Food Labeling Issues and Trends in Europe: Lessons for U.S. and European Practitioners from Recent Allergen Recalls

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Trade press reports have highlighted a spate of recent recalls relating to food and drink products in the United Kingdom resulting from labeling errors. *See* James Ridler, *Labelling Errors Spark Food Recalls*, Food Manufacture, Mar. 28, 2018, www.foodmanufacture.co.uk/Article/2018/03/28/Food-recalls-sparked-by-labelling-errors. Examples include foods recalled because of salt crystals not mentioned on the packaging (which represent a potential choking hazard), chocolate drinking straws with labels not in English (with allergen information therefore not easily comprehended), and several products that contained allergens not correctly mentioned on the label. If food businesses are part of a global food supply chain, they would be well advised to be aware of what will happen when recalls are required across several countries. Their own products may need to be recalled in other jurisdictions, and they may use ingredients from other jurisdictions that have been withdrawn or recalled from the market.

In the United Kingdom, the Food Standards Agency (FSA) is reviewing and recommending improvements for food retail sector withdrawal and recall mechanisms. The September 2017 final report focused on the recall process, but includes interesting findings on recalls due to labeling errors for allergens. *See* U.K. Food Standards Agency, *FSA/FSS Efficacy of Recalls, Final Report,* Sept. 6, 2017, *available at* https://acss.food.gov.uk/sites/default/files/recalls-efficacy-report.pdf. Over one third of consumers with food allergies or intolerances agreed that their opinion of the business improved following a well-handled recall. *Id.* at ¶ 5.4.1. This is important for food business operators worldwide: Getting the recall process right can have real benefits for the business and the brand.

Food regulations commonly refer to requirements for notification, withdrawals, and recalls. For the purposes of this article, "notification" means informing competent authorities that food in the market is unsafe. "Withdrawal" means removing the food from the supply chain/market, i.e., stopping the sale or supply of the food. "Recall" means any measure aimed at achieving the return of an unsafe food that has already been supplied or made available to consumers, e.g., tracing the affected products, communications to consumers, managing returns of the food, and managing disposition on return.

Notification, withdrawal, and recall are three separate steps. Notification and withdrawal do not always trigger recall because a food product might not yet have reached consumers, or it might have been withdrawn for a reason other than safety.

A product might be withdrawn or recalled for several safety-related reasons. Withdrawn or recalled products could contain harmful bacteria, such as salmonella or listeria. Products may exceed permitted pesticide levels or be physically contaminated, for example, with pieces of glass or metal. Allergen labels on withdrawn or recalled products may be missing or incorrect.

Legal Requirements for Notification, Withdrawal, and Recall

The EU General Food Law Regulation (GFL), 178/2002/EC, 2002 O.J. L 031, specifies food business operators' legal responsibilities for notifications, withdrawal, and recalls. EU regulations apply in all member states (including the United Kingdom, currently), and member states' legislation typically provides for regulatory enforcement.

The GFL outlines primary producer, importer, retailer, and distributor responsibilities. If a primary producer or importer has reason to believe a food product it has imported, produced, processed, manufactured, or distributed is not in accordance with the food safety requirements, it must immediately initiate procedures to withdraw the food in question from the market where the food has left its control and inform the competent authorities of the relevant member state. *Id.*, art. 19. A food is not in accordance with food safety requirements if it is injurious to health or unfit for human consumption within the meaning of the regulation. *Id.*, art. 14. If the unsafe food is still under the immediate control of the food business operator and has not entered the market, no notification is required. However, where the product may have reached the consumer, the food business operator must effectively and accurately inform the consumers of the reason for its withdrawal and, if necessary, recall products already supplied to consumers.

The GFL imposes separate obligations upon retailers and distributors who do not affect food packaging, labeling, safety, or integrity. Such parties must, within the limits of their respective activities, initiate procedures to withdraw from the market products not in compliance with the food safety requirements. They also must contribute to food safety by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers, and/or the competent authorities.

