REGULATORY MARKET SURVEILLANCE OF PRODUCTS

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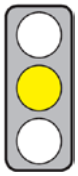
Centrum für Europäische Politik

KEY ISSUES

Objective of the Regulation: The surveillance of products presenting a risk is to be improved.

Parties affected: Consumers and companies, market surveillance authorities.



Pro: (1) Combining the provisions on market surveillance into one piece of legislation ensures greater legal certainty for companies and the market surveillance authorities.

(2) Standard effective market surveillance promotes competition in the internal market and increases investment and planning certainty for companies.

Contra: (1) The wording "product presenting a risk" is too imprecise. It should be replaced by "non-compliant" in order to make it clear that the market surveillance authorities have to examine compliance with all requirements under EU law.

(2) The deployment of RAPEX should remain restricted to products presenting a serious risk.

CONTENT

Title

Proposal COM(2013) 75 of 13 February 2013 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) No. 765/2008 of the European Parliament and of the Council

Brief Summary

In the absence of any indication to the contrary, references relate to Proposal for a Directive COM(2013) 75.

- **New rules on market surveillance and product safety**
  The "Product Safety and Market Surveillance Package" proposed by the Commission includes
  – the Regulation on market surveillance of products [COM(2013) 75 see this cep**PolicyBrief**]
  – the Regulation on consumer product safety [COM(2013) 78, see cep**PolicyBrief**], which contains duties for companies in particular,
  – the Communication on more product safety and better market surveillance [COM(2013) 74],
  – the Action Plan for product surveillance 2013–2015 [COM(2013) 76] and
  – the Report on the implementation of market surveillance [COM(2013) 77].

- **Background and aims of the Market Surveillance Regulation**
  – Regulatory "market surveillance" (Art. 3 No. 11) is to ensure that products in the EU internal market
    - do not represent a risk to "any aspect of public interest protection" – e.g. health, safety, consumer protection, the environment (Art. 3, No. 13) – and
    - comply with the harmonisation legislation (Art. 3, No. 18) which lays down EU-wide rules on the marketing of numerous types of products (cf. Recital 40) with requirements such as standards for health and safety.
  – The existing rules on market surveillance are "fragmented and confusing" [COM(2013) 74, p. 5]; they are dispersed between
    - the Regulation on accreditation and market surveillance (No. 765/2008),
    - the Directive on general product safety (2001/95/EC) and
    - numerous pieces of product-specific harmonisation legislation.
  – The proposed market surveillance Regulation will group the market surveillance provisions on "non-food products" into one piece of legislation as well as assimilating and simplifying them. This will (p. 2)
    - remove overlaps, inconsistencies and gaps,
    - ensure a "more even" application of the rules EU-wide,
    - give consumers better protection,
    - ensure a level playing field by preventing unfair business practices,
    - reduce the administrative costs of national market surveillance and customs authorities and
    - improve cross-border cooperation between the national authorities.

- **Area of Application**
  – The market surveillance Regulation applies to manufacturers, importers and traders (Art. 3, No. 8; hereinafter: "companies").

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– The market surveillance Regulation applies, in the case of product checks within the EU and as regards the international exchange of information and mutual assistance,
  - to all products which (Art. 2 (1))
    - are intended for consumers [COM(2013) 78, see cep**PolicyBrief**],
    - are not intended for consumers but are subject to harmonisation legislation (e.g. explosives, radio equipment, cableway installations; cf. Recital 40),
  - but not to certain categories of products such as in particular foods and medicines (Art. 2 (3) – (6)).
– The market surveillance Regulation applies, with regard to border controls, to all products which fall under EU legislation if the imported products are not already subject to other border control regulations (Art. 2 (2) in conjunction with Art. 14 et seq.)).

► **Rights and duties of the national market surveillance authorities**

– The national market surveillance authorities must ensure (Art. 4 (2)) that
  - no products presenting a risk are made available on the market and
  - measures are taken to remove the risk presented by the product.

  In this regard a distinction must be made between two categories of products presenting a risk ("product risks"):
  - "Products presenting a risk" run counter to public interests such as safety, health, the environment and consumer protection (Art. 3 (13)).
  - "Products presenting a serious risk" present an increased risk requiring rapid intervention and follow-up (Art. 3 (14)).
– The market surveillance authorities
  - perform sample checks involving the examination of documents, physical checks or laboratory checks (Art. 6 (1));
  - may enter premises and take any necessary samples of products (Art. 6 (4)),
  - alert users of products presenting a risk "where appropriate" (Art. 6 (2)).

