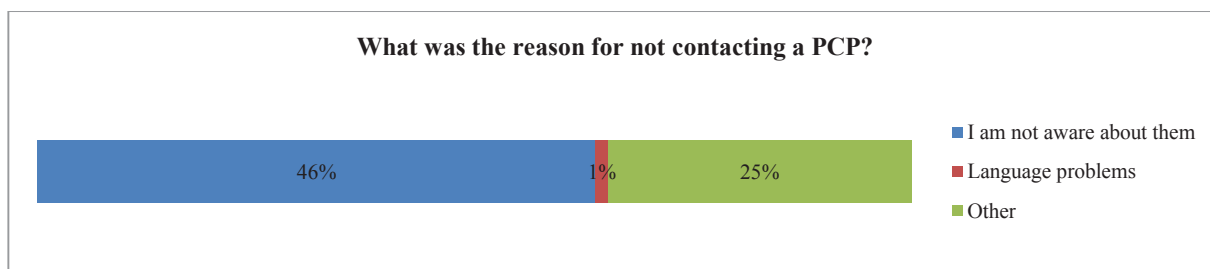
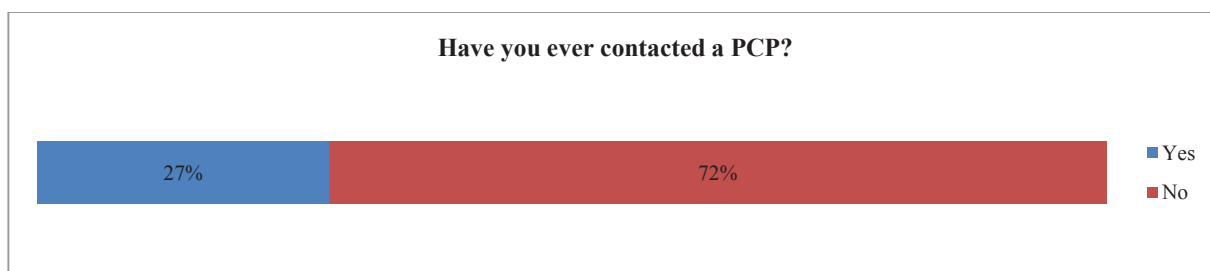
The European added value of the mutual recognition rules is also strongly underlined by the respondents. Most of them agree that having a common set of rules guarantees equal treatment, and that relying on national rules only would undermine the internal market.



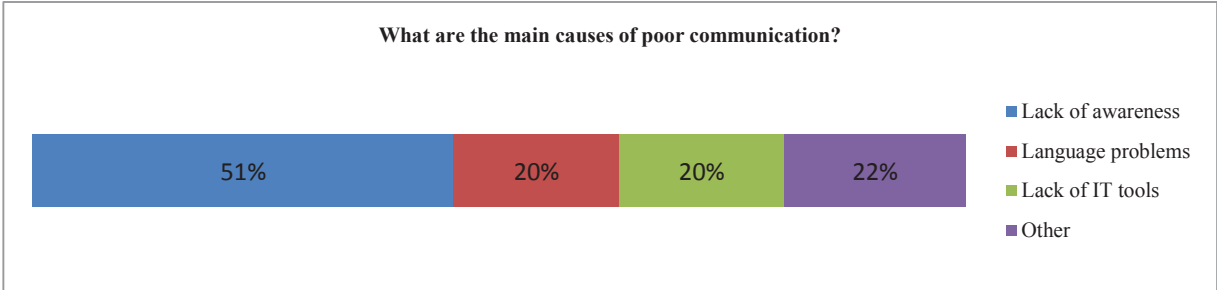
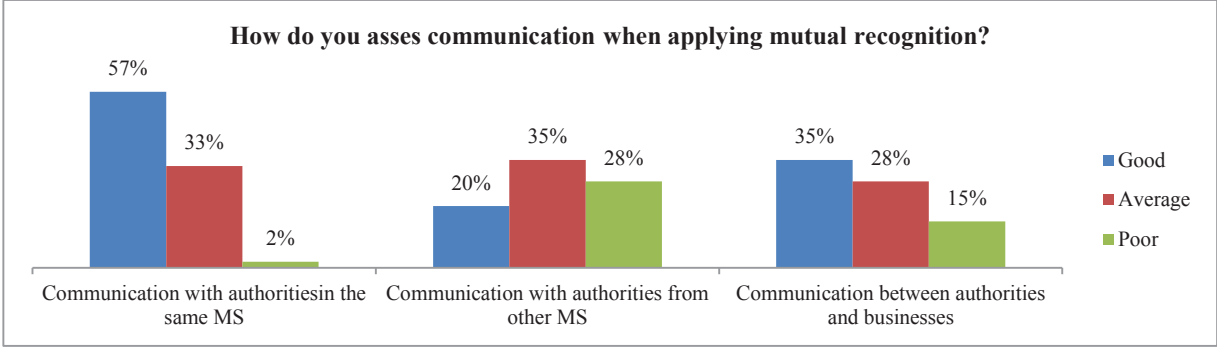


#### 4. ASSESSMENT OF COMMUNICATION WHEN USING MUTUAL RECOGNITION

Most of the businesses have never contacted a Product Contact Point (PCP) 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.



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



**5. PRIORITIES TO IMPROVE MUTUAL RECOGNITION**

Stakeholders have different views with regards to 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 of 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% |

| <b>Ranking of priorities by Member States</b>  |     |
|--|-----|
| 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% |

| <b>Ranking of priorities by citizens</b>   |     |
|--|-----|
| 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% |



## ANNEX 6: CASE STUDIES 2016

The case studies below were carried out in the framework of the Study on the costs and benefits of the revision of the Mutual Recognition Regulation (September 2016-February 2017).

### 1. MANUFACTURE OF OTHER FOOD PRODUCTS: FOOD SUPPLEMENTS

#### 1.1 Introduction

Food supplements 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;<sup>182</sup>

Other substances (e.g. amino acids).

The main rules for the marketing of these products by manufacturers are laid down in Directive 2002/46/EC, in which implementation and monitoring is entrusted to the individual Member States.

The Directive includes a list of substances that may be used for the production of food supplements, and was amended several times over recent years.<sup>183</sup>

During the first round of interviews, stakeholders – both from business associations and national authorities – highlighted how this sector still constitutes one of the main “grey areas”, where EU and national rules collide and combine, and where national authorities have the largest autonomy and room for manoeuvre in decision making and acceptance/denial on market entry.

Stakeholders underlined how this type of product suffers from a poor implementation of the principle of Mutual Recognition across the EU. Different MS authorities provide diverse and heterogeneous procedures and requirements to access the market, which are often difficult for companies to deal with.

#### 1.2 Background

The reference legislation on food supplements is harmonized to a limited extent, and provides a relatively loose regulatory framework based, as mentioned, on **Directive 2002/46/EC**.

The Directive provides a list of vitamins and minerals which may be used in the manufacture of food supplements, but it does not give information on the levels that these substances could have within the products, nor on any mix with botanicals or other substances. This creates a legal vacuum around which the “puzzle” of the food supplements industry rotates.

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182 Plant parts, concentrated sources of plants or their extracts or derivatives with a physiological effect.

183 Commission Regulation (EU) 2015/414, Commission Regulation (EU) No 119/2014, Commission Regulation (EU) No 1161/2011, Commission Regulation (EC) 1170/2009, Commission Directive 2006/37/EC

The coverage of this gap is *de facto* left to the Member States, which identify heterogeneous solutions that lead to various safety standards of products, levels of ingredients as well as their classification.

The three main issues that have to do with the mutual recognition<sup>184</sup> are:

**Maximum levels of vitamins and minerals.** 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;

**Substances other than Vitamins and Minerals.** Some Member States apply positive lists<sup>185</sup> with specific conditions to their use. In addition, some Member States may consider certain ingredients for medicinal use only;

**Botanicals and botanical preparation.** 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.

Stakeholders involved (i.e. businesses and consumers) call for greater transparency of the rules.<sup>186</sup> consumers push on the rise of the levels of consumer protection in Europe while companies are more interested in an increased harmonization of the rules, dictated especially by the costs to obtain certifications to export to other European countries.

Businesses, in order to facilitate their export, also try to create selling strategies of the products that, by modifying the labelling of these from "food supplement" to "medical device", may guarantee them an easier, faster and less expensive access to the market. This could be possible because, in the current legal environment, the same product can be – for example – considered to be a botanical food supplement in one EU country and as an herbal medicine in another one.<sup>187</sup> This option, however, can entail some other costs for companies when labelling a product as “medicine”.

Considering the **market**, it is estimated that approximately **20% of consumers** in several European countries use at least one type of food supplement, with big variations between North and South, (northern populations making more extensive usage).<sup>188</sup>

It is difficult, however, to have a clear picture of the market size. The entire **market** in recent years has been estimated to be worth **EUR 11 billion** in Europe,<sup>189</sup> and apparently has a growing trend, with a good share (around 20%) represented by botanicals.

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184 Food Supplement Europe (2016), *Input into the REFIT of the Mutual Recognition Regulation 764/2008*.

185 A “positive list” is an official register where all elements (or substances or products) allowed in the county are listed. It is opposite to a “negative list”, which contains all elements (or substances or products) not allowed in the country.

186 Food Supplements Europe, (2016) *Input into the REFIT of the Mutual Recognition Regulation 764/2008*; BEUC (2016), *Food Supplements*.

187 BEUC (2016), *Food Supplements – Challenges & risks for consumers*.

188 Ibidem.

189 Euromonitor data 2014.

With respect to the individual Member States, the biggest market is **Italy**, with a turnover of **EUR 3bn**, with around **25%** – EUR 300/400 million – coming from products that use **botanicals**.<sup>190</sup>

### 1.3 Stakeholders involved

| Stakeholder category | Organisation <sup>191</sup>                 | Description   |
|----------------------|---|---|
| Business Association | FoodSupplementsEurope                       | International association working to promote issues related to the industry of the food supplement in Europe. Members include other associations active at national level |
| Business             | French SME                                  | SME founded in 2003 with over 130 employees – all based in France – and turnover of over EUR 30 m in 2016   |
| Business             | Italian SME                                 | SME founded in the 1980s to produce and commercialise food supplements. Around 30 employees and turnover of more than EUR 15 m in 2016                                    |
| Business             | Dutch subsidiary of a multinational company | Holland-based subsidiary of a multinational company founded in 1947. Established over 25 years ago and with annual turnover of around EUR 15 m in the BeNeLux area        |

### 1.4 Practices and trends identified and main issues related to the application of Mutual Recognition<sup>192</sup>

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.

On the former, as already mentioned, different Member States follow different procedures and rules, in addition to a very dissimilar recognition and application of the principle, creating issues and obstacles companies may have to deal with when trying to enter a new market and often culminating in having different products for different countries.

On 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.<sup>193</sup>

#### Different countries, different rules

190 Stakeholders input.

191 In some cases, stakeholders have asked for not disclosing their contact details.

192 Please consider that the following sections are based on inputs collected from businesses and business associations.

193 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.

Since the sector is not fully harmonised and regulated to a limited extent at EU level,<sup>194</sup> companies and their products are subject to and need to comply with extensive national legislation. In this regard, three main areas have been highlighted by stakeholders, where main issues for companies arise:

**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 its' very neighbour – can consider them 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 product at national level. Member States tend to have 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:** It may happen 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 there is not complete uniformity in the national systems in place, with few Member States<sup>195</sup> 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 notify national authorities of 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 make companies investing time and resources to learn and handle them, especially in those countries with high level of restrictions.<sup>196</sup> 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.

Stakeholders underline how national authorities tend to focus on national legislation when deciding, without taking into account other EU MS-certifications or proof of the fact that the product is already lawfully marketed in another MS.

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 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 another Member State concerns the existence of

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194 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.

195 AT, NL, SE, SI and UK.

196 Such as AT, DE, FI, HR, SE.

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 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 so high to discourage it from pursuing such way. For instance, an Italian SME active in the area of food supplement suggested how, on average, costs for lawyers and appealing procedures can amount to around EUR 20,000 per product, but other stakeholders provided more extreme examples (see Box below);

**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, according to stakeholders, other possible options include:

**Adapting 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 repay 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 MS which can have similar rules and requirements and therefore targeting them with a single product that would easily comply with all different national regulations.

The box below presents more in details some of the experiences highlighted by stakeholders in different EU Member States.

### **Box 6-1: Examples of positive and negative experiences with mutual recognition in EU MS**

#### **Belgium**

Stakeholders underline how the Belgian case is one of the hardest for them to deal with, with so many difficulties in entering this market that – sometimes – leave them to no choice other than not marketing the product.

A French SME finds that in recent years the marketing of products have become increasingly difficult. While for some basic products (e.g. ginseng) there is no specific interpretation needed by Belgian authorities and the scrutiny can be quite fast and straightforward, for other, more complex products, after dealing with many questions and requests for clarification, the company saw its requests for notification and marketing to be refused by the Belgian authorities. Authorities did not accept the brand under which the product was marketed, which was, however, already lawfully marketed in at least another MS. Without any specific explanation given about the interpretation that led to this decision, the company is still expecting a definitive response after more than 2 years. Over EUR 10,000 and months have been spent by the company, waiting to be in front of a court to challenge the decision. Considering the turnover for the same product in similar markets, the company can assume to have a potential loss of turnover between EUR 200,000 and 500,000 for not entering the Belgian market.

A Holland-based subsidiary of an international company decided not to further pursue the entrance on the Belgian market with a product already lawfully marketed in another MS. The issue related to a product which, despite being accepted in other MS and proved not dangerous, had higher levels of ingredients than those allowed by the Belgian law. The decision not to enter the market was taken after that for months the company tried to get access to the market also through the support of SOLVIT and product contact points, without any success. The company estimates around EUR 100,000 spent in law suits.

#### **Netherlands**

The same Holland-based company faced a similar case in Netherlands, when trying to introduce a product onto the market through mutual recognition.

While no issues were apparently faced in the first few years, in 2013, after a change in the Dutch law, the company started seeing its requests delayed and eventually denied, under the motivation that the products was considered unsafe for local consumers, since the level of some ingredients was higher than the maximum level allowed in the country. Despite proving that the product was already lawfully marketed in another MS and that was not to be considered unsafe,<sup>197</sup> the company decided to challenge the decision in front of a Dutch court

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<sup>197</sup> The company specified how they submitted a proof of safety (considering the lists of products by EFSA, indicating that they could not find any suggestion that the product was unsafe in its components up to the level that was present in the product), evidence that

since no further explanation was given by national authorities. After two years, with no final decision, the company decided to market the product anyway, on the basis of the evidence they already provided. A late reaction of the national authorities, which seized the products, brought the company back to a national court, which decided that the fault was to be ascribed to national authorities, for not reacting sooner in stopping a product, and providing a motivation. However, such decisions was not decisive for the company, since it put the company in the position of starting the whole process to put the product into the market once again.

The company reported legal expenditures for around EUR 90,000, plus the time and effort needed to reach a final verdict. In addition, around EUR 500,000 of potential loss (in consumer price) were considered for 2016 only, due to the impossibility to market the product.

## Spain

While mutual recognition is difficult to implement in many countries, Spain is considered as one of the most positive examples. Companies encounter very few obstacles in entering the market – for both types of products and levels of ingredients, as long as they can prove that the product is already lawfully marketed in another MS. A French SME reported how the process, including a declaration by the Spanish distributor and the presentation of another MS notification of the validity of the product, took around 2-3 months and no more than EUR 1,000 for a single product, quite the opposite of many other Member States.<sup>198</sup>

## Other MS

*Baltic Countries* represent an interesting example of how the same product can be considered very differently across – in this case neighbouring – countries. An Italian SME saw its product being approved and lawfully marketed in Lithuania, while blocked in Estonia, under the motivation that it was considered as a medicine by the local authorities. The same product is still under review in Latvia, with a consultation among authorities whether it should be considered as a food supplement or not.

*Germany* is considered a highly regulated market, with one of the most stringent control and regulation systems. Issues are particularly related to plants and botanical products, which can be often considered medicines, with the need for companies to change the formula or some ingredients of their product. Such changes may cost around EUR 5,000 per product to a SME – and become very expensive if the company has to make changes to several products at once – plus additional time and costs to obtain a new certification, carry out new checks on quality and the need to require a new notification from the MS where the company is based.<sup>199</sup>

Notwithstanding such general difficulties, stakeholders highlighted also as the situation seems to be – slightly and slowly – improving with some positive signals from Member States in terms of application of mutual recognition. Member States appear to start drawing common rules and similar requirements (e.g. FR and IT in the field of botanical products), easing the

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the product was lawfully marketed and largely sold in another EU MS, a formal letter of approval from a scientists – also part of EFSA – and requesting a Dutch Research Institute to draft a report on the possible unsafety of the components, leading to no indications in this sense.

198 Stakeholders specified, nonetheless, how it is likely that time and costs vary heavily for different products.

199 Stakeholders underlined how German authorities may require a new notification for the modified product, to be produced by the original Member State, even if the product is not going to be marketed in such country.

work of companies, while other countries, originally very difficult to enter (e.g. SI), start accepting mutual recognition, even if at a very slow pace.

## **1.5 Conclusions**

Despite the heterogeneity of cases and requirements across the EU that could create some very different situations for companies, stakeholders seem to generally agree on the fact the mutual recognition is not working properly in the sector.

Complexity of products, intricacy and differences in national requirements, scarce knowledge or disposition of national authorities in considering mutual recognition do not facilitate the situation of companies, which, as a paradox, may find easier to export food supplements outside the EU than across our internal borders, often spending more resources in fighting decisions from authorities than their actual competitors.

And while a full harmonisation of the sector would probably solve many issues but it would probably be the hardest path to follow, changes seem to be definitely needed to improve the actual situation.

The main issue that companies highlight is an unbalanced situation between them – which have the burden of proof– and national authorities, which can too easily delay or deny market access without a full and clear explanation and little burden afterwards. In addition, open-ended procedures gives no real room for manoeuvre to companies when a decision is taken by national authorities, together with a general scarce attitude of national authorities in considering the principle.

The complexity of the sector, however, may require specific attention to measures and options to be implemented.

These are all elements that need to be addressed in order to improve the situation and facilitate a better application of mutual recognition.

## **2. PRODUCTS IN CONTACTS WITH DRINKING WATER**

### **2.1 Introduction**

The legislation of the European Union (EU) provides to Member States (MS) a set of rules concerning the production and commercialization of products which are in contact with drinking water.<sup>200</sup>

Such measures are due to be transposed by each MS: Directive 98/83/EC (Drinking Water Directive) established that it is up to individual MS to take all the necessary measures to ensure that materials and products in contact with drinking water do not generate any negative effect on human health.

However, the transposition and implementation of this provision by national legislators resulted in the emergence of a multitude of country-specific requirements, with MS pursuing the same objective (ensuring an adequate level of safety for consumers) through diverse provisions and test criteria, and different levels of stringency of rules.

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200 Directive 98/83/EC, *Drinking Water Directive*



This multitude of different national requirements creates a particularly challenging environment for manufacturers in the sector, also in the application of mutual recognition.

Companies are subject to a series of time-consuming and complex activities necessary to obtain the certifications, and it conveys an overall increase in costs that inhibits their propensity in trying to have access to new markets.

During the previous phase of the study, all categories of stakeholders highlighted the importance of this sector, and the need for intervention to a generally poor implementation of mutual recognition.

Particular emphasis will be placed on Water Taps, which represent one of the core products in the sector, with several stakeholders involved highlighting that the commercialization of this type of product in Europe remains quite challenging.

## 2.2 Background

The manufacturing sector of products in contact with drinking water spreads in a wide and articulated range.

A list can be summarized into the following categories:<sup>201</sup>

Safety and Protection valves,

Water treatment machineries,

Water Taps,

Pipes and fittings, and

Tanks and pumps

Overall, the market demand for this kind of products can be seen as driven by a multiplicity of factors such as:

The need to replace installed systems at the end of their lifecycle;

Provide for expansions to public networks for new buildings;

The trend towards a sophistication in terms of design (shape and external characteristics) and performances (water efficiency, control of leakage and reduction of costs).

Considering available information, it is possible to estimate the total turnover of the sector between **40 and 43 billion per annum**,<sup>202</sup> while the number of companies operating can be estimated at around **7,000 units**, with a heterogeneous distribution among small medium and large enterprises.<sup>203</sup>

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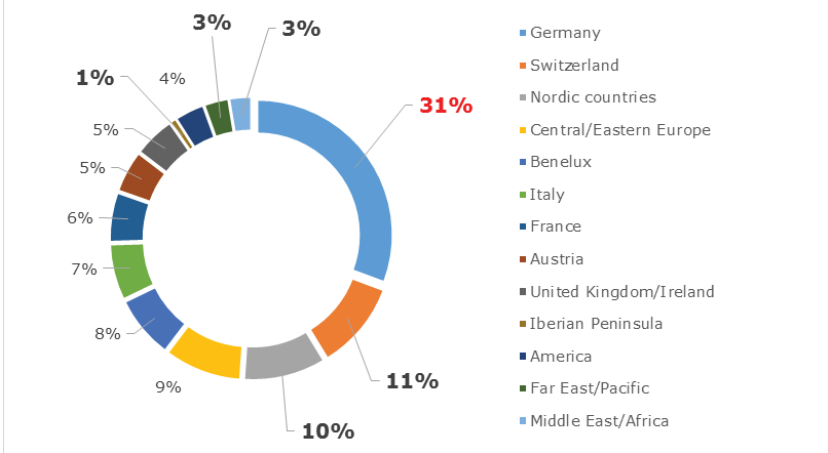
201 Figawa, *Effects of Article 10 of the EU Drinking Water Directive on test and certification costs for products in contact with drinking water*, 2016

202 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

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

In terms of Net Sales on the European Market the central and northern European countries are leaders, with **Germany, Switzerland and Nordic countries** on top, while companies from third countries (e.g. Far East, Middle East and Africa) together with the Iberian Peninsula (ES and PT) are instead at the bottom,<sup>204</sup> as shown in the figure below.

**Figure 6-1: Net Sales of Products in contact with Drinking Water (2015)**

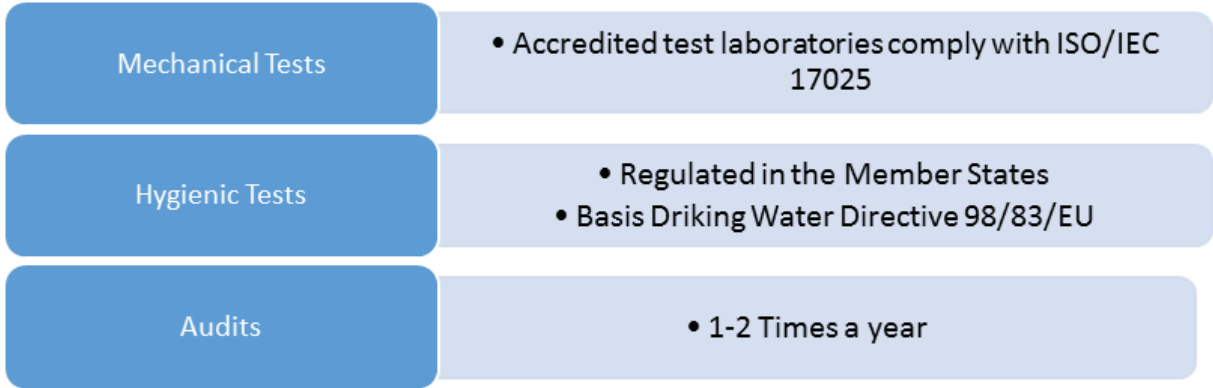


*Author’s elaboration based on stakeholder input*

All these products may be hazardous to human health, and therefore must comply with certain safety requirements.

**Tests and certifications** concerning the products that come into contact with drinking water fall mainly under two categories: **mechanical** and **hygienic**,<sup>205</sup> as presented in the following figure.

**Figure 6-2: Test and Certifications**



*Author’s elaboration based on stakeholder input*

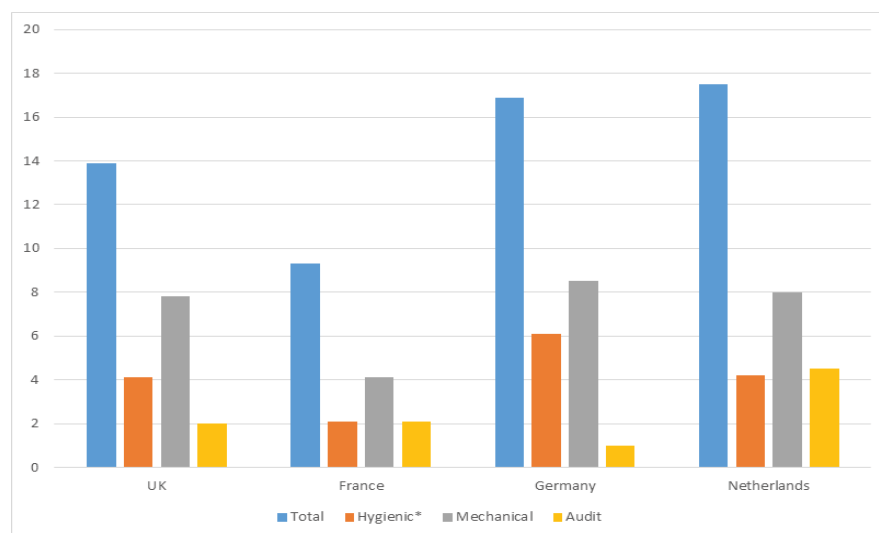
The cost-spread for these certifications as well as statutory audits is different among EU Member States.

204 Data and information provided by Stakeholders

205 Mechanical tests are related to issues like pressure fluctuation, closure, deformation, while hygienic tests are related to the possibility that there is a release of substances in the water.

In Germany, for example, audit 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.<sup>206</sup>

**Figure 6-3: Total Costs for Certifications**



*Author's elaboration based on stakeholder input*

### Water Taps

Water taps are among the products whose commercialization is more problematic, according to stakeholders. Water taps are basically valves used to control the release of water. Unfortunately there is a limited availability in terms of industry sector data, and databases cannot reach the level of granularity needed.

For this reason, to estimate the key variables useful to give a clear representation of the target market, a triangulation of the information provided by different stakeholders involved in the analysis, together with interviews with stakeholders and Eurostat data has been implemented.

Therefore, following figures can be estimated about the segment of the sector that is linked to the production of taps and valves in contact with drinking water, presented in the following table.<sup>207</sup>

**Table 6-1: Estimated data on water taps in the EU**

| Variable           | 2012   | 2013   | 2014   |
|--------------------|--------|--------|--------|
| Turnover (EUR mln) | 14,768 | 14,864 | 15,074 |
| N. of Enterprises  | 1403   | 1378   | 1393   |

Therefore, it could be estimated that the water taps segment covers about **35%** of the entire turnover. Plastic plates, sheets, tubes and profiles follow immediately with an average figure

<sup>206</sup> Figawa, *Member Survey*, 2016

<sup>207</sup> Eurostat, *Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) – C2814 Manufacture of other taps and valves*

of EUR 11.398 million. At the end of the list, we can find tanks, reservoirs and containers of metal (less than EUR 500,000).

Four member states are of particular interest in the current analysis: France, Germany, Netherlands and Great Britain. These countries are the promoters of an initiative, started in 2011, which aims to harmonize the tests for the hygienic suitability of products in contact with drinking water. This agreement was launched after the failure of the European Acceptance Scheme in 2006.<sup>208</sup>

These countries all together generate on average **50% of the sector turnover** in Europe, and they host around **one third of the total number of enterprises**.

**Table 6-2: Estimated data for the 4MS**

| Variable                  | 2012   | 2013  | 2014  |
|---------------------------|--------|-------|-------|
| 4MS Turnover<br>(EUR mln) | 7,4935 | 8,073 | 7,628 |
| 4MS N. of Enterprises     | 423    | 406   | 419   |

### 2.3 Stakeholders involved

| Stakeholder category | Organisation | Description  |
|----------------------|--------------|--|
| Business Association | FIGAWA       | German association based in Cologne, whose members are businesses related to gas and water sector. The association promotes technological development in the industry and try to improve cooperation between the German organizations and international bodies for the development of rules and regulations. |
| Business             | Geberit      | Multinational company based in Switzerland with over 10,000 employees and 125 years of activity. 80% of the turnover (over EUR2bn per year) is generated in the EU.  |

### 2.4 Practices and trends identified and main issues related to the application of Mutual Recognition

Interviews with stakeholders representing manufacturers of products and materials in contact with drinking water<sup>209</sup> 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)<sup>210</sup> requires MS to

208 This project intended to create a unique European system to assess hygienic aspects of products in contact with drinking water, source: <http://www.ceir.eu>

209 E.g. pipes, pumps, taps, valves, fittings, water heaters, catering equipment, seals, etc.; and materials such as elastomers, metals, plastics, etc.

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

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”. This was related to, for instance, in terms of the concentration of substances leaking from such materials, or the breeding of pathogenic microorganisms upon them.

However, as already mentioned, the implementation and monitoring measures are left to the MS, which have established their own national test and certification bodies<sup>211</sup> to assure the quality of materials and to issue licences for the sale of products in contact with drinking water. Each body assess 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 MS 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 MS. However, when they want to market that same product in other MS, they are typically required to repeat those same tests by the relevant bodies in each individual MS they want to enter, as MS not only have different test criteria, but also do not recognise each other’s tests. This practice does result into 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 enshrined in Regulation (EC) 764/2008. In fact, on the basis such a principle, a MS may not prohibit the sale on its territory of products which are lawfully marketed in another MS, even where those products were manufactured in accordance with technical rules different from those to which domestic products are subject. The current situation is especially difficult for SMEs which may not be able, due to limited resources, to fulfil the different test and certification requirements imposed in each MS.

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<sup>212</sup> at the same time in Europe, mainly due to additional testing and certifications that shall be taken in each MS 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 MS, 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 MS due to additional certification.

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211 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), Ministero 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).

212 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.

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 MS such as ES, FR, 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 MS, 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.

As emerged in the interviews, 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 association reported how also 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.

## **Box 6-2: European Drinking Water (EDW)**

Founded in 2015, the European Drinking Water (EDW, formerly ICPCDW) is a consortium of 25 European trade associations representing industries which manufacture and supply products and materials used in drinking water applications and connected to municipal drinking water supplies within the EU.

The coalition is open to any relevant business association and has a horizontal structure, as each member has equal rights to participate in and give its contribution to EDW meetings and activities. Members elect the chairman of the consortium and may withdraw from it at any time.

EDW purpose is to address the current lack of EU harmonised regulatory requirements for the conformity of products and materials used in applications involving contact with drinking water. The mission is to discuss and define a harmonized scheme for requirements and conformity assessment of products and materials used in drinking water applications that can be accepted in all EU Member States.

## **2.5 Conclusions**

Stakeholders highlighted how the actual application of mutual recognition to products in contact with drinking water needs to be improved. The absence of a harmonized scheme of requirements for products and materials accepted by all MS caused a fragmentation of the internal market in terms of quality marks and certifications across MS, as well as an impact on the level of consumer protection.

More importantly, the lack of awareness, mind-set or willingness by national authorities to apply mutual recognition in this sector, combined with companies reluctance to challenge them in front of a court, depict a situation in which businesses are unable to sell lawfully marketed products in a large number of EU MS at the same time.

On the opposite side, businesses have to deal with the costs of double testing and additional certifications and the foregone profits due to delayed market entry, as they have to wait several months being allowed entering the market of other MS.

## **3. FOOD CONTACT MATERIALS**

### **3.1 Introduction**

The present case study will examine a specific category of materials and articles intended to come into contact with food (food contact materials or FCMs), namely food packaging. This case study was identified in prior stages of the study as being relevant, both by competent authorities as by economic operators, due to the complexity of applying the Mutual Recognition Regulation 764/2008 to this context. This is principally due to the fact that food contact materials (including food packaging) are only partially harmonized at the EU level. In addition, the non-harmonised aspects of food contact materials are often subject both to extensive national regulation and to extended practical scrutiny by the competent authorities, which is justified by the potential impact on public safety and more precisely public health.

The case study therefore has the objective of understanding the magnitude of the costs and limitations to trade due to the actual suboptimal application of mutual recognition to food

contact-material, and the impact of available policy options to address the issue. This will provide further detail on the practical considerations and barriers that economic operators and competent authorities face when bringing products to the market, with the added element that any technical rules imposed by competent authorities are more likely to be linked (or linkable) to a public interest, specifically the protection of health. Given that competent authorities must, under Article 6.1 of the Regulation, specify technical or scientific evidence to the effect that “the intended decision is justified on one of the grounds of public interest set out in Article 30 of the Treaty or by reference to other overriding reasons of public interest”, the application of the Regulation to food packaging can be particularly relevant when assessing the policy options available to the legislator.

### 3.2 Background

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.

Apart from the Mutual Recognition Regulation, the FCM sector is more specifically regulated through the Food Contact Materials Regulation (EC) No 1935/2004. This Regulation establishes the principle of safety assessment and management, specifically regarding the risk of transfer of chemicals from such materials into foods. Some of these contact materials are covered by EU legislation, specifically active and intelligent materials (which are not inert by design), ceramics, plastics, and regenerated cellulose. 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.<sup>213</sup>

The FCM Regulation explicitly foresees a complementary role for the Member States, which are allowed under Article 5 of that Regulation to maintain or adopt national provisions in relation to FCMs, in the absence of specific measures adopted under the Regulation itself. Furthermore, the European Food Safety Authority (EFSA) is explicitly granted the authority to adopt specific measures aiming at protecting public health (i.e. to evaluate the safety of specific FCMs), which it does with some frequency.<sup>214</sup>

Thus, food packaging is subject to a relatively complex regulatory framework. The main principles are set out at the EU level via the FCM Regulation, which explicitly covers some materials but leaves others within the remit of the Member States. A producer of food packaging must therefore follow a specific procedure<sup>215</sup> towards the national competent authority<sup>216</sup> if no rules are available at EU level; and the national competent authority must forward such requests for authorisation to EFSA for EU level scrutiny. Decisions may be made at the national level, but only insofar as topics have not been harmonised at the EU level, and always taking into account the provisions of EU law, including the MR Regulation. Since specific guidelines are available at the EU level on how FCMs must be tested and

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213 See [http://ec.europa.eu/food/safety/chemical\\_safety/food\\_contact\\_materials/legislation\\_en](http://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/legislation_en)

214 See <http://www.efsa.europa.eu/en/topics/topic/food-contact-materials>, and specifically <http://www.efsa.europa.eu/en/science/food-ingredients-and-packaging> for decisions on food packaging

215 Illustrated here: <http://www.efsa.europa.eu/sites/default/files/applications/apdeskapplworkflowcm.pdf>

216 Published here: [https://ec.europa.eu/food/sites/food/files/safety/docs/cs\\_fcm\\_auth\\_ref\\_en.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_auth_ref_en.pdf)



assessed (by the European Reference Laboratory for Food Contact Materials EURL-FCM)<sup>217</sup>, in principle similar decisions should be made by the various Member States.

The sector itself is relatively complex and multi-layered, comprising various types of economic operators that interact to provide food packaging. The ‘Industrial guidelines on traceability of materials and articles for food contact’<sup>218</sup> distinguish between

- the processing of starting materials by the converters and producers;
- use of empty packaging by distributors or fillers;
- distribution of finished articles such as kitchenware/tableware by distributors or retailers;
- sale to end consumers of filled packaging by distributors or retailers.

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.<sup>219</sup> The Study found that this sector suffered a lack of harmonisation of materials listed under the framework regulation and that it was “*the object of issues in mutual recognition*”. Specifically, the study highlighted a lack of detail in relation to requirements and quality assurance towards 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, and the logic of the MR 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.

From the economic operators’ perspectives, the guidance which is available from the competent authorities is often described as being too generic and high-level to allow them to prepare authorisation requests with a sufficient degree of predictability. Access to national level legislation and the interpretative documents created by competent regulators in relation to the application of the legislation was often described as lacking, both on the nature of substances considered, the types of restrictions and numerical values imposed. Ambiguities on this point were seen as impeding mutual recognition, both for regulators and economic operators.

Competent authorities are available in all Member States under the FCM Regulation. However, for this case study it is worth underlining that the competences and activities of the authorities diverge relatively widely, and can vary depending on the substances involved, with not all substances being covered in all Member States. Even when competent authorities for a given substance are available in multiple Member States, their FCM schemes and

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217 See <https://ec.europa.eu/jrc/en/eurl/food-contact-materials>

218 See <http://www.apecal.org/wp-content/uploads/2015/04/1.-Industrial-Guidelines-Traceability-Jan2006.pdf>

219 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>

specific requirements for the authorisation of substances are not the same. EFSA acts as a mitigating factor on this point by establishing and supporting a Member State network<sup>220</sup> to facilitate share data needs further follow-up activities comparing national protocols.

As noted in the introduction, for this case study the main role of the Member State (or rather of its competent authority) under the FCM Regulation is to act as a contact point for economic operators that wish to submit requests for authorisation for specific substances to EFSA, and as a regulator with subsidiary competences (i.e. when the EU has not intervened to harmonise specific products) by applying national legislation, criteria and procedures to determine whether FCMs are safe, taking into account both the FCM Regulation and the MR Regulation.

### 3.3 Stakeholders involved

The following stakeholders have been contacted:

- Crown Europe, a manufacturer of packaging products and technology (including cans, closures, wrappings and tins).<sup>221</sup> It is a significant economic operator in this market, active in 40 countries, employing over 23,000 people and net sales of \$9.1 billion annually.
- APEAL, the Association of European Producers of steel for packaging<sup>222</sup>, a federation of the four major producers of steel for packaging (Arcelor Mittal, ThyssenKrupp, Tata Steel, and US Steel Kosice). APEAL represents 95% of the total European production of steel for packaging, and the production of up to 4.8 million tonnes of steel for packaging per year (equivalent to 42 billion steel cans).
- European Carton Makers Association (ECMA),<sup>223</sup> the International Network of Folding Carton Organisations, representing carton businesses, national carton associations and suppliers to the carton industry. ECMA represents 500 carton producers in nearly all countries in the European Economic Area. Around 70% of the total carton market volume in Europe, and a current workforce of about 45,000 people are represented.
- European Printing Ink Association (EuPIA),<sup>224</sup> founded in 2003 as a division of CEPE, the European Council of the Paint, Printing Ink and Artists' Colours Industry. EuPIA represents the interests of the European manufacturers of printing inks and related products.

### 3.4 Practices and trends identified and main issues related to the application of Mutual Recognition

Based on the currently available information, the following practices and trends can be highlighted:

- At the national level, requirements on declarations of conformity to be provided by economic operators and supporting documents lack guidance and associated quality

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220 See the Food Ingredients and Packaging (FIP) Scientific Network on Food Contact Materials (FCM); available at <http://www.efsa.europa.eu/sites/default/files/assets/fipnonplasticsnetworklist.pdf>

221 See <http://www.crowncork.com/about-crown>

222 See [www.apeal.org/about-us/](http://www.apeal.org/about-us/)

223 See <http://www.ecma.org/about-ecma/>

224 See <http://www.eupia.org/index.php?id=2>

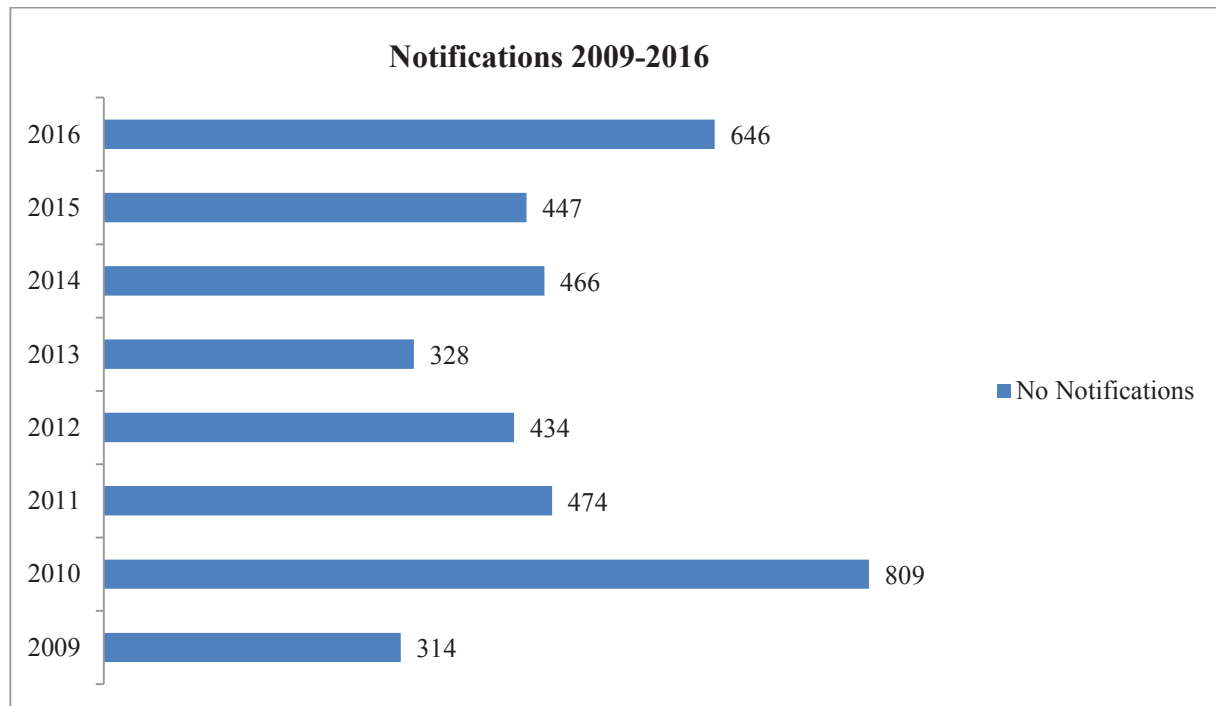
criteria. Self-regulation can address this to some extent by providing additional sectorial guidelines, but it is unclear whether these are known and applied in particular by SMEs.

- 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 MSs (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 MSs. 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, 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 MR 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 MR 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”.

## ANNEX 7: OVERVIEW OF NOTIFICATIONS

### 1. OVERVIEW NOTIFICATIONS REGULATION (EC) No 764/2008

Since the entry into force of the Regulation, the Commission received **3918** notifications of administrative decisions taken pursuant to article 6.2. These are notifications of administrative decisions taken on the basis of a national rule, and denying or restricting market access for products lawfully marketed in another Member State. The table below offers an overview of the number of notifications received per year (in 2009, notifications were sent only as from July, after the entry into force of the Regulation).



