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Proposal for a Regulation of the European Parliament and of the Council
on the mutual recognition on goods lawfully marketed in another Member
State

Delegations will find attached document SWD(2017) 477 final.

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COMMISSION STAFF WORKING DOCUMENT
STAKEHOLDER CONSULTATION - SYNOPSIS REPORT

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. 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 for products lawfully marketed in a Member State and not subject to European harmonisation legislation to enjoy the right to free movement, despite lack of compliance with national technical rules of the Member State of destination. However, the principle is not yet used at its full potential as shown in a recent evaluation of the mutual recognition principle. To improve the application of the mutual recognition principle, the Commission will present an EU-wide Action Plan to raise awareness, with a focus on problematic sectors. 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**¹ were asked to provide their feedback during their last 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 ideas for raising awareness on mutual recognition, welcomed by Member States, a preliminary analysis of the main problems generated by the suboptimal functioning of mutual recognition and the preliminary options for improving mutual recognition and asked for feedback from the delegations.

As regards the possible introduction of a declaration of compliance some Member States stressed the possible administrative burden on economic operators while acknowledging that such declaration would facilitate their tasks.

The Commission also presented options intended to incite national authorities to comply with the obligation to notify administrative decisions denying or restricting mutual recognition, such as more transparency and using an IT tool, and the possibility of creating a new fast track mechanism which would be an alternative to the costly and lengthy court procedures currently available.

The option of a system of prior authorisation to placing products on the market received opposition from many Member States expressed their opposition to this option, as it would hinder the free movement of goods.

As regards the option of ensuring free movement of goods guaranteed by compliance with European standards, Member States considered that focusing on essential requirements is more beneficial than using standards.

¹ 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.

Member States supported the possibility to enlarge and enhance the Product Contact Points as the Product Contact Points lack resources and staff.

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

2.2. Stakeholder conference of 17 June 2016

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

<http://ec.europa.eu/DocsRoom/documents/17963>

Presentations and discussions were followed by 3 workshops, with a balanced representation of national authorities, businesses and associations.

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). **45 authorities** from Member States replied to the public consultation. Individual companies (44) and business organisations (44) were equally represented.

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.

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 for entering a new market. Among them, half had their market access denied, and only 2% challenged this decision successfully.

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

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

2.3.2. Functioning of the Mutual Recognition Regulation

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

The majority of respondents are aware of the Regulation, and consider that most of the tools put in place are useful and still necessary. As regards whether or not the Regulation has met its objective, 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

National authorities ranked these costs as average, and agree, fully or partially, that the Regulation brings benefits in terms of facilitating market access.

For 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. High costs are also related to delays in entering a market, and to lost opportunities, when businesses relinquish entering a market because of different national rules that require adapting the products. The costs related to challenging administrative decisions denying market access are considered as less important, mainly because few economic operators choose to do so.

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

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.

Coherence

There is a consensus among respondents as regards the coherence of the Regulation.

EU added value

The European added value of the mutual recognition rules is also strongly underlined by the respondents.

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. 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.

2.3.4. Priorities to improve Mutual Recognition

If businesses rank the need for effective remedies as being the highest priority, Member States and citizens opt in favour of increasing awareness about mutual recognition.

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 principle², four different surveys were launched on 9 October 2014 and completed on 5 January 2015. The findings of the surveys and interviews show that the application of the mutual recognition principle is challenging and 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 remains problematic. Poor communication and cooperation among national authorities has also been pointed as a weakness.

² <http://ec.europa.eu/DocsRoom/documents/13381>

In the framework of the study assessing the costs and benefits of the different options envisaged for improving mutual recognition, a survey and interviews were carried out by the external contactor. The stakeholder consultation focused not only on the current functioning of mutual recognition – and its main issues – but also on how to revise the Regulation, through the policy options proposed by the Commission. Targeted surveys and interviews allowed an understanding of stakeholders' point of view about the Policy Options. 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 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. Businesses highlighted obstacles linked to the difficulty of obtaining easy access to information on relevant legislation and procedures in place (language barriers) and time to receive a response from national authorities. Both economic operators and national authorities agree that measures to improve the situation have to be taken. 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 call for more ambition to improve mutual recognition and trust among Member States. Some mention that the principle of mutual recognition could further be strengthened by the introduction of a presumption of conformity to independently (third party) tested products. Others stress the need to clarify the scope of the Mutual Recognition Regulation, to provide guidance for proportionality assessments and to share of best practices among Member States. Also, dissuasive means should be introduced to ensure that Member States notify according to their obligations in the Regulation. Moreover, effective remedies must be available to businesses in order for them to get quicker clarity on decisions taken against their products on the Single Market, including enhanced transparency to see the decisions. In addition, the Product Contact Points should be optimised and give businesses easy access to information about national decisions and technical rules. Also, there is an overall need for redeeming trust and strengthening cooperation among Member State authorities across the Single Market. 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

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

The overall objective of this initiative is to achieve a deeper single market for goods through more and better mutual recognition. This will be done by increasing awareness on mutual

recognition, enhancing legal certainty for businesses and national authorities when using mutual recognition and improving administrative cooperation and trust among authorities. This will result in unleashing the full potential of the internal market, by facilitating the use and application of mutual recognition, reducing the risk for businesses that their products will not get access to or will have to be unjustifiably withdrawn from the market and offering more choices at lower prices for consumers. While the expected benefits of more and better mutual recognition cannot be estimated with accuracy, a recent study on "The Costs of Non-Europe in the Single Market" shows that a reduction of trade barriers could lead to an increase of intra-EU trade of more than 100 billion EUR per year. The concept of trade barriers in this study is broader than mutual recognition only, but it provides an estimation of the expected benefits.

The EU added value of this initiative lies in having a common set of rules which guarantee equal treatment and allows a consistent, coherent and correct application of mutual recognition. Mutual recognition arises from Articles 34-36 of the Treaty on the Functioning of the EU and from the Court of Justice jurisprudence, and directly contributes to achieving the internal market for goods, one of the main achievements of the EU. Action by Member States alone would weaken the mutual recognition principle and dismantle it in 28 different and potentially contradicting national procedures.

The envisaged policy options included in this impact assessment were:

- Option 2 - Soft law to improve the functioning of mutual recognition (awareness raising, training, exchange of officials, etc.)
- Option 3 - Minimum legislative changes to Regulation (EC) No 764/2008 (transparency of administrative decisions, use of EU standards, enlarged role for PCPs)
- Option 4 - Comprehensive legislative changes to Regulation (EC) No 764/2008 (voluntary declaration of compliance, fast track appeal procedure, enhanced Product Contact Points and cooperation)
- Option 5 - Voluntary prior authorisation to placing on the market

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

The preferred option is option 4 (comprehensive legislative changes to Regulation (EC) No 764/2008), complemented by option 2 (the soft law measures).