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PROPOSAL

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

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(Text with EEA relevance)

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EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Achieving a deeper and fairer single market is one of the key political priorities of the European Commission.¹ The follow-up and the implementation of the Single Market Strategy, Upgrading the Single Market: more opportunities for people and business, adopted on 28 October 2015² constitute one of the main objectives of the 2017 Commission Work Programme.³

Within the Single Market, free movement of goods is the most developed of all four fundamental freedoms and generates around 25 % of EU GDP and 75 % of intra-EU trade. The EU accounts for around one sixth of the world's trade in goods. Trade in goods between EU Member States (intra-EU trade) was valued at EUR 3 110 billion in 2016⁴. However, there is still work to do to ensure a deep and fair European Single Market. Where there are no common rules, the principle of mutual recognition is not always being applied. The 'Goods Package' announced in the 2017 Commission Work Programme, intends to address this fundamental problem, with an initiative on mutual recognition.

Mutual recognition is essential for a proper functioning of the single market for goods. Where no specific EU legislation is in place, Member States are free to set national rules that lay down requirements to be met by products. Such national requirements can co-exist in various Member States, but, if divergent, may create barriers to intra-EU trade. The principle of mutual recognition requires that a good that is lawfully marketed in one Member State should not be prohibited in another Member State, unless the latter has sound reasons for banning or restricting its sale. Mutual recognition applies to products not subject to Union harmonisation legislation or only partly covered by it, such as a wide range of consumer products (textile, footwear, childcare articles, jewellery, tableware or furniture).

The adoption of Regulation (EC) No 764/2008 ('the Regulation')⁵ was a partial⁶ response to the weak application of the principle of mutual recognition in the field of goods, triggered by the lack of awareness about the principle, legal uncertainty when applying it and the lack of administrative cooperation among national authorities. The Regulation aimed mainly at establishing a procedural framework to minimise the possibility that national technical rules create unlawful obstacles⁷.

In December 2013, the Conclusions on Single Market Policy, adopted by the Competitiveness Council, noted that to improve framework conditions for businesses and consumers in the Single Market, all relevant instruments should be appropriately employed, including harmonisation and mutual recognition.⁸ The Commission was therefore invited to report to the Council on the sectors and markets where the application of the principle of mutual

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

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

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

⁴ Source Eurostat.

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

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

⁷ See the Evaluation.

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

recognition is economically most advantageous, but where its functioning remains insufficient or problematic. In its Conclusions on Single Market Policy of February 2015, the Competitiveness Council urged the Commission to ensure that the principle of mutual recognition would function effectively and to bring forward proposals to that effect, as appropriate⁹.

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.¹⁰ Building on it, the Commission Evaluation on the functioning of mutual recognition (REFIT) included an assessment of the functioning of the Regulation as well, in order to have a full picture of the obstacles impeding mutual recognition to function optimally (hereafter, the Evaluation).

The Evaluation concluded that mutual recognition is not functioning as it should and that the principle and the Regulation had limited effects in meeting the foreseen objectives in terms of raising awareness and of increasing legal certainty and administrative cooperation.

This initiative responds to the conclusions of the Evaluation. Its overall objective is to achieve a fairer and deeper single market for goods through more and better mutual recognition.

The specific objective will be to improve the functioning of mutual recognition by proposing several ambitious measures. Such measures aim at ensuring that the existing rights and obligations deriving from the mutual recognition principle are observed. In practice, this means that Member States continue to be able to protect their national legitimate public objectives and restrict the marketing of goods even if lawfully marketed elsewhere, if their decision is justified and proportionate.

First, clarifying the scope of mutual recognition, by clearly defining when it is applicable, will increase legal certainty for businesses and national authorities as to when the mutual recognition principle can be used.

Second, the introduction of a self-declaration to facilitate the demonstration of a product being already lawfully marketed, and of a problem solving system to deal with decisions denying or restricting market access will increase legal certainty about the application of mutual recognition and facilitate its application by businesses; both business and national authorities will know what they can reasonably expect when mutual recognition is, or ought to be, applied.

Last, setting up administrative cooperation, and putting in place an IT tool will enhance communication, cooperation and trust among national authorities, and thus facilitate the functioning of mutual recognition.

- **Consistency with existing policy provisions in the policy area**

- (a) 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 services¹¹.

The Directive contributes to ensuring more 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. This helps to prevent new trade barriers in the form of ‘technical regulations’ from arising before they are adopted, by enabling the

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

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

¹¹ OJ L 241, 17.9.2015, p. 1.

Commission and Member States to verify that the technical rule is compatible with EU law. This initiative has a different, complementary objective. It puts in place corrective measures, to ensure, once the rule is in force, that the rule is being applied correctly on a case by case basis in a manner that respects the principle of mutual recognition.

(b) Directive 2001/95/EC on General Product Safety¹²

The Directive ensures that products placed on the EU market are safe. It applies to non-harmonised consumer products. This draft Regulation also applies to the non-harmonised area, but addresses the situations where the competent authorities of a Member State intend to deny or prohibit the marketing or use of a non-harmonised consumer product, lawfully marketed in another Member State, for reasons other than solely 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.

(c) Regulation (EU) No 305/2011 on construction products¹³

This Regulation sets up Products Contact Points for Construction (PCPCs), to provide information on the provisions applicable to construction works and construction products. This initiative complements coherently the PCPCs. Nevertheless, in numerous Member States, the PCPC and the PCP have been merged, to offer a "one single entry point" for businesses. This initiative does not prevent such mergers in the future.

(d) The SOLVIT network¹⁴

SOLVIT is a service provided by the national administration in each EU Member State, as well as in Iceland, Liechtenstein and Norway. It helps business when their rights are breached by public authorities in another EU Member State, by aiming at finding a solution within 10 weeks. Thus, SOLVIT may be used, as an alternative to court proceedings, by businesses when facing a national decision denying or restricting market access on the basis of the mutual recognition principle. This initiative builds on the SOLVIT network and the recently adopted Action plan on reinforcing SOLVIT¹⁵; it enhances the existing mechanism in the area of goods, in order to facilitate challenging administrative decisions denying or restricting market access based on mutual recognition.

(e) EU harmonisation legislation

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. But EU harmonisation legislation covering every product and aspect of product is neither a feasible nor a desirable objective. It 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, in terms of

¹² OJ L 11, 15.1.2002, pp. 47.

¹³ OJ L 88, 4.4.2011, p. 5.

¹⁴ http://ec.europa.eu/solvit/what-is-solvit/index_en.htm.

¹⁵ COM(2017) 255 final.

designation, form, size, labelling or packaging, etc. This initiative ensures that when Member States do so, they comply with Articles 34 and 36 TFEU, and in particular with the mutual recognition principle.

- **Consistency with other Union policies**

The following ongoing / planned initiatives at EU level are of importance for mutual recognition:

- (a) The Single Digital Gateway¹⁶. The Gateway aims to improve the online availability, quality and findability of information and assistance services and procedures which are relevant for businesses and citizens.
- (b) Action plan on the reinforcement of SOLVIT¹⁷.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

This Regulation is based on 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. This Regulation aims at setting up rules and procedures for ensuring that free movement of goods lawfully marketed in another Member State is granted in full respect of the mutual recognition principle. It does not prejudice the Member States' regulatory autonomy in the area of non-harmonised goods.

- **Subsidiarity (for non-exclusive competence)**

Mutual recognition only applies in cross border situations where an economic operator would like to trade in a Member State a product already lawfully marketed in another Member State. Action by Member States alone cannot solve problems associated with the application of the principle of mutual recognition across the single market. To be effective, the application of the principle needs to be based on common solutions to be applied equally by all national authorities. Only such common procedures can guarantee that national authorities will apply the principle in the same manner, thus allowing companies to benefit from an equal treatment regardless of the country where they try to market their product. Leaving the procedural aspects of the application of the mutual recognition principle to each Member State would weaken the principle by dismantling the *modus operandi* into 28 different and possibly contradictory procedures. Therefore, EU action is both appropriate and justified to ensure the effective application of the principle. The EU has the responsibility to act to ensure the functioning of the single market for goods. Pursuant to Article 26(2) 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 of measures having equivalent effect to quantitative restrictions on imports of goods is one of the main principles of the TFEU (Articles 34 to 36).

¹⁶ Proposal COM(2017)256 for a Regulation of the European Parliament and of the Council on establishing a single digital gateway to provide information, procedures, assistance and problem solving services and amending Regulation (EU) No 1024/2012.

¹⁷ COM(2017)255.

- **Proportionality**

This proposal strikes a careful balance between, on the one hand, the regulatory autonomy Member States have for setting the level of protection they consider necessary for achieving legitimate public interests, and, on the other hand, the need to address the remaining obstacles to the free movement of goods lawfully marketed in other Member States and subject to Articles 34-36 TFEU.

The measures foreseen in this proposal do not extent beyond what is necessary to solve the identified problems and to achieve the objectives set. The foreseen costs on the Commission and Member States are considered as acceptable, and will be compensated by the savings incurred by businesses, and benefits for businesses, consumer and Member States alike.

- **Choice of the instrument**

This Regulation is based on Article 114 TFEU. It includes provisions aimed at improving the functioning of the Single Market for goods, by establishing rules and procedures for competent authorities of Member States and for businesses to ensure a smooth free movement of goods lawfully marketed in another Member State.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

The evaluation of the functioning of mutual recognition in the field of goods, i.e. the mutual recognition principle and the Mutual Recognition Regulation looked to what extent mutual recognition has achieved its original objectives in term of effectiveness, efficiency, relevance, coherence, and EU value-added. The findings show that that, in the field of goods, mutual recognition is still relevant and 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 mutual recognition principle is not functioning well. The majority of businesses 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, 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. As for the Regulation, which 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. It had a moderate effect with regards to the objectives set, 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 also had limited effects in raising awareness of the mutual recognition principle.