The analysis of the notifications received shows the following: only certain Member States are notifying: Portugal, Denmark, UK, Spain and Sweden and Belgium. However, certain Member States are reporting in their annual reports administrative decisions denying market access, without ever notifying these to the Commission. In 2009, the Commission received 314 notifications. The Member States notifying were Portugal, Denmark and UK. All notifications concerned precious metals, with the exemption of those from the UK, related to furniture. In 2010, a higher number of notifications were observed. The Commission received 809 notifications. The Member States notifying were Portugal, Denmark, the UK and Spain. Most notifications concerned, again, precious metals. Some notifications were received in the food and fertilizers area. Administrative decisions have been taken without being notified to the Commission. For example one Member State mentions in its yearly report to have issued a written notice as well as a decision for “products increasing yield”; these decisions were not notified to the Commission. From 2011, the number of notifications stabilised; the Commission received 474 notifications, with only two Member States notifying, Portugal and Denmark. Most notifications concerned precious metals. Some notifications were received in the area of food supplements (e.g. addition of folic acid in certain food). Administrative decisions denying market access are mentioned by certain Member States in their annual reports, but not notified to the Commission. In 2012, the Commission received 434 notifications. Member States notifying were Portugal, Denmark, Belgium and Spain. Most notifications concerned precious metals. Other sectors concerned were fertilisers, food

supplements, food additives (e.g. addition of caffeine in energy drinks), and vitamins (e.g. addition of vitamin B in energy drinks). In 2013, the Commission received 328 notifications. Member States notifying were Portugal, Denmark, Belgium and Spain. Most notifications concerned precious metals, fertilisers, food supplements. A slightly lower number of notifications were registered during 2013, without any reliable explanation. Administrative decisions are mentioned in the annual reports but never notified to the Commission: at least one case concerning a negative administrative decision was received through SOLVIT (fertilizers), 60 decisions were adopted by a regional authority (solar panels, car pieces, sanitary tap ware), 30 decisions affecting TV sets, 2 affecting fertilizers and 24 articles of precious metals. 20 cases where kit cars were denied market access were also taken and not notified. In 2014, the Commission received 466 notifications. Member States notifying were Portugal, Denmark, UK, the Netherlands and Spain. Most notifications concerned precious metals. Notifications were also received in the area of food: vitamins (e.g. levels of vitamin D & A), food additives (caffeine in chocolate), childcare articles (playpens). Other administrative decisions are mentioned by yearly reports but not notified to the Commission<sup>225</sup>; in one case, the adoption of 460 administrative negative decisions is highlighted in the annual reports, and none was notified to the Commission. In 2015, the Commission received 447 notifications. Member States notifying were Portugal, Denmark, Belgium and Spain. Most notifications concerned precious metals. Notifications were also received in the area of fertilisers, energy drinks and food supplements. Some Member States mention, in their annual reports, a certain number of administrative decisions taken following Article 6 (2) of the Regulation<sup>226</sup>, while these decisions have not been notified to the Commission. In 2016, the Commission received 646 notifications. Member States notifying were Portugal, Denmark, UK, Belgium and Spain. Most notifications concerned precious metals. Notifications were also received in the area of vitamins (e.g. iron, acid folic), food supplements and furniture. Some discrepancies appear between the annual reports and the notifications.

As regards the sectors concerned by these notifications, the analysis shows that precious metals is the most concerned sector. The fact that most of notifications relate to one category of products, i.e. precious metals, could be explained by the reluctance of Member States to apply the mutual recognition principle in an area where many of them have permanent and long-time established control bodies specifically devoted to assessing hallmarking and control of precious metals. This generated several infringement procedures, and the Court of Justice underlined in several rulings<sup>227</sup> that Member States have to respect the free movement of precious metals on the basis of the mutual recognition principle. For example, certain Member States require a compulsory marking of the product, by the Authorised Assay Office to indicate that it has been satisfactorily assayed (the nature of the metal and its standard of fineness), and did not accept marking by an Authorised Assay Office in another Member State. The Court rules that member States cannot prohibit the marketing of precious articles that have been hallmarked by an independent body in another Member State<sup>228</sup>. Because of the abundant jurisprudence of the Court on these issues, national authorities became over the time well acquainted with the application of the principle in this area, and with the obligation to notify contained in the Regulation. This is particularly the case of Portugal, accounting for 80% of all notifications received, as all of the decisions notified concern precious metals.

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225 4 cases observed

226 545 in one case and 32 in another case

227 The main cases being C-220/81 Criminal proceedings against Timothy Frederick Robertson and others, C-293/93 Criminal proceedings against Ludomira Neeltje Barbara Houtwipper, C-30/99 Commission v. Ireland

228 C-293/93 Criminal proceedings against Ludomira Neeltje Barbara Houtwipper

## **2. OVERVIEW OF MEMBER STATES ANNUAL REPORTS**

### **Overview 2010**

25<sup>229</sup> Member States submitted annual reports for their activity in 2010.

As these are the first reports after the application of the Mutual Recognition Regulation from 13 May 2009, they do not bring much information as many Member States underlined it was too early to draw effective conclusion on the implementation of the Regulation.

Some difficulties are already reported as regards certain categories of products, i.e. fertilizers and textiles. Most of the requests received concern precious metals, food supplements and additives, fertilizers and construction products.

Moreover, Member States raised the importance of PCPs, and that economic operators are still not very aware about their existence (e.g. Portugal reports 25 annual inquiries received, and consider that the low volume of inquiries is due to the lack of awareness about PCPs). Language issues with regards to PCPs are already mentioned by certain Member States.

The reports also mentioned that raising awareness about mutual recognition, guidelines and organising trainings remains necessary in order to ensure a smooth application of the mutual recognition principle (e.g. Slovakia, Romania, Spain, and the Netherlands). Some Member States (e.g. Germany) raised the difficulties encountered at national levels as regards the notification of administrative decisions restricting market access, due to the important number of national authorities involved.

### **Overview 2011**

For the period May 2010 to December 2011, 24<sup>230</sup> Member States submitted annual reports. There are disparities with regards to the content of the reports submitted; while some reports are very detailed and contain useful information for assessing the functioning of mutual recognition (e.g. France, Belgium, the Netherlands), other are just brief summaries informing on the absence of decisions for which a notification should be made (e.g. Slovenia, Estonia).

The Member States' yearly reports on the implementation of mutual recognition mention general issues with the implementation of the mutual recognition principle, in particular language and access to information as well as scope issues. PCPs encounter difficulties as they often need translation in order to deal with the requests received. The questions they have to deal with are often very complex, and relate to a wide category of products.

Some Member States point to the lack of administrative cooperation, and suggest the use of IMI for enhancing the way national administrations communicate among them (e.g. Spain, France, Sweden, and the Czech Republic).

The lack of awareness about mutual recognition is highlighted in numerous reports, and awareness raising campaigns and trainings are suggested by Member States in order to address this problem (e.g. Spain, France, the Netherlands, and Denmark).

7 Member States mentioned having issues with products subject to prior authorisation procedures, and required guidance from the Commission on this issue.

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229 Cyprus and Poland did not submit annual reports

230 Cyprus, Malta and Bulgaria did not submit annual reports

As regards problematic sectors, several Member States (12) listed fertilising products as one of the products for which they received the most queries, and highlighted the particular obstacles faced for a smooth application of mutual recognition to fertilising products (e.g. Belgium, Austria). Food is also a sector that Member States considered as problematic.

## Overview 2012

25<sup>231</sup> Member States submitted annual reports.

The problematic sectors pointed out in the annual reports are construction products, food, fertilisers and prior authorisation procedures. In the construction products area, Belgium notes an increase in the number of inquiries received, and underlines that the number of questions in this area accounts for 44% of the total number of questions received. This assessment is shared by Germany, the Czech Republic, and Italy. With regards to fertilisers in particular, 20 Member States listed fertilising products as one of the products for which they received queries through their PCPs. Seven Member States specifically listed fertilising products as being a difficulty for the smooth application of the MRR. Further, 10 Member States mentioned having issues with products subject to prior authorisation procedures. Difficulties are also raised as regards the concept of "lawfully marketed" (e.g. Slovakia).

Member States are also raising the issue of poor administrative cooperation; for example, Denmark points out that slow replied from PCPs are unsatisfactory for economic operators and risk undermining cooperation among authorities. Some Member States suggest putting in place a network of PCPs to enhance cooperation and communication (e.g. France, Czech Republic).

The annual reports are also indicating a certain number of administrative decisions denying or restricting market access that were taken at national level, without being notified to the Commission (e.g. Poland reports 22 decisions and 19 written notices).

The preventive effect of the Regulation is pointed out as being one of the benefits the Regulation brings (e.g. Slovakia, Bulgaria). This is because the principle has to be applied on a case by case basis, thus obliging national authorities to assess each individual case.

The lack of awareness about mutual recognition is often mentioned by Member States, and some suggest awareness raising campaigns as a useful means to address this issue (e.g. France, Slovakia).

## Overview 2013

All Member States submitted annual reports. There are disparities as regards the content of the reports submitted; while some reports are very detailed and contain useful information for assessing the functioning of mutual recognition (e.g. France, Belgium), other are just brief summaries informing on the absence of decisions for which a notification should be made (e.g. Malta, Greece, Estonia).

11 Member States highlight the lack of awareness about mutual recognition and the poor administrative cooperation among authorities. They suggest guidance and awareness raising campaigns in order to remedy this problem, as well as enhancing administrative cooperation.

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231 Malta and Cyprus did not submit annual reports.

As regards PCPs, the difficulties due to the wide range of products covered by mutual recognition are pointed out. Internal coordination is needed in order to be able to reply to economic operators within the deadlines, or an expert network to support the PCPs (e.g. Bulgaria). Furthermore, PCPs are also receiving questions outside the scope of their competences, and are complaining about language issues, as replies and questions need to be translated (e.g. Romania, Spain, Lithuania, France).

As regards problematic sectors, the food sector is mentioned by several Member States (e.g. Spain, Denmark) as well as fertilisers (10 Member States reported problems in this area, e.g. Belgium, Austria, Portugal). Articles of precious metal and construction products (**'new problems'** highlighted: the role of autonomous certifying bodies, gold-plating, non-acceptance of CE marked products, national quality marks and standards) continue to remain problematic.

As regards notifications, Slovenia suggests putting in place a database to share the notifications received by the Commission. As during precedent years, administrative decisions denying or restricting market access are being taken at national level (e.g. 30 decisions mentioned by Hungary in its annual reports) but not notified to the Commission.

Estonia mentioned difficulties as regards the identification of the applicable legal framework for some products, and the Czech Republic mentions difficulties as regards prior authorisations.

## **Overview 2014**

25 Member States have submitted the yearly report. There are disparities as regards the content of the reports submitted; while some reports are very detailed and contain useful information for assessing the functioning of mutual recognition, other are just brief summaries informing on the absence of decisions for which a notification should be made.

As regards notifications, some negative decisions are mentioned by yearly reports but not notified to Commission (4 cases noted). In one case, the adoption of 460 negative decisions is highlighted while none was notified.

The majority of issues underlined by Member States on the basis of notifications and requests for information concern a few specific categories of goods: articles of precious metals, foodstuffs, food additives and food supplements, fertilisers and construction products.

Other difficulties highlighted are related to the PCPs. Their role and identity are not widely known among economic operators and administrations (even national ones). Furthermore, linguistic difficulties were pointed out, as PCPs need often to translate inquiries and replies. Some Member State indicated that certain PCPs are extremely difficult to contact, by economic operators, other PCPs or researchers. Finally, the deadlines are considered too stringent, but nevertheless, mostly respected everywhere.

Difficulties still remain as to demonstrate that a product has been lawfully marketed in another Member State, even after the Commission adopted a guidance document on these issues. Other difficulties relate to economic operators' understanding of "harmonised" and "non-harmonised" areas, and thus on when the principle of mutual recognition may be used.

As regards the impacts of the Regulation, they are generally estimated as positive by Member States. Benefits are highlighted for economic operators and administrations too, as they are



for example less burdened with requests for conformity assessment. Member States tend to consider in their reports that the Regulation has great preventive importance, and the highest added value is estimated in terms of information provided to enterprises (especially SMEs) by the PCP as regards existing national technical requirements.

As regards suggestions for improving the application of the regulation, Member States refer to information and dissemination activities, in order to u-increase awareness, more contacts with and between PCPs, in order to enhance administrative cooperation, and common procedures and best practices.

## Overview 2015

22 Member States submitted annual reports. Generally, identifying recurrent problems and monitoring the application of the Mutual Recognition Regulation on the basis of the annual reports remains not straightforward. This is because the data received is not homogeneous or comprehensive enough to be considered as usable input, and the template suggested by the Commission is still not widely followed by Member States.

| Template reporting |   |
|--------------------|---|
| <b>Application</b> | <i>The number of decisions taken in the period, the authorities involved and the legal basis on which they were taken</i>                         |
| <b>Sectors</b>     | <i>An analysis of types of products and/or sectors in which the Regulation was applied most often</i>   |
| <b>PCP</b>         | <i>Information on the structure and functioning of the PCP (contact details, roles performed, staffing, number and nature of inquiries, etc.)</i> |
| <b>Assessment</b>  | <i>Any difficulties experienced – proposals for possible improvements</i>   |
| <b>Impact</b>      | <i>Impacts of the Regulation on the practical functioning of the mutual recognition principle</i>   |
| <b>AOI</b>         | <i>Any other possible element worth mentioning</i>  |

On the basis of the available information, the main difficulties identified relate to:

The "lawfully marketed" concept: the reports mention, despite guidance from the Commission, difficulties in assessing/demonstrating that a product has been lawfully marketed in a given Member State. Clarifications are required so as to improve the current situation and bring more legal certainty.

Lack of awareness about mutual recognition: this is a predominant issue highlighted in the reports, and Member States are almost unanimously calling for awareness-raising campaigns, to increase the level of knowledge about what mutual recognition is and how it works in practice.

Poor administrative cooperation and communication: the reports mention the lack of cross-border cooperation among authorities, and that some Product Contact Points are very difficult

to contact. Most reports underline the need for better cooperation among authorities, allowing for swift communication.

Prior authorisation procedures: differences in perception and interpretation relating to existing authorisation procedures in different Member States are also widely mentioned in the reports. However, the lack of details does not allow a clear understanding of why this is a problem and how it should be addressed.

The sectors where the application of mutual recognition is more problematic are fertilisers, food labelling, food supplements and hallmarks. In particular, food supplements are considered as a very problematic area for the application of mutual recognition and harmonisation is recommended to facilitate the free movement of goods.

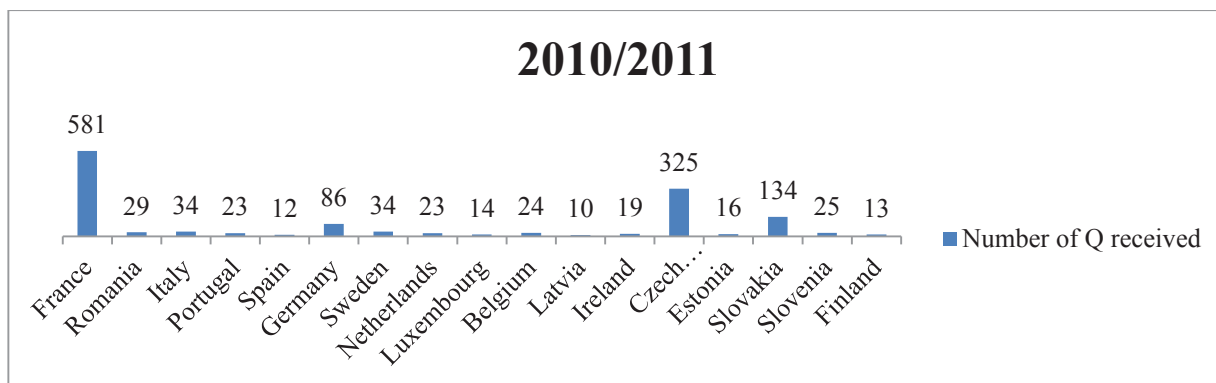
As regards the activity of PCPs, the number of questions received during 2015 amounted to 1645. Out of the 22 annual reports received, 16 only indicate the number of inquiries received. The other Member States mention the activity of PCPs, without indicating the number of questions they received. The most active Member States are France, Czech Republic and Belgium, followed closely by Hungary and Sweden.

The reports highlight the limitations PCPs encounter when exercising their activities. Often, they receive questions which are not within their remit. They are also affected by the complexity of the questions they receive, the variety of products covered by mutual recognition and language limitations. This affects the quality of the reply, and also the timely provision of information to economic operators; the strict deadlines for replying to economic operators are difficult to meet, although mostly adhered to. More and better administrative cooperation, supported by an IT tool for communication and translation purposes, is suggested as a remedy to these issues. Several Member States point out the low number of inquiries received by the PCPs, linked to the lack of awareness about the service they provide. Increasing awareness and providing a visual identity for PCPs could constitute an appropriate way of addressing this issue. Some Member States indicate that offering online information about mutual recognition and certain problematic sectors helped in optimising the functioning of the PCPs.

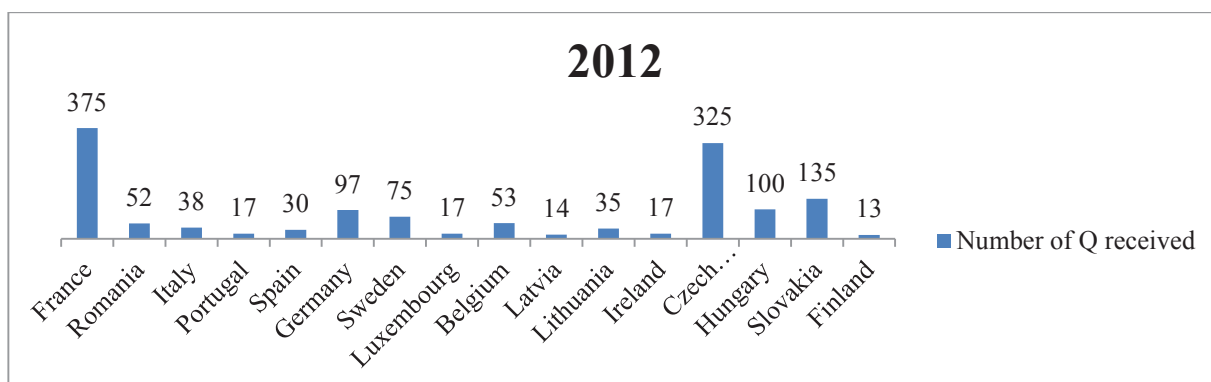
Only a few Member States provided input on the impacts of the Mutual Recognition Regulation on free movement of goods. Generally, the Regulation is considered useful as a pre-emptive instrument, as well as having the potential to facilitate free movement of goods. However, adjustments, especially in terms of awareness, legal certainty and administrative cooperation, are necessary in order for this potential to be fully realised.

### **3. OVERVIEW INQUIRIES RECEIVED BY PCPS**

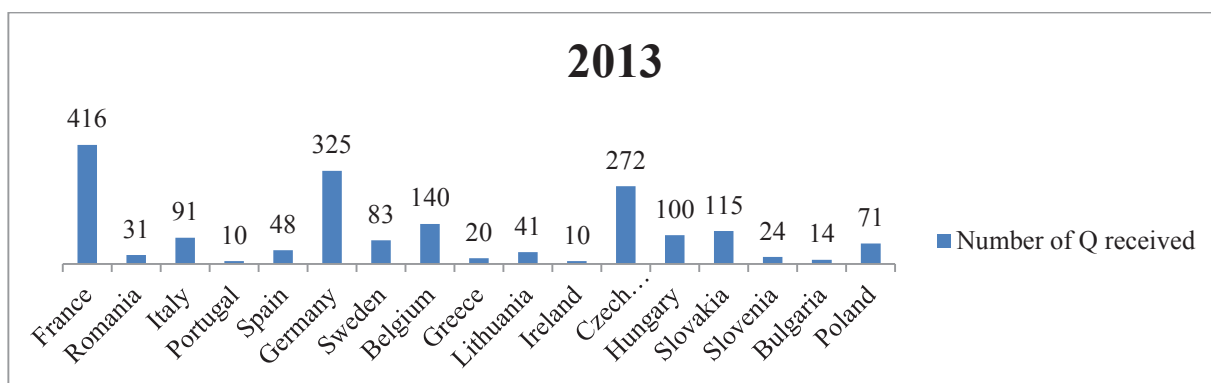
During 2010/2011, PCPs received 1402 inquiries. This number is based on the annual reports where Member States provided information on the number of questions received. The sectors accounting for most of the questions are fertilisers and foodstuff. The most active PCPs are France, Czech Republic, Slovakia and Germany.



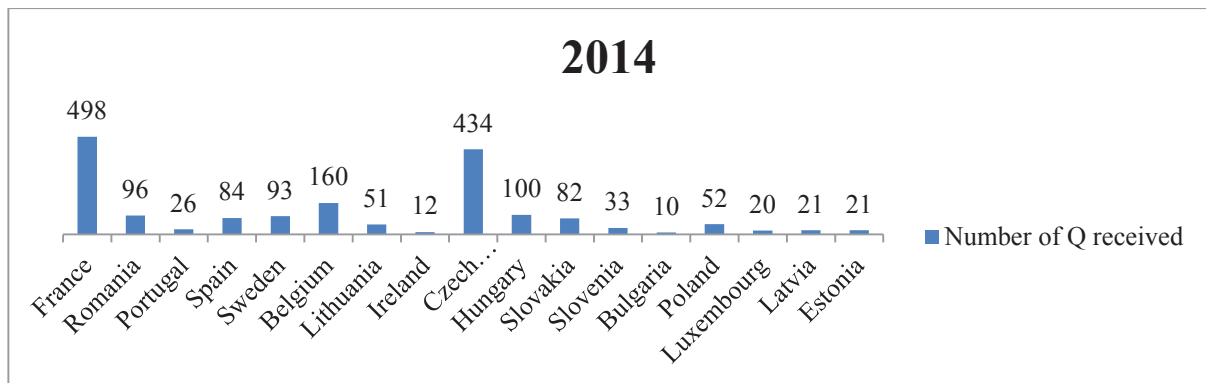
During 2012, PCPs received 1439 inquiries. This number is based on the annual reports where Member States provided information on the number of questions received. The sectors accounting for most of the questions are fertilisers and foodstuff. The most active PCPs are France, Czech Republic, Slovakia and Germany.



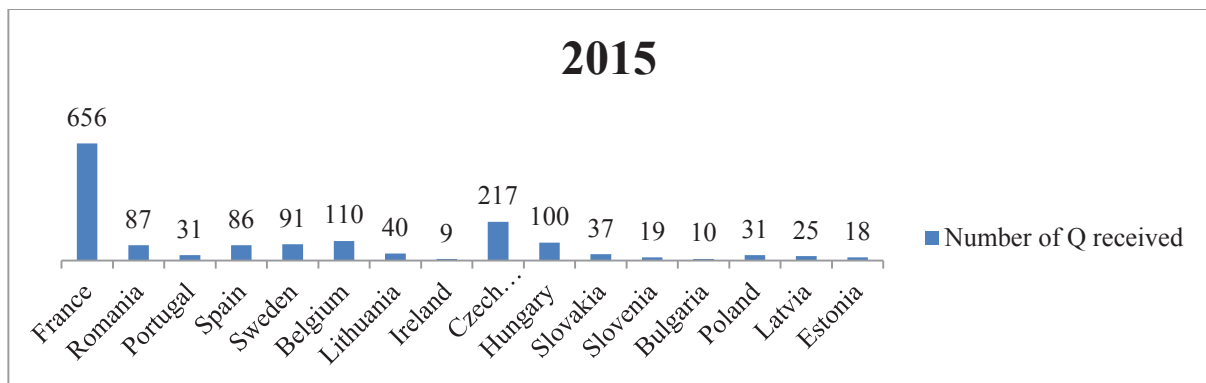
During 2013, PCPs received 1826 inquiries. This number is based on the annual reports where Member States provided information on the number of questions received. The sectors accounting for most of the questions are fertilisers, construction products and foodstuff. The most active PCPs are France, Czech Republic, Slovakia, Hungary, Belgium and Germany. Some Member States received a very low amount of questions, e.g. Ireland, Portugal.



During 2014, PCPs received 1793 inquiries. This number is based on the annual reports where Member States provided information on the number of questions received. The sectors accounting for most of the questions are fertilisers, construction products and foodstuff. The most active PCPs are France, Czech Republic and Belgium. Some Member States received a very low amount of questions, e.g. Ireland, Portugal.



During 2015, PCPs received 1546 inquiries. This number is based on the annual reports where Member States provided information on the number of questions received. The sectors accounting for most of the questions are fertilisers, construction products and foodstuff. The most active PCPs are France, Czech Republic and Belgium. Some Member States received a very low amount of questions, e.g. Ireland, Bulgaria.



## **ANNEX 8: RESULTS OF THE EXTERNAL EVALUATION PERFORMED BY DTI, TECHNOPSIS, E&Y AND VVA CONSULTING (2015)**

This chapter presents the results – findings – of the evaluation. It is mainly based on primary data collected through surveys and interviews (cf. Chapter 3 for more details on the methodologies used), some secondary (statistical) data from various sources, and supplemented with insights from the literature review and from position papers received from EU-level business associations.

The chapter begins with an overall question, i.e. ‘to what extent has the mutual recognition principle achieved its objectives?’ (section 5.1) The stakeholders’ views on this are discussed before the chapter proceeds to analyse more specific aspects of the mutual recognition principle and its application.

Section 5.2 takes the perspective of the *enterprises*, i.e. ‘to what extent do European enterprises know and understand the mutual recognition principle? Which strategies do they employ when exporting to other Member States, what are the costs to companies if the principle is not fully applied by the Member States, and are the administrative burdens of (non-)application of the mutual recognition principle proportionate?’

This is followed by section 5.3 taking the perspective of the *Member States*, i.e. ‘how well do Member State administrations know and understand the mutual recognition principle, and do they apply the principle correctly?’ This section also covers the more technical aspects of Member States’ application of the principle – notification practices, use of technical rules, mutual recognition clauses and prior authorisation procedures, as well as the dialogue between the Member States (product contact points).

Section 5.4 takes a crosscutting perspective, seeking to identify in which markets and which sectors problems are found most commonly.

Finally, section 5.5 summarises some of the key findings into a ‘typology of obstacles’ to full application of the mutual recognition principle.

### **1. STAKEHOLDER’S VIEWS ON WHETHER THE MUTUAL RECOGNITION PRINCIPLE HAS ACHIEVED ITS OBJECTIVES**

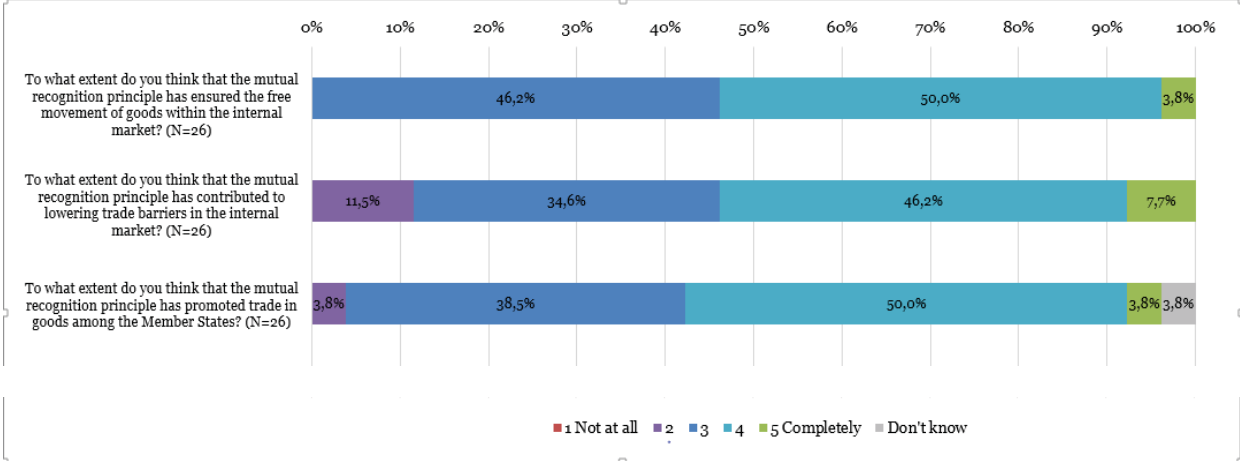
According to Regulation (EC) No. 764/2008, the objectives of introducing the mutual recognition principle are as follows:

- ensuring the free movement of goods within the internal market;
- lowering remaining trade barriers in the internal market; and
- promoting trade in goods among EU Member State.

From the three surveys with the product contact points, the national business and sector associations and the companies, it can be seen that there are stakeholders who perceive the mutual recognition to have, or nearly have, reached its stated objectives. However, there are also a substantial number of stakeholders, who think that the mutual recognition principle still has some way to go before it has achieved its objectives.

In the product contact point survey, the respondents are generally positive. Around half of the product contact points think that the objectives have been either completely reached or close to completely reached. The other half perceive the objectives to be partly reached, and a few product contact points say that there is quite a long way to go in terms of lowering trade barriers in the internal market (see Figure 8-1).

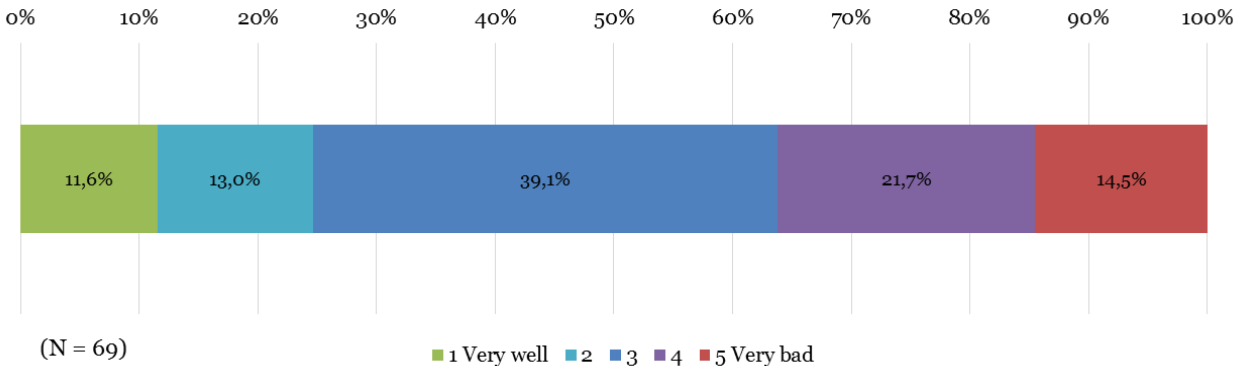
**Figure 8-1: Product contact point survey: To what extent has the mutual recognition principle achieved its objectives?**



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

The company survey reveals that among the companies that know about the mutual recognition principle, there is a slightly negative perception of how the mutual recognition principle works in practice. While one-fourth believes that it works as intended, more than one-third thinks the opposite and states that the principle works badly in practice as illustrated in Figure 8-2. The interviews with companies show that the main reason for stating that the mutual recognition principle works badly has to do with additional tests that national authorities ask the companies to perform, even though the mutual recognition principle should apply.

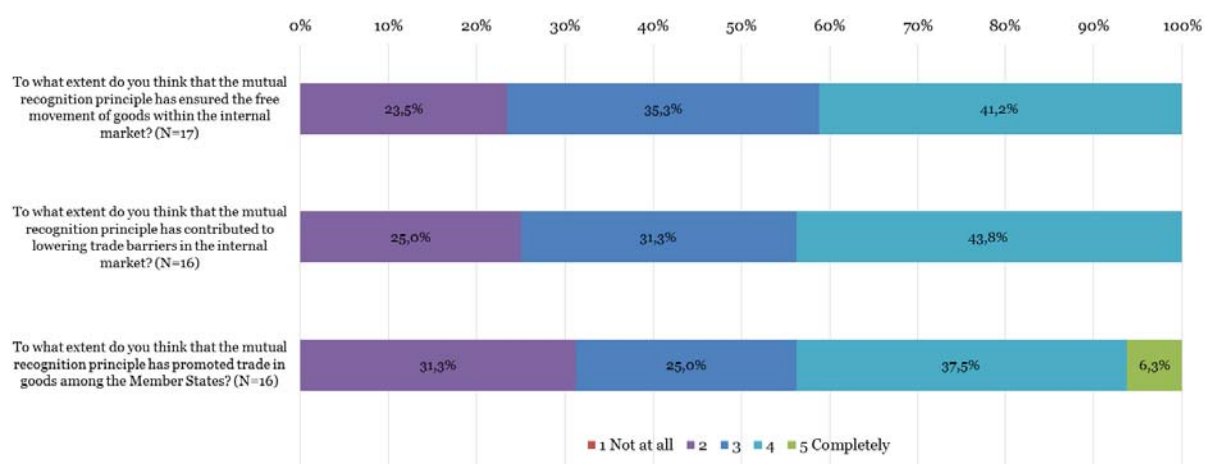
**Figure 8-2: Company survey: In your view, how well does the mutual recognition principle work in practice?**



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

The survey among national business and sector associations shows that around 40% of the respondents believe that the objectives either have been completely reached or are close to being completely reached. 25-35% of the respondents perceive the objectives to be partly reached, and around 25-30% of the respondents believe that there is still quite a long way to go before the objectives have been reached (see Figure 8-3).

**Figure 8-3: Business and sector association survey: To what extent has the mutual recognition principle achieved its objectives?**



Source: Questionnaire survey among national business and sector associations, running from 9 October 2014 to 5 January 2015, carried out by DTI

There are indications from the survey and the interviews that the mutual recognition principle is not applied to a satisfying extent. The Danish Business Association is one of the few business associations that actively monitor its members’ problems within the area of mutual recognition. The association estimates that 20% of its members experience problems with incorrect application of the mutual recognition principle. However, the figure is relatively old (from 2007). The Danish business association is carrying out a new survey of its members, but the results are not ready yet. In addition, the Spanish business association has a project called ‘Online for the identification of problems of Spanish companies in the European Single Market’. It aims to 1) collect information on the main problems, which, despite the implementation of the Single Market, hinder the activity of Spanish companies, and 2) seek solutions to these problems in collaboration with the competent authorities of the National or Community Administrations. According to the Spanish business association, one of the main obstacles refers to the incorrect application of the mutual recognition principle.

Positive aspects of the mutual recognition principle are mentioned in the interviews. Companies state that when mutual recognition works well, they are able to manufacture one version of their product only and sell it on different markets, thus lowering the costs. In addition, one company has found it easier to challenge ‘local wish lists’ from customers and distributors blamed on local regulations. Where there is malfunctioning of the principle (experienced by approx. 35% of the companies), this is mainly perceived to be related to the application of the principle.

Overall, the mutual recognition principle in itself works well as a legal concept to help stimulate trade. The literature, the questionnaire surveys and the interviews all point in the direction that it is not in the legal text as such, but rather in its application that challenges

arise. In addition, the legislation sometimes proves difficult to understand for both companies and Member State authorities. This means that there are various challenges associated with the application of the principle, which need to be addressed. A 2012 study by Copenhagen Economics also found that according to the SOLVIT and TRIS databases wrongful application of the legislation exists within the area of goods covered by mutual recognition.<sup>232</sup>

The impact assessment of the mutual recognition regulation estimated that perfect operation of mutual recognition inside the EU would produce a maximum increase of EU GDP by 1.8%. Furthermore, it was estimated that the failure to properly apply the principle of mutual recognition reduced trade in goods in the internal market by up to 10% or €150 billion.<sup>233</sup> Although the Mutual Recognition Regulation has created a better functioning internal market, there are still areas where the mutual recognition principle is not applied properly, and thus, there are still potentially benefits to be gained. The nature and extent of the challenges will be investigated in this analysis.

## **2. AWARENESS OF THE PRINCIPLE AMONG ENTERPRISES, STRATEGIES CONCERNING MUTUAL RECOGNITION, AND COST OF INSUFFICIENT APPLICATION OF THE PRINCIPLE**

This section takes the perspective of the *enterprises*, i.e. how well do they know the principle, do they use it in practice, and what are the costs to companies if the principle is not properly applied by the Member States? Finally, the question is asked whether the administrative burdens of (non-) application of the mutual recognition principle are proportionate.

### **Awareness and knowledge of the principle among enterprises**

There seems to be a lack of awareness of the principle of mutual recognition, particularly among enterprises. The consequence is that enterprises and competent (regional) authorities often take national technical rules for granted. Enterprises then adapt their products to local requirements, or get them retested, thereby incurring added costs and requiring additional time, or they may even completely refrain from entering the new market.<sup>234</sup> This is supported by input from the Member States' Consultative Committee to the Commission that shows that there are still uncertainties concerning how to handle the mutual recognition principle.<sup>235</sup> Moreover, most enterprises cannot afford a lengthy process discussing back and forth with Member State authorities, so they try to either solve the problem quickly or withdraw from a market.

The awareness and knowledge of the principle of mutual recognition among enterprises is somewhat mixed. The large companies exporting to other Member States seem mostly to have at least some awareness and understanding of the principle. Often, they have a legal department, which, among other things, focuses on the mutual recognition principle. From the perspective of the product contact points, more than 40% of the product contact points think that most (above 75%) large companies seeking to market a product in another Member State know and understand the mutual recognition principle. A third of the product contact points think that 50-75% of large companies know and understand the principle. For SMEs, the situation is very different. More than a third of the product contact points assess that among

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232 Copenhagen Economics (2012): Delivering a stronger single market

233 European Commission (2007): Accompanying document to the Proposal for a directive of the European Parliament and of the Council laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision 3052/95/EC Impact assessment

234 Interview with DG ENTR

235 For instance: European Commission (2010): Minutes of the second meeting of the consultative "Mutual Recognition Committee", held in Brussels on 19 November 2010 and European Commission (2011): Minutes of the third meeting of the consultative "Mutual Recognition Committee", held in Brussels on 30 November 2011

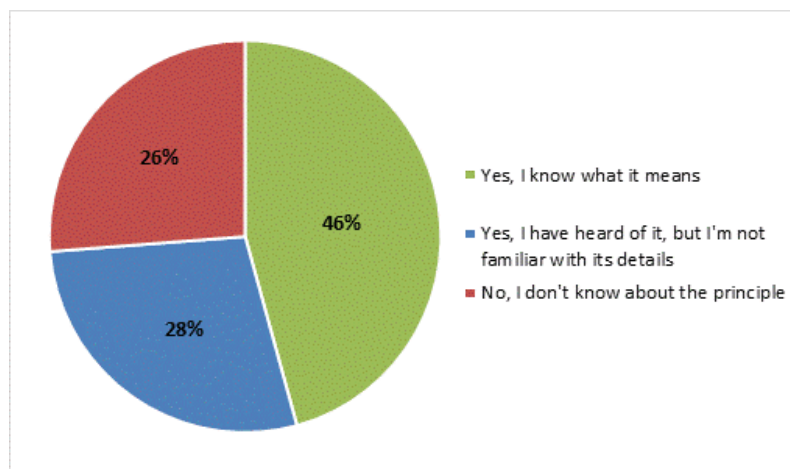


SMEs seeking to market a product in another Member State, less than 25% know and understand the mutual recognition principle, while 40% of product contact points believe that only between 25% and 50% of SMEs know and understand the principle (cf. Figure 8-4).

The experiences reported by the participating business organisations (both in the survey and in the interviews) are consistent with the assessment of the product contact points, i.e. that small companies generally do not have the same degree of awareness and basic understanding of the mutual recognition principle and clauses compared to large enterprises.

Asking companies directly about this, the company survey shows that about 75% of the companies participating in the survey either know what the principle of mutual recognition means or have heard of it, but are not familiar with its details (See Figure 8-4).

**Figure 8-4: Company survey: Do you know about the principle of mutual recognition?**



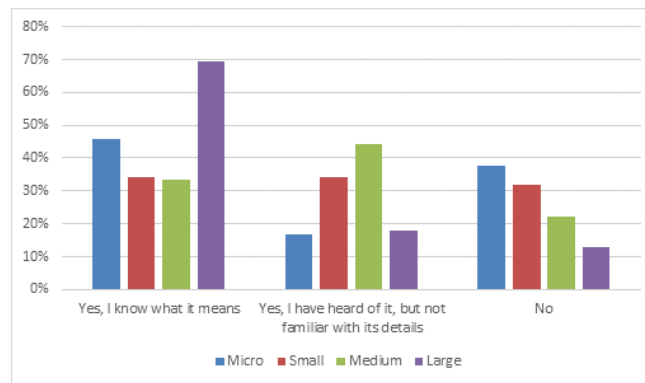
Note: N = 164.

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

The company survey confirms the experience of the product contact points and business organisations, i.e. that large companies have a much greater degree of awareness of the principle than small companies do. It is a bit surprising that many micro companies have a good understanding of the principle, see Figure 8-5 below.

There is no obvious explanation for this phenomenon. There may be a bias in the sample meaning that micro companies that take the trouble to answer the survey may be more familiar with and interested in the mutual recognition principle than micro companies as a whole. However, such a bias may of course also apply to the other company segments.

**Figure 8-5: Company survey: Do you know about the principle of mutual recognition? Micro (<10), Small (10-49), Medium (50-250) and Large (>250) companies**



Note: N = 164.

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

The companies in the survey were asked whether they have exported to other Member States - i.e. whether they have been in a position where the mutual recognition principle could apply. The majority of the companies in the survey, close to 75%, have sold goods in another Member State over the last three years. This is consistent with the share of companies that have heard about the mutual recognition principle. However, for most of the non-exporting companies, their decisions not to sell their goods in other EU countries were not influenced by concerns about the potential problems in meeting the technical rules applicable in other EU countries, and the decision not to export was related to other issues.<sup>236</sup>

#### *Awareness of the principle among business associations*

In the survey of business associations and in the subsequent interviews, it became clear that many business associations did not monitor the principle and consequently could not provide input to the evaluation. On the one hand, the business associations sometimes conclude that since they do not hear about the problem of mutual recognition from their members, the problem with less than full application of the mutual recognition principle cannot be a major problem. On the other hand, as an Austrian business association puts it, “You need to monitor the application of the mutual recognition principle in order to know if there are problems.”

Furthermore, the interviews also indicated that many business associations do not know much about the mutual recognition principle, the main reason being that they do not receive complaints from their members and therefore do not focus on the area. However, more information on the subject could potentially push some business and sector associations to be more aware of the application of the mutual recognition principle and actively investigate among their members whether they experience problems. The Commission could advantageously inform the business associations about the mutual recognition principle. A concrete suggestion from the Austrian business association was to use EEN to distribute such information, organise seminars on the subject, etc.

236 This specific indication is based on a very small number of answers (N = 23) and must be interpreted with this in mind.

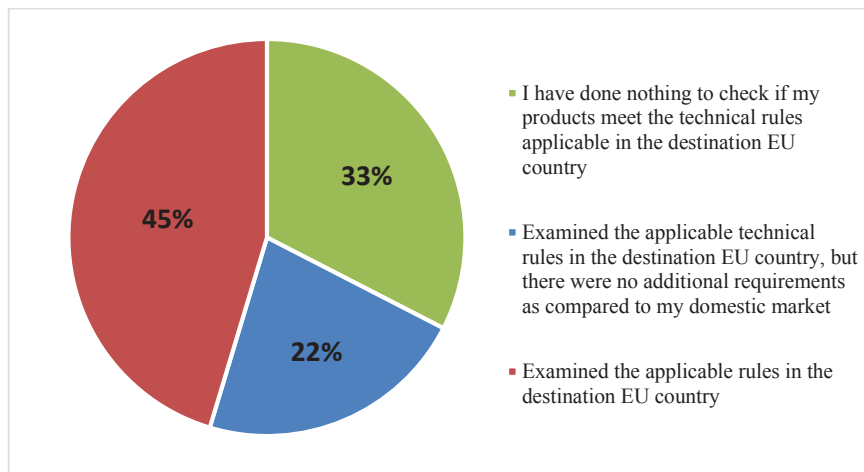
## Enterprise strategy and experience with mutual recognition when entering other Member State markets

Companies may choose different strategies when entering the market of other Member States, all of which affect the resources that they have to spend before the product can be marketed. The main strategies are:

- examining technical rules in the destination market;
- adapting their products to specific requirements/rules in the destination market;
- retesting their products as a result of requirements from customers and/or authorities; and
- relying on the principle of mutual recognition for products already marketed in another Member State.

