



NOTE

September 2016

Danish response to the public consultation on the possible revision of the Mutual Recognition Regulation (EC) No 764/2008 applying in the field of the free movement of goods

General remarks

The Danish Government welcomes and supports the Commission's initiative to improve the application and enforcement of the principle of mutual recognition and the Mutual Recognition Regulation (MR-Regulation). The Danish Government agrees with the objective to create better market conditions for European Businesses on the Single Market for goods by addressing the shortcomings in the current application of the MR-Regulation.

This calls for actions on various levels. This paper proposes some suggestions for further boosting the rules and procedures of mutual recognition.

The scope of the MR-Regulation should be clarified, better structures for proportionality assessments should be put in place, and an informal set-up could ensure better sharing of best practices among Member States. Also, dissuasive means should be introduced to ensure that Member States notify according to their obligations in the Regulation, e.g. by introducing legal consequences for non-notification. Moreover, effective remedies must be available to businesses in order for them to get quicker clarity on decisions taken against their products on the Single Market, including enhanced transparency to see the decisions. In addition, the PCPs should be optimised and give businesses easy access to information about national decisions and technical rules.

However, it is important not to view the MR-Regulation in isolation from other mechanisms and tools that apply in the non-harmonised area of goods. The Commission could also look into how Member State authorities in general could better assess the effect on the Single Market of new nation-

al legislation in the non-harmonised area. Also, there is an overall need for redeeming trust and strengthening cooperation among Member State authorities across the Single Market. National rules and requirements are typically upheld on specific cultural or historical grounds, because authorities do not examine the possibility that the level set by another Member State authority could, in fact, be safe enough.

Comments and suggestions

Clarification of the scope of the Mutual Recognition Regulation

The MR-Regulation is unclear on which products and situations are covered by the regulation. When Member State authorities have doubts about to which extend the rules and procedures apply, the risk of breaching their obligations under the Regulation rise. In order to improve the application of the MR-regulation, and in effect strengthen the principle of mutual recognition, authorities need to become much more confident in navigating among, and applying, the rules and procedures in practice.

Suggestions

- The Mutual Recognition Regulation should clearly state that its scope applies to products outside the harmonised area *as well as* non-harmonised parts of harmonised areas.
- Among others, the notions of “prior authorisation” and “lawfully marketed” remain to be clarified.
- *Clearer structures for the assessment of proportionality* should be put in place, combined with guiding tools, such as online access to selected case law on mutual recognition.
- Set-up of an informal environment for *better sharing of best practices* among Member States in connection with applying the MR-Regulation, e.g. within the Committee on mutual recognition.

As a starting point, the MR-Regulation should make clear that the Regulation applies to products outside the harmonised area *as well as* non-harmonised parts of harmonised legislation. In practice, Member States introduce national legislation in addition to harmonised legislation with no regard to the mutual recognition principle. One of the reasons for this could be the fact that the MR-Regulation does not clearly state that those national rules are also subject to the principle of mutual recognition.

Further, both Member State authorities and businesses have difficulties demonstrating when a product has been “lawfully marketed” and grasping the implications of “prior authorisation”, as both notions are vaguely described in the Regulation. As a result, authorities may tend to privilege their own national rules instead of mutually recognising other Member States’

technical rules and test results, because they often are much better acquainted with their own rules, testing schemes, etc.

A “*declaration of conformity*” could be a possible solution for businesses to show that their products have already been lawfully marketed in another Member State when entering a new market. However, before its introduction, an assessment must indicate an opportunity for adding actual value to the application and enforcement of the MR-Regulation - and if introduced, the declaration should be voluntary and the burden of proof should lie with the Member State authorities with a view to reduce burdens on businesses. Moreover, such a declaration should to the greatest extent possible build on existing data and structures within e.g. the context of market surveillance activities.

Moreover, *clearer structures for the assessment of proportionality* should be put in place to help authorities better decide on specific cases of conflicting national rules and grounds of justification. In addition, guiding tools, such as online access to selected case law on mutual recognition, could be launched with a view to guide authorities’ assessment of proportionality in specific cases.

Additionally, Member States could to a much greater extent benefit from *better sharing of best practices* in an informal environment for assessing and discussing difficulties and grey areas in connection with applying the MR-Regulation, e.g. within the Committee on mutual recognition. In this way, it could become clearer how national authorities should interpret the rules and procedures of the Regulation, and how to decide on specific cases of conflicting national rules and grounds of justifications.