Effectiveness

Despite the existence of the principle and the adoption of the Regulation, free movement of goods in the non-harmonised area remains problematic, mainly due to the lack of awareness and knowledge, the lack of legal certainty and the lack of trust and cooperation among national authorities. Businesses are still facing difficulties with regards to market access, even if their products are already lawfully marketed in other Member States. Thus, they often adapt their products or give up entering on a new market. Stakeholders' consultation shows that the level of awareness about mutual recognition increased over the years, but not sufficiently. All

stakeholders alike consider that awareness should be increased, and that this should be one of the Commission's main priorities. Legal certainty when using mutual recognition remains a major obstacle to free movement of non-harmonised products, and one of the main reasons why businesses and national authorities are reluctant towards mutual recognition. As regards administrative cooperation, the evaluation shows that it needs to be further enhanced in order to facilitate the application of the mutual recognition principle.

Efficiency

Relevant stakeholders were consulted in order to assess to what extent the costs generated by using the principle and the Regulation are proportionate to the benefits it achieved. In terms of costs, the Regulation generated few costs for national authorities: the implementation and functioning of the PCPs (EURO 7417-47 450, based on 1 FTE) and the costs related to the assessment of products lawfully marketed in another Member State (EURO 420 000 in one sector such as fertilisers). They consider these costs as average. The main costs incurred by businesses are rather due to the incorrect application of mutual recognition. They have to adapt their products, duplicate tests and procedures (EURO 1000-150 000 per product and market), or lose opportunities (EURO 40 000-500 000 per product and market) because they are obliged to renounce entering on a new market. Most of these costs were considered as important. In terms of costs-benefits, the perception is quite mixed. While national authorities tend to agree that the costs are proportionate to the benefits, businesses mostly disagree. They consider that the costs are significant, while the benefits were not achieved.

Coherence

The evaluation carried out shows that there does not seem to be any contradiction between mutual recognition and other EU policies for achieving the internal market and facilitating the free movement of goods in the EU. Rather, the mutual recognition principle and the Regulation complements and is coherent with a number of initiatives in this area such as the Product General Safety Directive 2001/95/EC¹⁸ "Single Market Transparency" Directive (EU) 2015/1535, the Construction Products Regulation (EU) No 305/2011, the SOLVIT network¹⁹ and EU harmonisation legislation.

Relevance

Mutual recognition aims at achieving deep market integration while respecting diversity and regulatory autonomy among Member States. It is seen as an alternative to harmonisation, allowing regulatory autonomy, when the latter is not necessary, justified and proportionate. 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.

EU added value

The evaluation shows 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

¹⁸ OJ L 001, 15.01.2002.

¹⁹ http://ec.europa.eu/solvit/what-is-solvit/index_en.htm.

and diversity. It is widely acknowledged that the objectives it sets out can be met only by acting at an 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.

- **Stakeholder consultations**

The members of the Mutual Recognition Consultative Committee were asked to provide their feedback during their last meetings on 2 December 2015 and 25 October 2016. Some representatives were not convinced that there are benefits in fully revising the Regulation, whilst all of them agreed that some adjustments are necessary and that many of the problems can be solved with soft law measures.

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. **153** replies were received during the public consultation. Businesses were strongly represented (91), followed by Member States authorities (45), and citizens (17). The results of the consultation show that, 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. As regards the Commission's priorities with regard to mutual recognition, businesses rank the need for effective remedies as being the highest priority, while Member States and citizens opt in favour of increasing awareness about mutual recognition.

The public consultation has been supplemented by a stakeholder conference organised by the Commission on 17 June 2016. The aim of the event was 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. Overall, participants supported the need to improve the functioning of mutual recognition and increase legal certainty as regards the application of the mutual recognition principle.

- **Collection and use of expertise**

A broad range of surveys, consultations and studies were carried out by the Commission or external contractors between 2014 and 2016, and offer a solid basis of expertise.

The functioning of the mutual recognition principle was subject to an external evaluation, carried out between 2014 and 2015. The magnitude of the problem and the impacts of the various options envisaged by the Commission were subject to a study, performed between 2016 and 2017.

- **Impact assessment**

An impact assessment was carried out in preparation of this initiative. It shows that less trade take place as regards products subject to mutual recognition. The comparison of the value of the intra EU exports with domestic consumption shows that for harmonised products the value of intra EU exports is 55% of domestic consumption, while for the non-harmonised and partially harmonised goods it represents only 35%. This is due to the obstacles encountered by businesses when trying to market their products under the mutual recognition principle. The financial costs caused by lack of mutual recognition are high for the businesses. For example, the need to adapt the products to the applicable national rules when mutual recognition is either denied or not used for penetrating the market are estimated to be between 1000 and 150

000 Euro per product and per market. Lost opportunities, i.e. businesses renounce entering a market due to different national rules requiring adaptation of the products have been estimated on average between 10 000 and 500 000 Euro per product and per market. A study done for the European Parliament²⁰ 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. Furthermore, 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. Around 87% of the enterprises are micro enterprises. According to the Commission's 2014 Competitiveness report, only 14% of SMEs are trading across borders in the EU compared to 85.4 % of large manufacturing firms.

The impact assessment received a positive opinion from the Regulatory Scrutiny Board on 7 April 2017. The Board considered that the report had an overall good presentation and recommended, as further improvement, to better explain the choice of options and how these would work in practice. The report should also draw clearer conclusions on how far the expected outcome of the revision will have an impact on the functioning of the mutual recognition on the ground and contribute to a well-functioning internal market. Finally, it should better assess the potential to simplify administration and reduce burdens. The recommendations contained in the positive opinion were incorporated in the report. In particular, the various options and the way they interact among them were better explained. The report details better how these options work in practice, with an emphasis on the consequences on the market of the preferred option. The report also better explains how the current regulatory burdens are due to the non-functioning of mutual recognition and clearly indicates how the preferred options will reduce those. The summary sheet and the positive opinion of the Regulatory Scrutiny Board are available here: XXXXX.

Besides option 1 (status quo), the envisaged policy options included in the 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 mutual recognition declaration, problem solving mechanism, 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).

Option 2 (Soft law) was supported by all stakeholders, but considered effective only if complemented by other comprehensive tools.

²⁰ 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).

Option 3 (minimum legislative changes to the Regulation) was considered by Member States and economic operators as potentially effective, however to a less extent than other options.

Option 4 was considered as the most effective in achieving the policy objectives and in reducing costs for business.

There was a consensus among stakeholders that option 5 (voluntary prior authorisation) cannot remove the existing obstacles to mutual recognition. It would mainly generate costs. For example, in the sector of biocides, it was assessed that the administrative costs related to this procedure would be between 18 and 20 million Euro per year.

Due to the complexity and variety of products falling under the scope of mutual recognition, it is very difficult to provide a quantitative assessment of the benefits. Option 4 combined with option 2 would increase awareness and knowledge about mutual recognition, while bringing legal certainty on the application of the principle and improving administrative cooperation among Member States. Not only more economic operators would become aware about the possibility to enter new markets without additional changes to their products, but those aware about mutual recognition and reluctant to use it will gain trust in the system. In particular it would facilitate the placing on the market of products lawfully marketed in other Member States, by framing and streamlining the discussions on whether or not the product can enter the market on the basis of mutual recognition and by reducing the risk to see market access denied. This would significantly reduce costs for businesses in terms of information, adaptation, delayed entry on the market and lost opportunities. Member States as well would benefit from this combination of options as they would be incentivised towards a more consistent and correct application of the mutual recognition principle. A reduction of trade barriers in general (see above) could lead to an increase in intra-EU trade of more than 100 billion EUR per year.

Similarly, it is very difficult to provide a quantitative assessment of the costs of the preferred options. Costs for economic operators are considered to be minimal, and this applies also to the voluntary mutual recognition declaration, where costs have been estimated as being minimal administrative work (it would take on average 20 minutes to an economic operator to fill in the declaration). Member States and the Commission would bear certain necessary costs, which can be estimated as follows: the soft law option involves costs related to the organisation and coordination of awareness and training events (500 000 Euro), as well as costs related to the exchange of officials' scheme (100 000 Euro). The problem solving mechanism involves an increased workload for the Commission, in terms of staff dealing with the appeals (3-4 additional FTEs). Increasing administrative cooperation among Member States also involves certain costs, estimated at 1 200 000 million Euro per year.

- **Regulatory fitness and simplification**

The initiative has been linked to the REFIT programme due to the impacts the malfunctioning of mutual recognition have on the functioning of the internal market. The Evaluation looked at how regulatory burdens can be reduced. It was concluded that 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, such as easier access to new markets. The introduction of a voluntary mutual recognition declaration will have a major impact in reducing administrative burdens for economic operators. Streamlining the procedures for accessing the market and communicating with national authorities will facilitate market access and therefore reduce costs for economic operators. Furthermore, better cooperation and communication among authorities will increase trust and therefore reduce delays when assessing the goods on the market.

4. BUDGETARY IMPLICATIONS

The proposal requires human and administrative resources, as well as operational appropriations, as highlighted in the financial statement.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

Every five years, the Commission will evaluate the Regulation and will submit a report to the European Parliament and to the Council. The report will assess the functioning of the Regulation and of the mutual recognition principle based, when applicable, on the criteria of effectiveness, efficiency, relevance, coherence and EU added value as well as their impact on the free movement of goods and on the internal market for goods, based on feedback collected from stakeholders, including relevant information from Member States. Specific indicators allowing assessing the impacts of the Regulation such as the number of notifications by competent authorities via the Information and Communication Support System, the speed of the procedures used or the number of information exchanges between competent authorities and Product Contact Points will be considered.

- **Detailed explanation of the specific provisions of the proposal**

Article 1 sets the subject matter of the Regulation, which is to establish rules and procedures for ensuring the right to free movement of goods lawfully marketed in another Member State.

Article 2 defines the scope of the Regulation.

Article 3 contains the definitions relevant for the Regulation.

Article 4 provides for a mutual recognition declaration, to be used on a voluntary basis by economic operators in order to facilitate the demonstration that a product has been lawfully marketed in another Member State. It sets out the conditions to be met by such declaration, and clarifies that it can be provided online.

Article 5 establishes the procedure to be followed by competent authorities of Member States when assessing if goods lawfully marketed in another Member State can be marketed on their territory on the basis of the mutual recognition principle.

Article 6 contains requirements addressing the temporary suspension of goods lawfully marketed in another Member State, in case such goods pose serious risks on health and safety or run contrary to public morality or public security.

