



28 March 2018

BusinessEurope's comments on the Commission's 'Goods Package'

REMARKS ON:

PROPOSED REGULATION FOR MUTUAL RECOGNITION
PROPOSED REGULATION FOR COMPLIANCE AND ENFORCEMENT
COMMUNICATION ACCOMPANYING THE GOODS PACKAGE

KEY MESSAGES

- 1** BusinessEurope supports the proposed 'Goods Package'. The package will contribute to improving the free movement of goods in the Single Market and creating a level playing field. While some further refinements of the proposals are necessary, we call upon the co-legislators to handle these files swiftly.
- 2** In the area of **mutual recognition**:
 - it is key that public interest grounds to deny mutual recognition are as clearly defined as possible. The proposal does not sufficiently address this;
 - companies should have recourse to an accessible problem-solving tool. Enhanced use of SOLVIT as proposed by the Commission in this context can be helpful, but only when Commission intervention within a limited timeframe is ensured.
- 3** In the area of **compliance and enforcement**:
 - the proposal should further specify that surveillance measures, fees and penalties should be proportionate, prioritising actions for the largest risk-reduction opportunities;
 - the proposal should further specify that company information must be treated with appropriate confidentiality measures, and there should be stricter criteria as to what information can be taken into account as evidence;
 - we oppose to the presumption of non-compliance throughout the EU on the basis of a decision of a single market surveillance authority without an appropriate dialogue mechanism where differences of opinion can be resolved.



1. Comments on the proposed Regulation for Mutual Recognition

General comments

We welcome the proposal for a new regulation in the area of mutual recognition, supplemented by the soft law measures foreseen in the Communication (under 3b and in the appendix). The legislative proposal addresses some of our key concerns, most notably the issue of the burden of proof and access to a direct remedy, while the soft law actions are aimed at enhancing capacity and knowledge at the national level.

However, while the introduction of a voluntary mutual recognition declaration can help documenting lawful marketing, the provisions on national justifications to deny mutual recognition are formulated in broad terms which may cause problems in practice. In this respect, we welcome that the Goods Package includes a report on the functioning of Directive 1535/2015. It is key that potential future barriers to the free movement of goods are prevented by a proper application of this Directive in practice. The 'single market clause' (Communication under 3(b)) is also related to national technical rules, however currently foreseen as a soft law measure. From our perspective it should ideally be included in the legislative proposal itself.

Specific comments

Legitimate public interest ground (Article 3(12) in conjunction with Article 5(5)(b); recital 4). The proposal explains that a legitimate public interest ground is a ground from Article 36 of the Treaty, or any other overriding reason of public interest. From recital 4 of the proposed regulation, the case law and examples listed in the Communication (footnote 21) it becomes clear that these can cover a very wide area of issues.¹ This makes it difficult for authorities to determine if a public interest ground is legitimate, but also for companies to assess *prima facie* if a refusal to mutual recognition is legitimately denied and if they should resort to a remedy. What is more, Member States sometimes use the exemptions with little or no justification. The Commission has an important role in providing more guidance, for example in soft measures complementing the proposed regulation, to ensure that definitions are clarified and that refusals of mutual recognition are reasoned and proportionate.

Burden of proof (Articles 4 and 5). We welcome that the Commission's proposal aims at improving the way to address the burden of proof, which is one of the main issues BusinessEurope has highlighted in the past. The proposal makes clear that it is for the national authority to explain why mutual recognition is refused.

- **Voluntary mutual recognition declaration** (Article 4). This declaration to demonstrate that goods are already lawfully marketed in another Member State could be helpful for economic operators to prove that their product is lawfully marketed and in reducing administrative burdens. It is positive that this can be done in the declaration of conformity (Article 4(9)). However, it is key that if such

¹ The communication refers to: public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property.



a declaration is submitted, no additional information beyond the evidence supporting the declaration is required. The proposal should also give further clarifications on the practical and legal value of the declaration. In addition, it is important that the mutual recognition declaration remains voluntary, and that companies who decide not to use this declaration are not subject to extensive requests by national authorities. Article 4(8) is too far-reaching in this respect, as ‘any relevant information’ could be requested.

