Food Safety and Regulatory Update

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Senior Vice President, Regulatory and Scientific Affairs & General Counsel
September 28, 2016
Labeling

- Genetically modified organisms
- “Natural”
- Proposition 65
GMO Labeling

- Mandatory AMS administered labeling program
- Law allows disclosure using different mechanisms, *i.e.*, on-pack text or symbol, or an electronic or digital link (such as Quick Response (QR) codes or SmartLabels)
- Preempts Vermont and other state labeling laws
- Food derived from an animal is not considered "bioengineered" solely because the animal consumed GMO feed
GMO Labeling

• Most basic meat products with multiple ingredients, *i.e.*, flavored pork tenderloins, deli meats and sausages, *etc.* exempt from labeling

• Some multi-ingredient meat and poultry products will have to bear GMO labeling – “predominant ingredient” test
GMO Labeling

• Law exempts products sold in restaurants and other “similar retail food establishments.”

• Food is not considered “non-GMO” simply because it’s not required to bear a disclosure.

• Law permits AMS to set minimal thresholds
GMO Labeling

• Recent FSIS and AMS Issuances
  1. “Pasture raised beef fed a vegetarian diet with no bioengineered ingredients”
  2. “Contains No GMO ingredients”

• Law expressly permits food certified under the national organic program to bear a “non-GMO” claim indicating the absence of bioengineering.
“Natural” Labeling

• New GMO law does not address “natural.”

• FDA request for information – comments filed

• FSIS officials working on “natural” rule for meat and poultry
IARC Evaluation of Red and Processed Meat

- Monograph late 2016 or early 2017

- Working with American Meat Science Association on nomenclature project

- Need for additional processed meat and poultry research

- Proposition 65 ramifications
Proposition 65

• Nitrites in combination with amines and amides – proposed listing referred to OEHHA Carcinogen Identification Committee (CIC) in 2015

• CIC hearing November 15; comments due October 17

• IARC monograph on red and processed meat
National Toxicology Program

• Request for Information: Report on Carcinogens


Whole Genome Sequencing of Foodborne Pathogens

– WGS increasingly being used by CDC, FSIS, and FDA to identify outbreaks

– WGS could, likely will, replace pulse field electrophoresis (PFGE) within next several years

– Meat Institute leading a food industry coalition regarding WGS and possible impact
Salmonella Policy

• FSIS increasing focus on Salmonellosis – poultry, beef, and pork

• *Salmonella* as an adulterant
  
  – CSPI amended petition: four serovars

  – FSIS official’s comments regarding testing beef primals and that *salmonella* is a “hazard reasonably likely to occur” in beef products likely to be ground or non-intact
Humane Slaughter/Animal Handling

• Non-ambulatory, disabled veal calf rule in effect

• Farm Sanctuary petition pending – likely to be denied
Sanitary Transportation Rule

- Effective date April 6, 2016
- Compliance date for large businesses: April 6, 2017
- Compliance date for small businesses: April 6, 2018
- “this rulemaking will complement FSIS’s efforts to promote the application of sanitary food transportation for FSIS-regulated meat, poultry, and egg products.”
- Global Cold Chain Alliance Best Practices can be downloaded at: http://www.gcca.org/resources/sanitary-transportation-food-compliance-resources
NOTIFICATION OF DISTRICT OFFICE OF MISBRANDED OR ADULTERATED PRODUCT IN COMMERCE
CURRENT ENVIRONMENT

• FSIS developing formal procedures to address isolated foreign material found in raw material at receipt
• Foreign Material Protocol for Customer Complaints developed
• Second FSIS survey will not be completed
Foreign Material Protocol for Customer Complaints

• Encourage all establishments to review their procedures for consumer complaints
• Encourage all establishments to ensure preventive maintenance programs are properly implemented
• Encourage all establishments to review the Best Practices guidance once available and consider updates to programs as appropriate
Purpose

• All establishments should have a method of receiving, investigating, and responding to complaints of foreign material by customers

• Documentation of actions taken in response to foreign material introduction
Principles

• Mechanism for collecting complaints and directing those complaints appropriately

• Analysis of complaints for veracity, completeness, food safety risks, potential trends, etc., with triage and escalation procedures as appropriate

• Communication of relevant information internally when applicable, and externally when appropriate

• Documentation of complaints, investigations, corrective actions, and analyses
Records and Corrective Action(s)

