Trends From 2011 FDA Warning Letters on Adulterated Food

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In the last few years, the U.S. Food and Drug Administration (FDA) has become much more inspection-oriented and enforcement-minded. The agency is conducting more inspections of food facilities and routinely issues Warning Letters based on insanitary conditions and violations of good manufacturing practices (GMPs). This is a significant shift from the agency's practices a few years ago.

To gain insight into FDA's enforcement priorities and current approach to inspections, we reviewed warning letters issued by FDA during 2011 regarding adulterated foods based on FDA inspectional findings. [1] An understanding of the agency's areas of focus and current inspectional practices, as signaled by warning letters, will assist food companies in preparing for future inspections and, ultimately, for FDA's implementation of the FDA Food Safety Modernization Act (FSMA).

Adulterated food can take several forms. The Federal Food Drug and Cosmetic Act (FFDCA) deems a food to be adulterated in several situations, including: "(1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; … (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered

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injurious to health." [2] The warning letters surveyed focused on foods that were adulterated on these bases.

Focus Areas for Warning Letters on Adulteration

In 2011, FDA issued 214 warning letters for adulterated food, more than half of which pertained to violations of the Hazard Analysis and Critical Control Point (HACCP) requirements for seafood and juice. Of these 214 warning letters, 122 were for facilities processing seafood or juice products, and 92 were for facilities processing other types of food. Through our review of these warning letters, we identified the following trends and patterns:

1. FDA Regularly Identifies Adulteration for Problems Beyond Actual Contamination of Food.

Of the more than 200 warning letters issued by FDA in 2011 regarding adulterated food, only a handful involved contamination of the food itself. Nine warning letters involved foods that contained a poisonous or deleterious substance (i.e., a pathogen such as *Listeria monocytogenes* or *Salmonella*). With only one exception, all of the warning letters for foods containing a pathogen also cited environmental testing that found the pathogen in the facility. Additionally, three warning letters involved actual contamination of the food by any filthy, putrid, or decomposed substance. Those three warning letters involved rodent activity and/or filth or insect activity.

2. Many Warning Letters for CGMP Violations Were Based Only on FDA's Visual Inspection of the Facility.

Rather than involving contamination of the food itself, the vast majority of warning letters for adulteration involved insanitary conditions in the plant, packaging, or storage facility. The majority of warning letters that cited violations of current Good Manufacturing Practices (CGMP) were based on a visual or walk-through inspection, rather than the results of tests on environmental samples taken from the facility. FDA found 46 facilities to have CGMP violations based on only a walk-through inspection of the plant, compared with 21 facilities with CGMP violations based on environmental findings.

FDA issued warning letters for CGMP violations after observing issues such as inadequate sanitation (e.g., visibly unclean equipment, rust on equipment, visible residue from previous day's production), inadequate employee hygiene practices (e.g., failure to wash hands thoroughly, use gloves, or wear hair nets), and pest activity.

3. Warning Letters Also Were Issued Following Positive Results from Environmental Testing.

In addition to the warning letters issued for CGMPs after a visual inspection, FDA also issued 21 warning letters for CGMP violations following positive results from environmental testing. Most of these warning letters involved *Listeria monocytogenes*, although FDA also issued warning letters regarding positive environmental findings for *Salmonella*, *Staphylococcus aureus*, and *E. coli*. In several of these cases, the bacteria were found not only in the plant but also in the food itself. In many cases where FDA's environmental testing showed positive results, FDA's warning letters also cited violations identified during a walk-through or visual inspection.

4. Numerous Warning Letters Were Issued For Violations of the Seafood and Juice HACCP Regulations.

The majority of warning letters for adulterated food involved violations of the HACCP requirements. FDA issued 115 warning letters for seafood HACCP violations and 7 warning letters for juice HACCP violations. FDA evaluated both the content and implementation of the HACCP plan in great detail. The agency issued warning letters for failures to:

- Conduct a hazard analysis for each kind of product produced and implement a written HACCP plan to control any food safety hazards that are reasonably likely to occur.
  - » Warning letters were most often issued for failing to list specific food safety hazards in the HACCP plan, such as undeclared allergens, *Clostridium botulinum*, Scombrotoxin (histamine), and parasites.
- Identify critical limits.
  - » Warning letters were typically issued because the critical limit was not considered adequate to control the food safety hazard. Specifically, FDA questioned the critical limits chosen by firms and recommended specific controls, such as a temperature at which the products should be stored.
- List monitoring procedures and their frequency in the HACCP plan for each critical control point.
- Implement monitoring procedures for critical control points.