► **Product checks**

– Where there is reason to believe that a product risk exists, the market surveillance authorities carry out a risk assessment (Art. 9 (1)) and check the product's "conformity" (Art. 13 (2))
  - with the requirements of harmonisation legislation relating to the potential risk,
  - with national health and safety legislation, or
  - with EU standards under the Standardisation Regulation [(EU) No. 1025/2012, Art. 2 (1); see cep**PolicyBrief**].
– Where a product risk does exist, the market surveillance authorities specify "without delay" the corrective measures to be taken by the responsible company (Art. 9 (3)) or by the authorities themselves (Art. 10 (2)).
– Possible corrective measures are (Art. 9 (4)):
  - bringing the product into compliance with harmonisation requirements ("conformity");
  - affixing warnings;
  - recalling (Art. 3, No. 15), withdrawing (Art. 3, No. 16) or destroying the product where it presents a serious risk.
– Irrespective of whether a product risk exists, a product must be taken off the market or recalled if
  - it fails to comply with harmonisation legislation ("formal non-compliance") and
  - the responsible company fails to establish conformity with the said legislation (Art. 9 (2)).
– A measure initiated by a national market surveillance authority must be implemented by all Member States if the Commission considers this to be justified (Art. 11 (2) and (5)).
– Where there is a "serious" product risk, the Commission may, by means of implementing acts (Art. 291 TFEU), withdraw products temporarily or permanently from the market (Art. 12 (1)).

► **Additional product checks at external EU borders**

– The customs authorities must check products when they are imported into the internal market ("release for free circulation", Art. 3, No. 17) for potential product risks. This may take place by way of the examination of documents, physical checks or laboratory checks (Art. 14 (1)).
– Where there is reason to believe that a product risk exists, the customs authorities will suspend importation (Art. 14 (3)).
– They will notify the responsible market surveillance authorities of this immediately (Art. 14 (4)).
– The suspended product may be imported if the national market surveillance authorities
  - do not request continuation of the import suspension within three working days (Art. 15 (1)) or
  - indicate that the product does not in fact present a risk (Art. 15 (2)).
– Where the market surveillance authorities confirm that a product does present a risk, it will
  - not be imported into the internal market (Art. 16 (1)),
  - be destroyed or rendered inoperable where the market surveillance authorities deem it to be necessary (Art. 16 (3)).
– The import-stop must also be implemented by all other Member States if (Art. 18 (2) and (5))
  - the product is subject to harmonisation legislation and
  - the Commission considers the import-stop to be justified.

- **Exchange of information and mutual assistance**
  - The Member States exchange information on products presenting a risk via the system for rapid exchange of information (RAPEX) run by the Commission (Art. 19).
  - For this purpose, they will report, in particular, (Art. 20 (1) and (2))
    - any corrective action taken by economic operators (Art. 9 (3))
    - any measure taken by market surveillance authorities (Art. 10 (1) or (4))
    - any refusal to import a product (Art. 16);
    - the origin and the supply chain of the product as well as the nature and level of the product risk.
  - All essential information on market surveillance will be stored in the "Information and Communication System for Market Surveillance" (ICSMS) run by the Commission. This includes in particular (Art. 21 (1))
    - all market surveillance authorities and their areas of competence;
    - complaints or reports about product risks;
    - the monitoring and assessment of market surveillance activities.
  - The market surveillance authorities must provide each other with mutual assistance by providing information, carrying out inspections and reporting on follow-up action (Art. 23).

Main Changes to the Status Quo

- Until now, market surveillance has been treated differently in several pieces of legislation depending on whether the product was a harmonised product [Regulation (EC) No. 765/2008 and various legal provisions on product harmonisation] or a consumer product (Directive 2001/95/EC). This resulted in overlaps and gaps in product categories. Market surveillance of all non-food products will now be regulated in one Regulation.
- Until now, RAPEX has only been used for the reporting of products presenting a "serious risk" [Regulation (EC) No. 765/2008, Art. 22 in conjunction with Art. 20]. Now it will also be used for the exchange of information on all "products presenting a risk".

Statement on Subsidiarity by the Commission

According to the Commission, market surveillance in the EU can only be effective if it is carried out with uniform rigour in all Member States and on all external borders. In addition, the exchange of information and cooperation between the Member States can only be regulated at EU level.

Policy Context

The Commission announced in 2012, in the European Consumer Agenda [COM(2012) 225, see cep**PolicyBrief**] and the Single Market Act II [COM(2012) 573], that it was going to introduce new rules on product safety and market surveillance.