- Substantiated complaint should prompt review of all relevant food safety and establishment records
- Corrective actions designed to prevent recurrence
FSIS DATA
### FSIS Updates: *Salmonella* in Beef and Ground Beef

**Salmonella** (% Positive) MT64(54) - Components: July 2014 to July 2016

<table>
<thead>
<tr>
<th>Row Labels</th>
<th>Total Analyzed</th>
<th><em>Salmonella</em> Positive</th>
<th>Percent Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced meat recovery (AMR)</td>
<td>14</td>
<td>1</td>
<td>7.14%</td>
</tr>
<tr>
<td>Cheek meat</td>
<td>192</td>
<td>22</td>
<td>11.46%</td>
</tr>
<tr>
<td>Head meat</td>
<td>119</td>
<td>14</td>
<td>11.76%</td>
</tr>
<tr>
<td>Heart meat</td>
<td>372</td>
<td>10</td>
<td>2.69%</td>
</tr>
<tr>
<td>Finely Textured Beef</td>
<td>27</td>
<td>1</td>
<td>3.70%</td>
</tr>
<tr>
<td>Weasand (esophagus) meat</td>
<td>34</td>
<td>5</td>
<td>14.71%</td>
</tr>
<tr>
<td>All Other</td>
<td>198</td>
<td>9</td>
<td>4.55%</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>956</strong></td>
<td><strong>62</strong></td>
<td><strong>6.49%</strong></td>
</tr>
</tbody>
</table>
Office of Policy and Program Development Policy Plans

- Redefining of beef products tested for STEC
- Performance standards for beef carcasses, boneless manufacturing trimming and ground beef
- Focus on *Salmonella* Dublin in dairy and veal
- Foreign contaminants and consumer complaints
- OPPD audit of generically approved labels
- Focus on claim verification
- Transporter animal welfare accountability
OTHER REGULATORY ISSUES

• Beef grade change allowing dentition and ossification to determine maturity
  – Support the proposal and will address implementation of revision

• Foot and Mouth Disease NAMI Work Group
  – Develop a Q & A with input from FSIS and APHIS that will address packer issues

• Posting of establishment specific data
Revisions to the Nutrition Facts Panel & Sodium Reduction Targets

Susan Backus
Vice President, Regulatory and Scientific Programs
NUTRITION FACTS PANEL AND SERVING SIZES REVISIONS
Nutrition Facts Panel: Key Changes

• Removes declaration of “Calories from fat”;
• Requires declaration of the gram amount of “added sugars” in a serving of a product
  – Establishes a Daily Reference Value (DRV) and requiring a percent Daily Value (DV) declaration for added sugars;
• Changes “Sugars” to “Total Sugars”
  – Requires “includes ‘x’ g Added Sugars” to be indented and declared directly below “Total Sugars” on the label;
• Updates the list of vitamins and minerals
  – Requires Vitamin D and Potassium and permits, rather than requires the declarations of Vitamins A and C;
• Updates certain reference values used in the declaration of percent DVs of nutrients on the Nutrition Facts and Supplemental Facts labels;
Nutrition Facts Panel: Key Changes

- Revises format of the Nutrition Facts and Supplemental Facts labels to increase the prominence of “Calories”;
- Removes requirement for footnote table listing the reference values for certain nutrients for 2,000 and 2,500 calorie diets;
- Footnote language points back to the Daily Value column and states “The % Daily Value (DV) tells you how much a nutrient in a single serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.”; and
- Requires the maintenance of records to support the declarations of certain nutrients under specified circumstances
  - Added sugars, dietary fiber (soluble and insoluble), Vitamin E, and folate and folic acid.
### Original Label

**Nutrition Facts**

<table>
<thead>
<tr>
<th>Amount Per Serving</th>
<th>Calories: 230</th>
<th>Calories from Fat: 72</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Fat</strong></td>
<td>8g</td>
<td>12%</td>
</tr>
<tr>
<td>Saturated Fat</td>
<td>1g</td>
<td>5%</td>
</tr>
<tr>
<td>Trans Fat</td>
<td>0g</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Cholesterol</strong></td>
<td>0mg</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Sodium</strong></td>
<td>160mg</td>
<td>7%</td>
</tr>
<tr>
<td><strong>Total Carbohydrate</strong></td>
<td>37g</td>
<td>12%</td>
</tr>
<tr>
<td>Dietary Fiber</td>
<td>4g</td>
<td>16%</td>
</tr>
<tr>
<td>Sugars</td>
<td>1g</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Protein</strong></td>
<td>3g</td>
<td>0%</td>
</tr>
</tbody>
</table>

* Percent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs.