As shown in Figure 8-6, two-thirds of the companies participating in the company survey check if their products meet the applicable technical rules before entering a new EU market. A minority of them do not experience any additional requirements for their products. However, one-third of the companies do not check if additional technical rules apply when entering a new EU market, probably because they trust that the mutual recognition principle works as intended.

**Figure 8-6: Company survey: When entering a new EU country, have you taken any of the following steps related to meeting technical rules applicable in that country?**



Note: N = 86.

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

For the companies that have examined the applicable rules in the destination Member State and judged that actions had to be taken<sup>237</sup>, 60% adapted their product(s) to local technical requirements, 22% retested their products, and 19% took ‘other steps’. The other steps (extracted from the open answers to the survey) primarily included doing both of the above and sometimes refraining from entering the market of the Member State in question.

237 37 companies answered this question

### Textbox 8-1

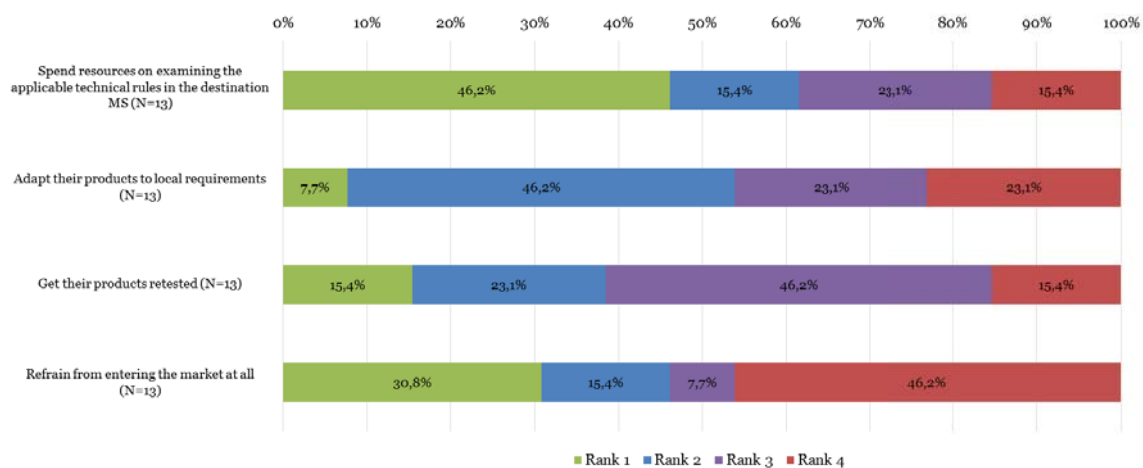
[We usually] check our product with national authorities, and nine out of 10 times we are told that we need to adapt our product to local requirements.

Medium-sized company, construction sector (company survey)

(Particularly experiences problems in France and Germany)

The business associations were also asked about how the companies prepare for entering a new market. They also pointed to the spending of resources on examining the applicable technical rules in the destination Member State as a very frequent choice. Thus, two-thirds of business associations responded that this was very frequently or frequently done by companies. Almost half of the business associations also see businesses frequently refraining from entering the market at all.

**Figure 8-7: Business and sector association survey: Companies may apply one or more of the following strategies when entering a new market (within the internal market). How do they react? Rank from 1-4, where 1 is the highest priority and 4 is the lowest**



Source: Questionnaire survey among national business and sector associations, running from 9 October 2014 to 5 January 2015, carried out by DTI

However, in the personal interviews stated, retesting was the issue indicated most frequently by the business associations as a major cost element. It was also a requirement that the companies often faced, particularly because Member States require that testing of the product is done in the destination Member State or by specific laboratories (which may include laboratories outside the Member State in question). The statement from a business association in the text box below supports this.

### Textbox 8-2: On company strategies when met with national technical requirements although mutual recognition should apply

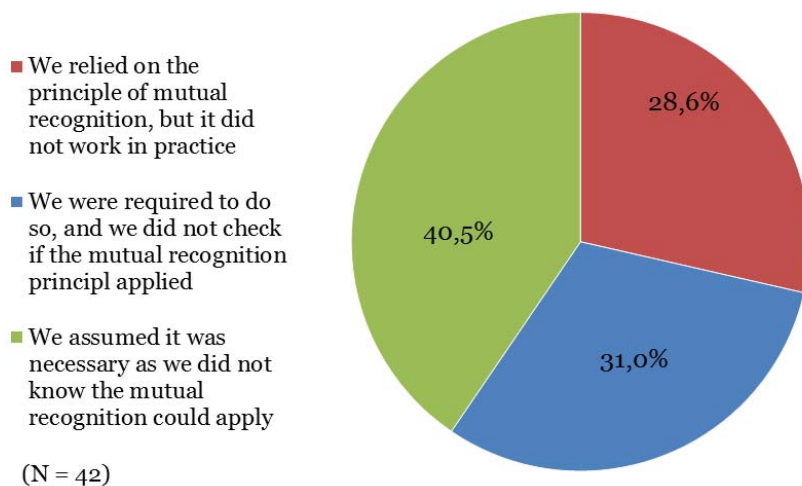
Their strategy depends on how big the company is. The big companies can either choose to retest, if the market is important to them, or they may be big enough to say “we know the law” and they challenge. They dare to take the fight. Small companies adapt, depending on how important the market is or on how many markets they operate. They cannot challenge it

because they cannot afford it, and they fear the authorities and cannot afford to take the conflict. Therefore, when they call us they want to be anonymous when we take the matter further. It is dangerous for them.

*National business association, Northern European Member State*

When asked why these steps were taken, more than 40% of the companies answered that they simply assumed it was necessary, as they did not know if the mutual recognition principle applied to their product. Almost a third took such steps because they were required for acceptance in the local market and did not check whether the mutual recognition principle could apply. Nearly 29% relied on the principle, but it turned out that it did not work in practice, meaning that the companies believed that they had the legal right to introduce the products, but the national authorities still asked for testing or adaptation.

**Figure 8-8 Company survey: Why did you take these steps related to meeting technical rules?**



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

In addition to lack of awareness of the mutual recognition principle among companies, many of the steps that companies think they need to take when entering another Member State market boil down to 'legal uncertainty' due to differences in testing methods, use of prior authorisation procedures, because the legislation is difficult to understand, or because the authorities in the destination Member State do not apply the legislation correctly. In the company survey, more than half of the companies rank legal uncertainty concerning the understanding of the mutual recognition principle/legislation as the first or second most important barrier to an effective functioning of the mutual recognition principle.

**Figure 8-9: Company survey: What are the obstacles to effective mutual recognition? Rank from 1-4**



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

A concrete example of national requirements forcing companies to adapt or withdraw their products is the case of bisphenol A in France.

### Textbox 8-3: Bisphenol A in France

Bisphenol A is a plastic softener, which is forbidden in baby products, but allowed in other plastic products. France has been looking to extend the ban on bisphenol A to other plastic products, and certain other plastic products were included in the ban on 1 January 2015. Companies may then choose to adapt all of their products to the requirements of the French market, or just the ones that they want to market in France. In any case, this has a substantial economic impact on the companies. The costs may be indirect, as companies may decide to withdraw their products or market other products without bisphenol A. It can also affect competition in the sense that competition is lower in the French market due to fewer products without bisphenol A being marketed, which may again affect consumers.

Source: Interview with Eurocommerce

The product contact points were also asked about companies' strategies with respect to technical rules, and their answers indicate that based on their experience companies do indeed spend resources on examining technical rules and adapting to the requirements of the Member State(s) where they want to market their products. When they do this it is due to a lack of awareness of the mutual recognition principle. The majority of the product contact points (59%) report that this occurs between 10% and 50% of the time, while 14% of the product contact points report that companies from other Member States do this between 50% and 75% of the time. This is particularly pronounced in the construction product industry and in the food and food additives industries.

Regarding the product contact points' experience with enterprises from other Member States adapting their products to local requirements due to lack of awareness of the mutual recognition principle, 45% of the product contact points reported that companies from other Member State adapt their products less than 10% of the time, 35% of the product contact points stated that this occurred between 10% and 50% of the time, while 20% reported that it happened more the 50% of the time. Again, it was found that product adaptation is

particularly pronounced within the construction product industry, though the majority of the product contact points were not able to identify the sectors in which this occurred.

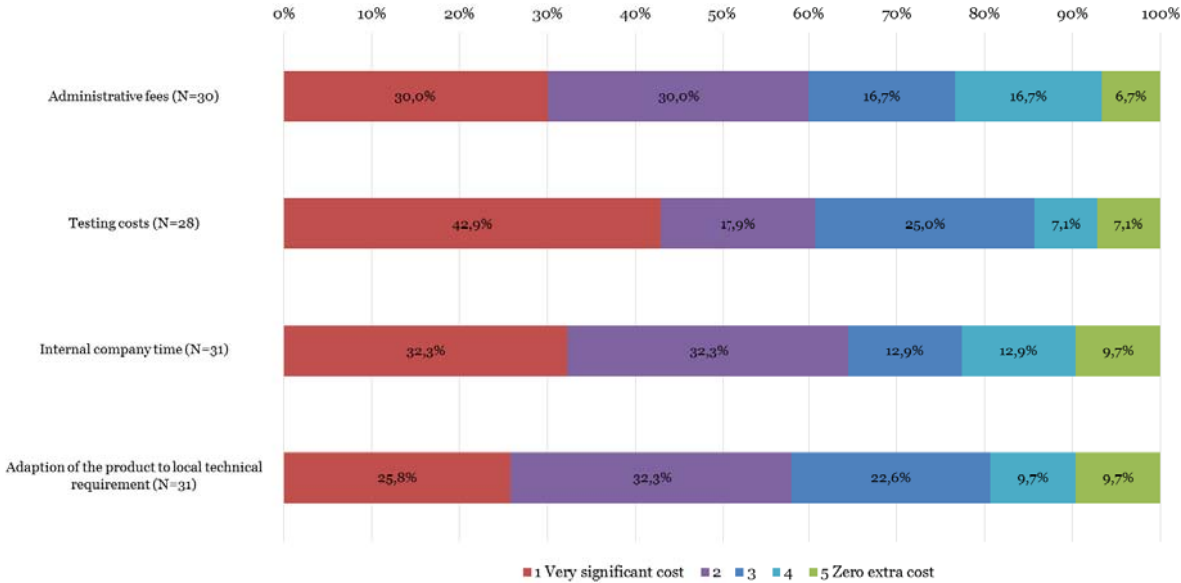
With respect to how often enterprises from other Member State have their products retested, due to lack of awareness of the mutual recognition principle, none of the product contact points reported that this is the case in more than 50% of the time, whereas 55% of the product contact points indicated that this is the case in only less than 10% of the time. Again, the construction product industry was pointed out as the sector where this problem is most widespread by some product contact points, but the majority of product contact points was not able to pinpoint any sectors where the problem is particularly pronounced.

When asked how often enterprises from other Member States simply refrain from entering the market at all, due to the lack of awareness of the mutual recognition principle, 90% of product contact points reported that they see this happening less than 25% of the time, while the remaining 10% experience this between 25% and 75% of the time. Most product contact points have not been able to indicate which sectors are particularly exposed to this problem.

**Costs to the companies resulting from less than full application of the mutual recognition principle**

The companies that decided to take steps to meet local technical requirements, such as retesting and/or adapting the products, indicate that there are significant costs associated with the administrative burden, retesting of products and the actual adaptation of the product as shown in the Figure 8-10 below.

**Figure 8-10: Company survey: What are the typical cost items involved and how significant are they?**



Note: N=28-31 (not all companies answered all questions)  
 Source: Questionnaire survey among companies, running from 9 October 2014 to 5 January 2015, carried out by DTI

The companies that have answered this question particularly perceive testing as being costly – more than 40% of the companies have rated testing as being a very significant cost. The testing costs vary considerably, depending on the sector and the product, but some examples from different sectors are provided in Table 8-1.

Internal company staff time and administrative costs are perceived to be very significant by 32% and 30% of the companies, respectively. In the company interviews, 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 the companies 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.

The company survey and the subsequent interviews revealed a rather wide range of costs in different sectors. The costs are presented in Table 8-1. Few companies were able to put a figure on the costs they face because of 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. Table 8-1 summarises some of the characteristics of the companies that provided cost estimates.

**Table 8-1: Overview of the companies that provided estimates for the costs of adapting or retesting products**

| Sector                                       | Size of company | Knowledge of MR principle | Percentage of export goods falling under MR principle | Costs of adaptation or retest (percentage of yearly turnover or euros) |
|--|-----------------|---------------------------|---|--|
| Articles of precious metals                  | Small           | yes, but not in detail    | 100   | 10   |
| Childcare products                           | Small           | no                        | 10  | 50,000 EUR   |
| Childcare products                           | Large           | yes, but not in detail    | 90  | 1  |
| Childcare products                           | Micro           | no                        | 5   | 10   |
| Childcare Products                           | Small           | no                        | 50  | 0,3  |
| Childcare products                           | Medium          | yes, but not in detail    | 5   | Company originates from MS where national rules are stricter           |
| Construction products                        | Large           | yes                       | 70  | 0,5  |
| Construction products                        | Medium          | yes                       | 20  | 2  |
| Construction products                        | Small           | yes                       | 40  | 10   |
| Construction products                        | Large           | yes                       | 10  | Testing costs, see case  |
| Construction products                        | Medium          | yes, but not in detail    | 75  | 2,000-9,000 EUR/test   |
| Construction products                        | Small           | yes                       |   | Tailor-made products, agree on terms with client                       |
| Construction, retail                         | Large           | yes                       |   | 50,000-100,000 EUR/test  |
| Electrical products                          | Medium          | no                        | 20  | 7  |
| Electrical products                          | Large           | yes, but not in detail    | 10  | 2  |
| Fertilisers                                  | Large           | yes                       | 5   | 20   |
| Fertilisers                                  | Small           | yes                       | 50  | 10   |
| Fertilisers and potting soil                 | Large           | yes                       | 60  | 1  |
| Food   | Large           | yes                       | 1-5   | 5  |
| Food   | Large           | yes                       | 80  | 0,1  |
| Food additives and food supplements          | Large           | yes, but not in detail    | 60  | 5  |
| Garments for children                        | Medium          | yes, but not in detail    | 10  | 0,2  |
| Medical devices and technical aids           | Large           | yes, but not in detail    | 50  | 20   |
| Paper industry, packaging for foodstuff etc. | Large           | yes                       | 100   | 0,0025   |
| Production of metal devices                  | Medium          | yes, but not in detail    | 5   | 1  |
| Sports equipment                             | Large           | yes                       |   | Document and testing costs, see also case                              |
|  | Large           | yes                       | 50  | 10   |
|  |                 | yes                       | 30  | 5  |

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



Two relevant cases were identified within the area of **water tap production**. This product is particular because the tap is in contact with drinking water, and the product is therefore classified as a product having contact with food. EN standards cover mechanical, functional and physical requirements for taps and hoses. However, the use of positive material lists, substance migration, noise, odour, flavour or appearance of the water is still regulated by national testing or certification requirements. Taps are only mentioned in the Drinking Water Directive (*DWD, 98/83/EC*) where EU Member States have to ensure that materials used in the distribution of drinking water do not release substances in concentrations higher than necessary for the purpose of their use. This means that all Member States can (and do) apply their own rules, and the testing procedures vary among the Member States. The approaches of Member States differ when it comes to national certification systems. The existence and the role of national regulatory bodies and toxicity committees also vary. Often competences fall within different authorities. One of the companies has calculated that for each product in the category of taps the certification and testing costs are up to €50,000. In addition, the cost of getting a new composition approved (to be used for the production of water taps) is between €50,000 and €100,000 (see Case 4). The other company cited testing costs for a single component of approx. €2,000 and for the final product approx. €8000-9000. In addition, tests can be rather time-consuming. For instance, a test to determine whether the component or final product contains nickel takes up to 18 weeks (see Case 2).

Much work has been done to try to secure a common testing system but, so far, the Member States have not been able to agree on this. The prioritisation of product requirements is different, as is sometimes the jurisdiction of competences. However, a group of Member States has undertaken some positive steps: Germany, the UK, the Netherlands and France have agreed on a common positive list of materials.

In theory, the mutual recognition principle should apply to this area. However, it is clear from the cases that in reality it does not, as Member States require that national tests be carried out before accepting the taps on the markets. One company perceives the request for national tests as a market protection measure, an observation that is further strengthened by the fact that a working group under CEN (consisting of company representatives) has failed to find a solution to the problem of requiring national tests (see Case 2 for further information).

Even though certification and test requirements are different in different countries, the basic purpose and parameters are similar. Irrespective of the reasoning behind the request for national tests, the tests result in significant costs for companies.

Another example has to do with paper products, which come in contact with food. Here, the company in question experiences that their Italian customers require the product to be tested according to Italian standards. The company perceives this request to be due to lack of knowledge. One test costs around €700, which the company does not see it as a major cost rather as an unnecessary and perhaps a bit annoying cost (see Case 1).

Within the area of **construction products**, companies still feel that the mutual recognition principle is not necessarily respected. The Construction Products Regulation (305/2011) has replaced the Construction Products Directive (89/106/EE). This regulation aims to prohibit the use of conflicting national marks of declaration of performance and ensure that any product that is CE marked is freely allowed onto the market in the EEA without further

testing. Mutual recognition applies to non-CE marked products in the non-harmonised area only.<sup>238</sup>

Several companies mention that there is a specific problem in Germany. As a Commission case from 2011 shows, the German standardisation body is so dominant on the market in terms of drawing up standards, certifying products, etc., that distribution of products on the German market is virtually impossible without conforming to this institute's standards, although the mutual recognition principle may apply.<sup>239</sup> Moreover, the issue was mentioned in the literature in 2012, where a Danish flooring company experienced that for products sold in Germany, the relevant authority Deutsches Institut für Bautechnik requires more stringent tests. In addition to the CE label, additional health and environmental impacts of products need to be tested and monitored by an external, German party. This has led to a significant increase in costs for the company, i.e. first due to the requirement for additional external monitoring; second, because the German Institute did not accept the Danish testing results produced to obtain the Danish Indoor Label, which forced the company to undertake additional testing in Germany. In addition, it has also led the company to limit the number of products it offers in the German market as additional testing is counted in millions of Danish kroner per product.<sup>240</sup>

Another company experienced that as long as construction products are not harmonised, Member States have a tendency to require national approvals or even extra tests. Germany and Belgium are highlighted as Member States where the company has experienced this.

Another (Portuguese) company acknowledges that outside the harmonised area and in areas where there is no CE-marking, Member States have different requests for certification and tests. Since the company produces tailor-made products, all terms and conditions are agreed with customers before producing. However, in public tenders it can be problematic that Member States have different rules, because there may be rules/requests for tests that the company cannot foresee and take into account, since they do not know the national markets well enough. If they were selling standard products (in non-harmonised areas with no CE-marking), the differences between Member State would have been a greater issue (see Case 10).

The **food and food supplement sectors**, particularly with respect to food enrichers such as vitamins, is another area where companies experience many national rules. According to the product contact point and company interviews, Member States like Denmark and Spain have rather strict rules with respect to the maximum amount of vitamins and minerals present in food and food supplements, whereas other countries, such as the UK, have less strict rules or even, in some cases, rules for including particular enrichers such as iron in wheat. The amount of vitamins and minerals is not (yet) harmonised, whereas the types of vitamins and minerals permitted for use in food and food supplements are harmonised by Directive 2002/46/EC.<sup>241</sup>

One large company provides an example from Denmark, which is one of the countries where the rules for enriched food (with added vitamins and minerals) are strict. In some areas, Denmark has special rules justified by food safety.<sup>242</sup> Danish policy is to not let enriched

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238 European Commission (2011): Guidance document - The application of the Mutual Recognition Regulation to non-CE –marked construction products

239 Case C-171/11 – Reference for a preliminary ruling of 30.3.2011

240 Copenhagen Economics (2012): Delivering a stronger single market

241 European Commission (2010): Guidance Document - The application of the Mutual Recognition Regulation to food supplements

242 see also TRIS notification 2014/203/DK, where it is highlighted that “The Danish Veterinary and Food Administration finds that, in the interests of protecting human health, there is a need for national regulation until common rules have been introduced” <http://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2014&num=203>

foodstuffs onto the market (by keeping the tolerated level of enrichers close to zero), unless special permission is given by the Danish Veterinary and Food Administration (which rarely happens according to the company in question). Enriched foodstuffs are thus effectively blocked from the Danish market, and the mutual recognition principle is not applied in this area. The company in question has chosen not to contest the rule since the policy is very firm, and Denmark is such a small market that it is not worth the cost of having the policy tested. The company simply refrains from marketing the products in question in Denmark. It is estimated that this product type could amount to 5% of annual sales (i.e. foregone revenues), see Case 8 for further information.

The above-mentioned company as well as the Spanish product contact point call for further harmonisation in the area of enriched food and food supplements. The Spanish product contact point stated that as the rules on food enrichers and food supplements (vitamins, minerals) are stricter in Spain than in other Member State, it is difficult for the mutual recognition principle to function properly in this sector. Spain has, for instance, prior authorisation procedures in this area to ensure that foreign companies comply with the national legislation. The situation is quite resource consuming, both for the companies, but also for the product contact points. However, it may be challenging to harmonise the allowed amounts of vitamins and minerals in food, as the acceptable levels appear to differ considerably in various Member States.

Product classification differences can also cause problems. Within the area of **fertilisers**, companies typically experience barriers because, as mentioned above, there are different classifications of products as fertilisers in different Member States. Within the area of fertilisers, Commission services estimate that the current situation in the market, where fertilisers are categorised very differently in different Member States, costs economic operators around 26 million euros in total on a yearly basis. These costs stem from placing a new product on the market. By listing the authorised ingredients, the Commission estimates that the costs for economic operators will be reduced to around 1 million euros.<sup>243</sup>

Another example (but in a different sector) was mentioned in the case of a French sports equipment company that had to withdraw certain exercise products from the German and UK market, as they resembled a weapon and therefore were classified as a weapon in these two countries. The strategy for economic operators in this type of case was withdrawal from the market, resulting in missed market opportunities (see Case 9).

### **Proportionality of the administrative burdens**

The typical administrative burdens associated with the implementation of the principle of mutual recognition mainly affect the companies seeking to export products into a particular market. These burdens are closely related to the requirement from different Member States for national tests, even though the mutual recognition principle should apply. As previously discussed, Member States sometimes use the derogations allowed under the mutual recognition principle (protection of public health, safety, etc.) without substantial justifications. In principle, the Member States are only allowed to use the derogations under strict conditions, but in reality, the reasons for establishing technical rules are not always well justified.

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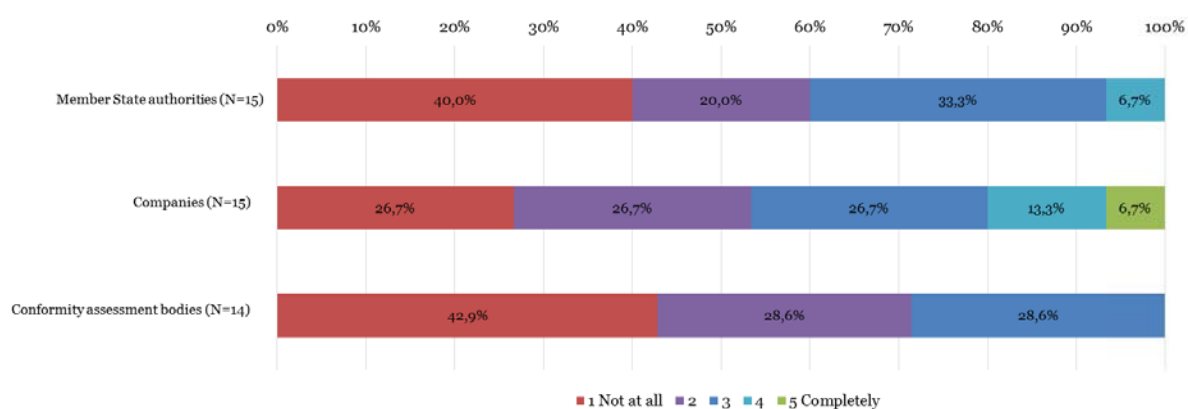
243 Information provided by Commission services

This means that if the mutual recognition principle was functioning efficiently, the companies would not be subject to the burden of having to adapt or retest their products. These burdens, imposed on companies from the incorrect application of the mutual recognition principle, cannot be justified, but the problem is that the only alternative that companies feel that they have would be a court case, which is both too costly and takes too long. The burdens of carrying out the alternative would then be even greater. Several companies have stated that they do not consider discussing the fairness of the technical rules with Member State authorities as an option (too costly and takes too long), and simply just follow the demands. In a few cases, if the market is small, the company has chosen not to enter that market.

Product contact points also experience that administrative burdens exist, which again is due to incorrect application of the mutual recognition principle or, sometimes, the lack of trust between Member States. For instance, within the area of fertilisers, some Member State authorities have expressed strong concerns to the Commission that their administrations might be overwhelmed if many fertilising materials lawfully placed on the market in other Member States with different technical requirements were to be placed on their markets over a short period. National authorities would not be able to react within the period provided for by the Mutual Recognition Regulation. Member States are concerned that this could lead to a situation where products lawfully marketed in another Member State would be marketed in their territories as well, without giving the receiving Member State any impact on the parameters used for the assessment of their potential risks for health and the environment. There are also concerns that inappropriate or low quality products will enter the market.<sup>244</sup> These concerns may have to do with the different classifications of fertilisers in different Member States mentioned in the product contact point interviews, but also that the Member States do not put sufficient trust in each other's regimes.

The product contact point survey revealed that the product contact points perceive that administrative and regulatory burdens particularly exist for companies as illustrated in Figure 8-8.

**Figure 8-11: Product contact point survey: Are there administrative and regulatory burdens for the following stakeholders?**



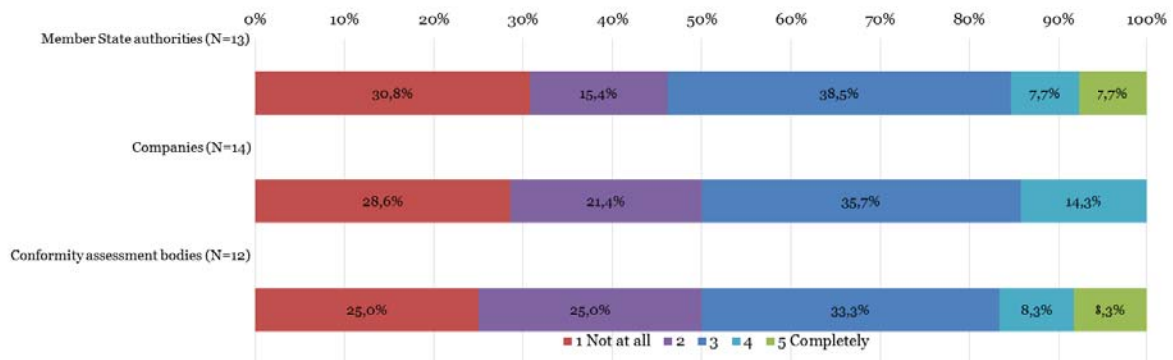
Source: Questionnaire survey among PCPs, running from 9 October 2014 to 5 January 2015, carried out by DTI

When it comes to the proportionality of the burdens, around one-fourth of the product contact points find the burdens not to be proportionate at all, neither for Member State authorities,

244 Information on fertilisers provided by the Commission services

companies nor for conformity assessment bodies. However, it is important to underline that the burdens are a result of the incorrect application of the mutual recognition principle, and not a result of the implementation of the principle as such.<sup>245</sup>

**Figure 8-12: Product contact point survey: Are the burdens considered proportionate?**



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

The requirements for the product contact points are relatively limited. Under Regulation 764/2008 (Art. 10), the product contact points are required to inform economic operators of the technical rules applicable to specific types of products, contact details of the relevant competent authorities, and available solutions for resolving potential disputes between the competent authorities and the economic operators. In addition, product contact points are required to respond to the economic operator within 15 working days, but in practice, this obligation is often transferred to the competent authority. The competent authority is clearly requested to answer the questions from the economic operators and to notify the Commission and the economic operator about any refusals of market access within 20 working days (Art. 6.2). The main administrative burden identified in the product contact point interviews associated with the implementation of the mutual recognition principle is that answers to the economic operators and/or to the other product contact points must be translated into English. This can be difficult for competent authorities not used to communicating in English, and burdensome for the product contact points if the answer contains many technical terms. The possibility of establishing an electronic system for exchanging information between product contact points was already mentioned in the Mutual Recognition Regulation, and as mentioned earlier (section 0), the IMI system could be a means to limiting this burden.

### 3. AWARENESS AND APPLICATION OF THE PRINCIPLE BY THE MEMBER STATES

While the previous section took the perspective of the companies, this section takes the perspective of the Member States, their knowledge and understanding of the mutual recognition principle, and whether the principle is applied correctly by the Member States. The section covers issues such as notification practices, use of technical rules, mutual recognition clauses and prior authorisation procedures, as well as the dialogue between particularly product contact points in the different Member States. We begin with setting the

<sup>245</sup> Unavoidable costs are to check whether the mutual recognition principle applies. In addition, certain costs may be unavoidable when the technical rules of the Member State of destination comply with Articles 28 to 30 EC Treaty (European Commission (2007): Accompanying document to the Proposal for a directive of the European Parliament and of the Council laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision 3052/95/EC Impact assessment)

framework by taking a brief look at how the product contact point system is organised in the Member States.

### **Organisation of the product contact point system in the Member States**

The product contact point is the contact for the economic operator for questions pertaining to the application of the mutual recognition principle. Regulation 764/2008 states that “Member States shall designate Product Contact Points in their territories and shall communicate their contact details to the other Member States and to the Commission.” At the request of an economic operator, the product contact points shall within 15 days provide information on:

- the technical rules applicable to a specific type of product in the Member State in question;
- the contact details of the competent authorities within the Member State: and
- the remedies generally available in the Member State in the event of a dispute between the competent authorities and an economic operator.

Finally, the product contact points in the different Member States are expected to work together to solve potential issues for economic operators<sup>246</sup>. The detailed set-up of the product contact point function is left to the Member State.

The organisation and function of the product contact points vary significantly between Member States. Most Member States – both large and small – have a single product contact point, which is responsible for all queries regarding product-related EU legislation, including the Construction Products Regulation. In a few Member States (Estonia, Latvia and Poland), the product contact point function is split between a general product contact point and a product contact point specifically for construction products. In a small number of Member States (the Netherlands, Portugal and Romania), the product contact points’ responsibilities are divided between 6-7 sector ministries or inspectorates.

In almost all Member States, the product contact point (or the co-ordinator, where there are several product contact points) is located within the ministry responsible for industry/business and the internal market, often as part of a group or team dealing with internal market policy. Only in Slovenia is the product contact point placed in an independent institute (the Slovenian Institute for Standardisation).

A few product contact points handle queries (or part of queries) themselves. In Malta, the product contact point is responsible for all communication with companies, meaning that companies receive all answers from one authority. However, this setup is unique to Malta (and difficult, if not impossible, to handle in a large Member State), and in most cases queries from economic operators are passed on to the responsible ministry, department or directorate or, occasionally, the relevant local authority. This is, for instance, sometimes the case in Germany, where the responsible authority for the product is often found at Länder level. A rather extreme version of the decentralised setup can be found in France and Italy, where the product contact point is not a central unit in charge of the mutual recognition concept, but simply the contact point towards the Commission. As mentioned, in the case of Italy, the appointed product contact point claims not to deal with the mutual recognition topic at all.

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<sup>246</sup> Regulation (EC) No 764/2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC

This means that there is no single contact point for economic operators in Italy. Rather, they must contact the relevant ministry in charge of their product and receive their answer from this authority – without the product contact point being involved.

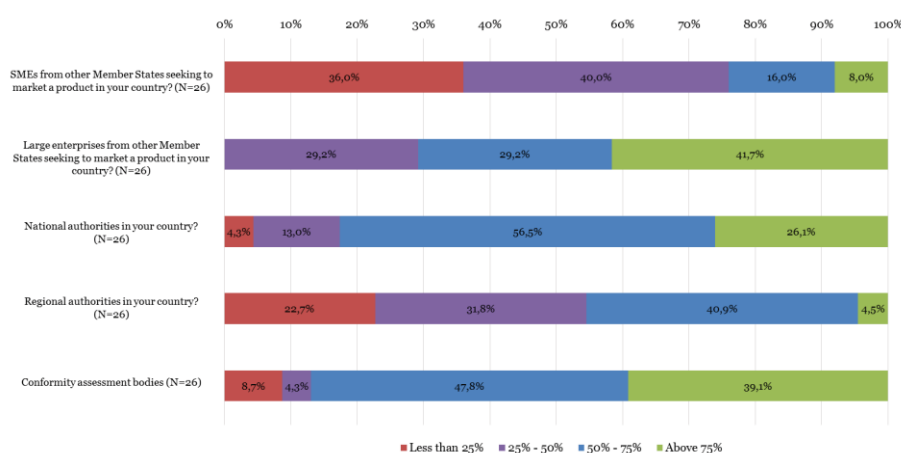
The responsible authority either replies directly to the company making the query, or passes the decision or answer back to the product contact point, which then communicates with the company. The first model, where the responsible authority replies directly to the company without involving the product contact point, appears to be the most widespread solution. In these cases, the product contact point may have little information on the outcome of the queries, as decisions can be notified directly by the competent authority without informing the product contact point (or not notified at all). The effects of this decentralised setup is analysed in further detail in section 5.3.3.

Although it was not a specific question in the interviews, a few product contact points provided examples of the volume of queries received, which ranged from 15-20 a year up to approx. 100 a year. The figures provided in these examples seem rather low and could indicate that many companies bypass the product contact point and go directly to the responsible ministries or authorities. However, there is no evidence to support this hypothesis further. In many cases, construction products and food additives are the areas where most queries are made. Both national and foreign companies use the product contact point system. In some countries (such as the Czech Republic), enquiries mainly come from national companies, whereas in other Member State such as Cyprus, the enquiries are mainly from foreign companies.

### Awareness and knowledge of the principle among national administrations

The product contact points were asked about their view of different stakeholders’ knowledge and understanding of the principle. Figure shows the answers.

**Figure 8-13: Product contact point survey: Based on your experience as a product contact point, what percentage of the main stakeholder groups know and understand the mutual recognition principle?**



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

As for knowledge of the mutual recognition principle among authorities in the Member States, the general assessment of the product contact points is that most *national authorities* are aware of and understand the principle of mutual recognition (third row in Figure 8-11). In the qualitative interviews, the knowledge of the mutual recognition principle among

authorities and enterprises was discussed too. 80% of the product contact points report that the majority of national authorities are relatively well versed in the mutual recognition principle.<sup>247</sup> However, the interviews showed that there are uncertainties among national authorities, which are sometimes rooted in the fact that some national authorities are more in touch with the mutual recognition principle than others are. Those national authorities that seldom get queries within their area are sometimes not very familiar with the principle. In one Member State, the product contact point stated that most of the authorities are not aware of the principle and do not know how to use it, which clearly is problematic. The product contact point of the Member State in question acknowledged the need for informing more about the mutual recognition principle, preferably with the support of the European Commission. In addition, the Spanish product contact point reports that companies lack information on the principle of mutual recognition and that in their opinion more information and dissemination activities are needed.

Several product contact points address the need for additional awareness campaigns, as the relevant authorities also need to be kept informed about any developments within the field of mutual recognition. In Member States where the product contact point has carried out such information campaigns, the knowledge of the mutual recognition principle and its application among the relevant authorities increases, although economic operators have not evaluated whether there is a real effect of these campaigns. Where the need for awareness campaigns is recognised but not acted upon, the reason is invariably a lack of resources for such activities.

In some Member States, there are specific areas where uncertainties arise, such as in the non-harmonised part of construction products. Ireland has assigned a specific technical rules coordinator in each government department, which helps to reduce uncertainty. However, it should also be mentioned that not all product contact points seem to have a thorough insight into the level of knowledge in the national authorities, simply because they are not contacted with questions from the relevant authorities, and they are not actively investigating whether the relevant authorities understand the mutual recognition principle well enough. In other words, the problem lies in the lack of communication/exchange of information between the product contact points and the relevant authorities. While this seems to be the situation in some Member States, other product contact points indicate in the personal interviews that they make an effort to inform regional and local authorities about the functioning of the mutual recognition principle.

Although the product contact points generally perceive the knowledge among national authorities to be fairly high, the qualitative interviews reveal that companies sometimes experience that a) the national authorities cite ‘health’ or ‘safety’ as a reason for not allowing a product on the market without justifying it further and b) the authorities do not easily accept innovative products. As can be seen from **Figure** , 21% of the companies in the company survey perceive the lack of knowledge or correct application of the mutual recognition principle by authorities to be the greatest obstacles to effective mutual recognition.

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247 80% of the PCPs state that more than 50% of all national authorities know and understand the mutual recognition principle



**Figure 8-14: Company survey: What are the obstacles to effective mutual recognition? Rank from 1-4**



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

As an example, one company experienced a situation where their application regarding fortification with iron in breakfast cereals was accepted, while the production of a cereal bar using the same fortified cereals was perceived as a different case, and had to be looked at again without automatically guaranteeing mutual recognition. This example may indicate that the competent authorities act in a rather rigid manner, an issue that is also raised by several business associations and the Swedish product contact point. This will be discussed in more detail in the following.

The surveyed product contact points also perceive a rather large share of the conformity assessment bodies to be well aware of the mutual recognition principle. However, at least one company example shows that although the conformity assessment bodies may be aware of the principle of mutual recognition, it is not always accepted. Germany has regional rules for approval of construction products falling outside of the harmonised area. In October 2014, the Commission notified that Germany must not ask for additional stamps or approvals<sup>248</sup>, but companies still face problems with it. The same company has also experienced issues with product types (surface coatings) where tests are not required in their home country, but they are required in Germany. In practice, the company tests its products in Germany, as the test facilities cannot be found in their home country because a test is not required there. Testing costs amount to approx. €7,000 per product, and the tests need to be repeated on a regular basis.

The situation is considerably different at the regional (and local) levels where around half of the product contact points assess that less than 50% of the regional authorities in their country are aware of the mutual recognition principle. If they are not directly involved in queries, this is not necessarily problematic. However, if they are, it is clearly problematic with regard to a proper application of the mutual recognition principle.

248 [http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item\\_id=7860&lang=en](http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=7860&lang=en)

## Notification practices

The relevant authorities are notifying the decisions not to allow a product on the market to the Commission. In addition, the product contact points report once a year to the Commission on the application of the mutual recognition principle and meet once a year in the mutual recognition consultative committee to discuss the matter. The notes from meetings in the consultative committee revealed that there are apparent discrepancies between the number of notifications received by the Commission and the number of decisions made by the Member State authorities reported in the annual reports. In 2012, there were at least 51 cases where the decision not to allow a product into the market was not communicated to the Commission.<sup>249</sup> There may be several reasons for this. One is that in some Member States with a decentralised administrative structure, regional or local bodies adopt negative decisions that are notified neither to the central government (which prepares the annual reports) nor to the Commission. Another reason is that there still seems to be some misunderstandings as to the scope of the Mutual Recognition Regulation as well as to its relationship with other pieces of EU legislation. Thus, several negative decisions that were adopted by some Member States do not seem to have been considered to be among those decisions referred to in Article 2(1) of the Mutual Recognition Regulation and therefore not communicated to the Commission.<sup>250</sup>

In the interviews, the product contact points were asked whether it sometimes happened that negative decisions were not notified to the Commission. However, almost all product contact points stated either that no refusals had been made at all or that all refusals were notified. Three product contact points stated that they did not monitor this issue, because the authorities making the decision to refuse a product entry to the market do not notify the product contact point. However, they ask for information once a year when preparing the yearly reports on the application of the mutual recognition principle to the Commission. Only one product contact point admitted that in one or two cases refusals had been made without notifying the Commission. When asked what it would take for their country to notify more refusals, most product contact points were consistently of the opinion that there is no need for improvement, since everything is notified or no refusals have been made. One product contact point suggested that notification should be made a legal obligation, supported by a system of relevant sanctions.

However, adding to this picture is the decentralised structure of the product contact point system discussed above. Although the product contact points receive a yearly update when they are to report to the Commission on the notifications, the decentralised system favoured by many Member State poses a risk that inconsistencies appear, and this can be an explanation for the discrepancies explained above. In some Member States, such as Germany, the responsibility for notifications is at the regional (Länder) level, meaning that all competent authorities at this level can adopt decisions according to Regulation 764/2008 and would then need to notify the Commission. In addition, even in areas where the ECJ has delivered an unequivocal judgment, national administrations often still fail to apply the principle of mutual recognition correctly. Janssens (2013) suggests that this is due to weak monitoring of ECJ case law in several Member State.

Some product contact points receive a copy of the decision/answer or are otherwise kept informed about the decisions made. Other product contact points, such as the one in Belgium,

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249 Note: 'At least' because the UK reported 'several' cases. These were not communicated to the Commission; some of them at least because they allegedly took place within the framework of an informal dialogue with the economic operators. European Commission working document (2012): Yearly reports on the application of Regulation (EC) No 764/2008

250 European Commission (2012): Yearly reports on the application of Regulation (EC) No 764/2008-2012

are in charge of sending out all decisions. In the Czech Republic, the product contact point has a network of experts at each relevant authority, and the product contact point works in close cooperation with these. In Poland, there is frequent communication with the relevant authorities, thus keeping the product contact point updated on any cases. In Portugal, where the product contact point function is divided between seven ministries, each product contact point has to report about the questions received and copy written answers to the Portuguese Institute for Quality, which then keeps track of queries. According to one of the Portuguese product contact points, this provides a very good overview of the situation in the country regarding the application of the mutual recognition principle. A simpler version of this system could be that the relevant authorities copy the product contact point on the final communications with the economic operators, and that the product contact point has to record this information in a database as one of its obligations.

### **Use of technical rules**

According to the Mutual Recognition Regulation, Member States may put technical rules in place but these must be justified (cf. section 4.2). However, Member States sometimes mistake safety for quality. For example, Member States present mutual recognition clauses, which state that a product should be allowed, “provided the product offers a similar level of protection as the products in the Member State.” This statement is not compatible with EU law, as it should not specify a ‘similar level’ – the product is either safe or not safe. If a product from country X is already safe, but the product in country Y is safer, it is not a valid reason for excluding the product from country X.<sup>251</sup> Business organisations have indicated that Member States use these barriers too often.<sup>252</sup> They are not necessarily perceived as intentional attempts to keep a product out of the market, but rather as problems with fully understanding the application of the mutual recognition principle. For instance, innovative products that do not easily fit into pre-defined boxes of what a product can do can pose problems. In these instances, it is often seen that the national authorities demand extra tests that are not necessary, since the product is already approved in its home country.<sup>253</sup> Three business associations stated that the Member State authorities tend to be risk averse and act in a cautious manner, thus making it difficult for companies with innovative products to enter markets in other Member States even though they are proven safe in their home country.

