

RESPONDING TO A CLIENT'S FOOD SAFETY ISSUE

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CHAPTER 2.1

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I. INTRODUCTION

You receive a desperate call from a client, a food producer, seeking your advice on how to deal with a possible food safety issue. The client has received a positive test result for *E. coli* O157:H7 or *Listeria monocytogenes* or [insert your deadly pathogen of choice here]. What do you do? What do you tell the client?

For any attorney who routinely represents food businesses, this scenario is likely to occur at some point in time. When it does occur, it is critical to take prompt action to control the situation, prevent harm to the public, and minimize the client's liability and expenses. Having a game plan before an incident like this occurs, therefore, can be extremely helpful.

This article—while not comprehensive—outlines some of the key steps attorneys should advise their clients to take in the immediate response to a food safety issue. These steps need not necessarily occur in the order presented and likely will overlap to some extent.

II. ASSEMBLE THE TEAM

The first step in responding to a potential food safety issue is to assemble the team of people who will be responsible for assessing and investigating the incident and carrying out the company's response. Ideally, the client will have a thorough recall plan in place before the emergency situation arises, and that plan will identify the recall team members. The team should include a person who will have overall responsibility for managing the situation, as well as personnel with expertise in manufacturing, distribution/sales, quality assurance, food safety and hazard analysis, public relations, and legal affairs. If an outside food safety consultant is engaged, that should be done through counsel using an *Upjohn* letter so that the consultant's work can be protected under the attorney-client privilege as much as possible.

III. CONFIRM AND IDENTIFY THE PROBLEM

The next step in dealing with a potential food safety issue is to confirm and identify the problem. Understanding the scope and source of a contamination incident likely will be an ongoing process that will take time. As soon as a serious health risk is suspected, it may be advisable to halt all production and stop shipments of the product so the potential problem can be contained pending the investigation.

Be aware that initial lab screening results are just "presumptive positives" and may, in fact, be false positives. Screening results must be confirmed to determine whether pathogens actually have

contaminated the client's products. While the client always should err on the side of protecting consumers' health, it also is important not to overreact to unreliable information.

Other steps that should be taken as soon as possible include:

- Identifying affected lots and where the products went;
- Identifying affected customers;
- Conducting a risk analysis; and
- Performing a root cause investigation.

An experienced food safety professional is essential to performing the hazard analysis and root cause investigation well.

IV. NOTIFY FDA, IF REQUIRED

Section 417(d) of the Food Drug & Cosmetic Act (21 USC § 350f) requires the person responsible for a registered food facility to report a food to FDA through an electronic portal when "there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals." These are the same criteria as a Class I recall.

The law requires that the "responsible party" submit a report to the FDA "as soon as practicable, but in no case later than 24 hours after" such determination has been made. 21 USC § 350f(d). A "responsible party" is defined as "a person that submits the registration under section 415(a) for a food facility that is required to register under section 415(a), at which such article of food is manufactured, processed, packed, or held." *Id.* § 350f(a)(1). Note that not all food producers or handlers are required to be registered with FDA (for example, farms) and, therefore, are exempt from this requirement. FDA does not dictate the time frame for how long a company has to conduct its investigation before reaching the conclusion that it has a reportable food.

A company need not submit a report to FDA when: (1) the adulteration originated with the company; (2) the company detected the adulteration before any affected article of food was transferred to another person; and (3) the company corrected the adulteration or destroyed the product. *Id.* § 350f(d)(2).

Significantly, to encourage companies to report contaminated food to FDA, the law provides that the notification to FDA "shall not be considered an admission that the article of food involved is adulterated or caused or contributed to a death, serious injury, or serious illness." 21 USC § 350f(m).

V. PROTECT CONSUMERS

Once the client has determined that it likely or definitely has a food safety issue, steps should be taken to stop the problem from expanding and to recall the affected products. If the company has not already halted production and distribution of affected products based on the suspicion of contamination, that should be done once contamination is confirmed if necessary prevent the further manufacture or shipment of adulterated products. As soon as the client has solid information about the nature of the contamination and the identity of affected products, it should issue a recall notice to customers and, for widely distributed products, to the public in general. After issuing the recall, the client should assess whether the recall was effective and whether more can be done to recall all affected products.

If the contamination originated in a raw material supplied by another company or at a facility not controlled by the client, the client also should notify that company so that it can conduct its own recall.

VI. PROTECT THE CLIENT

All of the steps described above, if done promptly and well, will help to minimize harm to the client. The best protection for the client is to prevent people from getting ill or dying. Aside from that, attention should be paid to protecting the client's reputational and legal interests. The following are some of the steps that should be taken in this regard.

A. Manage communications

Persons skilled in public relations and crisis management should be involved at the outset to help the company manage communications about the food safety issue. The PR team should work with legal counsel to ensure that communications are factually accurate, consistent, and do not make unwarranted admissions.

While communications need to be managed to protect the client, the primary goal of the communications strategy must be to provide adequate warnings to protect consumers. Companies that hide information or obfuscate will suffer worse damage to their reputations than those that put their customers' safety first.

B. Preserve evidence

Early in responding to a food safety incident, the client—with assistance from legal counsel and technical experts—should put in place systems to collect and preserve evidence that may become relevant to the company's internal investigation, investigation by regulators, and possible litigation. Such evidence might include physical samples, product testing results, manufacturing records, shipping records, customer complaints and communications

about the food safety issue. The client also should be maintaining evidence regarding its costs and other economic losses to substantiate insurance claims and claims for indemnification.

Before issuing a recall notice, the client should prepare for how it will handle consumer calls, as such calls can be an important source of information about potential claimants. Personnel who will take consumer calls should be prepared with questionnaires to get as much information as possible about the callers' purchase and use of the recalled products, their health, and any costs the callers have incurred.

C. Prevent creation of bad evidence

Hopefully, your client will catch a potential food safety issue and stop distribution of the products before anyone is physically injured. However, even in the best case scenario, food safety incidents may lead to litigation. Clients should be advised that all documents and other evidence they create may one day be discoverable in litigation. Clients also should be advised as to when the attorney-client and other privileges apply and—maybe more importantly—when they do not apply.

D. Protect the client's rights to indemnification

Clients dealing with food safety incidents and recalls can incur enormous costs and losses. It is extremely important to determine what insurance coverage the client may have for liability and for recalls. If a raw material supplier or service provider (such as a contract manufacturer) caused or contributed to the problem, counsel should review the client's contracts with those other companies to see if they provide for indemnification. Insurance companies and other indemnitors should be put on notice of the client's claims as soon as possible.

VII. CONCLUSION

A food safety scare is the worst nightmare for any food business. By paying attention to the considerations discussed in this article, an attorney helping a client in handling a food safety incident can play an important role in minimizing the potential harm both to consumers and the client.