INCEPTION IMPACT ASSESSMENT

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This Inception Impact Assessment is provided for information purposes only and can be subject to change. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content and structure.

A. Context, Subsidiarity Check and Objectives

Context

Achieving a deeper and fairer single market that builds on its strength and fully exploits its potential in all its dimensions, represents one of the key political priorities of the European Commission. The follow-up and the implementation of the Single Market Strategy, Upgrading the Single Market: more opportunities for people and business, adopted on 28 October 2015 are one of the main objectives of the 2016 Commission Work Programme.

This initiative implements the Single Market Strategy with respect to mutual recognition for the single market in goods. A key element for strengthening the single market for goods is 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 more and better mutual recognition.

Mutual recognition is seminal for a proper functioning of the single market for goods through the elimination of technical obstacles to a genuine free movement. The principle of mutual recognition itself is embedded in Articles 34 and 36 of the Treaty on the Functioning of the European Union (TFEU), and its further elaboration resulted from established case law.

The principle applies to products that are not subject to EU common rules (harmonisation legislation) or to aspects of products falling outside the scope of such legislation. Under the mutual recognition principle, different national technical rules continue to co-exist within the single market. The principle 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. Exceptions to this principle regard limited restrictions that 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 proportionate to the aim pursued.

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 establishing a procedural framework to minimise the possibility that national technical rules create unlawful obstacles to the free movement of goods between Member States. Trade barriers in the form of national technical rules are

2 Communication from Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Upgrading the Single Market: more opportunities for people and business, COM 2015 550/2
4 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 rules to products lawfully marketed in another Member State and repealing Decision 3052/95/EC (Text with EEA relevance), OJ L 218 of 13.8.2008, p. 21-29. In accordance with Article 12(1) of the Regulation, Member States have an obligation to send the Commission an annual report on the application of the regulation. Pursuant to Articles 6(2) and 7(2), Member States have to notify administrative decisions addressed to economic operators and concerning the prohibition of the placing on the market, modifications and additional testing of a product or the withdrawal of the product from the market.
already being prevented; Directive (EU) 2015/1535 requires from Member States to notify all draft technical rules in order to verify that the rule is compatible with EU law. 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 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. 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. 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.

### Issue

The principle of mutual recognition helped in improving businesses’ access to other Member States’ markets. While much was achieved to date, the outcome is not yet optimal; the objectives set out were not achieved, mainly because the procedural requirements of Regulation 764/2008 proved to be insufficient to ensure an easy, reliable and user friendly application of the mutual recognition principle. The external evaluation identified the most recurrent bottlenecks impeding the principle of mutual recognition to reach its full potential. Other shortcomings were identified in light of the experience with the application of the Regulation and through input by relevant stakeholders. Overall, these can be summarised as follows:

First, it is sometimes difficult, both for businesses and for responsible national authorities, to assess if mutual recognition can be applied to a specific product. The scope of the Regulation is unclear as regards the products and situations covered by mutual recognition; for example, prior authorisations to placing on the market are not fully covered. The product list established by the Regulation and intended to provide a picture of the products which can be covered by mutual recognition is not very efficient in providing the necessary information and lowering the efforts companies and national authorities put in assessing if the principle is applicable or not. This problem is particularly affecting certain specific sectors such as constructions, fertilisers, etc. In addition, applicable national technical rules often don’t contain a (clear) mutual recognition clause, specifying that the national rules don’t apply to products lawfully marketed in other Member States.

Second, in situations where mutual recognition could be applied, the application of the principle is sometimes knowingly disregarded because potential users don’t find it reliable enough. Businesses and national authorities have difficulties in demonstrating that the product was lawfully marketed in a given Member State. Furthermore, national authorities often tend to privilege their own rules (with whose cultural and historical background they are well acquainted) and insist on applying them at the cost of mutual recognition. Also, companies cannot easily challenge decisions hindering market access and this creates a lot of legal uncertainty. Companies as well often consider that nothing good can come from challenging national authorities and prefer to comply with national rules instead of relying on mutual recognition and take the risk of having market access denied.

Lastly, there is a lack of efficient communication among all players involved in the application of the mutual recognition principle. This applies to communication inside the national administrations, between administrations of different Member States, between Member States and the Commission and also to communication between businesses and administration. On the one hand, the communication among Product

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7 Evaluation criteria covered were effectiveness and efficiency


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Contact Points is not optimal, as there is insufficient cooperation among the involved / responsible national authorities dealing with mutual recognition. On the other hand, the communication between Product Contact Points and companies is not satisfactory either, as there are long delays for replying to the inquiries received. Finally, communication between Product Contact Points and the Commission is not optimal as there are flaws in notifying the decisions hindering market access to the Commission. Language related issues add further difficulties to proper communication.