Along these lines, the interviews with the national business associations and the position papers received from Business Europe<sup>254</sup> and Orgalime<sup>255</sup> revealed that national technical barriers are often perceived to be unjustified. Sometimes, Member States do not provide the necessary justification when introducing a national technical regulation – a requirement that is clearly stated in Art. 8 of Directive 98/34 governing the notification procedure. According to several business associations, Member States also often cite general ‘safety reasons’ or ‘health reasons’ – even when these are too vague to justify a new national rule.

To analyse the number of new technical regulations that are being proposed in the Member States, which potentially can create barriers in the Internal Market, the TRIS database was investigated. TRIS (Technical Regulation Information System) is part of the 98/34 procedure, which aims to prevent creating barriers in the internal market before they materialise. Member States notify their legislative projects regarding products and Information Society services to

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251 Interview with DG ENTR

252 Interview with Eurocommerce

253 Interview with DI, the Danish Business Association

254 Business Europe (2014): Position Paper: Evaluation of the application of the principle of mutual recognition of goods

255 Orgalime (2014): Position Paper: Suggestions for improving the application of the mutual recognition principle

the Commission, which analyses these projects in the light of EU legislation. Member States participate on an equal footing with the Commission in this procedure and are able to issue their opinions on the notified drafts. Thus, TRIS helps stakeholders to be informed of new draft technical regulations. It also allows Member State to participate in the 98/34 procedure.<sup>256</sup>

Data from the TRIS database shows that in 2014 the Member States submitted 685 new draft technical regulations. Table 8-2 shows an overview of the draft technical regulations submitted the last three years.

**Table 8-2: Overview of draft technical regulations submitted to TRIS, 2012-2014**

| 2012  |               |                 | 2013  |               |                 | 2014  |               |                 |
|-------|---------------|-----------------|-------|---------------|-----------------|-------|---------------|-----------------|
| Total | With comments | Incl. MR clause | Total | With comments | Incl. MR clause | Total | With comments | Incl. MR clause |
| 755   | 227           | 69              | 728   | 191           | 79              | 685   | 224           | 57              |

Source: TRIS database, <http://ec.europa.eu/growth/tools-databases/tris/da/search/>

From Table 8-2, it appears that the total number of draft technical regulations submitted to TRIS has decreased slightly over the past few years. Of the 685 draft technical regulations in 2014, Member States or the Commission had comments for 224 draft technical regulations. Fifty-seven of these included the term ‘mutual recognition clause’, which is an indication that the technical regulation pertains to the Mutual Recognition Regulation. The sectors where the technical regulations are found differ considerably, but the sectors with the most draft technical regulations include the construction sector (67 cases), foodstuffs (39 cases), and chemical products (21 cases).<sup>257</sup> Although many of these undoubtedly are justified, it is potentially a very large number of new technical regulations that companies have to take into consideration to assess whether the mutual recognition principle applies or not. For instance, in 2014 Italy stated that all non-alcoholic fruit-flavoured beverages must contain no less than 20 per cent natural fruit juice, stating health protection as the justification. Several objections, among others from the Commission, led to the amendment of this proposal.<sup>258</sup>

The view across product contact points is quite varied, when asked about the extent to which Member States as a whole have limited their use of technical rules, and span the scale from ‘not at all’ to ‘to a very high degree’. Views are similarly split when it comes to the extent to which their own countries have limited the use of technical rules over the past five years (since the Mutual Recognition Regulation came into force in 2009 (see Figure 8-13).

256 <http://ec.europa.eu/growth/tools-databases/tris/en/>

257 <http://ec.europa.eu/enterprise/tris/en/search/>

258 2014/316/I, <http://ec.europa.eu/growth/tools-databases/tris/da/index.cfm/search/?trisaction=search.detail&year=2014&num=316&mLang=EN>

**Figure 8-15: Product contact point survey: The effects of the mutual recognition principle as perceived by product contact points**



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

Perhaps the most striking finding from Figure 8-13 is that about one in five of the product contact points did not know the answer to the question of whether their own Member State had limited the use of technical rules. The evaluator assigns this finding to the decentralised setup governing the mutual recognition principle identified in many Member States, which is true for at least three of the Member States that did not know the answer to this question (the rest were EFTA-countries). A requirement that the product contact points need to actively collect this information would probably significantly change this picture, and more importantly: it would help to ensure that the use of technical rules does not increase without good justifications.

#### *Application of the principle (administration towards companies)*

Another issue that emerges from the product contact point interviews is that there is a lack of clarity concerning what kinds of documentation the companies should submit to document that their products are lawfully marketed in another Member State. One product contact point even states that clarification as to what ‘lawfully marketed’ means could be useful. While the concept ‘lawfully marketed’ is not defined as such in the Mutual Recognition regulation itself, Regulation (EC) No 765/2008 defines the concepts of ‘making available and placing on the market’. ‘Making available on the market’ means any supply of a product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge. ‘Placing on the market’ means the initial making available of a product on the Union market. Thus, for products that are subject to the Mutual Recognition Regulation, the Commission considers the concept of ‘marketing’ to mean any supply of a product for distribution, consumption or use in another Member State or in an EFTA state that is a contracting party to the EEA Agreement. ‘Lawful marketing’ is therefore perceived by the Commission as marketing in another Member State or an EFTA state that is a contracting party to the EEA Agreement in accordance with the applicable national legislation.<sup>259</sup>

259 European Commission (2013): Commission working document: Guidance document. The concept of “lawfully marketed” in the Mutual Recognition Regulation (EC) No. 764/2008

Several product contact points point out that the lack of clarity concerning what documentation companies should be requested to submit to document ‘lawful marketing’ complicates and delays the process both for companies that do not know beforehand which documentation will be required and for the authorities in the destination Member State. Several product contact points thus called for guidelines to help determine for each product (group) what kinds of documentation will be needed to prove the companies’ claims. Regulation 764/2008 states in Article 4 that companies should submit ‘relevant information concerning the characteristics of the product or type of product in question’ as well as ‘relevant and readily available information on the lawful marketing of the product in another Member State’. The Mutual Recognition Regulation does not specify the means of evidence that may be used by economic operators to demonstrate that a product has been lawfully marketed in another Member State or in an EFTA state. This avoids imposing any additional administrative burden and does not limit in any way the means of evidence that an economic operator may present as part of the information mentioned by Article 4(b) to the authorities of the Member State of destination. In its guidance document<sup>260</sup>, the Commission states that to demonstrate the actual marketing of the product in another Member State, or in an EFTA state, *any* piece of evidence should be deemed suitable. This evidence could be a product invoice, product label, catalogue with evidence of a date, sale or tax records, registrations, licences, notifications to/from the authorities, certifications, extracts from public records, etc.<sup>261</sup> Obviously, this limits the burdens on the economic operators that they do not need an official statement, which is intentional. However, it also leaves the product contact points with little guidance on when, for instance, a product invoice is sufficient proof that a product has been marketed in another Member State in accordance with the applicable national legislation. This may again lead to additional administrative burdens on companies if the product contact point is unsure of the validity of the documentation and asks for additional documentation to be supplied.

#### *Use of Mutual Recognition clauses*

Mutual recognition clauses refer to a clause in a particular national legislation clearly stating that if a product meets the conditions set out by the destination Member State, it can be marketed in that Member State. An example of a mutual recognition clause is presented below:

*“The application of this law is subject to Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State, and to subsequent amendments”.*<sup>262</sup>

Alternatively:

*“The requirements of this law do not apply to products lawfully marketed and/or produced in other Member State or in Turkey or to products legally produced in EFTA states which are*

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260 European Commission (2013): Commission working document: Guidance document. The concept of “lawfully marketed” in the Mutual Recognition Regulation (EC) No. 764/2008

261 European Commission (2013): Commission working document: Guidance document. The concept of “lawfully marketed” in the Mutual Recognition Regulation (EC) No. 764/2008

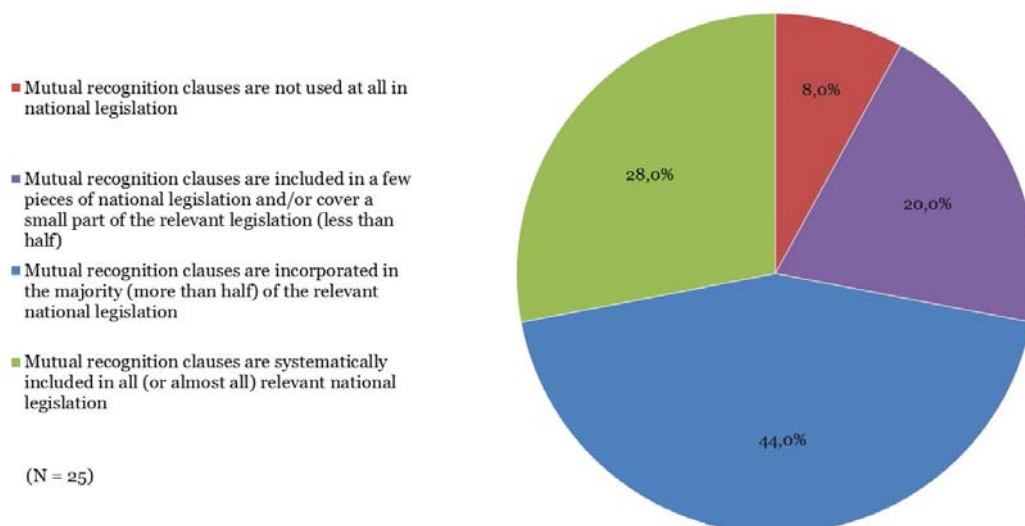
262 European Commission (2010): Guidance document – the relationship between Directive 98/34/EC and the Mutual Recognition regulation

*signatories to the EEA Agreement, provided that they provide a level of protection equivalent to that sought by this law”.*<sup>263</sup>.

In 1998, the European Court of Justice delivered an important judgement (the so-called *foie gras* case). The judgement states that a Member State must include a mutual recognition clause for products from other Member States, when a regulation on composition and production methods reserves the use of a certain trade description to products, which meets the conditions set out by the destination Member State.<sup>264</sup>

Many of the Member States are seeking to incorporate mutual recognition clauses in their legislation. From the product contact point survey, it can be seen that in three quarters of the countries whose product contact points participated in this evaluation, mutual recognition clauses are incorporated in the majority or all relevant national legislation. Mutual recognition clauses are only included in a few pieces of national legislation (Cyprus, Greece, Latvia, Lichtenstein, and Luxembourg) or not at all (the Netherlands) in about 1/4 of the countries.

**Figure 8-16: Product contact point survey: To what extent is the mutual recognition principle implemented in the national law of your country through so-called “mutual recognition clauses”?**



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

When the national authorities implement these clauses, the aim is to make it easier for companies and authorities to navigate on the internal market. The introduction of mutual recognition clauses in regulations is perceived by at least three product contact points<sup>265</sup> to render the mutual recognition principle more effective, and these product contact points call on the mutual recognition clauses to be enforced. Some product contact points are actively encouraging the relevant authorities to implement such clauses, but this practise could be even more widespread than indicated. Thus, even though there are differences between the Member

263 Presentation by Katrin Hendrix, DG ENTR Unit C5, Elimination of technical barriers to trade – principle of mutual recognition

264 European Commission (2003): Commission interpretative communication on facilitating the access of products to the markets of other Member States: the practical application of mutual recognition (2003/C 265/02)

265 “At least” because the question did not specifically address mutual recognition clauses, but asked what would render the mutual recognition principle more effective

States regarding the extent to which the mutual recognition principle is implemented in national legislation through mutual recognition clauses, the majority of the Member States do have such clauses and several see them as an effective tool towards rendering the mutual recognition principle more effective.

### **Use of prior authorisation procedures**

A prior authorisation procedure is an administrative procedure established by the legislation of a Member State in accordance with which, before a product may be placed on that Member State's market, the competent authority of that Member State must give formal approval following an application.<sup>266</sup>

Prior authorisation procedures are by definition a barrier to trade. The Court of Justice has repeatedly held that national legislation, which makes the marketing of products subject to a prior authorisation procedure, restricts the free movement of goods.<sup>267</sup> Therefore, in order to be justified with regard to the fundamental principle of the free movement of goods within the internal market, a mandatory prior authorisation procedure should:

- pursue a public interest-objective recognised by EU law; and
- be non-discriminatory and proportionate; i.e., it should be appropriate to ensure achievement of the aim pursued but not go beyond what is necessary in order to achieve that aim.<sup>268</sup>

Prior authorisation procedures may be justified and proportional, but Member States may also use them to delay the approvals of products that are due to enter the market. An effect may be that SMEs or economic operators with products of low added value (such as fertilisers, which are usually marketed in nearby countries due to high transport costs) end up not entering the market.<sup>269</sup> In addition, there is ample anecdotal evidence of national authorities demanding that a product be tested nationally.<sup>270</sup>

In the survey, the following distribution on the use of prior authorisation procedures can be seen:

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266 European Commission: THE APPLICATION OF MUTUAL RECOGNITION REGULATION (EC) 764/2008 TO PRIOR AUTHORISATION PROCEDURES, Draft Informal Guidance Document

267 European Commission: THE APPLICATION OF MUTUAL RECOGNITION REGULATION (EC) 764/2008 TO PRIOR AUTHORISATION PROCEDURES, Draft Informal Guidance Document. Judgments include: Judgment of the Court of Justice of 22 January 2002, Canal Satélite Digital SL, Case C-390/99., paragraph 43.; Judgment of the Court of 10 November 2005, Commission v Portuguese Republic, Case C-432/03., paragraph 52.; Judgment of the Court of 15 July 2004, Nicolas Schreiber, C-443/02., paragraphs 49-50.

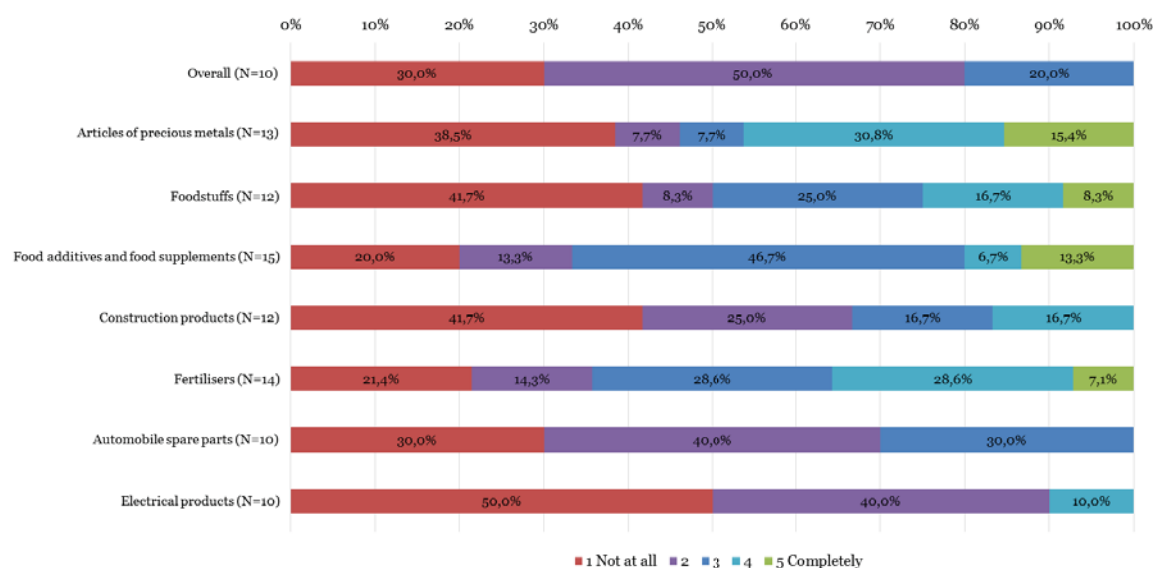
268 European Commission: THE APPLICATION OF MUTUAL RECOGNITION REGULATION (EC) 764/2008 TO PRIOR AUTHORISATION PROCEDURES, Draft Informal Guidance Document.

269 Interview with DG ENTR

270 Interview with Eurocommerce



**Figure 8-17: Product contact point survey: To what extent are prior authorisation procedures used in your country and for which sectors?**



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

Overall, relatively few product contact points were able to answer this question. The number of respondents varies between ten and fifteen. Only ten of the product contact points were able to provide an overall figure on the use of prior authorisation procedures. Of these ten product contact points, 80% state that the overall use of prior authorisation procedures is very low, ranging between ‘not at all’ and ‘to a low degree’. However, it is clear that prior authorisation procedures are especially used regarding articles of precious metals, food additives and food supplements, foodstuffs, and fertilisers. While product contact points may not be aware of the overall use of Prior Authorisation Procedures, they do know a few specific sectors where it is used. Again, the decentralised structure that exists in many Member States is an explanatory factor for this. In the qualitative interviews, some product contact points stated that they had no knowledge of the matter since such procedures are in the domain of the sector ministries and, apparently, any use of Prior Authorisation Procedures is not brought to the attention of the product contact point.

In the interviews carried out in the Member States, seven product contact points stated that they do not know about the situation, and four product contact points stated that Prior Authorisation Procedures are not used in their country. The majority of product contact points mentioned that such procedures are rarely used, and mostly in areas that affect human health and safety. The types of products that were most frequently indicated by product contact points as being subject to these procedures are fertilisers (11 Member States), food and food additives (four Member States), construction products in the non-harmonised area (four Member States), medical products (three Member States), automobile spare parts (two Member States), precious metals (two Member States) and animal traps (two Member States). It should be kept in mind that as a relatively large part of the product contact points do not have a good overview of this, the actual use of prior authorisation procedures may be higher than stated here.

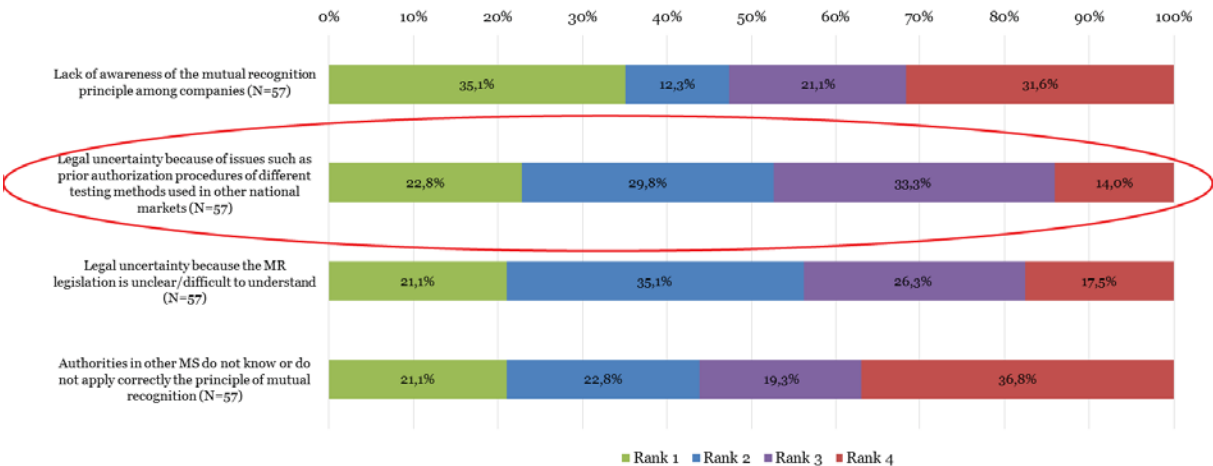
According to the qualitative interviews with the product contact points, ‘fertilisers’ are the sector where the prior authorisation procedures are most frequently used. Prior authorisation procedures concerning fertilisers are mainly used because the product is classified differently

in different Member States. For instance, in some Member States a fertiliser is classified as an herbicide supplement, whereas in other Member States, the same product is classified as a fertiliser. The same is true for food supplements. Particularly the permitted amount of certain enrichers, such as vitamins and minerals, is larger in some Member States than in others. The Member States with the strictest rules therefore often feel the need to introduce prior authorisation procedures. In a draft impact assessment of fertilisers carried out by the Commission, the same pattern can be identified.

Nine product contact points state that in their Member States, prior authorisation procedures are applied within this area, and the yearly reports of the Member States on the implementation of the mutual recognition principle show that 20 Member States out of 27 specifically mentioned issues relating to fertilisers. In addition, fertilisers are reported as one of the product categories for which economic operators submit many information requests to product contact points, which means that economic operators are uncertain about the requirements applicable in the different Member States. In February 2010, DG ENTR published a guidance document on the application of the Mutual Recognition Regulation to prior authorisation procedures.<sup>271</sup> However, as stated above, the yearly reports on the implementation of the mutual recognition principle do not show that this guidance document has eased the difficulties of economic operators in this regard within the area of fertilisers, particularly because there are still problems with what constitutes a fertiliser. The different definitions in different Member States result in almost all Member States perceiving the Mutual Recognition Regulation as not having the potential to create a functioning internal market for fertilisers<sup>272</sup>.

Companies were asked to rank the obstacles to effective mutual recognition. Here, prior authorisation procedures and differences in testing methods were ranked second.

**Figure 8-18: Company survey: What are the obstacles to effective mutual recognition? Rank from 1-4**



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

271 [http://ec.europa.eu/enterprise/policies/single-market-goods/free-movement-non-harmonised-sectors/mutual-recognition/index\\_en.htm](http://ec.europa.eu/enterprise/policies/single-market-goods/free-movement-non-harmonised-sectors/mutual-recognition/index_en.htm)  
 272 Information on fertilisers provided by the Commission services

## Differences in testing methods

According to an interview with (the then) DG MARKT, a common problem witnessed by the Commission is that products falling under the scope of the mutual recognition regulation are not accepted in other Member States due to the requirement to be tested again. In many cases, this can be difficult to resolve, as Member States claim that they need the testing for public health or safety reasons. However, as shown in section 4.1.4, the reasons are not always well justified. From a business perspective, the experience is that economic operators faced with this type of problem resolve the problem quickly by carrying out the necessary tests, or withdraw from the market. Businesses can generally not afford lengthy cases and potentially lose money in the process.<sup>273</sup> One company stated that they are aware that the concerns are not always well enough justified, but that court cases can take many years, which companies cannot afford to wait for. There is also the issue of court case costs for companies.

With respect to testing, most of the answers from the product contact points fall in one of two categories: 1) those that do not know the answer to this question, as they lack insight into other Member States' testing procedures (around 40% of the product contact points), and 2) those that accept the tests from other Member States (around half of the product contact points). Many product contact points highlight that the testing methods used in their country conform to European standards and are thus generally not different from those used in other Member States. However, this is contradicted by findings from the company survey and the company cases, which show that for approx. 60% of the companies, testing costs are either a 'very significant' or a 'significant cost'.

Clearly, there are instances where national tests are required by the destination Member State. Two aspects stand out from the interviews. One is when a non-accredited laboratory has tested the product. Here, the tests sometimes need to be repeated, or companies have to provide evidence that the test is performed by an equivalent of an accredited body, which puts a higher burden of proof on the companies. The other issue is related to the first issue and has to do with outdated legislation. In a specific example from Sweden, the maritime authorities had rules for testing the level of emissions from ships (NOx) but the rules were outdated. This implied that tests by bodies accredited according to the regulation had to be accepted, but also that tests from bodies that had been accredited according to an international agreement should be accepted, and also tests from non-accredited bodies (but with additional evidence that the bodies had competences equivalent to accredited bodies).

Closely related to the issue of outdated legislation is that some administrators apply the rules directly and do not consider the mutual recognition principle. Often, they only change their administrative processes if the regulation is changed. The Swedish product contact point perceives the issue of outdated legislation and its routine application (i.e. without considering the mutual recognition principle) to be a problem all over the EU. We do not have additional evidence on this from the product contact point interviews, but anecdotal evidence from the company interviews and the interviews with business associations suggests that it can be particularly difficult for innovative products to gain immediate acceptance in other Member States, although they are considered safe in the home Member State. As an example, one company produces a tap water system with pipes installed in the wall, but in at least one Member State the rule is that the pipes need to be visible, despite the fact that it has been proven in numerous tests that the pipes in the system do not leak. This is an example of a product that does not comply with legislation that was adopted before the innovative idea

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273 Interview with Eurocommerce

came onto the market. Business associations and companies have seen examples of Member State authorities acting in a precautionary manner and simply applying the old legislation, even though the innovative product should be covered by the mutual recognition principle.

The companies may also experience barriers related to testing if a standardisation/test body is so dominant on the market that even though the company is not legally required to conform to its standards, in practice it is impossible to market products on the market without doing so. This issue is explained in more detail below.

#### **Textbox 8-4: The case of Italian copper fittings (construction product) in Germany**

In 2011, an Italian company, manufacturing and selling copper fittings, took a case to court in Germany. In 2000, the Italian company has been granted a water industry certificate necessary for operating on the German market for five years. However, in 2005, amendments were made to the certification process, including a 3000-hour test. Subsequently, the Italian company's certificate was cancelled, since the company had not produced the said test. The company found this cancellation unlawful and saw it as a protectionist measure, and took the case to court since the case law of the European Court of Justice had so far not produced any reliable assessment. In short, the company was not successful in its claim, mainly because the conditions laid down by the European Commission with respect to the lawful drawing-up of technical standards was fulfilled, and that the 3000-hour test was not introduced for discriminatory reasons. In addition, companies were given the opportunity to take part in the standardisation process. However, the Court and the Commission consider it highly problematic if a standardisation body is so dominant on the market in terms of drawing up standards, certifying products, etc., that distribution of products on the market is virtually impossible without conforming to this institute's standards, particularly when producers are free to develop other standards or products. In essence, this is a problem of a dominant player on the market, which forces the companies to adapt to its standards, although the mutual recognition principle may apply. The Court called for further clarification on this issue, and it is still not clear what legal steps (if any) could be taken to solve this issue.

Source: ECJ: Case C-171/11 – Reference for a preliminary ruling of 30.3.2011

#### **Communication among product contact points and between product contact points and the Commission**

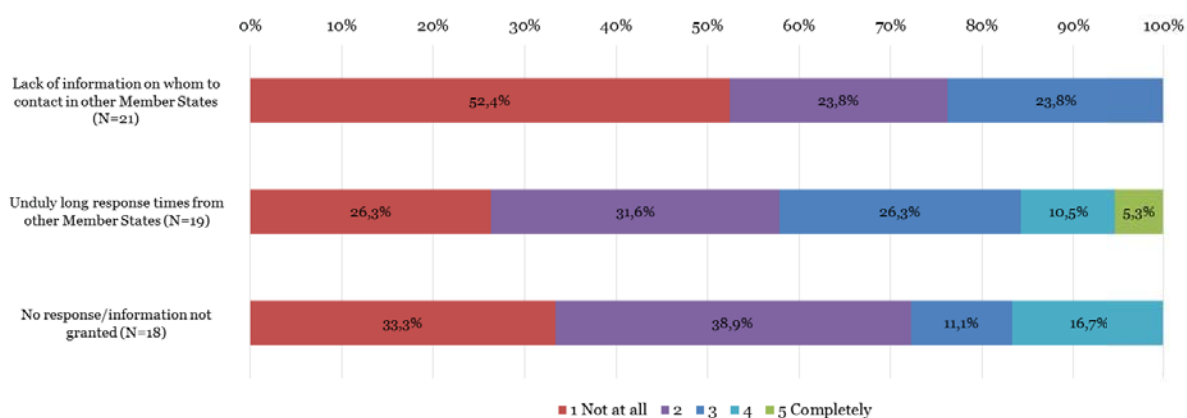
Another challenge related to the application of the mutual recognition principle is the slow communication between product contact points that is sometimes encountered. In a Commission report from 2012 regarding yearly reports on the application of Regulation (EC) No 764/2008-2012, the example was presented of the Danish product contact point staff in some instances having to ask for the Commission's assistance in order to receive answers. Slow replies are unsatisfactory (and potentially costly) for businesses and risk undermining the cooperation between authorities in the product contact point network. The French product contact point mentioned similar issues in the 2012 report. However, it is also clear from the report that there are great differences in product contact point response times. Moreover, the Polish product contact point indicated the need for exchanges of experience, good practices and broad discussions on the subject of the operation of the product contact points, and the practical application of the provisions of the 'goods package' among those directly involved in

the activities of the product contact points.<sup>274</sup> This also indicates a need to debate whether the communication in the product contact point system could be improved.

The product contact point survey indicated that barriers to dialogue with other Member States do exist, but also that not all product contact points experience this.

Figure indicates that the main problems are unduly long response times from other Member States and lack of response/information not granted by other product contact points. One out of four product contact points stated that there were no problems with delays, while the remainder reported some or significant problems with unduly long response times from other Member States. When asked whether information is sometimes not granted or no answer provided, two-thirds of the product contact points reported some or significant problems regarding this issue.

**Figure 8-19: Product contact point survey: Do barriers to dialogue with other Member States exist? (For instance in connection with requests for information on specific products)**



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

The interviews with product contact points provided similar indications. Some product contact points have little dialogue with other Member States and can therefore not report any problems, whereas other product contact points have only experienced good dialogue with fast and accurate answers. However, eight product contact points highlight problems with either unsatisfactory response times by some Member States, and/or information that is not sufficient to help the economic operators.

The product contact points that mentioned **unsatisfactory response times** by some Member States gave different examples of this. One product contact point stated that sometimes the wait is 40-50 days for a response from another Member State, rather than the 15 working days, which is the normal time allowed within the product contact point network. Sometimes, according to another product contact point, it can take a long time for the product contact points even to confirm that they have received the question. Another product contact point states that sometimes the communication is excellent and answers are received within a few days, but that there are also cases where getting in contact is very difficult:

274 European Commission (2012): Yearly reports on the application of Regulation (EC) No 764/2008-2012

“I would say that 20% of the cases are handled in a rather bad manner. One has to ask over and over again, and still it is not certain that they will answer at all”.

The feeling among those product contact points that commented on this issue is that the majority of the dialogue is effective and timely, but that a few Member States repeatedly contribute to significant delays. However, none of the interviewees wanted to identify these Member States.

Two product contact points question the 15 working days, which as mentioned above is the time allowed product contact points to answer a request. They find it difficult to answer within that period, typically if the request needs to be distributed to local authorities with limited knowledge of English. Then it is often the duty of the product contact point to translate the answer into English, which can take some time as the technical wording in an area outside of the product contact point’s competence can cause problems.

In addition, some product contact points have experienced issues with the **language and/or quality of the reply**. It appears that some product contact points reply in their national language and/or link to the national legislation in their original language. Others send a general answer that is not concrete enough for the product contact points asking the question to advise the companies adequately. The quality of the information varies, and one product contact point has experienced receiving contradicting information. Another product contact point states that problems such as these obviously delay the process for the companies. The product contact points in question cannot always help the companies in an optimal way, as they cannot read and communicate the relevant regulation to the company. As a result, the companies perceive the response time from the product contact point to be slow and the service level to be inadequate. In that way, it becomes even more difficult for the product contact points to communicate enquiries and issues regarding market access, national requirements, etc.

Some product contact points have called for a translation tool for authorities to be able to process the requests more effectively when the question or the answer is provided in a language not understood by the other party. Clearly, there needs to be some kind of quality control of such a translation tool to ensure that the translation is correct. The Commission could assist with this, particularly if the IMI system were to be used for communication among the product contact points, as discussed below.

The IMI system is one of the systems discussed in the literature, which might be used as a communication tool for the national authorities. The system, its possibilities and possible limitations are discussed in Textbox .

#### Textbox 8-5: The IMI system

- The IMI system has been in operation since 2008. It is a tool that allows authorities to communicate with each other and in some cases with the Commission. The system offers different flexible workflows. It allows competent authorities to communicate with each other on a one-on-one basis, or the competent authorities can communicate, for example, a piece of legislation to a number of other partners. Shared repositories can also be put into the system.
- Since IMI is for competent authorities, it could be used as a communication platform for product contact points. In addition, the ministries under which the product contact

### Textbox 8-5: The IMI system

points are established are often already using the IMI. However, a legal basis is required for cooperation/communication between product contact points. Therefore, the annex of the IMI Regulation would need to be amended to include a reference to this legal provision.

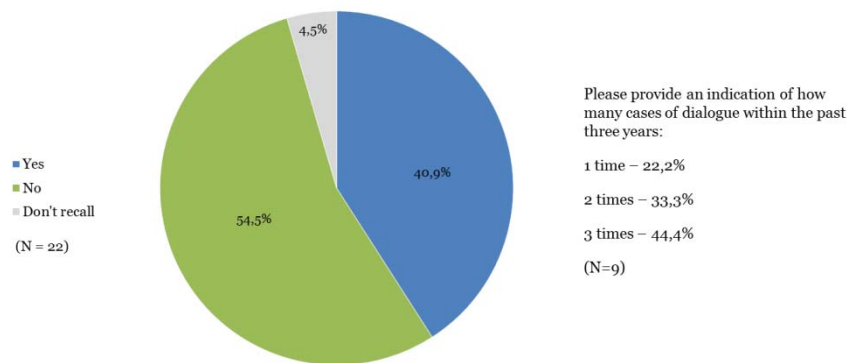
- Two features of the IMI system are particularly interesting for the national authorities, i.e. the multilingual approach and the security issue. The IMI system has a high level of traceability and security - features that are important to the authorities. With respect to the language issue, if a German national authority wants to ask a question, it can do so in German, and, e.g., a Portuguese authority can answer in Portuguese. However, as stated above, to ensure high quality in the translation, it is important that the translation be carried out either by a translator or, if carried out automatically, be checked by a translator. Currently, the system only provides an automatic translation, which is not likely to be sufficient for questions of a regulatory nature.
- In the Mutual Recognition Regulation, there are two articles where the IMI system could be of use:
  - 1. Network of product contact points – the IMI system can work as a communication platform for the product contact points, when they need to communicate to assist economic operators.
  - 2. Obligation to notify (Art. 6) - at present, notifications are sent to the Commission by e-mail. A more transparent and structured solution for notifications could be to use the IMI system. Moreover, the IMI system could be used as a way of storing the notifications. Art. 6 obliges product contact points to notify both companies and the Commission, but for the time being, only the Commission can be notified via IMI.
- DG GROW is looking at expanding the system in the future by offering a separate mechanism by which external actors like companies can interact with the IMI back office. It will be a different system, as due to security reasons IMI needs to be kept as a tool for public administration only, but the proposed new system would be connected with relevant features of the IMI system.

Lastly, it is important to note that the IMI is about cooperation and the use of the system is not obligatory, which means that Member States need to agree to use the IMI system. Therefore, it is important to sound out the Member States to see if there is a need for such a system, and a willingness to use it.

Source: Interview with DG MARKT and [http://ec.europa.eu/internal\\_market/imi-net/about/index\\_en.htm](http://ec.europa.eu/internal_market/imi-net/about/index_en.htm)

In the survey, the product contact points were also asked about **dialogue with the European Commission**. Nine product contact points (41%) have at some point engaged in dialogue with the Commission concerning the mutual recognition principle (apart from the yearly meetings in the Mutual Recognition Committee and the yearly reports that have to be submitted to the Commission), but only to a limited extent (maximum three cases in the last three years).

**Figure 8-20: Product contact point survey: Have you engaged in dialogue with the European Commission concerning the mutual recognition principle?**



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

There are a few explanations for the rather limited dialogue with the Commission. First, the product contact points report to the Commission once a year on the situation regarding the application of the mutual recognition principle, and they have a yearly meeting in the Mutual Recognition Committee. It may be that the product contact points believe that this communication is sufficient for them to inform the Commission of any shortcomings. Secondly, a great number of product contact points do not see any problems with the communication, or are not aware of any problems in the dialogue, and therefore may not see the need to interact with the Commission. For the latter group, the decentralised structure in many Member States can be the reason for product contact points not being aware of any issues, and therefore not communicating with the Commission.

### **Legal uncertainty**

Literature shows that stakeholders frequently face legal uncertainties regarding the scope of the application of the principle of mutual recognition.<sup>275</sup> It is often unclear to which categories of products mutual recognition applies, and since the principle of mutual recognition is based on the case law of the European Court of Justice, the legislation on mutual recognition does not and cannot contain a comprehensive list of products or aspects of products to which the principle should apply. Consequently, enterprises as well as national administrations need extensive knowledge of EU law in order to establish whether the principle of mutual recognition applies to a specific product or aspects of it.<sup>276</sup>

Findings from the literature review show that there is some uncertainty about how and when to apply the mutual recognition principle in practice. Businesses, product contact points and national administrations have all mentioned this issue.<sup>277</sup> For instance, the Spanish product

275 First Report on the application of Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0292:FIN:EN:PDF>.

276 ToR Evaluation of the application of the principal of mutual recognition in the field of goods.

277 European Commission (2012): First Report on the application of Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC. The information comes from the yearly reports on the application of the Mutual Recognition Regulation that Member States are required to submit to the Commission under Article 12(1) of the mutual recognition Regulation. The reports must include information on the number of written notices sent pursuant to Article 6(1) and the types of products concerned; sufficient information concerning any decisions taken pursuant to Article 6(2), including the grounds on which those decisions were based and the types of products concerned; and the number of decisions taken pursuant to Article 6(3) – intended negative decisions finally not adopted, and the types of products concerned.



contact point reported in the 2012 Annual report that companies lack information on the principle of mutual recognition, and that in their opinion more information and dissemination activities are needed.<sup>278</sup>

In the product contact point interviews conducted by the evaluation team it was found that approx. 50% of the product contact points state that the national authorities may not be fully aware of the application of the mutual recognition principle (cf. section 0 where this was discussed in more detail). However, in the interviews it is also mentioned that the product contact points and the national authorities sometimes experience difficulties with the application of the mutual recognition principle, particularly in the non-harmonised part of the construction sector and with food supplements. As mentioned above, the problem exists in the area of food supplements, the problem because of the differences in the amounts of enrichers that the Member States will allow in their food, and therefore there are very different national rules. These will prevail until the amounts of vitamins allowed in food supplements potentially are harmonised.<sup>279</sup>

### **Means or actors that render certain aspects of mutual recognition more (or less) effective than others**

The product contact points were asked if they could provide examples of means or actors in the system that contribute to making mutual recognition work more effective or less effective – in other words, good practices, or bad practices. This section concludes on some of the key issues that were identified in the previous analysis.

#### *Lack of awareness*

As discussed above, both in lack of awareness among companies and among some Member State authorities is an important barrier to effective implementation of the mutual recognition principle. Several product contact points call for awareness campaigns directed at different target groups to increase the effectiveness of the mutual recognition principle. Some product contact points call for the assistance of the Commission to carry out information campaigns, also because it would expand the reach of the information and, in one instance, because the product contact point has difficulties in financing the information campaigns. However, in other Member States, product contact points undertake seminars and training (e.g. Cyprus, Denmark, Lithuania, Slovakia, Slovenia, and Sweden). In Croatia, the interaction between the Mutual Recognition Regulation and, for example, Directive 98/34 is explained regularly to the competent authorities. The product contact point, which is also the Croatian 98/34 Central Unit, performs regular educational seminars and meetings with authorities and business associations. In Denmark, the product contact point has developed a guide on the use of the principle of mutual recognition that can be accessed on its website.

#### *Lack of trust*

The personal interviews with the business associations revealed that there are examples of Member States putting up barriers when requirements in one Member State are not equivalent to those of the destination Member State. These Member States require *equivalence of requirements*, which is very different from recognition of requirements, and this is a problem. Lack of trust in other Member States' procedures, interpretations and/or requirements – possibly due to a lack of understanding of each other's working practices – are often cited as

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278 European Commission (2012): Yearly reports on the application of Regulation (EC) No 764/2008-2012

279 European Commission (2010): Guidance Document - The application of the Mutual Recognition Regulation to food supplements

leading to these situations. This lack of trust can also result in authorities taking a very restrictive view of the mutual recognition principle. Whereas the main rule is that products should be sold freely and only be stopped in extraordinary circumstances, in practice lack of trust can result in authorities taking the opposite perspective, i.e. looking at the safety aspects/consumer interests with the free movement aspect as a secondary consideration. This can increase the use of prior authorisation procedures and/or different testing methods, which again can create legal uncertainty. In its position paper from 2014 produced for this evaluation, Orgalime suggests that an improvement in the market surveillance in all Member States is a key factor in improving trust and thereby improving the functioning of the mutual recognition principle. Increased and better market surveillance is expected to reduce the duplication of conformity assessment controls by authorities (as the level of trust is raised), which in turn benefits the economic operators.

In one case, the lack of trust reached all the way to companies. The perception of the product contact point in question was that companies know the mutual recognition principle very well and simply state that they are allowed to put the product on the market. Likewise, the product contact point believed that companies are ‘misusing’ the mutual recognition principle by putting their product first on a market where it is easy to be accepted and then using the mutual recognition principle to put their products on other markets. However, this is exactly what the mutual recognition principle should do, i.e. ensure that, in principle, products that are lawfully marketed in one Member State must be admitted to the market of any other Member State. Again, the lack of trust in other Member States is perceived to be the main reason behind this statement. If this lack of trust did not exist, the accusation of companies ‘speculating’ in where to market their products first would not exist either. However, it also demonstrates a lack of understanding of the reasoning behind the mutual recognition principle.

#### *Organisation of the product contact point function*

Another issue emerging from the interviews with the product contact points concerns the organisation of the product contact point and other internal market functions in the Member State administrations. The evaluator has no means objectively to assess the effectiveness of one set-up vs. another with respect to, e.g., response times or the correctness with which the mutual recognition principle is applied. However, comparing remarks from the different product contact points, it seems that grouping together related functions such as the product contact point, the contact point for construction products, and staff working with other internal market issues, seems to create good dynamics and increase the pool of knowledge available to the product contact point. This could be an example of good practice. A very different model for organising the product contact point function is found in a small minority of Member States where the product contact point function is divided between several ministries, departments, or other units, with one coordinating product contact point. The advantage of such a system is that the individual product contact points may have better insight into the specifics of their domain. The effectiveness of such a set-up depends very much on the details, in particular whether the lack of a single entry point for companies is balanced with good guidance on where to direct inquiries. In one of the Member States with this type of organisation, the view of the interviewed business association of the system was negative, since it was seen as confusing for companies. Table 8-3 presents an overview of the different set-ups in different Member States.

**Table 8-3: Overview of the different product contact point setups in Member States**

| Single contact point for practically all product-related EU legislation | PCP incorporated in a wider team dealing with Single Market policy | PCP responsibility divided among several ministries | One PCP, several national/regional authorities with product responsibility |
|---|--|---|--|
| Examples of Member States: Malta  | Examples of Member States: Denmark, UK                             | Examples of Member States: Portugal                 | Examples of Member States: Germany, Italy, France                          |

Source: PCP interviews

In Denmark and the UK, the product contact points have been incorporated in a wider team in the relevant ministry/authority dealing with the Single Market policy. This means that all questions regarding rules and regulations related to the functioning of the Internal Market can be answered by the same authority, which simplifies matters for the economic operators. Along these lines, Orgalime suggests in its position paper<sup>280</sup> that the product contact point function could be strengthened, for instance, by incorporating product contact points, SOLVIT, EEN and other supportive structures into a single contact point at national level.

A good practice emerging from the product contact point interviews is that product contact point functions are better informed about the outcome of the queries, which they pass on to other authorities in their country, would appear to be preferable to product contact points that do not receive a copy of the answer/decision or are otherwise not informed of the outcome. While having an overview of what actually happens when a query is made may not be a precondition for an effective system, at least an overview can contribute to identifying any bottlenecks or other problems in the system, which is the basis for addressing any such problems.