<table>
<thead>
<tr>
<th>Serving Size</th>
<th>2/3 cup (55g)</th>
</tr>
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<tr>
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<td>230</td>
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* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

### New Label

**Nutrition Facts**

8 servings per container

<table>
<thead>
<tr>
<th>Amount per serving</th>
<th>Calories: 230</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Fat</strong></td>
<td>8g</td>
</tr>
<tr>
<td>Saturated Fat</td>
<td>1g</td>
</tr>
<tr>
<td>Trans Fat</td>
<td>0g</td>
</tr>
<tr>
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<td>0mg</td>
</tr>
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<tr>
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</tr>
<tr>
<td>Sugars</td>
<td>1g</td>
</tr>
<tr>
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</tr>
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<td>Trans Fat</td>
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</tr>
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<tr>
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<td>1g</td>
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</tr>
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* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.
RACC/Serving Size Changes: Key Changes

Single Serving Containers

• All containers, including containers of products with a “large” RACC, containing less than 200 percent of the RACC be labeled as a single-serving container.
   – Example: Can of soup
RACC/Serving Size Changes: Key Changes

Dual Column Labeling

• All containers/units that may be consumed in one or more sittings, or shared, that are at least 200 percent and up to and including 300 percent of the RACC, must be labeled with a column of nutrition information within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values (DV) for the entire container.

  – The label also must declare the quantitative amounts and percent DVs for a serving less than the entire container).
## Nutrition Facts

2 servings per container

<table>
<thead>
<tr>
<th>Serving size: 1 cup (255g)</th>
<th>Per serving</th>
<th>Per container</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Calories</strong></td>
<td>220</td>
<td>440</td>
</tr>
<tr>
<td>Total Fat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saturated Fat</td>
<td>5g</td>
<td>10g</td>
</tr>
<tr>
<td>Trans Fat</td>
<td>2g</td>
<td>4g</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>15mg</td>
<td>30mg</td>
</tr>
<tr>
<td>Sodium</td>
<td>240mg</td>
<td>480mg</td>
</tr>
<tr>
<td>Total Carbs</td>
<td>35g</td>
<td>70g</td>
</tr>
<tr>
<td>Dietary Fiber</td>
<td>6g</td>
<td>12g</td>
</tr>
<tr>
<td>Total Sugars</td>
<td>7g</td>
<td>14g</td>
</tr>
<tr>
<td>Incl. Added Sugars</td>
<td>4g</td>
<td>8g</td>
</tr>
<tr>
<td>Protein</td>
<td>9g</td>
<td>18g</td>
</tr>
<tr>
<td>Vitamin D</td>
<td>5mcg</td>
<td>10mcg</td>
</tr>
<tr>
<td>Calcium</td>
<td>200mg</td>
<td>400mg</td>
</tr>
<tr>
<td>Iron</td>
<td>1mg</td>
<td>2mg</td>
</tr>
<tr>
<td>Potassium</td>
<td>470mg</td>
<td>940mg</td>
</tr>
</tbody>
</table>

*The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.*
Food Serving Sizes Get a Reality Check

Serving Size Changes
What’s considered a single serving has changed in the decades since the original nutrition label was created. So now serving sizes will be more realistic to reflect how much people typically eat at one time.

<table>
<thead>
<tr>
<th>CURRENT SERVING SIZE</th>
<th>NEW SERVING SIZE</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 SERVINGS</td>
<td>3 SERVINGS</td>
</tr>
<tr>
<td>1 PINT</td>
<td>1 PINT</td>
</tr>
<tr>
<td>200 CALORIES</td>
<td>270 CALORIES</td>
</tr>
</tbody>
</table>

Packaging Affects Servings
Package size affects how much people eat and drink. So now, for example, both 12 and 20 ounce bottles will equal 1 serving, since people typically drink both sizes in one sitting.

1 SERVING PER BOTTLE FOR EITHER BOTTLE SIZE
Implementation and Compliance

• Must be on packages by July 26, 2018
• July 26, 2019 for manufacturers with less than $10 million in annual food sales.
  – Products introduced into interstate commerce on or after July 26, 2018 (or July 26, 2019 for manufacturers with less than $10 million in annual food sales) would need to include the new version of the Nutrition Facts and Supplement Facts labels.
What is Next?

