



Maija Laurila
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DG SANCO
European Commission
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Dear Ms Laurila,

BUSINESSEUROPE would like to give DG SANCO more details of the concerns we still have with regard to the current European Commission proposal for the Product Safety and Market Surveillance Package and amendments added by the European Parliament.

Since the start of discussions on the Product Safety and Market Surveillance Package, BUSINESSEUROPE called for proportionality and legal clarity to be the decisive factor when defining requirements. In fact, a revision of the General Product Safety Directive was welcomed with the expectation of enhancing legal certainty and simplification.

However, many requirements in the European Commission proposals for a Product Safety and Market Surveillance Package (including subsequent amendments by the European Parliament) are harmful for businesses as they lack clarity and proportionality.

It seems that a direct alignment of Decision 768/2008 is given more weight than simplification and better regulation. The supplementary requirements added by the European Parliament on economic operators will not bring more safety for consumers. Instead, economic operators within the non-harmonized area, which is characterized by low-risk products, risk getting stricter requirements than economic operators within harmonized sectors.

The current European Commission proposals including subsequent amendments by the European Parliament will lead to higher administrative burdens and costs for businesses. Furthermore, several of the new requirements are open to interpretation and will be difficult for market surveillance authorities to enforce and check. This could lead to an uneven level playing field for businesses across the Member States.



These concerns have already been expressed in previous BUSINESSEUROPE position papers and letters.¹ At annex you will find a more detailed list of some concrete issues that BUSINESSEUROPE would like to convey in order to clarify the objectives of legal certainty and simplification on the Product Safety and Market Surveillance Package.

Yours sincerely,

Jérôme P. Chauvin
Deputy Director General

cc: Mr Hans Ingels, Head of Unit, Internal Market and its International Dimension, DG ENTR

¹ [BUSINESSEUROPE position paper \(23 May 2013\)](#).
[BUSINESSEUROPE letter to members of the EP IMCO Committee \(24 September 2013\)](#)
[BUSINESSEUROPE letter to member of the EP \(3 March 2014\)](#)



Annex

Consumer Product Safety Regulation

Scope (Art 2.1)

Products covered by specific harmonized legislation (i.e. New Legislative Framework Directives) should be excluded from the scope in order to ensure legal stability and clarity.

The proposal that the regulation should apply to products '*which are likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them*' is too open to interpretation. It should be stated that products placed on the market for specific use by professionals are not covered by the scope. Also, the inclusion of second-hand products could be problematic if this means retroactive legislation for products placed on the market before the coming into force of the Consumer Product Safety Regulation. This would undermine efforts on waste efficiency.

As a consequence of the above, the draft regulation covers a very wide range of products with very different kinds of risks. This is a big challenge for creating a clear and unambiguous text and leads to defining requirements which might be appropriate for high risk products, but lead to disproportionate requirements for low risk products. Similarly, the Consumer Product Safety Regulation does not take into consideration the extra burdens which will be put on SMEs.

Identification of economic operators (Art 8.7 & 10.3)

Requiring both the manufacturer and the importer's name and address to be printed on the product, unless this is not possible (in which case the proposal states that it should be on the packaging or accompanying documents), is disproportionate for a great number of small low-value products that pose no or an inherently low risk, such as: pencils, post cards or coffee mugs. Furthermore, if deemed appropriate with regard to the risk, it would be more expedient to have a web-address instead of a postal address. More information on the product can be provided on a website. This would also serve as an easy access for consumers to get more information on the product and the manufacturer.

Sample testing of marketed products (Art 8.3 & EP Am: 73 Art 10.6 EP Am: 77 11.4(a) new)

The requirement for both manufacturers and importers to carry out sample testing of products made available on the market is disproportionate for a great number of small, low-value products that pose no or an inherently low risk. Such a requirement poses a number of questions on how to carry out such testing in practice. It gives an unclear position with regard to the legal responsibility for the product. Which testing procedures should be applied? How is such testing to be documented for market surveillance authorities? And as proposed by the EP, how would a 'judicial officer' be involved?