As a consequence, companies may support additional non justified costs in order to enter on a new market or may even lose market opportunities. Consumers don’t benefit from more choices on the market and thus lower prices.

### Subsidiarity check

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.

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

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

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

### Main policy objectives

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

The specific objectives are:

- To increase legal certainty for businesses and national authorities when using the mutual recognition principle;
- To improve communication and cooperation among users and strengthen the role of Product Contact Points
- To reduce the risk for businesses to see market access denied

### B. Option Mapping

The following legislative and non-legislative options are identified at this stage:

**1. Status quo**

This option implies maintaining the Mutual Recognition Regulation unchanged.

**2. Revision of the Mutual Recognition Regulation**

This option refers to introducing legislative means to further boost the application of the mutual recognition principle. These can be subdivided as follows:

**2.1 Rendering mutual recognition easier to apply (complementary options)**

Option 2.1 a- Clarify the scope of the Regulation as regards the products to which mutual recognition could apply

Option 2.1 b- Develop a clearer mutual recognition clause to be included in national technical rules
2.2 Transforming mutual recognition into a reliable tool (complementary options)

Option 2.2 a- A self-declaration of conformity with the technical rules of the Member State where the product is being lawfully marketed proving presumption of conformity for the economic operators wishing to enter another market, to be issued by the economic operator himself.

Option 2.2 b- A declaration of conformity with the technical rules of the Member State where the product is being lawfully marketed proving presumption of conformity for the economic operators wishing to enter another market, to be issued by a body designated by the Member State in which the product is legally marketed, e.g. by the national Product Contact Point established in accordance with Regulation 764/2008.

Option 2.2 c- Introducing dissuasive means to ensure that the obligation for national authorities to notify administrative decisions denying or restricting mutual recognition is respected.

Option 2.2 d- Ensuring that effective remedies are available to economic operators who wish to take action against an administrative decision denying mutual recognition and to thus reduce the impact of costly and lengthy court procedures.

2.3 Improving communication to better support the application of mutual recognition (complementary options)

Option 2.3 a- Strengthen the role of Product Contact Points, to become a “first port of call” for information on applicable rules for products (i.e. to also cover harmonized products), to integrate them into a wider network and to provide online information through the ‘Single Digital Gateway’.

Option 2.3 b- Using new IT tools for notifying decisions hindering market access and for communication between Product Contact Points such as the Internal Market Information tool (IMI) or ICSMS (i.e. the general information support system referred to in Article 23 of Regulation (EC) No 765/2008).

Option 2.3 c- Strict deadlines to reply to requests made from one authority to the other.

3. Further harmonisation

Option 3.1- Harmonising technical requirements in specific fields where mutual recognition does not appear sufficient to ensure free movement of goods.

Option 3.2- Harmonising certain basic requirements that a product would need to satisfy such as, for example, minimum traceability requirements.

Option 3.3 –Ensure that products lawfully marketed in one Member State and complying with European standards effectively enjoy the right of free movement in the EU.

Baseline scenario – no EU policy change

The baseline scenario is the “status quo”, i.e. maintaining the Mutual Recognition Regulation unchanged.

Options of improving implementation and enforcement of existing legislation or doing less/simplifying existing legislation

Possible options range from improving the implementation of the Regulation as it currently stands by non-legislative initiatives such as soft law instruments (e.g. additional guidelines for the application of the Regulation), an action plan to increase awareness on the mutual recognition principle to revising the current Mutual Recognition Regulation.

Since its entry into force, the Commission services published several guidelines on the application of the principle of mutual recognition in various sectors and on what “lawfully marketed” stands for. Neither option is sufficient to address the problems described. These have not resulted in the expected improvement, in particular as regards the proof of lawful marketing of a product in a Member State.

More and better mutual recognition can be achieved through revisiting the legislative framework, possibly through a revision of the Mutual Recognition Regulation, and enhancing its implementation in particular by increased awareness from businesses and national authorities.