FSIS Proposed Rule at OMB – July 25

– Expect similar proposal to update label and RACCs for certain products
  • late 2016, early 2017

– FSIS indicated companies can comply with the FDA regulation prior to finalization of FSIS’ rule – must comply with FSIS and any changes once issued.
  • Federal Register notice in next few weeks.
SODIUM REDUCTION TARGETS
Draft Sodium Reduction Guidance
3 Step Process to Set Targets

• Developed 150 food categories
  – Packaged and restaurant foods

• Determined baseline sodium concentration (mg/100g)
  – Based on sales weighting

• Set quantitative goals
  – Target mean levels -- apply to average sodium levels of food in a category, not individual products and
  – Recommend upper bounds -- apply to all individual products and discourage products with excessive sodium.
Information FDA Considered

• Survey of available food technology literature
  – Role of sodium (e.g. food safety)
  – Sodium reduction in food/food category
  – Comments

• Market surveys
  – Sodium content in high-selling products
  – Identified products in 2010 that had lowest sodium concentrations

• Consultation with experts

• Reviewed other sodium reduction initiatives
Sales Weighting

• Focus on:
  – Manufacturers whose products make up a significant proportion of national sales in one or more categories
  – Restaurant and similar retail food chains that are national or regional in scope

• Intended to provide more weight to commonly consumed products – dominant sellers in each product category

• More reflective of sodium intake from the U.S. food supply (10% of products account for top 80% of sales)

• Company could assess own portfolio of products against category targets by determining sales-weighted mean for products in a category
Draft Sodium Reduction Guidance

• Targets
  – Short-term targets (2 year, goal = 3,000 mg/day)
  – Long-term targets (10 year, goal = 2,300 mg/day)

• 150 Categories
  – dairy-cheese; fats, oils and dressings; fruits, vegetables and legumes; nuts and seeds; soups; sauces, gravies, dips, condiments and seasonings; cereals; bakery products; meat and poultry; fish and other seafood; snacks; sandwiches; mixed ingredient dishes; salads; other combination foods; and baby/toddler foods
Comment Solicitation - 1

- Are there categories where foods have been grouped together that should be separated on the basis of different manufacturing methods or technical effects relating to the potential for sodium reduction? Conversely, are there categories which could be merged due to similar sodium functionality and potential for reduction? Are there foods that contribute to sodium intake that we have not effectively captured? Are the categories amenable for use by restaurant chains and if not, how should they be modified to make them amenable for use by restaurant chains?

- Are the baseline sodium concentration values reasonably representative of the state of the food supply in 2010? For categories that do not appear representative, what food products are not adequately represented? Are there situations in which our method of quantification could lead to unrepresentative baseline values?

- Are there categories for which the 2-year target concentration goals are infeasible? If so, why are these targets not feasible, e.g., for technical reasons? What goals would be feasible in the short-term (2-year), and why? For reference, a supplementary memorandum to the docket is provided to further describe the type of information needed, “Target Development Example: Supplementary Memorandum to the Draft Guidance” (Ref. 7).

- Are the short-term (2-year) timeframes for these goals achievable? If the timeframes are not achievable, what timeframes would be challenging, but still achievable?
Comment Solicitation - 2

- Are there categories for which the 10-year target concentration goals are infeasible? If so, why are these targets not feasible, e.g., for technical reasons? What goals would be feasible in the long-term (10-year), and why? For reference, a supplementary memorandum to the docket is provided to further describe the type of information needed, “Target Development Example: Supplementary Memorandum to the Draft Guidance” (Ref. 7).

- Are the long-term (10-year) timeframes for these goals achievable? If the timeframes are not achievable, what timeframes would be challenging, but still achievable?

- What specific research needs or technological advances (if any) could enhance the food industry’s ability to meet these goals? What are possible innovations in the area of sodium reduction and are there any unintended consequences associated with their use?

- What amendments to FDA’s standard of identity regulations in 21 CFR parts 130-169 are needed to facilitate sodium reduction by permitting alternative ingredients to be used in standardized foods? For example, amendments could include revisions to specific standards (e.g., cheese or cheese products) and to the general requirements for foods named by use of a nutrient content claim (e.g., “reduced sodium”) and a standardized term under 21 CFR 130.10.
Concerns

- Food Safety
- Shelf-life
- Functionality
- Palatability
- Standards of identity
- Feasibility
- Technology
- Consumer preference
Draft Sodium Reduction Guidance

• Short-term target comment period closes October 17, 2016
• Long-term target comment period closes December 2, 2016
Questions?