#### **4. MARKETS AND SECTORS WITH THE MOST PROBLEMS**

##### **Sectors with the most problems**

The minutes of the second meeting of the consultative Mutual Recognition Committee indicate that in 2010 and 2011 the product types that received the most inquiries or were subject to notifications were articles of precious metal, foodstuffs, food additives and food supplements, automotive spare parts, construction products and fertilisers.<sup>281</sup> The latest report published by the Commission (2012) on the application of the mutual recognition principle highlighted that the majority of decisions, requests for information and complaints received by the national administrations also concern specific categories of goods. In addition to precious metals<sup>282</sup>, foodstuffs, food additives and food supplements, construction products,

280 Orgalime (2014): Position paper: Suggestions for improving the application of the mutual recognition principle

281 European Commission (2010): Minutes of the second meeting of the consultative “Mutual Recognition Committee”, held in Brussels on 19 November 2010 and European Commission (2011): Minutes of the third meeting of the consultative “Mutual Recognition Committee”, held in Brussels on 30 November 2011.

282 However, this is a very specific case involving hallmarking of jewelry, where a Member State allowed hallmarking done by companies in China and other Member State would not accept this as hallmarking. Source: Interview with DG MARKT, DG ENTR.

fertilisers, and automobile spare parts as mentioned above, the report now also mentioned electrical products and spring water.<sup>283</sup>

The Commission's yearly reports on the application of the Mutual Recognition Regulation (2008-2012) shows that problems regarding construction products and food and foodstuffs seem to be a recurring issue. For instance, in Belgium, two major categories account for some 65% of all queries, i.e. construction products (44%) and consumer products<sup>284</sup> (21%). This suggests that there is still a relatively high level of uncertainty and/or problems in relation to these two types of products in the non-harmonised sectors. The situation in Poland follows this pattern, with the majority of the queries falling under construction products (42%) and consumer products<sup>285</sup> (12% on average). Subjects that recurred were how to document that a product has been lawfully placed on the market, CE marking, labelling, and the relationship between the Construction Products Regulation and mutual recognition procedures. Many of the answers to these issues can be found in the Commission's guidelines on the application of the mutual recognition principle. Other examples are seen in Latvia, which had inquiries and/or notifications regarding fertilisers, textiles, foodstuffs, and construction products; in Denmark, which particularly had queries regarding construction; and in the Netherlands, where there were inquiries within the construction products, (spring) water, cosmetics, fertilisers and biocides, and food supplements sectors.<sup>286</sup> However, as the subsequent product contact point interviews showed, queries do not necessarily mean that there are problems with the application of the mutual recognition principle. For instance, 70% of the queries in Spain are related to construction products, but since a large part of the area is harmonised, the issues do not arise in this area. Rather, the problems are within the area of food and food supplements, as national Member State rules differ considerably within this area.

The Commission's Enterprise Europe Network (EEN) carries out an SME survey (still pending) in all Member States asking, among other things, if and where SMEs have experienced problems with doing business in Europe. Around 21% of the reported cases (1648 out of 7817), concerned problems related to free movement of goods in the internal market. The sectors with the most problems related to the free movement of goods were foodstuffs (15%), construction products (9%), machines (8.5%), and agricultural products (6%).<sup>287</sup>

Food and construction products are also the sectors highlighted in the company interviews. As mentioned in section 4.2.3, it is particularly enriched food and the amount of vitamins and minerals allowed (within the food sector); water taps in contact with food (within construction) as well as the rather specific issue in the construction sector of the lack of respect of the mutual recognition principle, particularly in Germany.

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283 European Commission (2012): First Report on the application of Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC. The information comes from the yearly reports on the application of the Mutual Recognition Regulation that Member States are required to submit to the Commission under Article 12(1) of the Mutual Recognition Regulation. The reports include at least the information on the number of written notices sent pursuant to Article 6(1) and the type of products concerned; sufficient information concerning any decisions taken pursuant to Article 6(2), including the grounds on which those decisions were based and the type of products concerned; and the number of decisions taken pursuant to Article 6(3) – intended negative decisions finally not adopted, and the type of products concerned.

284 Not specified further in the reports

285 Not specified further in the reports

286 European Commission (2012): Yearly reports on the application of Regulation (EC) No 764/2008-2012

287 EEN Database, SME survey, <http://ec.europa.eu/yourvoice/ipm/forms/dispatch?form=smefeedback&lang=en> (accessed mid-January 2015)

Data from the SOLVIT<sup>288</sup> database also provides evidence of some areas where challenges to the free movement of goods occur. Generally, businesses tend to account for a very small number of SOLVIT cases, compared with the number of cases submitted by private individuals. In 2013, there were only 132 closed cases submitted by businesses, amounting to 9% of all cases. Moreover, very few SOLVIT cases involved the free movement of goods. In 2013, SOLVIT only had 30 cases (2% of all cases in 2013)<sup>289</sup> within the area of free movement of goods.<sup>290</sup> Previous SOLVIT reports and an analysis by the Centre for European Policy Studies<sup>291</sup> suggest that the low representation of businesses has to do with the fact that businesses prefer to have more legal certainty than SOLVIT can provide. Another reason is that proving that a particular national restrictive measure is unjustified calls for technical expertise and formal powers that SOLVIT centres do not have.<sup>292</sup>

Of the cases that SOLVIT received regarding the free movement of goods, some of the cases that could not be informally resolved include the following:<sup>293</sup>

#### Textbox 8-6: Examples of unsolved SOLVIT cases

- Labelling to show that a food product contains nuts. The Member State concerned rejected the argument that given the small quantity of nuts in the product, the wording 'contains traces of nuts' would be sufficient to protect consumers. The problem could not be resolved through SOLVIT.
- Certification of solar panels. A Member State insisted on certification by a national body, as it did not accept another Member State's certification (required to qualify for a grant). The applicants decided to go to court.
- Difficulty with importing fertilisers. Products from another Member State were not recognised as fertilisers, as the authority concerned interpreted the word 'fertilisers' differently. The case was closed because it could not be informally resolved, and the Commission started its own informal procedure against the country concerned.
- Transit of defence products through a Member State. The country of origin considered the transit licensing procedure to be disproportionate. Given its political sensitivity, the case could not be informally resolved.
- Acceptance of hallmarking by an organisation accredited by another Member State. This is generally also a politically sensitive matter, and it was impossible for the SOLVIT centres to resolve this case informally.
- Marketing of nutrition supplements. These products were marketed legally in many EU countries, but one Member State required them to be registered as medicinal products, refusing to let them be marketed as nutrition supplements. It was not possible to find an informal solution.
- The proportion of alcohol in a canned drink. These drinks were legally marketed in one

288 SOLVIT is a service provided by the national administration in each EU country and in Iceland, Liechtenstein and Norway. SOLVIT offers assistance when your EU rights as a citizen or as a business are breached by public authorities in another EU country and you have not (yet) taken your case to court. Source: [http://ec.europa.eu/solvit/what-is-solvit/index\\_en.htm](http://ec.europa.eu/solvit/what-is-solvit/index_en.htm)

289 [http://ec.europa.eu/internal\\_market/scoreboard/performance\\_by\\_governance\\_tool/solvit/index\\_en.htm](http://ec.europa.eu/internal_market/scoreboard/performance_by_governance_tool/solvit/index_en.htm)

290 [http://ec.europa.eu/internal\\_market/scoreboard/performance\\_by\\_governance\\_tool/solvit/index\\_en.htm](http://ec.europa.eu/internal_market/scoreboard/performance_by_governance_tool/solvit/index_en.htm)

291 Pelkmans and de Brito (2012): Enforcement in the EU Single Market, Centre for European Policy Studies

292 [http://ec.europa.eu/internal\\_market/scoreboard/performance\\_by\\_governance\\_tool/solvit/index\\_en.htm](http://ec.europa.eu/internal_market/scoreboard/performance_by_governance_tool/solvit/index_en.htm)

293 [http://ec.europa.eu/internal\\_market/scoreboard/performance\\_by\\_governance\\_tool/solvit/index\\_en.htm](http://ec.europa.eu/internal_market/scoreboard/performance_by_governance_tool/solvit/index_en.htm)

Member State, but the alcohol content meant they could not be sold in another Member State because of the latter's national legislation. As the national law was undergoing reform at the time, the relevant authorities were unable to resolve the problem informally.

- Registration of a certain type of trailer. The authorities of one Member State refused to register certain trailers. This made it impossible to sell them in that country. The issue was already under discussion in formal EU meetings between the authorities responsible for vehicle registration, so SOLVIT was unable to provide a solution. The matter was further taken up bilaterally between the respective authorities.

When discussing the SOLVIT cases with the then DG MARKT, the interviewee particularly recalls problems in the 'grey areas', for instance, with respect to food additives (the issue being whether these should be considered as food or vitamins/medicines), general food products (for instance, does it contain nuts, which may be considered important in some countries and not in others). Particularly the first issue with vitamins and minerals in food is also an area that has repeatedly been highlighted by product contact points and companies alike.

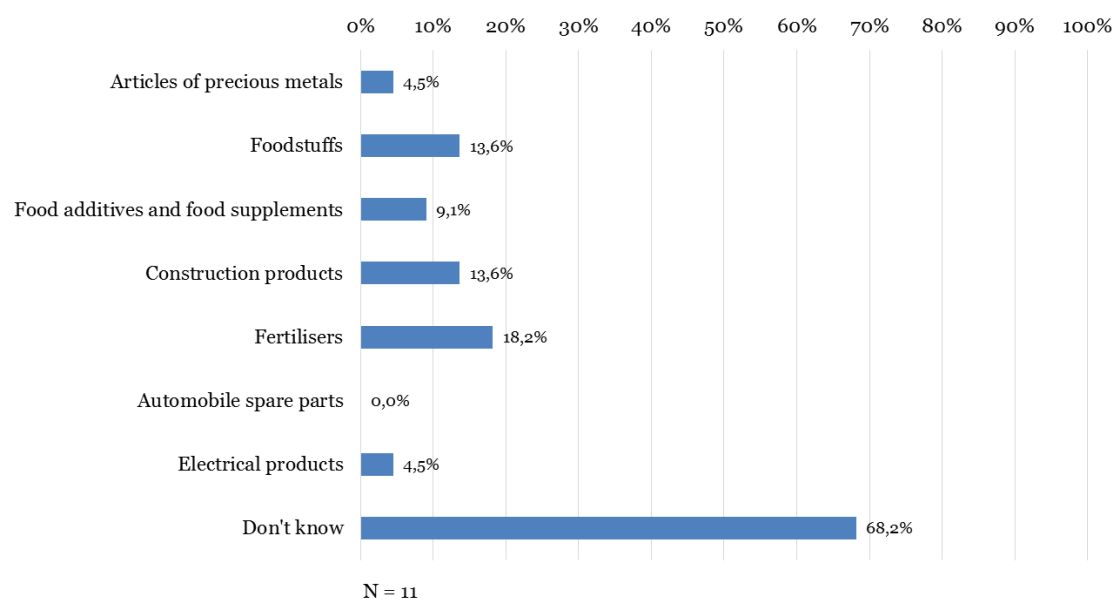
Another particular problem voiced by DG MOVE has to do with ship classification. A ship needs to be certified by a recognised classification society. Some products fall under the marine equipment directive and are thereby harmonised, but many types of equipment, such as engines, do not fall under that directive and are thus non-harmonised. This can lead to a situation where, for instance, a ship engine is built into different ships, but has to be inspected by four or five different classification societies, depending on which is responsible for the classification as a whole. This creates extensive administrative burdens for the economic operator.<sup>294</sup> However, this particular problem was only mentioned in one interview with the Commission and not highlighted by any economic operators.

The business associations particularly highlight fertilisers, construction products and foodstuffs as sectors where issues regarding the application of the mutual recognition principle are particularly pronounced, but many are not able to point to specific sectors (see Figure ).

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294 Interview with DG MOVE

**Figure 8-21: Business and sector association survey: Are there some sectors/subsectors where this problem is particularly pronounced? Please indicate which ones**



Source: Questionnaire survey among national business and sector associations, running from 9 October 2014 to 5 January 2015, carried out by DTI

Fertilisers were also mentioned in the product contact point interviews and in the SOLVIT-cases above. As mentioned previously, prior authorisation procedures are often used for fertilisers as the product is classified differently in different Member States.

In the company survey, the sectors represented by respondents are particularly construction products (42), nursery and childcare products (25), electrical products (15), foodstuffs (15), and articles of precious metals (12). Obviously, these are also the problematic sectors identified in the company survey. However, the evaluation team has experienced that companies mostly participate in surveys if they either see a benefit from it or feel that the subject needs to be addressed. It is therefore also interesting that the sector ‘Nursery and childcare products’ is relatively well represented. From the interviews, it seems that the challenges in this sector are similar to the ones experienced in the food sector, i.e. that certain Member States put up stricter rules than others do. One company interview revealed that the UK put up specific standards for the flammability of baby sleeping bags, citing safety as a reason. This clearly protects UK producers that respect these standards, but also limits the market for producers from other EU Member States.

The product contact point survey revealed that the sectors where product contact points believe that enterprises most often spend resources examining the technical rules are construction (nearly 45%), food and food additives/supplements (around 50%), and articles of precious metals and fertilisers (approx. 20% each).<sup>295</sup> The same sectors are predominant when it comes to the product contact points’ perception of the sectors in which economic operators most often adapt their products to local requirements. Problems with retesting of products are mainly perceived to be within the construction and food/food additives and supplements sectors.

295 The percentages do not add up to 100 as the respondents were able to select more than one sector

When it comes to the companies refraining from entering a foreign market, the product contact points perceive these problems to be most pronounced within the sectors of fertilisers, food/food additives and food supplements, and construction products.

To sum up, the sectors where the literature review, surveys and interviews most consistently point to problems with the application of the mutual recognition principle are:

- the non-harmonised area of construction where no CE-marking applies (for instance in the area of water taps);
- a general issue with construction products where the mutual recognition principle is not respected, particularly in Germany (an infringement case have been launched by the Commission<sup>296</sup>); and
- the area of enriched food where Member States tolerate different levels of vitamins and minerals.

Another area frequently mentioned is fertilisers, where the Member States have different definitions of what constitutes a fertiliser as described in section 0. Finally, nursery and childcare products (different standards in different Member State) and ship classification (demand for national tests) have emerged from the survey and the interviews respectively as sectors with problems in applying the mutual recognition principle.

The economic importance of the construction products and food sectors is considerable. Construction products are a large market, with a total (EU-28) turnover in 2012 of approx. 770 million euros. Moreover, in 2012, approx. 1.6 million persons were employed in this sector.<sup>297</sup>

In the food sector, the total (EU-28) turnover in 2013 was approx. one billion euros and the sector employed 315,000 persons.<sup>298</sup> The sector was growing slightly, with food and drink industry production in the EU increasing by 0.43% in Q4 of 2014.<sup>299</sup>

For fertilisers, the total (EU-28) turnover is 390 million euros, and the sector employs around 10,000 people.<sup>300</sup> Thus, the sector is of less economic importance in the EU than construction and food, but it is also one of the sectors with the greatest problems in reaching a common decision on what constitutes a fertiliser.

### **Markets with the most problems**

As can be seen from the company survey, the three largest national markets in the EU – Germany, France and the United Kingdom – clearly stand out in terms of the frequency of obstacles encountered by the surveyed companies.

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296 <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:62013CA0100>

297 Eurostat SBS: Annual detailed enterprise statistics for construction (Electrical, plumbing and other construction installation activities, Electrical installation, Plumbing, heat and air conditioning installation, and Other construction installation), and Annual detailed enterprise statistics for industry (Manufacture of bricks, tiles and construction products, in baked clay, Manufacture of concrete products for construction purposes, Manufacture of plaster products for construction purposes, and Manufacture of machinery for mining, quarrying and construction)

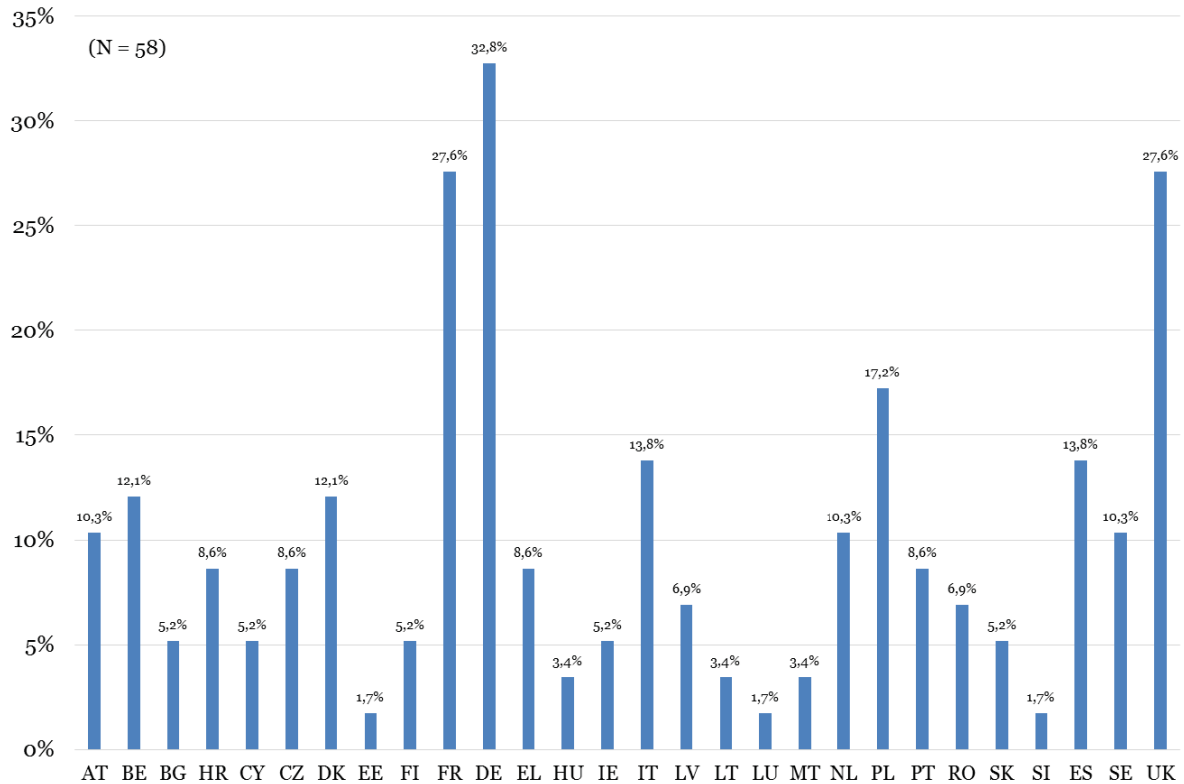
298 Eurostat SBS: Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E), Manufacture of food products

299 FoodDrinkEurope, [http://www.fooddrinkeuropa.eu/uploads/publications\\_documents/FoodDrinkEurope\\_Economic\\_Bulletin\\_-\\_Q4\\_of\\_2014.pdf](http://www.fooddrinkeuropa.eu/uploads/publications_documents/FoodDrinkEurope_Economic_Bulletin_-_Q4_of_2014.pdf)

300 Eurostat SBS: Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E), Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms



**Figure 8-22: Company survey: In which national markets have you experienced obstacles?**

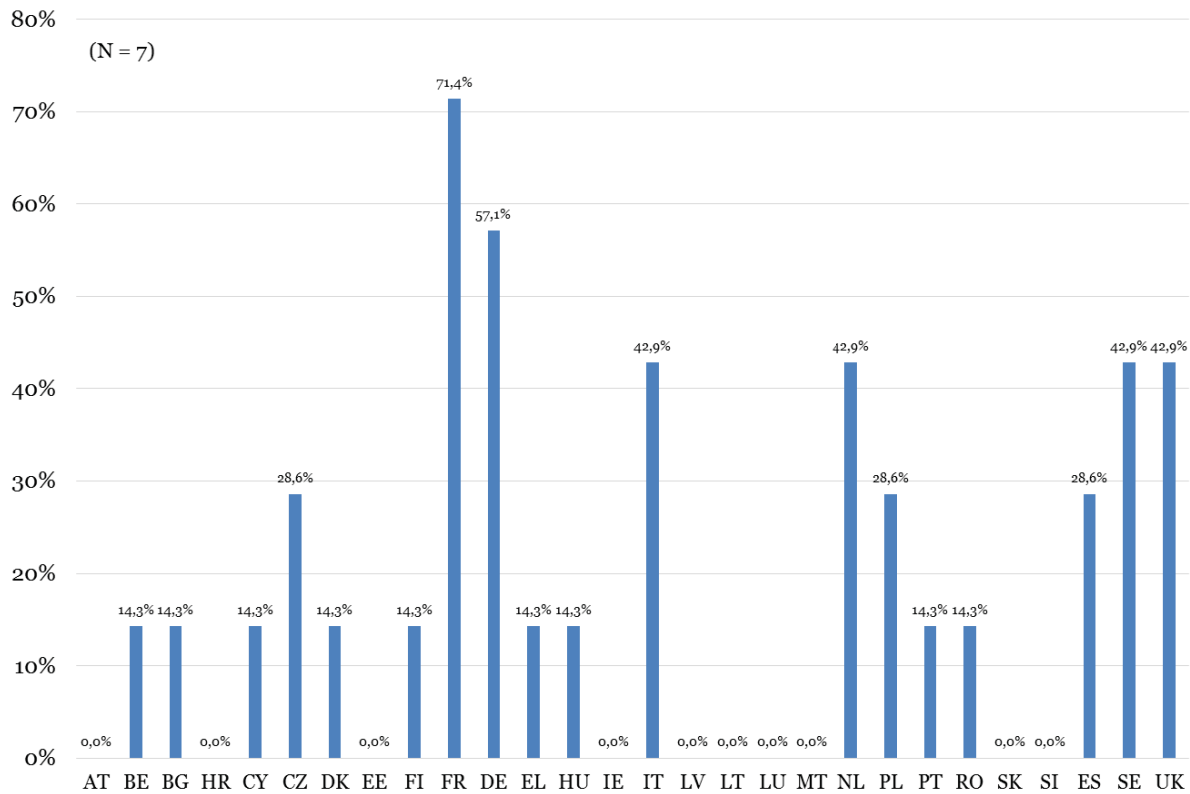


Source: Questionnaire survey among companies, running from 9 October 2014 to 5 January 2015, carried out by DTI

This does not necessarily indicate that obstacles to mutual recognition are more widespread in these markets compared to other national markets. It could simply reflect the fact that these markets are the largest in the EU and that many companies export to these markets and, consequently, there are more opportunities for companies to have experienced obstacles in terms of mutual recognition. As the interviewed companies also participated in the survey, the Member States in which these companies experience problems are obviously the same as those presented in the figure above.

The survey among national business and sector associations shows a similar picture. France, Germany and the UK are still the markets where problems most frequently occur for the business and sector associations' members, but also Italy, the Netherlands and Sweden are mentioned as Member States where economic operators frequently experience problems.

**Figure 8-23: Business and sector association survey: In which national markets do your members experience barriers due to prior authorisation or testing?**



Source: Questionnaire survey among national business and sector associations, running from 9 October 2014 to 5 January 2015, carried out by DTI

Although the number of business and sector associations being able to answer this question is rather low, the indications in this table are similar to the ones found in the company survey.

*Influence of macro-economic aspects on application of mutual recognition*

By using macro data<sup>301</sup> from the Eurostat database, the team investigated if Member States with a high share of cases/issues related to the application of the mutual recognition principle share a similar macroeconomic context. The company survey indicated that Germany followed by France and the United Kingdom were the Member States where the largest number of companies across the EU experienced obstacles related to the application of mutual recognition. The common denominator for these countries is that they are the largest intra-EU importers measured in terms of imports in € millions. Belgium, the fourth largest intra-EU importer, is also mentioned as being among the countries where relatively many companies experience problems. As could be seen in the tables presented in section 4.5, it was clear that none of the Member States stood out in terms of trade pattern, although some clearly experienced higher levels of intra-EU trade than others did.

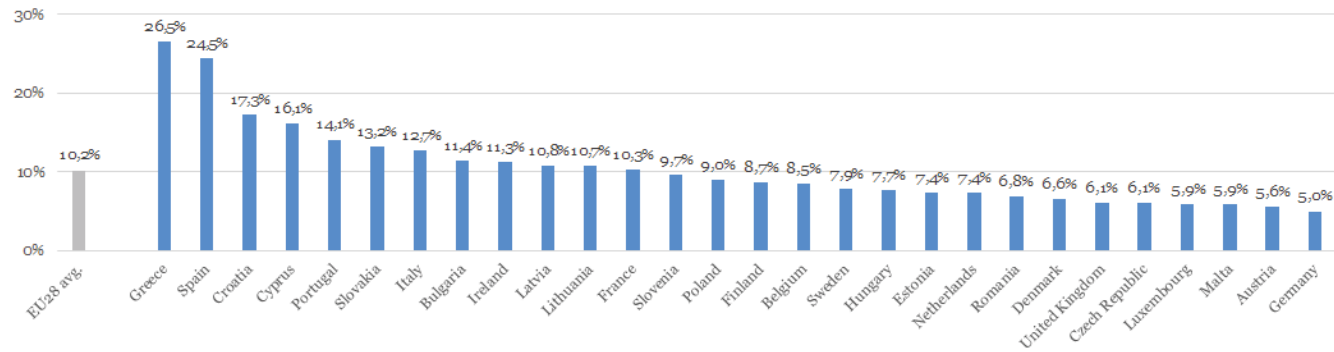
However, it should also be noted that the culture in different Member States might influence whether economic operators experience problems. For instance, in Germany, the interviews

301 Increases or decreases in intra-EU trade in terms of sectors and markets, EU export by sector, EU import by sector, Unemployment rate, EU direct investments, Inflation, Consumer activity

indicate that at least in the construction sector, the German authorities seem to favour their own national tests and perceive them to be superior to other Member States' tests.

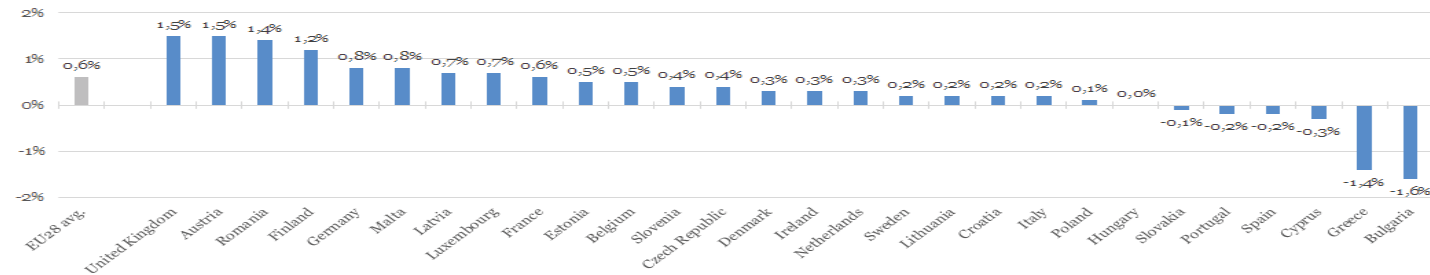
Other countries indicated as troublesome in this context by the survey participants are Poland, Italy and Spain. Part of the explanation in a macro context could be that these countries have experienced particularly severe economic problems in the wake of the financial crisis (especially Spain and Italy). However, many countries with high unemployment rates are not mentioned in the company survey to be problematic in a mutual recognition context, so it is not possible to draw a correlation. For an overview of the unemployment and inflation rates in all Member States see Figure 8-24 and Figure 8-25.

**Figure 8-24: Unemployment rates by Member State, 2014**



Source: Eurostat

**Figure 8-25: Inflation rate by Member State, 2014**



Source: Eurostat

The product contact points were also asked whether they believed that macro-economic aspects influenced the application of the mutual recognition principle in the Member States – for instance, whether the economic crisis may have led to a certain degree of protectionism in the home market. However, in general, the product contact points did not believe that this was the case – at least not for their own countries. A few product contact points remarked that there might be an increased number of companies from the Member States that are most severely affected by the crisis trying to enter other markets, i.e. exporting their way out of problems in their domestic market. This is for instance seen in Italy. However, the product contact points did not generally believe that this affected the way the mutual recognition principle was applied.

The business associations were also asked this question, but most did not have any opinion. Only two business associations (one from the North Europe and one from South Europe) mentioned that they suspected a certain degree of protectionism in some markets after the crisis. However, this is very difficult to detect and often disguised as public support schemes or public procurement with specific objectives (such as environmental, safety, health, etc., concerns), resulting in requirements that tend to favour the Member State’s domestic producers.

In sum, it cannot be concluded that macro-economic aspects have a significant impact on the application of the mutual recognition principle. Rather, the application (or lack thereof) is founded in Member State traditions with respect to tests, inertia in national/regional administrations towards handling new products that do not fit the pre-defined boxes of legislation (particularly if these products come from other Member State) and lack of trust in the administration of other Member States.

## 5. TYPOLOGY OF OBSTACLES

The above analysis has identified a number of obstacles, which are summed up in Table 8-4.

**Table 8-4: Overview of sectors and types of obstacles**

| Sectors                                       |               |   |  |   |                                  |  |  |                                    |
|---|---------------|---|--|---|----------------------------------|--|--|------------------------------------|
| Types of obstacles                            |               |   |  |   |                                  |  |  |                                    |
|   | Lack of trust | Lack of knowledge of MR principle – competent authorities | Difficulties for companies challenging non-application of MR | Lack of knowledge of MR principle – companies | Insufficient dialogue among PCPs | Request for national tests in the area of MR principle | Differences in Member State national standards | Lack of acceptance of MR principle |
| Construction – water taps                     | X             |   |  |   |                                  | X (general issue)                                      |  |                                    |
| Construction - non-harmonised area in general | X             |   |  |   |                                  |  |  | X (particularly DE)                |

| Sectors                                 |   |   |   |   |   |   |  |  |
|---|---|---|---|---|---|---|--|--|
| Types of obstacles                      |   |   |   |   |   |   |  |  |
| Enriched food                           | X |   |   |   |   |   | X (general issue, but e.g. DK, ES have strict standards) |  |
| Fertilisers                             | X |   |   |   |   |   | X  |  |
| Ship classifications                    | X |   |   |   |   | X |  |  |
| Nursery and childcare products          | X |   |   |   |   |   | X (UK have strict rules)                                 |  |
| Innovative products (different sectors) | X | X |   |   |   |   |  |  |
| Across sectors                          | X | X | X | X | X |   |  |  |

The different types of obstacles are discussed in more detail below.

### **Lack of trust**

The Member States' lack of trust in each other's procedures, interpretations and/or requirements - possibly due to a lack of understanding of each other's working practices - is often cited as leading to authorities taking a very restrictive view of the mutual recognition principle. This means that products are not allowed in other Member States on the grounds of safety and/or consumer interests in instances where the mutual recognition principle should apply, and can potentially lead to Member States increasing their use of prior authorisation procedures.

### **Lack of knowledge of mutual recognition principle – competent authorities**

This obstacle is related to competent authorities acting in a cautious manner and simply applying the old legislation, even though an innovative product should be covered by the mutual recognition principle. This means that it can be particularly difficult for innovative products to gain immediate acceptance in other Member States, although they are considered safe in the home Member State.

### **Difficulties for companies in challenging non-application of mutual recognition**

Several companies have stated that although they are positive that the mutual recognition principle applies to their product, they do not insist on this towards the competent authorities. The main reason is that it is perceived to be a costly and lengthy process to test if the mutual

recognition principle applies, in terms of money and loss of market share if the process takes too long. This is particularly true for SMEs, but large companies are also hesitant to take this step. In addition, as the mutual recognition principle is based on case law, more court cases would give a clearer overview of how to apply the principle for Member State authorities but as mentioned above, companies are unwilling to take cases to court.

### **Lack of knowledge of mutual recognition principle – companies**

The lack of awareness of mutual recognition by companies implies that companies often do not know with which obligations they need to comply, or which rights can be upheld in certain product areas.<sup>302</sup> Thus, before entering a market, companies may check the national requirements and adapt their products accordingly, without checking/knowing that the mutual recognition principle could apply. Better knowledge may result in companies being able to avoid these costs (depending on how firm the Member State authority is on the demands and how costly it would be for the company to test if the principle applies). This is a general problem across sectors.

### **Slow and insufficient dialogue among product contact points**

The evaluation has shown that the dialogue between competent authorities and between competent authorities and the Commission is too slow and incomplete at times. This can result in companies getting the information later than the 15 working days defined in the Mutual Recognition Regulation, and companies can perceive the information that they receive as incomplete and unhelpful. This too is a general problem across sectors.

### **Request for national tests in the area of the mutual recognition principle**

In non-harmonised areas where the mutual recognition principle should apply, the evaluation has shown examples of Member States still demanding national tests. There are indications in this evaluation that it is sometimes done because the Member States do not trust the procedures in other Member States, and sometimes for market protection reasons. An example is found within the area of water taps. Examples of costs incurred by the companies include the cost of getting approval of a new composition to be used for the production of water taps (€50,000 to €100,000), testing costs for a component (approx. €2,000) and for a final product (€8,000-9,000). In addition, the tests can take up to four to six months. A similar situation has arisen in the shipping sector, where a ship needs to be certified by a recognised classification society. Some products, such as engines, are not harmonised and fall under the mutual recognition principle. However, the principle is not always respected, meaning that a ship engine may have to be inspected by four or five different classification societies, depending on which is responsible for the classification as a whole. This creates extensive administrative burdens for the economic operator<sup>303</sup>, without being able to put a figure on that cost.

### **Differences in Member States' national standards**

This type of obstacle is an issue in the food and food supplement sectors, especially with respect to food enrichers such as vitamins and minerals. The obstacle arises when certain Member States have strict rules justified by the national food administrations. The amount of vitamins and minerals is not (yet) harmonised whereas the types of vitamins and minerals

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302 Position paper – Business Europe

303 Interview with DG MOVE

permitted for use in food and food supplements have been harmonised by Directive 2002/46/EC<sup>304</sup>. This means that the Member States can set very low levels (close to zero %) of the vitamins and minerals allowed, in effect blocking enriched foodstuff as is the situation in Denmark. Examples of actions taken by economic operators are to refrain from marketing the products in question in Denmark. Denmark is perceived to be such a small market that it is not worth the cost of having the policy tested. It is estimated that this product type could amount to 5% of annual sales of the company in Denmark (i.e. foregone revenues). Similar examples of certain Member States putting up strict rules have identified in the nursery and childcare sector. The challenges in this sector are similar to the ones experienced in the food sector.

### **Lack of acceptance of the mutual recognition principle because of established national standards**

This problem is quite specific to the construction products sector and is particularly prevalent in Germany. However, as Germany is a large market with imports from many other Member States, this is of great importance to the entire construction products sector. The main problem lies in the German standardisation body being so dominant on the market in terms of drawing up standards, certifying products, etc., that distribution of products on the German market is virtually impossible without conforming to this institute's standards.<sup>305</sup> In essence, this is a problem of a dominant player on the market forcing companies to adapt to its standards. This means that companies are not able to apply the mutual recognition principle on the German market. Instead they are instead forced to have their product tested according to German standards.

## **6. CONCLUSIONS: EFFECTIVENESS AND EFFICIENCY**

The conclusions will address the effectiveness and efficiency of the mutual recognition principle based on the findings of the study as far as possible.

The recommendations primarily focus on two main areas:

- *What, if anything, can be done to render mutual recognition more effective as a means to achieve its stated objectives?*
- *How can any barriers to effective mutual recognition be overcome?*

As these two questions are closely interlinked, the evaluation team presents the recommendations to these questions together.

### **Effectiveness**

Effectiveness of the application of the mutual recognition principle is the extent to which the objectives of the mutual recognition principle have been achieved or whether there has been significant progress towards them, what successes and difficulties have been identified, and to what extent the chosen solutions have proved appropriate. In order to determine effectiveness, the study also examined whether any external factors have had a significant negative or indeed positive impact on inter-EU trade flows, with the aim of isolating the effects of the

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304 European Commission (2010): Guidance Document - The application of the Mutual Recognition Regulation to food supplements  
305 ECJ: Case C-171/11 – Reference for a preliminary ruling of 30.3.2011



mutual recognition principle from other factors. In the present evaluation, the following evaluation questions have been examined with respect to effectiveness:

- To what extent has the mutual recognition principle achieved each of its stated objectives as a mechanism and means?<sup>306</sup>
- What are the barriers to effective mutual recognition?
- Are there any aspects/means/actors that render certain aspects of mutual recognition more or less effective than others, and – if so – what lessons can be drawn from this? How were the objectives achieved?

These questions are addressed below.

*The extent to which the mutual recognition principle as a mechanism and means has achieved its stated objectives*

According to Regulation (EC) No. 764/2008, the objectives of introducing the mutual recognition principle are as follows:

- ensuring the free movement of goods within the internal market;
- lowering remaining trade barriers in the internal market; and
- promoting trade in goods among EU Member State.

The overall conclusion is that the mutual recognition principle is still not fully achieving its objectives. The findings from the literature review, the questionnaire surveys and the interviews all point in the direction that it is not from the legal text as such, but rather in its application that challenges arise. In the product contact point survey and the business and sector association survey, around half of the respondents state that the principle has largely achieved its objectives, whereas the other half find that there is still some way to go, particularly regarding the application of the principle. The company survey reveals that among the companies that know about the mutual recognition principle, more respondents think that the principle works poorly in practice (one-third of the respondents) than those who think that it works as intended (one-fourth).

The TRIS<sup>307</sup> database shows that in 2014 there were close to 700 notifications of new technical rules. Although the number has been decreasing over the past three years, it is still a high number of potential new technical rules for economic operators. Some of them are undoubtedly justified, but it is a large number of notifications, which can indicate that there might be problems with the application of the mutual recognition principle.

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306 The aim of the regulation is to strengthen the functioning of the internal market by improving the free movement of goods (Regulation (EC) No 764/2008, Art. 1) by applying a mutual recognition clause in national legislation, establish procedures in Member State that limits the use of technical rules, and increase the knowledge of the n among economic operators and citizens.

307 TRIS stands for the Technical Regulation Information System and helps businesses to be informed about new draft technical regulations and allows them to participate in the 98/34 procedure, a procedure allows the Commission and the Member States of the EU to examine the technical regulations Member States intend to introduce for products (industrial, agricultural and fishery) and for Information Society services before their adoption. (<http://ec.europa.eu/growth/tools-databases/tris/en/> and <http://ec.europa.eu/growth/tools-databases/tris/en/about-the-9834/the-aim-of-the-9834-procedure/>)

### *Barriers to effective mutual recognition*

The evaluation shows that there are still significant barriers towards meeting the goal of ensuring free movement of goods within the internal market as well as the goal of promoting trade of goods between EU Member States. The typical barriers are:

- Lack of trust in the authorities (including market surveillance) of other Member States, which leads to some Member State administrations adding requirements (such as extra tests) which are not in accordance with the mutual recognition principle.
- Lack of knowledge of the application of the mutual recognition principle among competent authorities, particularly concerning innovative products, where it is not always clear to the competent authorities under which categories these products fall and if the mutual recognition principle applies.
- Difficulties for companies in determining if the mutual recognition principle applies. Currently, enterprises and business associations perceive the process of verifying if the mutual recognition principle applies to be too slow and costly. This means that companies often refrain from standing on their right and simply abide by the demands from the Member State in question.
- Companies' lack of awareness of the mutual recognition principle, which results in companies checking the national requirements and adapting their products accordingly before entering a market without checking/knowing that the mutual recognition principle might apply.
- Difficulties for product contact points and economic operators alike to determine what documentation companies should (be requested to) submit to document that their product is lawfully marketed in another Member State. The Commission has issued a guidance document, stating that to demonstrate the actual marketing of the product in another Member State, or in an EFTA state, *any* piece of evidence should be deemed suitable.<sup>308</sup> Obviously, this limits the burdens on the economic operators that they do not need an official statement, which is intentional. However, it also leaves the product contact points with little guidance on when, for instance, a product invoice is sufficient proof that a product has been marketed in another Member State in accordance with the applicable national legislation. This may again lead to additional administrative burdens on companies if the product contact point is unsure of the validity of the documentation and asks for additional documentation to be supplied.
- The dialogue between competent authorities and between competent authorities and the Commission is too slow and incomplete at times, not infrequently resulting in delays and incomplete and unhelpful information to the economic operators.
- Request for national tests in the area of mutual recognition principle. For instance, this is seen within water taps and ship classification, and it appears to be a cross-European issue in both sectors.
- Differences in Member States' national definitions and standards. This obstacle is seen in several sectors, including foodstuff, fertilisers, and nursery and childcare products.

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308 European Commission (2013): Commission working document: Guidance document. The concept of "lawfully marketed" in the Mutual Recognition Regulation (EC) No. 764/2008

- Lack of acceptance of the mutual recognition principle (particularly an issue in the construction products sector, and particularly in Germany and to some extent in Belgium).

*Means or aspects rendering certain aspects of mutual recognition more or less effective than others*

Member State' lack of trust in each other's procedures, interpretations and/or requirements is an important barrier to a better functioning of the mutual recognition principle. The lack of trust can imply that authorities are taking a restrictive view of the products that can be allowed onto the market of the Member State in question and thereby they do not apply the mutual recognition principle the way it was intended. This can result in an increase in prior authorisation procedures and/or tests, which increases the costs for economic operators.

Lack of awareness among companies and among some Member State authorities is an important barrier to effective implementation of the mutual recognition principle. Several product contact points call for awareness campaigns directed at different target groups to increase the effectiveness of the mutual recognition principle. Some product contact points call for the assistance of the Commission to carry out information campaigns, also because it would expand the reach of the information. In some Member States, product contact points perform seminars and training for competent authorities and sometimes for business associations. In Denmark, the product contact point has developed a guide on the use of the principle of mutual recognition that can be accessed on its website.

There are indications in the evaluation that grouping together related functions such as the product contact point, the contact point for construction products, SOLVIT, EEN, and staff working with other internal market issues appears to create good dynamics and increases the pool of knowledge available to the product contact point. This could be an example of good practice which is found in Denmark and the UK. This means that all questions regarding rules and regulations related to the functioning of the Internal Market can be answered by the same authority, which simplifies matters for the economic operators.

A good practice emerges from the product contact point interviews. A system in which product contact points are better informed about the outcomes of the queries that they pass on to other authorities in their country would appear to be preferable to a system in which product contact points do not receive a copy of the answer/decision or are otherwise not informed of the outcome. While having an overview of what actually happens when an inquiry is made may not be a precondition for an effective system, at least an overview can contribute to identifying any bottlenecks or other problems in the system, which is the basis for addressing any such problems.

### **Efficiency**

Efficiency arises from the relationship between the resources applied and the results achieved. Thus, the analysis sets out to answer if the effects obtained are reasonable compared to the costs (administrative burdens, etc.). In this context, the evaluation questions enquire as to whether the desired impacts have been achieved, at what cost, and if this represents a good return (economic, social or scientific) on the costs involved. In the present evaluation, the following efficiency evaluation questions were posed:

- To what extent have the effects been achieved at a reasonable cost?

- To what extent is the administrative and regulatory burden created by the implementation of the principle of mutual recognition considered proportionate for stakeholders and other relevant actors (Member State authorities, etc.)?
- What aspects of mutual recognition are the most efficient or inefficient, especially in terms of resources that are mobilised by stakeholders during the different phases of the process?
- What good practices can be identified?
- How can costs/administrative burden be reduced?
- To what extent can measures be taken to improve the positive effect of mutual recognition on the free movement of goods and what measures would these be?

