

Life Sciences Litigation

ADVISORY

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Crisis Management: Strategies for Food Companies - Key Obligations of Food and Feed Business Operators

Regulation 178/2002/EC ("the Regulation"), covers the key obligations for food and feed business operators who are *responsible* for the *safety* of their products. The European Commission Health and Consumer Protection Directorate-General identifies these key obligations as:

- safety
- responsibility
- traceability
- transparency
- emergency
- prevention
- co-operation

The Regulation also provides a legal framework for food and feed safety, including crisis management: traceability, notification requirements, recall and withdrawal of products.

You must ensure compliance with all production and distribution requirements and have systems in place to respond immediately to food safety issues. You must evaluate the situation; perform a risk assessment; communicate with the authorities, customers, consumers and media; initiate appropriate action to solve the problem; perform an audit to review how the crisis was handled. A crisis management plan is essential and should identify crisis management team members and their key responsibilities, and include strategies for communication with the authorities and the general public.

Traceability – Art. 18 of the Regulation requires *traceability* of food and feed, or ingredients that are processed in food and feed, at all stages of manufacture and distribution. A food operator must ensure that it has information readily available about its suppliers, production processes within its own premises, packaging and labelling, shipping, and customer records. Information must trigger internal and external notification obligations. It is essential to have comprehensive and consistent documentation and file storage systems. Appropriate documentation is also crucial for insurance and liability issues.

Risk Evaluation – Evaluation of the risk is essential - this includes scientific assessment. Depending on the outcome of a risk assessment, companies may be obliged to inform, notify, or even withdraw and recall the product(s) in question. Again, the availability and comprehensiveness of information about the situation is crucial for a quick and accurate risk assessment.

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Precautionary Principle – This applies where public health must be protected even if there is not full supporting evidence or data and a comprehensive risk assessment cannot be made. (Article 7 of the Regulation).

Notification – Information management is a crucial part of handling every crisis. The Regulation requires that food and feed business operators inform the authorities immediately if they have reason to believe that their food is not safe (*transparency*). There are specific information obligations which may be time-sensitive. While legal notification obligations may not arise at an early stage, evaluation of the circumstances will require having information available or disclosing information for strategic purposes, rather than legal requirements.

Communication – Communication is two-way: First, a company needs to have a crisis management plan in place that clearly defines information and communication obligations and structures within the company, locally and internationally. Second, information will need to be communicated outside the company to customers, authorities, consumers, and the media. An efficient and comprehensive documentation system assists such communication. You must identify who has to be informed, the content of the communication and when it should be given. In addition, address lists of authorities, customers, and suppliers, clear and comprehensive documentation about supplies, controls, and sales, etc. should be readily available in a consistent and complete form.

You must inform:

1) Authorities – who have the right to notify the general public about risks with food and feed. Information must identify individual products, the suspected risks, and required reaction. You must inform the authorities at an early stage in order to control the information provided by them and protect the company from product liability claims.

2) Consumers – must be given appropriate information as quickly as possible e.g. via news paper adverts and if necessary, a recall of the product. The information must specify the reason for the withdrawal of the product.

3) Customers – for products in the distribution chain you must inform customers of actual or suspected risks and appropriate measures to control the risks. The customers themselves have similar legal obligations. The obligations of a retailer or distributor not involved in the packaging, labelling or safety of products are limited to assistance in the withdrawal and recall of products and traceability.

4) Suppliers – if the problem is connected to an ingredient obtained from a supplier, or to identify the source of the problem, if it is still unclear.

Withdrawal and Recall – Withdrawal and recall may be required if products do not comply with food safety requirements or pose a danger to public health. The traceability of products is crucial to fulfil this obligation.

Rapid Alert System for Food and Feed – (RASFF) provides for exchange of information between Member States and the Community. It is coordinated by the Commission and involves the European Food Safety Authority (EFSA). This system should be monitored to ensure issues are detected as early as possible. A co-ordinated approach is required between affiliated companies in different Member States to submit information to national authorities promptly as well as through RASFF.

Conclusion

The legal framework of the Regulation specifies obligations to:

- retain documents for traceability purposes
- notify authorities
- withdraw and recall products

It requires a company's crisis management plan to be fine-tuned with the precautionary principle, the Rapid Alert System and rights of national authorities to communicate information to consumers. Food and feed manufacturers must be aware of the issues identified above and ensure all appropriate steps are taken should a crisis occur.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our life sciences litigation practice group:

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