SIDLEY

Best Recall Practices Guidelines – Part 2 – Food Products

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In the second part of our series on product recalls, we focus on the rules governing recalls and withdrawals of food products from the EU and Swiss market. We will examine the recall procedures for food, as regulated under Regulation 178/2002 laying down the general principles and requirements of food law (General Food Law Regulation) and the European Commission's guidance on the implementation of certain aspects of the General Food Law Regulation (General Food Law Guidance) as well as the respective Swiss laws.[1]

The EU food legislation does not introduce special definitions for food withdrawal or recall. However, it is generally understood that a withdrawal is the process by which a product is removed from the supply chain, and there is a prevention of further distribution, display, or offer of the product. Recall, on the other hand, applies to the removing of a product that is already in the possession of consumers. Swiss law is more specific, as it defines these two measures in Article 84 of the Federal Ordinance on Foodstuffs and Utility Articles.

Typically, withdrawals and recalls of unsafe foods are conducted for the whole batch, lot, or consignment of food of the same class or description unless it is determined through detailed assessment that the rest of the batch, lot, or consignment is in fact safe for consumption.

Key comment #1 — Documentation: Meeting the exception to the withdrawal and recall requirement for the affected batches, lots, or consignments will generally require a detailed assessment and documentation from the food business operator (FBO) to show that the remaining food is safe. Competent authorities (CAs) often expect (or even request) to be consulted.

What triggers the withdrawal or recall?

Food products must comply with numerous requirements to ensure that they are safe and acceptable for consumption. Accordingly, to protect public health, no food product can be placed on the EU or Swiss markets if it is deemed unsafe.

The General Food Law Regulation provides that food is considered unsafe if it is (i) injurious to health or (ii) unfit for human consumption. Food is considered to be "injurious to health" if it has the potential to harm human health. This includes harm that may only materialize or become apparent over a long period of time.

[1] Where there is no material difference between the two legislations, reference is made only to the General EU Food Law Regulation and Guidance applicable in the EU.

Food can be rendered "unfit" for various reasons, including by way of contamination, by the presence of foreign objects, by unacceptable taste or odor and by more obvious detrimental deterioration such as putrefaction or decomposition.

In addition to the rules of safety of the General Food Law Regulation, FBOs may also be required to comply with additional provisions governing food safety, for example, legislation on maximum residue levels or maximum contaminant levels, and product-specific legislation such as infant formulae.

Key comment #2 — Considerations in determining whether food is unsafe: Information provided to consumers, including information on the label or other available information about avoidance of specific adverse health effects for a particular category of foods, can play a key role in determining whether the food is in fact unsafe. If essential information on the use of food is not supplied or is incorrect, this could render the food unsafe. For example, where a food or a food ingredient may pose a risk to the health of a specific group of consumers, for instance, food allergies to nuts or other ingredients, and the FBO has failed to effectively communicate that information, that food could be considered unsafe for consumption.

Must the withdrawal and recall be reported?

Once the FBO determines that a food product is unsafe and decides to withdraw or recall it, it must report this to the relevant national competent agency of the concerned EU member state(s) and to the relevant cantonal CAs. CAs will monitor that the FBO has taken the appropriate measures to address the risks posed by the food placed on the market and to order or take additional measures if necessary for avoiding the risks.

Should the food product be removed *before* it has been placed on the market or if it is under the immediate control of a particular FBO, there is no obligation to notify the CAs.

What are the obligations of FBOs?

Under the General Food Law Regulation, the primary legal responsibility for ensuring compliance with food law falls on the FBO, who must, *inter alia*,

- monitor the food quality at all stages of production, processing, and distribution within the businesses under their control
- promptly order a withdrawal or recall
- notify the CAs of the withdrawal or recall
- inform the CAs if they consider or have reason to believe that a food placed on the market may be injurious to health
- promptly notify consumers of the reasons for the withdrawal or recall

- cooperate with the CAs
- have a traceability system in place at all stages of production, processing, and distribution and make the gathered information available to CAs on request
- adequately label or be able to identify the food they place on the market
- cooperate with operators in different parts of the food distribution chain where necessary to ensure the withdrawal of unsafe food from the market

Key comment #3— Contractual obligations in cases of recalls or withdrawals: The traceability obligation relies on the "one step back, one step forward" approach, which implies that FBOs must identify the immediate supplier(s) and immediate customer(s) of their products. Without prejudice to sector specific rules, however, the General Food Law Regulation does not expressly require FBOs to establish a link (so-called internal traceability) between incoming and outgoing products. Nevertheless, an internal traceability system allows FBOs to act swiftly in case of a recall or withdrawal and to take targeted and accurate action.

FBOs may also want to make sure that contracts with distributors and others in the supply chain require immediate notification in case of any detected issues. That way, necessary action can be assessed and implemented swiftly. This will ultimately save costs in terms of time and in avoiding unnecessary wider disruption.

Are withdrawals and recalls published?

In the EU, the European Food Safety Authority (EFSA) coordinates the Rapid Alert System for Food and Feed (RASFF). In cases where the food poses serious direct or indirect risk to human health, the CAs must notify the European Commission via RASFF. Consumers can access certain information on food recalls and public health warnings in all EU countries through the RASFF Consumers' Portal.

According to Commission Implementing Regulation (EU) 2019/1715, notifications by the CAs through the RASFF depends on the nature of the risk:

- Alert notifications are sent when a food presents a **serious health risk** and when rapid action is required; CAs must report within 48 hours.

- Information notifications are used when a **risk has been identified** about food placed on the market, but the other CAs do not have to take rapid action; CAs must report without undue delay.

- **Border rejections** concern food and feed consignments that have been tested and rejected at the external borders of the EU/European Economic Area when a health risk has been found; CAs must report without undue delay.

- News notifications are used for **information related to the safety of food** that has not been communicated as an alert or an information notification but that is judged interesting for the CAs.

These tools can be a useful source of information for FBOs to monitor the expectations of the CAs.

For Switzerland, the Federal Food Safety and Veterinary Office (FSVO) has a comparable coordinating role as the one EFSA is exercising in the EU. The CAs or the FSVO will take all appropriate measures, including the notification of alerts and information to the wider public.

Penalties for noncompliance

The EU food law legislation does not introduce specific penalties for noncompliance with EU food legislation. However, the EU member states have the obligation to introduce "effective, proportionate, and dissuasive" penalties at national level. Such may include administrative investigations, fines, and injunctions. For example, in Italy, pecuniary administrative sanctions, ranging from €2,000 to €18,000, may be imposed on FBOs who place food products on the market in breach of the General Food Law Regulation. In some EU member states, including France, Italy, and Ireland, FBOs may also face criminal fines and criminal liability.

For example, FBOs placing an unsafe food product of animal origin on the French market, without withdrawing or recalling the product in a timely manner, may be charged with criminal fines up to €3 million and may face additional sanctions such as permanent or temporary closure for up to five years.

In Italy, pecuniary administrative sanctions may be imposed on FBOs who breach the General Food Law Regulation with sanctions varying between €2,000 and €18,000.

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.