

# A model for food manufacturers in crisis

Dealing effectively with foodborne illness outbreak and food product recalls: The importance of careful, factual investigation

When a food processor first learns that its products are suspected of causing illnesses and that it may need to institute a product recall, the first reaction usually is to determine whether the allegations are true. Then, if they are true, what is the source of the alleged contamination and who is to blame? This gut-reaction to find answers is totally appropriate. However, the manner in which the company conducts its internal investigation is critical to protecting its legal rights and interests.

The internal factual investigation should begin immediately. It is vital to determine the appropriate scope of a recall to best protect consumer health and safety. An immediate and careful factual investigation also is critical to government regulations and the potential civil and criminal litigation.

By starting the investigation immediately, the company may be able to get a head start on any potential adversaries—such as the news media, government regulators, and lawyers for injured parties—in evaluating the potential magnitude of the company's exposure with respect to any potential lawsuits or government-led investigations. Learning as much as possible about what may have gone wrong internally enables the company to shape a coherent strategy as it prepares to meet whatever legal, regulatory and public relations challenges lie ahead.

There are important steps companies should take to conduct a thorough internal factual investigation.

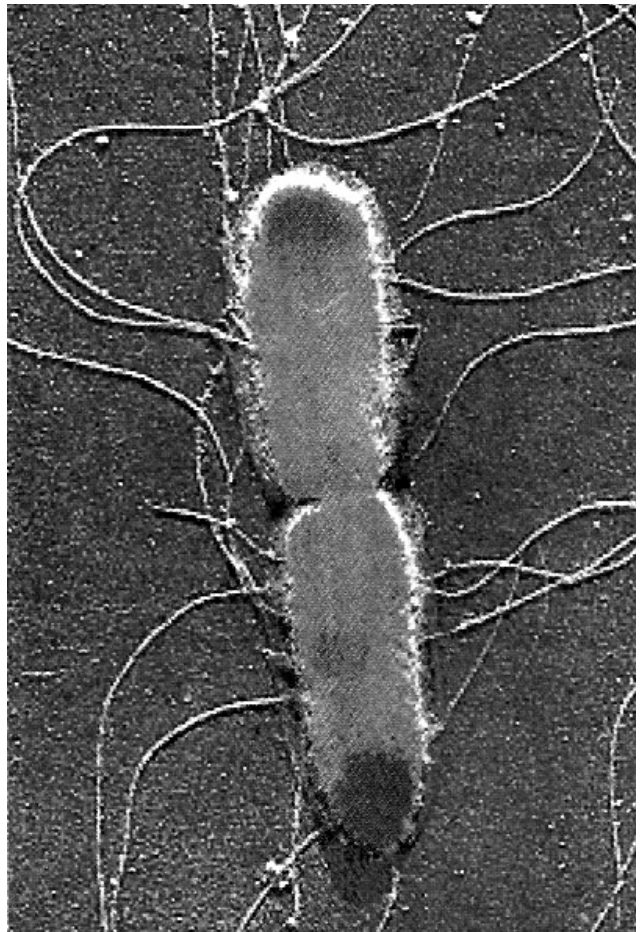
## 1. Get your company's attorneys involved.

We strongly recommend involving the company's in-house and/or outside counsel in the internal investigation immediately. Attorneys are generally experienced in conducting investigations and knowledgeable about how to interview people who possess relevant information. Moreover, while the goal of the investigation is to learn the good, the bad, and the ugly facts, companies may want to be able to keep confidential all discussions with employees and management that are part of the investigation. As a general rule, many types of communication with company lawyers in an investigation conducted in anticipation of litigation or regulatory actions will remain confidential and privileged.

Having its attorney direct and participate in the investigation therefore gives the company an opportunity to listen to employees speak candidly about their knowledge of certain events without having to disclose those discussions to adversaries—including competitors—should litigation be commenced.

## 2. Interview employees in key departments.

A company's employees are the best source of information during an investigation. They will know background facts, details and idiosyncrasies about the manufacturing process and business operations that are not necessarily contained in any document.