Legislative Procedure

13 February 2013	Adoption by the Commission
Open	Adoption by the European Parliament and the Council, publication in the Official Journal of the European Union, entry into force

Options for Influencing the Political Process

Leading Directorate General:	DG Enterprise and Industry
Committees of the European Parliament:	Internal Market and Consumer Protection (leading), Rapporteur Sirpa Pietikäinen (EVP-Group, FI)
Committees of the German Bundestag	Economy and Technology (leading), Food, Agriculture and Consumer Protection, European Union Affairs, Legal Affairs
Leading Federal Ministries:	Economy and Technology (leading)
Decision mode in the Council:	Qualified majority (Adoption by a majority of the Member States and with 260 of 352 votes; Germany: 29 votes)

Formalities

Legislative competence:	Art. 114 TFEU (Internal Market) and Art. 33 TFEU (Customs Cooperation)
Form of legislative competence:	Shared competence (Art. 4 (2) TFEU)
Legislative procedure:	Art. 294 TFEU (ordinary legislative procedure)

ASSESSMENT

Economic Impact Assessment

Ordoliberal Assessment

Compliance with the ever increasing number of product requirements is not currently guaranteed by appropriate market surveillance. Overlaps and gaps in the existing legislation as well as a lack of coordination between the market surveillance authorities in the individual Member States make it more difficult to identify

unlawful products and to initiate appropriate measures. Too many products are still managing to enter or remain on the European market even though they do not comply with the applicable EU product requirements.

Combining the provisions on market surveillance into one piece of legislation reduces overlaps and gaps in the existing legislation and thus **ensures greater legal certainty both for the companies concerned and the market surveillance authorities.**

Standard effective market surveillance also **promotes competition in the internal market** because all companies in one industry are subject to the same requirements when it comes to manufacturing and marketing their products. Complying with product standards such as health, safety and environmental requirements affords continuous innovation and often involves substantial costs. Therefore - irrespective of whether the content of the requirements is appropriate in the individual case - **checking whether the statutory product requirements are being complied with is fundamental in order to guarantee investment and planning certainty for companies**.

Uniform and rigorous **market surveillance** across the EU **can still not be guaranteed** however. This is **because there are** stark **differences between the Member States as regards both the capacity and willingness to carry out conscientious market surveillance.** This problem is exacerbated not least due to the continual increase in new product requirements, such as those issued under the Ecodesign Directive (2009/125/EC; see cep**PolicyBrief**).

Impact on Efficiency and Individual Freedom of Choice

The wording used by the Commission **"product presenting a risk" is too imprecise and** can therefore be given very different interpretations by the market surveillance authorities. It **should be replaced by "non-compliant" in order to make it clear that the market surveillance authorities have to examine compliance with product requirements under EU law**.

The exchange of information via RAPEX should remain limited to products presenting a serious risk to avoid overloading the system with too many reports which could jeopardise its ability to function effectively.

Impact on Growth and Employment

The administrative work required to ensure effective market surveillance may delay the movement of goods in the internal market and on its external borders but it is necessary in order to guarantee legal and planning certainty which, in turn, is needed to provide the incentives for innovation to stimulate growth. The costs involved in carrying out checks and risk assessments must be set off against increased product safety, more reliable consumer information and reduced risk to the environment.

Impact on Europe as a Business Location

As market surveillance applies to all products being traded within the EU, irrespective of where they are produced, European companies will not be any more burdened than the foreign competition. On the contrary, they will be protected against competing products coming from countries outside the EU which do not comply with the product regulations.

Legal Assessment

Legislative competence

Unproblematic. In order to safeguard the functioning of the internal market in general, and the free movement of goods in particular (Art. 26, 28 et seq. and 114 TFEU), the EU is empowered to issue regulations on the market surveillance of products potentially presenting a risk and on the cooperation of customs authorities at border controls (Art. 33 TFEU).

Subsidiarity

Unproblematic.

Proportionality

A breach of harmonisation legislation which does not give rise to any risk to the consumer or the environment should not inevitably result in the product having to be taken off the market. In such cases, warning notices, imposing a duty to rectify the breach and a fine, are sufficient to ensure compliance with the law.

Conclusion

Combining the provisions on market surveillance into one piece of legislation ensures greater legal certainty both for the companies concerned and for the market surveillance authorities. Standard effective market surveillance promotes competition in the internal market and is fundamental for guaranteeing investment and planning certainty for companies. Uniform market surveillance cannot be guaranteed, however, due to differences in the capacity and willingness of the national market surveillance authorities. The wording "product presenting a risk" is too imprecise. It should be replaced by "non-compliant" in order to make it clear that the market surveillance authorities have to examine compliance with all requirements under EU law. The exchange of information via RAPEX should remain restricted to products presenting a serious risk.