

March 2018

## Mutual recognition of goods lawfully marketed in another Member State

*Impact assessment (SWD(2017) 471 final, SWD(2017) 472 final (executive summary)) of a Commission proposal for a regulation of the European Parliament and of the Council on the mutual recognition of goods lawfully marketed in another Member State (COM(2017) 796 final)*

### Background

This note seeks to provide an initial analysis of the strengths and weaknesses of the European Commission's [impact assessment](#) (IA) accompanying the above [proposal](#), adopted on 19 December 2017 and referred to Parliament's Committee on Internal Market and Consumer Protection (IMCO).<sup>1</sup>

The proposal aims to introduce a new regulation laying down rules and procedures concerning the application by Member States of the principle of mutual recognition<sup>2</sup> in relation to goods lawfully marketed<sup>3</sup> in another Member State, to achieve a fairer and deeper single market for goods (explanatory memorandum, p. 2).

The proposal follows the [Competitiveness Council Conclusions of 2-3 December 2013](#) on single market policy recalling that 'in order to improve framework conditions for businesses and consumers in the Single Market, all relevant instruments should be used including harmonisation as well as mutual recognition, as appropriate'. In addition the Council conclusions invited the Commission 'to identify sectors and markets where the application of the principle of mutual recognition is ... insufficient or problematic, and report its findings to the Council by mid-2015' (Council conclusions, p. 2).<sup>4</sup>

The European Parliament has regularly taken a stand on issues relating to the single market, adopting several resolutions over time, including its [resolution of 15 February 2017](#) on the annual report on the Single Market Governance within the European Semester 2017. In this resolution, it anticipated 'a Commission proposal for a revision of the Mutual Recognition Regulation' and emphasised that 'the principle of mutual recognition is not applied and respected properly by Member States ... ' (point 27).

### Problem definition

The problem identified by the IA is that **mutual recognition is not functioning well**,<sup>5</sup> referring to 'the weak use of the principle and the limited impacts that Regulation (EC) No 764/2008 [has] had in achieving the envisaged objective of ensuring free movement of goods in the Single Market' (IA, p. 13). The problem is comprehensively described and well evidenced (see the 'quality of data, research and analysis' section of this briefing).

<sup>1</sup> See M. Szczepański, [Mutual recognition of goods](#), EU legislation in progress, EPRS, 2018.

<sup>2</sup> The principle of mutual recognition is embedded in Articles 34 and 36 of the Treaty on the Functioning of the European Union (TFEU), and further elaborated from the case law of the Court of Justice of the European Union.

<sup>3</sup> The 'Mutual Recognition' [Regulation \(EC\) No 764/2008](#) defines the practical modalities of the implementation of the mutual recognition principle. However, it does not define the concept of 'lawfully marketed' for products falling within its scope, i.e. not subject to harmonisation. Furthermore, there is no jurisprudence of the Court of Justice of the European Union on this concept. However, a Commission guidance document, [COM\(2013\) 592 final](#), provides user-friendly guidance on the concept.

<sup>4</sup> In response to these Council conclusions, the Commission assigned to an external contractor the evaluation of the application of the principle of mutual recognition, to assess its functioning in terms of efficiency and effectiveness (SWD(2017) 475 final, p. 7). See DTI, Technopolis, EY and VVA Consulting, Evaluation of the application of the principle of mutual recognition in the field of goods, [Final report](#) prepared for the European Commission, DG ENTR, June 2015.

<sup>5</sup> See A.I. Dinu, [Mutual Recognition Regulation](#), implementation appraisal, EPRS, 2017.

The IA identifies **four drivers**, which are described in a clear way (IA, pp. 16-24), namely:

1. lack of awareness around the mutual recognition principle and Regulation (EC) No 764/2008 (IA, pp. 17-18);
2. legal uncertainty regarding the scope of mutual recognition (IA, pp. 18-20);
3. legal uncertainty regarding the application of mutual recognition and unreliability of the outcome, i.e. whether a product will be allowed on the market or not (IA, pp. 20-23);
4. lack of trust and cooperation among authorities (IA, pp. 23-24).