Technical documentation (Art 8.4, Art 8.5 & Art 10.8)

Technical documentation is to be drawn up 'proportionate to the possible risks of a product'. Does this mean that there should always be a technical file, but that its contents will depend on the possible risks, or does it mean that it is up to the manufacturer to decide whether there should be a technical file or not?

Many products under the scope of the proposal for a Consumer Product Safety Regulation are low-risk products with a very short life cycle. It is not proportionate to require technical documentation for *all* products to be kept for 10 years. Neither is it possible for an importer to *keep* such documentation due to confidentiality reasons. In the New Legislative Framework it is required that the importer ensures that the requested documentation is made available to the market surveillance authorities upon request.

Marking obligations (Art 8.6, Art 8.7 & Art 10.3)

The proposal for a Consumer Product Safety Regulation provides obligations for specific markings to allow the identification of the product. Such requirements are imposed for *all* products, irrespective of the possible risks of the product and product's use and life cycle. This is not proportionate. The European Parliament has even added that manufacturers indicate that consumers should retain the 'medium' with this information if the marking is not directly on the product (EP Am: 67 8.6(1)(a) new). Such a requirement gives rise to a number of questions relating to its implementation in practice and appropriateness.

Aspects for assessing the safety of products (Art 6)

Including aspects to assess the safety of products under Chapter I, which applies to *all* consumer products, (i.e. including products covered by specific harmonized legislation) might create confusion and conflicting interpretations. To enhance legal clarity this article should be moved to Chapter II.

In addition, including 'vulnerable consumers' (Art 6.1(d)) and 'consumer expectations' (Art 6.2(h)) when assessing the safety of products is too vague and covers a wide spectrum of situations which escapes normal conditions of liability. Manufacturers cannot be liable for all situations involving vulnerable consumers nor consumer expectations.

Delegated acts (Art 13.3 & Art 15.3)

The proposal for a Consumer Product Safety Regulation grants the Commission the power to adopt delegated acts on identification of economic operators (Art 13.3) as well as delegated and implementing acts on traceability of products (Art 15.3). The provisions on secondary rulemaking undermine legal predictability and risk complicating the rules on product safety. They also create big challenges to transparency and proper consultation of stakeholders.



Market Surveillance Regulation

Lack of distinction between formal non-compliance and non-compliance (Art 19.1)

The lack of distinction between formal non-compliance and non-compliance leading to unsafe products may give rise to different interpretations and disproportionate measures. Thus, the definition of 'products presenting a risk' is unclear and will be difficult to apply in practice. Furthermore, when all products 'presenting a risk' will have to be notified to RAPEX, the notion of a 'risk based approach' to market surveillance will be watered down.

General obligations of economic operators (Art 8(1),(2), Art 9(3) & Art 9(1))

The wording of this article should be aligned with relevant articles of the New Legislative Framework (Decision 768/2008) or at least refer to the applicable sector directives. The examples below show how different enforcement practices might create an uneven level playing field in the context of providing information and technical documentation.

In articles 8(1), (2) and 9(3): economic operators are obliged to make *any* documentation available to market surveillance authorities. However, it should be specified that the type of information/ documentation which can be asked for depends on the "*role*" of the operator in the supply chain. A distributor should not be obliged to provide technical documentation. As this information/ documentation belongs to the manufacturer and is often of confidential nature.

Furthermore, the amount and type of documentation/ information required should be justified. Authorities should not have the right to require *all* the technical documentation if an extract is sufficient. The wording 'further to a reasoned request' and 'documentation necessary to demonstrate the conformity of the product' would be in line with Decision 768/2008 (Art R 2.9).

If any readily available test results and risk assessments have already been carried out or issued in relation to a product, market surveillance authorities should not only "take due consideration" of such tests (Art 9(1)), but include them fully in their assessment.

Penalties and blacklisting (EP Am 129: Art 31(1)(a) new & EP Am 131: Art 31(1)(b) sub 2 new)

Amendments proposed by the European Parliament to centrally define a level of penalties and to propose blacklisting of companies will not lead to a decrease in rogue traders from the market. This provision might prove to be counterproductive as rogue traders can easily change their name (also applicable to: EP Am 90: Art 18(2)(a) new & EP Am 91: Art 18(2)(b) new) of the draft Consumer Product Safety Regulation (above)).

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