The first four evaluation questions will be concluded upon below. The last two questions, i.e. how costs/administrative burdens can be reduced and what can be done to improve the positive effect of mutual recognition on the free movement of goods, are addressed in the recommendations.

As mentioned above very few companies have been able to give an indication of the costs associated with the improper functioning of the mutual recognition principle. Likewise, the business associations do not have a good overview of the costs either (cf. section 3.4). Section 5.2.3 and the company cases provide some examples of the costs incurred by companies, but they should be viewed as examples only.

*The extent to which the effects have been achieved at a reasonable cost*

In theory, if the mutual recognition principle works perfectly, the effects of the principle should be achieved without companies having to carry out an assessment of national technical rules (if the companies' products do not fall under the exemptions to the mutual recognition principle).

In the present evaluation, the administrative burdens mentioned by the stakeholders primarily relate to incorrect (or non-)application of the principle. None of the burdens mentioned were a result of the implementation of the principle as such.

In addition, the requirements for the product contact points are relatively limited. The main administrative burden identified in the product contact point interviews associated with the implementation of the mutual recognition principle is that answers to the economic operators and/or to the other product contact points must be translated into English. This can be difficult for competent authorities not used to communicating in English and burdensome for the product contact points if the answer contains many technical terms. The possibility of establishing an electronic system for exchanging information between product contact points was already mentioned in the Mutual Recognition Regulation, and as mentioned earlier in the evaluation, the IMI system could be a way of limiting this burden.

*The extent to which the administrative burdens are considered proportionate*

The typical administrative burdens associated with the implementation of the principle of mutual recognition mainly concern the companies. These burdens are closely related to the

requests from different Member States that national tests be conducted, even though the mutual recognition principle should apply. The burdens imposed on companies resulting from the incorrect application of the mutual recognition principle are not proportionate, but the problem is that the only alternative that companies feel that they have would be a court case, which is both too costly and takes too long. The burdens of choosing the alternative would then be even greater than simply complying with the requirements. The evaluation shows that these costs are particularly pronounced for SMEs, as they lack the competences and financial ability to complain to the authorities or take the case to court.

#### *Most efficient/inefficient aspects of mutual recognition in terms of resources mobilised*

First, companies, in particular, find the requests for national tests in areas where the mutual recognition principle should apply to be a resource-consuming aspect of the incorrect functioning of the mutual recognition principle. Such costs are particularly found in the construction products sector. Direct costs of retesting can run from a few hundred euros to tens of thousands, depending on the product. Adding to this is the time that the company spends waiting for the test results, and the repetition of the tests that is frequently required.

Second, strict rules in certain Member States, particularly within the area of enriched food, close the markets in question for some companies, unless they are willing to adapt their products to local requirements. In some cases, where the markets are small (such as Denmark, the example given in the report), companies decide to withdraw from the market, but in large markets companies often adapt their products. For enriched foods, this requires several production lines and can potentially be very costly (without any companies being able to put a figure on this).

Third, the product contact points mostly find it difficult to point to specific aspects that impact the efficiency of the mutual recognition principle in terms of the resources required. The procedure and the requirements depend very much on the product concerned. However, a few product contact points point to prior authorisation procedures in general as being the most demanding in terms of resources. Several product contact points complain that there are not enough resources (personnel) for the product contact point function as such, which impacts the efficiency of the whole process by creating delays. The Commission has published a number of guidelines on the application of the mutual recognition principle, but a number of product contact points still call for Commission assistance to help explain the principle to national authorities and economic operators alike, primarily due to the above-mentioned resource issues.

#### *Good practices*

Several product contact points are attempting to distribute knowledge on the application of the mutual recognition principle to competent authorities and sometimes to business associations. This is done through seminars and training. In one case (Denmark), the product contact point has developed a mutual recognition manual. The logic behind this is that when competent authorities are well informed about the application of the mutual recognition principle, companies are met with fewer groundless demands for retesting, etc., which limits the burdens on companies. Likewise, as outlined above, if the knowledge about internal market issues is pooled, the knowledge available to the product contact point is increased. In Denmark and the UK, the product contact points have been incorporated into a wider team in the relevant ministry/authority, which also deals with the Single Market policy. This means that all questions regarding rules and regulations related to the functioning of the Internal

Market can be answered by the same authority, which simplifies matters for the economic operators.

Some product contact points actively follow up on the notifications or they are copied in communications when decisions are sent to the companies and to the Commission. Ensuring that the product contact points are copied in the correspondence with the companies regarding this matter could be a way to ensure better transparency and that product contact points are informed about the use of e.g. prior authorisation procedures without increasing the administrative burdens of the sector ministries. In addition, when product contact points are aware of the use of instruments, such as prior authorisation procedures, they have a chance to challenge the justifications of the uses and perhaps contribute to decreasing the use. This can lower the administrative burdens of companies.

## 7. RECOMMENDATIONS

### **Better monitoring of the implementation of the mutual recognition principle**

The product contact points should be actively involved in monitoring the actions of the competent authorities. The product contact points could be actively monitoring the actions that the competent authorities take in the field of mutual recognition, advising the competent authorities in the field of the mutual recognition principle or holding meetings a couple of times a year where all relevant competent authorities meet and exchange experiences with the application of the mutual recognition principle. Some product contact points take up an active, coordinating role, but many product contact points do not.

#### **Recommendation 1**

The evaluator recommends that the product contact points be given a more active role in terms of monitoring the implementation of the mutual recognition principle, for instance, by being required to following up with competent authorities and coordinating actions. In some cases, this would also necessitate improved overall capacity through additional funding, improved knowledge, etc.

### **Setting up a mechanism for easier demonstration of “lawful marketing” for economic operators**

The evaluation showed that several product contact points point out that the lack of clarity concerning what documentation companies should be requested to submit to document ‘lawful marketing’ complicates and delays the process both for companies that do not know beforehand which documentation will be required and for the authorities in the destination Member State. Also, the situation may lead to additional administrative burdens on companies if the product contact point is unsure of the validity of the documentation and asks for additional documentation to be supplied. A mechanism to make it easier for economic operators to demonstrate that the products that they market have previously market in their home Member State could therefore advantageously be introduced. The mechanism could for instance be a manual (distributed to all product contact points) or an online “mutual recognition encyclopaedia”. Both of these could be based on the already existing guidelines for the application of the mutual recognition principle.

## Recommendation 2

The evaluation team recommends to introduce a mechanism, that makes it easier for economic operators to demonstrate “lawful marketing” of their products towards other Member States.

### **Better insight into the magnitude of the problem of incorrect application of the mutual recognition principle, particularly for SMEs**

The evaluation showed that many of the business and sector associations and product contact points had little insight into the magnitude of the problem of incorrect application of the mutual recognition principle. The companies also had difficulties in determining the level of cost incurred, and the answers received from the companies varied considerably. Thus, it is recommended to discuss further with companies (particularly SMEs) how heavy and unmanageable the incorrect application of the mutual recognition principle is.

## Recommendation 3

The evaluation team recommend additional discussions with economic operators (particularly SMEs) on the burdens associated with incorrect application of the mutual recognition principle.

### **Improve dialogue among competent authorities**

The evaluation shows that the dialogue among competent authorities works well in many cases, but it is lacking in other cases. Two important barriers to an effective dialogue (and thereby obstacles to helping companies more quickly) are slow response times by some Member States and answers in the national language.

One solution to the language issue, which may in turn shorten the response rates (if this problem also is linked to language issues), could be to use the IMI system of the mutual recognition legislation. One relevant aspect of the IMI system is its multilingual approach, meaning that Member States can post questions and answers in their national language. This could potentially resolve some of the issues regarding the communication between the competent authorities, although it is likely that further development of the system and/or involvement of translators will be necessary. However, it is also important that the competent authorities be required to communicate with their European counterparts so that they can provide good advice to the economic operators. The 15-day time limit for answering an inquiry is already incorporated in the Mutual Recognition Regulation, but the product contact points could be required to monitor the competent authorities better and offer their help, if necessary.

## Recommendation 4

The evaluation team recommends that to improve the dialogue between competent authorities, particularly with respect to the language issue, the Commission should look into whether the IMI system could be used as a communication tool.

In addition, it is recommended that the product contact points be required to monitor the competent authorities more than now and offer assistance if necessary. This could be part of a

major revision of the product contact point setup.

### **Ensure a better dialogue between the competent authorities and the Commission**

There are apparent discrepancies between the number of notifications received by the Commission and the number of decisions made by the Member State authorities reported in the annual reports. This means that some decisions falling under the Mutual Recognition Regulation appear to be adopted but not notified to the Commission. The product contact points do not always appear to be informed of the decisions made by the relevant ministries or agencies. In some cases, once a request from a company has been passed on to the relevant ministry, the product contact point does not hear about it anymore. Some product contact points actively follow up on the notifications, or see the correspondence when decisions are sent to the companies, while others only receive information when the relevant ministries send it to them. The good practice of staying in the loop ensures that the product contact points know about the notifications sent to the Commission, without imposing large administrative burdens on them. It is therefore important that the product contact points be required to be more active in following up on the requests that they receive from economic operators.

In addition, there are indications in the evaluation that grouping together related functions such as the product contact point, the contact point for construction products, SOLVIT, EEN, and staff working with other internal market issues, seems to create good dynamics and increase the pool of knowledge available to the product contact point. This would mean the same authority could answer all questions regarding rules and regulations related to the functioning of the Internal Market. This simplifies matters for the economic operators. In order to promote a more effective set-up of the product contact point function in the Member State a more detailed framework for the roles, rights and obligations vis-à-vis other national authorities and companies could be specified at EU level.

### **Recommendation 5**

The evaluation team recommends that the product contact point systems in the Member States be set up in such a way that product contact points are informed about the decisions, for instance, by receiving copies of the decisions made by the competent authorities. This setup would require a more detailed framework on the role of product contact points and their obligations vis-à-vis competent authorities. We therefore recommend the introduction of a more detailed framework for the set-up and functioning of the product contact point in the Member State at EU level.

In addition, it is recommended to group functions and activities related to Internal Market issues within relevant Member State administrations to create better dynamics and a single access point for economic operators.

### **Harmonisation of certain areas**

Particularly in the areas of construction products (a particular problem was highlighted concerning water taps) and food enrichers, different Member States have different perceptions of appropriate standards and safety levels.

Within the area of water taps, there are indications from companies that the certifications asked for by different Member States are not that different content-wise, but the Member



States still refuse to allow a product on the market that has not been tested according to national standards. This could indicate that the certifications serve to protect the national markets. As the trust, which is necessary for the mutual recognition principle to function properly, is not present in this case, harmonisation could be a solution in this particular case.

Within the area of enriched food, different policies exist which make a proper functioning of the mutual recognition principle difficult. The amount of vitamins and minerals is not (yet) harmonised, whereas the types of vitamins and minerals permitted for use in food and food supplements are harmonised by Directive 2002/46/EC.<sup>309</sup> This means that the Member States can set very low levels (close to 0%) of the vitamins and minerals allowed in effect blocking enriched foods in their markets. The Member States have very diverging standards for enriched food, and it is expensive for the companies to comply with this. However, since the standards are very different in different Member States, it seems unlikely that the Member States can come to an agreement concerning a harmonised amount. The same may be true for fertilisers, where the draft impact assessment carried out by the Commission shows lack of trust among the Member States. Moreover, that the perception of what constitutes a fertiliser varies greatly among Member States.

### Recommendation 6

The evaluation team recommends investigating whether areas exist where harmonisation would limit the use of technical rules and incorrect application of the mutual recognition principle and thus ease the burdens on economic operators.

#### Awareness-raising campaigns

First, the analysis shows that there is a need for increasing the awareness of the mutual recognition principle among companies and national and regional authorities. It is important that companies and authorities at all levels are well aware of the mutual recognition principle and its application so that companies can stand on their own rights and national authorities can guide the companies properly and reduce the use of national technical rules. In addition, the analysis shows that national authorities/sector ministries or agencies sometimes act cautiously and do not allow innovative products into the market that may not fit into existing rules, although the product is deemed safe on the home market. Awareness-raising campaigns could help guide the sector ministries and agencies.

Finally, the analysis shows that the reasons for not applying the mutual recognition principle correctly can be a result of lack of awareness of the application of the mutual recognition principle, a desire for high standards in a non-harmonised area, or imposing a form of protectionism. When the first option is the case, awareness-raising campaigns can potentially help in reducing the number of cases in which national technical rules are being imposed.

### Recommendation 7

The evaluation team recommends carrying out awareness-raising campaigns aimed at companies, regional and national authorities as well as business associations.

The European Commission could play a role in awareness-raising campaigns among national and regional authorities. This could be done by:

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309 European Commission (2010): Guidance Document - The application of the Mutual Recognition Regulation to food supplements

## Recommendation 7

- drafting training/information material;
- making available easy-to-understand information for economic operators on what mutual recognition is, how it is applied (providing specific examples), etc.; and
- participating in events and meetings at the Member State level (potentially aimed at sectors such as construction and food, where problems exist), partly to ensure that the mutual recognition principle and its application are properly explained, and partly to show that incorrect application of the principle is a serious matter at the European level.

Subsequently, the product contact points could be in charge of arranging awareness-raising campaigns targeted at companies.

Lastly, awareness-raising campaigns towards business and sector associations may contribute to increasing the knowledge of the mutual recognition principle among the associations and allow them better to spot and assist companies that may experience difficulties with the application of the principle. A concrete suggestion is to use the EEN as a platform for this.

In addition, the awareness-raising campaigns could also potentially help reduce the legal uncertainties that many companies experience. Improper understanding of the mutual recognition principle by companies may imply that the legislation is difficult to understand, which then creates legal uncertainty. It also means that these companies, and in particular SMEs, suffer from an information imbalance vis-à-vis the competent authorities in the Member States. Likewise, if authorities in other Member States are perceived as either not knowing the mutual recognition principle well enough or not applying it properly, this can increase the use of prior authorisation procedures and/or different testing methods, which in turn can create legal uncertainty.

### Sectors on which to focus

The evaluation has shown that there are a number of sectors where action particularly could be taken.

Particularly **construction products** (both the non-harmonised area in general and water taps) and **food**, particularly the area of enriched food are areas where the literature repeatedly highlights these sectors as problematic, and the evaluation has shown indications from companies that incorrect application of the mutual recognition principle creates costs for companies. As mentioned above, the economic importance of the construction and food sectors is considerable.

Fertilisers, ship classifications, and nursery and childcare products are sectors where there have been problems, but the indications of the extent of the economic burdens for companies are less clear and are difficult to quantify overall. In particular, there are some issues concerning a common understanding at EU-level of what constitutes a fertiliser.

A number of issues cut across sectors such as problems with innovative products, and the application of the mutual recognition principle in these cases.

## ANNEX 9: SHORT COMPANY CASES

The short company cases were developed in the context of the external evaluation of the functioning of the mutual recognition principle performed in 2015 by DTI, Technopolis, EY and VVA Consulting. These cases are derived from the answers to the questionnaire survey for companies, and in some cases, they are supplemented with a short interview with the company.

### Company 1

Company 1 is a large Swedish company, active in the paper industry (producing packaging for foodstuffs, etc.). All of its exported products fall under the principle of mutual recognition. The company knows the principle of mutual recognition.

When exporting, the company has taken the necessary steps to check the applicable rules in the EU destination country. In some cases, the company has had to retest its products. In particular, this has occurred when its customers demanded that a specific test was carried out to show that the product complied with the national legislation (in this case, the Italian legislation concerning paper in contact with food), despite the fact that the paper already complied with rules in the home Member State and in all other Member States. The company has tried to raise this issue with their Italian customer, but both the customer and the company's own sales office in Italy state that this has to be done as Italian legislation requires it. The company perceives this demand as a lack of knowledge of the mutual recognition principle.

In this case, the additional tests were the result of companies in the host country not being aware of or not accepting the mutual recognition principle. However, the retesting costs quoted for Company 1 are perceived to be rather low. For the company, the costs have mainly involved internal staff time. One test amounts to approx. €700, and every product needs to be tested. In addition, if a chemical additive in a product is changed, the product needs to be retested. The company has only experienced these issues in Italy. In addition, the Italian authorities are not perceived as taking the necessary steps to ensure that the retesting demands by Italian customers actually comply with the mutual recognition principle.

As illustrated by the example of exports to Italy, the mutual recognition principle did not work in practice for Company 1, even though the company relied on it. Nevertheless, the company perceives that the mutual recognition principle in itself is working well, but it is not always applied properly.

Source: Questionnaire survey among companies, running from 9 October 2014 to 5 January 2015 and interview with the company

### Company 2

Company 2 is a medium-sized Danish company. It works within the construction sector. 75% of its exported products fall under the principle of mutual recognition. The company has exported products to other EU Member States in the last three years, and has heard about the principle of mutual recognition of goods, but is not familiar with the details of the principle.

Before entering a new market, the company has examined the applicable rules in the importing EU country. Afterwards, the company has retested its products. The costs related to these applications, which include administrative fees, testing costs, internal company staff

## Company 2

time, and adaptation of the product to local technical requirements, have been very high.

However, the company does not even check to verify if the mutual recognition principle applies, since in their area (water taps, which are classified as components related to drinking water and thereby products related to food), each of the Member States have their own tests and do not respect any of the tests carried out in other Member State.

Within the company's sector, EN standards cover mechanical, functional and physical requirements for taps and hoses. However, water taps are only mentioned in the Drinking Water Directive (*DWD, 98/83/EC*) where EU Member States have to ensure that materials used in the distribution of drinking water do not release substances in concentrations higher than necessary for the purpose of their use. This means that all Member State can (and do) apply their own rules, and the testing procedures vary among the Member State.

Much work has been done to try to secure a common testing system; but so far, the Member States have not been able to agree on this. However, a group of Member States has undertaken some positive steps forward, and Germany, UK, the Netherlands and France have agreed on a common positive list of materials.

In theory, the mutual recognition principle should apply to this area, but in reality it does not, as each Member States requires that national tests be carried out before accepting the taps on their markets. The company perceives the request for national tests as a market protection measure.

The required tests result in significant costs for companies. Although certification and test requirements are different in different countries, the basic purpose and parameters are similar. This causes duplication of efforts and costs. In some Member States, it is enough to show test certificates for each component, whereas in other Member States, the entire product needs to be tested. Testing costs for a component is approx. €2,000 and for a final product around €8,000-9,000. In addition, tests can be rather time-consuming. For instance, a test to determine whether the component or final product contains nickel takes up to 28 weeks.

Thus, the company perceives the principle of mutual recognition to be functioning very badly, and the company does not believe that the mutual recognition principle has contributed to lowering trading barriers. The two largest obstacles to a better functioning of the mutual recognition principle are the lack of awareness of the mutual recognition principle among companies as well as the fact that the authorities do not know the mutual recognition principle well enough or do not apply it correctly. Both obstacles may have been important, but particularly the fact that the national authority has insisted on national requirements that do not comply with the mutual recognition principle is important in this case. Company 2 has experienced the above-mentioned obstacles in Austria, Belgium, Finland, France, Germany, the Netherlands, Sweden, and the UK. In addition, the company has experienced that insurance companies are not willing to insure houses where water taps are not tested according to national standards. The same is happening in Sweden.

Source: Questionnaire survey among companies, running from 9 October 2014 to 5 January 2015 and interview with the company

### Company 3

Company 3 is a large Swedish company in the food sector. It has sold goods in other EU Member States for the past three years. The company knows the principle of mutual recognition, and estimates that 80% of its exports fall under the principle of mutual recognition.

Whenever the company has entered a new market, it has examined the applicable local rules and adapted its product to them. The cost of taking these steps amounts to 0.1% of the annual turnover. The two most significant costs in this process are internal company staff time and adaptation of the product to local technical requirements. The adaptation of the product to local technical requirements mainly has to do with changing the language of the information stated on the package. In addition, in some Member State the kind of information required on the packaging differ. The company states that their clients confront them with these demands - not the authorities. Changing the language or information on the package amounts to € 1,000-1,500, plus person hours (approx. 1 day).

The company has experienced that the mutual recognition principle did not work in practice, even though the company relied on it. However, it is the application of the mutual recognition principle that did not work in practice, rather than the principle itself. According to Company 3, overall, the mutual recognition principle works 'well', when properly applied, and the company has only experienced that it was not properly applied in the few instances mentioned above. The company believes that mutual recognition has lowered trade barriers and comments: '[The principle] makes it easier to challenge local "wish lists" and differentiate "need to have" from "nice to have"'. The two most important obstacles to effective mutual recognition are legal uncertainty because the mutual recognition legislation is unclear (perceived in this case to be the application of the legislation) and that the authorities in other Member States do not know the principle well enough or do not apply the principle correctly. Company 3 has experienced these obstacles in Austria, Germany, and Greece.

Source: Questionnaire survey among companies, running from 9 October 2014 to 5 January 2015 and interview with the company

### Company 4

Company 4 is a Swedish company, producing and selling furniture and other products for the home. The company is present in 18 Member States. Thus, harmonised product requirements are the key to being efficient and cost-effective in the production and distribution of products. The company has experienced problems with the application of the mutual recognition principle within the area of water taps for kitchen and bathroom sinks.

Water taps are a non-harmonised product category. Therefore, national certifications are required to place the products on national markets. EN standards cover mechanical, functional and physical requirements for taps and hoses. However, the use of positive material lists, substance migration, noise, odour, flavour or appearance of the water are still regulated by national testing or certification requirements. Taps are only mentioned in the Drinking Water Directive (*DWD, 98/83/EC*). EU Member States have to ensure that materials used in the distribution of drinking water do not release substances in concentrations higher than necessary for the purpose of their use. This means that Member States can (and do) apply their own rules, and the testing procedures vary among the Member States. The approach of Member States differs when it comes to national certification systems. The existence and the

## Company 4

roles of national regulatory bodies and of toxicity committees are also different. Often competences fall within different authorities.

However, based on the company policy to use only materials with a lead content below 0.2%, it has very few options to choose from the positive list. Company 4 calculates that for each product in the taps category, the certification and testing costs are up to €50,000. In addition, the cost of getting a new composition approved (to be used for the production of water taps) is between €50,000 and €100,000. It is also a rather time-consuming process, since the testing requires six months, as there is a bottleneck in the capacity for testing.

At present, there are four different water efficiency labelling schemes in Europe. However, the company has not been able to adopt any of these labelling schemes, because their acceptance and recognition among consumers is limited by geography.

The types of costs that the company face include additional costs of respecting and aggregating 17 different certification schemes for the same product.

Company 4 would benefit greatly from better application of the mutual recognition principle.

Source: Interview with the company, written case on taps provided by the company

## Company 5

Company 5 is a medium-sized company operating within the area of childcare products. The company is based in the UK. The company has heard about the principle of mutual recognition, but it is not familiar with the details of the principle. Approx. 5% of the company's exports fall under the mutual recognition principle.

The company has a mixed view of the mutual recognition principle. The principle has a positive side. Thus, countries asking for own tests and standards dramatically increase the companies' stocks, while the mutual recognition principle helps to decrease stocks by reducing inventories and facilitating sales efforts. However, the company representative believed that the principle may allow lower quality products coming into the UK, while not complying with British safety standards. The British nightwear standard is one of the exemptions under the mutual recognition principle. This prevents other EU producers from selling nightwear in the UK if they do not comply with British nightwear standards. However, with their main product, a baby sleeping bag, British standards for baby sleeping bags cannot prevent non-compliant products from coming into the UK. This will be a serious risk for the consumer. This is the negative side of the mutual recognition principle.

However, as far as the company knows, certainly for childcare products, such as baby sleeping bags, British standards are higher than those in most EU countries are. The British authorities have imposed specific UK standards in the market for such products, citing child safety as a reason (as far as the company knows). This helps the British company, but is a barrier for producers in other EU countries. Since the UK rules are stricter than the rules in other EU Member State that the company sell to, if they just comply with UK standards they are on the safe side in most markets.

Source: Questionnaire survey among companies, running from 9 October 2014 to 5 January 2015 and interview with the company

## Company 6

Company 6 is a large Danish company operating in the construction products area. The company knows the mutual recognition principle and estimates that 70% of its exports fall under the mutual recognition principle.

When the company has entered a new EU market, it has typically examined the applicable rules in the destination Member State, and often it has had to retest its products. The company does not think that the mutual recognition principle works well, but it is clear that it is the application of the principle, rather than the actual principle itself, that is the problem.

The company has a rather specific problem in Germany, where most of its obstacles occur. Germany has regional rules for approval of construction products falling outside of the harmonised area. In October 2014, the Commission notified that Germany must not ask for additional stamps or approvals<sup>310</sup>, but the company (claiming not to be the only one) still experience these obstacles. In addition, the company has experienced issues with product types (surface coatings) where tests are not required in their home country, but they are required in Germany. In practice, the company tests its products in Germany, as there are no test facilities in Denmark because a test is not required there. Testing costs amount to approx. €7,000 per product, and the tests need to be repeated on a regular basis. In addition, whenever there is a new chemical in the surface coatings (which sometimes can change if the supplier is changed), the test must be repeated too.

The company is currently investigating whether the test results obtained in Germany can be used in France too, as there are similar requirements. This remains to be seen; otherwise, the tests may have to be repeated in France.

Source: Questionnaire survey among companies, running from 9 October 2014 to 5 January 2015 and interview with the company

## Company 7

Company 7 is a large Danish company operating in the construction products sector. The company knows the mutual recognition principle and estimates that 10% of the company's exports fall under the mutual recognition principle.

When the company has entered a new market, the company has experienced that whether construction products are CE-marked or not, national approvals are necessary. This means that the company needs national approvals, which can require additional documentation, and in some instances, it needs to carry out additional tests. In particular, the company has experienced problems in Belgium and Germany, because there are national fire codes that the company must follow.

The costs are particularly associated with obtaining the additional documentation, and in some instances carrying out the additional tests. This means that legal uncertainty associated with different testing methods is the most prominent obstacle towards a better functioning of the mutual recognition principle for this company. The costs have not been quantified for this case.

Source: Questionnaire survey among companies, running from 9 October 2014 to 5 January 2015 and interview with the company

310 [http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item\\_id=7860&lang=en](http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=7860&lang=en)

## Company 8

Company 8 is a large company operating in the food sector, headquartered in Switzerland. However, the two respondents to the survey and subsequent interviewees are based in Germany and Denmark. Between 1% and 5% of the company's exports fall under the mutual recognition principle. Both interviewees knew the mutual recognition principle well.

The mutual recognition principle is perceived to work to an average extent. However, the company's issues regarding the principle are primarily related to the application of the principle. In circumstances where the mutual recognition principle is applied properly the principle has contributed to lowering of trade barriers. The effect is that the company can manufacture the same product for different Member States without having to change the recipe. However whether the principle is applied properly is only obvious if it is explicitly confirmed by authorities (e.g. in case of prior authorisation procedures which are not in place for the application of the mutual recognition principle in all Member States). However, if such procedures exist they can have the disadvantage of being time consuming and burdensome. The notion in Article 6(4) of Regulation 764/2008/EC according to which "the product shall be deemed to be lawfully marketed" does not work, if the national competent authorities do not start the time periods specified in Article 6(2) by sending a written notice that they intend to adopt a decision as referred to in Article 2(1).

There are also examples of cases where the mutual recognition principle should apply in theory, but where Member State authorities are not applying it properly. One example comes from Denmark, where the rules for enriched food (or rather, the level of vitamins and minerals in food) are strict. The amount of vitamins and minerals allowed in food are not (yet) harmonised, whereas the types of vitamins and minerals permitted for use in food and food supplements are harmonised by Regulation 1925/2006/EC and Directive 2002/46/EC. In some areas, Denmark has special rules justified by food safety. Danish policy is not to let enriched foodstuffs onto the market (by keeping the tolerated level of enrichers close to zero), unless special permission is given by the Danish Veterinary and Food Administration. According to the company, enriched foodstuffs are thus effectively blocked from the Danish market, and the mutual recognition principle is not applied in this area. Company 8 has chosen not to contest the justification of the food safety concerns, since the policy is very firm, and Denmark is such a small market that it is not worth the cost and time of having the policy tested. The company simply refrains from marketing the products in question in Denmark. It is estimated that this product type could amount to 5% of annual sales (i.e. foregone revenues). In other, more important markets, the company may adapt the products in question to suit the national requirements.

Another issue, which has now been resolved at least in Denmark, are the rules for tolerances in the declared amounts of vitamins and minerals in foodstuffs (natural variations occur so that the amounts contained in a specific product are allowed to fluctuate around a median value). The Danish tolerance rules were stricter than those of a number of other EU countries, which meant difficulties in marketing the product. The company discussed whether to contest the policy as a matter of principle, but recently the issue was solved by the adoption of the EU Guidelines on Tolerances. Although such guidelines are not legally binding and do not constitute a legal harmonisation they were accepted alongside with the national standards in Denmark.

Source: Questionnaire survey among companies, running from 9 October 2014 to 5 January 2015 and two interviews with the company



## Company 9

Company 9 is a large French company operating within the sector of sports equipment. The respondents are well aware of the principle of mutual recognition.

When entering a new market, the company typically examines the applicable rules in the destination Member State and adapts the products to the local technical requirements. The company does so because its strategy is to conform to all requirements applicable in the countries where it operates to guarantee high product quality and safety to its customers.

Nevertheless, the company has experienced problems with different classifications of products in different Member States. In two cases, the company had to withdraw certain gym products from the German and UK markets because they resembled a weapon. Consequently, the product was classified as a weapon in these two countries. The company has local legal advisors who can discuss with authorities and argue that the products conform to French law. However, particularly in the German case, the advisor told them that the German law pertaining to weapons is so strong that the company could not do much about it. The strategy was to withdraw the product from the market, resulting in a missed market opportunity. The company needs to get its products on the market quickly, so there is no time for arguing with administrations about withholding products, etc. This means that the company just does what it is asked to do by the administrations. It may have the right to market certain products in certain markets, but there is no time to check this.

In addition, the company experienced a situation in Spain where a request from the Spanish government stated that to sell bicycles in Spain, a conformity assessment had to be attached to each bicycle. The company's bicycles conform to European standards, but in Spain, the company's legal advisor said that a 1998 decree had to be respected.

According to the company's many countries use national technical rules, and since this involves quite a large number of authorities, it appears that many of them are not aware of European law. Thus, differences in testing methods as well as authorities in other Member State not correctly applying the mutual recognition principle are the two greatest obstacles to an effective functioning of the mutual recognition principle.

Source: Questionnaire survey among companies, running from 9 October 2014 to 5 January 2015 and interview with the company

## Company 10

Company 10 is a small Portuguese company active in the construction sector. The respondent knows what the principle of mutual recognition means.

Within the non-harmonised area of construction products, there are clearly different requirements among Member States. However, Company 10 produces tailor-made products, which means that terms and conditions are agreed with customers before the products are produced. They have a certification system (procedure for certifying their products), and send a copy of this to the customers. Sometimes there are small differences in interpretations between Portugal and Belgium, for instance, but they are resolved during the contracting phase. Before they prepare a large product order, they reach an agreement on these issues with the customer.

As the company produces customer-specific products, it is not such a big problem that there

### Company 10

are different rules in different Member States in the non-harmonised area. They can handle any differences in the contracting phase. However, in public tenders it can be problematic that the Member States have different rules, because there may be rules/requests for tests that the company cannot foresee, since they do not know the national markets well enough, and therefore cannot take these into account.

If the company were selling standard products, mutual recognition would have been a greater issue. In Portugal, many companies within the construction sector produce products in serial batches. Here, the CE mark is often used. If no CE-mark exists, companies must be more attentive to rules in other Member State.

Source: Questionnaire survey among companies, running from 9 October 2014 to 5 January 2015 and interview with the company

The following cases are derived from the survey and have not been supplemented with an interview.

### Company 11

Company 11 is a medium-sized Danish company operating in electrical products. It has sold goods to other EU Member States the last three years and knows the principle of mutual recognition. Around 50% of its exports fall under mutual recognition.

When the company has entered a new market, it has examined the applicable rules in the destination EU country and adapted its product to the local requirements. The company is not able to state the cost of the adaptation to these local requirements. However, the company states that the typical costs involved are administrative costs, testing costs and internal staff costs, and that they are all significant costs.

The company has met local technical requirements, since it assumed it was necessary and did not think that mutual recognition would apply.

The company states that mutual recognition works 'well', but it does not know whether it has lowered any trade barriers. Lack of awareness among companies and legal uncertainty because the legislation is unclear are the two biggest obstacles to effective mutual recognition. The company has experienced these obstacles in Germany and France. It happens approximately twice a year that the company decides not to enter a new market in the EU for legal reasons. Over the years, the number of decisions not to enter a new EU market for legal reasons has remained constant.

Source: Questionnaire survey among companies, running from 9 October 2014 to 5 January 2015

### Company 12

Company 12 is a small Belgium company operating in the construction products sector with 40% of its exports covered by the mutual recognition principle. The company is well aware of the principle of mutual recognition.

When entering a new market, the company has examined the applicable rules in the destination EU country, and retested its product afterwards. The company stated that the costs

## Company 12

of these steps amount to approx. 10% of the company's annual turnover. The costs that have been very significant involving administrative fees, testing costs, and internal company staff time.

Although the company states that it is well aware of the mutual recognition principle, the company has retested its product, as it believed that this was required to adapt the product to local requirements. Thus, it did not check if the mutual recognition principle applied in this case.

This company believes that the principle works 'badly', and it does not know if it has helped to lower trade barriers. However, it is likely that it is not the principle itself that does not work well, but rather the understanding of the principle and its application. This is seen in the company's answers regarding the most important obstacles to the effective functioning of the mutual recognition principle. First, the company states that the legal uncertainty, in terms of the mutual recognition legislation being unclear, is a prominent obstacle. The second obstacle that the company highlights is that the authorities in other Member States do not know the mutual recognition principle well enough or do not apply the principle of mutual recognition correctly. These obstacles have meant that on three occasions the company has decided not to enter another EU market. The costs of these decisions are not specified, but are in addition to the costs amounting to 10% of the company's turnover as stated above.

Source: Questionnaire survey among companies, running from 9 October 2014 to 5 January 2015

## Company 13

Company 13 is a small company from the Netherlands involved in the production of metal devices. It has sold goods in other EU Member States within the last three years and it knows the principle of mutual recognition well. Around 25% of its exports fall under the mutual recognition principle.

The company has done nothing to check if its products meet the local requirements in the destination EU Member State (and has not subsequently experienced problems). This company believes that the mutual recognition of goods principle works very well and that it has helped in lowering trade barriers. In answer to how the principle has lowered the trade barriers, the company commented, "In the past in our sector, all countries had their own, different requirements. Now there is just one applicable directive."

The two greatest obstacles to effective mutual recognition are the lack of awareness of the principle among companies and the fact that the authorities in other Member State do not know or do not apply the principle correctly. The company has experienced these obstacles in Germany.

Source: Questionnaire survey among companies, running from 9 October 2014 to 5 January 2015

## Company 14

Company 14 is a medium-sized Spanish company selling children's clothing. The company has sold goods in other EU Member States over the past three years. The company has heard of the principle of mutual recognition, and estimates that 10% of its exports fall under the

## Company 14

principle of mutual recognition.

When the company has entered a new market, it has typically examined the applicable rules and adapted its products to local requirements. These steps cost 0.2% of the annual turnover, meaning that the typical costs involved are not perceived by the company to be significant.

The company adapted its products because it assumed that it was necessary, as the company did not know that the mutual recognition principle could apply. This means that even though the level of the costs (amounting to 0.2% of the turnover) does not appear to be high, and even though the company does not perceive the costs of adapting its products as significant, there might be costs that could be avoided if the mutual recognition principle were applied correctly.

The company perceives the principle of mutual recognition to be working in an ‘average’ way, and it does not know if the principle has helped in lowering trade barriers. The reason for this statement is perceived by the evaluator to be mainly found in the incorrect application of the mutual recognition principle and not in the principle itself. Also, the company lists the two greatest obstacles to effective mutual recognition to be the lack of awareness of the mutual recognition principle among companies (including itself) and legal uncertainty because the mutual recognition legislation is unclear (or difficult to know when to apply).

Source: Questionnaire survey among companies, running from 9 October 2014 to 5 January 2015

## Company 15

Company 15 is a medium-sized Lithuanian company. The company produces stainless steel devices to be used in the food, brewing, milk, alcohol, chemical, and biofuel industries. It has sold goods to other EU Member States over the past three years. The company is aware of the mutual recognition principle, but does not know it in detail. The principle of mutual recognition applies to 5% of its exports.

Whenever the company has entered a new market, it has examined the local technical requirements and adapted its products to them. The requirements and the costs that follow this adaptation process is a figure corresponding to 1% of the company’s annual turnover. The two most significant costs to the firm are testing costs and administrative fees.

The main reason for the company to adapt its products to the local requirements was that it thought it was required, and it did not know that the mutual recognition principle could be applied. Whereas the company does know about the mutual recognition principle, but not in detail, the above experience suggests that a higher degree of awareness of the principle internally in the company could potentially reduce the adaptation costs. The company also lists lack of awareness of the mutual recognition principle among companies as one of the greatest obstacles to effective functioning of the mutual recognition principle. However, it should also be noted that the company estimates that only 5% of its exports fall under the mutual recognition principle. Hence, the adaptation and testing costs mainly reflect those of products outside the scope of the principle.

Source: Questionnaire survey among companies, running from 9 October 2014 to 5 January 2015

## Company 16

Company 16 originates from Belgium and operates within the sector of precious metals. The company has less than 10 employees, and 100% of its exports fall under the mutual recognition principle. The company exports to the UK in particular. Over the last three years, it has sold goods to other EU Member States. Company 16 is well aware of the principle of mutual recognition.

When Company 16 exports, it examines the applicable rules in the destination EU country, and afterwards adapts its products to the local technical requirements. The company estimates that the costs of the adaptation process correspond to approx. 10% of its annual turnover. On a scale from 1 to 5 (1 being very costly), the administrative fees and adaptation of the product to local technical requirements are estimated to be at around 3.

The company assumed that it had to adapt its goods to the local requirements, since it did not know (enough) about the principle of mutual recognition.

Company 16 states that the mutual recognition principle operates in an ‘average’ way. It also believes that the mutual recognition principle has contributed to lowering the trade barriers as ‘some goods can now be sold in other EU countries without the need to adapt them to national laws’.

According to the company, the two greatest obstacles to a better functioning of the mutual recognition principle are the lack of awareness of the principle among companies and the legal uncertainty related to prior authorisation procedures or different testing methods. Particularly the lack of awareness among companies (including their own) suggests that a better functioning of the mutual recognition principle has to do with the company’s need to better understand where the principle applies, rather than a malfunctioning of the principle itself. In addition, the legal uncertainty related to prior authorisation procedures and/or different testing methods has to do with the national authorities’ application of the principle.

As 100% of the company’s exports fall under the mutual recognition principle, and as the costs associated with adapting the company’s products correspond to around 10% of the company’s turnover, initially there are significant benefits to be reaped for this company by ensuring a better application of the principle. In addition, on 15 occasions, the company has decided not to market a product in another Member State, due to issues such as authorisation procedures. This figure has remained constant over the years. This means that there also may be significant economic benefits to be reaped by the company if it is able to sell products in new EU markets if the mutual recognition principle is applied properly.

Source: Questionnaire survey among companies, running from 9 October 2014 to 5 January 2015

## Company 17

Company 17 is a large UK-based company that produces child safety, childcare and child use articles. Around 90% of its exported products are recognised under the principle of mutual recognition, and it has exported to other EU Member States within the last three years. The company has heard about the principle of mutual recognition, but it is not familiar with its details.

When the company has entered a new market, it examined and adapted its products to the applicable rules in the destination Member State. The costs of this adaptation amount to

## Company 17

around 1% of total annual turnover, a figure that is perceived to be quite high, as the company has a large turnover. The cost of administrative fees has been very significant. Testing costs, internal company staff time, and adaptation of the product to local technical requirements have been rather costly too.

The reason for adapting the products to local requirements was that the company was told that it was required. However, the company did not check if the mutual recognition principle applied.

According to Company 17, the mutual recognition principle works poorly. The two biggest obstacles to effective mutual recognition are related to the authorities' lack of knowledge of the correct application of the principle and the legal uncertainty related to the lack of clarity of the mutual recognition principle. In addition, it is the evaluators' understanding that the company's own lack of knowledge of the mutual recognition principle plays a role in this assessment, since the company never checked whether the mutual recognition principle applied - even though it estimates that 90% of its exports fall under the principle.

The company has experienced these obstacles in Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Malta, Poland, Portugal, Romania, Spain, and Sweden. On five occasions, the company has decided not to market its product in another Member State, particularly due to issues related to prior authorisation procedures or different testing methods.

Source: Questionnaire survey among companies, running from 9 October 2014 to 5 January 2015

## Company 18

Company 18 is a small German company active in the childcare products sector. In the last three years, the company has sold goods in other Member States. The company states that it does not know about the principle of mutual recognition. Nevertheless, it assumes that the mutual recognition applies to 50% of its export goods.

When the company has entered a new market, it has examined and then adapted its products to the applicable rules in the destination Member State. The cost of taking these steps corresponds to approx. 0.3% of the annual turnover. In this respect, administrative fees as well as testing costs are very significant.

Company 18 took these steps because it believed that it was required to do so, and therefore did not check if the mutual recognition principle applied. Moreover, it can be seen from the above statements that the company was also not familiar with/did not know about the mutual recognition principle.

Despite not knowing about the principle of mutual recognition, the company believes that this principle works badly in practice. Given the above statements, this is most likely because the company does not know the principle well. This is further supported by the fact that the company believes that the two biggest obstacles to an effective functioning of the mutual recognition principle are the lack of awareness of the principle among companies and the legal uncertainty, because the mutual recognition legislation is unclear. The company has run into obstacles when operating in France, Poland, Sweden and the UK. Over the years, the company has decided not to enter a market approximately twice a year. Thus, there may

### Company 18

also be economic benefits to be reaped by the company being able to enter new markets, if its awareness of the application of the mutual recognition principle increases.

Source: Questionnaire survey among companies, running from 9 October 2014 to 5 January 2015

### Company 19

Company 19 is a large German company operating in the sectors of medical devices and technical assistance devices (such as wheelchairs). The company has sold goods in other EU Member States within the last three years. Company 19 has heard about the principle of mutual recognition, but it is not familiar with its details. The company estimates that 50% of its exports fall under the principle of mutual recognition.

Each time the company has entered a new market, it has examined the applicable rules in the destination EU country and then adapted its product to local requirements. The costs of the steps to comply with the local requirements amount to a figure corresponding to approx. 20% of the company's annual turnover. Administrative fees, testing costs, internal company staff time, and adaptation of the product to local technical requirements are all very significant costs to the company.

The company tried to rely on the principle of mutual recognition, but it did not work in practice, mainly because local authorities did not respect the mutual recognition principle.

The company believes that the mutual recognition principle works in an 'average' way and does not know if it has helped in lowering trade barriers. The greatest obstacles to a better application of the mutual recognition principle are legal uncertainties due to issues of prior authorisation procedures and the fact that the authorities in other Member States do not know the principle well enough or do not apply the principle correctly. The company has primarily experienced obstacles in Sweden. On six occasions, it has decided not to enter another EU market due to these legal issues. Over the years, the company has more and more often decided not to enter another EU market for legal reasons. Thus, in addition to the costs of adapting its product to local requirements, there are potentially benefits to be gained if the company can enter new markets because of better application of the mutual recognition principle particularly by Member State authorities.

