



To: Members and Substitutes of the  
Internal Market & Consumer Protection  
Committee (IMCO)

24 September 2013

Dear IMCO members and Substitutes,

**RE: Your vote on the Schaldemose and Pietikäinen draft reports on the product safety and market surveillance package**

It is essential to clarify and simplify the current legal framework on product safety and strengthen market surveillance. The interplay between the various layers of EU product safety legislation is complex and currently leads to uncertainties and incoherence in the internal market. The same is true for the overlapping pieces of legislation on market surveillance.

In view of the European Parliament's Internal Market Committee vote on the product safety and market surveillance package scheduled to take place on 17 October, BUSINESSEUROPE would like to share with you its views on some key elements.

BUSINESSEUROPE calls for simplification efforts that would ease enforcement of the rules and help increase compliance levels of products on the market, which would boost consumer confidence and stimulate sales.

After having initially welcomed the Package's intention to simplify the current legal framework on product safety, we are disappointed to see that many of the amendments being discussed by the IMCO committee would result in the exact opposite: many of proposals risk complicating the legislation and weakening the competitiveness of European business and industry.

In this context, we urge IMCO members to take account of the business position presented at annex.

We remain at your full disposal if you wish to discuss these or other points further.

Yours sincerely,

Markus J. Beyrer

## **ANNEX TO BUSINESSEUROPE LETTER IN VIEW OF THE VOTE**

### **Comments on MEP Christel Schaldemose's draft report on a new Regulation on Consumer Product Safety**

#### *Scope*

A clearer separation between legislation applicable to harmonised and non-harmonised consumer products would simplify the compliance with product rules by economic operators and their enforcement by market surveillance authorities.

Whilst the general principle that all non-food consumer products must be safe applies across the board, the more detailed obligations on economic operators only apply to those operators that are not subject to corresponding obligations laid down in specific product sector harmonising legislation. In this context Chapters II on the 'Obligations of economic operators' and Chapter III on 'European standards providing presumption of conformity' do not apply to products subject to safety requirements laid down in Union harmonisation legislation. Under no circumstances should this be changed.

To obtain even further legal certainty however, BUSINESSEUROPE believes that the legislator could also consider excluding products that fall under specific EU legislation from Chapter I. Otherwise the primary purpose of the package – to clarify and simplify the regulatory framework making it easier for companies to comply and thereby strengthening product safety in the EU- is undermined.

BUSINESSEUROPE also believes that the draft Regulation's proposal to 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 and it would be better to factor in the stated intent of the supplier. 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 new Regulation.

#### *Precautionary Principle*

BUSINESSEUROPE favours an approach to risk that is proportionate and based on risk assessment rather than one that disregards scientific or technical certainty.

The draft report includes numerous references to the precautionary principle, which is unnecessary as it is already clearly detailed in Article 191 of the Treaty on the Functioning of the EU. It is also a principle that is designed for use by the legislator in case of scientific uncertainty. It is not meant to be used by the manufacturer in his risk assessment.

As one of the main aims of the Regulation is to provide a clearer framework for product safety legislation it is essential to ensure that the Regulation does not impose further burdens on those sectors that are regulated.

These same arguments apply to MEP Sirpa Pietikäinen's draft report.

### *CE+ Marking*

BUSINESSEUROPE strongly opposes the proposal (whether voluntary or mandatory) to supplement or replace the current CE mark with a new CE+ mark, which would indicate that the marked product has been tested by an independent third party. This would add confusion, complexity, costs and administrative burdens to the marketing of products in the EU without any corresponding benefits for the consumer. Besides, RAPEX also includes third party tested goods.

CE-marked products that have been lawfully placed on the market have undergone the applicable conformity assessment procedures, which can include third party certification. However, third party testing should not be required for all products. This would constitute a disproportionate deviation from the risk-based approach to conformity assessment as conveyed by the New Legislative Framework modules, and would weaken the competitiveness of EU industry in the global marketplace.

Experience has shown that marks can be easily forged. A new mark would therefore not prevent unsafe products being placed on the market. Instead, public authorities should rather focus their limited resources on ensuring an efficient and equally high level of enforcement of the current CE marking and conformity assessment system.

### *Country of origin*

In a time when companies to a large extent benefit from global sourcing, it may be a challenge to determine the real country of origin. Sector directives under the New Legislative Framework and Chapter II of the proposal clearly states that it is the economic operator who places a product on the market (i.e. by production or import of a product) that is responsible for a product's compliance to EU legislation and that he must indicate an address where he can be contacted.

On the proposal for a mandatory indication on the product of origin issue, the views of the EU business community diverge.

Most BUSINESSEUROPE members see no added value in making the marking mandatory as it will not in itself lead to more product safety or better traceability, but will involve time-consuming procedures and thus lead to higher costs for manufacturers and importers.

Some BUSINESSEUROPE members support the proposal for consumer products to bear a mandatory indication of the country of origin, believing that it would supplement basic traceability requirements.