As regards driver 1, the IA states that the surveys carried out in 2014 (see the 'stakeholders' consultation' section of this briefing) showed a low level of awareness among businesses regarding mutual recognition, with 54 % of them declaring 'not knowing about it or having heard of it but not being familiar with the details' (IA, p. 17). In the public consultation of 2016, 30 % of responding businesses reported to be unaware of the mutual recognition principle (IA, pp. 73-74). As regards driver 2, the IA states that it is not straightforward to determine whether a product might benefit from the application of the mutual recognition principle, as mutual recognition applies to a wide range of products or aspects of products which are not covered (fully or partially) by EU harmonisation legislation. However, legal uncertainty appear to be, in turn, the outcome of: the sub-optimal functioning of the product contact points (PCPs) established by the Mutual Recognition Regulation; the user-unfriendliness of the Commission's database listing the products to which mutual recognition might apply; and the insufficient use of the mutual recognition clause in national regulations. The IA provides some figures for two of these 'sub-drivers' (IA, pp. 19-20). As regards driver 3, the IA comprehensively describes the main elements hindering the practical application of mutual recognition, providing supporting figures whenever possible. For example, between € 5 000 and € 100 000 per product and per market are estimated to be necessary to challenge administrative decisions denying or restricting market access (IA, p. 22). As regards driver 4, the IA refers to the replies of the PCPs interviewed during the survey carried out in 2014, but the few figures reported in the pie chart of Figure 3-3 (IA, p. 23) are indicated as those resulting from the public consultation of 2016. Even though the IA invites us to refer to the report prepared by DTI, Technopolis, EY and VVA Consulting (2015), the explanations provided under this driver could have been better substantiated.

The IA describes the consequences of the identified problem and its likely evolution without EU action. It provides some estimates of the costs sustained by economic operators due to testing and adaptation of the products to local technical requirements, or due to delays in entering a market (IA, pp. 24-28). For instance, costs of delayed entry into a market are estimated to be between € 3 000 and € 500 000 per product and per market, and between € 10 000 and 500 000 for lost opportunities when businesses give up entering a market due to the need to adapt their products to different national rules (IA, p. 25). According to the IA, without EU action, the issue identified and its underlying drivers would remain unchanged in the medium term. Obstacles to the free movements of goods deriving from the existence of national rules would continue to be addressed by referring to the two pieces of legislation supporting the use of mutual recognition, namely [Directive \(EU\) 2015/1535](#) and Regulation (EC) No 764/2008 (IA, pp. 28-30).<sup>6</sup> However, it is not clear why the IA only discusses the problem in the medium term and not in the longer term too.

## Objectives of the legislative proposal

The IA identifies **one general objective**, 'to achieve a fairer and deeper single market for goods through a higher level of and better mutual recognition' (p. 31). In addition, it identifies **four specific objectives**, namely: 1) increase awareness of mutual recognition; 2) increase legal certainty, for businesses and national authorities, as to when the mutual recognition principle can be used; 3) increase legal certainty concerning the application of mutual recognition; 4) enhance administrative cooperation, communication, and trust among national authorities (IA, pp. 31-32).

The IA identifies **seven operational objectives** (pp. 60-61). These are defined after selecting the preferred options (IA, p. 59), in line with the Commission's [better regulation toolbox](#) (tool #16, p. 100). They are:

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<sup>6</sup> This means that when Member States wish to adopt a national 'technical regulation' regarding a 'product', as respectively defined in Articles 1(a) and 1(f) of Directive (EU) 2015/1535, they 'shall communicate to the Commission ... all requests made to standards institutions to draw up technical specifications or a standard for specific products for the purpose of enacting a technical regulation for such products in the form of draft technical regulations, and shall state the grounds for their enactment' (Article 4). After being adopted, its application to individual cases (national decisions denying market access to a product), and obstacles to the free movements of goods will be addressed by Regulation (EC) No 764/2008 (IA, p. 28).

