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SECRÉTARIAT GÉNÉRAL

Direction A – Greffe

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REGULATORY SCRUTINY BOARD OPINION

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

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EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
Ares(2017)

Opinion

Title: Impact Assessment / Mutual recognition of goods

Overall opinion: POSITIVE

(A) Context

The principle of mutual recognition requires that a Member State does not prohibit goods that are lawfully marketed in another Member State, unless the latter has sound reasons for banning its sale. Mutual recognition is a key concept for the proper functioning of the single market for goods through the elimination of technical obstacles to a genuine free movement. The principle of mutual recognition is embedded in Article 34 and 36 of the Treaty on the Functioning of the European Union (TFEU). The Mutual Recognition Regulation (EC) 764/2008 specifies further how it should be implemented in practice.

This impact assessment examines options to amend the Mutual Recognition Regulation, taking into account the results of the evaluation on the application of the mutual recognition principle and Regulation.

(B) Main considerations

The Board notes the overall good presentation of this impact assessment report.

The Board gives a positive opinion, with a recommendation to further improve the report with respect to the key aspects mentioned hereafter.

- (1) The report does not clearly explain the choice of the options and how these would work in practice.**
- (2) The report does not draw clear 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.**
- (3) The report has not assessed the potential to simplify administration and reduce burdens (REFIT).**

(C) Further considerations and adjustment recommendations

(1) Problem definition

Based on available evidence, the report should more clearly explain the most problematic aspects of mutual recognition. It should explain to what extent the Mutual Recognition Regulation has been ineffective. It should elaborate on the issue of lack of trust between national administrations: the evaluation identifies this as one of the factors for the non-

functioning of the mutual recognition. Moreover, the report should better assess why mutual recognition is not working in the Member States by presenting additional evidence.

The IA report should be a self-standing document. Therefore, it should summarize the findings of the evaluation. In particular, the report should present in more detail the problems encountered with the current Regulation, including why Product Contact Points are not functioning.

(2) Options

In view of the acknowledged ineffectiveness of the current Regulation, the report should explain whether certain provisions of the current Regulation could be removed or amended. For instance, it should clarify why it is necessary to preserve the Product Contact Points despite their suboptimal functioning.

The report should clarify the construction of the options and how they would work in practice. For instance, it should explain the design of options 3 and 4. The report should clarify the limits of options 3a (compliance with European standards) to better demonstrate the benefits of option 4 (in particular 4b: declaration of compliance). For both options, it should clearly mention the risks and responsibilities for stakeholders. In particular, the report should clarify that the burden on proof will shift from companies to national administrations. In short, it should explain how the more ambitious alternatives in option 4 would supersede options 3a and 3b

The report should make clear how the fast-track provision would work in practice and what will happen to the list of products.

(3) Impacts

The analysis of impacts should refer to experience from existing single market tools (in particular from the harmonised field) and the risks involved. The report should outline the existing Commission and Member State commitments, in particular in terms of resources. It should explain the changes which the initiative would make for them.

Given the likely increase in burden for national administrations, the report should make realistic (quantified) estimates of resource implications. It should further justify that the legal certainty provided by the declaration of compliance (option 4b) would outweigh the corresponding administrative burden.

Given the initiative's REFIT dimension, the report should more clearly identify the potential for simplification. It should also estimate the potential reduction of administrative burden for companies (identified in the related evaluation).

The report should explain to what extent this initiative and others under revision (e.g. market surveillance, Solvit, Single Digital Gateway) would have a meaningful impact on the functioning of the internal market for goods.

(4) Comparison of options

In the absence of solid evidence, the report should better substantiate the high scores given to some of the options. For instance, what evidence is there to show that the action plan (option 2) would have a very positive impact ('++') on the increase of awareness?

(5) Future monitoring and evaluation

The report should outline more clearly operational monitoring and evaluation arrangements. It should indicate benchmarks against which the Commission will assess the success of the initiative.

Some more technical comments have been transmitted directly to the author DG

(D) RSB scrutiny process

The lead DG shall ensure that the recommendations of the Board are duly taken into account in the report prior to launching the interservice consultation.

Full title	Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) 764/2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State
Reference number	2017/GROW/005
Date of RSB meeting	5 April 2017



EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
Ares(2017)

Opinion

Title: Evaluation / Mutual recognition of goods

Overall opinion: POSITIVE

(A) Context

According to the Mutual Recognition principle, a Member State of destination may not prohibit the sale on its territory of products that are lawfully marketed in other Member States. This applies even for products that were made in accordance with different technical rules. A Member State can only deny market access if there are overriding public interest concerns such as protection of health, consumers, environment, etc. Mutual recognition helps the single market for goods to function properly. It is in Articles 34 and 36 of the Treaty on the Functioning of the European Union (TFEU) and applicable case law.

This evaluation assesses how well mutual recognition is functioning in the field of goods. It covers the mutual recognition principle itself and Mutual Recognition Regulation 764/2008, which defines practical implementation modalities.

(B) Main considerations

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

- (1) There is scope to improve the description and the relative importance of the main problems encountered in the application of the mutual recognition principle and the corresponding Regulation. Why do the key instruments put in place by the Regulation not deliver?**
- (2) While being a REFIT evaluation, it does not clearly estimate existing regulatory burdens on companies or public administrations, or the potential for cost savings.**
- (3) The report does not provide clear conclusions on whether the Mutual Recognition Regulation remains relevant or not, or on the extent to which there is scope to remedy its ineffectiveness.**

(C) Further considerations and recommendations for improvement

(1) Effectiveness and magnitude of the problem

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

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

(2) Baseline

The baseline should analyse how the situation would have evolved without the Regulation. It should show to what extent the observed evolution correspond to the estimates foreseen in the 2007 impact assessment accompanying the Regulation. It should also show to what extent the objectives of the Regulation were attained or not.

(3) Efficiency

The report should quantify costs and benefits as much as possible and identify the unnecessary regulatory burden. This is particularly important given the REFIT dimension. The report should clearly indicate the efforts made to obtain quantified data. The evaluation should compare figures against other estimates available (from statistics, studies, etc.) to show their robustness.

(4) Relevance

The report should discuss in this section how the lack of effectiveness of mutual recognition (both the principle and the Regulation) has no apparent major negative effects on the goods markets. In particular, the report should assess the relevance of the main measures of the Regulation, given their lack of effectiveness. The report should better analyse how new developments in e-commerce affect mutual recognition and its application.

(5) Conclusions

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

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

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

Some more technical comments have been transmitted directly to the author DG.

(D) RSB scrutiny process

The lead DG is advised to ensure that these recommendations are duly taken into account in the report prior to launching the interservice consultation.

Full title	REFIT evaluation accompanying the proposal for a Regulation on mutual recognition of goods
Reference number	2015/GROW/056
Date of RSB meeting	5 April 2017