Where the subject may be perishable but the insight isn't.

How To Prepare For An FDA Inspection And Recall

Jim Prevor's Perishable Pundit, July 14, 2009

We have written much about food safety, including coverage of the **spinach crisis of 2006**, the "Import Alert" on certain **Honduran Cantaloupes**, a botulism outbreak tied to consumer mishandling of some **carrot juice**, the **Salmonella Saintpaul** outbreak — thought initially to be related to tomatoes and then, seemingly to certain chili peppers — and, more recently, recalls related to **pistachios** and **sprouts**.

One thing that tied all these food safety issues together is the involvement of the Food & Drug Administration. What companies are obligated to do, when they ought to comply, what the powers of the FDA actually are, how companies can appeal or object… these are all common questions that we have addressed in various ways at various times over the years.

Fortunately, we received a letter written by three partners and an associate at one of the world's largest and most geographically diverse law firms to help members of the industry better understand the FDA and the rights of individuals and companies when dealing with the FDA.

Be aware that these contributors speak for themselves and not their law firm. Also be aware that there are many sub-specialties in dealing with laws related to the FDA. For example, we ran a piece **here** that linked to a *Food and Drug Law Journal* article on the FDA and Import Alerts. The piece also included an interview with the lawyer who wrote the piece.

Note also that among the correspondents who have written this piece is one Harold Gordon. Harold is a well known litigator in New York legal circles; he is also the son of Myra Gordon, the Executive Administrative Director at the Hunts Point Market.

Harold, along with co-authors William J. Hine and Jennifer L. Del Medico, recently wrote a column for Pundit sister publication, **PRODUCE BUSINESS**, titled **Beware Of Bribery Beyond Our Borders**. It is an excellent primer on the U.S. Foreign Corrupt Practices Act and a reminder to US companies dealing abroad as to some activities that can get them in real trouble.

Recently we ran a piece, titled **FDA's Pistachio 'Warning': The Other Side Of The Story**, which told the story of a woman who was shocked by the behavior of a local FDA agent and who decided to do what she felt was necessary rather than what she was told to do by the FDA agent. It is a fascinating story and raises all kinds of questions. The following letter provides some guidance on

how to manage one's interaction with the FDA:

Given the Pundit's impressive recent coverage of the pistachio recall, we thought the industry might appreciate a primer on some basic steps produce and other food industry companies can take now to minimize the pain of a future recall:

Are You Ready To Recall?

Earlier this year, the nation's second largest pistachio processor voluntarily recalled more than 2 million pounds of nuts because they may have been contaminated with salmonella. A widespread pistachio recall, which included dozens of additional companies, came on the heels of a highly publicized peanut recall. But it's not just nuts. This year, certain brands of olives, sprouts, eggs, sun dried tomatoes, dried yellow potatoes and other products have also been voluntarily pulled from grocers' shelves.

No company wants to be associated with a recall. But any produce company that is involved in the growing, processing, or wholesale or retail distribution of produce needs to think about how their organization would perform under intense media and regulatory scrutiny should their product become the next pistachio or peanut. Smart companies should be armed with a recall contingency plan that an expert has vetted and the company has tested.

Working with the FDA

The United States Food and Drug Administration ("FDA") is responsible for the safety and purity of all food products with the exception of meat, poultry and eggs, which are regulated by the United States Department of Agriculture. FDA inspectors may inspect a business without warning so long as the time is reasonable and the inspectors present their credentials and written notice to the owner, operator or company employee in charge. Courts have said that weekend inspections outside of normal business hours are reasonable.

What is a "reasonable" time for an FDA inspection will undoubtedly turn upon the particular facts and circumstances and the urgency dictated by any alleged tainted product. Inspectors must be given access to records the FDA needs to determine, whether food is adulterated and presents a threat or serious adverse health consequence to humans or animals. Such records may include hardcopy or electronic documents. Generally, inspectors may not examine food recipes or financial, pricing, research or sales data, other than data regarding product shipment. Inspectors must also be allowed to copy records and take photographs and samples, but they must leave a receipt for any samples taken.

Companies should train employees on all shifts regarding the potential for unannounced inspections, which should include training on how to interact with inspectors, how to respond to record requests, and what to expect generally during the inspection. For example, an owner or employee may ask to see the inspectors' credentials and identification, although it is not permissible to keep inspectors from entering while contacting an FDA office for confirmation. Management and employees should strike a cooperative approach to an FDA inspection, assisting FDA inspectors in gathering relevant books and records, as obstructing an inspection can give rise to criminal or civil penalties.