- a) enhance awareness of mutual recognition through, inter alia, regular training sessions for businesses and national authorities and the exchange of officials in national authorities;
- b) ensure that Member States introduce a mutual recognition clause in all relevant national technical rules which are notified under Directive (EU) 2015/1535;
- c) introduce a voluntary declaration of compliance facilitating the effective right to free movement within the internal market for products lawfully marketed in another Member State;
- d) ensure that businesses can appeal national decisions denying market access through a fast-track procedure (based on SOLVIT and, where appropriate, on Commission intervention);
- e) streamline the notification procedure for administrative decisions denying mutual recognition via an IT tool;
- f) strengthen the role of PCPs as a central point for information on all products, i.e. those falling under EU legislative acts introducing harmonised requirements regarding product manufacture (harmonised products), and those not falling (fully or partially) under such harmonised requirements (non-harmonised products);<sup>7</sup>
- g) set up an administrative cooperation forum where all national authorities could participate and discuss issues related to the application of mutual recognition.

The general and specific objectives appear to be clear and consistent with the manner in which the problem and its underlying drivers have been defined (see also IA, Figure 6-1, pp. 40-41). All operational objectives are clearly linked to the specific objectives and appear to be sufficiently detailed. On the whole, these operational objectives appear to be relevant and achievable, even though none of them is time-bound, thus not meeting entirely the recommendations included in the better regulation toolbox (tool #16, pp. 100-101).

## Range of options considered

		DRIVERS			
		1 LACK OF AWARENESS OF THE MUTUAL RECOGNITION PRINCIPLE AND REGULATION (EC) NO 764/2008	2 LEGAL UNCERTAINTY REGARDING THE SCOPE OF MUTUAL RECOGNITION	3 LEGAL UNCERTAINTY REGARDING THE APPLICATION OF MUTUAL RECOGNITION AND UNRELIABILITY OF THE OUTCOME	4 LACK OF TRUST AND COOPERATION AMONG AUTHORITIES
<b>RETAINED OPTIONS</b>	1 BASELINE	-	-	-	-
	2 SOFT LAW INSTRUMENTS	2a Awareness-raising campaigns* and training**	2b Design a clearer mutual recognition clause	2a Awareness-raising campaigns* and training** 2b Design a clearer mutual recognition clause 2c Exchange of officials	2c Exchange of officials
	3 MINIMUM LEGISLATIVE CHANGES***	3c Enlarge the role of PCPs	3c Enlarge the role of PCPs	3a Guarantee that products lawfully marketed in one Member State and complying with European standards enjoy the right of free movement in the EU 3b Reinforce the obligation to notify administrative decisions denying or restricting mutual recognition (to ensure more transparency)	3b Reinforce the obligation to notify administrative decisions denying or restricting mutual recognition (to ensure more transparency) 3c Enlarge the role of PCPs
	4 COMPREHENSIVE LEGISLATIVE CHANGES***	4d Strengthen the role of PCPs**** and put in place a mandatory administrative cooperation among Member States	4a Clarify the scope of the Mutual Recognition Regulation	4b Introduce a self-declaration of compliance 4c Introduce a fast-track appeal procedure (against national decisions denying or restricting market access)	4d Strengthen the role of PCPs**** and put in place a mandatory administrative cooperation among Member States
	5 LEGISLATIVE CHANGES***	-	Introduce a voluntary prior authorisation to place products on the market of another Member State		-
<p>* On mutual recognition, among economic operators and national authorities</p> <p>** On the implementation of the mutual recognition principle</p> <p>*** To the Mutual Recognition Regulation (EC) No 764/2008</p> <p>**** To be achieved also by facilitating the delivery of their services in accordance with the legislative proposal COM(2017) 256 final on establishing a single digital gateway to provide information, procedures, assistance and problem-solving services</p>					

Source: author, based on IA

<sup>7</sup> Annex 5 contains several tables of harmonised, non-harmonised, or partially harmonised products/sectors (IA, pp. 115-125).

The baseline scenario is analysed in a sufficiently comprehensive way (IA, pp. 28-30), while the four retained options 2 to 5, shown above, are illustrated with a greater level of detail (IA, pp. 34-41).