Food manufacturers, importers, distributors, and retailers must immediately notify the appropriate authority when they

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have placed a product on the market that may be injurious to human health, and should inform the authority of consumer risk prevention steps they have taken. *Id.*, art. 3. "Placing on the market" means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer.

To comply with these provisions, EU entities purchasing food products from outside of the EU will want to build in contractual protections to satisfy themselves as to the provenance and safety of food products, such as visiting production facilities or reviewing independent safety audit results. They also will want to ensure that products can be traced easily so that if a recall is required, the issue can be isolated quickly and an alternative source of supply found.

The minimum legal requirements for recall among EU member states should all be the same because the EU GFL applies in all EU member states. However, some countries may have additional implementation and enforcement requirements. For example, German food testing facilities that detect problematic substances must notify the competent German authority at the same time that they notify the food business operator. *See* Lebensmittel-, Bedarfsgegenstände – und Futtermittelgesetzbuch [LFGB] [Food and Feed Code] Sept. 2005, German Federal Law Gazette, § 44 ¶ 4a. Food businesses can react more quickly and proactively to widespread recalls if they are aware of specific member state–level procedures and if they have trusted advisors in key markets.

Non-EU European countries such as Switzerland and Norway are not governed by EU food law but have their own similar food laws. The U.K. government intends to "carry over" EU law after the United Kingdom leaves the EU, and while it is possible that, over time, the legal systems may diverge, the EU systems on food safety have become so embedded in the United Kingdom (and indeed many originated in the United Kingdom) that it is unlikely that the notification, withdrawal, and recall systems will change significantly.

INFOSAN and RASFF

Some food recalls will be reported on information exchanges, such as the International Network of Food Safety Authorities (INFOSAN) or the Rapid Alert System for Food and Feed in Europe (RASFF), but notifications will be made only where affected food has been or may have been distributed to other countries. Created in 1979, RASFF enables members to share information efficiently. RASFF members include 28 EU national food safety authorities; the European Commission; the European Food Safety Authority; and non-EU states Norway, Liechtenstein, Iceland, and Switzerland. After Britain leaves the EU, it will no longer be a member state but will very likely remain a member of RASFF.

RASFF provides continuous service to ensure that RASFF members can send, receive, and respond to urgent notifications, which can lead to products being recalled from the market internationally. The interactive and searchable RASFF portal and database provide public access to summary information about the most recently transmitted RASFF notifications and past notifications.

When one member state recalls food products, RASFF quickly alerts other member states' authorities. For example, the database shows that on April 11, 2018, RASFF notified Belgium that there was nicotine in dried organic goji berries imported from China via the Netherlands. Food business operators should therefore consider whether corrective action or recall is also required in another member state. They may opt to contact competent authorities before they become aware through RASFF, to ensure that the information being provided to that authority is fully up-to-date. RASFF can also notify food business operators about issues with ingredients that have been supplied into the relevant production facility from another country in Europe.

Food manufacturers, importers, distributors, and retailers must immediately notify the appropriate authority when they have placed a product on the market that may be injurious to human health, and should inform the authority of consumer risk prevention steps they have taken.

RASFF's 2016 annual report details notifications made to it from food authorities across Europe. *See* EU, *2016 Annual Report: Rapid Alert System for Food and Feed (RASFF)*, 2017, *available at* https://ec.europa.eu/food/sites/food/files/safety/docs/rasff_annual_report_2016.pdf. The report details 107 notifications for allergens, 87 of which were alerts, i.e., notifications requiring rapid action. *Id.* at 40. In 2016, milk, soya, nuts, and gluten were the most commonly reported allergens; cereals and bakery products were the most common subjects of notifications—in particular by Germany, reporting on products of German origin to a large extent. In six cases, consumers suffered from allergic reactions due to the presence of an allergen that was not indicated on the label. However, the report also makes clear that not all notifications in relation to allergens are in accordance with EU law, which does not require the labeling of allergens that may be present in a product due to cross-contamination (although clearly, even where this is not a legal requirement, food business operators should avoid cross-contamination where it could have safety implications for allergen sufferers).