Source: Questionnaire survey among companies, running from 9 October 2014 to 5 January 2015

### Company 20

Company 20 is a medium-sized company based in the UK operating in the construction products sector. It has sold goods to other Member State the last three years. The company knows what mutual recognition means, and assumes that 20% of its export goods fall under the principle of mutual recognition.

When entering a new EU market the company examines the local technical requirements, and comments, "[We] check the case with the national authorities, and nine out of 10 times we need to adapt to the local requirements." These adaption costs amount to 2% of the company's annual turnover. Especially the adaptation to local requirements accounts for significant costs. Even though the company relied on mutual recognition, the principle did not work in practice, potentially because the national authorities did not know the mutual

## Company 20

recognition principle well enough or did not apply the principle correctly.

In this company's view, the principle works 'badly'. This is interpreted as referring to the application of the principle rather than the mutual recognition principle itself. However, the company perceives the principle as having helped to lower trade barriers, just not in its sector. In addition, 80% of the company's exports fall outside the scope of the mutual recognition principle, which means that the problem could be that the principle simply does not apply to most of the company's products.

The two largest obstacles to a better functioning of the mutual recognition principle are that the national authorities do not know about the mutual recognition principle or do not apply it correctly, and that there is legal uncertainty due to prior authorisation procedures. It therefore seems that the lack of understanding of the application of the mutual recognition principle among national authorities is what constitutes some of the adaptation costs for the company. The company has experienced obstacles in France and Germany. On 10 occasions, the company has decided not to enter another EU market for legal reasons. Over the years, the times where the company has decided not to enter another EU market for legal reasons has decreased slightly. However, there might still be benefits to be obtained here for the company as well.

Source: Questionnaire survey among companies, running from 9 October 2014 to 5 January 2015

## Company 21

Company 21 is small a German company working with childcare products. It has sold goods to other Member States for the past three years. The company states that it does not know about the principle of mutual recognition. Still, it assumes that 10% of its exports fall under the principle.

When entering a new market, the company examines the applicable rules and adapts its products to them. The costs of these adaptations are approx. €50,000 annually. The typical costs involved are administrative fees, testing costs, and adaptation to the local requirements, and they are all perceived to be very significant costs.

The reason for adapting its products was that the company did not know that the mutual recognition principle may have applied, and therefore the company thought that it had to adapt its products to local requirements.

According to Company 21, the mutual recognition principle works 'very badly'. It is not necessarily the legislation in itself, but rather that the company did not know about the principle and that it may have been difficult to understand the legislation. Thus, the problem is rather a lack of awareness of the principle than the principle itself. This is further supported by the fact that the company perceives the two greatest obstacles to an effective functioning of the mutual recognition principle to be lack of awareness of the mutual recognition principle among companies and legal uncertainty due to unclear mutual recognition legislation. The company has experienced these obstacles in France and Sweden.

Source: Questionnaire survey among companies, running from 9 October 2014 to 5 January 2015



## Company 22

Company 22 is a micro company based in the UK producing childcare products. It has sold goods in other EU Member States for the past three years. The company does not know the mutual recognition principle, but still estimates that 5% of its exports fall under the mutual recognition of goods principle.

When the company enters a new market it examines local requirements and often ends up retesting the product or adapting it to local requirements. The costs of these requirements correspond to approx. 10% of the annual turnover.

The typical costs, linked to testing and adaptation of the product to the local requirements, are very significant. The company assumed it was necessary to adapt to the local requirements as they did not know or check if the mutual recognition principle applied.

According to the company, the mutual recognition works in an 'average' way. The two greatest obstacles to an effective functioning of the mutual recognition principle are lack of awareness of the principle among companies, and that the authorities do not know the mutual recognition principle, or do not apply the principle correctly. Company 23 has experienced these obstacles in Germany. Thus, better awareness and application of the principle by companies and national authorities alike could potentially reduce the adaptation costs for Company 23. However, it should also be kept in mind that only 5% of the company's exports falls under the principle. Hence, the potential economic gains may be limited.

Source: Questionnaire survey among companies, running from 9 October 2014 to 5 January 2015

## Company 23

Company 23 is a large, Portuguese company operating in the fertiliser sector. The company has sold goods to other EU Member States in the past three years. The company knows about the mutual recognition principle. About 5% of its exports fall under the mutual recognition principle.

When entering a new market, Company 23 examines local requirements and adapts to them. The adaptation costs amount to approx. 20% of the company's annual turnover. The typical costs involved are administrative costs, internal company staff time, and adaptation of the product to local requirements. All of these are very significant costs.

When entering a new market, Company 23 has tried to rely on the mutual recognition principle, but it has not worked in practice. This is probably because only 5% of the company's products fall under the mutual recognition principle. In addition, the company believes that the principle works very well and that it has helped to lower trade barriers. Thus, the mutual recognition principle may function well in practise, and the costs of adapting to local requirements may be related to the fact that few of the company's products actually fall under the mutual recognition principle.

The company has experienced obstacles in Bulgaria and Italy. On 20 occasions, the company has decided not to enter a new EU market for legal reasons.

Source: Questionnaire survey among companies, running from 9 October 2014 to 5 January 2015

## ANNEX 10: OVERVIEW OF DIRECTIVE EU 2015/1535 (TRIS)

Directive (EU) 2015/1535 was adopted on 9 September 2015 and repealed and replaced Directive 98/34/EC. The Directive requires the Member States to notify the Commission and each other of any draft ‘technical regulations’ for products before they are adopted in national law, with a view to boosting transparency and control with regard to those regulations. Since national technical regulations might create unjustified barriers to trade between Member States, notification in draft form and subsequent evaluation of their content help to diminish this risk.

There is a two-pronged procedure for this exchange of information:

- the first part of the Directive relates to the European standardisation bodies and the procedures for information on new national initiatives which should lead to the formulation of national standards, compliance with which is not compulsory;
- the second requires Member States to take part in a system of reciprocal transparency and monitoring of draft technical regulation within the meaning of the Directive, compliance with which is compulsory and non-observance of which could impede the proper functioning of the single market.

The Directive enables the Commission and the Member States to identify potential barriers to trade and take action to ensure that they are either not brought into force, or are made compatible with EU law.

The Directive and the Regulation have differing objectives:

- a) The Directive seeks to prevent trade barriers in the form of ‘technical regulations’ before they are adopted, by enabling the Commission and Member States to verify that the technical rule is compatible with EU law.
- b) The Regulation applies after a ‘technical rule’ has been adopted; it seeks to ensure that any authorities taking decisions based on such rules apply the principle of mutual recognition correctly in individual cases.

The two acts apply at different stages in the life cycle of a technical rule. While the Directive is a preventive mechanism which precedes the adoption of a technical rule, the Regulation is a corrective measure once the rule is in force, ensuring on a case by case basis that the rule is being applied correctly.

To guarantee the transparency of national legislative initiatives and ensure that the Internal

Market functions correctly, Article 8 of the Directive requires Member States to forward immediately to the Commission any draft technical regulation they plan to adopt, along with the grounds for the proposed measures.

Generally, and if the proposed technical rule is considered justified, the Commission requests

Member States to include in the notified text a ‘mutual recognition clause’, in the interests of transparency and legal certainty for national administrations and economic operators.

Nevertheless, even a national technical rule which has been notified under the Directive could still create barriers to the free movement of goods since it has to be implemented by the national administration. Any misunderstanding or flawed interpretation by the competent authority might result in the rule being wrongly applied. Moreover, the technical rule might not reflect the latest technological developments and product innovation. Thus, a rule that, during the notification procedure under the Directive, showed no risk of creating trade barriers, can still throw up a barrier for a product which has been lawfully placed elsewhere in the internal market. In that event the Regulation should be applied on a case-by-case basis.

In the light of the Commission interpretative communication on the practical application of mutual recognition<sup>6</sup>, Member States are still invited to insert into their draft national technical regulations mutual recognition clauses for products which have been lawfully manufactured and/or marketed in another Member State of the European Union or in Turkey, or lawfully manufactured in an EFTA State that is a contracting party to the EEA agreement.

The standard mutual recognition clause may be supplemented by a reference to the applicability of the Regulation.

The reference to the Regulation might be worded as follows:

‘The application of this law is subject to Regulation (EC) No 764/2008 of the European

Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State, and to subsequent amendments.’

From 2011 to 2013, the Commission received 2114 notifications (675 in 2011, 734 in 2012 and 705 in 2013).

The construction sector saw the highest number of notifications over the reporting period. Many measures related to energy efficiency of buildings and concrete structures, road pavements and constituent materials, fire safety of buildings. Construction was again followed by agricultural products, foodstuffs and beverages. In this sector, several measures concerned 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 increased 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).

Below, the latest report on the application of the Directive provides more details on its implementation on the ground.



Brussels, 17.7.2015  
COM(2015) 338 final

**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE  
COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE**

**THE OPERATION OF DIRECTIVE 98/34/EC FROM 2011 TO 2013**

{SWD(2015) 137 final}

## EXECUTIVE SUMMARY

This report analyses the application of the procedures laid down by Directive 98/34/EC<sup>311</sup> from 2011 to 2013 as regards technical regulations and for 2011 and 2012 as regards standards (the standardisation part of Directive 98/34/EC was repealed as of 1 January 2013 by Regulation (EU) No 1025/2012 on European standardisation<sup>312</sup>, in order to better address future challenges in European standardisation). It highlights the important contribution of the notification procedure to the functioning of the single market and to the implementation of the Better Regulation policy<sup>313</sup>.

The standardisation part consists of the information procedure on standards, the Commission requests to the European Standards Organisations (ESOs)<sup>314</sup> for standardisation work (mandates), and formal objections against standards. Each of these activities has proved to be an important element in the functioning of the single market. The information procedure has brought transparency to standards at national and thus also European level and has encouraged National Standards Bodies (NSBs) to continue to take initiatives at European level, which in turn promotes European harmonisation. Formal objections have enabled Member States and the Commission to ensure that standards meet the goals of regulation when used for the purposes of 'New Approach' legislation. Mandates have provided the means by which the relationship between the Commission services and standardisation bodies is determined; the interface between the policy level and its technical expression.

In the field of technical regulations, the notification to the Commission of national technical regulations prior to their adoption has again proved to be an effective instrument of prevention of barriers to trade and of cooperation between the Commission and the Member States and among the Member States themselves. The notification procedure has been an important tool for guiding national regulatory activity in certain emerging sectors and improving the quality of national technical regulations - in terms of transparency, readability and effectiveness - in non-harmonised or partly harmonised areas. The greater clarity in the legal framework of the Member States has helped economic operators reduce the cost of accessing the regulations and applying them correctly.

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311 Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998, laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204 of 21.07.1998), as amended by Directive 98/48/EC (OJ L 217 of 05.08.1998).

312 Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council, OJ L 316, 14.11.2012, p. 12–33.

313 Action plan for improving the regulatory environment, COM(2002) 278 final. See also Better Regulation for Growth and Jobs in the European Union, COM(2005) 97 final; Implementing the Community Lisbon programme: A strategy for the simplification of the regulatory environment, COM(2005) 535 final; A strategic view of Better Regulation in the European Union, COM(2006) 689; Second strategic review of Better Regulation in the European Union, COM(2008) 32, Third strategic review of Better Regulation in the European Union, COM(2009) 15 and Smart Regulation in the European Union; COM(2010)543.

314 CEN (European Committee for Standardisation), CENELEC (European Committee for Electrotechnical Standardisation) and ETSI (European Telecommunications Standards Institute).

## **PART I: STANDARDISATION**

### **1. INTRODUCTION**

This section describes the operation of the standardisation part of Directive 98/34/EC covering three main activities: the information procedure on standards, Commission requests to the European Standards Organisations for standardisation work (mandates<sup>315</sup>), and formal objections against standards supporting New Approach Directives. It provides and explains statistics for the period 2011-2012, as the standardisation part of Directive 98/34/EC was repealed as of 1 January 2013 by Regulation (EU) No 1025/2012 on European standardisation.

### **2. INFORMATION PROCEDURE**

The information procedure in the field of standards is designed to monitor the new standardisation activities introduced by the NSBs (as recognised under Directive 98/34/EC). The notification system was set up mainly to allow other bodies to comment, participate in the work or request an initiative to be taken at European level (see Annex 1).

#### **2.1 Operation of the procedure from 2011 to 2012**

The procedure continued to operate successfully from 2011 to 2012. From the reports provided by CEN and CENELEC each year, it is possible to see that the annual average of national measures remained relatively stable in 2011 and 2012. Annex 2 gives a breakdown of notifications by Member State.

Comparing the statistics of 2011-2012 with the previous periods, the number of notifications made by the EU27 countries continued to be stable with between 1750 and 2000 notifications per year (not considering the exceptional situation in 2010).

The sectoral breakdown (Annex 3) shows that the construction sector, in its broadest sense, continues to dominate the national notifications in CEN. Food products and petroleum products have also been a significant area in CEN. In CENELEC, electrical accessories, electric cables, and electrical installations in buildings have been significant subsectors both in 2011 and 2012.

The information disseminated under the procedure continued to give rise to requests for further information by the Commission services, as well as queries regarding the standstill (Article 7) arising either from notifications or other sources.

Apart from the rather exceptional situation of 2010 the number of notifications has been relatively stable, or even decreasing since 2006. This applies also to the Member States which joined the EU in 2004 and 2007 and could be interpreted as a sign of good integration in the system as the standardisation activity appears to be moving from the national to the European level. In general the procedure is well applied and works correctly.

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315 Mandates are requests representing an invitation to ESOs that may be accepted under certain conditions.

## **2.2 Conclusion**

The information procedure still plays an important role in encouraging national standardisation bodies to bring their initiatives to the European level, thus encouraging the single market and European harmonisation. Notifications from EU 12 Member States are stable which can be considered as a good sign of their integration in the system.

As of 1 January 2013, the standardisation part of Directive 98/34/EC was repealed by Regulation (EU) No 1025/2012 on European standardisation in order to better address future challenges in European standardisation. This relates in particular to the increased development of standards for services, the evolution of standardisation deliverables other than formal standards, and increased requirements on the inclusiveness of the European standardisation system. Regulation (EU) No 1025/2012 however maintains a similar information procedure operated under Directive 98/34/EC, even though with minor changes.

## **3. MANDATES**

Standardisation “mandates” are a well-established Commission tool to obtain technical specifications that support European legislation and/or policy. They are requests to the ESOs for standardisation work and provide a reference framework for that work (see Annex 1). They are indispensable in cases where standards support legislation, for example in the context of the 'New Approach' Directives.

### **3.1 Operation of the mandating process 2011-2012**

In the reporting period, a total of 43 mandates were issued to the ESOs, with 8 amendment mandates. The ratio of amendments is relatively higher compared to that of previous years (see Annex 4). Also the number of mandates concerning New Approach Directives (13, plus the 8 amendments) has increased compared to the previous period.

The mandating process functions well. The informal consultation carried out before the documents are circulated to the members of the Committee on Standards and Technical Regulations means that a mandate normally has consensual agreement before the formal consultation starts.

The European standardisation stakeholders – ANEC (European association for the co-ordination of consumer representation in standardisation), ECOS (European Environmental Citizens Organisation for Standardisation), NORMAPME (European Office of Crafts, Trades and Small and Medium-sized Enterprises for Standardisation) and ETUI-REHS (European Trade Union Institute – Research, Education, Health and Safety) were well-integrated into the process during the reporting period. This brings greater transparency to the informal consultation.

In order to increase transparency further, DG Internal Market, Industry, Entrepreneurship and SMEs maintains a database of mandates. It contains all mandates issued in the past with the numbering series M/xxx. This database is publicly accessible on the internet at:

<http://ec.europa.eu/growth/tools-databases/mandates/index.cfm?fuseaction=search.welcome>

The practice of giving a follow-up to all the mandate consultations to the Committee on Standards and Technical Regulations by means of an updated list has continued throughout the period.

### 3.2 Trends in mandates

In the reporting period, mandates were issued in support of a broad spectrum of legislation. The most significant areas include legislation on construction products, ecodesign, consumer protection, and environmental protection. The breadth of legislative areas shows the importance conferred on the model.

The subject matter for mandates continues to broaden. At the same time, mandates issued for the New Approach Directives are still very important, and their number has actually increased compared to the previous reporting periods. Mandates in other policy areas continue to be numerous, in particular consumer protection and the environment.

The number of mandates supporting legislation outside the New Approach (see Annex 4) has remained relatively high compared with the last period and shows that this co-regulatory model continues to be adopted across a broad range of EU policies. Mandates supporting Directive 2009/125/EC (the Ecodesign Directive) have been a major contributor in this field.

Six mandates<sup>316</sup> were issued during the period 2011–2012 in support of the Ecodesign Directive. These mandates are aimed at products such as household dishwashers, lamps, air conditioners, pumps or fans.

This trend for the use of mandates in support of legislation outside the New Approach and in new areas reflects the situation that European standardisation is increasingly used in support of the better regulation policy. This has been recognised in, and indeed encouraged by, the Commission Communication of 2011 'A strategic vision for European standards: Moving forward to enhance and accelerate the sustainable growth of the European economy by 2020'<sup>317</sup>.

The number of mandates supporting European policy continued to drop and is for the second consecutive time slightly inferior compared to the previous reporting period. Nevertheless, amongst the five policy mandates are some key initiatives to promote interoperability such as the mandate on smart grids or the mandate on the space industry.

No mandate for standardisation in the service sector was issued during this period.

### 3.3 Conclusion

The process of mandating is well-established and is today governed by Regulation (EU) No 1025/2012. The informal consultation of the ESOs and all interested parties (in particular those European stakeholders representing the users of future standards) prior to the consultation of the Committee on Standards and Technical Regulations is essential.

To improve transparency in the functioning of the Committee on Standards and Technical Regulations, the Commission services continued in the reporting period in the practice

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316 Mandates M481, M485, M488, M495, M498 and M500 make reference to the Directive 2005/32/EC  
317 COM(2011) 311 final of 01.06.2011.



introduced in 2006 to invite the European standardisation stakeholders ANEC, ECOS, ETUI-REHS and NORMAPME, to participate in its enlarged meeting.

The process of mandating has proved to be instrumental in enlarging the role of standardisation in new areas of EU legislation and policy.

#### **4. FORMAL OBJECTIONS**

The New Approach directives contain safeguards for cases where a harmonised standard cannot enable products to meet the essential requirements of the directives concerned. When such cases occur, the Member States or the Commission may introduce a formal objection to the standard in question on which the Committee on Standards and Technical Regulations is consulted (see Annex 1 for the details of the procedure).

##### **4.1 Operation of the procedure from 2011 to 2012**

Compared to previous years, the number of objections that have given rise to Commission Decisions has slightly decreased during the reporting period. Only one Decision was adopted by the Commission which restricted the presumption of conformity. This Decision however concerned two formal objections against an identical harmonised standard (see Annex 5).

##### **4.2 Conclusion**

The procedure in general has worked adequately. Compared to the previous reporting period, the process from receiving the objection to issuing the Decision was shortened significantly in 2011 and 2012.

In a similar way to the mandates, and for the sake of transparency, the Commission makes decisions on formal objections public in a consolidated way, and makes an updated table of the actions in relation to the formal objections available to the Committee on Standards and Technical Regulations at each meeting.

#### **5. NEW LEGISLATIVE FRAMEWORK**

As of 1 January 2013, the standardisation part of Directive 98/34/EC was repealed by Regulation (EU) No 1025/2012 on European standardisation which introduced significant changes with respect to the information procedure, mandating procedure and formal objections.

A specific report on the implementation of the Regulation (EU) No 1025/2012 for the period from 2013 to 2015 will be presented to the European Parliament and to the Council in accordance with Article 24(3) of the Regulation.

## **PART II: TECHNICAL REGULATIONS**

### **1. DEVELOPMENTS 2011-2013**

The notification procedure for national technical regulations (the procedure) allows the Commission and the Member States of the EU to examine preventively the technical regulations Member States intend to introduce for products (industrial, agricultural and fishery) and for Information Society services (see Annex 6). It applies in a simplified manner to the European Free Trade Association (EFTA) Member States which are signatories to the Agreement on the European Economic Area (EEA) and to Switzerland and Turkey (see Annex 9).

#### **The major benefits of the procedure**

- It allows new barriers to the internal market to be detected before they have any negative effects, thus avoiding long and costly infringement proceedings.
- It allows the detection of protectionist measures which might be drawn up by Member States under exceptional circumstances, such as an economic and financial crisis.
- It allows Member States to ascertain the degree of compatibility of notified drafts with European Union legislation.
- It allows an effective dialogue between Member States and the Commission when assessing notified drafts.
- It is a benchmarking tool allowing Member States to draw on the ideas of their partners in order to solve common problems regarding technical regulations.
- It allows economic operators, including small and medium-sized enterprises (SMEs), to make their voices heard and to adapt their activities in good time to future technical regulations. This right of scrutiny is used extensively by economic operators, helping the Commission and national authorities to detect any barriers to trade.
- It contributes to the application of the subsidiarity principle.
- It is a regulatory instrument which can be used to identify areas where harmonisation is necessary.
- It helps to improve the quality of national and EU regulations in line with the "*Better regulation*" approach.
- It contributes to improving competitiveness of enterprises in the context of industrial policy.

## 1.1 Use of the procedure within the context of “Better regulation”

In its Communication *"Better regulation for growth and jobs in the EU"*<sup>318</sup> the Commission has highlighted that the preventive control mechanism established by Directive 98/34/EC is crucial for improving national regulations on products and Information Society services.

In the framework of the Commission's action plan to simplify and improve the regulatory environment<sup>319</sup>, Member States have been invited to submit impact studies (or their conclusions) together with notified drafts, where such studies have been carried out internally. The analysis of these impact studies encourages the Member States to reflect in advance on the most appropriate instrument to be used, and allows the Commission to check the necessity and proportionality of the measures proposed.

The cooperation between the Commission and the Member States within the context of the 98/34/EC notification procedure helps to improve the clarity and consistency of the notified draft national legislations. This cooperation will be intensified with a view to ensuring a clear and legible regulatory framework for economic operators while guaranteeing a high level of protection for public health, consumers and the environment.

The national authorities are encouraged to consider the following aspects in particular:

- the wording of drafts: clarity, consistency, transparency and legal certainty in the application of the texts;
- the possibility of accessing all regulations in a given sector through the publication both on paper and on-line of consolidated versions of the texts;
- the identification and avoidance of procedures imposing unnecessarily complex and onerous administrative burdens on economic operators, particularly when placing a product on the market.

## 1.2 Use of the procedure to improve competitiveness

In the framework of the EU 2020 strategy, a new approach of the industrial policy based on competitiveness analysis of legislation has been proposed.

In this context, in the latest update of the Communication on Industrial Policy of 10 October 2012 - *Communication of the Commission to the European Parliament, to the Council, to the European Social and Economic Committee and to the Committee of the Regions - A stronger European industry at the service of economic growth and re-launch - COM (2012)582 final* – the Commission underlined that:

*“Governance and regulatory obstacles to the Internal Market also arise from policy areas that are regulated by Member States, for example technical rules, refusals to apply mutual recognition and mismatches between the 27 different sets of taxation rules. An upstream analysis of draft technical rules can prevent the emergence of regulatory obstacles. This is precisely the objective of the 98/34 notification procedure, which requires draft legislation containing technical rules on products and information society services to be communicated*

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318 See supra, footnote 3.

319 See supra, footnote 3.

*to the Commission before they are adopted. The preventive nature of this procedure has avoided a large number of contraventions of free movement of goods rules. This notification procedure can also be used, however, to improve national legislation in line with "Better Regulation" principles and through benchmarking. Its potential can be further exploited by recommending that Member States use competitiveness proofing in the context of national impact assessments."*

The Communication of the Commission on industrial policy makes an explicit reference to Directive 98/34/EC which, beside to its role as an instrument for prevention of obstacles to intra-EU trade has the task to encourage Member States to proceed to a competitiveness analysis of national legislation.

This approach was endorsed by the Committee on Industry, Research and Energy of the European Parliament in its ***Report of 18 December 2013 on reindustrialising Europe to promote competitiveness and sustainability ((2013/2006(INI))*** where it encouraged further exploitation of the potential of the 98/34 notification procedure and suggested that the Member States introduce competitiveness proofing in impact assessments conducted at the drafting stages of national legislative processes, in the wider framework of the 'Single Market Test' called for in Parliament's resolution of 7 February 2013 with recommendations to the Commission on the governance of the Single Market.

In this context, Member States, as of March 2014, have been invited to prepare on a regular basis a competitiveness analysis of the national legislation notified under the scope of the procedure established by Directive 98/34/EC.

### **1.3 Improvements in managing the 98/34 procedure**

The Commission continued conducting various campaigns during 2011-2013 to increase transparency and dialogue with the national authorities. The TRIS (*Technical Regulations Information System*) database has seen continuous improvement.

The Commission worked on the revamping of the TRIS public website, (<http://ec.europa.eu/growth/tools-databases/tris/en/>), to explain the 98/34 procedure in a more accessible way and to reach a wider audience, especially SMEs. The website ensures public access to the notified drafts, in the 23 official languages of the EU, and to essential information regarding the procedure. A constant increase in the number of on-line consultations has been observed: from 2011 to 2013 the number of searches rose by 10% to reach approximately 212,000 searches in 2013 (see Annex 10). More than 4300 economic operators subscribed to the TRIS mailing list, which is a rise of 25% since 2010.

In 2012-2013, the Commission also produced a video on the 98/34 procedure. The message was to explain in a simple and attractive way the functioning of the procedure and its benefits for enterprises, to encourage active participation by enterprises, especially SMEs, and explain how they can make best use of the existing tools (websites, databases, alert systems). This video was published on 11 September 2013 and is accessible using the following link - <http://www.youtube.com/watch?v=ziuAklsNKdI>. It has been promoted on social networks and was viewed 2675 times by stakeholders since its publication.

## 2. APPLICATION OF THE 98/34 PROCEDURE

### 2.1 Effectiveness: general overview

#### ► Volume of notifications and sectors involved

From 2011 to 2013, the Commission received 2114 notifications (675 in 2011, 734 in 2012 and 705 in 2013).

**Like in the previous reporting period, the construction sector saw the highest number of notifications over the reporting period.** Many measures related to energy efficiency of buildings and concrete structures, road pavements and constituent materials, fire safety of buildings. Construction was again followed by **agricultural products, foodstuffs and beverages**. In this sector, several measures concerned 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 increased 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) (see Annex 8.3).

#### ► Issues examined

In the **non-harmonised areas**, subject to compliance with Articles 34-36 (free movement of goods) and 49 and 56 (right of establishment and freedom to provide services) of the Treaty on the Functioning of the European Union (TFEU), the Commission's reactions were intended to draw Member States' attention to potential obstacles to trade which could be created by an unnecessary measure disproportionate to the objective pursued. Thus the Commission ensured compliance with these principles and in addition continued to invite Member States to insert mutual recognition clauses into each draft technical regulation falling outside the harmonised area.

In the **harmonised areas**, the reactions were intended to ensure that national measures were necessary, justified and compatible with EU secondary legislation.

- In 2011, 2012 and 2013 Member States notified 512 draft technical regulations in the field of **construction**. These drafts concerned all types of construction products, *inter alia*, bridge structures and concrete road structures, pitched roof coverings for buildings, fire-fighting and rescue equipment, thermal insulation, synthetic fill materials, concrete structures, electrical installations on and in concrete structures, metallic materials in contact with drinking water.

In particular, the Commission examined draft technical regulations setting additional technical requirements or tests for construction products impeding the free movement of products labelled with the CE mark. The notified drafts were examined principally under Directive 89/106/EEC on construction products<sup>320</sup> and Regulation (EU) No

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320 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, OJ L 40, 11.2.1989, p. 12–26.

305/2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC<sup>321</sup>.

The Commission also examined draft legislation prohibiting the installation of fossil oil furnaces and natural gas furnaces in new buildings except when oil and gas furnaces use only renewable energy. The notified draft was examined under Directive 2009/142/EC on gas appliances (GAD)<sup>322</sup> and Directive 92/42/EEC on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels<sup>323</sup>.

Technical regulations relating to energy efficiency of buildings were assessed under Directive 2012/27/EU on energy efficiency<sup>324</sup>, Directive 2010/31/EU on the energy performance of buildings<sup>325</sup> and Directive 2009/125/EC establishing a framework for the setting of ecodesign requirements for energy-related products<sup>326</sup>.

- In the foodstuffs and agricultural sectors, from 2011 to 2013 Member States notified 393 draft technical regulations. These drafts concerned, *inter alia*, materials coming into contact with foodstuff, energy drinks, trans fats in food products, wine and spirits, labelling of foodstuff, in particular nutritional declarations, quality marks, the well-being of fur animals and the marketing of fur products.

Certain Member States notified draft regulations imposing restrictions on or prohibition of food packaging containing bisphenol A and in particular packaging for foods intended for children between 0 and 3 years, as well as concerning health warning to be affixed to packaging containing bisphenol A. These notifications have been examined under the Treaty provisions on the free movement of goods and Regulation (EC) No 1935/2004 concerning materials and articles intended to come into contact with food.<sup>327</sup>

During the relevant period the Commission examined many notifications concerning the hygiene of foodstuffs and issued detailed opinions and comments on the basis of Regulations (EC) No 852/2004 on the hygiene of foodstuffs<sup>328</sup>, (EC) No 853/2004 laying down specific hygiene rules for food of animal origin<sup>329</sup> and (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption<sup>330</sup>.

Other notifications concerned the labelling of foodstuff and the Commission assessed their compatibility with Directive 2000/13/EC on the approximation of the laws of the

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- 321 Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC, OJ L 88, 4.4.2011, p. 5–43.
- 322 Directive 2009/142/EC of the European Parliament and of the Council of 30 November 2009 relating to appliances burning gaseous fuels, OJ L 330, 16.12.2009, p. 10–27.
- 323 Council Directive 92/42/EEC of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels, OJ L 167, 22.6.1992, p. 17–28.
- 324 Directive 2012/27/EU of the European Parliament and of the Council of 25 October 2012 on energy efficiency, amending Directives 2009/125/EC and 2010/30/EU and repealing Directives 2004/8/EC and 2006/32/EC, OJ L 315, 14.11.2012, p. 1–56.
- 325 Directive 2010/31/EU of the European Parliament and of the Council of 19 May 2010 on the energy performance of buildings, OJ L 153, 18.6.2010, p. 13–35.
- 326 Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products, OJ L 285, 31.10.2009, p. 10–35.
- 327 Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, OJ L 338, 13.11.2004, p. 4–17.
- 328 Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, OJ L 139, 30.4.2004, p. 1–54.
- 329 Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin, OJ L 139, 30.4.2004, p. 55–205.
- 330 Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption, OJ L 139, 30.4.2004, p. 206–320.

Member States relating to the labelling, presentation and advertising of foodstuffs<sup>331</sup> and Regulation (EU) No 1169/2011 on the provision of food information to consumers.<sup>332</sup>

- In the Information Society services sector there were 99 notifications. Numerous notifications were in the area of gambling, while others concerned, *inter alia*, copyright in the digital environment, on demand audio-visual media services, electronic commerce, electronic signature and other trust services.
- Since 2011, Member States have notified a series of technical regulations concerning measuring instruments. These drafts concerned various types of measuring devices such as gas, electricity and heat meters, taximeters or prism refractometers and provided for specific requirements which these instruments have to fulfil. The notifications on gas, electricity and heat meters and taximeters were mainly analysed under Directive 2004/22/EC on measuring instruments<sup>333</sup>. The novelty consisted of projects of new smart metering systems, also falling under Directive 2004/22/EC, which are quite complex due to the needs of the combination of engineering with IT and communication, data privacy and security aspects.
- In the chemicals sector the Commission received 76 notifications. Some of them regarded the annual declaration of nanoparticle substances as well as draft legislation banning the import and sale of products containing certain phthalates intended for indoor use or which may come into contact with skin or mucous membranes. The notified drafts were mainly examined under Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)<sup>334</sup>.
- In the environment sector the Commission examined 141 draft regulations. Some notified drafts established conditions for the use of environmental claims on plastic objects and packaging while others prohibited the marketing of non-biodegradable shopping bags. These notifications have been mainly analysed in the light of Directive 94/62/EC on packaging and packaging waste<sup>335</sup>.

The 98/34 procedure has also allowed the Commission to intervene in sectors where harmonisation was envisaged or under way at European Union level and thus has prevented Member States from introducing divergent national measures. Pursuant to Articles 9(3) and 9(4) of Directive 98/34/EC, the Commission has blocked the adoption of notified draft legislation for twelve months from the date of notification in the fields of: type-approval requirements for masses and dimensions of motor vehicles and their trailers; marketing and

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331 Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, OJ L 109, 6.5.2000, p. 29–42.

332 Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, OJ L 304, 22.11.2011, p. 18–63.

333 Directive 2004/22/EC of the European Parliament and of the Council of 31 March 2004 on measuring instruments, OJ L 135, 30.4.2004, p. 1–80.

334 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, 30.12.2006, p. 1–849.

335 European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste, OJ L 365, 31.12.1994, p. 10–23.

use of explosives precursors; the indication of the origin of olive oil on the label and the methods for such indication; compounds terms for spirit drinks; electronic identification and trust services for electronic transactions; fertilisers allowed in organic production. Through this type of intervention, not only has the Commission avoided the fragmentation of the market in areas where harmonisation was envisaged or under way, but it has also granted greater certainty and stability in the legal framework of Member States and of the European Union to the benefit of economic operators and of the competitiveness of European enterprises.

### ► **Reactions**

The Commission issued detailed opinions in relation to 208 notifications, which represents 9.8% of the total number of drafts notified by the Member States over the reporting period. This figure shows a 29.2% increase in the number of detailed opinions issued by the Commission compared to the previous three years. For their part, the Member States issued 205 detailed opinions. Of the 910 comments issued during the reporting period, 425 were made by the Commission and 485 by the Member States (see Annexes 8.4 and 8.6).

In 12 cases, the Commission invited the Member States concerned to postpone the adoption of the notified regulations for one year from the date of their receipt because there was European Union harmonisation work under way in the area (see Annex 8.5).

### **2.3 Use of the urgency procedure**

Out of a total of 2114 notifications, the Member States made 87 requests to apply the urgency procedure to notified drafts. The Commission confirmed its strict interpretation of the exceptional conditions required by Directive 98/34/EC, namely serious and unforeseeable circumstances relating in particular to the protection of health and safety. As a result, use of the urgency procedure was refused where the justification was not sufficiently established or was based on purely economic grounds or national administrative delay as well as in cases where no unforeseeable circumstances were demonstrated. The urgency procedure was deemed justified in 56 cases, in particular concerning psychotropic substances, control of narcotics, radioactive waste, infection of bees, poisonings caused by methanol intoxication, explosive precursors, protection of cash transports, prohibition of products that are harmful to health, prohibition of the possession and use of fireworks not intended for private individuals. (see Annex 8.7).

### **2.4 Notification of ‘fiscal or financial incentive measures’**

According to Directive 98/34, Member States have to notify fiscal and financial incentives, i.e. technical regulations which are linked to fiscal or financial measures affecting the consumption of products or services by encouraging compliance with such technical regulations. The specificity of such technical regulations is that the standstill period does not apply.

During the period 2011-2013 Member States notified 112 draft regulations as *‘fiscal or financial measures’*. The Commission observes that often national legislation is misclassified as *‘fiscal or financial measure’* in the meaning of Directive 98/34/EC when it contains any fiscal or financial measures but not the incentive to comply with such technical regulations. In order to help Member States to correctly classify these technical regulations the Commission



drafted Guidelines on the definition and notification of *'fiscal or financial measures'* for the purposes of Directive 98/34/EC.

## 2.5 Follow-up to Commission reactions

From 2011 to 2013, the ratio between the number of responses given by Member States and the volume of detailed opinions issued by the Commission was satisfactory (an average of 86% over the period). This percentage is the main indicator used to assess Member States' commitment to meeting their obligations under the procedure. The number of completely satisfactory responses was higher in comparison with the previous reporting period (an average of 48.4% over the period 2011-2013 in comparison with 32.5% over the period 2009-2010) (see Annex 8.8), showing an increased compliance of Member States with the internal market legal framework following the Commission's reaction. The effect of Commission's reactions was even more remarkable in the case of notified draft technical regulations which were withdrawn following the delivery of a detailed opinion (24 cases for the reporting period). For other notified draft technical regulations the dialogue is still on-going.

## 2.6 Follow-up to the notification procedure

For all other cases where the potential breaches of the EU internal market law have not been entirely cleared within the framework of the 98/34/EC procedure, the Commission conducted further investigations which in some cases, eventually led, to EU Pilots or to infringement proceedings (Article 258 of the TFEU) on subjects such as quality and transparency of the supply chain for virgin olive oils, taxation of food products with high sugar, salt, and/or caffeine content, environmental protection product charges, traditional food production, wine and spirits, banning of products intended for indoor use which contain certain types of phthalates, products made of leather, hide and fur, minimum content of fruit juice that must be contained in non-alcoholic fruit-based beverages and plastic bags.

Two of the infringement proceedings brought against Member States during the reporting period were grounded on the breach of obligations under Directive 98/34/EC.

## 2.7 Dialogue with the Member States

The regular meetings of the Committee on Standards and Technical Regulations allowed views to be exchanged on points of general interest and also on specific aspects of the procedure.

As regards technical regulations, the discussions particularly concerned the role of notifications for national competitiveness issues and competitiveness proofing; access to documents of the Commission under Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents<sup>336</sup>; the obligation for Member States to communicate to the Commission the final text of a notified technical regulation; and the legal consequences of the delivery of a detailed opinion under Article 9(2) of Directive 98/34/EC.

The Commission made presentations concerning Regulation (EU) No 1169/2011 on the provision of food information to consumers; the review of Regulation (EC) No 1907/2006

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336 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43-48.

(REACH); the Product Safety and Market Surveillance Package; the evaluation report of Directive 2006/123/EC on services in the internal market<sup>337</sup>; the state of play of the internal market in the construction sector; issues related to technical regulations in the area of renewable energy sources; notifications about metrology and notifications in the railway sector, in particular notification obligations in the framework of Directive 2004/49/EC on safety on the Community's railways<sup>338</sup> and Directive 2008/57/EC on the interoperability of the rail system within the Community<sup>339</sup>.

Guidelines on the definition and notification of '*fiscal or financial measures*' for the purposes of Directive 98/34/EC, and guidelines on the "*One-stop-shop for the 98/34 notification procedure and for the notification procedures laid down in specific EU rules*" were presented by the Commission.

Seminars were also held in several Member States, allowing direct dialogue between the Commission and the national authorities involved in the procedure and helping the latter to become familiar with the highly technical elements of the procedure.

## 2.8 Requests for access to documents issued under Directive 98/34

From 2011 to 2013 the Commission received 272 requests for access to documents issued in the framework of the 98/34 procedure. The major part of them concerned detailed opinions and comments delivered by the Commission. In 167 of the cases, access to the requested documents was given. In the other cases, access to documents was refused while the dialogue with the Member States, aimed at removing the potential obstacle to trade, was ongoing.

## 2.9 Conclusion

During the period 2011-2013, the usefulness of the procedure has again been confirmed in terms of effectiveness, transparency and administrative cooperation.

The preventive and networking approach of the 98/34 procedure has substantially reduced the risk of national regulatory activities being carried out in a way that would create technical barriers to the free movement of goods within the internal market. The high number of detailed opinions and comments issued during the reporting period demonstrates that there is still a risk of fragmentation of the internal market for goods. On average 86% of the detailed opinions issued by the Commission during the period were replied to by the Member States concerned and dialogues followed to remove any incompatibility with EU law and ensure the free movement of goods within the internal market, thus avoiding infringement procedures.

The 98/34 procedure has also confirmed its usefulness in providing the possibility to identify areas where harmonisation at EU level might be an option.

When applying Directive 98/34/EC the Commission remains vigilant regarding the principle of better regulation and the need to sustain a favourable environment for the competitiveness

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337 Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market, OJ L 376, 27.12.2006, p. 36–68.

338 Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification, OJ L 164, 30.4.2004, p. 44–113.

339 Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community, OJ L 191, 18.7.2008, p. 1–45.

of the European economy. Notified drafts continue to be available electronically, free of charge and in all the official languages of the EU, thus providing the opportunity for economic operators and other stakeholders to comment on them.

Efforts will continue in order to ensure a clear legal framework for economic operators aiming at enhancing the competitiveness of European enterprises in the EU and abroad, taking into account the links between the 98/34 procedure and that established by the Agreement on Technical Barriers to Trade (TBT) in the context of the World Trade Organisation (WTO). Further promotion of the Directive and its stronger implementation together with a stronger link with follow-up policy and legislative actions are crucial in order to fully achieve its objectives.

## **ANNEX 11: SUMMARIES OF THE MEETINGS OF THE CONSULTATIVE “MUTUAL RECOGNITION COMMITTEE”**

### **1. MINUTES OF THE FIRST MEETING OF THE CONSULTATIVE ‘MUTUAL RECOGNITION COMMITTEE’ HELD IN BRUSSELS ON 4 MARCH 2009**

The consultative “Mutual Recognition Committee” was set up by Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC (JO L218 of 13.8.2008, p. 21).

The committee met for the first time on 4 March 2009. The attendance list is attached hereto.

The following matters were discussed.

#### **RULES OF PROCEDURE**

The Commission presented the draft rules of procedure which were sent to delegates in English, French and German. This draft corresponds to the standard text of the rules of procedure which was approved by the Commission on 31 January 2001 (OJ C 38, 6.02.2001, p. 3).

The Commission indicated that the draft rules of procedure will be translated into all official EU languages and then sent to the members of the committee for approval. Any member of the committee who does not express his opposition or intention to abstain from voting on the draft rules of procedure within the time-limit laid down in the message shall be considered to have given his tacit agreement (written procedure).

#### **INDICATIVE LIST OF PRODUCTS**

The Commission presented the work in progress with respect to the indicative and non-exhaustive list referred to in Article 12(4) of Regulation (EC) No 764/2008 (see attachment).

#### **PRODUCT CONTACT POINTS**

The Commission reminded all Member States of their obligation to designate Product Contact Points (PCP) in their territories and to communicate their contact details as stated in Article 9 of the Mutual Recognition Regulation.

The Commission invited delegations to inform the committee of the state of the play regarding the establishment of their PCP.

#### **GUIDANCE DOCUMENTS**

The Commission presented a summary of the six draft guidance documents (see attachment):

- (1) The application of the mutual recognition regulation to weapons and firearms
- (2) The application of the mutual recognition regulation to articles of precious metals

- (3) The relationship between the Directive 98/34 and the mutual recognition regulation
- (4) The application of the mutual recognition regulation to food supplements
- (5) The relationship between the Directive 95/2001 and the mutual recognition regulation
- (6) The application of the mutual recognition regulation to narcotic drugs and psychoactive substances

The chair clarified that these documents are not legally binding but just drafts that need to be improved with the contributions and expertise of the members of the Committee.

#### ANY OTHER BUSINESS

#### **Contacts between committee members and the Commission**

The Commission explained that all future communications between the Commission and the committee members within the context of the committee will go via CIRCA (see <http://circa.europa.eu/>).