The retained options seem consistent with the manner in which the problem has been defined. The IA provides a comparison among them in achieving the specific objectives with respect to the criteria of effectiveness, efficiency, and coherence (IA, pp. 56-59). The table above shows that some of the retained options include what appear to be sub-options to choose from. In reality the **preferred option**, which is a **combination of option 2 and option 4** (IA, p. 59), envisages retaining all of them. The IA states that option 2 could be combined with any of the other legislative options, while options 3, 4 and 5 would be mutually exclusive (IA, p. 32). However, the IA could have benefited from explaining why option 4 alone was not selected, as this one was considered to be superior to option 2 in all aspects, except for its effectiveness with regard to the specific objective 1, i.e. increasing awareness of mutual recognition (IA, Table 8-1, p. 58). With regard to option 4, the IA could have better explained the added value of introducing a self-declaration of compliance (sub-option 4b) as it 'will not guarantee absolute market access for the relevant products, given that the application of mutual recognition can be objected to by national authorities when this is justified and proportionate for the protection of legitimate public interests' (IA, p. 38). In addition, the IA could have better explained how this self-declaration will help facilitating the right to free movement within the internal market for products lawfully marketed in another Member State (operational objective c), also in the light of the possibility of being 'voluntary' (IA, p. 38).

Finally, the IA could have better explained the differences, if any, between the proposed declaration of compliance (with the technical rules of the Member State where the product is being lawfully marketed) and the EU declaration of conformity.<sup>8</sup> The IA, in fact, states only that 'a similar declaration of compliance is already required for products within the scope of Union harmonisation legislation' (IA, p. 37), without specifying what the similarities are with the EU declaration of conformity. In this regard, the description provided in Annex 8 of the IA (pp. 149-154) does not bring clarity; on the contrary, a third reference to a supplier's declaration of conformity (SDoC) in international trade is introduced (IA, pp. 156-172).

The IA briefly considers three additional options, namely (IA, pp. 32-33):

- To repeal the Mutual Recognition Regulation. This option is discarded at an early stage because, according to the IA (pp. 32-33), Regulation (EC) No 764/2008 remains relevant, and common procedures for the application of mutual recognition are still necessary, regardless of the shortcomings identified over time.
- To introduce a declaration of compliance issued by a third party, that would be a body designated by the Member State in which the product is legally marketed. This option is also discarded at an early stage because: it would imply 'heavy costs' for economic operators;<sup>9</sup> the responsibility concerning the compliance of the product would remain with the economic operator; and it would appear disproportionate, as it would apply to all types of products, and contrary to the current situation for harmonised products. However, the IA could perhaps have explained better why it considered the option of introducing a declaration of compliance issued by a third party while, at the same time, stating that 'such third party declaration of compliance could have been voluntary or mandatory' (IA, p. 33). This is, incidentally, the same aspect not sufficiently clarified for the preferred option 4c. In addition, the evidence provided for concluding that the option would imply heavy costs for businesses appears to be scarce.
- To propose further harmonisation measures covering certain common aspects of all products (e.g. traceability). This option is discarded because 'products will remain partly harmonised products, and for the elements not subject to the EU harmonisation legislation, they will still be subject to mutual recognition and to potentially conflicting national rules' (IA, p. 33).

## Scope of the impact assessment

The IA provides an assessment of the economic impact of the retained options for businesses, Member States, and the EU budget. The impacts of each policy option are assessed both quantitatively and qualitatively, depending on the options (and sub-options) analysed and the availability of information/data (IA, pp. 41-43, 45-47, 49-51, 53-55). Social impacts are expected to be neutral, very limited or limited, depending on the options

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<sup>8</sup> This is the document that states that the product satisfies all the relevant requirements of the applicable legislation, and it is obligatory in various sectors (see, for instance, IA, pp. 151-152); by signing it, the manufacturer assumes responsibility for the compliance of the product. See also Annex 8 (IA, pp. 149-154).

