Hot Topics in Food Law

ASTA's 2017 Fall Regulatory Workshop

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Agenda

- Ready-to-Eat (RTE) Foods
- HHS OIG Report on FDA Inspections
- ORA Program Alignment
- Regulatory Reform Docket
- HHS & FDA Leadership
- Questions

Definition of RTE

- *Ready-to-eat food (RTE food)* means any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards
- Questions to ask when assessing if your food is RTE?
  - Does your Food Safety Plan control for all of the hazards identified through your hazard analysis?
  - Have you validated that your process controls achieve adequate lethality for biological hazards?
  - Does your process potentially introduce additional hazards that require control?
  - Is any further preparation necessary to ensure the food is safe for consumption?

Definition of RTE

- At what point is consumption as RTE “foreseeable”?
  - Labeling and advertising (e.g., recipes)
  - Specifications
  - Cooking instructions
  - Statements such as “for food safety…”
  - Product depiction/appearance
  - Historical use
  - Consumer feedback, reports
  - Consumer illnesses
  - Potential for abuse

Hazard Analysis Requirements

- The hazard evaluation section must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen
- The hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:
  - Labeling
  - Intended or reasonably foreseeable use

Testing Provisions in the PC Rule

- You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. To do so you must conduct activities that include the following, as appropriate to the facility, the food, and the nature of the preventive control and its role in the facility's food safety system:
  - (1) Product testing, for a pathogen (or appropriate indicator organism) or other hazard
  - (2) Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples

§ 117.136 (NRTE Disclosures and Assurances)

- If you rely on a commercial entity downstream to ensure that an identified hazard will be significantly minimized or prevented, you must:
  - Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control [identified hazard]"; and
  - Annually obtain from your customer written assurance that the customer will (as applicable)
    - Establish and follow identified procedures to SMOP the hazard
    - Manufacture, process, pack or hold the food in accordance with applicable food safety requirements, or
    - Only sell to another entity that agrees in writing to do the same

RTE Implications and Next Steps

- Need to take a close look at your products and how they are used
  - Labeling matters, but reasonable use trumps (see, e.g., frozen peas)
- Validation is necessary if the food will be positioned as RTE
- Flexibility/Responsibility to develop robust testing programs
  - Testing provisions are not limited to RTE foods

RTE Implications and Next Steps

- If foods are not RTE, then § 117.136 applies; but compliance is complicated
- Industry working to preserve the category of NRTE food
- FDA is actively working on guidance on the definition of RTE foods
  - FDA's position: The label of NRTE products should be very clear that the product is NRTE – cooking instructions are not enough

OIG Report on Domestic Food Facility Inspections

- Department of Health and Human Services' Office of Inspector General (OIG) issued a report this month on its review of:
  - FDA's inspection of domestic food facilities; and
  - FDA's advisory and enforcement actions taken in response to significant inspection violations
- Key Takeaway: **FDA should do more to ensure the food supply is safe by taking "swift and effective action" to ensure facilities promptly correct problems identified during inspections**

OIG Report – Key Findings

1. **FDA is on track to meet the initial inspection timeframes FSMA mandates, but challenges remain to meet those timeframes going forward.**
   - To meet shorter inspection cycle for non-high-risk facilities, FDA must increase pace from 8,125 to 12,000 inspections per year
   - Inaccurate information leads to "attempted" inspections
   - FDA lacks policy to reschedule attempted inspections on a timely basis
2. **Although FDA is on track to meet the FSMA inspection mandates, this did not result in an increase in the number of facilities inspected.**
   - Facilities inspected decreased from 17,000 in 2004 to 16,000 in 2015
   - Proportion of facilities inspected decreased from 29% in 2004 to 19% in 2015
3. **FDA did not always take action to ensure facilities corrected significant inspection violations.**
   - FDA took no advisory or enforcement action after 22% of inspections with significant inspection violations