Nevertheless, there is still a significant number of allergen labeling error recalls. A search on the RASFF portal shows, for example, that there were allergen alerts in relation to undeclared or mislabeled nuts across Europe on a number of occasions in 2017 and early 2018, including undeclared peanuts in seasoned sunflower seeds from China (notified by the United Kingdom and distributed to the United Kingdom and Ireland); undeclared peanuts in wafer biscuits from

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Russia (notified by Finland); the presence of peanut in roasted hazelnut meal from Georgia (notified by the Commission, distributed in Lithuania); and undeclared peanuts in protein chocolate peanut butter bar from the United States (notified by the Netherlands, distributed in Netherlands and Belgium). Other allergen-related alerts from products originating in the United States included undeclared gluten and milk ingredients in granola and fruits mixes (distributed in the United Kingdom and Ireland) and undeclared peanut and nuts in mint chocolate protein bars (distributed in Belgium, Cyprus, Czech Republic, Estonia, Finland, France, Germany, Ireland, Poland, Slovenia, Spain, and the United Kingdom). For a number of these alerts, the information was also provided to INFOSAN. In the United Kingdom, allergy alerts are issued in cases where foods are being recalled, either because the allergy label is missing or incorrect, or if there is any other risk specific to consumers with an intolerance or a food allergy. In June 2017, the Food Standards Agency issued a report following a data analysis on food alerts from 2013 to 2016. *See* U.K. Food Standards Agency, *Review of Food Withdrawal and Recall Processes: Data Analysis of FSA Food Alerts 2013–2016*, June 2017 *available at* https://acss.food.gov.uk/sites/default/files/june-2017-food-alerts-analysis.pdf. It found that during this three-year period half of the food alerts related to allergens, significantly more than those for bacterial contamination. Furthermore, the number of food alerts in 2015 and 2016 was more than double that seen in the previous two years (and the increase is across the board, not greatly differentiated by the issue type or notifier). The report notes that the cause of the increase is not known, but it may be at least partly attributable to the introduction of requirements in December 2014 to label allergens under the EU Food Information for Consumers Regulation (FIC). The fact that the proportion of recalls and food alerts in the United Kingdom appears to be greater for allergen labeling than across the EU generally (at least according to the RASFF report) may suggest that the prevalence of this issue varied across member states.

Legal Requirements and Responsibilities for Labeling in the EU

The EU FIC was adopted on October 25, 2011. Council Regulation No. 1169/2011/EC, 2011 O.J. L 304 22.11.2011. The EU FIC has applied directly in member states since December 13, 2014 (except the mandatory nutrition declaration that has applied since December 13, 2016). The EU FIC applies to food business operators at all stages of the food chain, with "food business'" meaning any undertaking, whether for profit or not, carrying out any of the activities related to any stage of production, processing, and distribution of food. *See* General Food Law Regulation, *supra*, at art. 3.

Even food business operators conducting business-to-business transactions need to ensure that they have sufficient information to allow them to comply with the EU FIC. Member states' respective laws enforce the EU FIC. In the United Kingdom, regulations set offences and penalties for breach of the requirements, delegate competent authorities to inspect and enforce, and deal with matters where member states have discretion under the EU FIC. Member states have discretion to determine how allergen information should be made available for food that is not prepacked. The operator under whose name food is marketed, or the importer into the EU, is responsible for providing the relevant information to INFOSAN or RASFF. The EU FIC requires that prepacked foods have mandatory particulars in a minimum font size either on the pack or on top of a label attached to it. All operators must ensure compliance with the requirements within their business.