Article 7 avoids duplicating notification to the Commission, when the administrative decision to be notified is also a measure falling under RAPEX.

Article 8 provides for a mutual recognition problem solving mechanism allowing economic operators to challenge an administrative decision denying or restricting market access by referring it first to the SOLVIT network. Such administrative decision shall be subject to an assessment by the Commission at the request of the relevant SOLVIT centre .

Article 9 establishes the tasks of the Product Contact Points.

Article 10 sets the framework for administrative cooperation among competent authorities.

Article 11 provides for an IT tool to be used for the purposes of communication and exchange of information among competent authorities of Member States and between competent authorities of Member States and the Commission.

Article 12 contains financing of activities to be carried out in support of this Regulation.

Article 13 clarifies how the Union's financial interests will be protected.

Article 14 requests the Commission to periodically report to the European Parliament and the Council on the functioning of mutual recognition, including the functioning of this Regulation.

Article 15 establishes a committee and the implementing powers this Regulation confers on the Commission.

Article 16 repeals Regulation (EC) No 764/2008.

Article 17 sets out the entry into force and application of this Regulation.

The Annex provides for a standardised template for the Mutual Recognition Declaration.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee²¹, Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) The internal market comprises an area without internal frontiers in which the free movement of goods is ensured in accordance with the provisions of the Treaties. Quantitative restrictions on imports and all measures having equivalent effect are prohibited between Member States. That prohibition covers any national measure which is capable of hindering, directly or indirectly, actually or potentially, intra-Union trade in goods. Free movement of goods is ensured in the internal market by harmonisation of rules at Union level setting common requirements for the marketing of certain goods or, for goods or aspects of goods not covered by Union harmonisation rules, by the application of the principle of mutual recognition.
- (2) Obstacles to the free movement of goods between Member States may be unlawfully created if, in the absence of Union harmonisation rules covering goods or a certain aspect of goods, a Member State's competent authority applies national rules to goods of that type lawfully marketed in another Member State, requiring the goods to meet certain technical requirements, for example requirements relating to designation, form, size, weight, composition, presentation, labelling or packaging. The application of such rules to goods lawfully marketed in another Member State could be contrary to Articles 34 and 36 of the Treaty even if the rules apply without distinction to all goods.
- (3) The principle of mutual recognition derives from the case-law of the Court of Justice of the European Union. According to this principle, Member States may not prohibit the sale on their territory of goods which are lawfully marketed in another Member State, even where the goods have been produced or manufactured in accordance with different technical rules. But the principle is not absolute. Member States can oppose the marketing of goods lawfully marketed elsewhere, when such restrictions are justified on the grounds set out in Article 36 of the Treaty or on the basis of other

²¹ OJ C , , p. .

overriding reasons of public interest, and which in either case are proportionate to the aim pursued.

- (4) The concept of overriding reasons of public interest is an evolving concept developed by the Court of Justice in its case-law in relation to Articles 34 and 36 of the Treaty. This concept covers, *inter alia*, the effectiveness of fiscal supervision, the fairness of commercial transactions, protection of consumers, protection of the environment, the maintenance of press diversity and the risk of seriously undermining the financial balance of the social security system. Such overriding reasons, where legitimate differences exist from one Member State to another, may justify the application of national rules by the competent authorities. However, such decisions need to be duly justified, and the principle of proportionality must always be respected, regard being had to whether the competent authority has in fact made the least restrictive decision possible. Furthermore, administrative decisions restricting or denying market access in respect of goods lawfully marketed in another Member State must not be based on the mere fact that the goods under assessment fulfil the legitimate public objective pursued by the Member State in a different way from the way that domestic goods in that Member State fulfil that objective.
- (5) Regulation (EC) No 764/2008²² was adopted in order to facilitate the application of the mutual recognition principle, by establishing procedures to minimise the possibility of creating unlawful obstacles to the free movement of goods which have already been lawfully marketed in another Member State. Despite the adoption of that Regulation, many problems still exist as regards the application of the mutual recognition principle. The evaluation carried out between 2014 and 2016 showed that the principle does not function as it should and Regulation (EC) No 764/2008 has had limited effect in facilitating its application. The tools and procedural guarantees put in place by Regulation (EC) No 764/2008 failed in their aim of improving the application of the mutual recognition principle. For example, the Product Contact Points network which was put in place in order to provide information to economic operators on applicable national rules and the application of mutual recognition is barely known or used by economic operators. Within the network, national authorities do not cooperate sufficiently. The requirement to notify administrative decisions denying or restricting market access is complied with rarely. As a result, obstacles to free movement of goods in the internal market remain.
- (6) In December 2013, the conclusions on the Single Market Policy adopted by the Competitiveness Council noted that to improve framework conditions for businesses and consumers in the Single Market, all relevant instruments should be appropriately employed, including mutual recognition. The Council invited the Commission to report on the cases where the functioning of the mutual recognition principle is still inadequate or problematic. In its Conclusions on the Single Market Policy of February 2015 the Competitiveness Council urged the Commission to take steps to ensure that the principle of mutual recognition functioned effectively and to bring forward proposals to that effect.
- (7) Regulation (EC) No 764/2008 has several shortcomings, and should therefore be revised and strengthened. For the sake of clarity, Regulation (EC) No 764/2008 should be replaced by this Regulation. This Regulation should establish clear procedures to ensure the free movement to goods lawfully marketed in another Member State and to ensure that free movement can be restricted only where Member States have legitimate

²² OJ, L 218, 13.8.2008, p.21

public interest grounds for doing so and the restriction is proportionate. It ensures that existing rights and obligations deriving from the mutual recognition principle are observed, by both economic operators and national authorities.

- (8) This Regulation should not prejudice further harmonisation of conditions for the marketing of goods, where appropriate, with a view to improving the functioning of the internal market.
- (9) Trade barriers may also result from other types of measures falling under the scope of Articles 34 and 36 of the Treaty. Those measures may, for example, include technical specifications drawn up for public procurement procedures or requirements to use official languages in the Member States. However, such measures should not constitute national technical rules within the meaning of this Regulation and should not fall within its scope.
- (10) National technical rules are sometimes given effect in a Member State by means of a prior authorisation procedure, under which formal approval must be obtained from a competent authority before the goods can be placed on the market there. The existence of a prior authorisation procedure in itself restricts the free movement of goods. Therefore, in order to be justified with regard to the fundamental principle of free movement of goods within the internal market, such a procedure must pursue a public interest objective recognised by Union law, and it must be proportionate and non-discriminatory. The compliance of such a procedure with Union law is assessed in the light of the considerations set out in the case-law of the Court of Justice. As a result, administrative decisions denying or restricting market access exclusively on the grounds that the goods do not have a valid prior authorisation should be excluded from the scope of this Regulation. When, however, an application for mandatory prior authorisation of goods is made, any intended administrative decision to reject the application on the basis of a technical rule applicable in that Member State should be taken in accordance with this Regulation, so that the applicant can benefit from the procedural protection which this Regulation provides.
- (11) It is important to clarify that the types of goods covered by this Regulation include agricultural products. The term 'agricultural products' includes products of fisheries, as provided for in Article 38(1) of the Treaty.
- (12) It is important to clarify that the term 'producer' includes not only the manufacturer of goods, but also the person who presents himself as the producer of goods, such as agricultural products, which were not obtained by a manufacturing process.
- (13) Decisions of national courts or tribunals assessing the legality of cases in which, on account of the application of a national technical rule, goods lawfully marketed in one Member State are not granted access to the market of another Member State, and decisions of national courts or tribunals applying penalties, should be excluded from the scope of this Regulation.
- (14) To benefit from the principle of mutual recognition, goods must be lawfully marketed in another Member State. It should be clarified that, for goods to be considered as lawfully marketed in another Member State, the goods need to comply with the relevant rules applicable in that Member State, and to be being made available to end users in that Member State.
- (15) The evidence required to demonstrate that goods are lawfully marketed in another Member State varies significantly from Member State to Member State. This causes unnecessary burdens delays and additional costs for economic operators, while

preventing national authorities from obtaining the information necessary for assessing the goods in a timely manner. This may inhibit application of the mutual recognition principle. It is therefore essential to make it easier for economic operators to demonstrate that their goods are lawfully marketed in another Member State. Economic operators should be able to benefit from a process of self-declaration, which should provide competent authorities with all necessary information on the goods and on their compliance with the rules applicable in that other Member State. The use of the declaration does not prevent national authorities from taking a decision restricting market access, on the condition that such a decision is proportionate and respects the mutual recognition principle and this Regulation.

- (16) The producer, or the producer's representative, should be responsible for filling in the information in the mutual recognition declaration as the producer knows the goods best. However, the information that the goods are being made available to end users in the relevant Member State may be in the possession of an importer or a distributor, rather than the actual producer. It should therefore be permissible for another economic operator to fill in this information in place of the producer.
- (17) The mutual recognition declaration should continue to give accurate and complete information on the goods at any point in the future. The declaration should therefore be kept up to date, as necessary, to reflect changes, for example changes in the relevant technical rules.
- (18) In order to ensure that the information provided in a mutual recognition declaration is comprehensive, a harmonised structure for such declarations should be laid down for use by economic operators wishing to make such declarations.
- (19) It is important to ensure that the mutual recognition declaration is filled in truthfully and accurately. It is therefore necessary to provide for economic operators to be responsible for the information contained in the declaration.
- (20) In order to enhance the efficiency and competitiveness of businesses operating in the non-harmonised area, it should be possible to benefit from new information technologies for the purposes of facilitating the provision of the mutual recognition declaration. Therefore, economic operators should be able to make their declaration available online.
- (21) This Regulation should also apply to goods in respect of which only some aspects are covered by Union harmonisation legislation. Where, pursuant to Union harmonisation legislation, economic operators are required to draw up an EU declaration of conformity to demonstrate compliance with that legislation, it should be permissible for the information provided in the mutual recognition declaration under this Regulation to be included as part of that EU declaration of conformity.
- (22) Where producers decide not to make use of the mutual recognition declaration mechanism, it should be for the Member State to request the information that it considers necessary for the assessment of the goods, taking due account of the principle of proportionality.
- (23) Directive (EU) 2015/1535 of the European Parliament and of the Council requires Member States to communicate to the Commission and to the other Member States any draft national technical regulation concerning any product, including agricultural and fish products, and a statement of the grounds which make the enactment of that regulation necessary. It is necessary, however, to ensure that, following the adoption of such a national technical regulation, the principle of mutual recognition is correctly

applied in individual cases to specific goods. This Regulation should lay down procedures for the application of the mutual recognition principle in individual cases by, for example, requiring Member States to indicate the national technical rules on which the administrative decision is based and the legitimate public interest ground on which the administrative decision is justified. This requirement does not, however, oblige Member States to justify the national technical rule itself, but rather the application of that national technical rule with respect to a product lawfully marketed in another Member State.

