BUSINESSEUROPE

Mr Stefano Soro
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DG SANCO, Directorate B, Unit 3
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Dear Mr. Soro,

BUSINESSEUROPE would like to provide you with some comments in the framework of the ongoing consultation on the development of the RAPEX risk assessment guidelines (RAG) for non-food consumer products.

As our reply to the consultation does not fit in easily with the questionnaire we hope that the following written comments will be of useful input to you.

In principle, we support the European Commission's development of guidelines as these can serve to contribute to the development of a common approach to assessing serious risks leading to a common basis for RAPEX notifications. Well-defined, public RAGs that provide clear criteria for RAPEX notifications can contribute to more coherent market surveillance in the EU.

However, we feel that there are some ambiguities which need to be clarified, which are the following:

- The concept of 'serious risk' from the RAG needs to be put in a clearer perspective with those of other applicable EU legislation.

Fragmentation of policies needs to be avoided and the RAG should be fully in line with applicable standards that deal with risk assessment and safety issues. Business needs a common understanding of the risk concepts across all EU market surveillance in order to avoid legal uncertainty.

- A stronger link is needed with new Regulation 2008/765/EC of 9/07/08

The new Regulation setting out the requirements for accreditation and market surveillance relating to the marketing of products imply that the use of the RAPEX system shall be extended for notifying serious risks for all products placed on the Community market under harmonised legislation.

The Regulation highlights that information tools will be geared to extending existing tools (such as RAPEX) as opposed to creating new ones. Therefore, we believe that

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more is needed on the relationship between the provisions of the new Regulation and the existing RAPEX system in the context of these guidelines.

- Caution is needed when applying the RAG to the harmonised area

In connection to the above point, when the RAPEX notifications system is used for products covered by harmonised legislation the RAGs should put more emphasis on the circumstances involving the product. This is because the risks related to the product itself will have been previously assessed by the manufacturer according to the applicable requirements of product specific legislation, including any standards.

In this context, safety is ensured first by actual compliance to the requirements of the applicable (specific) legislation. Consequently, it should be stated clearly in the guidelines that the first step in the procedure is to check the relevant documents (including the risk assessment made by the manufacturer). The RAG could indeed be a valuable and necessary tool for addressing any residual risks or if there is a non-conformity. In cases of non compliance corrective measures should be taken, proportionate to the circumstances and along the procedures set out in the New Legal Framework. In all cases there should be dialogue between the enforcement authorities and the company concerned.

BUSINESSEUROPE underlines that the guidelines should in any case not be used to assess possible non-conformity of products subject to harmonised legislation in general, but used appropriately in cases where:

- A non-conformity to the essential safety requirements of specific legislation has been detected (by checks of the manufacturer's declaration of conformity, and where relevant, the product technical file and applicable standards);
- Where there is neither harmonised legislation nor any appropriate standard for assessment of the relevant risk.

As BUSINESSEUROPE we strongly support a co-ordinated approach to market surveillance and support the development of common guidelines for assessing 'serious' risks under the RAPEX procedure.

We look forward to further cooperation with you.

Yours sincerely,

Jérôme P. Chauvin
Director
Legal Affairs Department
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