A food processor should interview employees in the following key areas:

- **Plant management:** In order to effectively start and undertake a thorough internal factual investigation, the investigators need to know the organizational structure of the plant operations, as well as the key players involved in the manufacture, sales, marketing and delivery of the implicated product to customers and end users.  
Plant executives should assist in making a list of key employees in each of these areas so that the factual investigation is comprehensive and thorough.
- **Quality Assurance employees:** Managers, supervisors, and technicians should be interviewed about all food safety practices and policies, testing procedures and results, as well as employee concerns or complaints about the company's food safety practices. On-site laboratory personnel, who are usually part of the Quality Assurance department, can provide information about testing protocols for the suspected contamination. These employees should be asked to provide a firsthand account of the working relationship and inspection history of the plant by on-site USDA, FSIS, or FDA inspectors.
- **Engineering personnel:** If a specific production line or area is suspected as a source of contamination, investigators should determine whether there were any ongoing or problematic equipment repairs and whether any remodeling or renovations occurred in those areas.
- **Sanitation managers and cleaning crews:** These service providers, whether they are employees or vendors, will be able to offer information about the nature and frequency of their work in various parts of the plant, particularly those areas that are suspected as the source of bacterial contamination.
- **Production management:** Employees who oversee the day-to-day production of the company's food products will need to be thoroughly interviewed regarding their food safety practices, as well as for specific information about important dates or events that may become the focus of the investigation.
- **Shipping/Transportation personnel:** They likely will be able to provide information about the specific shipping of the food product in question. These individuals are vital because they can help confirm that any recall notification was indeed comprehensive by:
  - 1) Identifying where affected product was shipped and when;
  - 2) Ensuring that warehouse products were not overlooked; and
  - 3) Gauging the amount of product in transit and being returned.
- **Customer service department and sales and marketing personnel:** If a recall has been instituted, these employees should be interviewed because it is essential to document the steps that were taken to ensure

an effective recall. The company's internal investigators will want to know the procedures by which customers and consumers were alerted to the potential problem with the product, and the company will need to document what decisions were made as it started a recall and why.

### 3. Collect relevant documents.

In addition to conducting interviews, the company and its attorneys should designate, collect, and retain all documents concerning the suspected contamination and the recall because these documents may be requested by government investigators or litigants. At the very least, these documents may provide insight into what may have occurred at the plant that placed the company in its current exposed position. Immediately upon learning of any suspected problem with the product that could result in a recall, investigation, or litigation, the company should notify all employees to maintain all documents at their desks, in their file cabinets, and in their e-mail system. No document—whether it be paper or electronic in form—should be discarded until the company's executives have consulted with its attorneys to determine whether document distribution or destruction is lawful or appropriate.

Indeed, as many litigants have learned to their chagrin, in a prosecutor's or jury's eyes – as well as in the court of public opinion via the news media – the news that documents were destroyed is a most unfavorable fact. Indeed, the act of destroying documents may have a more detrimental affect on the company than if the documents had been available as evidence in court.

Once the company has put the relevant document preservation protocols in place, it should focus on locating, reviewing and storing documents from relevant departments at the affected plant, including:

- Documents relating to the development and implementation of standard sanitation operation procedures at the plant.
- Quality assurance records for the plant, including documents related to the sanitation records for the areas of the plant that are suspected of contamination.
- Documents related to the company's regulatory compliance and food safety programs.
- Records related to any capital improvements and maintenance at the plant, particularly in the areas of the plant that are suspected of contamination.
- Any other documents that relate to practice and procedures for ensuring good manufacturing, safety and sanitation practices, including records related to bacteria testing programs and production and packaging specifications.
- Documents relating to the development and implementation of Hazard Analysis and Critical Control Point (HACCP) systems and good manufacturing practices at the plant.

- USDA Non-Compliance Reports and Process Deficiency Reports issued to the company, and documents reflecting actions the company took in response to them.
- Recall and recall-decision documents, including all records related to the notification the company provided to its customers, such as phone logs and letters, and how it responded to calls and other communications from consumers, if any.

In addition, the company's attorneys must locate and review any and all related internal e-mail communications. These often can be the most harmful evidence, either because they may contain smoking-gun types of admissions that are easy to overlook in electronic inboxes or simply the usual informality of e-mail communications can easily be misinterpreted by an outside reader.

Because communicating via e-mails is now prevalent and usually revealing, it is important that the company direct its information/technology department, immediately upon learning of facts that could lead to an investigation or litigation, to maintain an archive of the e-mail accounts of relevant employees so that the company can later review these communications as part of its internal investigation.

#### 4. Consider expert testing.

If the company needs to find the exact source of the alleged contamination, or wants to confirm that alleged contamination does not in fact exist, it may contemplate hiring an independent company to conduct tests on the food products and on any production equipment implicated in the manufacture of the products suspected of contamination.

Before hiring an independent test company, food processors should know that any test results and findings the independent tester obtain may not be protected or confidential and therefore may be discoverable during litigation.

However, the retention of an expert by the company's legal counsel may provide some valuable protections. Food processors should always consult with their attorneys before hiring a food safety and/or testing consultant as part of conducting a thorough factual internal investigation. **FP**

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