- (24) As decisions denying or restricting market access for goods already lawfully marketed in another Member State should be an exception to the fundamental principle of free movement of goods, it is appropriate to establish a clear procedure designed to ensure that such decisions observe the existing obligations deriving from the mutual recognition principle. Such procedure ensures that decisions taken are proportionate and respect the mutual recognition principle and this Regulation.
- (25) While a competent authority is assessing goods before deciding whether or not it should deny or restrict market access, it should not be able to take decisions suspending market access, except where rapid intervention is required to prevent harm to safety and health of users or to prevent the goods being made available where the making available of such goods is generally prohibited on grounds of public morality or public security, including for example the prevention of crime.
- (26) Regulation (EC) No 765/2008 of the European Parliament and of the Council²³ establishes a system of accreditation which ensures the mutual acceptance of the level of competence of conformity assessment bodies. The competent authorities of Member States should therefore not refuse test reports and certificates issued by an accredited conformity assessment body on grounds related to the competence of that body. Furthermore, in order to avoid as far as possible the duplication of tests and procedures which have been already carried out in another Member State, Member States should also accept test reports and certificates issued by other conformity assessment bodies in accordance with Union law. Competent authorities should be required to take due account of the content of the test reports or certificates presented.
- (27) Directive 2001/95/EC of the European Parliament and of the Council²⁴ specifies that only safe products may be placed on the market and lays down the obligations of producers and distributors with respect to the safety of products. It entitles the authorities to ban any dangerous product with immediate effect or, for the period needed for the various safety evaluations, checks and controls, to ban temporarily a product that could be dangerous. It also describes the procedure for authorities to apply appropriate measures such as those referred to in Article 8(1)(b) to (f) thereof, in case of products posing a risk, and it also establishes the obligation to notify those measures to the Commission and other Member States. Therefore, competent authorities should be able to continue applying that Directive and in particular the provisions contained in Articles 8(1)(d) to (f) and Article 8(3) of that Directive.
- (28) Regulation (EC) No 178/2002 of the European Parliament and of the Council²⁵ establishes, *inter alia*, a rapid alert system for the notification of a direct or indirect risk to human health deriving from food or feed. It obliges Member States to notify the

²³ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

²⁴ OJ L 11, 15.1.2002, p. 4.

²⁵ OJ L 31, 1.2.2002, p. 1.

Commission immediately, under the rapid alert system of any measure they adopt which is aimed at restricting the placing on the market of, withdrawing or recalling food or feed in order to protect human health, and which requires rapid action. Competent authorities should be able to continue applying that Regulation and in particular the provisions contained in Articles 50 (3) and 54 of that Regulation.

- (29) Regulation (EU) 2017/625 of European Parliament and of the Council²⁶ establishes a harmonised Union framework for the organisation of official controls, and official activities other than official controls, along the entire agri-food chain, taking into account the rules on official controls laid down in Regulation (EC) No 882/2004 and in relevant sectoral legislation. It lays down a specific procedure to ensure that economic operators remedy a situation of non-compliance with feed and food law, animal health and animal welfare rules. Competent authorities should be able to continue applying that Regulation and in particular the provisions contained in Article 138 of that Regulation.
- (30) Any administrative decision taken by competent authorities of Member States pursuant to this Regulation should specify the remedies available so that an economic operator can bring proceedings before the competent national court or tribunal. The decision should also refer to the problem-solving procedure provided for in this Regulation.
- (31) Effective solutions for economic operators wishing for a business friendly alternative when challenging administrative decisions denying or restricting market access are essential to ensure a correct and consistent application of the mutual recognition principle. In order to guarantee such solutions, and to avoid legal costs, especially for SMEs, a non-judicial problem -solving procedure should be available for economic operators.
- (32) The Internal Market Problem Solving Network (SOLVIT) is a service provided by the national administration in each Member State aiming to find solutions for citizens and businesses when their rights are breached by public authorities in another Member State. The principles governing the functioning of SOLVIT are set out in the Commission Recommendation 2013/461/EU²⁷.
- (33) The SOLVIT system has proved to be an effective non-judicial, problem-solving mechanism that is provided free of charge. It works under short deadlines and provides practical solutions to citizens and businesses when they are experiencing difficulties with their Union rights being recognised by public authorities. Therefore, economic operators should have to rely on SOLVIT first before the problem-solving mechanism under this Regulation can be triggered. Where the economic operator, the relevant SOLVIT centre and the involved Member States in question all agree on the appropriate outcome, no further action should be required.

²⁶ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

²⁷ Commission Recommendation 2013/461/EU of 17 September 2013 on the principles governing SOLVIT (OJ L 249, 19.9.2013, p. 10).

- (34) However, where the SOLVIT's informal approach fails, and serious doubts remain regarding the compatibility of the administrative decision with the mutual recognition principle the Commission should be empowered to look into the matter and provide an assessment to be taken into account by the competent national authorities at the request of the SOLVIT centre. The Commission's intervention should be subject to a reasonable time-limit, in compliance with the European Code of Good Administrative Behaviour.
- (35) The opinion of the Commission as regards an administrative decision denying or restricting market access should only cover the questions of whether the administrative decision is compatible with the mutual recognition principle and whether it complies with the requirements of this Regulation. This is without prejudice to the Commission's powers under article 258 of the Treaty and the Member States' obligation to comply with the provisions of Union law, where systemic problems identified as regards the application of the mutual recognition principle can be further addressed.
- (36) It is important for the internal market in goods that businesses, and in particular SMEs, can obtain reliable and specific information about the law in force in a given Member State. Product Contact Points should play an important role in facilitating communication between national authorities and economic operators, by disseminating information about specific product rules and how mutual recognition is applied in their territory. Therefore, it is necessary to enhance the role of Product Contact Points as the principal providers of information on all product-related rules, including national rules covered by mutual recognition.
- (37) In order to facilitate the free movement of goods, Product Contact Points should be required to provide information, free of charge, on their national technical rules and the application of the principle of mutual recognition. Product Contact Points should be adequately equipped and resourced. In accordance with Regulation [*Single Digital Gateway – COM(2017)256*] they should provide information through a website and be subject to the quality criteria required by that Regulation, and be subject to the quality criteria set out in that Regulation.
- (38) Cooperation between competent authorities is essential for the smooth functioning of the mutual recognition principle and for creating a mutual recognition culture. Product Contact Points and national competent authorities should therefore be required to cooperate and exchange information and expertise in order to ensure a correct and consistent application of the principle and of this Regulation.
- (39) For the purposes of notifying administrative decisions denying or restricting market access, of allowing communication between Product Contact Points and of ensuring administrative cooperation, it is necessary to provide Member States with access to an information and communication support system.
- (40) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council²⁸.

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Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers.

- (41) Where for the purposes of this Regulation it is necessary to process personal data, this should be carried out in accordance with Union law on the protection of personal data. Any processing of personal data under this Regulation is subject to Regulation (EU) 2016/679 of the European Parliament and of the Council²⁹ and Regulation (EC) No 45/2001 of the European Parliament and of the Council³⁰, as the case may be.
- (42) Reliable and efficient monitoring mechanisms should be established to provide information on the application of the Regulation and on its impact on the free movement of goods. Such mechanisms should not go beyond what is necessary to achieve these objectives.
- (43) For the purposes of raising awareness about the mutual recognition principle and ensuring that this Regulation is applied correctly and consistently, the Union should finance awareness-raising campaigns and other related activities aiming at enhancing trust and cooperation between competent authorities and economic operators.
- (44) In order to remedy the lack of accurate data related to the functioning of the mutual recognition principle and its impacts on the single market for goods, Union should finance collection of such data.
- (45) The financial interests of the Union should be protected through proportionate measures throughout the expenditure cycle, including the prevention, detection and investigation of irregularities, the recovery of funds lost, wrongly paid or incorrectly used and, where appropriate, administrative and financial penalties.
- (46) The Commission should carry out an evaluation of this Regulation. The evaluation should be based on the five criteria of effectiveness, efficiency, relevance, coherence and added value and should provide the basis for impact assessments of possible further measures.
- (47) It is appropriate to defer the application of this Regulation in order to allow competent authorities and economic operators sufficient time to adapt to the requirements laid down in it.
- (48) The Commission should carry out an evaluation of this Regulation against the objectives it pursues. Commission should use the data collected on the functioning of the mutual recognition principle and its impacts on the single market for goods as well as information available in the information and communication support system to evaluate this Regulation. Commission should be able to ask Member States request for additional information necessary for the evaluation. Pursuant to point 22 of the Interinstitutional Agreement of 13 April 2016 on Better Law Making³¹, the evaluation, based on efficiency, effectiveness, relevance, coherence and value added, should provide the basis for impact assessments of options for further action.
- (49) Since the objectives of this Regulation, namely to ensure a smooth, consistent and correct application of the mutual recognition principle, cannot be sufficiently achieved by the Member States and can, therefore, by reason of their scale and effect, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union. In

²⁹ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

³⁰ Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

³¹ OJ L 123, 12.5.2016, p. 1.

accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

HAVE ADOPTED THIS REGULATION:

Chapter I

General provisions

Article 1

Subject matter

This Regulation lays down rules and procedures concerning the application by Member States of the principle of mutual recognition, in individual cases, in relation to goods lawfully marketed in another Member State and subject to Articles 34 and 36 of the Treaty.

This Regulation also provides for the establishment and maintenance of Product Contact Points in Member States and for cooperation and exchange of information in the context of the principle of mutual recognition.