In addition to revising the current legal framework, the Commission also aims at adopting an action plan to improve the application of the mutual recognition principle on the ground. This action plan would allow addressing the lack of awareness and legal uncertainty covering the application of the mutual recognition principle via several potential tools such as:

- A training programme for national officials in specific problematic areas.
- Development of guidelines, best practices and exchanges of experience.
The Action Plan will not be covered by this impact assessment, which refers exclusively to the revision of the Mutual Recognition Regulation.

**Options that take account of new technological developments**

Digital developments will be appropriately addressed, in particular as regards a strengthened role for Product Contact Points, by providing relevant EU and national content online. To this end, Your Europe website could serve as the dedicated website on the application of the mutual recognition, which could, in the long term, be integrated in a new Single Digital Gateway.

In addition, the scope of the (IMI) Regulation on the Internal Market Information System could be extended to include the Mutual Recognition (MR) Regulation and thus offer an e-platform for all notifications to the Commission. The IMI regulation provides a legal framework for the system, setting out scope, actors, roles, responsibilities and data protection measures. The annex to the IMI regulation lists the legal acts, articles and provisions covered by the system. The revised MR regulation would need to have an article modifying the Annex to the IMI Regulation to include the specific provisions of the MR Regulation to be implemented through IMI.

Another option would be the extension of the scope of ICSMS to include the Mutual Recognition Regulation. ICSMS creates the basis for an effective and efficient cooperation between the market surveillance bodies in Europe. Supported by the internet, it enables a comprehensive exchange of information between all the national authorities.

**Preliminary proportionality check**

The forthcoming impact assessment will properly test the options for their proportionality.

Without prejudging the outcome of the impact assessment, option 2 could have positives impacts as regards additional administrative burdens on businesses and national administrations dealing with the mutual recognition principle. The impact assessment will particularly focus on comparing the costs resulting from the non-functioning of the mutual recognition principle (restricted market access) with the benefits of introducing tools which will facilitate the application of the mutual recognition principle and thus market access.

**C. Data Collection and Better Regulation Instruments**

**Data collection**

A public consultation open to key stakeholders will be launched in the first quarter of 2016 (open for 12 weeks). Significant data is already available and was mainly gathered through:

- The external evaluation of the application of the principle of mutual recognition in the field of goods, covering the effectiveness and efficiency of the application of the principle, finalized in 2015.
- The first application report on the functioning of the Mutual recognition and the numerous guidance documents published to date.
- The assessments of annual reports from Member States on the application of the Mutual Recognition Regulation.
- Notifications of draft national technical regulations received pursuant to Directive (EU) 2015/1535 (former Directive 98/34).
- Inputs from Member States and stakeholders, as well as management of relevant complaints and cases addressed to SOLVIT.

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10 See above footnote 5.
Additional data will be gathered through various means of consultation, in order to confirm the magnitude of the problem, costs associated with certain options, as well as their potential economic impacts.

The evaluation of the Mutual Recognition principle did not include a full ex-post assessment of the Mutual Recognition Regulation but covered some elements of this procedure. In its analysis, it pointed out that the functioning of the Regulation might not be optimal and noted some deficiencies (e.g. flaws in notifications of decisions hindering market access, malfunctioning of the Product Contact Points network, etc.). Therefore, building on those findings and with the view to complete the picture on how this regulation is functioning, the Mutual Recognition Regulation will be evaluated according to the 5 standard evaluation criteria (effectiveness, efficiency, coherence, relevance, EU added value).

Consultation approach

The stakeholder consultation related to this initiative will be launched by early 2016. The consultation strategy consists of a mix of an open consultation and targeted meetings.

The open online public consultation will be launched early 2016 and will run for 12 weeks. The questionnaire will be published on the 'Your voice in Europe' portal: [http://ec.europa.eu/yourvoice/consultations/index_en.htm](http://ec.europa.eu/yourvoice/consultations/index_en.htm)

The consultation (questionnaires) will be opened to all interested parties, with a specific focus on businesses (including their umbrella organisations) and national authorities. Business organisations, chamber of commerce and business networks such as Europe Enterprise Network will be used to reach out to SMEs.

The Commission will also consult the Consultative Committee established pursuant to Mutual Recognition Regulation at least at its annual meetings. Finally, data and facts will be gathered through bilateral ad hoc contacts with key stakeholders and representative business organisations.

**Will an Implementation plan be established?**

- ☑ Yes
- ☐ No

Not applicable (Regulation directly applicable)

**D. Information on the Impact Assessment Process**

An impact assessment will be carried out with work starting the first quarter of 2016.

