# Client Alert

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# European Commission Plans to Change Consumer Product Safety Rules

**By Alistair Maughan and Emma Muncey**

The European Commission plans to introduce new rules to improve the safety regime applicable to non-food consumer products distributed in the EU.

The Commission has put forward a new package of measures to provide more consistency across the EU in relation to consumer product identification and traceability, and better coordination of the way in which national authorities check consumer products and enforce product safety rules.

The package will not apply to food products. These measures will place additional obligations on manufacturers, importers and distributors whose products are placed on the European market or made available in the EU. These obligations are expected to come into effect in 2015.

## BACKGROUND

Consumer product safety and market surveillance are issues that are heavily linked to one another. Consumer product safety concerns the safety of products marketed to consumers and the rules imposed to make sure that available consumer products are safe. Market surveillance is the monitoring of available products in relation to their safety. This involves gathering scientific and technical knowledge concerning safety issues, following up on complaints, monitoring accidents and verifying that corrective action has been taken.

The consumer product regulatory picture in the EU is currently somewhat fragmented. There are several different sets of EU legislation, as well as a variety of market surveillance tools. These include:

- **Directive 2001/95/EC on general product safety** which contains the core safety provisions with which consumer products must comply (with the exception of products covered by specific sectoral legislation, such as food and medical devices). Under this Directive, national authority bodies in each EU Member State are tasked with responsibility for market surveillance to check that: (i) products meet the applicable safety requirements; (ii) steps are taken to make products compliant; and (iii) sanctions are applied where necessary.
- **Directive 87/357/EEC on food-imitating products** which applies to products that are not edible but that could be easily confused with foodstuffs because of their appearance, smell or packaging. Under this Directive, Member States must carry out checks to ensure that no such products are marketed. If a Member State bans a product under the terms of this Directive, it must inform the Commission and provide the details needed to inform the relevant authorities in other Member States.

- **Regulation (EC) 765/2008 on accreditation and market surveillance** which sets out the requirements for accreditation and market surveillance relating to the marketing of products. It establishes obligations for market surveillance authorities and requires certain procedures to be in place, *e.g.,* for following up on complaints. In addition, the Regulation prescribes that Member States must establish, implement and periodically update national market surveillance programmes.

- **The Rapid Alert Information System (RAPEX)** which is the EU alert system that facilitates the rapid exchange of information between Member States and the Commission on measures taken to prevent or restrict the marketing or use of products posing a serious risk to the health and safety of consumers (with the exception of food and medical devices which are covered by other mechanisms). All measures ordered by national authorities and measures taken voluntarily by manufacturers, importers and distributors are reported by RAPEX. The Commission publishes a weekly overview of the products posing a serious risk as reported by the national authorities.

- **The Information and Communication System for Market Surveillance (ICSMS)** which is an IT system operated by the Commission to provide a comprehensive communication platform for the market surveillance authorities of Member States in relation to the: (i) reliable exchange of information among authorities; and (ii) implementation of EU market surveillance policy. The system allows information on non-compliant products (*i.e.*, test results, product identification data, photographs, risk assessments, accident information and information on measures taken by surveillance authorities) to be shared quickly and efficiently among national authorities. Some of this information is also available to the public.

From 2009 to 2011, the Commission held extensive public consultations on the EU consumer product safety regime. The conclusion of that exercise was that the current legislation on consumer product safety and market surveillance contains gaps and overlaps, making the interplay between the different pieces of relevant legislation "*complex*" and "*difficult to understand*". This has led to confusion for manufacturers, importers and distributors, and also for national enforcement authorities. The degree of regulatory fragmentation has hampered the effectiveness of product safety and market surveillance activity in the EU.

## THE NEW PACKAGE

In February 2013, following its public consultation exercise, the Commission announced its planned changes to the EU's consumer product safety and market surveillance regime.

The Commission's package of proposals includes two legislative measures and one non-legislative measure:

- a proposal for a new Regulation on consumer product safety which will simplify the safety rules for consumer products and merge them into a single piece of legislation;

- a proposal for a single Regulation on market surveillance for products, unifying and simplifying existing fragmented legislation; and

- a multi-annual action plan of 20 separate actions to be taken by the Commission over the next three years to improve market surveillance rules.

The Regulation on consumer product safety will not apply to products that are subject to corresponding sector-specific EU harmonisation legislation (*e.g.*, food and medicinal products).

One significant change for producers and EU importers is the Commission's shift from legislation by "Directive" to a "Regulation", which ought to help by minimising legal differences between different EU countries.

Under the current system, the laws are contained in Directives (such as the current Directive on general product safety) which are not directly applicable in each Member State. Each Member State has to 'implement' each Directive into its national laws by introducing new national legislation that provides the same or a higher level of product safety protection than the Directive. As is the case with the current Directive on general product safety, this often leads to slightly different levels of protection being afforded in different Member States.