Article 2

Scope

1. This Regulation applies to goods of any type, including agricultural products, and to administrative decisions taken or to be taken by a competent authority of a Member State ('the Member State of destination') in relation to any such goods lawfully marketed in another Member State, where the decision meets the following criteria:
 - (a) the basis for the decision is a national technical rule applicable in the Member State of destination;
 - (b) the direct or indirect effect of the decision is to deny or restrict market access in the Member State of destination.
2. The reference in paragraph 1 to 'administrative decisions' includes any administrative step that has the same or substantially the same legal effect as a decision.
3. For the purposes of this Regulation, a 'national technical rule' is any provision of a law, regulation or other administrative provision of a Member State, which has the following elements:
 - (a) the provision covers an area or aspect that is not the subject of harmonisation at Union level;
 - (b) the provision either prohibits the making available of goods, or a type of goods, on the domestic market in that Member State or else it makes compliance with the provision compulsory, de facto or de jure, whenever goods, or goods of a given type, are being made available on that market;
 - (c) the provision does at least one of the following:
 - (i) it lays down the characteristics required of those goods, or goods of that type, such as their levels of quality, performance or safety, or dimensions, including the requirements applicable to the goods or type of goods as regards the name under which they are sold, terminology, symbols, testing and test methods, packaging, marking or labelling, and conformity assessment procedures;

- (ii) it imposes on those goods, or goods of that type, other requirements that are imposed for the purposes of protecting consumers or the environment and that affect the life-cycle of the goods after they have been made available on the domestic market in that Member State, such as conditions of use, recycling, reuse or disposal, where such conditions can significantly influence either the composition or nature of the goods, or type of goods, or the making available of them on the domestic market in that Member State.
- 4. Paragraph 3(c)(i) also covers production methods and processes used in respect of agricultural products, as referred to in the second subparagraph of Article 38(1) of the Treaty or products intended for human and animal consumption, as well as production methods and processes relating to other products, where these have an effect on their characteristics.
- 5. A requirement for prior authorisation does not itself constitute a national technical rule for the purposes of this Regulation, but a decision to refuse prior authorisation based on a national technical rule may be a decision to which this Regulation applies if it fulfils the other requirements of paragraph 1.
- 6. This Regulation does not apply to:
 - (a) decisions of a judicial nature taken by national courts or tribunals;
 - (b) decisions of a judicial nature taken by law enforcement authorities in the course of the investigation or prosecution of a criminal offence as regards the terminology, symbols or any material reference to unconstitutional or criminal organisations or offences of a racist, discriminatory or xenophobic nature.
- 7. Articles 5 and 6 shall not affect the application of the following provisions:
 - (a) Article 8(1)(d) to (f) or Article 8(3) of Directive 2001/95/EC;
 - (b) Article 50(3)(a) and Article 54 of Regulation (EC) No 178/2002;
 - (c) Article 138 of Regulation (EU) 2017/625.

Article 3 **Definitions**

For the purposes of this Regulation, the following definitions shall apply:

- (1) 'lawfully marketed in another Member State' means that the goods or type of goods comply with the relevant rules applicable in that Member State and are made available to end users in that Member State;
- (2) 'making available on the domestic market in a Member State' means any supply of the goods for distribution, consumption or use on the market within the territory of that Member State in the course of a commercial activity, whether in return for payment or free of charge;
- (3) 'restricting market access' means imposing conditions to be fulfilled before the goods can be made available on the domestic market in the relevant Member State, or conditions for keeping the goods on that market, which in either case require the modification of one or more of the characteristics of those goods, as described in Article 2(3)(c)(i), or the performance of additional testing;
- (4) 'denying market access' means any of the following:

- (a) prohibiting the goods from being made available on the domestic market in the relevant Member State or from being kept on that market;
 - (b) requiring the withdrawal or recall of the goods from that market;
- (5) 'prior authorisation' means an administrative procedure under the law of a Member State whereby the competent authority of that Member State is required, on the basis of an application by an economic operator, to give its formal approval before goods may be made available on the domestic market in that Member State;
 - (6) 'producer' means any natural or legal person who manufactures the goods or has the goods designed or manufactured, and markets them under his name or trademark, or any other natural or legal person who, by putting his name, trademark or other distinguishing feature on the goods presents himself as its producer;
 - (7) 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from the producer to act on the producer's behalf with regard to the making available of the goods on the domestic market in question;
 - (8) 'importer' means any natural or legal person established in the Union who makes the goods from a third country available on the Union market for the first time;
 - (9) 'distributor' means any natural or legal person in the supply chain established in the Union, other than the producer or the importer, who makes the goods available on the domestic market in the relevant Member State;
 - (10) 'economic operator' means any of the following in relation to the goods: the producer, the authorised representative, the importer or the distributor;
 - (11) 'end user' means any natural or legal person, residing or established in the Union, to whom the goods have been or are being made available either as a consumer, outside any trade, business, craft or profession, or as a professional end user in the course of his industrial or professional activities;
 - (12) 'legitimate public interest ground' means any of the grounds set out in Article 36 of the Treaty or any other overriding reasons of public interest.

Chapter II

Procedures concerning application of the mutual recognition principle in individual cases

Article 4

Mutual recognition declaration

1. The producer of goods, or goods of a given type, that are being or are to be made available on the domestic market in a Member State ('the Member State of destination') may draw up a declaration (a 'mutual recognition declaration') in order to demonstrate to the competent authorities of the Member State of destination that the goods, or goods of that type, are lawfully marketed in another Member State.

Alternatively, the producer may mandate his authorised representative to draw up the declaration on his behalf.

Within the mutual recognition declaration, the specific information related to the marketing of the goods or type of goods may, however, be filled in by any economic operator.

2. The mutual recognition declaration shall follow the structure and contain the information specified in the Annex.

The declaration shall be completed in one of the official languages of the Union and, where that language is not the language required by the Member State of destination, it shall be translated by the economic operators into the language or languages required by the Member State of destination.
3. Economic operators shall be responsible for the content and accuracy of the information that they themselves provide in the mutual recognition declaration.
4. Economic operators shall ensure that the declaration is kept up to date at all times to reflect any changes in the information provided by them in the declaration.
5. The mutual recognition declaration may be supplied to the competent authority of the Member State of destination for the purposes of an assessment to be carried out under Article 5. It may be supplied either in paper form or by electronic means.
6. Economic operators may make the declaration available on a website, provided that the following conditions are satisfied:
 - (a) the goods type or series to which the declaration applies are easily identifiable on the website;
 - (b) the website is monitored to ensure the availability of and access to the declaration;
 - (c) there are instructions provided on how to navigate the website and access the declaration.
7. If a mutual recognition declaration is supplied to a competent authority of the Member State of destination in accordance with the requirements of this Article, then for the purposes of any assessment of the goods under Article 5:
 - (a) the declaration, together with any evidence reasonably required by the competent authority to verify the information contained in it, shall be accepted by the competent authority as sufficient to demonstrate that the goods are lawfully marketed in another Member State; and
 - (b) the competent authority shall not require any other information or documentation from any economic operator for the purpose of demonstrating that the goods are lawfully marketed in another Member State.
8. If a mutual recognition declaration is not supplied to a competent authority of the Member State of destination in accordance with the requirements of this Article, the competent authority may request any of the economic operators to provide the following documentation and information in order to demonstrate for the purposes of an assessment under Article 5 that the goods are lawfully marketed in another Member State:
 - (a) any relevant information concerning the characteristics of the goods or type of goods in question;
 - (b) any relevant information on the lawful marketing of the goods in another Member State;
 - (c) any other information the competent authority considers useful for the purposes of its assessment.

9. Where the goods for which the mutual recognition declaration is being supplied are also subject to a Union act requiring an EU declaration of conformity, the mutual recognition declaration may be included as part of that EU declaration of conformity.

Article 5
Assessment of goods

1. Where a competent authority of a Member State has doubts as regards goods which the economic operator claims are lawfully marketed in another Member State, the competent authority shall contact the relevant economic operator without delay and shall carry out an assessment the goods.
2. In carrying out assessments under paragraph 1, the competent authorities of Member States shall take due account of the content of test reports or certificates issued by a conformity assessment body and provided by any economic operator as part of the assessment. Competent authorities of Member States shall not refuse certificates or test reports issued by a conformity assessment body accredited for the appropriate field of conformity assessment activity in accordance with Regulation (EC) No 765/2008 on grounds related to the competence of that body.
3. Where, on completion of an assessment under paragraph 1, the competent authority of a Member State takes an administrative decision with respect to the goods, it shall communicate its decision within 20 working days to the relevant economic operator referred to in paragraph 1, to the Commission and to the other Member States. Notification to the Commission and to the other Member States shall be done by means of the system referred to in Article 11.
4. The administrative decision referred to in paragraph 3 shall set out the reasons for the decision in a manner that is sufficiently detailed and reasoned to enable an assessment to be made of its compatibility with the mutual recognition principle and with the requirements of this Regulation.
5. In particular, the following information shall be included:
 - (a) the national technical rule on which the decision is based;
 - (b) the legitimate public interest ground on which the decision is justified;
 - (c) the technical or scientific evidence considered, including any technical or scientific developments that have occurred since the national technical rule was adopted;
 - (d) a summary of the arguments put forward by the relevant economic operator;
 - (e) the evidence demonstrating that the decision is appropriate for the purpose of achieving the objective pursued and that it does not go beyond what is necessary in order to attain that objective.
6. The administrative decision referred to in paragraph 3 shall specify the remedies available under the law in force in the Member State concerned and the time limits applicable to those remedies, and it shall also include a reference to the procedure under Article 8.
7. The administrative decision referred to in paragraph 3 shall not take effect before it has been notified to the relevant economic operator under that paragraph.

