ALLERGEN CONTROL UNDER THE US FOOD SAFETY MODERNIZATION ACT (FSMA)

STEVEN GENDELM
VP, FOOD ALLERGENS DIVISION
IEH LABORATORIES AND CONSULTING GROUP

Laboratories & Consulting Group
# FSMA 1 LAW

## 7 MAJOR RULES

<table>
<thead>
<tr>
<th>Rule</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preventive Controls</td>
<td>Final</td>
</tr>
<tr>
<td>Human Food</td>
<td></td>
</tr>
<tr>
<td>Foreign Supplier Verification</td>
<td>Final</td>
</tr>
<tr>
<td>Sanitary Transportation</td>
<td>Final</td>
</tr>
<tr>
<td>Intentional Adulteration</td>
<td>Proposed</td>
</tr>
<tr>
<td>Preventive Controls</td>
<td>Final</td>
</tr>
<tr>
<td>Animal Feed</td>
<td></td>
</tr>
<tr>
<td>Produce Safety</td>
<td>Final</td>
</tr>
<tr>
<td>Third Party Certification</td>
<td>Final</td>
</tr>
</tbody>
</table>
BASIC PHILOSOPHY

• Three simple steps
  • Implement GMPs
  • Do a hazard analysis
  • Implement needed preventive controls
PREVENTIVE CONTROLS FOR HUMAN FOODS RULE

• Two major parts
  • Modernized GMPs
  • Hazard Analysis and Preventive Controls
“MODERNIZED” GMPs

• New wording:
  • “protect against allergen cross-contact and contamination”
PREVENTIVE CONTROLS

• Implemented through a Food Safety Plan
• FSP must be based on a Hazard Analysis
• Hazard Analysis identifies
  1. “Known or reasonably foreseeable” hazards
  2. “Hazards requiring a preventive control”
FOOD SAFETY PLAN
COMPONENTS

• Hazard analysis
• Preventive controls
• Supply-chain program
• Procedures for monitoring
• Corrective action procedures
• Verification procedures
• Recall plan
WHAT ARE PREVENTIVE CONTROLS?

- Process controls
- Food allergen controls
- Sanitation controls
- Supply-chain controls
- Recall plan
HOW DOES THIS RELATE TO HACCP AS WE KNOW IT?
ONE FLAVOR OF HACCP

Prereqs

CCP
ANOTHER FLAVOR OF HACCP

PRP

OPRP

CCP
PREVENTIVE CONTROLS

GMP

PrevCont

Process Controls
PREVENTIVE CONTROLS

- Allergen Controls
- Sanitation Controls
FDA says that it doesn’t matter what you call the control – as long as it works and you control all of your hazards
ALLERGEN CONTROLS

(2) Food allergen controls. Food allergen controls include procedures, practices, and processes to control food allergens. Food allergen controls must include those procedures, practices, and processes employed for:

(i) Ensuring protection of food from allergen cross-contact, including during storage, handling, and use; and

(ii) Labeling the finished food, including ensuring that the finished food is not misbranded
ALLERGEN CONTROLS

- Allergen Hazard Analysis
  - Considers intended allergens
    - Ingredients and sub-ingredients
  - Considers unintended allergens
    - Cross-contact
    - EMA
ALLERGEN CONTROLS

• Supply Chain Applied Control
  • When a supplier controls a hazard
  • Control need to be documented
• GMPs and Transport Rule require prevention of cross-contact during transport
ALLERGEN CONTROLS

• In a facility
  • Segregate
  • Separate
  • Sequence
  • Sanitation
ALLERGEN CONTROLS

• Labeling
  • The label needs to be correct
  • The label needs to be on the right product
    • Matching the label and the product can be a Preventive Control
ALLERGEN CONTROLS

• Supply chain controls (again)
  • You might be a supplier controlling a hazard for someone else
DOCUMENTS AND RECORDS

• Food Safety Plan
  • Including documentation of all decisions
• Implementation Records
  • Monitoring
  • Verification
  • Validation
  • Corrective Actions
DOCUMENTS AND RECORDS

- Record reviews
  - Specific time frames
THE TAKE HOME MESSAGES

• The world of food safety regulation in the US is evolving rapidly
• Multiple new interlocking regulations are coming into effect
• These rules will have an international impact
THE TAKE HOME MESSAGES

• MANUFACTURERS ARE RESPONSIBLE FOR DEVELOPING AND JUSTIFYING THE FOOD SAFETY SYSTEMS THEY USE
  • Scientific data are critical
  • Documentation is essential
    • Continuously
  • Allergen control needs to be an integral part of all food safety systems
THANKS FOR YOUR TIME

www.iehinc.com

IEH Laboratories & Consulting Group

Steven Gendel
Vice President,
Division of Food Allergens

15300 Bothell Way NE
Lake Forest Park, WA 98155
p 206.940.5308 | f 206.306.8883
Steven.Gendel@iehinc.com