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REVISION OF THE GENERAL PRODUCT SAFETY DIRECTIVE RESPONSE TO PUBLIC CONSULTATION

Introduction

BUSINESSEUROPE welcomes the opportunity to submit comments in the context of the current public consultation on the revision of Directive 2001/95/EC on general product safety (the GPSD).

BUSINESSEUROPE considers that a revision of the GPSD at this point is premature, given that it is to a large extent triggered by the New Legislative Framework (NLF)¹, which only entered into force in January 2010. In this context, the effectiveness of the new market surveillance regime and of the sector legislation to be aligned with the NLF should be awaited and assessed first before a revision of the GPSD is launched. This would also be in line with Article 40 of Regulation 765/2008/EC on accreditation and market surveillance which requires the Commission to submit a report by September 2013 on the application of this Regulation, of the GPSD and of any other relevant Community instrument addressing market surveillance.

Any future changes to the GPSD must be evaluated in the context of the overall EU regulatory regime for products: the NLF (including all sector specific legislation) and the GPSD together. Legislation based on the NLF sets requirements using legislative procedures that provide for extensive consultation with the Council and European Parliament, allowing for a widespread involvement of stakeholders such as business, at both the national and European level. The GPSD operates through comitology which can be at odds with important principles of democratic balance and stakeholder involvement.

BUSINESSEUROPE suggests that a GPSD revision should predominantly aim to improve the consistency of the legislation in support of product safety and guarantee decision making at the right political levels. Not only will this serve the public interests better but it will also be beneficial for authorities, consumers and economic actors alike. Rather than focusing on legislative technicalities in isolation, a political vision should be developed on the total palette of regulatory instruments needed to ensure safety and other public interests. We advocate that the Commission elaborates on such a vision before embarking on a revision of the GPSD.

¹ The NLF consists of two complementary instruments: Regulation 765/2008/EC on accreditation and market surveillance and Decision 768/2008/EC establishing a common framework for the marketing of products.



Present regulatory framework for goods

The New Legislative Framework (NLF) defines how regulatory requirements for products are set, what economic actors must do to ensure, demonstrate and declare compliance, and how authorities can verify compliance and act upon shortfalls. Legislation based on the NLF constitutes the harmonised domain which covers both consumer and professional products and addresses public interests including, but not limited to, safety.

For products in the non-harmonised domain no specific EU requirements exist. However, as far as the safety of consumer products is concerned, the GPSD provides for a general safety requirement. The content of this general requirement is to be specified by national rules, standards or further relevant elements (Article 3 GPSD). Following the principle of mutual recognition, a product lawfully marketed in one Member State and not subject to Union harmonisation should be allowed to be marketed in any other Member State, even when the product does not fully comply with the technical rules of the Member State of destination.

BUSINESSEUROPE is of the opinion that the above-mentioned provisions for the harmonised and non-harmonised area adequately cover foreseen safety risks for all products traded in the EU market. However as innovation proceeds, serious and urgent safety issues may manifest themselves unexpectedly after a product has been placed on the market. The GPSD gives authorities the powers and means to act swiftly in such situations. This may include measures such as mandatory risk warnings, product trade suspension, recalls, and the introduction of new specific EU product requirements addressing the just discovered safety risk.

The New Approach Directives, to which the NLF is applicable, are decided upon by the Council and European Parliament, on a proposal from the Commission. They contain essential safety requirements and use a mechanism of presumption of conformity with voluntary standards. During the whole process there are several requirements to consult stakeholders. The GPSD however mainly thrives on comitology and empowers the Commission to develop measures for unsafe products with a much more limited stakeholder involvement.

While the urgency of incident handling can justify shortcut procedures, BUSINESSEUROPE urges for a single and democratic procedure to define permanent product requirements.



Principles for a coherent regulatory framework for goods

In BUSINESSEUROPE's view, the regulatory framework for goods must include instruments and procedures to:

- Pro-actively set solid requirements addressing anticipated threats to public interests;
- Ensure, demonstrate and declare compliance to requirements by economic actors;
- Empower authorities to verify compliance and act upon shortfalls;
- Take rapid corrective action by the authorities upon unexpected, serious threats;
- Swiftly define temporary requirements to avoid repetitive damage caused by formerly unexpected serious threats that became apparent.

These instruments must obey general principles of good regulation including:

- Proportionality, taking into account the magnitude and seriousness of the risk;
- Effectiveness, efficiency, consistency and transparency;
- Respecting and enabling a level competitive playing field;
- Requirements setting via democratic processes including stakeholder involvement;
- Legal certainty.

In this context, BUSINESSEUROPE envisions the following objectives for a future revision of the GPSD:

Setting specific product safety requirements:

BUSINESSEUROPE believes that legislation based on the New Legislative Framework (NLF) should govern the setting of permanent, specific EU product requirements, including those addressing formerly unanticipated safety risks unveiled by incidents that may first have been swiftly and temporarily addressed under the GPSD.