Article 6

Temporary suspension of market access

1. While the competent authority of a Member State is carrying out an assessment of goods pursuant to Article 5, it shall not temporarily suspend the making available of those goods on the domestic market in that Member State, except in one or the other of the following situations:
 - (a) under normal or reasonably foreseeable conditions of use, the goods pose a serious risk, including one where the effects are not immediate, which requires rapid intervention by the competent authority;
 - (b) the making available of the goods, or goods of that type, on the domestic market in that Member State is generally prohibited in that Member State on grounds of public morality or public security.
2. The competent authority of the Member State shall immediately notify the relevant economic operator, the Commission and the other Member States of any suspension pursuant to paragraph 1. The notification to the Commission and other Member States shall be made by means of the system referred to in Article 11. In cases falling within point (a) of paragraph 1 of this Article, the notification shall be accompanied by a technical or scientific justification demonstrating why the case is considered to fall within that point.

Article 7

Notification under the Rapid Information Exchange System (RAPEX)

1. If the administrative decision referred to in Article 5 or the temporary suspension referred to in Article 6 is also a measure which is required to be notified through RAPEX as referred to in the General Product Safety Directive 2001/95/EC, a separate notification to the Commission under this Regulation is not required, provided that the following conditions are met:
 - (a) the RAPEX notification indicates that notification of the measure also counts as notification under this Regulation;
 - (b) the supporting evidence required for the administrative decision under Article 5 or for the temporary suspension under Article 6 is enclosed with the RAPEX notification.

Article 8

Problem-solving procedure

1. This Article applies if an economic operator affected by an administrative decision has submitted the decision to the Internal Market Problem Solving Network (SOLVIT) and, during the SOLVIT procedure, the Home Centre asks the Commission to give an opinion to assist in solving the case.
2. The Commission shall, within three months of receipt of the request referred to in paragraph 1, enter into communication with the relevant economic operator or operators and the competent authorities who took the administrative decision in order to assess the compatibility of the administrative decision with the principle of mutual recognition and this Regulation.

3. Following completion of its assessment, the Commission may issue an opinion identifying concerns that should, in its view, be addressed in the SOLVIT case and, where appropriate, making recommendations to assist in solving the case.
4. The Commission's opinion shall be considered during the SOLVIT procedure referred to in paragraph 1.

Chapter III

Administrative cooperation, monitoring and communication

Article 9

Tasks of the Product Contact Points

1. Member States shall designate and maintain Product Contact Points on their territory and ensure that their Product Contact Points have sufficient powers and are adequately resourced for the proper performance of their tasks. They shall ensure that Product Contact Points deliver their services in accordance with Regulation (*Single Digital Gateway – COM(2017)256*).
2. Product Contact Points shall provide the following information online:
 - (a) information on the principle of mutual recognition and the application of this Regulation in the territory of that Member State, including information on the procedure set out in Article 5;
 - (b) the contact details of the competent authorities within that Member State by means of which they may be contacted directly, including the particulars of the authorities responsible for supervising the implementation of the national technical rules applicable in the territory of that Member State;
 - (c) the remedies and procedures available in the territory of that Member State in the event of a dispute between the competent authority and an economic operator, including the procedure described in Article 8.
3. Where necessary to complement the information provided online under paragraph 2, Product Contact Points shall provide, at the request of an economic operator or a competent authority of another Member State, any useful information, such as an electronic copy of or an electronic link to the national technical rules applicable to specific goods or a specific type of goods in the territory in which the Product Contact Point is established and information as to whether that the goods or goods of that type are subject to a requirement for prior authorisation under national law.
4. Product Contact Points shall respond within 15 working days of receiving any request under paragraph 3.
5. Product Contact Points shall not charge any fee for the provision of the information under paragraph 3.

Article 10

Administrative cooperation

1. The Commission shall provide for and ensure efficient cooperation and exchange of information between the competent authorities and the Product Contact Points of the various Member States.

2. Product Contact Points in the Member State in which an economic operator claims to be lawfully marketing his goods shall provide the competent authorities of other Member States, upon request and within 15 working days, with any relevant information relating to those goods.
3. Member States shall ensure that their competent authorities and Product Contact Points participate in the activities referred to in paragraph 1.

Article 11

Information and communication support system

1. For the purposes of Articles 5, 6, and 10, the Union information and communication support system set out in [Regulation on compliance and enforcement] shall be used, except as provided in Article 7.
2. The Commission shall adopt implementing acts specifying the details of the system referred to in paragraph 1 and its functionalities for the purposes of this Regulation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 15(2).

Chapter IV Financing

Article 12

Financing of activities in support of this Regulation

1. The Union may finance the following activities in support of this Regulation:
 - (a) awareness-raising campaigns;
 - (b) education and training;
 - (c) exchange of officials;
 - (d) the functioning of cooperation amongst Product Contact Points and the technical and logistic support for this cooperation;
 - (e) collection of data related to the functioning of the mutual recognition principle and its impacts on the single market for goods.
2. The Union's financial assistance with respect to activities under this Regulation shall be implemented in accordance with Regulation (EU, Euratom) No 966/2012 of the European Parliament and the Council³², either directly or by delegating budget implementation tasks to the entities listed in Article 58(1)(c) of that Regulation.
3. The appropriations allocated to activities referred to in this Regulation shall be determined each year by the budgetary authority within the limits of the financial framework in force.

³² Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

Article 13

Protection of the financial interests of the Union

1. The Commission shall take appropriate measures to ensure that, when activities financed under this Regulation are implemented, the financial interests of the Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by the recovery of the amounts wrongly paid and, where appropriate, by effective, proportionate and dissuasive administrative and financial penalties.
2. The Commission or its representatives and the Court of Auditors shall have the power of audit, on the basis of documents and of on-the-spot inspections, over all grant beneficiaries, contractors and subcontractors who have received Union funds under this Regulation.
3. The European Anti-fraud Office (OLAF) may carry out investigations, including on-the-spot checks and inspections in accordance with the procedures laid down in Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council³³ and Council Regulation (Euratom, EC) No 2185/96³⁴ with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union in connection with a grant agreement or grant decision or a contract funded under this Regulation.
4. Without prejudice to paragraphs 1, 2 and 3, cooperation agreements with third countries and with international organisations, contracts, grant agreements and grant decisions, resulting from the implementation of this Regulation shall contain provisions expressly empowering the Commission, the Court of Auditors and OLAF to conduct such audits and investigations, in accordance with their respective competences.

Chapter V

Review and Committee procedure

Article 14

Evaluation

1. By (...), and every five years thereafter, the Commission shall carry out an evaluation of this Regulation against the objectives it pursues and shall submit a report thereon to the European Parliament, to the Council and to the European Economic and Social Committee.
2. For the purposes of paragraph 1, the Commission shall use the information available in the system referred to in Article 11 and the data collected as referred to in Article 12(1) (e). The Commission may also ask Member States to submit any relevant information for evaluating the free movement of goods lawfully marketed in another Member State and of the effectiveness of this Regulation, as well as an assessment of the functioning of the Product Contact Points.

³³ Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.9.2013, p. 1).

³⁴ Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities, OJ L292, 14.11.1996, p.2.

Article 15

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Chapter VI
Final provisions

Article 16

Repeal

Regulation (EC) No 764/2008 is repealed.

Article 17

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2020.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

- 1.1. Title of the proposal/initiative
- 1.2. Policy area(s) concerned in the ABM/ABB structure
- 1.3. Nature of the proposal/initiative
- 1.4. Objective(s)
- 1.5. Grounds for the proposal/initiative
- 1.6. Duration and financial impact
- 1.7. Management mode(s) planned

2. MANAGEMENT MEASURES

- 2.1. Monitoring and reporting rules
- 2.2. Management and control system
- 2.3. Measures to prevent fraud and irregularities

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

- 3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected
- 3.2. Estimated impact on expenditure
 - 3.2.1. *Summary of estimated impact on expenditure*
 - 3.2.2. *Estimated impact on operational appropriations*
 - 3.2.3. *Estimated impact on appropriations of an administrative nature*
 - 3.2.4. *Compatibility with the current multiannual financial framework*
 - 3.2.5. *Third-party contributions*
- 3.3. Estimated impact on revenue

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Regulation of the European Parliament and of the Council on mutual recognition of goods

1.2. Policy area(s) concerned in the ABM/ABB structure³⁵

Title 02: Internal market, industry, entrepreneurship and SMEs

Activity 02 03: Internal market for goods and services

Activity 02 03 01: Operation and development of the internal market of goods and services

1.3. Nature of the proposal/initiative

☒ The proposal/initiative relates to a new action

☐ The proposal/initiative relates to a new action following a pilot project/preparatory action³⁶

☐ The proposal/initiative relates to the extension of an existing action

☐ The proposal/initiative relates to an action redirected towards a new action

1.4. Objective(s)

1.4.1. The Commission's multiannual strategic objective(s) targeted by the proposal/initiative

In December 2013, the Conclusions on Single Market Policy, adopted by the Competitiveness Council, noted that to improve framework conditions for businesses and consumers in the Single Market, all relevant instruments should be appropriately employed, including harmonisation and mutual recognition. In its Conclusions on Single Market Policy of February 2015, the Competitiveness Council urged the Commission to ensure that the principle of mutual recognition would function effectively and to bring forward proposals to that effect, as appropriate. In response, the Commission adopted on 28 October 2015 the Single Market Strategy, Upgrading the Single Market: more opportunities for people and business; the strategy constitutes one of the main objectives of the 2017 Commission Work Programme. It calls for more and better mutual recognition, to be achieved by an EU wide action plan on awareness raising and by revisiting the current legal framework to introduce a voluntary declaration of compliance to facilitate free movement of goods in this area.

1.4.2. Specific objective(s) and ABM/ABB activity(ies) concerned

Specific objective No

More specifically, the proposal intends to enhance the free movement of goods already lawfully marketed in another Member State, by:

³⁵ ABM: activity-based management; ABB: activity-based budgeting.

³⁶ As referred to in Article 54(2)(a) or (b) of the Financial Regulation.

- introducing a voluntary declaration of compliance to frame and streamline the discussion between economic operators and national authorities on the lawfulness of the marketing of the product;
- establishing a safeguard procedure to allow economic operators wishing to challenge administrative decisions denying or restricting market access efficient means for doing so;
- strengthening the Product Contact Points by enhancing their role as the prime providers of information on national rules covered by mutual recognition. It will also enhance administrative cooperation between Contact points for an effective information exchange across borders;
- using an IT tool for the purposes of communication among authorities and notification of administrative decisions denying market access;
- providing the basis for an EU-wide action plan to raise awareness on mutual recognition.