By contrast, a Regulation is directly applicable in each Member State. This means that each Member State must follow the Regulations as published by the Commission and no corresponding national legislation is needed in order for the Regulations to have an effect in each Member State. It is on this basis that the Commission's new proposed Regulations will replace all current national provisions on consumer product safety and market surveillance.

This Regulation-driven approach prevents different levels of protection being afforded in different Member States so that manufacturers, importers and distributors can conduct their business on the basis of a single regulatory framework rather than face a potentially confusing patchwork of Member States' national laws. If a Member State wishes to impose higher national levels of protection than the Regulations provide, those draft national provisions will have to be reviewed and approved by the Commission according to strict criteria. This procedure will help the level of protection to stay consistent in all Member States.

## WHAT WILL THE KEY CHANGES BE?

The key changes that the Commission's package implements are:

- definition of clearer responsibilities in relation to labelling, identification, product information and corrective actions for manufacturers, importers and distributors when placing consumer products on the EU market;
- creation of a more cooperative system of market surveillance across the EU contained in a single set of rules but still conducted at national level;
- alignment of consumer product safety rules across all Member States;
- improved traceability of consumer products throughout the supply chain, enabling a swift and effective response to safety problems (*e.g.*, recalls) via more stringent rules on the provision of information about product origin;
- more effective tools to enforce safety and other product-related requirements and to take action against dangerous and non-compliant products across all sectors; and
- streamlined procedures for notification about dangerous products so that RAPEX will be the single alert system regarding products presenting a risk.

## WHAT NEW OBLIGATIONS WILL THERE BE FOR MANUFACTURERS, IMPORTERS AND DISTRIBUTORS?

As under the current legislation, manufacturers, importers and distributors will need to ensure that a product is safe. However, there are also additional obligations for manufacturers, importers and distributors under the proposed measures. Importers and distributors will not be able to place a product on the EU market until it complies with the general safety requirements and the obligations set out below. In addition, if a product does not comply, importers and distributors have an obligation to: (i) take the necessary corrective action to make the product comply; (ii) withdraw the product; or (iii) recall the product.

Manufacturers will need to draw up technical documentation proportionate to the possible risks of a product. This documentation will contain: (i) a general description of the product including any properties relevant to assessing its safety; (ii) an analysis of the possible risks associated with the product; and (iii) the solutions adopted to eliminate or mitigate such risks. This documentation must be kept for 10 years after the product has been placed on the market and must be made available to market surveillance authorities on request. Manufacturers will also need to ensure that each of their products bear a type, batch or serial number, etc., allowing the identification of a product (or if the size or nature of a product doesn't allow it, on the packaging or in accompanying documentation). Finally, manufacturers will need to indicate their names, registered trade names or registered trade marks and addresses on products (or if the size or nature of a product doesn't allow it, on the packaging or in accompanying documentation).

Importers will need to need to ensure that manufacturers have complied with the requirements set out above and will also need to indicate their names, registered trade names or registered trade marks and addresses on a product (or if the size or nature of a product doesn't allow it, on the packaging or in accompanying documentation). Additionally, importers will need to ensure that products are accompanied by instructions and safety information, where necessary, and keep the technical documentation provided by the manufacturer for a period of 10 years after each product has been placed on the market.

Distributors will need to ensure that manufacturers and importers have complied with their requirements as set out above.

The Commission plans to provide guidance to help businesses, particularly small and medium-sized enterprises, to identify their obligations under the new measures.

## WILL THERE BE ANY BENEFITS FOR MANUFACTURERS, IMPORTERS AND DISTRIBUTORS?

The more coherent rules on consumer product safety and market surveillance should reduce administrative burdens and compliance costs for businesses, especially for small and medium-sized enterprises. In the future, businesses should be able to identify easily the set of rules applicable to their commercial activity so that they will save on costs caused by legal uncertainty. The new rules should be more user-friendly and accessible and set out in a chronological or sequential manner. Finally, improved coordination of product safety checks should help to eliminate unfair competition from dishonest or rogue operators.

## TIMETABLE

In terms of process, the Commission's proposals will now proceed to the European Parliament and the Council of the EU for consideration, as part of the normal legislative process.

The Regulations and action plan are both expected to come into effect in 2015.

## CONCLUSION

The Commission has acknowledged that the existing EU legislation and tools regarding consumer product safety and market surveillance are fragmented and disorganised and, therefore, present compliance problems.

The Commission hopes that the proposals outlined above will improve, strengthen and harmonise the rules in relation to consumer product safety and market surveillance throughout the EU. As set out above, it is likely that manufacturers, importers and distributors will find that there are additional obligations relating to labelling, product identification and corrective actions imposed on each of them as a result of the new rules. However, these obligations will vary for each Member State where products are sold depending on the current level of protection in each of those Member States compared to the protection given by the Commission's proposed package of new measures.

**Contact:**

**Alistair Maughan**
44 20 7920 4066
amaughan@mofo.com

**Emma Muncey**
44 20 7920 4165
emuncey@mofo.com

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