An Inter-Service Steering Group (ISSG) chaired by DG Internal Market, Industry, Entrepreneurship and SMEs (GROWTH) will be established to this purpose. Its members will include representatives of:

- Legal Service of the Commission
- 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 will meet at least three times over the period necessary to achieve the work.

**E. Preliminary Assessment of Expected Impacts**

Option 1- status quo is expected to maintain the current situation, i.e. obstacles for companies in getting access to new markets, implying costs related to re-testing, lost markets and opportunities, etc.

Option 2- revising the current Mutual Recognition Regulation is most likely expected to improve the application of the principle of mutual recognition and to facilitate market access especially for SMEs. This will result in lowering the costs related to the assessment of national technical rules, the costs related to re-testing products and the
costs related to lost markets and opportunities. Some costs might be entailed for national administrations, mainly linked to allocating adequate resources for their strengthened Product Contact Points.

Option 3: Further harmonisation is expected to facilitate free movement but only for certain categories of products (those concerned by the harmonisation); for the other products the current situation will be maintained, i.e. obstacles for companies in getting access to new markets, implying costs related to re-testing, lost markets and opportunities, etc.

**Likely economic impacts**

The initiative is aimed at ensuring more and better mutual recognition. By creating a fairer level playing field for SMEs and businesses operating across borders, it will contribute to a genuine free movement of goods in the single market.

In economic terms, a wider use of mutual recognition would significantly boost intra-EU trade flows. Applied specifically to goods, the impact of a ‘perfectly’ functioning market for goods where mutual recognition applies has been estimated to amount to an EU GDP increase of up to 1.8%. The forthcoming impact assessment will properly look into both the costs associated to a suboptimal application of the principle of mutual recognition and the economic impact of various options. An in-depth economic analysis will be made by an external contractor, in close cooperation with the Commission services.

An improved application of the principle of mutual recognition will directly benefit businesses by facilitating their trade within the single market and by creating a fairer level playing field within domestic markets.

**Likely social impacts**

The initiative is likely to benefit consumers whose choice will increase by the introduction of new products into different national markets. At the same time, the impact assessment will need to assess whether the stricter application of the mutual recognition principle could lead to either lower or higher standards of consumer safety/protection or other protected public interests in the Member State of destination.

**Likely environmental impacts**

The use of digital means (e.g. self-declaration) is likely to ensure a higher level of protection of the environment. Improved functioning of the mutual recognition is unlikely to have a direct impact on the environment or environmental standards applied to non-harmonised products.

**Likely impacts on simplification and/or administrative burden**

The initiative will reduce the administrative burden for businesses, while possibly increasing the administrative burden for the national authorities (e.g. Product Contact Points).

For businesses, this would result in replacing the current diversity of documents required in various Member States in order to prove lawful marketing of a given product in the Member State of origin with one self-declaration on lawful marketing. In turn, the burden of proof belongs to national administrations that have to justify and notify the interested party and the Commission all refusals to grant mutual recognition of a product.

**Likely impacts on SMEs**

SMEs will be positively impacted by the initiative. It can be assumed that they will enjoy most of the expected benefits. Improving the application of the principle of mutual recognition and addressing the current problems faced by SMEs when trading outside a domestic market within the single market is likely to generate more growth.

**Likely impacts on competitiveness and innovation**

Benefits may be expected from an improved application of the principle of mutual recognition. Eliminating current obstacles to the proper application of mutual recognition will result in bigger market opportunities for companies and, thus, impact positively on their growth and competitiveness.

Furthermore, the growth potential for companies with innovative products will be increased, as current practice shows that these companies encounter problems in benefiting from the mutual recognition principle. Most of the time, innovative products are not regulated and companies face problems when trying to market them in another Member State. Benefiting from a presumption of conformity due to the self-declaration of conformity will help them in demonstrating that their products are lawfully marketed.

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## Likely impacts on public administrations

Member States are at the forefront of the effective application of the principle of mutual recognition and need to ensure appropriate resources in strengthening their competent authorities. Therefore, administrations of EU Member States, in particular Product Contact Points, may be affected to the extent to which appropriate resources will be needed to perform the entrusted tasks and to provide timely information to interested parties. Cooperation between and inside national administrations may also be streamlined through the initiative.

## Likely impacts on third countries, international trade or investment

Increased trust in the application of mutual recognition should encourage importers of non-harmonised products to target additional markets of EU Member States, thus some increase of imports should be expected.