ABM/ABB activity(ies) concerned

Activity 02 03: Internal market for goods and services

Activity 02 03 01 : Operation and development of the internal market of goods and services

1.4.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

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

- Increasing awareness about mutual recognition.
- Increasing legal certainty for businesses and national authorities about when the mutual recognition principle can be used.
- Increasing legal certainty about the application of mutual recognition; both business and national authorities should know what they can reasonably expect when mutual recognition is, or ought to be, applied. This will reduce the risk for businesses that their products will not get access to, or will have to be unjustifiably withdrawn from the market.
- Enhancing communication, cooperation and trust among national authorities, so that they can act as a facilitating tool to ensure the functioning of mutual recognition.

1.4.4. Indicators of results and impact

Specify the indicators for monitoring implementation of the proposal/initiative.

The following set of indicators is envisaged:

- Number of events organised (awareness campaigns and trainings), and number of persons participating in the events or receiving the training, as well as their level of satisfaction
- Number of officials participating in the exchange of officials' scheme

- Number of notifications of draft national rules containing a mutual recognition clause
- Level of satisfaction of economic operators using the voluntary Mutual Recognition Declaration, and their input in terms of costs reduction
- Number of notifications of administrative decisions denying or restricting market access
- Number of cases introduced by business in SOLVIT and resolution rate
- Number of appeals to the Commission and number of binding decisions adopted by the Commission
- Number of complaints received on the misapplication of the mutual recognition principle
- Number of requests received by PCPs, deadlines for responding and level of satisfaction of economic operators
- Number of administrative cooperation meetings organised and number of participants

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term

The proposal intends to reduce administrative burdens by allowing:

- to improve knowledge about when and how the mutual recognition principle can be used;
- easier access to information on mutual recognition;
- to facilitate the demonstration that a product has been lawfully marketed in another Member State and thus subject to the application of the mutual recognition principle;
- access to free and efficient means to challenge administrative decisions denying or restricting market access.

1.5.2. Added value of EU involvement

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.

1.5.3. Lessons learned from similar experiences in the past

The application of the mutual recognition principle, which derives from the jurisprudence of the Court of Justice, was subject to several interpretative

communications and to Regulation (EC) No 764/2008. The Regulation put in place several procedural guarantees intended to facilitate the application of the mutual recognition principle. Despite this, the application of the principle is still problematic; most economic operators are either not aware about the principle or either don't rely on it. National authorities are also cautious in granting market access for products already lawfully marketed in another Member State and subject to mutual recognition. Also, the lack of reliable data made the evaluation of the impacts the principle has on the internal market very difficult.

1.5.4. *Compatibility and possible synergy with other appropriate instruments*

The proposal complements and is coherent with a number of initiatives in the area of free movement of goods, such as 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, Directive 2001/95/EC on General Product Safety, Regulation (EU) No 305/2011 on construction products, The SOLVIT network and EU harmonisation legislation.

1.6. **Duration and financial impact**

☐ Proposal/initiative of **limited duration**

- ☐ Proposal/initiative in effect from [DD/MM]YYYY to [DD/MM]YYYY
- ☐ Financial impact from YYYY to YYYY

☒ Proposal/initiative of **unlimited duration**

- Implementation with a start-up period from 2018 to 2020,
- followed by full-scale operation.

1.7. **Management mode(s) planned³⁷**

☒ **Direct management** by the Commission

- ✓ by its departments, including by its staff in the Union delegations;
- ☐ by the executive agencies

☐ **Shared management** with the Member States

☐ **Indirect management** by entrusting budget implementation tasks to:

- ☐ third countries or the bodies they have designated;
- ☐ international organisations and their agencies (to be specified);
- ☐ the EIB and the European Investment Fund;
- ☐ bodies referred to in Articles 208 and 209 of the Financial Regulation;
- ☐ public law bodies;
- ☐ bodies governed by private law with a public service mission to the extent that they provide adequate financial guarantees;
- ☐ bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that provide adequate financial guarantees;

³⁷

Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: http://www.cc.cec/budg/man/budgmanag/budgmanag_en.html.

- ☐ persons entrusted with the implementation of specific actions in the CFSP pursuant to Title V of the TEU, and identified in the relevant basic act.
- *If more than one management mode is indicated, please provide details in the 'Comments' section.*

Comments

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2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

Every five years, the Commission will review the application of this Regulation and will submit a report to the European Parliament and to the Council. The report will assess the functioning of the Regulation and of the mutual recognition principle, as well as their impact on the free movement of goods and on the internal market for goods, based on feedback collected from stakeholders, including relevant information from Member States.

2.2. Management and control system

2.2.1. Risk(s) identified

The introduction of an IT tool to facilitate communication and notification of administrative decisions denying or restricting market access entails some technical risks. However, the Commission is the owner of the IT tool to be used for the purposes of the proposal, and is responsible for its daily operation, maintenance and development. The system is developed and hosted by an internal supplier which ensures a high level of business continuity.

2.2.2. Information concerning the internal control system set up

In order to address the risks identified in 2.2.1, the Commission will ensure regular meetings with Member States, and will provide training and guidance in order to allow a smooth and easy implementation of the proposal.

2.2.3. Estimate of the costs and benefits of the controls and assessment of the expected level of risk of error

The risks identified under 2.2.1 will be addressed by the provision of assistance and information to the stakeholders concerned.

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures.

For the purposes of combating fraud, corruption and any other illegal activity, the provisions normally applicable to the activities of the Commission, including Regulation (EU, EURATOM) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF), will apply in the context of the single digital gateway without any restriction.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
			from EFTA countries ³⁹	from candidate countries ⁴⁰	from third countries	within the meaning of Article 21(2)(b) of the Financial Regulation
	0203 Internal market for goods and services	Diff./Non-diff. ³⁸				
	020301 Operation and development of the internal market of goods and services	Diff.	YES	NO	NO	NO

³⁸ Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.

³⁹ EFTA: European Free Trade Association.

⁴⁰ Candidate countries and, where applicable, potential candidate countries from the Western Balkans.

3.2. Estimated impact on expenditure

These measures will be covered by the allocations already foreseen in the official financial programming of the Commission, no additional resources are necessary.

3.2.1. Summary of estimated impact on expenditure

EUR million (to three decimal places)

Heading of multiannual financial framework	Number	02 03 Internal market for goods and services
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DG: GROW			Year 2018	Year 2019	Year 2020	TOTAL 2018-2020
• Operational appropriations						
02 03 01	Commitments	(1)	0,700	0,300		1,000
	Payments	(2)	0,350	0,500	0,150	1,000
Number of budget line	Commitments	(1a)				
	Payments	(2a)				
Appropriations of an administrative nature financed from the envelope of specific programmes ⁴¹						
Number of budget line		(3)				
TOTAL appropriations for DG GROW	Commitments	=1+1a +3	0,700	0,300		1,000
	Payments	=2+2a +3	0,350	0,500	0,150	1,000

⁴¹ Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

• TOTAL operational appropriations	Commitments	(4)				
	Payments	(5)				
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)				
TOTAL appropriations under HEADING 1 of the multiannual financial framework	Commitments	=4+ 6	0,700	0,300		1,000
	Payments	=5+ 6	0,350	0,500	0,150	1,000

If more than one heading is affected by the proposal / initiative:

• TOTAL operational appropriations	Commitments	(4)							
	Payments	(5)							
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)							
TOTAL appropriations under HEADINGS 1 to 4 of the multiannual financial framework (Reference amount)	Commitments	=4+ 6							
	Payments	=5+ 6							

Heading of multiannual financial framework	5	‘Administrative expenditure’
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EUR million (to three decimal places)

		Year 2018	Year 2019	Year 2020	Year	Followin g years	Enter as many years as necessary to show the duration of the impact (see point 1.6)			TOTAL 2019-2020
DG: GROW										
• Human resources			0,690	0,690						1,380
• Other administrative expenditure			0,135	0,195						0,330
TOTAL DG GROW			0,825	0,885						1,710

TOTAL appropriations under HEADING 5 of the multiannual financial framework	(Total commitments = Total payments)		0,825	0,885						1,710
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EUR million (to three decimal places)

		Year 2018	Year 2019	Year 2020	Year N+3	Enter as many years as necessary to show the duration of the impact (see point 1.6)			TOTAL
TOTAL appropriations under HEADINGS 1 to 5 of the multiannual financial framework	Commitments	0,700	1,125	0,885					2,710
	Payments	0,350	1,325	1,035					2,710

3.2.2. Estimated impact on operational appropriations

- ☐ The proposal/initiative does not require the use of operational appropriations
- ☒ The proposal/initiative requires the use of operational appropriations, as explained below:

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs ↓			Year 2018		Year 2019		Year 2020		Following years		Enter as many years as necessary to show the duration of the impact (see point 1.6)						TOTAL (2018-2020)	
	OUTPUTS																	
	Type ⁴²	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	Total No	Total cost
SPECIFIC OBJECTIVE No 1 ⁴³ Enhancing administrative cooperation between Contact Points																		
- Output	Exchange of officials ⁴⁴		5	0,200	10	0	15	0	15	150								0,200
- Output	Visual identity for PCPs		1	0,100		0		0										0,100
Subtotal for specific objective No 1			6	0,300	10	0	15		15	150							46	0,300
SPECIFIC OBJECTIVE No 2 Raising awareness on mutual recognition																		
- Output	Trainings		20	0,400	40	0,300	40	0									100	0,700
Subtotal for specific objective No 1			20	0,400	40	0,300	40	0									100	0,700

⁴² Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

⁴³ As described in point 1.4.2. 'Specific objective(s)...'

⁴⁴ Commitment in 2018 and implementation between 2018-2020.