Neither management nor any employees need, however, to agree to a voluntary in depth interview by an FDA inspector unrelated to questions simply designed to find relevant records or samples. It would be advisable to contact counsel before agreeing to let FDA inspectors interview anyone. In addition, someone should be tasked with maintaining a record and copies of all documents taken during an inspection, questions asked or other steps taken by inspectors.

Should you refuse the FDA inspectors access to conduct their inspection, the inspectors may obtain an inspection warrant in order to conduct their investigation. If a firm has denied the FDA inspectors access in the past, the inspector may obtain a preemptive inspection warrant.

The FDA does not currently have the authority to force produce or food companies to recall food products. The FDA may, however, seek court authorization to seize and destroy adulterated or misbranded food products. FDA officials may also provide the public with information about food products they believe pose risks to public health. The FDA's authority to

order recalls may change, as Congress is currently considering legislation that would authorize the FDA to order mandatory food recalls.

The Recall Process

The FDA classifies recalls into three categories. Generally, the FDA tailors its involvement in a recall to the so-called recall class or category, and is most heavily involved in Class 1 recalls.

*• **Class 1**: Recalls of dangerous or defective products that predictably could cause serious health problems or death. Examples include food found to contain the botulinum toxin or food with undeclared allergens such as peanuts, dairy products, selfish and soy.*

*• **Class 2**: Recalls of products that might cause a temporary health problem or pose only a slight threat of a serious nature; for example, unapproved food additives.*

*• **Class 3**: Recalls of products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing laws, for example, a failure to label retail food in English.*

For the most part, product recalls are voluntary, but the FDA may request a recall if a producer is not willing to remove the subject product from the market without the FDA's written request. However, the FDA's regulations state that it will only request a recall in "urgent situations." The FDA considers a situation urgent where the producer has refused to take action and the FDA has determined that (1) the product distributed presents a risk of illness or injury or gross consumer deception; and (2) agency action is necessary to protect the public health and welfare. Should a company decline the FDA's request for a recall, the FDA may take legal action against the producer.

Generally, from both a legal and public relations perspective, a voluntary recall is far more preferable than forcing the FDA to take action. When dealing with the FDA, and in particular in the context of a recall, cooperation is expected and may benefit the company in potential civil litigation that may follow a recall. Proof that a producer cooperated with the FDA or other responsible agencies may, for example, be used to overcome allegations that punitive damages are appropriate as the company acted "willfully and wantonly." In other words, it is usually in the company's best interest to show that it is acting to preserve consumer safety and to assist the FDA as this can provide helpful evidence to fight claims that might later be brought by consumers or others.

Reduce the probability of recall

No company wants their name connected with a recall. While you cannot eliminate the possibility of a recall, you can take steps to reduce the chances that your company will suffer the expense and negative publicity associated with a recall, or far worse, litigation related to a recall.

*• **Work with credible suppliers.** Conduct appropriate due diligence on the companies that are supplying ingredients and hire an independent outside party to conduct supplier audits. Be sure to communicate to suppliers your specifications and food safety requirements for all incoming goods, not just ingredients, including raw materials and packaging materials. Make sure that all of these incoming goods are thoroughly inspected before being used.*

*• **Develop and maintain quality management systems covering quality assurance and control.** These systems will help prevent adulteration and substandard quality.*

*• **If your company manufacturers, packs or stores food products, comply with the FDA's current Good Manufacturing Practices.***

*• **Develop a customer inquiry and complaint database to identify potential issues before they become problems.** Train your customer service personnel to take uniform and detailed information from each complainant.*

*• **Make sure your products are traceable.** In addition to markings identifiable by the consumer, ensure that production, shipping and sales records contain batch/lot/serial numbers and shipping dates.*

• ***Be proactive.*** *If a story in the media suggests a problem with the type of food that you produce (even if it has not mentioned your company), assemble your recall team and review relevant internal records and manufacturing and storage procedures.*

Develop and test a recall contingency plan

Be prepared for the worst. Time is a critical factor when facing a recall. The FDA's guidelines encourage producers to develop a contingency plan for dealing with recalls prior to an issue arising. While this is not required by the FDA, having and following a recall plan can go a long way in preventing or reducing liability for your company in the event the worst happens.