### *Defining products*

BUSINESSEUROPE is concerned about the request for the Regulation to take into account the notion of child-appealing products when assessing product safety. The safety of consumers, especially children, is of great concern to business. However, given the fact that nearly every product could be considered, in one way or another, appealing for a child due to its colours, sound and shape, it is key to stress the essential supervisory role of parents.

Manufacturers cannot be held responsible for shortcomings and negligence in a child's education and supervision and risk management cannot be taught by restrictions in the design of products.

Proper enforcement of the legislation combined with ad hoc campaigns in the press in certain situations would be much more effective.

BUSINESSEUROPE is also concerned about the proposal to totally ban food imitating products. The Regulation should be aligned with the food imitating products directive 87/357 which would ban a food imitating product if it were to endanger the health or safety of consumers, but not if the food imitating product is actually safe.

Generally speaking, care needs to be taken in product definitions and this also applies to MEP Pietikäinen's draft report. BUSINESSEUROPE is concerned that Amendment 15 (in MEP Pietikäinen's report) may lead to confusion. The notions of 'substance', 'preparation' and 'good' are introduced without giving a more precise definition of a product. Then exceptions are introduced in the product definition. But some of these exceptions are already covered by the exceptions of the scope (Art 2).

#### **Comments on MEP Sirpa Pietikäinen's draft report on a new Regulation for Market Surveillance**

BUSINESSEUROPE welcomes many elements in this draft report, namely the provision that strengthens industry's participation in the European Market Surveillance Forum, the fact that reference laboratories should be accredited as per NLF provisions and the rapporteur's support for the establishment of a pan-European injuries database. These are all issues that BUSINESSEUROPE called for.

In particular, it is positive that MEP Pietikäinen's report aims to tackle the problem of market surveillance authorities sometimes acting disproportionately or arbitrarily when taking action against a product, despite conformity or compliance with relevant legislation. In these cases BUSINESSEUROPE fully supports the proposal that it should be the market surveillance authority who should demonstrate that the product presents a risk and believes that this will contribute to better legal certainty for business. BUSINESSEUROPE is also pleased to see a reference to 'reasoned' requests by market surveillance authorities to economic operators when the authorities require documentation and information.

#### *Mandatory third party auditing of quality management systems of economic operators*

BUSINESSEUROPE is concerned about MEP Pietikäinen's proposal to the Commission to investigate introducing the option for mandatory third party auditing of quality management systems of economic operators. This would be a bureaucratic pre-market measure, be costly for companies (SMEs in particular) and would not contribute to more compliance.

#### *Definition of risk*

BUSINESSEUROPE believes it is necessary to distinguish (safety) risk from other non-conformity issues, to have better definitions of the various degrees of safety risks and

to distinguish material non-conformity of the product itself from formal non-conformity relating to flaws in the documentation or marking. Proportionality must be ensured so that the different categories of non-conformity do not lead to the same measures. The report tries to clarify the notions of (safety) risks versus non-compliance but they remain entangled in a confusing manner.

BUSINESSEUROPE believes that only safety issues represent a risk. Other shortcomings should be referred to as non-compliance.

BUSINESSEUROPE proposes the following definitions:

- Non-compliance = not meeting legal requirements under Community legislation (can refer to any of the 3 following points, or to material non-compliance not related to safety)
- Risk: related to the probability to impact safety
- Serious risk: same as above but the severity needs clarifying (= effects and occurrence chance) and urgency (how fast to act).
- Formal non-compliance = shortcomings in marking and paperwork while product itself is fine.

Furthermore, only goods with a serious risk should be notified via RAPEX.

#### *Fees and Penalties*

Effective market surveillance requires considerable financial resources, which it is generally agreed are lacking.

However, BUSINESSEUROPE urges caution with regard to the proposal to partly finance market surveillance by fees charged to economic operators. In no way should this be used as an incentive for market surveillance authorities to take unnecessary corrective actions as a way of making financial gains.

Regarding penalties, these must be proportionate and dissuasive. BUSINESSEUROPE does not believe that harmonised penalties can be fixed at European level. In particular, BUSINESSEUROPE is concerned about the proposal in the draft report to set administrative penalties for the relevant economic operator at no less than 10% of its total annual turnover in the preceding financial year. This figure, which could easily exceed the profit of the whole year, would cause major disruptions for companies, their employees and the economy at large.

BUSINESSEUROPE also urges caution with regard to the proposal for the Commission to publish all sanctions imposed by Member States as this may cause reputational damage that is disproportionate to the actual irregularity detected by the authority.

It should not be up to the market surveillance authorities themselves to determine the conditions for charging fees/penalties but should be left to the legislator in the Member States. Lastly, it is also essential that surveillance authorities refrain from targeting economic actors on minor non-compliance issues such as insignificant editorial errors in declarations of conformity.

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