- **Certificates and test reports** (Article 5(2)). We welcome the fact that the proposed regulation entails a provision emphasizing that Member States should in principle recognize certificates and test reports from conformity assessment bodies. We would ideally like the text to be stronger in wording than ‘taking due account’.
- **Obligation to provide a reasoned decision** Article 5(4) and (5). We welcome that Article 5 specifies in more detail what national authorities should include in their administrative decision, in particular that the decision should be sufficiently detailed and reasoned and that it specifies the available remedies. Such a duty to explain is an important mechanism to prevent unjustified refusals to the principle of mutual recognition.

Communication when market access is denied (Article 5(3) and 6(2)). According to the proposal, the Commission and all Member States will need to be informed of both administrative decisions (Article 5(3)) and any temporary suspension of market access (Article 6(2)). We welcome these provisions, as they can increase the awareness of the challenges encountered across the EU and contribute to faster problem solving. We also appreciate that in case of suspension where there is a serious risk, all Member States are notified of the technical or scientific justifications.

Temporary suspension of market access (Article 6). Market access should only be temporarily suspended when there is a serious risk. If there are no indications of such a risk, suspension would be a disproportionate measure. A reasoned decision, based on objective and verifiable criteria, should be required.

SOLVIT as a problem-solving tool for Mutual Recognition (Article 8). The Commission proposes the use of SOLVIT as a problem-solving tool in the area of mutual recognition. While we have some concerns on the current functioning of SOLVIT for companies, we understand the Commission’s intention to make use of existing tools rather than creating new ones. The action plan on SOLVIT, released in May 2017 as part of the ‘Compliance Package’, may improve the functioning of the SOLVIT centres in practice. Also, we welcome the possibility of Commission involvement in the SOLVIT procedure. We want to stress that the procedure should be short as reasonably possible, and that the deadlines for the Commission to respond should not be open-ended but fixed. In addition to what is foreseen in the proposal, there should be an independent possibility for companies to involve the Commission in the problem-solving process and further clarifications on the applicable deadlines in case of Commission involvement. The Commission should also be able to intervene in the SOLVIT process on its own initiative.



Product Contact Points (Article 9-10). The Commission wants to ensure a good functioning of the Product Contact Points. We appreciate the explicit link with the Single Digital Gateway proposal in Article 9 and the Commission's involvement with improved administrative cooperation between the Product Contact Points in Article 10. It would be useful if Article 9(3) also explicitly included a reference on how to carry out the relevant national administrative procedures required for lawful marketing. These procedures should not be too burdensome or costly. Member States should contribute to ensure proper visibility of the Product Contact Points and/or of the future Single Digital Gateway in which these Product Contact Points are to be included.

2. Comments on the proposed Regulation for Compliance and Enforcement (Market Surveillance)

General comments

BusinessEurope welcomes the goal and overall content of the proposal for a new regulation on compliance and enforcement, as it responds to a number of problems in the area of market surveillance we have signalled in the past. We support the purpose of the proposed regulation as explained in recital 1 and 14, namely the creation of a level playing field with fair competition in the Single Market, which necessitates stronger enforcement of harmonisation regulation including on products entering the European Union.

Market surveillance authorities should maintain a good balance of enforcement priorities between harmonized and non-harmonized products. Market surveillance actions should be directed at where the largest gains in terms of risk-reduction are to be found, and carried out in a proportionate manner. Since the proposal provides for extensive powers for market surveillance authorities, these powers should be as uniform as possible across member states, used proportionally, sufficiently guarantee the confidentiality of company information, and should be well balanced by appropriate appeal procedures with practicable time lines. The proposal aims to facilitate such conditions. BusinessEurope suggests that these provisions should be further strengthened.

Market surveillance needs adequate resources, suitable facilities and skilled officers in order to function well. This requires considerable financial resources at a national and European level. Therefore, we strongly recommend sufficient allocation of the post-2020 MFF budget to national market surveillance authorities and for the coordination of enforcement activities at EU level. With regards to resources for market surveillance authorities, the Commission's Impact Assessment accompanying the proposal flags the lack of resources as an important constraint to proper controls.²

Specific comments

EU responsible person (Article 4). The proposal introduces the new concept of a 'responsible person' within the EU for products coming from third countries. We are supportive of an obligation for companies not based in the EU to designate a contact point as this can improve enforcement and through that help to preserve a level playing

² [Impact Assessment](#), under 1.4.2.



field. It is however important that obligations and responsibilities are fair and clear for the different operators involved; for example, logistics service providers should not be held responsible to verify this, neither be assumed to be in this role. There should also be sufficient safeguards to ensure that this obligation is respected in practice. While the proposal is a step in the right direction, it may have done more to ensure market surveillance on products from outside the EU that are directly sold to the consumer.