<sup>9</sup> The IA, in its footnote 76 (p. 33), provides some quantifications of these costs, contained in [SWD\(2014\) 23 final](#), concerning the evaluation of the internal market legislation for industrial products.

considered and 'to the extent that these can be assessed and quantified' (IA, p. 43). Some of the retained options are not expected to have environmental impacts (IA, pp. 43 and 55) while others are expected to bring about some additional transport emissions, not quantified, resulting from an increase in intra-EU trade (IA, pp. 47 and 52). Impact on intra-EU trade is mentioned very briefly with regard to options 2 and 3, which are not expected to lead, on their own, to a significant increase in such trade (IA, pp. 42 and 46). Impact on public administrations is not mentioned, whereas the impact on administrative simplification for businesses is briefly dealt with (IA, pp. 44, 47, 52 and 55). Considering the methodological complexity of quantifying costs for the retained options, due also to the variety of products involved, and the difficulties surrounding the availability of information and data, the IA appears to provide a reasonable support to the analysis of their economic impacts. However, the analysis regarding the impact on competitiveness is largely missing (see the 'SME test/competitiveness' section of this briefing).

## **Subsidiarity/proportionality**

The explanatory memorandum of the proposal states (p. 4) that the legal basis is Article 114(1) of the Treaty on the Functioning of the European Union (TFEU), and that action by Member States alone cannot solve cross-border problems associated with the application of the principle of mutual recognition across the single market. The application of the principle needs to be based on common solutions applied equally by all national authorities in order to be effective (IA, pp. 31-32). According to the IA, only such common procedures, enabled by coordinated EU action, can guarantee that national authorities will apply the principle of mutual recognition in the same manner (IA, p. 31). In addition, the IA states that the added value of the mutual recognition rules was acknowledged by stakeholders replying to the public consultation run in 2016 (see the 'stakeholder consultation' section of this briefing). The IA appears to have considered some of the relevant issues included in the necessity/relevance and EU added value tests, in line with the Commission's [better regulation toolbox](#) (tool #5, pp. 27-29). However these are not considered in a coherent way and are scattered throughout the IA, with the specific section of the IA dealing with the analysis of subsidiarity consisting of just a few lines (IA, pp. 30-31). The deadline for the submission of reasoned opinions by national parliaments on whether the proposal complies with the principle of subsidiarity was 29 March 2018. Reasoned opinions had not been submitted by national parliaments at the time of writing. Scrutiny had been completed by the parliaments of three Member States, and was in progress in the parliaments of eight Member States.

## **Budgetary or public finance implications**

The explanatory memorandum states only that the proposal will have a budgetary impact on the Commission's human and administrative resources, as well as on its operational appropriations (p. 10), which are detailed in the financial statement (pp. 30-52). It also states that the costs envisaged for the Commission and Member States are considered as acceptable, and will be compensated for through the savings incurred by businesses, and through benefits for businesses, consumer and Member States alike (p. 5). Costs for Member States and the EU budget are assessed and quantified, wherever possible, when the IA discusses the policy options (IA, pp. 41-56). For example, the exchange of officials (option 2c), covering about 300 exchanges, could be realised with a budget of around €510 000, covering the travel and subsistence allowances for the officials participating in the scheme (IA, p. 43).

## **SME test/Competitiveness**

The identified problem, with its underlying drivers, is particularly relevant for SMEs. According to the IA (p. 13), national technical rules act as barriers, particularly for SMEs, who might decide as a result not to adapt their products to the rules applicable in another Member State, and, consequently, not to sell their products in other Member States. Identifying the applicable national rules, requirements and administrative procedures is also particularly challenging for SMEs (IA, pp. 24-25). Only about 14 % of the roughly two million manufacturing SMEs (0-249 employees) in the EU-28 are trading across borders in the EU, compared to 85.4 % of large manufacturing firms, translating into lost opportunities for businesses as well as costs resulting from delays in entering a market (IA, p. 25). An SME test has been carried out, whose summary results are illustrated in Annex 9 (IA, pp. 173-174). Competitiveness is mentioned briefly three times in the IA (pp. 25, 46-47, 57) and twice in the annexes (Annex 2, p. 70 and Annex 8, p. 158). From the scattered, and limited, instances provided in the IA, it is reasonable to state

that the analysis regarding the impact on competitiveness appears to be insufficiently developed and that the statements provided could, perhaps, have been supported by evidence.

