



European Commission
Commissioner Borg
DG Health & Consumer Affairs
1049 Brussels

Brussels, 13 December 2012
AB/EG/12L-Borg-Isolated cases-EN2

SUBJECT: Review of the General Product Safety Directive

Dear Mr Borg,

We are writing on behalf of UEAPME, the European Association of Craft, Small and Medium-Sized Enterprises, which represents approximately 12 million SMEs across Europe and UGAL, the Union of Groups of Independent Retailers of Europe, which represents 25 groups of independent retailers and associations of those groups, bringing together more than 300,000 independent retailers and representing more than 5 million jobs.

The General Product Safety Directive (GPSD 1) is currently under review. This review is likely to result in a General Product Safety Regulation as well as a linked Market Surveillance Regulation (the New Regulations). The New Regulations should be used as an opportunity to reduce certain administrative burdens that have come to light due to the uncertainty of specific rules set down by the GPSD 1.

A particularly burdensome problem for SME retailers, experienced under the GPSD 1, is how to deal with *“isolated cases”*. The guidelines accompanying the GPSD 1 (1) illustrate that circumstances exist which, while safety issues may arise in relation to a product, do *“not require any verification, monitoring or action by the authorities and do not provide information useful for risk assessment or consumer protection”* (2). This may be because solid evidence exists that any risk has been fully controlled or that only a limited number of products or batches are concerned, which have been managed.

Whilst a single consumer complaint may exist which identifies a perceived risk, the reality may often be that any damage is due to the misuse of the product by the

(1) Guidelines for the Notification of Dangerous Products to the Competent Authorities of the Member States by producers and distributors in accordance with Article 5(3) of Directive 2001/95/EC

(2) Guidelines for the Notification of Dangerous Products to the Competent Authorities of the Member States by producers and distributors in accordance with Article 5(3) of Directive 2001/95/EC, Chapter 3.3

consumer, rather than an inherent dangerous defect, design or risk posed by the product. In these cases, **no** notification to competent authorities should be made. This avoids proliferation of RAPEX notifications and promotes active risk management between supply chain partners.

Whether or not a particular identified incident represents an isolated case will not always be immediately obvious to SME retailers, even if they belong to a wider group structure. This is because such retailers do not have the same resources (e.g. in-house testing facilities) to assess product risk, as an integrated retail chain would have. Producer input is required to confirm the existence, or not, of an isolated case.

If an SME retailer is uncertain as to whether or not an isolated case is present, two particular scenarios can arise:

Scenario i) only very obvious public health risks will be passed on to competent authorities when identified, leaving considerable potential important risk information under the radar (the ‘tip of the iceberg’ problem).

Scenario ii) the retailer may take a highly cautious view of all feedback concerning products and may contact the competent authorities immediately, often unnecessarily. This can lead to notification overload for competent authorities.

In **Scenario iii)**, the initial processing of the notifications requires time and resources on the part of Member State competent authorities. It also can lead to unjustified RAPEX (3) notifications by a competent authority on the basis of information unnecessarily passed on by retailers. Such a notification could potentially expose the retailer to large litigation costs as a co-defendant with the appropriate competent authority, via the chain of causation in a civil case.

Isolated cases: the pragmatic legislative solution

There is one simple solution to clarifying the obligations of SME retailers in isolated cases.

We advocate for the inclusion of a concrete clause on “isolated cases” in the text of the New Regulations.

The relevant clause **already exists** in the Guidelines to the GPSD 1 and states: *“distributors who have doubts about the safety of a product or whether a dangerous product represents an ‘isolated case’ must transmit to the producer the information they have. They can also contact the competent authorities for advice on how to proceed (4).*

(3) For further information see: Results of the Public Consultation on the Revision of the General Product Safety Directive

(4) Guidelines for the Notification of Dangerous Products to the Competent Authorities of the Member States by producers and distributors in accordance with Article 5(3) of Directive 2001/95/EC, chapter 4.1

Since this wording *has previously been accepted* by the European Commission, MEPs, Member States and other stakeholders, this should be acceptable for future use in the New Regulations, as well.

The above-mentioned text clearly expresses a preference for initial action to be B2B cooperation between distributors and producers. This is a vital concept, which must be further strengthened in order to limit the negative consequences explained in scenarios i), ii) and iii) above.

Move from soft to hard law

Due to the “soft” nature of the GPSD 1 guidelines, there are **no legal guarantees** that their interpretation of isolated cases will be reflected in Member State legislation.

The influence of the GPSD 1 guidelines on SMEs is very doubtful. Such non-binding, “soft law” guidelines, only available via an obscure hyperlink from a European Commission webpage, are unlikely to be consulted, and known, by SME retailers.

“Hard law” provisions (i.e. a relevant Directive or the national implementation thereof) are the only way in which legal certainty can be achieved for SME retailers and only in this way will the “Smart Regulation” approach, in line with the “Think Smart First Principle”, be respected in the case of isolated cases.

We are convinced that such a legal provision on isolated cases in the New Regulations will clarify how SME retailers should best deal with isolated cases. This will reduce the administrative burden on SMEs, reduce the risk of expensive litigation, facilitate an effective supply chain for consumer goods, contribute to the efficient work of Member State competent authorities and ensure overall product safety in Europe.



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