Declaration of conformity on website (Article 5). The proposed regulation stipulates that the declaration of conformity has to be published on the website of the manufacturer. While this already happens in practice in many cases, we wonder if this should be a mandatory obligation. In particular because the declaration of conformity and the CE marking are not consumer labels and not intended as an information for end-users, perhaps other ways of better informing consumers should be considered.

Product Contact Points (Article 6). The proposal provides that Product Contact Points are extended to harmonised products and will provide information on request and free of charge of information considering the relevant legislation. We find this a positive element, that can improve the information for economic operators, and also allows for the provision of more integrated information beyond the harmonised/non-harmonised divide.

Compliance partnership agreements (Article 7). The proposal introduces the possibility of cooperation between market surveillance authorities and market operators through compliance partnership arrangements. This is encouraging as it can increase efficiency at both ends and shift the focus to capable compliance management processes. These agreements should however not result in unfair competition with existing consultancies active in this area or put some businesses at disadvantage; in addition, these agreements should not create ambiguity between authorities and the companies they have to inspect.

Memoranda of understanding with stakeholders (Article 8). The proposal also introduces the possibility of enhanced cooperation between market surveillance authorities, organisations representing companies and/or end-users through memoranda of understanding. The acknowledgement of such cooperation practices is a positive development, which can allow for better cooperation with both market operators and organisations representing end-users. It can allow for better use of existing insights in compliance issues in specific markets. These memoranda should not result in ambiguity between authorities and the companies they have to inspect.

Activities and powers of market surveillance authorities (Article 12 and 14). We welcome that the proposal is explicit about the activities and powers of market surveillance authorities as this can help to make them more uniform, which will foster cooperation, efficiency and transparency. We acknowledge that for proper enforcement the authorities need appropriate powers. However, because the powers proposed are very extensive, it is necessary to ensure that these powers are justified and well-defined. Powers must also be balanced by a legal obligation to execute them in a proportional manner, and with sufficient safeguards - in particular for confidential information. While the proposal includes such elements of balance, BusinessEurope suggests these elements should be further strengthened. Also, we repeat our earlier pleas for more effective appeal procedures in the national context for economic operators.



- Article 12 does not contain a specific reference to proportionality, whereas this would be appropriate especially for Article 12(3)(b). We would also appreciate a clear reference to the confidentiality of company information in this Article.
- Proportionality should have a more central role in Article 14. For example, Article 14(3)(f) provides for the powers to take samples free of charge. This could easily become a disproportionate burden on companies where the product concerned is expensive, and even more so where the product eventually turns out to be compliant or the non-compliance is in non-material issues such as minor documentation errors.
- The power to perform checks on companies' internal procedures (Article 14(3)(b)) is too invasive. Market surveillance authorities should not have the power to interfere with internal compliance procedures of companies. The power to request any representative of staff member to provide 'any kind of information' relating to the subject-matter of the inspection, and to record their answers (Article 14(3)(e)(3)), is too far-reaching as well.
- It is key to strike the right balance between the confidentiality of company information and effective market surveillance. Currently the protection of companies in Article 16 is weak in comparison to the surveillance powers. We suggest that market authorities should be liable for damage resulting from failure to maintain confidentiality in a proportionate manner. In addition, exchange of private company information between authorities both in the EU and with third countries (Article 34-35) should only be possible when necessary and proportionate to the objectives.

Restrictive measures (Article 17). We fully support that restrictive measures shall be proportionate and state the grounds on which they are based, but we have a concern about the implementation of this provision. Economic operators should have the possibility to obtain substantive motivation of proportionality to exercise their procedural rights in a time frame matching the urgency of the case.

Introduction of EU testing facilities (Article 20). The proposal would introduce the possibility for the Commission to designate EU testing facilities. We consider this a positive development to the extent that it would potentially allow for a better use of the existing facilities and for more efficient use of surveillance resources at an EU scale. For these benefits to materialize, we suggest that the regulation should state more firmly that market surveillance authorities are obliged to recognize the test results from any accredited test facility in the EU. We further urge the Commission to ensure, in the actual implementation of this measure, a level playing field between private, public and designated test facilities and better define the role of the latter.

