EUROPEAN COMMISSION

Brussels, 18.9.2013
C(2013) 5725 final

Mr Winfried KRETSCHMANN
President of the Bundesrat
Leipziger Straße 3 - 4
D – 10117 BERLIN

Dear President,

The Commission would like to thank the Bundesrat for its Opinion on the Commission proposal for a Regulation of the European Parliament and of the Council on market surveillance of products and amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC,2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EU) No 305/2011, Regulation (EC) No 764/2008 and Regulation (EC) No765/2008 of the European Parliament and of the Council {COM(2013) 75 final}.

The Commission welcomes that the Bundesrat supports the objectives pursued by the proposed Regulation, i.e. to harmonise market surveillance in the Member States and to improve the functioning of the internal market.

The Commission notes that the Bundesrat is concerned that the proposed Regulation would not help in simplifying the current legal framework for market surveillance but would instead put additional burdens on national authorities, and therefore considers that the new regulation should more closely reflect the principles of Regulation (EC) No 765/2008.

However, the Commission observes that its proposed Market Surveillance Regulation (hereinafter 'the proposal') does not depart in substance from Regulation (EC) No 765/2008 and the principles of the New Legislative Framework [1], which remain a major landmark in setting up the market surveillance framework for the internal market. The purpose of the proposal is to integrate in one single piece of legislation the market surveillance rules developed in the area of harmonised products and those contained in Directive 2001/95/EC on General Product Safety[2] (the "General Product Safety Directive" or simply GPSD).

The Opinion of the Bundesrat contains a number of very detailed suggestions addressed to the German Federal Government with the aim of improving the Commission's proposal during the on-going negotiations. The Commission acknowledges these suggestions and, when

[1] OJ L 218, 13.8.2008, p. 30 and p.82.
[2] OJ L 11, 15.1.2002, p. 4.

relevant, will consider them in the context of the negotiations with the European Parliament and the Council.

Without prejudice to these negotiations, the Commission would like to make a number of comments in response to the more specific issues raised, particularly in point 4 of the Bundesrat's opinion. These comments are reflected in the annex enclosed to this letter.

The Commission hopes that these clarifications address the concerns raised by the Bundesrat and looks forward to continuing our political dialogue in the future.

Yours faithfully,

Maroš Šefčovič
Vice-President

Commission reply to the Opinion of the Bundesrat on the Commission proposal for a Regulation of the European Parliament and of the Council on market surveillance of products and amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC,2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EU) No 305/2011, Regulation (EC) No 764/2008 and Regulation (EC) No765/2008 of the European Parliament and of the Council {COM(2013) 75 final}

Scope

As the proposal aims at having as far as possible a single set of rules for all products, it also repeals market surveillance provisions contained in a number of sector-specific Union harmonisation legislative instruments. The underlying idea is that requirements specific to any sector are reflected in the product-related requirements laid out in those directives or regulations, but do not usually justify different arrangements for market surveillance. However, the proposal does not preclude the application of more specific market surveillance rules where appropriate and acknowledges certain exceptions to the application of horizontal provisions.

Where appropriate, the Commission will provide additional guidance to clarify the interaction between more specific sectoral market surveillance rules and the proposed Market Surveillance Regulation.

Compliance versus risk-based approach to market surveillance

For harmonised products, compliance with EU harmonisation legislation remains a key concept of the proposal. Products found to be not compliant with material product requirements laid down in EU legislation should be considered as products presenting a risk. Conversely, compliant products are presumed not to present a risk. Indeed essential requirements laid down in EU harmonisation legislation provide the benchmark for the desired level of protection of a given public interest (e.g. safety) as established by the legislator. Action can be taken against compliant products if new evidence – which could not be reflected in established legislation, i.e. evidence that could not be taken into account when the legislation was drafted - shows that the product nevertheless presents a risk. This principle is consistent with the New Legislative Framework.

