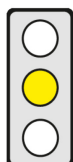


KEY ISSUES

Objective of the Regulation: The principle of mutual recognition in the field of the free movement of goods is to be strengthened: Goods that are already lawfully marketed in a Member State should not be subject to hasty bans or restrictions in other Member States due to only divergent product requirements.

Affected parties: Companies, authorities in the Member States, particularly regulatory and market surveillance authorities



Pro: (1) Authorities will be able to check more easily whether goods are already lawfully marketed in a Member State.

Contra: (1) Due to the complexity of foreign technical rules, authorities will still tend to ban goods that do not comply with national regulations.

(2) The Regulation should provide for a deemed approval which would apply where an authority fails to adhere to the Regulation's requirements.

The most important passages in the text are indicated by a line in the margin.

CONTENT

Title

Proposal COM(2017) 796 of 17 December 2017 for a **Regulation on the mutual recognition of goods** lawfully marketed in another Member State

Brief Summary

Note: Article numbers refer to the Proposal for a Regulation COM(2017) 796.

► Background

- One of the EU's main objectives is to establish an internal market (Art. 3 (3) TEU, Art. 26 TFEU). This includes the free movement of goods (Art. 28 TFEU). As a result, quantitative restrictions on imports or "measures having equivalent effect" are prohibited between Member States (Art. 34 TFEU).
- Divergent national "technical rules" e.g. regarding the quality, safety, composition or packaging of goods, can restrict the free movement of goods between Member States.
- The "principal of mutual recognition" (hereinafter "Principle"), established by the Judgement of the ECJ in the Cassis-de-Dijon case [ECJ, Judgement of 20.02.1979, REWE v. Bundesmonopolverwaltung für Branntwein, Case 120/78, EU:C:1979:42, para. 8 -14.], aims to strengthen the free movement of goods. This means that a Member State is prohibited from banning or restricting goods in its own market which are lawfully marketed in another Member State even where the goods do not comply with its national "technical rules".
 - The principle applies to goods for which no or only partially harmonised EU regulations exist.
- The principle permits exceptions. Member States may adopt "technical rules" for
 - especially the protection of health and life, public security (Art. 36 TFEU) and/or
 - mandatory requirements of public interest that are recognised by the CJEU ("mandatory requirements").
- According to the Commission, the Principle is not being adequately applied by the authorities in the Member States.

► Objective of the proposed Regulation

- This proposed Regulation aims to remove problems regarding the application of the Principle by
 - introducing a "mutual recognition declaration" (hereinafter "declaration") whereby a company can state that goods are lawfully marketed in another Member State,
 - tightening the requirements applicable to Member States' authorities regarding the application of the Principle,
 - introducing a "problem-solving procedure" in cases where a company invoking the Principle encounters problems with an authority in another Member State and
 - extending the requirements applicable to the existing national "Product Contact Points".
- The proposed Regulation is to replace the existing Regulation [(EC) No. 764/2008].

► "Mutual recognition declaration"

- The evidence required to demonstrate that goods are lawfully marketed in another Member State varies significantly (Recital 15). The Commission wants to make it easier to provide this evidence.
- A standard EU-wide, voluntary "mutual recognition declaration" will be introduced.

