

## Best Recall Practices – Part 3 – Consumer Goods

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In part three of this series on product recalls, we focus on the rules governing recalls and withdrawals of consumer products from the EU and Swiss market. We examine the recall procedures, set out in Directive 2001/95/EC on general product safety ([GPSD](#)), its related guidance set out in the Commission Decision for the notification of dangerous consumer products to Competent Authorities (CAs) ([GPSD Guidelines](#)), Regulation 765/2008 on accreditation and market surveillance ([Market Surveillance Regulation](#)) and Regulation (EU) 2019/1020 on market surveillance and compliance of products ([New Market Surveillance Regulation](#)), as well as the corresponding Swiss law ([Federal Act on Foodstuffs and Utility Articles](#)).

The GPSD sets out the general rules applicable to safety of products in the EU. It defines a number of terms relevant to product withdrawal and recall. Specifically, it provides that a withdrawal is a measure aimed at preventing the distribution, display, and offer of a product that is dangerous to consumers, and a recall is any measure aimed at achieving the return of a dangerous product that has already been supplied or made available to consumers by the producer or distributor. Swiss law contains equivalent definitions of the two measures mentioned above in Article 84 of the [Federal Ordinance on Foodstuffs and Utility Articles](#).

The rules set out in the GPSD for consumer goods apply only to the extent there is no other EU legislation covering the relevant category of products. For example, wellness products that are currently not targeted by specific EU legislation would be subject to the notification requirement of the GPSD, whereas recalls of medical devices and food must (also) follow product-specific legislation. In this regard, Swiss law follows suit.

**Key comment #1 — Risk analysis:** Before placing a product on the market, producers have to carry out a risk analysis to identify all possible risks the product may pose, and determine the essential safety requirements applicable to the product. This analysis must be documented and included in the technical documentation of the product. In addition, the producer must document how it addresses the risks identified to ensure that the product complies with the applicable essential requirements (for example, by applying harmonized standards). It is important to always have these documents ready for inspection.

### *What triggers the withdrawal or recall?*

As a general threshold, for a consumer good to be placed on the EU market, it must be safe. Under the GPSD, a product is safe if it meets all statutory safety requirements under European or national law. If there are no applicable regulations or harmonized standards, the product's compliance may be determined according to other reference documents such as national standards, Commission recommendations or codes of practice. Consumer

products are considered safe if they do not present any risk to consumers, or only the minimum risks compatible with the product's use.

After the product is placed on the market, the producer (e.g., manufacturer) or distributor must take immediate steps (including by withdrawing or recalling the product if necessary) if the product poses risks to consumers that are incompatible with the applicable safety requirements.

Mandatory withdrawals or recalls typically occur as a last resort. This will usually be the case where the producer does not cooperate with the relevant CAs or does not take adequate steps to remedy the risk on a voluntary basis.

**Key comment #2 — Noncompliance:** Noncompliance is a term that covers non-safety-related breaches of applicable rules. In case of noncompliance, the CAs will typically first oblige the producer to make the product comply with applicable rules and to end the infringement within a reasonable time period. If compliance is not met, the CAs may take steps to restrict or prohibit the placing on the market of the product and, if necessary, have it withdrawn or recalled from the market.

### ***Must the withdrawal and recall be reported?***

Under the GPSD, reporting a withdrawal or a recall to the relevant CA is mandatory under certain circumstances. If the producer and distributor discover that a product that they have placed on the market is not safe, they must immediately inform the CAs but not later than 10 days after discovering product is not safe. Where the product presents a “serious risk,” this must be reported to the relevant CAs within three days. As part of this coordination, the producer and distributor must share any action undertaken to prevent risks to consumers, including withdrawal and recall.

Producers and distributors may reach out to CAs if there is evidence of a potential problem to discuss whether a notification is appropriate. There is no obligation to notify the CAs if the noncompliance does not affect the safety of the product.

**Key comment #3 — Coordinating Notifications to the CAs:** The obligation to notify applies to both producers and distributors within the limits of their respective activities and in proportion to their responsibilities. To avoid confusion as to who should first provide information to the CAs, it is advisable to allocate this obligation in the contracts with every economic operator involved in the supply chain.

### ***What are the obligations of producers and distributors?***

Under the GPSD, the primary legal responsibility for ensuring compliance falls on the producer. The producer must, *inter alia*,

- place only safe products on the market

- monitor the safety of products placed on the market, especially by passing on information on product risks, keeping and providing the documentation necessary for tracing the origin of products
- inform the CAs if they consider or have reason to believe that a product placed on the market is not safe and, if so, promptly order a withdrawal or recall
- cooperate with the CAs, at the request of the latter, on action taken to avoid the risks posed by products which they supply
- provide consumers with information about the inherent risks of the product where such risks are not immediately obvious to the consumer

In turn, distributors must

- act with due care to help ensure compliance with the applicable safety requirements
- participate in monitoring of the safety of products placed on the market
- inform the CAs if they consider or have reason to believe that a product placed on the market may not be safe
- keep and be ready to provide the documentation necessary for tracing the origin of products
- cooperate with the producers to avoid any risks of products placed on the market
- cooperate with the CAs

### ***Are withdrawals and recalls published?***

The European Commission coordinates the Rapid Information System (RAPEX), which the CAs use to communicate information to one another about consumer products posing serious risk to the health and safety of consumers. The information sent by the national authorities is published daily on the [Safety Gate](#).

According to the [RAPEX Guidelines](#), the CAs must report two types of measures via RAPEX:

- **compulsory measures**, adopted by the CAs, often in the form of an administrative decision, which oblige a producer or distributor to take preventive or restrictive action in relation to a specific product that they have made available on the market
- **voluntary measures**, which include (i) preventive and restrictive measures adopted voluntarily by a producer or distributor; and (ii) recommendations and agreements with producers and distributors concluded with the CAs, including agreements that are not in written form and result in preventive or restrictive action taken by producers/distributors in relation to products posing a serious risk that they made available on the market

Switzerland is not a member of the RAPEX notification system because the corresponding agreement with the EU has not yet concluded. Therefore, RAPEX notifications are not sent

to Switzerland, but distributors of consumer goods in Switzerland have the same obligations as those in the EU. Furthermore, EU distributors are also obligated to inform their customers in Switzerland about their recalls. The distributor in Switzerland is in turn obliged to inform the cantonal CA if they did supply noncompliant articles or articles that are hazardous to health

The Swiss Federal Food Safety and Veterinary Office operates a recall system through an app called [RecallSwiss](#) alerting the public to dangerous products, withdrawals, and recalls.

### ***Penalties for noncompliance***

EU law does not introduce specific penalties for noncompliance with the GPSD or other consumer goods legislation. However, the EU member states are required to have “effective, proportionate, and dissuasive” penalties at national level. Such penalties may include administrative or criminal investigations, fines, or injunctions.

In Switzerland, specific penalties for offenses against the food legislation are defined in the [Swiss Act on Foodstuff and Utility Articles](#). These penalties range from a maximum of CHF 20.000 for negligent contraventions to custodial sentences up to five years for offenders acting in a professional capacity or for personal gain.

To read Part 1 of our Best Recall Practices Guideline on Medical Devices, please click [here](#), and for Part 2 on Best Recall Practices on Food Products, please click [here](#).

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