## Simplification and other regulatory implications

The explanatory memorandum states that the proposal is consistent with several other pieces of existing or proposed legislation and notably the EU harmonisation legislation (pp. 2-4).<sup>10</sup>

In addition, the proposal is part of the 'goods package' comprising another legislative [proposal](#),<sup>11</sup> and a communication, [COM\(2017\) 787](#). The two proposals are linked, as explained in the communication, because through their implementation the Commission would like to address two remaining structural weaknesses of the single market for goods, namely (Communication, pp. 1-2):

- the insufficient enforcement and compliance of EU harmonised product safety rules, as there are still too many unsafe and illicit products on the market despite the existence of far-reaching rules;
- the insufficient use of the mutual recognition for those products that do not fall (fully or partially) under harmonised EU product safety rules and therefore may face market access difficulties in another Member State, even if considered safe and in line with the public interest of the Member State manufacturing them.

Finally, the proposal is linked to the REFIT programme, due to the impacts that the suboptimal functioning of mutual recognition has on the operation of the internal market. A REFIT evaluation<sup>12</sup> of the functioning of mutual recognition<sup>13</sup> in the field of goods has been carried out. However, the IA is not very convincing in providing clear evidence of the added value of the proposed new regulation in terms of simplification and reduction of regulatory cost for businesses, at least based on the content of its Annex 8 (IA, pp. 126-139).

## Quality of data, research and analysis

The analysis of the identified problem, and its underlying drivers, builds on the Commission report [COM\(2012\) 292 final](#), regarding the first assessment on the application of Regulation (EC) No 764/2008. In addition, it builds on the [evaluation](#) carried out by DTI, Technopolis, EY and VVA Consulting (2015), regarding the application of the principle of mutual recognition in the field of goods, and on the REFIT evaluation of the functioning of the mutual recognition in the field of goods. It build also on a study concerning the costs and benefits of the revision of the Mutual Recognition Regulation, aiming to estimate the magnitude of the problem caused by a suboptimal functioning of mutual recognition, and to analyse the impacts of the different options envisaged for addressing this problem. The study is referenced in footnote 27 of the IA (p. 14), and mentioned in Annexes 1 (p. 66), and 2 (p. 80), but it was not publicly available on the DG GROW website at the time of writing.<sup>14</sup> The analysis builds also on the desk research conducted by the Commission, on the assessment of additional literature and jurisprudence, listed in Annex 7 (IA, pp. 140-148), on the analysis of complaints (based on Directive (EU) 2015/1535) received from economic operators, and on stakeholders' views (see the following section of this briefing). All this provides ample and detailed insights on the different issues considered in the IA, making the overall analysis, and the assessments of the retained options, reasonably sound. However, the IA states that several factors made '... the evaluation of the application of mutual recognition a difficult exercise'. A specific chapter of Annex 1 provides an assessment of the robustness of the findings of the IA (pp. 67-69). Annex 4 illustrates extensively the analytical model used to estimate the costs associated with a sub-optimal functioning of the mutual recognition principle (IA, pp. 86-114) along with the methodological challenges, e.g. the lack of an updated list of non-harmonised and partially harmonised products/sectors or the use of different nomenclatures at sectorial/product level in statistics.

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<sup>10</sup> Namely: [Directive \(EU\) 2015/1535](#) on the provision of information in the field of technical regulations, [Directive 2001/95/EC](#) on general product safety, [Regulation \(EU\) No 305/2011](#) on the marketing of construction products, Commission proposal [COM\(2017\) 256 final](#) on establishing a single digital gateway, and Commission recommendation 2013/461/EU on principles governing the functioning of the internal market problem solving network ([SOLVIT](#)).

<sup>11</sup> Proposal for a regulation laying down rules and procedures for compliance with and enforcement of Union harmonisation legislation on products, [COM\(2017\) 795](#). See also, C. Collovà, [Strengthening the market surveillance of products](#), initial appraisal of a Commission impact assessment, EPRS, 2018.