Mandatory particulars include the legal, customary, or descriptive name of the product; an ingredient listing; a net quantity declaration; a durability indication (i.e., use by or best before dates); the name and address of the food business operator under whose name the food is marketed, or the importer into the EU; nutrition information (which has been mandatory since December 13, 2016, for most products); origin labeling for certain products (including for primary ingredients in all foods for which whole product origin is volunteered); and a quantification of ingredients that appear in the name of food or are usually associated with the food, or pictures emphasizing ingredients. *See* EU FIC arts. 9, 10. There are some exemptions for smaller pack sizes, which might apply to products such as chewing gum, where there is limited space available.

The EU FIC requires that the mandatory particulars appear in a language easily understood by the consumers in the member state. However, exporters to Europe should be aware that member states have discretion to stipulate that the particulars must be given in that state's official language. For example, Italy requires that the mandatory particulars be printed in Italian. *See* EU FIC art 9.

Allergen labeling requirements are specific and stringent, and violations may lead to recalls, particularly if the ingredient label does not include a present allergen. The EU FIC requires that allergen information is provided in the required ingredient list of the product in a specified format. It must be in a different typeset, with the derivative followed by the allergen, for example: cheese (milk) and prawns (crustacean). The EU FIC specifies 14 allergens: the components of cereals containing gluten (wheat, rye, barley, oats, spelt, and kamut, and their derivatives; not "gluten" itself); crustaceans; eggs; fish; milk; nuts; soybeans; celery; mustard seeds; sesame seeds; sulphur dioxides and sulphites; lupin; and molluscs. *See* EU FIC, Annex II.

In many jurisdictions, in addition to potential enforcement liability for noncompliance with EU FIC allergen labeling or other requirements, a person who has suffered loss or damage (for example, an injury or illness due to allergen mislabeling) can also make a claim for financial compensation from a person or company that has negligently breached a duty of care.

Implications for U.S. Food Business Operators

EU food labeling requirements and the trend of recalls for labeling errors relating to allergens have several practical implications for businesses exporting to Europe. Non-EU food companies should be aware of the EU's labeling requirements, and should expect that European importers will want details of traceability systems for U.S. exporters' ingredients, so that they can quickly identify a contaminated or mislabeled ingredient's source and isolate the products to minimize the extent of any required withdrawal or recall. European importers also will require exporters to comply with the EU FIC's mandatory particulars for labeling and will require appropriate documentation thereof with shipments. European food importers also will seek assurances as to the safeguards U.S. food companies have in place to ensure that allergens are controlled and fully identified on labels/accompanying information. Exporters should ensure that all contractual documentation is clear as to where the responsibilities lie for labeling, for example, between the manufacturer, importer, and/or third-party packaging/labeling company. Consider local language requirements—for example, if a company is exporting to Italy, but its products' labels are in English, is the exporter required to comply with local language requirements and provide the mandatory information in Italian? If a food company has only one importer into the EU that subsequently distributes a product across Europe, the local language requirements are unpredictable. Exporters also should ensure accurate allergen labeling by requiring ingredient suppliers to conduct allergen risk assessments, instituting label and shipping documentation quality control procedures, updating exports' labels when ingredients change, and using dedicated packing lines to reduce the risk of mislabeling.

Where an issue is identified in one country that will or might require notification to competent authorities, such as withdrawing or recalling a food product, other European countries will receive RASFF alerts, and a company's exports to other European countries also will be affected. A food exporter should prepare for investigations and recalls in multiple countries by retaining a team of advisors in key European markets. Remember that the RASFF notification also may be extended to INFOSAN, which means non-European countries also will quickly become aware of a European-notified issue.

As described at the beginning of this article, recent FSA research has found that, when handled well, recalls are likely to have a positive impact on the issuers' image, as consumers considered them to be taking ownership. The FSA report analyzed which communication methods were successful, consumers' perceptions of the recall process, and who tends to take responsibility (manufacturer or retailer) for each stage of the process. The report assesses current practice rather than proposing precise change, but it does note that this is an opportunity to "protect and expand on elements of the process that are working well" in light of Britain's imminent exit from the EU. *See FSA/FSS Efficacy of Recalls, Final Report, supra*, at ¶ 6.3.