Dissuasive means to ensure fulfilment of national authorities’ obligations

According to Commission statistics, only 5 Member States notified their decisions in accordance with the MR-Regulation in 2014. Therefore, a better structure should be put in place to ensure that all Member State authorities notify in accordance with their obligations under the Regulation.

Suggestions

- The MR-Regulation should include *consequences of non-notification* of decisions in accordance with the Regulation, e.g. non-notified decisions cannot be enforced like it is the case of non-notification under the Transparency Directive (2015/1535/EU).
- The Commission should introduce a systematic follow up assessment of Member State authorities’ grounds of justifications of derogation from the principle of mutual recognition. This could be combined with the introduction of *a mandatory proportionality test*.

A structured framework already exists for the notification of new national technical regulations for goods outside the harmonised area in accordance

with the Transparency Directive (2015/1535/EU). The principle of mutual recognition is very closely linked to this framework, as Member State authorities take the decisions under the MR-Regulation on the basis of these technical regulations. Thus, similar legal consequences could be introduced to ensure that Member State authorities fulfil their obligations to notify under the MR-Regulation.

Furthermore, a *systematic follow-up mechanism* should be introduced for assessing the grounds of justifications of derogations from the principle of mutual recognition. The absence of such a mechanism upholds a great deal of legal uncertainty on the Single Market for goods. Currently, the Regulation lists a selection of legitimate reasons that authorities may use to justify decisions to deny market access for a product lawfully marketed in another Member State. As a rule, these legitimate reasons are only allowed under strict conditions, but in reality, they are applied in various situations without any further case-by-case examination. Such a mechanism could be combined with the introduction of *mandatory proportionality tests* for Member State authorities to carefully explain the grounds of justifications in national decisions taken in accordance with the Regulation.

Ensuring that effective remedies are available to economic operators

Today, when European businesses meet requirements of e.g. additional testing, they can either choose to retest the product, and adhere to the national decision, or challenge the decision taken against their market access, if they believe that e.g. the grounds of justification are disproportional and unnecessary.

However, when a business chooses to challenge a decision, they are currently left with year-long proceedings in national courts and high costs of awaiting these court proceedings. As a result, businesses simply adapt their products to the national requirements in question, because challenging them do not match the risk of losing profits and new market opportunities, especially for small businesses.

Suggestions

- A set-up should be put in place for European businesses to have access to *effectively challenge decisions* adopted against the free movement of their products.
- Businesses should have *better access to see notifications* of Member State decisions taken in accordance with the MR-Regulation, as it is the case of notifications in accordance with the Transparency Directive (2015/1535/EU).

Businesses should be able to get quicker clarity to obstacles they meet when entering new markets, and reduce the costs that may follow with national requirements of, for instance, additional testing – which for small businesses

can be potentially fatal. In that way, existing unlawful technical barriers would be reported and addressed.

Additionally, the notification procedure for the decisions taken in accordance with the MR-Regulation could be more transparent. Businesses should have access to see and follow the notifications of decisions to enhance legal certainty and due process in cross-border trade. Such a framework already exists for the notifications of new technical regulations under the auspices of the Transparency Directive (2015/1535/EU). Similarly, businesses should have access to see the decisions taken in accordance with the MR-Regulation, and the grounds of justification of those decisions.

Strengthening the Product Contact Points and introducing strict deadlines

The PCPs should help businesses get easy access to information about Member State decisions and technical regulations in relation to the principle of mutual recognition. However, in practice businesses have to contact each Member State individually, and because the functioning of the PCPs has never been legally formalised, the service levels in Member States are very varied, e.g. in terms of language and quality of replies as well as response time. This is also manifested in the fact that some Member States have created an easy online overview of already adopted decisions, etc., while others do not have a website nor provide an e-mail address.

Suggestions

- The handling and response, including response times, should become more streamlined and structured for businesses to be properly informed and get the necessary help in an effective manner.
- As part of the announced governance framework for the Single Digital Gateway, the Commission should introduce common quality criteria for the content, functioning and level of integration of each portal, including the PCPs.

Final remarks

The Danish government is looking forward to the coming work on the possible revision of the Mutual Recognition Regulation. It is important to ensure that the Commission and Member States are both ambitious and determined to reach an outcome that will, in fact, facilitate a better application and enforcement of the principle of mutual recognition.

In the coming work it is, therefore, important to balance between the needs of Member States and European businesses: the difficulties Member States have with applying the rules and procedures of the MR-regulation in practice *as well as* the difficulties businesses face in cross-border trade with goods, including the fact that they cannot get quick and efficient access to challenge the technical barriers they meet on the Single Market.