<sup>12</sup> See [SWD\(2017\) 475 final](#), [SWD\(2017\) 476 final](#) (executive summary).

<sup>13</sup> Mutual recognition consists of a principle and of a legal act, Regulation (EC) No 764/2008, defining the practical modalities of the implementation of the principle; the REFIT evaluation, therefore, assessed the functioning of both.

<sup>14</sup> Published on EU bookshop website 1 March 2018. See EY, Tech4i2, Time.lex, and CEPS, Study on the costs and benefits of the revision of the Mutual Recognition Regulation (EC) No 764-2008, [Report](#) prepared for the Commission, DG GROW, August 2017.

## Stakeholder consultation

Four different surveys were launched on 9 October 2014 and completed on 5 January 2015 in the framework of the external evaluation carried out by DTI, Technopolis, EY and VVA Consulting (2015) (IA, p. 66). These consisted of a company survey, a survey of national business associations, a survey of national sector associations, and a PCPs survey. Qualitative interviews with national business associations and PCPs in each Member State were carried out following the surveys, to get a better picture of the implementation of the mutual recognition principle in the Member States.<sup>15</sup> In addition, the Commission gathered stakeholders' views through a 17-week online public consultation conducted between 1 June and 30 September 2016. The results are briefly described in Annex 2 of the IA (pp. 70-78), and a [factual summary](#), is provided in a document available on the DG GROW website.<sup>16</sup> This includes detailed statistics on the 153 replies received. The IA provides a brief summary of the stakeholders' views regarding the priority in addressing the four identified drivers as well as their support to the different tools/measures envisaged under each option (IA, pp. 34-40). Stakeholders' views on the four retained policy options are summarised in the section of the IA dealing with the analysis of impacts (IA, pp. 44-45, 48-49, 52-53, 55-56). Finally, the Commission organised a [conference](#) on 17 June 2016 ('Single market for products: fresh ideas to unleash the full potential') to gather information and views on the main issues related to the functioning of the mutual recognition principle and identify possible ways forward.<sup>17</sup> Stakeholders' views were also discussed in bilateral meetings that took place during 2016 (IA, p. 66). In the light of what has been mentioned before, it is apparent that the Commission has consulted a broad range of stakeholders, whose views have been extensively analysed and illustrated in the supporting documents referenced in the IA. However, the IA warns that 'the results of the stakeholders' consultation may need to be treated with caution, as the consultations, targeted or opened, were not representative of different sectors, Member States and company types'. In addition 'the surveys carried out in 2014-2015 by the external consultant registered a low rate of responses ... the businesses survey did not result in a representative sample. There was a significant geographical bias with respect to the geographical coverage.... In addition, large companies were over-represented.... Only a minority of sectors and Member States were represented in the survey' (IA, pp. 67-68). With regard to the 17-week online public consultation, 'businesses actively participated but without reaching a representative sample; large companies were over-represented, as ... they only represent 1 % of the EU's company population' (IA, p. 68). However, according to the Commission, 'the stakeholders' consultation was ... reliable enough to be used as a basis for further decision making' (IA, p. 69).

## Monitoring and evaluation

The Commission will monitor the implementation and effectiveness of the proposed new regulation through a set of quantitative and qualitative indicators (explanatory memorandum, p. 10), illustrated in the IA (p. 61). These appear to be consistent with the corresponding operational objectives. As a general remark, the section on monitoring and evaluation would have benefited from including the (expected) targets indicated for each operational objective under the corresponding indicator(s). In addition, it would have benefited from including time-bound targets. The IA acknowledges the lack of accurate quantitative data on mutual recognition, e.g. size of the market, number of products, etc. (IA, p. 60). The IA states that this problem will be addressed with a systematic survey, also by using existing tools available at EU level, such as the [Innobarometer](#) (IA, p. 60). The Commission will evaluate the regulation every five years, and will submit a report to the European Parliament and to the Council containing an assessment of the functioning of the regulation and of the mutual recognition principle as well as their impact on the free movement of goods within the internal market (explanatory memorandum, p. 10). However, the monitoring indicators appear to be missing from the legislative proposal, although it does include the measures identified under the preferred options 2 and 4 to which the indicators refer.