For this reason, you may want to consider preparing a recall manual for your company and encouraging all employees to become familiar with the process. Consider including the following in your recall contingency plan:

• Prepare a statement of purpose that articulates the recall plan's goals including: (1) protection of the customer; (2) removal of the offending product from commerce; (3) compliance with federal and state regulations; and (4) protection of the company's assets.

• Identify recall team members. Make sure there is a representative from the following departments: production, distribution, consumer affairs, legal, regional sales, purchasing, marketing, public relations, accounting, and quality assurance. Several areas can be represented by one person. Should your company not have these various personnel positions, consider hiring third-party public relations specialists to handle the media and a law firm to help guide the process and advise on legal issues.

• Assign clear responsibilities to recall team members. For example, designate a team member as the individual responsible for communicating with regulatory agencies (which should be done with counsel) and another responsible for communicating with the press. Streamlining communications with interested parties will ensure that the firm's message is consistent and clear. In addition, consider assigning recall members responsibility to gather information that the FDA will require once you notify them that you intend to undertake a recall.

• Establish a system for fact gathering about a defective product. The recall plan should include a list of questions, regardless of whether the complaint is internal or external, including: (1) product identification; (2) complaint source; (3) the complaint; (4) the reason for the complaint; (5) support for the complaint.

• Address the following areas: (1) suspension of production; (2) notification of distributors, wholesalers or end users; (3) collection of recalled product; and (4) disposal of recalled product.

• Keep a written log of all of your actions, including: (1) when the complaint was received; (2) when the recall team met; (3) when the initial risk was evaluated; (4) when testing was done; (5) when production or distribution was stopped; (6) when and how interested parties were notified. This information can be critical should legal action later be taken related to the recall.

• Consider conducting a "recall" dry run to test your plan. Determine how quickly your team can identify and segregate specific products and inform those who might be affected by distributing, selling or consuming the product. Document the results of your mock recall in writing.

A recall can be an incredibly expensive and damaging process for any produce or food industry company. But with careful advance planning guided by experienced professionals, your company can be ready to better navigate the process and limit the pain of recall.

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We appreciate the time that these attorneys and Jones Day put into this letter in order to help the industry.

The letter is chock full of helpful information and filled with good advice. We would add just three points:

First, although courtesy and cooperation are important, these are not synonyms for capitulation. The FDA field offices are not staffed with the caliber of person at FDA headquarters. Just because someone with a badge shows up and tells you that you must recall, as the song says: “It ain’t necessarily so.”

There have been cases in which personnel from local FDA field offices walked in demanding a recall and companies that had retained top notch epidemiological talent to do an independent assessment of the epidemiology were able to elevate the situation to Washington, D.C. and get headquarters to understand that the field office was misinterpreting the epidemiology and no recall was required.

Part of a good recall plan is that each firm needs to know A) What epidemiologist are you going to call for an independent assessment of the facts — and remember you need someone with a reputation so the FDA will listen, and B) What law firm will you call, and, though your usual firm down the block may be fine for many purposes, you really need someone with the contacts and staff time to escalate the situation to FDA in Washington, D.C. if that is required.

Second, when testing your recall plan, make sure you do so under less-than-ideal conditions. For example, if you have a food safety director who is the key person at the crux of your plan, assume that she will be at her daughter’s wedding in Tahiti when this hits. Your CEO is surely going to have just boarded a flight to Sydney when the FDA shows up. Plans have to be tested by surprise with real life conditions. Planning your test recall so that nobody important is on vacation is unrealistic and guarantees you won’t be fully prepared.

Third, be wary of “solutions” that don’t really solve the problem. For example, many firms realize that their communication capabilities will be overrun as the media and customers inundate the switchboard after an announcement. Recognizing this, companies will decide to hire a telemarketing firm to receive calls. This may be more polite than a busy signal, but that telemarketing company will not be able to provide substantive answers to customers or the media. There are general answers such as regular web site updates, and there is the need to figure out a mechanism to triage calls so that specific responses can be provided by knowledgeable staff. Remember rumor fills a vacuum — if you don’t get accurate information out there, you can count on inaccurate information spreading like wildfire.

Many thanks to Harold K. Gordon, William J. Hine, Sharyl A. Reisman, Jennifer L. De Medico and Jones Day for helping executives in the industry prepare for dealings with the FDA.