OIG Report – Key Findings

4. **When FDA took action, it typically relied on facilities to correct significant violations voluntarily. FDA's actions were not always timely, nor did they always result in correction of the violations.**
   - FDA responded to significant inspection violations with advisory action 73% of the time
   - Nearly half of all warning letters issued 4 months or longer after inspection
   - When FDA conducted follow-up inspections, 20% cited with significant inspection violations resulting in Official Action Indicated (OAI) classification, 75% with identical violations to previous inspection
5. **FDA did not consistently conduct timely follow-up inspections to confirm facilities had corrected significant inspection violations.**
   - 48% of significant inspection violations had no follow-up inspection within a year
   - 17% had no follow-up inspection at all

OIG Recommendations and FDA Response

1. **FDA should improve how it handles attempted inspections to ensure better use of resources.**
   - FDA has adopted policy to immediately reschedule inspections for facilities that are temporarily not operating

2. **FDA should take appropriate action against all facilities with significant inspection violations.**
   - FDA has developed a report that can display OAI inspection classifications and resulting regulatory action(s), which can be used to track compliance activities more efficiently

OIG Recommendations and FDA Response

3. FDA should improve the timeliness of its actions, including warning letters, so companies do not continue to operate under harmful conditions.

- FDA focuses its efforts on scenarios that may involve an immediate public health risk
- FDA is allowing district offices to initiate advisory actions without prior review by the Center or the Office of Chief Counsel for acidified food and juice HACCP violations
- Creation of the Office of Dietary Supplement Programs will allow agency to better compete for government resources to better regulate the supplement industry

4. FDA should conduct timely follow-up inspections to ensure facilities correct significant inspection violations.

- FDA is developing a system to track activities concerning each specific inspection observation or violation to ensure they are corrected for all facilities that receive an OAI classification
- FDA has created an oversight group, Strategic Coordinated Oversight of Recall Execution (SCORE), to increase the timely response to inspections that warrant follow-up

FDA Program Alignment Initiative

- Shift from 20 geography-based district offices to program-specific division offices where staff are aligned by FDA-regulated product
  - 12 new division offices dedicated to human and animal food
  - New Office of Human and Animal Food Operations (OHAFO)
- Stand up day for new organizational structure was May 15, 2017
- Over time, food companies will be inspected by individuals trained in food inspections, not drug or device inspections
- Goal is to create a more proficient workforce and increase efficiency of FDA operations

FDA Program Alignment Initiative

- Import Program Reorganization
  - Previously 1 import district office, now 5 import-specific division offices covering all product areas
- New Office of State Cooperative programs under OHAFO serves as single national program for state cooperative programs (e.g., Retail Food Protection Program)
- Laboratory Reorganization
  - Instead of labs reporting to regions, they will report to ORA's Office of Regulatory Science
  - Most laboratories will also be program specific (i.e., food labs or drug labs)

FDA Regulatory Reform Docket

- FDA issued a broad request for comment to assist in identifying regulations it could modify, repeal, or replace to reduce the regulatory burden on the public
- Issued as part of its implementation of the Trump administration's regulatory reform agenda
  - EO 13777 directs each agency to establish a Regulatory Reform Task Force to evaluate existing regulations and make recommendations regarding their repeal, replacement, or modification
  - Information submitted in response to the request for comment will supplement FDA's review of its regulations
- Presents an opportunity for industry to identify regulations that are outdated, ineffective, or unnecessary; impose costs greater than their associated benefits; or limit job creation

FDA Regulatory Reform Docket

- FDA's request includes a number of specific questions, such as:
  - Have regulated entities had difficulties complying with the regulation?
  - Does the regulation impose requirements that are also provided for in voluntary or consensus standards or guidance by third party organizations?
  - Could the goal of the regulation be achieved by less costly means that would provide the same level of public health protection?
- Comments due December 7, 2017

HHS Leadership Changes

HHS Leadership Changes

FDA APPROVED

Concluding Thoughts

- It's a busy time to be in the food industry!

Questions/Discussion

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