#### **The role of Product Contact Points under the forthcoming Construction Products Regulation**

Some delegations expressed their concerns about an IMCO amendment of the Commission's proposal for a Regulation of the European Parliament and of the Council laying down harmonised conditions for the marketing of construction products [COM(2008)311 final]. This amendment seeks to broaden the role of Product Contact Points.

#### CONCLUSION OF THE MEETING

The Commission also informed the committee that the management of the Mutual Recognition Regulation (EC) 764/2008 will be transferred to unit ENTR/C/2 with effect from 1 May 2009.

Finally, the Commission suggested that another meeting of the committee should be organised after having gained some experience with the implementation of the Regulation in the Member States. Consequently, the Commission took the view that it was too premature to announce a date for the next meeting.

#### **2. MINUTES OF THE SECOND MEETING OF THE CONSULTATIVE 'MUTUAL RECOGNITION COMMITTEE' HELD IN BRUSSELS ON 19 NOVEMBER 2010**

The consultative Mutual Recognition Committee held its second meeting on 19 November 2010. The attendance list and the PowerPoint presentations are attached hereto.

The following matters were discussed.

#### GUIDE TO THE APPLICATION OF THE TREATY PROVISIONS GOVERNING THE FREE MOVEMENT OF GOODS

The Commission presented the updated 2010 version of the Guide to the application of Treaty provisions governing the free movement of goods, prepared and drafted by Unit C2 of the

Directorate-General for Enterprise and Industry. The guide was distributed to the participants in their respective language.

The Commission indicated that all Member States will be provided with links to the guide in all official languages<sup>340</sup>.

#### GUIDANCE DOCUMENTS ON THE APPLICATION OF THE MUTUAL RECOGNITION REGULATION

The Commission presented the final versions of the Guidance documents on the application of the MRR. The documents were made available immediately after the meeting in all official languages on the DG's homepage and links with access to these documents were sent to the Member States<sup>341</sup>.

The seven guidance documents are the following:

- (1) The application of the Mutual Recognition Regulation to weapons and firearms
- (2) The application of the Mutual Recognition Regulation to articles of precious metals
- (3) The relationship between Directive 98/34/EC and the Mutual Recognition Regulation
- (4) The application of the Mutual Recognition Regulation to food supplements
- (5) The relationship between Directive 2001/95/EC and the Mutual Recognition Regulation
- (6) The application of the Mutual Recognition Regulation to narcotic drugs and psychotropic substances
- (7) The application of the Mutual Recognition Regulation to prior authorisation procedures.

The Commission pointed out that these documents are not legally binding and may be amended in the course of time, especially as a result of the evolution of the case-law of the European Court of Justice.

Guidelines in regard to the construction sector were proposed to be added but the Commission stressed that ongoing legislative procedures within that sector have to be finalised before such guidelines can usefully be prepared.

#### DISCUSSION ON THE APPLICATION OF THE MUTUAL RECOGNITION REGULATION AND THE MEMBER STATES' REPORTS

The Commission briefly presented the notifications received and the Member States' reports. The Commission proposed to report after the end of the calendar year and to organise training for the PCPs.

The Commission drew *inter alia* attention to the following:

- There are apparent discrepancies between the number of notifications received by the

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340 The guide is available in all language versions at [http://ec.europa.eu/enterprise/policies/single-market-goods/free-movement-non-harmonised-sectors/index\\_en.htm](http://ec.europa.eu/enterprise/policies/single-market-goods/free-movement-non-harmonised-sectors/index_en.htm)

341 The guidance documents are available at <http://ec.europa.eu/enterprise/policies/single-market-goods/free-movement-non-harmonised-sectors/mutual-recognition/>

Commission and the number of decisions taken by the MS authorities reported on in the annual reports (some decisions falling within the MRR seem to be adopted, but not notified to the Commission);

- products most often concerned are articles of precious metal, foodstuffs, food additives and food supplements, construction products and fertilisers;
- difficulties encountered concern *inter alia* the interpretation of some terms used in MRR (eg. “placing on the market” and “lawful marketing”, “conditions of use”, “administrative decisions”; “economic operator”), the identification of products, the lack of established channels of communication among the competent authorities from MSs, no common linguistic regime.

It was concluded that PCPs play an important and useful role in the application of the MRR and that there is increasing awareness of the mutual recognition principle - both within national administrations and by economic operators. Economic operators should be able to find PCP’s contact details easily (web pages, e-mail) and the channels of communication between national administrations could be reinforced.

#### DATABASE IN REGARD TO PRODUCT CONTACT POINTS AND LIST OF PRODUCTS

The Commission presented the database in regard to PCPs and the list of products. The Member States were asked to check their contact details by CIRCA. The document with the updated contact details will be translated into all the official languages and published in the Official Journal.

#### Internal Market Information System (Imi): State Of Play

The Commission presented the internal market information system (IMI) and its possible role in the application of the MRR. The Commission concluded that the suggestion to expand the IMI system to cover the MRR seems to be a useful measure, but needs to be explored further.

#### Any Other Business

The Commission informed the committee about the request from the EFTA secretariat and some EEA/EFTA countries to participate in future committee meetings and proposed that representatives of the EFTA secretariat and EEA/EFTA countries would be invited to the next committee meeting. No objections were raised to this proposal.

#### Next Steps/Conclusion

The Commission indicated that the committee should continue to meet annually and suggested that reports should be submitted on a calendar-year basis. To this end, the Commission suggested that the next report would cover the period from May 2010 to May 2011 and then the Commission could request the supplementary report for the remaining part of 2011, so that reporting on a calendar-year basis would be possible from 2012. The Commission would inform the Member States more precisely about the reporting obligations in due time.

### **3. MINUTES OF THE THIRD MEETING OF THE CONSULTATIVE 'MUTUAL RECOGNITION COMMITTEE' HELD IN BRUSSELS ON 30 NOVEMBER 2011**

The committee held its third meeting on 30 November 2011. The attendance list and the PowerPoint presentations are attached hereto.

The following matters were discussed.

#### **PRESENTATION OF NEW GUIDANCE DOCUMENTS ON THE APPLICATION OF THE REGULATION**

The Commission presented the new two final versions of the Guidance documents on the application of the MRR. The documents had been made available prior to the meeting in all official languages and will be soon published on the DG's homepage.

##### **Guide to the application of the mutual recognition regulation to non-CE-marked construction products**

The Commission presented this new guidance document which had previously been distributed to the participants in their respective languages. The Commission highlighted the new and most relevant issues related to the new Construction Products Regulation (CPR).

##### **Guide to the application of the Mutual Recognition Regulation to fertilisers and growing media**

The Commission presented this second new guidance document which had been also previously distributed to the participants in their respective languages. The Commission presented general aspects related to the fertilisers sector.

#### **THE APPLICATION OF THE REGULATION - MEMBER STATES' REPORTS, NOTIFICATIONS**

The Commission briefly presented the Member States' reports and the notifications received.

The Commission drew inter alia attention to the following:

- There are evident discrepancies between the number of notifications received by the Commission and the number of decisions taken by the MS authorities reported on in the annual reports (some decisions falling within the MRR have been adopted, but not notified to the Commission);
- Products most often concerned are articles of precious metal, foodstuffs, food additives and food supplements, automotive spare parts, construction products and fertilisers;
- Difficulties encountered concern inter alia the actual role of PCP, the alleged lack of clarity of the deadlines and steps of the procedure, and the difficulties to demonstrate that a product has been lawfully marketed in another MS;

The perceived impact of the MRR is usually estimated as positive and with a great preventive importance.



There have been several re-occurring requests from the MS, especially that of additional information, training sessions and workshops for PCPs.

The Commission informed the meeting about the possible revision of the existing guidance documents, indicating that even if open to receiving comments on them, the documents will not be revised in the immediate future. Some new guidance documents may be presented if suggestions received.

### **INTERNAL MARKET INFORMATION SYSTEM (IMI) - UPDATE ON THE STATE OF PLAY**

The Commission presented information on the state of play of the Internal Market information system (IMI). The current proposal for an IMI Regulation was also discussed.

The Commission is of the opinion that this option may be further explored.

### **NEXT STEPS - THE PREPARATION OF THE COMMISSION'S REPORT IN 2012**

The Commission informed the meeting about its obligation of reviewing the application of the MRR during 2012. A report thereon will be submitted to the European Parliament and to the Council.

The report by the Commission is expected during May 2012.

From 2012 yearly reports will follow calendar years.

### **ANY OTHER BUSINESS**

The Commission mentioned that EFTA representatives (EFTA Surveillance Authority and Norway) are present for the first time in this committee meeting. It is expected that the MRR will be adopted soon under the EEA Agreement.

#### **4. MINUTES OF THE 4TH MEETING OF THE CONSULTATIVE 'MUTUAL RECOGNITION COMMITTEE' HELD IN BRUSSELS ON 7 DECEMBER 2012**

The committee held its fourth meeting on 7 December 2012. The attendance list and the PowerPoint presentations are attached hereto.

The following matters were discussed:

### **PRESENTATION OF THE FIRST REPORT ON THE APPLICATION OF REGULATION (EC) NO 764/2008**

The Commission presented its first report on the application of Mutual Recognition Regulation 764/2008/EC (COM(2012) 292 final) adopted on 15 June 2012.

The report confirms that the Regulation works by and large in a satisfactory way and that there is no need for amendments at present. It also shows that there are certain specific categories of products where the difficulties in the application of the Regulation seem to concentrate, such as articles of precious metals, foodstuffs, food additives and food supplements, construction products, fertilisers, automobile spare parts, and electrical products.

In the report's conclusions, the Commission proposes that close and regular monitoring through the consultative committee on mutual recognition takes place especially on the following areas:

- difficulties to demonstrate that a product has been lawfully marketed in another Member State;
- difficulties in identifying which legal provisions apply and which are the relevant national authorities in charge;
- different testing methods relied upon by the Member States and their possible compatibility through mutual recognition; and
- the role of prior authorisation procedures.

### **THE APPLICATION OF THE REGULATION - MEMBER STATES' REPORTS, NOTIFICATIONS**

The Commission briefly presented the Member States' reports and the notifications received.

The Commission drew inter alia attention to the following:

- the majority of issues (notifications + requests for information) concerning few specific categories of goods;
- difficulties highlighted by the MS;
- impact of the Regulation in the free movement of goods (underlining its pre-emptive importance);
- requests from the MS; and
- requests from the Commission.

MS were then invited to make a tour de table with the view to share among members of the Committee the main issues raised in their national reports, notably difficulties encountered in applying the Regulation and how they were addressed, areas/products most concerned, and the number of decisions taken by the MS authorities during the reporting period.

### **THE LINK BETWEEN DIRECTIVE 98/34/EC AND REGULATION 764/2008**

Presentation attached. The Commission underlined the role of Directive 98/34 in preventing trade barriers under the form of 'technical regulations' before they are adopted, by enabling the Commission and MS to verify that the technical rule is compatible with EU law.

### **SOLVIT**

Presentation attached. The Commission suggested that Product Contact Points (PCP) may advise companies to go to SOLVIT, if the concerned case falls under its competence (cross border element and related to a situation of improper application of a given national law).

## **NEXT STEPS**

The Commission reminded the conclusion of its report according to which the Regulation works by and large in a satisfactory way and that there is no need for amendments at present.

The Commission highlighted that at this stage raising awareness is essential. Members of the Committee were invited to ensure a wide dissemination of information in order to reach end users: citizens and economic operators. The Commission expressed its availability to participate in national events, if need be.

The Commission also insisted that notifications should be addressed to unit ENTR/C2.

Furthermore representatives of MS were invited to update contact details for both committee members and PCP.

The 2012 report by the MS is expected before 28 February 2013

## **THE PCP WORKSHOP (WITH PARTICIPATION OF THE MEMBERS OF THE PCP NETWORK)**

The workshop was organized following suggestions to facilitate PCPs to meet among themselves and with the Commission with the aim of inter alia minimizing discrepancies in the number of notifications undertaken under the Regulation and the number of the decisions taken by Member States' authorities.

The following points were discussed: prior authorization, legally marketed in another member state, Relation between GPSD and 764/2008 , intention to adopt a decision, decisions by customs authorities, functioning of PCPs and the Internal Market Information System data base (IMI).

### **5. MINUTES OF THE 5TH MEETING OF THE CONSULTATIVE 'MUTUAL RECOGNITION COMMITTEE' HELD IN BRUSSELS ON 6 DECEMBER 2013**

The committee held its fifth meeting on 6 December 2013. The attendance list and the PowerPoint presentations are attached hereto.

The following matters were discussed:

## **ADOPTION OF THE NEW RULES OF PROCEDURE**

The Commission presented the draft rules of procedure which were sent to delegates in English. This draft corresponds to the standard text of the rules of procedure which was approved by the Commission on 12 July 2011 (OJ C 206, 12.7.2011, p. 11-13). The Commission also detailed the main changes as regards the existing rules of procedure.

After announcing an agreed modification the rules of procedure were adopted.

## **PRESENTATION OF THE COMMISSION'S GUIDANCE DOCUMENT "THE CONCEPT OF 'LAWFULLY MARKETED' IN THE MUTUAL RECOGNITION REGULATION (EC) NO 764/2008"**

The Commission presented its 10th guidance document on the application of the Mutual Recognition Regulation, "The concept of 'lawfully marketed' in the Mutual Recognition Regulation (EC) No 764/2008", adopted on 16 August 2013.

This guidance document offers additional precisions on the concept of 'lawful marketing', details the obligations for both enterprises and administrations under the Mutual Recognition Regulation, and takes the view that any piece of evidence should be deemed suitable to demonstrate the actual marketing of the product in another Member State or in an EFTA state that is a contracting party to the EEA Agreement.

### **MEMBER STATES' REPORTS, NOTIFICATIONS**

MS were then invited to a tour de table in order to share the main issues raised in their national reports.

The Commission then briefly presented the Member States' reports and the notifications received during the reporting period and drew attention to the following main points:

- The majority of notifications and requests for information concern a few specific categories of goods,
- Difficulties highlighted by the MS,
- Impact of the MRR regarding the free movement of goods (underlining its preventive importance and the information role of the PCP),
- Requests from the MS,
- Requests from the Commission:
  - a. Representatives of MS were invited to update contact details for both Committee members and Product Contact Points (PCP), whenever necessary.
  - b. As regards the next round of national reports, the Commission indicated that the 2013 report is expected before 31 March 2014.

### **MUTUAL RECOGNITION AND PRIVATE LAW BODIES**

The Commission has identified certain situations that do not fall under the scope of the Mutual Recognition Regulation but that nevertheless seem to cause problems with regard to free movement of (non-harmonised) products and with regard to the application of the mutual recognition principle. Several examples were discussed.

The Commission called for continuing discussion on this area.

The Commission raised the issue of the notification mechanism which should help preventing these problems. As it covers only standards, and only the national standardization bodies, this area is being further reflected upon.

## **NEXT STEPS - THE EVALUATION OF THE PRINCIPLE OF MUTUAL RECOGNITION**

The Commission highlights the efforts of the LT Presidency to better enforce the principle of mutual recognition.

The principle of mutual recognition will be evaluated during 2014 and the members of the committee will be contacted, among other relevant actors, by the contractor conducting this evaluation.

The Commission was thanked for undertaking the revision of the principle. MS stressed that business organizations are an important actor and that not only administrations should be contacted. It was also stressed that there are still problems within the goods area and that the number of notifications and MS notifying may be too low. The importance of awareness raising activities was underlined by several MS.

### **6. MINUTES OF THE 6TH MEETING OF THE CONSULTATIVE 'MUTUAL RECOGNITION COMMITTEE' HELD IN BRUSSELS ON 5 DECEMBER 2014**

The committee held its sixth meeting on 5 December 2014. The attendance list and the PowerPoint presentations are attached hereto.

The following matters were discussed:

#### **INTRODUCTION**

In the opening address, the Commission Director for "Single Market for Goods", outlined the timing of the ongoing evaluation of the application of the principle of mutual recognition (in this specific case, mutual recognition in goods), as well as the overall approach in mapping the situation, by identifying - with the view to presenting avenues for an improved application of the principle - both the markets/areas most affected by the incorrect application of mutual recognition, and the problems encountered. The main message referred to the Competitiveness Council meeting of 4-5 December 2013, identifying:

- the further use and application of the mutual recognition principle in the priorities for enhancing the single market;
- the collective responsibility of all agents involved;
- the importance of the support of Member States both during the evaluation and for the correct application of mutual recognition;
- a call for cooperation between Member States, and between Member States and the Commission.

The important role of Product Contact Points (PCP) as the first interlocutor for economic operators was also underlined.

## **PRESENTATION OF THE ONGOING EVALUATION OF THE APPLICATION OF THE PRINCIPLE OF MUTUAL RECOGNITION IN THE FIELD OF GOODS**

The Commission's contractor for the evaluation of the application of the principle of mutual recognition in the field of goods (the Danish Technological Institute) presented the current state of the exercise and the preliminary findings of the ongoing surveys which have been tailor-made for national authorities and businesses.

### **MEMBER STATES' REPORTS, NOTIFICATIONS**

The Commission presented the yearly analysis of reports and Member States' notifications, indicating the need to make the reports more homogeneous and to notify the Commission about all decisions when mutual recognition was denied, as specifically required by the Mutual Recognition Regulation. Reference was made to several decisions denying mutual recognition, but not notified by the concerned Member States to the Commission. Discontinued notifications remain a recurrent problem in the application of the Regulation. The general problem of lack of cooperation between PCP was also underlined. The Commission reiterated the message that Member States are the ones applying mutual recognition, hence their feedback and support in identifying what is not functioning is essential.

Next year's reports, covering the application of the Mutual Recognition Regulation during 2014, should be addressed to the Commission before 31 March 2015.

The problem of non-notification of decisions was highlighted, and the need for interchange of best-practices mentioned. The need for an IMI system was underlined.

Member States were then invited to do a tour de table with the view to sharing among members of the Committee the main issues raised in their national reports.

### **NEXT STEPS - THE USE OF THE INTERNAL MARKET INFORMATION SYSTEM (IMI) FOR NOTIFICATIONS, ESTABLISHING A TELEMATIC NETWORK, AND STRUCTURED INFORMATION FROM THE PCP**

In the afternoon session, the Commission presented a demonstration of the possible use of IMI for the Member States' notifications, and opened an introductory debate on establishing a telematic network of PCP, as provided for in Article 11 of the Mutual Recognition Regulation. The Commission explained that extending the use of IMI to include the Mutual Recognition Regulation would require adoption of an implementing act.

While in general the message of streamlining the framework for notifications by using IMI was well received by the MS representatives, they also referred to the necessity of internal consultation at MS level before they could accept. The Commission explained that this is a first proposal, all Member States would have to accept the use of IMI before a decision could be made. Alternatively, Member States were invited to propose other means to improve a current situation in which notifications are not sent to the Commission, as required by the Mutual Recognition Regulation. A note on IMI use for the notifications under the Mutual Recognition Regulation will be sent shortly to all MS.

## **ANY OTHER BUSINESS AND CONCLUSION**

Some experiences of promoting mutual recognition and single market instruments were shared. The need for a common visual identity of PCPs, and a rationale for promotional activities to support a common single market tool was also underlined.

As regards the minutes of the meeting, in accordance with Article 10(1) of the Rules of Procedure, a draft version of the minutes will be sent to the members of the committee within 15 working days. The members of the committee are then invited to send any written comments they may have on the minutes to the Chairperson. The committee shall be informed of those comments.

In accordance with Article 10(2) of the same Rules of Procedure, a summary report for the European Parliament would be drawn up under the auspices of the Chair, briefly describing each item on the agenda. The report would not mention the individual position of the members in the committee's discussions.

The Commission concluded the meeting by thanking the members of the committee for their participation, and the interpreters for their work.

### **7. MINUTES OF THE 7TH MEETING OF THE CONSULTATIVE ‘MUTUAL RECOGNITION COMMITTEE’ HELD IN BRUSSELS ON 2 DECEMBER 2015**

The consultative “Mutual Recognition Committee”, established by Article 13 of Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC (OJ L218 of 13.8.2008, p. 21) (MRR), held its seventh meeting on 2 December 2015.

The agenda, the attendance list and the presentations are attached hereto.

## **INTRODUCTION**

The Commission (COM) welcomed the participants and presented the modalities of the meeting, including administrative and linguistic arrangements. The committee was then called to adopt the proposed draft agenda and the following agenda was adopted:

- (1) Presentation of the Single Market Strategy and its implementation
- (2) Options to achieve more and better mutual recognition in the single market for products
- (3) Guidelines for improving consistency across Member States' in providing information to businesses through PCPs and PCPCs.
- (4) Member States' annual reports.
- (5) The potential use of the Internal Market Information system for the purposes of the Regulation (EC) 764/2008 on Mutual Recognition (Member States' notifications)
- (6) Any other business

Delegates included also representatives from the Points of Contact for Products (PCPs) and Points of Contact for construction products (PCPCs).

## **PRESENTATION OF THE SINGLE MARKET STRATEGY AND ITS IMPLEMENTATION**

COM presented the Single Market Strategy (SMS) including an outline of the possible options initially considered for the strengthening of the application of the principle of mutual recognition.

### **OPTIONS TO ACHIEVE MORE AND BETTER MUTUAL RECOGNITION IN THE SINGLE MARKET FOR PRODUCTS**

COM detailed the major problems identified as regards the proper application of the principle of mutual recognition<sup>1</sup>, those measures envisaged for its strengthening as well as the calendar and indicative initial options for the revision of the MRR.

COM then presented an outline of the Single Digital Gateway (SDG) initiative. The initiative would aim at offering online the complete package of information and procedures necessary to do business in the Single Market, covering both services and goods and a better inter-linkage of the various existing portals and services on the EU and national level.

It was underlined that we are still in a brainstorming phase and input is needed. It was asked about the stakeholder workshop envisaged on 15 March 2016. COM replied business stakeholders and Member States would be invited (three delegates per Member State).

As regards possible options not yet mentioned for the improvement of mutual recognition, it was mentioned the possibility of revising the scope of the MRR, for instance making it also covering negative decisions addressed to end users. COM mentioned the additional possibility of relying on standards. The issue of problems posed by national standards interacting with EU standards was also raised, and it was requested more streamlined approaches treating the goods area as a whole.

COM proposed Member States to provide input on any other additional options for the revision of the MRR to be provided to COM before 15/12/2015.

### **GUIDELINES FOR IMPROVING CONSISTENCY ACROSS MEMBER STATES' IN PROVIDING INFORMATION TO BUSINESSES THROUGH PCPS AND PCPCS.**

COM presented its project to develop guidelines for improving consistency of online provision of information by PCPs and PCPCs, with the support of an external assessor ECORYS. Specific issues related to construction products to continue in the afternoon's session.

External Evaluation of the Application of the mutual recognition principle in the field of goods - final report: <http://ec.europa.eu/DocsRoom/documents/13381>

### **MEMBER STATES' ANNUAL REPORTS**

In the afternoon's session COM presented the analysis of the yearly reports and Member States' notifications, indicating the need to make the reports more homogeneous and to notify



the Commission about all decisions when mutual recognition was denied, as specifically required by the Mutual Recognition Regulation.

Next year's reports, covering the application of the Mutual Recognition Regulation during 2015, should be addressed to the Commission before 31 March 2016.

**THE POTENTIAL USE OF THE INTERNAL MARKET INFORMATION SYSTEM FOR THE PURPOSES OF THE REGULATION (EC) 764/2008 ON MUTUAL RECOGNITION (MEMBER STATES' NOTIFICATIONS)**

COM referred to the presentation made at the last meeting and the note ("The potential use of the Internal Market Information system for the purposes of the Regulation (EC) 764/2008 on Mutual Recognition")<sup>2</sup> addressed to the national authorities, requesting their feedback by October this year. The proposal was supported by a majority of Member States who provided a response.

COM then outlined the use of IMI for notifications under the MRR and addressed particular concerns raised by Member States in response to the note, clarifying that:

- a) MS can opt to register all authorities that need to notify in IMI, or, can register central authorities that notify on behalf of other authorities, in which case the central authorities would be able to indicate the details of the authority that took a decision.
- b) Notifications should be sent within a period of 20 working days from the expiry of the time limit for the receipt of comments from the economic operator (as per Article 6(2)). The relevant provisions of the MRR do not provide for any follow-up such as informing on possible challenges and appeal procedures. The only further actions that would be offered in IMI once a notification has been sent would be withdrawal and resubmission due to error.
- c) sharing notifications with other Member States through IMI would be left to the discretion of the sender.
- d) any exchange of comments on the notification would be limited to the sender and COM for the purposes of confirming completeness and correctness only. Other MS would not be able to comment.
- e) an exchange of information between PCP's would not be included due to mixed feedback from Member States.
- f) a "free text" field might be useful to provide information on, for instance, products perceived as a risk to health or environment.

COM indicated the main advantage of sharing notifications would be transparency, which in itself leads to better practices, motivating those authorities not yet notifying.

In view of the generally positive position of the committee towards the use of IMI, COM asked whether any of the presents had any fundamental problem with the use of IMI for notifications under the MRR. In view of the committee members in the meeting not having any fundamental concern against the use of IMI, this is then considered as a positive response for moving on to an IMI pilot project for the notifications under the Mutual Recognition

Regulation - and that any fundamental concern could be raised as comments to the committee's draft minutes. Member States will also be consulted in the IMI committee.

### **ANY OTHER BUSINESS AND CONCLUSION**

Operative conclusions of the meeting:

- As regards the already concluded external report on the application of the principle of mutual recognition in the field of goods, the Commission would like to present it in the Council and will draft a Staff Working Document summarising it.
- Initial ideas on the options initially envisaged for the revision of the Mutual Recognition Regulation requested - indicative deadline for their reception by COM: 15/12/2015.
- A draft for an optional template for the yearly reports of the Member States under the Mutual Recognition Regulation to be sent to the Member States for comments.
- Positive response for moving into an IMI pilot project for the notifications under the Mutual Recognition Regulation. Member States will be consulted in the IMI committee.
- As regards the next meeting of the committee: to be possibly held before summer, to discuss and assess the possible options for the revision of the Mutual Recognition Regulation.
- Action to be taken by COM as regards metadata of the list with PCP contact details ([http://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/contacts-list/index\\_en.htm](http://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/contacts-list/index_en.htm))

As regards the minutes of the meeting, in accordance with Article 10(1) of the Rules of Procedure, a draft version of the minutes will be sent to the members of the committee before the Christmas break. The members of the committee are then invited to send any written comments they may have on the minutes to the Chairperson. The committee shall be informed of those comments. A final version of the minutes will then be distributed.

In accordance with Article 10(2) of the same Rules of Procedure, a summary report for the European Parliament would also be drawn up under the auspices of the Chair, briefly describing each item on the agenda. The report would not mention the individual position of the members in the committee's discussions.

The Commission concluded the meeting by thanking the members of the committee for their participation, and interpreters for their work.

### **8. MINUTES OF THE 8TH MEETING OF THE CONSULTATIVE ‘MUTUAL RECOGNITION COMMITTEE’ HELD IN BRUSSELS ON 25 OCTOBER 2016**

The consultative “Mutual Recognition Committee”, established by Article 13 of Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC (OJ L218 of 13.8.2008, p. 21) (the Regulation), held its eight meeting on 25 October 2016.

## **INTRODUCTION**

The Commission (COM) welcomed the participants and presented the modalities of the meeting, including administrative and linguistic arrangements. The committee was then called to adopt the proposed draft agenda and the following agenda was adopted:

1. Annual reports
2. Results of the public consultation
3. State of play of the evaluation of the Mutual Recognition Regulation
4. The future of mutual recognition
5. AOB

## **ANNUAL REPORTS (WD01)**

COM presented the annual activity of Member States in 2015 based on the annual reports submitted and on the administrative decisions notified. The presentation underlined the main difficulties encountered by Member States when applying mutual recognition and the impacts of the Regulation on free movement of goods. COM highlighted the need to receive from Member States reports containing data homogeneous and comprehensive enough to be considered as usable input for monitoring the application of the Regulation and identifying recurrent problems. This can be achieved by using the template suggested by COM. Also, COM pointed out that not all administrative decisions restricting or denying market access are being notified and reiterated that national authorities are bound to notify to the Commission these decisions, as provided for under articles 6(2) and 7(2) of the Regulation.

## **RESULTS OF THE PUBLIC CONSULTATION (WD02)**

COM presented the results of the public consultation carried out between 1.06.2016 and 30.09.2016. A summary of all contribution received following the stakeholders consultation (including individual contributions) will be annexed to the evaluation of the functioning of mutual recognition and to the impact assessment. COM indicated that the results will be published on the COM website and annexed to the evaluation and impact assessment.

## **PRELIMINARY EVALUATION OF THE FUNCTIONING OF MUTUAL RECOGNITION (WD03)**

COM presented an overview of the ongoing evaluation of the functioning of mutual recognition. COM explained that the evaluation covers the mutual recognition principle and Regulation, and looks at how effective, efficient, coherent relevant and with EU added value these are. COM explained that discrepancies appear between the annual reports indicating a certain number of administrative decisions taken, complaints received from businesses and the notifications received.

## **THE FUTURE OF MUTUAL RECOGNITION: ACTION PLAN (WD04)**

COM presented actions that could be included in the action plan for raising awareness on mutual recognition and asked for feedback and input on these actions.

### **THE FUTURE OF MUTUAL RECOGNITION: PROBLEM DEFINITION (WD05)**

COM presented a preliminary analysis of the main problems generated by the suboptimal functioning of mutual recognition, as identified in the framework of the ongoing evaluation.

### **THE FUTURE OF MUTUAL RECOGNITION: OPTIONS (WD06)**

COM presented the preliminary options for improving mutual recognition, which will be considered in the framework of the impact assessment, and asked for feedback from the delegations. COM asked input on an option concerning the repeal of the Regulation. Delegations don't support such option.

### **CONCLUSION**

The Chair welcomed the interesting discussion and the very constructive input received during the meeting. As the work on evaluation the functioning of mutual recognition and reaching to more and better mutual recognition is still in progress, delegations will be kept informed on this progress and asked for additional input, via CIRCA BC.

Comments on the documents submitted for discussion during the meeting should be sent to COM before **1.12.2016**.

The next meeting of the Committee will take place most probably in 2017, after the summer.

## **Breaking down barriers: Back to Basics, Please!**

*A company survey on trade barriers in the Single Market*

### **1. EXECUTIVE SUMMARY**

The objective of this survey is to clarify if barriers to the free movement in the Single Market, identified in previous DI-studies (e.g. from 2004, 2007 and 2012), are still existing and if new barriers have been created.

The survey is based on qualitative telephone interviews with company executives and relevant technical managers from 35 DI member companies, covering many different sectors.

**The main conclusions** are that, though marketing within the Single Market by a large majority of the companies *generally is* considered to be relatively easy and straightforward, **those who experienced barriers ten years ago, still experience the same degree of barriers today.**

National requirements on product characteristics, including special requirements on documentation and testing, have the consequence that companies often have to double test, change product characteristics, or in some cases give up marketing products in certain countries.

Barriers are mainly found in the following product areas:

- Construction products (different fire protection rules, requirements for supplementary testing, environmental requirements)
- Products under the General Product Safety Directive (non-harmonised area)
- Products in contact with water
- Products in contact with foodstuffs
- Medical products (different labelling requirements)

- Innovative products, e.g. no standards available

Also at country level, we see the same Member States as previously reported. To be mentioned especially are countries such as the UK, Germany, Sweden, Norway, the Netherlands and Belgium. It should be taken into consideration, however, that the survey is based on Danish companies and therefore barriers are typically found in countries that take the majority of Danish exports.

### **Policy recommendations – The way forward**

Based on the findings of the survey, DI identifies four policy recommendations to be considered in connection with the follow-up on the European Commission's Single Market Strategy:

- European institutions to keep continuous and high focus on the well-functioning of the free movement in the Single Market
- The principle of mutual recognition should be better defined and consolidated
- The establishment of a 'Quick Assessment Procedure'
- New national technical regulations to be subject to an impact assessment

The recommendations are further developed at the end of the paper.

## **2. INTRODUCTION**

The Single Market is a cornerstone of the European integration project. Designed to allow goods, services, capital and people to move more freely across national borders, the Single Market make it easier for businesses to import and export their products. However, many companies still face a variety of trade related barriers that limit their potential for growth. This is **a matter of growing concern, also giving rise to a certain surprise**, considering that several Single Market strategies and action plans have been launched in order to cope with the remaining barriers.

During the years, DI has carried out surveys among our members to take the temperature of the Single Market as experienced by businesses. We now found that it was time to make yet another survey to check the state of affairs, especially in the light of previous and present political actions to improve the free movement within the Single Market.

Therefore, **the objective of this study** has been to identify and map some of the trade barriers that companies face in the Single Market. A large majority of the interviewed companies were also surveyed in previous similar studies conducted in 2004, 2007 and 2012, respectively. An important focus of this study has been to uncover whether previously detected barriers still exist today and how companies cope in practice.

The survey looks at the Single Market and the free movement of **goods as well as services**. The area of goods has come far in terms of harmonising product requirements and building a legal foundation, which has since paved the way for the service sector. Today, goods and services are often interlinked, and barriers in one sector may thus influence the total package.

### 3. METHODOLOGY

The survey is based on **qualitative telephone interviews** with company executives and relevant technical managers from 35 selected DI member companies. All interviews followed a semi-structured interview guide to ensure a certain level of consistency in the conducted interviews while also providing the respondents with the opportunity to bring up new issues outside of the questionnaire.

Roughly, **two thirds of the companies (22 of 35) are SMEs** with less than 250 employees, while the rest (13 of 35) are large enterprises with more than 250 employees.

In the selection of companies to be included in the survey, a **maximum representation of different product/service areas** was pursued.

The underlying assumption is that if one company has a problem due to national regulation, the same challenge will be experienced by other companies within the same product/service category.

The survey includes the following sectors: construction products, machinery, medical equipment, foodstuff, IT equipment, electrical products, maritime equipment, pressure equipment, consumer products such as furniture, tableware, bicycles and services.

Almost all companies in this survey have experience in European-wide trade, although a few have chosen no longer to export their products to other markets due to different reasons.

The survey **builds on previous studies** from 2004, 2007 and 2012 and is as such the latest set of results in a larger time-series study.

Like the previous studies, this survey has sought to establish:

- Do companies feel that marketing their products in other Single Market countries is easy and straightforward?
- Do European product/service standards exist within the companies' area of activity? If so, do companies adhere to these standards?
- What are the types of barriers that companies continue to meet in daily business? How do companies tackle such barriers?

Recalling the qualitative nature and scope of this survey, the aim is not to set up another highly statistically valid analysis of the current situation on trade barriers within the Single Market, but rather to illustrate some of the concrete examples of the challenges that companies continue to face.

Consequently, the results and conclusions of this survey cannot be taken to apply universally or be used to draw statistical generalisations. However, it is interesting to note that **the main findings are very much in line with previous Commission surveys.**

#### 4. MAIN FINDINGS

##### **Confirming results from previous surveys: Barriers still exist!**

Overall, the product/service areas experiencing barriers and administrative burdens are the same as previously detected. Despite several initiatives from i.a. the Commission, not much seems to have changed in the last ten years.

##### **National regulation prevails over mutual recognition...**

24 out of 35 companies currently experience barriers to the free movement on *some* markets.

Countries such as the UK, Germany, Sweden, Norway, the Netherlands, Belgium and Poland are most frequently mentioned.

The typical barriers are: Stricter national requirements for documentation, testing and administration, often due to special national regulation or different interpretation of EU-rules. To some degree, also changes in product characteristics are needed.

Barriers are mainly found in the following product areas:

- Construction products (different fire protection rules, requirements for supplementary testing, environmental requirements)
- Products under the General Product Safety Directive (non-harmonised area)
- Products in contact with water
- Products in contact with foodstuffs
- Medical products (different labelling requirements)
- Innovative products, e.g. no standards available

The trend of an increasing demand for national testing and new requirements for e.g. labelling especially relates to environmental concerns.

##### **... Yet, Single Market trade is considered relatively easy**

On a positive note, when asked for the respondents' overall experience, a large majority *generally* find it relatively easy and straightforward to market and sell their products and services in other EU countries.

This is not surprising, as the basic principles and legislation for goods and services *are* in place and have indeed been so for a number of years.

**Common EU-regulation is preferred** as the basis for marketing products and *does* make life easier in most product areas. Furthermore, the study confirms that European and international standards are followed to a wide extent.



In spite of this overall positive perception of trade within the Single Market, **many respondents, however, have to adapt their products and/or marketing strategies** to comply with different national requirements, an adaptation which should not be needed.

Furthermore, big as well as small companies point to the **increasing number of burdensome EU-regulation**, such as e.g. environmental requirements, the construction product regulation and the RoHS.

Generally, a vast majority of companies accept stricter requirements *if* they are based on common regulation, while additional national rules or different national application in practice are considered a substantial burden.

**To ensure a level playing field, effective and more homogenous market surveillance is called for**

Across almost all sectors, companies ask for a more frequent and especially a more homogenous market surveillance. Companies see market surveillance as a means to ensure a level playing field.

In particular insufficient compliance of performance declarations in the construction sector is mentioned in this context.

Also within the field of dietary supplements, inconsistent surveillance is reported. Certain countries tend to focus more on non-safety related issues like labelling than on actual safety concerns.

## **5. CASE EXAMPLES**

### **Installation of steel chimneys complicated by national H&S training requirements**

An SME manufacturing and installing steel chimneys primarily within the Single Market has experienced that requirements for national training courses within health and safety for workers have increased considerably and differ from one country to another. This hinders flexibility in the posting of workers and represent a considerable increase in costs. A special challenge is experienced in Poland where the project manager must be on site during the complete installation phase. This complicates supplies and increases costs.

The certification process under the standard EN 1090 on welding poses severe problems for sub-suppliers.

### **Wood burning stoves must find a balance between environmental requirements and energy efficiency**

An SME exports wood burning stoves and accessories to all European countries and ends up being squeezed between optimization of emission targets and energy efficiency – requirements that are going into opposite directions. New labelling requirements addressed to consumers are increasing, e.g. regarding energy efficiency. Irrespective of testing results according to the Nordic Swan standard, the stoves must be retested according to different national standards on several markets.

This means that launching a new type costs about ½ million DKK (corresponding to abt. 70,000 euro) alone in performing tests. To this come annual or biannual audits from national test organizations, amounting to abt. 5-6,000 euro per audit. Additional to the actual costs, the administration of such different testing procedures takes a lot of time and resources.

### **CE-marked chipboards for construction and industry without free movement**

The manufacturer experiences that there is still more regulation, e.g. on environmental characteristics. Technical documentation often has to be adapted to local tradition. In Norway, a special national technical approval is required. National regulation often leads to new testing, which is considered to be mandatory. The company asks for more market surveillance as not all products on the market fulfill performance requirements.

### **Acoustic ceilings – covered by the CPR and European standards but also by different national regulations**

A large company has decided to adapt to national requirements, but nevertheless point out that they have extra testing costs of around 60,000 euro without any added value and resulting in time delays for launching new products. The supplementary testing is caused by different national fire regulation requirements in e.g. the UK, Germany and Belgium; emission test requirements coming up in e.g. France, Belgium and Lithuania; and special national requirements on documentation, e.g. on waste disposal.

### **Upholstered furniture – a well-known obstacle for exports to the UK**

Even if furniture is under the scope of the General Product Safety Directive and covered by European standards, special requirements in the UK for upholstered furniture – even for garden furniture – means that a special range of products has to be developed for the UK. Due to fire protection, foam and textiles must be treated with flame resistant chemicals, which for environmental reasons are not wanted on other markets.

The consequence for one specific company is that they need to have a double stock of furniture (binding capital of abt. 150,000 euro). There are extra initial costs for each product (abt. 50,000 euro per type), for which reason they have been forced to reduce the product range in the UK by abt. 25 p.c.

### **Export of environmentally friendly, innovative CE-marked product hindered by national regulation**

Some years ago, a small Danish manufacturer developed an intelligent solution for efficient pest control, completely without the use of poison. Since then, the products are in demand by an increasing number of countries around the world. The system monitors rodent activity and protects against rats entering the building or gaining a foothold in the area.

The product is CE-marked under the Low Voltage Directive, but nevertheless meets many national obstacles in the form of national legislation aimed at animal protection (e.g. in Sweden and Germany). The de facto blocks the marketing of the products, even if they are proved to be both efficient and better than poison which remains in nature.

## Different packaging requirements for pharmaceutical products

Pharmaceutical products have to be registered in each Member State before marketing. Member States have different requirements as to the information that must be or is allowed on the packaging. This makes it impossible to introduce common packaging, even where the same languages may be used. As an example, Finland requires a triangle in the ‘blue box’, but this is not allowed in Sweden. Belgium requires a bar code sticker on the packaging, which is not permitted on other markets. Italy has a special ‘bollini sticker’, and France requires two red lines on the blister cards.

The consequence is reduced product range on some markets and a higher amount of scraps.

## Also large companies suffer from burdensome regulations

Even for a large company – manufacturing many different types of products – it seems difficult to stay updated on new regulations and requirements. New labelling requirements to the effect that the manufacturer’s address must be on each product is mentioned as a very costly new requirement. Different interpretation of the RoHS directive; confusion in many Member States (e.g. Estonia, Latvia, Hungary and Lithuania) as to the use of performance declarations, and whether or not a product is under the Construction Product Regulation – are other burdensome concerns in practice.

For products in contact with water, many different rules and requirements for testing apply: some Member States want testing of the materials used (e.g. Germany); others want to test the final product (e.g. Denmark).

## 6. POLICY RECOMMENDATIONS – THE WAY FORWARD...

- DI welcomes the 2015 **Single Market Strategy** and push for concrete action.

The European institutions should keep continuous and high focus on the well-functioning of the free movement in the Single Market. New technologies and developments require new solutions. Yet, if the basics are not in place and well understood, then the foundation for the free movement is at stake.

National legislators and administrators should be trained in basic principles to ensure the well-functioning of common rules, and there must be a better coordination at European level.

- The **principle of mutual recognition** should be better defined and consolidated through a revision of EU-regulation [764/2008](#) *laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State*.

Awareness of the principle of mutual recognition should be raised among national authorities, the judiciary and the business community.

For the business community the awareness is not enough if businesses continue to stand alone in their assessment of their right to market their product on a new

market, being left with the only option of a possible costly court case against market authorities.

The SOLVIT system should be reinforced, but experience shows that it cannot solve cases where a special national regulation is in force, not respecting the mutual recognition principle.

- The **establishment of a ‘Quick Assessment Procedure’** could promote better application of mutual recognition in goods and services and would improve the transparency of national decisions.

The ‘Quick Assessment Procedure’ could assess whether mutual recognition should apply when a Member State exerts a national technical rule on a product or service that is already being lawfully marketed in another Member State.

The procedure would produce a non-binding opinion. This could give the economic operator further insight before contentious proceedings and also add transparency to national decisions (helping similar business sectors make informed choices). It would demonstrate particularly problematic areas to the Commission and act as a deterrent to Member States.

The procedure would be carried out by a forum of Member States on a rolling basis (e.g., represented by officials responsible for the Product Contact Points). The forum should meet quarterly and businesses should have direct access for transmitting specific cases of conflicting national technical rules and possible refusal of marketing of a lawfully marketed product in another Member State.

- **New national technical regulations** should be subject to an impact assessment with respect to the principle of free movement, and their justification and proportionality should be documented and based on special conditions of the Member State in question.

The European Commission should use the European Semester to discuss special national requirements with Member States creating barriers to the free movement.