- The declaration follows a given structure (Art. 4 para. 2) and contains, in particular (Annex I to the proposed Regulation):
 - a precise description of the goods,
 - details about the marketing, such as the Member State in which the goods are already being marketed and the date on which this first occurred, as well as
 - information on the lawfulness of the marketing, such as
 - the statutory regulations complied with in that Member State and/or
 - conformity assessments carried out.
- The declaration may be made available on paper or online, e.g. on company websites.
- For assessment purposes, authorities in the Member States that receive a declaration from a company (Art. 4 para. 7),
 - are only permitted to require evidence from companies in order to check the information contained in the declaration but no additional evidence and
 - must accept the declaration and any requested evidence as proof that the goods are lawfully marketed in another Member State.
- Authorities in a Member State may, however, continue to assess the goods according to their national requirements and ban or restrict market access (Art. 5 para. 1, Recital 15) if
 - one of the aforementioned exceptions to the Principle applies and
 - this decision is proportionate.
- **Requirements applicable to authorities in the Member States regarding application of the Principle**
 - Authorities in a Member State that want to restrict or ban market access to goods that are already lawfully marketed in another Member State, must
 - communicate their decision within 20 working days to the Commission, the other Member States and the company affected (Art. 5 para. 3) and
 - set out verifiable reasons for their decision (Art. 5 para. 4) and in particular include the following information (Art. 5 para. 5):
 - the national technical rules on which the decision is based,
 - the technical or scientific developments that have occurred since the national technical rule was adopted and were taken into account when making the decision,
 - the legitimate grounds of public interest on which the decision is based,
 - evidence demonstrating that the decision is proportionate and
 - a summary of the arguments put forward by the affected company,
 - refer in the decision to the “problem-solving procedure” and legal remedies.
- **Extending the SOLVIT procedure to include a “problem-solving procedure”**
 - SOLVIT is a problem solving network of Member States that helps citizens and companies that encounter problems with the authorities of another Member State when asserting their internal market rights [Commission Recommendation C(2013) 5869]. The SOLVIT procedure liaises and is designed as follows:
 - Every Member State has a SOLVIT centre to which its citizens and companies can turn to for assistance.
 - This SOLVIT centre (home centre) examines the issue and, provided no court proceedings have been initiated, contacts the SOLVIT centre in the Member State in which the problem has arisen (lead centre).
 - Where possible, the lead centre may try to solve the problem with the authority that is causing the internal market-related problem, within ten weeks. It regularly informs the home centre.
 - The Commission wants to extend the SOLVIT procedure to include the possibility of a formal opinion of the Commission where problems exist in applying the Principle (“problem-solving procedure”).
 - In this regard, the home centre will be able to ask the Commission to give a formal opinion on whether the action of an authority in another EU country is compatible with the Principle (Art. 8 paras. 1 and 2). The opinion must be considered during the procedure (Art. 8 para. 4).
- **Requirements applicable to Product Contact Points**
 - Product Contact Points in the Member States will provide the following information, online and free of charge, regarding the legal situation in a Member State (Art. 9 para. 2):
 - the requirements applicable to authorities in the Member State regarding application of the Principle,
 - the contact details of the competent authority for the purpose of making contact directly.
 - Within 15 days, Product Contact Points provide,
 - at the request of an authority in another EU country, any relevant information about goods that are already lawfully marketed in the Member State of the Product Contact Point (Art. 10 para. 2, Art. 9 para. 3),
 - at the request of a company, “any useful” information, in particular (Art. 9 para. 3 and para. 4)
 - the “technical rules” applicable in the Member State of the Product Contact Point and/or
 - information on whether marketing of the goods is subject to prior authorisation by an authority.

- The Commission ensures efficient cooperation and exchange of information between competent authorities and the Product Contact Points (Art. 10 para. 1).

Main Changes to the Status Quo

- ▶ Until now, authorities in the Member States could require the information which they considered necessary as proof for the lawful marketing of goods in another Member State. Now, the mutual recognition declaration should conclusively apply in this regard.
- ▶ Until now, only the company and the Commission had to be notified when a product was rejected by an authority. Now, the other Member States must also be notified. In addition, the technical or scientific developments, which have occurred since the national technical rule was adopted, must be taken into account when making the decision.
- ▶ Until now, the Commission was not formally involved in the SOLVIT procedure for solving individual cases. Now, the Commission can be asked for an opinion which must be taken into account in the procedure.
- ▶ In future, the Product Contact Points provide selected information online.

Statement on Subsidiarity by the Commission

The procedures envisaged by the proposed Regulation ensure that authorities in the Member States apply the Principle in a uniform way so that all companies receive equal treatment and divergent decisions are avoided.

Legislative Procedure

19 December 2017	Adoption by the Commission
03 September 2018	Vote in the Committee
Open	Adoption by the European Parliament and the Council, publication in the Official Journal of the European Union, entry into force

Options for Influencing the Political Process

Directorates General:	DG Internal Market, Industry, Entrepreneurship and SMEs
Committees of the European Parliament:	Internal Market and Consumer Protection (leading) Rapporteur: Ivan Štefanec (EVP)
Federal Ministries:	Federal Ministry for Economic Affairs and Energy
Committees of the German Bundestag:	Economic Affairs and Energy (leading)
Decision-making mode in the Council:	Qualified majority (acceptance by 55% of Member States which make up 65% of the EU population)

Formalities:

Competence:	Art. 114 TFEU (Internal Market)
Type of legislative competence:	Shared competence (Art. 4 (2) TFEU)
Procedure:	Art. 294 TFEU (ordinary legislative procedure)

ASSESSMENT

Economic Impact Assessment

The principle of mutual recognition is rarely applied by authorities in the Member States. Consequently, where a company wants to market its goods in another Member State, it generally has to adapt the goods to the technical rules of that Member State. Where the cost of adapting the goods is too high, the company will decide not to bother. It is therefore appropriate that the Commission wants to strengthen the Principle.