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<sup>15</sup> A brief summary of the main findings of these surveys and interviews is provided in Annex 2 of the IA (pp. 79-80).

<sup>16</sup> The DG GROW website contains also a [background document](#) to the public consultation, the contributions received by [public authorities](#), [businesses or business organisations](#), and [citizens, consumer organisations or other stakeholders](#), and the individual [position papers](#) submitted by several stakeholders, whose contents is very briefly summarised in Annex 2 of the IA (pp. 80-81). The questionnaires submitted to [businesses](#), [public authorities](#), [consumers and citizens](#) can also be consulted (in all official EU languages) on the DG GROW website.

<sup>17</sup> The [conferences minutes](#) are available on the DG GROW website, as well as a copy of its web stream (until mid-May 2018).

## Commission Regulatory Scrutiny Board

On 7 April 2017, the Commission's Regulatory Scrutiny Board (RSB) adopted a [positive opinion](#) on a draft version of the IA report, although recommending improvements with respect to some issues. For example, the RSB recommended that the IA explain more clearly the most problematic aspects of mutual recognition, elaborate on the issue of lack of trust between national administrations, and explain clearly how options have been 'constructed'. The final version of the IA summarises, in a clear and comprehensive way, how it has addressed the RSB's recommendations (IA, Annex 1, pp. 62-65), in line with the better regulation guidelines. It appears to have addressed most of the improvements requested by the RSB, even though some aspects could have been clarified further. This is the case, for instance, with regard to the lack of trust between national administrations or the reasons why PCPs are not functioning. The IA states that the aspect of lack of trust has been further elaborated and presented as a problem driver in section 3.2.4 ('lack of trust and cooperation among authorities', pp. 23-24). However, the analysis of this aspect appears to be missing from the aforementioned section, which provides some 'structural' explanations for a suboptimal administrative cooperation (e.g. lack of a common address book/network). With regard to PCPs, it appears that the IA has answered the RSB's recommendation by providing more information, but not in a structured and systematic way. Information regarding PCPs is, in fact, scattered throughout the entire IA, which might perhaps have benefited from including a stand-alone section illustrating why PCPs are not functioning or are functioning in a sub-optimal way.

## Coherence between the Commission's legislative proposal and the IA

The proposal seems to be aligned with the analysis carried out in the IA. The measures identified under the preferred option 2 are mentioned under recital 43 of the legislative proposal. However, this recital does not mention explicitly the training activities envisaged under sub-option 2a, or the action plan referenced in the IA (p. 34). Measures identified under the preferred option 4 are included in specific articles.

## Conclusions

The IA clearly defines the problem, as well as the general and specific objectives. Operational objectives appear to be relevant and achievable, even though none of them is time-bound. As such, they appear not to be entirely set according to the recommendations included in the better regulation toolbox. The IA presents a reasonable range of options and chooses a combination of soft law measures and legislative changes (options 2 and 4). Among the measures proposed, the introduction of a declaration of compliance could have benefited from further substantiation of its added value. The analysis of impacts focuses on the economic impact of the retained options for businesses, Member States, and the EU budget. The impacts of each policy option is assessed both quantitatively and qualitatively, depending on the option analysed and the availability of information/data. While an SME test was conducted, the analysis regarding the impact on competitiveness is largely missing. Social and environmental impacts are mentioned very briefly. The Commission has consulted a broad range of stakeholders, whose views have been extensively analysed and illustrated. The research, analysis, and supporting evidence included or referenced in the IA provide ample and detailed insights on the different issues considered, making the overall analysis, and the assessments of the retained options, reasonably sound.

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*This note, prepared by the Ex-Ante Impact Assessment Unit for the European Parliament's Committee on Internal Market and Consumer Protection (IMCO), analyses whether the principal criteria laid down in the Commission's own better regulation guidelines, as well as additional factors identified by the Parliament in its Impact Assessment Handbook, appear to be met by the IA. It does not attempt to deal with the substance of the proposal. It is drafted for informational and background purposes to assist the relevant parliamentary committee(s) and Members more widely in their work.*

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