The British Standards Institute (BSI) Group invited comments on a draft Code of Practice for recalls, including food, in late 2017. The draft Code is no longer available for view because the BSI is currently considering and responding to public comments, but the draft promoted the benefits of and assisted with pre-planning for corrective action, as well as guidance on the recall process itself.

A "good" recall should be timely, well-defined from its outset, and limited in scope. Local enforcement agencies, business customers, distributors, consumers, and global regulators should communicate regularly. Food companies can limit reputational damage by ensuring that the returns and disposal of affected products are well-managed—although in practice, the retailer is more likely to manage such aspects. It can be helpful to monitor the effectiveness of the recall throughout and conduct a thorough assessment afterward to pinpoint any areas that could be improved next time around.

Exporters can prepare for global recalls by developing thorough recall protocols. The written policy and protocol can include chain-of-command procedures, checklists, customer, government agency, and press notification templates that the exporter can use immediately when a problem arises.

Food businesses can ensure recall readiness by keeping accurate records, including product codes and batch numbers, product identity and traceability procedures, product complaint details, warranty returns, insurance and legal claims (important for identifying trends), quality control records (important to prevent issues and for establishing due diligence), and product distribution records. Food businesses also should be able to quickly contact customers; internal team members; and an external team of legal, media, and scientific testing experts. Digital recordkeeping resources like batch code traceability also can facilitate the recall process, but even accurate and easily accessible paper records will greatly assist with managing a recall properly.

Food businesses should regularly review their insurance coverage. Businesses should, but do not always, know whether their policy covers them for product liability claims and recall process costs, and whether that coverage applies to all jurisdictions in which they conduct business. Food businesses with international insurance coverage should keep their providers up-to-date when they enter or exit a country's marketplace.

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EU-based businesses facing a food safety problem must first decide whether the law requires them to withdraw and/or recall the product. Where a product is simply below normal quality standards, or there is a minor or technical breach that does not impact safety or would be unlikely to result in enforcement action, it is more likely that withdrawal from market would suffice. However, some circumstances may dictate that a company withdraw or recall a product to protect its reputation and customer satisfaction independently of any strict legal obligation.

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If a recall is legally required, the best approach will almost certainly be working through the checklist drawn up in advance in a recall policy and protocol. This checklist will likely include nominating the person or people who will assess the problem, contacting the local enforcement agency (although this will likely be done by the EU importer in the first instance), and following the corrective action plan. The corrective action plan's contents will depend on the type of business, its place in the supply chain, and the recall's nature and extent, but will typically prescribe targeted communication to corporate customers and public consumers about the recall's scope and the product's shipping date, sources, and destinations to consumers and corporate customers.

Direct business-to-business phone or email alerts to those in a business's supply chain are particularly effective. Food businesses also can partner with local and national enforcement authorities to notify businesses and consumers. Alternatively, trade associations could notify their members on behalf of the business. The action plan and any communications with other businesses and the public should cover whether and how the food company will manage returns, make itself available via phone or website chats, stop shipments, issue refunds or replacements, coordinate with retailers, manage product disposition, coordinate with insurers, update regulators on the recall's status, and ultimately improve the food company's quality control and assurance processes.

Emerging global food recall trends indicate that food business operators exporting to the EU should familiarize themselves with the EU's food notification, withdrawal, and recall laws and regulations. Food business operators also should plan for a recall before any issue is identified by developing and regularly reviewing thorough recall policies and protocols and insurance coverages. For those exporting from the United States to the EU, understanding and conscientiously following these legal and practical obligations can be beneficial to anticipate the demands of European customers and to ensure that contractual documentation clearly defines the roles and responsibilities of both parties.