TOTAL COST	26	0,700	50	0,300	45	0									146	1,000
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3.2.3. Estimated impact on appropriations of an administrative nature

3.2.3.1. Summary

- ☐ The proposal/initiative does not require the use of appropriations of an administrative nature
- ☒ The proposal/initiative requires the use of appropriations of an administrative nature, as explained below:

EUR million (to three decimal places)

	Year 2019	Year 2020	Year	Following years	Enter as many years as necessary to show the duration of the impact (see point 1.6)			TOTAL (2019-2020)
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HEADING 5 of the multiannual financial framework	0203	0203						
Human resources	0,690	0,690						0,138
Other administrative expenditure	0,135	0,195						0,330
Subtotal HEADING 5 of the multiannual financial framework	0,825	0,885						1,710

Outside HEADING 5⁴⁵ of the multiannual financial framework								
Human resources								
Other expenditure of an administrative nature								
Subtotal outside HEADING 5 of the multiannual financial framework								

TOTAL	0,825	0,885						1,710
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The appropriations required for human resources and other expenditure of an administrative nature will be met by appropriations from the DG that are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

⁴⁵ Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

3.2.3.2. Estimated requirements of human resources

- ☐ The proposal/initiative does not require the use of human resources.
- ☒ The proposal/initiative requires the use of human resources, as explained below:

Estimate to be expressed in full time equivalent units

	Year 2019	Year 2020	Year	Fo llo wi ng ye ars	Enter as many years as necessary to show the duration of the impact (see point 1.6)		
• Establishment plan posts (officials and temporary staff)							
XX 01 01 01 (Headquarters and Commission's Representation Offices)	5	5					
XX 01 01 02 (Delegations)							
XX 01 05 01 (Indirect research)							
10 01 05 01 (Direct research)							
• External staff (in Full Time Equivalent unit: FTE)⁴⁶							
XX 01 02 01 (AC, END, INT from the 'global envelope')							
XX 01 02 02 (AC, AL, END, INT and JED in the delegations)							
XX 01 04 yy⁴⁷	- at Headquarters						
	- in Delegations						
XX 01 05 02 (AC, END, INT - Indirect research)							
10 01 05 02 (AC, END, INT - Direct research)							
Other budget lines (specify)							
TOTAL	5	5					

XX is the policy area or budget title concerned.

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

Description of tasks to be carried out:

Officials and temporary staff	<ul style="list-style-type: none"> – Develop, apply and monitor the EU policy on mutual recognition for goods – Implement the new Regulation on mutual recognition of goods – Implement the Action Plan on Mutual Recognition for Goods as set out in the Single Market Strategy [COM(2015)550]
External staff	

⁴⁶ AC= Contract Staff; AL = Local Staff; END= Seconded National Expert; INT = agency staff; JED= Junior Experts in Delegations.

⁴⁷ Sub-ceiling for external staff covered by operational appropriations (former 'BA' lines).

3.2.4. *Compatibility with the current multiannual financial framework*

- The proposal/initiative is compatible the current multiannual financial framework.
- The proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.

In order to cover the additional allocations, at least a partial redeployment will be necessary and it will be implemented during the annual budgetary procedure.

- The proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework.

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts.

3.2.5. *Third-party contributions*

- The proposal/initiative does not provide for co-financing by third parties.

3.3. Estimated impact on revenue

- ☒ The proposal/initiative has no financial impact on revenue.
- ☐ The proposal/initiative has the following financial impact:
 - ☐ on own resources
 - ☐ on miscellaneous revenue

EUR million (to three decimal places)

Budget revenue line:	Appropriations available for the current financial year	Impact of the proposal/initiative ⁴⁸						
		Year N	Year N+1	Year N+2	Year N+3	Enter as many years as necessary to show the duration of the impact (see point 1.6)		
Article								

For miscellaneous ‘assigned’ revenue, specify the budget expenditure line(s) affected.

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Specify the method for calculating the impact on revenue.

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⁴⁸ As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 25 % for collection costs.

ANNEX

Name of the proposal/initiative:

Regulation of the European Parliament and of the Council on mutual recognition on goods

- (1) NUMBER and COST of HUMAN RESOURCES CONSIDERED NECESSARY
- (2) COST of OTHER ADMINISTRATIVE EXPENDITURE
- (3) METHODS of CALCULATION USED for ESTIMATING COSTS
 - (a) Human resources
 - (b) Other administrative expenditures

This annex must accompany the legislative financial statement when the inter-services consultation is launched.

The data tables are used as a source for the tables contained in the legislative financial statement. They are strictly for internal use within the Commission.

(1) Cost of human resources considered necessary

- ☐ The proposal/initiative does not require the use of human resources
☒ The proposal/initiative requires the use of human resources, as explained below:

HEADING 5 of the multiannual financial framework		EUR million (to three decimal places)											
		Year 2019		Year 2020		Year		Year N+3		... enter as many years as necessary to show the duration of the impact (see point 1.6)		TOTAL	
		FTE	Appropriations	FTE	Appropriations	FTE	Appropriations	FTE	Appropriations	FTE	Appropriations	FTE	Appropriations
• Establishment plan posts (officials and temporary staff)													
XX 01 01 01 (Headquarters and Commission's Representation Offices)	AD	5	690.000 €	5	690.000 €								
	AST												
XX 01 01 02 (in Union Delegations)	AD												
	AST												
• External staff ⁴⁹													
XX 01 02 01 ('global envelope')	AC												
	END												
	INT												
XX 01 02 02 (in Union Delegations)	AC												
	AL												
	END												
	INT												
	JED												
Other budget lines (specify)													
Subtotal – HEADING 5 of the multiannual financial framework		5	690.000 €	5	690.000 €								

XX is the policy area or budget title concerned.

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

⁴⁹ AC = Contract Staff; AL = Local Staff; END = Seconded National Expert; INT= agency staff; JED = junior experts in delegations.

Outside HEADING 5 of the multiannual financial framework		Year N		Year N+1		Year N+2		Year N+3		... enter as many years as necessary to show the duration of the impact (see point 1.6)		TOTAL	
		FTE	Appropriations	FTE	Appropriations	FTE	Appropriations	FTE	Appropriations	FTE	Appropriations	FTE	Appropriations
• Establishment plan posts (officials and temporary staff)													
10 01 05 02 (Direct research)	AD												
	AST												
XX 01 05 01 (Indirect research)	AD												
	AST												
• External staff ⁵⁰													
XX 01 04 yy Sub-ceiling for external staff from operational appropriations (former 'BA' lines).	- at Headquarters	AC											
		END											
		INT											
	- in Union delegations	AC											
		AL											
		END											
		INT											
		JED											
		AC											
		END											
		INT											
XX 01 05 02 (Indirect research)	AC												
	END												
	INT												
10 01 05 02 (Direct research)	AC												
	END												
	INT												
Other budget lines (<i>specify</i>)													
Subtotal – Outside HEADING 5 of the multiannual financial framework													
XX is the policy area or budget title concerned. TOTAL													

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

⁵⁰ AC = Contract Staff; AL = Local Staff; END = Seconded National Expert; INT= agency staff; JED = junior experts in delegations.

(2) Cost of other administrative expenditure

- ☐ The proposal/initiative does not require the use of administrative appropriations
☒ The proposal/initiative requires the use of administrative appropriations, as explained below:

EUR million (to three decimal places)

	Year 2019	Year 2020	Year	Following Years	... enter as many years as necessary to show the duration of the impact (see point 1.6)			TOTAL 2019-2020
HEADING 5 of the multiannual financial framework								
At headquarters:								
02.010211.00.01.10 - Mission and representation expenses	0,005	0,005						
02.010211.00.02.20 - Conference and meeting costs	0,030	0,090						
XX 01 02 11 03 - Committees ⁵¹								
XX 01 02 11 04 - Studies and consultations								
02 03 01- Information and management systems	0,100	0,100						
XX 01 03 01 – ICT equipment and services ⁵²								
Other budget lines (specify where necessary)								
In Union delegations								
XX 01 02 12 01 - Missions, conferences and representation expenses								
XX 01 02 12 02 - Further training of staff								
XX 01 03 02 01 - Acquisition, renting and related expenditure								
XX 01 03 02 02 Equipment, furniture, supplies and services								
Subtotal HEADING 5 of the multiannual financial framework	0,135	0,195						0,330

XX is the policy area or budget title concerned.

⁵¹ Specify the type of committee and the group to which it belongs.

⁵² ICT: Information and Communication Technologies: DIGIT must be consulted.

EUR million (to three decimal places)

	Year N	Year N+1	Year N+2	Year N+3	... enter as many years as necessary to show the duration of the impact (see point 1.6)	TOTAL
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Outside HEADING 5 of the multiannual financial framework								
XX 01 04 yy - Expenditure on technical and administrative assistance (not including external staff) from operational appropriations (former 'BA' lines)								
- at Headquarters								
- in Union delegations								
XX 01 05 03 - Other management expenditure for indirect research								
10 01 05 03 - Other management expenditure for direct research								
Other budget lines (specify where necessary)								
Sub-total – Outside HEADING 5 of the multiannual financial framework								

XX is the policy area or budget title concerned.

TOTAL HEADING 5 and Outside HEADING 5 of the multiannual financial framework								
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The administrative appropriations required will be met by the appropriations which are already assigned to management of the action and/or which have been redeployed, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of existing budgetary constraints.

- (3) Methods of calculation used to estimate costs
- (a) Human resources

This part sets out the method of calculation used to estimate the human resources considered necessary (workload assumptions, including specific jobs (Sysper 2 work profiles), staff categories and the corresponding average costs)

HEADING 5 of the multiannual financial framework
NB: The average costs for each category of staff at Headquarters are available on BudgWeb: https://myintracomm.ec.europa.eu/budgweb/EN/pre/legalbasis/Pages/pre-040-020_preparation.aspx
<ul style="list-style-type: none"> • Officials and temporary staff <p>The average cost for an official (expressed as an FTE) is 138 000 EUR.</p>
<ul style="list-style-type: none"> • External staff

Outside HEADING 5 of the multiannual financial framework
<ul style="list-style-type: none"> • Only posts financed from the research budget
<ul style="list-style-type: none"> • External staff

- (b) Other administrative expenditure

*Give details of the method of calculation used for each budget line
and in particular the underlying assumptions (e.g. number of meetings per year, average costs, etc.)*

HEADING 5 of the multiannual financial framework
For missions, 5 missions per year are foreseen, and one mission has an average cost of 1000 EUR. The average cost for a conference / expert meeting is 30 000 EUR.
Outside HEADING 5 of the multiannual financial framework