The GPSD should manage incidents to protect consumers from the immediate, serious threats that cannot be adequately addressed by NLF instruments given the magnitude, nature and urgency of each case. Instruments may include mandatory risk warnings, trade suspension, recalls, and setting of temporary requirements through comitology.

Temporary measures can address individual products or categories as the case may require, and should be enforceable until permanent measures take effect.



This does not mean that new legislation would necessarily always be needed. Indeed, this could be disproportionate as often solutions to product safety can be reached by adding elements to existing standards, drafting new standards or amending existing legislation. However, BUSINESSEUROPE believes that the **GPSD should in general not serve to define permanent specific EU product requirements**, especially not for entire product categories.

In this way the GPSD will avoid creating a separate body of requirements and will instead focus on managing urgent safety problems and, based on those, can prioritise new elements for the harmonised domain. This will also guarantee that permanent specific EU requirements for product categories are defined via a single, democratic procedure, thereby maximising legal certainty and regulatory consistency whilst not compromising safety.

The use of the GPSD in the harmonised domain should be made exceptional. Directives based on the NLF intend to comprehensively regulate the safety of covered products and include essential safety requirements. Moreover, Article R33 of Decision 768/2008 provides for a particular procedure for the Commission to take appropriate action in cases of compliant products which nevertheless present a risk to health and safety. Therefore, in the harmonised domain, the use of the GPSD instruments should be limited to other most pressing and serious risks.

As to temporary requirements defined by the GPSD, BUSINESSEUROPE welcomes the use of standards but urges to apply them similarly to what was introduced originally by the New Approach. That is, compliance with a standard can give presumption of conformity but shall essentially be voluntary. Non-compliance to the standard should thus not automatically give assumption of non-conformity if the supplier has an alternative underpinning of why the product is safe. Any other approach would unnecessarily limit freedom of ways to meet the requirements and thereby stifle competition and innovation, which may even go at the expense of improving safety.

Standardisation procedures

BUSINESSEUROPE sees no compelling reason for changes to the procedure for the adoption of standardisation mandates and the elaboration of European standards as foreseen under Article 4 of the GPSD.

The consultation characterises the making of mandates as "a slow, bureaucratic and inefficient process". We believe this is rather misguided as the same procedure works reasonably well in other areas of Community legislation.

The procedure laid down in Directive 98/34/EC for the issuance of formal mandates is and remains necessary in order to ensure proper stakeholder involvement and a thorough business impact assessment, in order for the future standards to reflect market need and relevance.

Regarding the proposed use of standards other than those adopted by the European Standardisation Organisations, we urge to maintain consistency of procedures between



the harmonised and the non-harmonised domains. We draw attention to the discussions on this subject going on in the context of the review of the general legal framework for standardisation.

It seems that the present proposals on GPSD standardisation procedures are mainly inspired by a desire to speed up the process for addressing emergency cases quickly. In connection to the above discussion on permanent versus temporary measures setting, a clear demarcation is needed on the kinds of cases for which requirements and standards need to be adopted more quickly, with certain conditions applicable for speedier procedures as to their scope of application and guarantees for proportionality. In addition, mandates should not evolve into detailed, quasi mandatory requirements.

Alignment with the New Legislative Framework – Market Surveillance

Concerning the suggested alignment of the market surveillance provisions contained in Regulation 765/2008 and the GPSD, BUSINESSEUROPE believes that coherence and consistency are of the essence. Only a clear and easy-to-implement regulatory framework can support efficiency of enforcement throughout the EU.

As things currently stand, the area of harmonised consumer products comes under the market surveillance provisions of both the GPSD and the Regulation. This situation of overlap creates confusion amongst market surveillance authorities with regard to the enforcement of relevant legislation and can create legal uncertainty for economic operators and consumers.

BUSINESSEUROPE calls on the Commission to use any future revision of the GPSD to aim at **uniformity of rules on market surveillance**, covering all products placed on the market, whether consumer or professional products, whether in the harmonised or the non-harmonised domains.

BUSINESSEUROPE appreciates that effective market surveillance and incident handling require adequate instruments, some of which necessitate requirements for economic actors. However, **proportionality is of the essence and we are concerned about legislative overshoot**. Given the nature of many products in the non harmonised domain we strongly suggest defining GPSD requirements for traceability and other issues such as labelling in a less stringent way than as currently defined in the NLF.

As an example, traceability is essential to deny rogue economic actors an easy route to ignore the law. However, printing the factory and importer's name and address on each and every pencil would be highly disproportionate and against the interest of the consumer. Likewise, any evaluation of recall effectiveness should take into account the nature of the product, distribution chain, and typical use patterns.



Further aspects addressed in the public consultation

Services

BUSINESSEUROPE believes that the scope of the GPSD with regard to services should not be revised since the current GPSD notion of a 'product' is just right: it is intended for or likely to be used by consumers and is made available in the course of a commercial activity, including in the context of providing a service. We would oppose any extension of the Directive's scope to products used by service providers, even in the context of a service provided to a consumer, as they are professional users.

Online Trade

The GPSD states that it should apply to products irrespective of the selling techniques, including distance and electronic selling. In this context, no legislative changes are needed in this area.

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