EUROPEAN COMMISSION
Impact Assessment Board

Brussels,
D(2012)

Opinion

Title

DG SANCO and DG ENTR - Impact Assessment on a proposal for a Directive 2001/95/EC on general product safety and the proposal for a Regulation of the European Parliament and of the Council on market surveillance for products

(draft version of 17 August 2012)*

(A) Context

The free movement of safe and compliant products is one of the cornerstones of the European Union. While the EU adopted harmonisation rules for a large number of industrially manufactured products and the General Product Safety Directive (2001/95/EC) for consumer products, the free movement provisions of the Treaty and the mutual recognition principle govern the remaining product categories. Furthermore, the General Product Safety Directive (GPSD) together with Regulation (EC) No 765/2008 provide today an EU legal basis for market surveillance of all consumer products (harmonised or not) and for all harmonised products (consumers and professional). However, the existing regulatory framework leads to overlapping product safety and market surveillance requirements, creating confusion on the part of both operators and national authorities. Moreover, the market surveillance has not kept pace with the increasingly globalised market and remained largely national-oriented. This impact assessment therefore examines how to consolidate and amend the instruments concerned.

(B) Overall assessment

The report should be improved in a number of respects. Firstly, it should better present the drivers that lead to the presence of unsafe or otherwise non-compliant products on the EU market and identify the most significant ones. In particular, the report should better explain if the ineffectiveness of existing legislation on product safety and market surveillance stems from its form, substance, implementation or a combination thereof. Secondly, it should present the policy options in greater detail, clarify how they differ from the status quo and explain how they are expected to work in practice. This should include a proper justification for discarding some options, particularly if promoted by stakeholders. Thirdly, the report should present the magnitude of impacts with more caution, namely when the evidence is lacking or inconclusive. For example, it should substantiate the alleged significant decrease in costs of economic operators or the slight increase in costs for national market surveillance authorities. Furthermore, the report should estimate costs to be borne by the EU budget. Finally, it should better present the different views of the main stakeholder groups on all key aspects.

In their written communication with the Board, DG SANCO and DG ENTR accepted to amend the report along the lines of these recommendations.

* Note that this opinion concerns a draft impact assessment report which may differ from the one adopted

(C) Main recommendations for improvements

(1) Improve the problem definition and the baseline scenario. The report should present the problem drivers in a more concrete and structured way and indicate those that are considered to contribute most to the presence of unsafe/non-compliant products on the single market (e.g. related to border controls). It should better explain if the ineffectiveness of existing legislation on product safety and market surveillance is related to its form, substance, implementation or a combination thereof. Furthermore, the report should clarify the role and responsibility of retailers/distributors in ensuring product safety in general and explain the distribution of related competences at EU and national level. It should also explain to what extent the divergent sanction regimes and consumer unawareness or indifference contribute to the problem. It should then develop the baseline scenario by better explaining why the numerous ongoing and planned activities (such as the market surveillance enhancing actions, training, peer reviews or guidance) are not expected to improve the current situation.

2) Better present and explain the content of the options. The report should describe the content of measures under each of the identified options in detail and clarify which problem drivers and objectives they aim to address. In particular, it should explain what alignment of the product safety requirements "as much as possible" means, describe all new obligations that would be imposed on producers/importers of non-harmonised consumer products and clarify if there are any genuine alignment alternatives. The report should also explain how: (i) the foreseen obligations for national surveillance authorities differ from the status quo, (ii) the envisaged single forum of market surveillance is expected to bring change in practice and (iii) the divergences in safety evaluations of identical products by Member States will be addressed. Finally, the main text should recall all the options or measures favoured by stakeholders but discarded, with a proper justification for doing so and/or indication of further analytical steps (e.g. in relation to safety requirements for services, non-harmonised professional products or products marketed via the Internet).

3) Strengthen the assessment of impacts. The report should provide a more nuanced assessment of impacts that would duly reflect the lack of conclusive evidence. For example, it should justify the "substantial" decrease in costs of economic operators caused by the alignment of legislation or the "slight" increase in costs for national authorities. In doing so, the report should indicate if and under what conditions some Member States will be impacted more than others. Given that the financial burden will be borne mostly by the EU budget, the report should estimate the resources needed and identify their source. It should also address expected indirect (social or other) impacts. Importantly, simplification measures should be recalled as part of the preferred policy package, their impacts described in detail and synergies with the remaining part of the package highlighted.

4) Better present stakeholders' views. The report should present the divergent views of stakeholders more accurately, particularly when they are conflicting or contrary to the presented arguments (e.g. related to the performance of market surveillance authorities, effective traceability or a need for an EU coordination body). Furthermore, consumer views should be presented in a separate section rather than included under "other stakeholders".

Some more technical comments have been transmitted directly to the author DG and are expected to be incorporated in the final version of the impact assessment report

(D) Procedure and presentation
The report would benefit from better structure, more focus and neutral language. It should explain (preferably in an Annex) how the market surveillance is currently organised, including the existing processes for cooperation. In order to keep the length of the report at a reasonable level, all the background, illustrative or duplicative information should be moved to an Annex. The executive summary should be amended in line with the above remarks and shortened to a maximum of 10 pages.

(E) IAB scrutiny process	
Reference number	2010/SANCO/031 and 2012/SANCO+/019
External expertise used	No
Date of IAB meeting	19 September 2012 (Written Procedure)