Financing and recovery of costs (Article 21). We find it positive that the proposal states that market surveillance authorities need to have sufficient financial resources (Article 21(1)). The proposal also states that market surveillance authorities can charge administrative fees to the economic operator in case of non-compliance (Article 21(2)). In view of a fair distribution of compliance related efforts and cost among economic



operators, it is indeed key that paying fees by companies for market surveillance only applies to non-compliant cases, not for those products that are investigated but turn out to be compliant. Likewise, the proposal should clarify stronger that fees must be proportionate to the nature and likely impact of any non-compliance found.

Use of evidence in investigation findings (Article 25). We oppose to the obligation on Member States to presume non-compliance of products on their territory if the same products are deemed non-compliant in another Member State in Article 25(3), as it may automatically elevate the most restrictive disproportionate measure among market surveillance authorities to the EU level. Practice shows that harmonisation legislation leaves room for interpretation, which results in diverging opinions among market surveillance authorities. Since such interpretations are not necessarily proportionate, there should be a dialogue mechanism where differences of opinion between two or more different surveillance authorities and economic operators can be discussed and resolved. Such a mechanism could for example be included in the Union Product Compliance Network, and would also serve to converge to more uniform interpretations and sense of what is to be considered proportionate. Economic operators should have a direct and formalised possibility to trigger this mechanism.

Customs and market surveillance authorities (Article 26-30). We welcome updated rules to improve cooperation between customs and market surveillance authorities. It is key that non-compliant products are, where possible, intercepted at the point of entry to the EU and that relevant information is shared promptly between involved parties. At the same time, such control and the resulting measures or sanctions must not constitute a trade barrier unreasonably impeding imports from third countries. Border control authorities should only suspend release for free circulation if there is a significant probability of non-compliance or risk. Such controls should be performed in a swift manner. This might otherwise be a burden on companies using imported components in their value chain and favour companies using components manufactured in the EU.

Union Product Compliance Network (Article 31-34). The establishment of an EU network (“Union Product Compliance Network”) could improve market surveillance coordination, especially because Member States would have to designate a single liaison authority (Article 11). We welcome this development and the Commission’s administrative support in the setting up and coordination of this network. We also appreciate the possibility or participation of business associations in administrative coordination groups (Article 32(3)). However, the tasks and competences of the existing coordination groups need to be further clarified. Clear terms of reference will enhance the ability of business associations in contributing meaningfully to the administrative groups.

Financing activities (Article 36). We strongly recommend sufficient allocation of the post-2020 MFF budget – either by establishing a specific budget line or by ensuring adequate allocations to DG GROW for the achievement of the objectives of the proposed Regulation - both for national market surveillance authorities and to put into effect coordination of enforcement activities at EU level. Article 36(5) should make explicit that budgetary allocations are not limited to the current financial framework and also extend to the future MFF.



Penalties (Article 61). We agree that penalties have to be effective, proportionate and dissuasive and support a case-by-case assessment that takes into account the company's previous actions and financial situation. The newly established Union Product Compliance Board could in our view foster convergence over time on this issue.

3. Comments on the Communication accompanying the 'Goods Package'

Companies still face considerable obstacles to the free movement of goods in the Single Market, mainly due to national regulatory barriers and the uneven playing field caused by rogue players that do not comply with EU regulation. Too often, companies have to change their products or labelling, to re-test their products to accommodate national requirements that are unjustified, or find their position undermined by non-compliant products that go undetected. This is why BusinessEurope welcomes the Commission's efforts to improve the legislative framework regarding Single Market for goods with proposals for new regulations in the area of mutual recognition and market surveillance ('compliance and enforcement').

Supporting legislative proposals in the area of mutual recognition and market surveillance with soft-law measures and administrative support is key, because problems with the free movement of goods are not exclusively related to the regulation but also to the application of the rules. Creating a culture of compliance with legal rights and obligations for actors involved is very important and will contribute to better implementation of the new legislative proposals from the Goods Package. BusinessEurope therefore also welcomes the Commission's efforts to improve the implementation of the legislative framework with soft law measures and administrative support.

From the perspective of companies it can be difficult to determine what their rights in the Single Market are and which legislation applies, for example how exactly their product is subject to harmonised and / or non-harmonised legal provisions. This is in particular the case for SMEs who want to engage in cross-border trade in the Single Market. The Goods Package, in conjunction with the proposals for a Single Digital Gateway and the action plan on SOLVIT from the 'Compliance Package' presented on 2 May 2017, can help to improve this situation. Taken together, the proposals can enhance access to information for companies (through the Product Contact Points) and to problem-solving procedures for companies (through SOLVIT) regarding the free movement of goods.

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