Non-compliance with requirements such as CE-marking or labelling is not necessarily unrelated to the risk presented by a product. They might for instance suggest that the manufacturer has disregarded applicable legislation: in such a case the fact that a manufacturer disregards formal requirements may be an indication that he or she also disregards the essential product requirements (see Article 9(2)). If however formal non-compliance does not bring about material risks (relating to health and safety or other public interested protected by EU legislation), the proportionate response will be to ask the economic operator to rectify non-compliance without necessarily restricting the circulation of the product. This would not prevent market surveillance authorities from imposing fines. The Commission therefore agrees that the check of compliance with formal product requirements remains within the remit of market surveillance and the proposed new Regulation.

The Commission agrees that when checking compliance the decisive factor is compliance with the requirements and not with the standards, although it recalls that compliance with harmonised standards provides a presumption of compliance with the requirements, unless the standard has been challenged.

Market surveillance should actively enforce all requirements of internal market legislation and not only those relating to health and safety – which are of course very relevant; otherwise compliant economic operators will be left alone to face the unfair competition of unscrupulous operators.

Rules on risk assessment

There is an inherent link between compliance evaluation and risk assessment. As mentioned in the section above, compliance is assessed against product requirements which – as the opinion of the Bundesrat acknowledges – are already based on "extensive, scientific, product-related risk assessment" and constitute the level of risk accepted by the legislator. A non-compliant product presents a level of risk higher than the level accepted by the legislator. When assessing non-compliance a market surveillance authority is relying on the risk assessment underpinning existing legislation at the moment of its adoption. Additional risk assessment could only be justified on the basis of new evidence not yet accounted for in the legislation.

The reference to Annex I of Regulation (EC) No 1907/2006 is relevant because it puts forward the specific risk-assessment criteria to be taken into account when it comes to chemical substances. This however does not prevent the REACH competent authorities from discussing and elaborating any necessary additional guidance in the relevant working group.

The guidelines on risk assessment developed for the Community Rapid Information System (RAPEX) notifications in the field of health and safety are regarded as helpful by market surveillance authorities. In accordance with Action 5 of the Multi-annual Plan for Market Surveillance {COM(2013) 76 final}, the Commission is now developing, with the contribution of Member States, an EU general risk assessment methodology for the assessment of risks in other areas (notably environmental protection). Once finalised the extended methodology is expected to have the same status as the current RAPEX guidelines.

Extension of the RAPEX system

The extension of the use of the RAPEX rapid alert system responds to the need to ensure a swift exchange of information among authorities on all measures taken for both serious and less than serious risks. This is essential to widen the impact of national measures from the territory of a single Member State to the whole EU.

Empowerment of the Commission to adopt implementing measures to specify the carrying out of market surveillance (Articles 6 and 12)

The organisation of market surveillance at national level is a national competence; however it should follow general rules set at EU level. General requirements of a national market surveillance framework are already laid down in Regulation (EC) No 765/2008. Any Commission implementing act specifying some of these requirements would be defined in accordance with the rules of Regulation (EU) No 182/2011 which defines the rights of the Member States.

National market surveillance programmes (Article 7)

Information contained in general market surveillance programmes provides for an insight on how market surveillance is organised in each Member State (who is competent for what, how authorities coordinate their actions at national level, cooperation with customs, etc.). The extent of financial resources, staff, technical and other means are essential pieces of information in this regard. General market surveillance programmes contribute to transparency on the fulfilment of the requirements of Articles 5 and 6 of the proposal.

Reporting obligations

The Commission welcomes the use of any technical means, notably the Information and Communication System on Market Surveillance (ICSMS), to allow reporting with the least possible burden on market surveillance authorities. For this reason, the proposal provides a stronger legal basis for the mandatory use of ICSMS.

Internet advertising and exhibitions

According to the proposal market surveillance authorities would be empowered to make all appropriate checks on products falling within the scope of Article 2(1). The requirements applicable to those products are however set respectively in the consumer product safety regulation proposal {COM(2013) 78 final} and in the Union harmonisation legislation. The market surveillance regulation proposal does not modify those requirements and the conditions for their applicability.

Fees

The provision on fees clarifies that market surveillance authorities can charge fees to cover wholly or partly the costs of their activities. That is not an obligation but an opportunity, especially for Member States that currently lack such a legal basis.