Hot Topics

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September 2017
- Labeling Claims and Compliance
- Notification of Adulterated or Misbranded Products
LABELING CLAIMS AND COMPLIANCE
Labeling

• Label Compliance Guideline- August 2017
  – New special statements and claims-Appendix 1
  – Added new factual statements and claims-Appendix 2
  – Clarified types of changes that do not need LPDS review-Appendix 3
  – Clarified types of changes that need LPDS review-Appendix 4
  – Blanket Approvals- Appendix 5
  – Special statements and claims that can be generically approved after initial application sent to LPDS- Appendix 6
  – Additional Information for Label Approval- Appendix 7
Labeling

• When a label needs to be submitted to LPDS:
  – Religious Exempt 9 CFR 412.1(c)(1)
  – **Labels for export with deviations from domestic requirements 9 CFR 412(c)(2)**
  – Special Statements and claims 9 CFR 412 (c)(3)
  – Labels for temporary approval 9 CFR 412 (c)(4)
Labeling

• Statements and Claims that can be generically approved after the first approval- Appendix 6

• Once claim is approved through LPDS, changes that do not impact the claim typically are allowed.
  – Example: Angus, no added hormones, grass fed, Certified Halal, Certified Kosher, For cooking only.
  – Note* Natural and Organic cannot be generically approved.
Labeling

• Changes that **cannot** be made to special statements and claims without additional LPDS review
  – If the change(s) could potentially affect the statement or claim label must be submitted to LPDS
Labeling

• Adding a new supplier to an existing sketch approval can be handled outside typical sketch approval process
• Submit a letter of request with the following information:
  – Previous sketch approval number
  – Dates
  – Copies of label
  – Supporting documentation for new supplier
• LPDS contact: Ms. Kierra Lucas  Kierra.lucas@fsis.usda.gov
• (301) 504-0878 or 0879
Labeling

• Blanket Approvals- Appendix 5
  – Multiple approvals for labels all bearing a common claim.
  – Provide a list of products that would fall under the claim with label application
Labeling

• Recent change:
  – Natural and minimally processed
    • Minimally processed now on the list of claims that need to be submitted to LPDS.
    • Plants used to use minimally processed to define natural
    • Use Documentation Needed to substantiate Animal Raising Claims to support minimally processed.
One more thing...

• Read the compliance guideline before determining if label needs to be submitted!
  – In some cases reviewers will take time to explain why the label can be generically approved, then reject the label!
NOTIFICATION OF ADULTERATED OR MISBRANDED PRODUCTS

A YEAR LATER.... WHERE ARE WE?
What has not changed?

• Establishments should maintain a foreign material response procedure to provide a method of receiving, investigating, and responding to complaints of foreign material by customers.

• Establishments must maintain preventive measures to protect product from foreign material introduction from all sources and document actions taken in response to a foreign material introduction.
What hasn’t changed?

- Still a regulatory requirement under 9 CFR §418.2 that establishments are to notify the District Office within 24 hours of determining that an adulterated or misbranded product has been received by or shipped from the establishment into commerce (outside of an inspected establishment).
Notification of FSIS

• If notifying under 418.2 the notification should include:
  • How you determined the information valid, e.g., the fact that it is your product; the basis for the product being adulterated or misbranded; and whether there is remaining product still in commerce.
  • All information regarding the investigation, nature of the foreign material, risk analysis (see above) should be included in the notification to the District Office.
  • Notification does not equal recall.
    • The documentation and support provided as part of the notification will assist in the determination of the need for a voluntary recall by the establishment.
What has changed?

• FSIS issued Directive 8140.1, Rev. 1
  – When an official meat or poultry establishment receives adulterated or misbranded product intended for further processing, IPP are to use FSIS Form 8140-1 to notify IPP at the producing establishment and the applicable District Offices.
FSIS Form 8140-1

Not used when:

• The establishment receiving the adulterated or misbranded product elects to notify the DO directly as required in 9 CFR 418.2;

• The establishment receives adulterated or misbranded product for further processing under USDA seal

• The establishment receives adulterated or misbranded product under other control measures with the intent to treat the product to make it not adulterated or misbranded (e.g., *E. coli* O157:H7 positive product received for cooking under appropriate controls).
Where are we today?

- FSIS is meeting with Industry Trade Association representatives September 11th to review “best practice document”
- FSIS continues to focus on foreign material as a concern and expects establishments to have procedures to prevent and control
- FSIS requires notification as per 418.2 if adulterated product is in commerce
- FSIS will consider recall on a case by case basis
- FSIS considers – whether there have been consumer complaints, CCMS complaints, injuries, product type (children, hospital, military), whether object is embedded in the product or visible
  - [FDA CPG Sec. 555.425 Foods, Adulteration Involving Hard or Sharp Foreign Objects](https://www.fda.gov/regulatory-information/search-federal-policy-guidance-documents/foods-adulteration-involving-hard-or-sharp-foreign-objects) may be used as a guide to assist in determining the risk of the foreign material; however FSIS does not rely on this exclusively.
OTHER HOT TOPICS OF INTEREST