The fact that the principle of mutual recognition is only rarely applied results in particular from two problems: Firstly, when assessing – e.g. whether product safety requirements in another EU country are comparable to national ones – **the authorities in the Member States are often confronted with complex foreign provisions**, whose technical, historical and cultural background they are not aware of, **so they tend to ban goods** that do not meet the national technical rules. **Secondly, national traders often require compliance with national rules** so that they can sell imported goods more easily. In this case, the producing company could not sell its goods to a trader in another EU country without adapting them, even if the national authority recognised the Principle. **The proposal from the Commission does little to solve these two problems.** Application of the Principle is therefore unlikely to increase.

Against this background, we evaluate the details of the proposed Regulation as follows: The mutual recognition declaration reduces bureaucracy costs for companies that wish to rely on the Principle because they only have to

gather the necessary information once and - aside from the necessary translations - can then use it for all Member States.

Publication of the declaration on the company's website aims to prevent hasty bans by authorities because if they discover goods that do not correspond to national rules they can in future look at the manufacturer's website to see if the goods are already lawfully marketed in another Member State. The extent to which national authorities will actually do this is however doubtful.

It is appropriate, where the Principle is not applied, that the burden of proof should in future still lie with the authority responsible for banning the goods from being marketed. The fact that, in future, the necessary grounds will also contain the technical or scientific developments that have occurred since the national technical rule was adopted and which were taken into account when making the decision, indirectly encourages the authorities to take account of such developments. Although this is sensible because national rules are sometimes several decades old and technically outdated, this addition will have little practical relevance since, in practice, the grounds are only provided in the event of court proceedings, which companies often shy away from. National authorities may even have the right to secure their decisions by submitting the necessary reasons on appeal, as is the case in Germany.

Until now, companies have had difficulty challenging the decision of an authority [SWD(2017) 471, p. 13] because – following a possible objection procedure – this can only take place in national courts. These courts – like the authorities – are generally unfamiliar with the rules in other Member States and therefore often find in favour of the authorities. What is more, such court proceedings are expensive. **The problem solving mechanism, i.e. the possibility of obtaining an opinion from the Commission, significantly enhances the SOLVIT procedure.** It will be difficult for the authorities and courts in the Member States to ignore these opinions. **It is however doubtful whether the Commission has the necessary resources to prepare such opinions on a regular basis.**

The fact that the Product Contact Points have to provide certain information online, only minimally reduces the search costs for companies. The basic problem still exists: companies and Product Contact Points have to wrestle with huge language difficulties. A noticeable improvement in the work of the Product Contact Points is therefore unlikely.

Legal Assessment

Legislative Competency

Unproblematic.

Subsidiarity.

Unproblematic. The proposal for a Regulation aims to make it easier to rely on the EU-law principle and to unify the procedural rules in this regard.

Proportionality with respect to Member States

The proposal for a Regulation is proportionate. The duty to accept **the reciprocal recognition declaration** as conclusive evidence that goods are lawfully marketed, **does not excessively restrict the power of authorities to investigate the facts of a case**; it is in any case not possible to require more evidence than that contained in the model declaration. **The Regulation should provide for a deemed approval which would apply where an authority fails to adhere to the Regulation's requirements** when applying the Principle – such as in relation to the reasons when restricting or banning goods – or where the authority exceeds a certain period of time for its assessment. Such approval would avoid legal insecurity and signals that marketing of respective goods is in accordance with the rules of the internal market.

Compatibility with EU Law in other respects

For reasons of legal clarity, the Regulation should include a reference to the fact that the time limits for formal legal remedies are not suspended by the problem-solving procedure, and that the party seeking redress is not allowed to be penalised in the problem-solving procedure if she applies for legal remedies as a precaution in order to comply with the time limits.

Conclusion

The fact that the principle of mutual recognition is only rarely applied arises from two problems: Firstly, the authorities in the Member States are often confronted with complex foreign provisions so they tend to ban goods. Secondly, national traders often require compliance with national rules. The proposal does little to change these two problems. Publication of the declaration on the company's website aims to prevent bans by authorities as, in future, they will be able to look at the manufacturer's website to see if the goods are already marketed in another Member State. The possibility of obtaining opinions from the Commission enhances the SOLVIT procedure. The question is whether the Commission has the resources to prepare such opinions on a regular basis. The reciprocal recognition declaration does not excessively restrict the power of authorities to investigate the facts of a case. The Regulation should provide for a deemed approval which would apply where an authority fails to adhere to the Regulation's requirements.