- Identify appropriate corrective actions in the HACCP plan or take an appropriate corrective action when a deviation from a critical limit occurs. FDA questioned specific corrective actions and objected to the following:
  - » Corrective actions that did not address correcting the causes of problems (e.g. a malfunction in a cooler, a deviation in brine strength, or a temperature deviation).
  - » Re-cooking potentially adulterated product as a corrective action.
- Implement the record keeping system listed in the HACCP plan.
- Implement an affirmative step which ensures that imported fish and fishery products are processed in accordance with the seafood HACCP regulation.

The warning letters typically focused on specific procedures that were either not identified in the HACCP plan or not implemented for a particular product.

In many cases where FDA issued a warning letter for a HACCP violation, it also found violations of CGMPs. The seafood and juice HACCP regulations require firms to monitor sanitation conditions and practices to ensure compliance with CGMPs. Occasionally, CGMP violations were the sole basis for a warning letter regarding a seafood or juice product.

5. Warning Letters Focused on Certain Product Categories.

In addition to enforcing the seafood and juice HACCP regulations, FDA's warning letters also focused on violations of the regulations for acidified foods, low-acid canned foods, and the prevention of *Salmonella* in shell eggs. This indicates that FDA considers these foods to present a higher risk than other categories. Warning letters in these categories (excluding seafood and juice HACCP) comprised approximately 10 percent of the warning letters issued in 2011 on adulterated food.

Additionally, the warning letters tended to focus on bakery and bread products, produce, cheese, confections (e.g., chocolates, candy, nuts, dried fruits), and soy products. The focus on these product areas may indicate these foods are included in the agency's enforcement priorities for the coming year as well.

Implications for FMSA

As FDA implements FSMA, we can expect to see more warning letters for adulterated food that conform to these themes. The seafood and juice HACCP letters are indicative of the type of scrutiny that FDA is likely to apply to food safety plans after FSMA is implemented. For example, the agency will likely scrutinize the specific analyses underlying food safety plans and question the scientific basis for the underlying critical limits.

Additionally, the warning letters provide insight into the scope of violations that will be subject to reinspection fees under FSMA. Because all inspections resulting in warning letters due to adulteration are necessarily considered "Official Action Indicated" for reasons material to food safety, the violations discussed in these warning letters are of the type that, in the future, would trigger a reinspection and corresponding fees under FSMA. [3]

1. Note we have since reviewed FDA warning letters issued during the first six months of 2012, and the trends from the first half of 2012 largely mirrored those observed in 2011. More than half of the 90 warning letters issued between January and June 2012 involved violations of HACCP. Approximately ten percent involved violations of the acidified foods, low-acid canned foods, and shell egg regulations. The remaining warning letters involved CGMP violations for human food products. Only three cases involved actual contamination of the food; in two cases the contaminant was a filthy, putrid, or decomposed substance and in one case the contaminant was inorganic arsenic. In 17 cases, FDA based findings of CGMP violations on visual inspections alone, compared to 5 cases where the agency also conducted environmental testing. The categories of food for which FDA issued warning letters mirrored the 2011 patterns, with more than half involving seafood or juice and with an emphasis on baked goods, produce, spices, nuts, and soy products.
2. FFDCA § 402(a); 21 U.S.C. § 342(a).
3. The firms that received warning letters in 2011 would mostly not be subject to reinspection fees because FDA has announced that it will not impose reinspection fees for any initial inspections conducted prior to October 1, 2011. But firms receiving warning letters in 2012, based on an inspection on or after October 1, 2011, would be subject to reinspection fees.