

Responding Rapidly as Inspections and Recalls Rise

By John M. Toth

From spinach and fresh ginger to meat and dairy products, highly publicized food product recalls have created a public perception of an unsafe food supply and inadequate regulation. The U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) have responded with more frequent and aggressive inspections of food producers. James F. Neale, a McGuireWoods LLP litigation partner who focuses on product and consumer issues, urges industry clients to develop response strategies that not only preserve positive relations with industry regulators, but also provide a more accurate view of the efforts made by producers to provide safe products. Neale says the best way for food companies to meet these goals begins with “an integrated inspection and recall response plan that will support regulatory integrity, provide timely, accurate information and meet the scrutiny of plaintiffs’ lawyers should litigation ensue.”

Accommodating Guests

“It helps if food companies have facility-specific as well as product-specific inspection response protocols,” Neale advises, “because producers often deal simultaneously with multiple inspectors, and those inspectors expect a quick and complete response in today’s sensitive atmosphere.” Inspectors from the USDA are

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frequent visitors—often with resident inspectors stationed in larger plants. FDA inspectors generally make less frequent but sometimes more intense inspections, often without notice. The FDA also has the Office of Criminal Investigation (OCI), whose almost 200 special agents can present search warrants for a probable cause inspection.

An effective response protocol, regardless of the inspecting body—or how familiar the inspectors may be with your company and its facilities—often starts with a designated inspection coordinator and a trained backup. “The strength of your response frequently depends on the knowledge and training of your coordinators,” Neale says. While inspectors are not generally authorized to take photos or request trade secrets, they can ask for additional information, and inspection coordinators must be able to respond promptly. “Written company responses within two weeks used to be acceptable, but no longer,” Neale says.

It's Not Just Food

Since the **U.S. Consumer Product Safety Commission (CPSC)** was created, a company involved with consumer products has had an obligation to notify the CPSC when the company had reason to believe that a product contained a defect that could create a substantial product hazard, presented an unreasonable risk of serious injury or death, or violated a safety standard. Once the CPSC made a determination of a defect or hazard, it conducted a mandatory recall. In the late 1990s, the CPSC adopted the **Fast Track Product Recall Program**. Through this program, companies are able to conduct voluntary recalls with the CPSC—without a determination of an actual defect or hazard by the CPSC.

McGuireWoods Partner Michael R. Daglio notes that company-initiated voluntary recalls now comprise the vast majority of consumer product recalls, although the CPSC still retains its authority to conduct mandatory recalls. Daglio urges in-house counsel for any consumer product company to create an internal system that funnels information on potential defects directly to the legal department. "In-house counsel is best positioned to evaluate the issue and determine whether there is need for disclosure to the CPSC or other action," he says.

vital for legal counsel also to be on the root cause team to make sure the investigation meets the company's legal obligations while preserving the protections the law provides to the company. Because regulatory agencies often issue their own public communication on the root cause findings reported to them by a company, and because there is no such

thing as 'confidential' agency communication, counsel's involvement at an early stage can ensure that root cause findings will focus where they should—on operational resolutions, not liability issues."

Working Together

Neale and Spivey stress that food product companies and their in-house counsel should make every effort to maintain a good working relationship with the USDA and FDA, despite the intensified inspection and recall pressure. "The USDA and FDA feel public pressure for 'action' as much as the companies do," Spivey says, "but a cooperative approach generally produces the best results for everyone—the public included." And, as Neale notes, "If companies are proactive and responsive in inspection and recall situations, the regulators will feel less compelled to take an unnecessary adversarial stance." ●

A Second Dimension

Recalls add a second dimension to the food safety issue. The only mandatory food recall authority is that of the FDA over infant formula, but the USDA can expand the scope of any voluntary company recall and can also encourage seizure of recalled products. Because a company potentially faces business, regulatory and legal consequences from a recall, McGuireWoods litigation Partner Angela M. Spivey recommends full involvement of in-house counsel to help deal with what she calls the "multiheaded monster" of possible regulatory and litigation accountability, public misperception and even employee morale issues that may stem from a recall decision. As a beginning matter, the decision to recall should be made by a team that includes the appropriate decision makers. For example, depending on the product and the distribution network involved, the recall team, in addition to legal counsel, might include the CEO or other senior decision maker and responsible executives from quality, distribution, production, public communication and regulatory affairs or other areas of the company. "Making sure that the company speaks with one voice and provides informed, accurate and timely information is paramount," says Spivey.

Getting to the Root

The recall effort also commonly will include a root cause analysis to identify the source of the problem. "There will be overwhelming pressure after any recall for the company to quickly report a reason for the problem, even when not all the facts are known," Spivey warns. Companies should resist that pressure. "The public wants to know that any problems have been resolved, but to keep the public's trust and the regulator's trust, it's important to be as accurate as possible," Spivey says. As in the case of the recall team, the composition of a root cause team will vary, but may include technical specialists, facility managers, maintenance officials and microbiologists or other scientists. Spivey emphasizes, "It is

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