2017 Regulatory Issues Review

April 5, 2017

Meat Industry Summit
Al Almanza
Administrator, Food Safety and Inspection Service, USDA
Regulatory and Scientific Affairs Update

April 5, 2017
Meat Industry Summit

Susan Backus
Vice President, Regulatory and Scientific Programs
Regulatory Issues

- GIPSA
- Humane Slaughter/Animal Handling
- Antibiotic Use and Resistance
- Whole Genome Sequencing
- Labeling
December 20, 2016 – Interim final rule and two proposed rules

Interim final “Scope” rule – eliminates the need for a plaintiff to show harm or likely harm to competition in P&S litigation

Proposed rule: “unfair practices” and “unreasonable preferences”

Proposed rule: Poultry grower ranking systems
“Scope”

- Effective April 22
  - Comments filed March 24
  - Requested extension of effective date

- IFR conflicts with holdings in eight appellate circuits

- IFR encourages lawsuits to be filed against packers and poultry integrators
“Unfair Practices” and “Unreasonable Preferences”

• Not as prescriptive as 2010 proposal

• Illustrative list of conduct or action that would be illegal, *e.g.*, retaliatory action, limiting by contract legal rights and remedies, certain practices involving poultry, *etc.*

• Comments filed March 24
Poultry Grower Ranking Systems

• Four general criteria: the fourth one is

  – Whether a live poultry dealer has demonstrated a legitimate business justification for use of a poultry grower ranking system that may otherwise be unfair, unjustly discriminatory, or deceptive or gives an undue or unreasonable preference or advantage to any poultry grower or subjects any poultry grower to an undue or unreasonable prejudice or disadvantage

• Vague and not exclusive
Humane Slaughter/Animal Handling

- Agency policy regarding non-establishment employees
- Farm Sanctuary petition pending – likely to be denied
Antibiotic Use and Resistance

- Judicious Use of Medically Important Antimicrobials: Request for Information
  - Comments submitted March 13.
Whole Genome Sequencing of Foodborne Pathogens

• Foundation meetings a success
  – Identified research priorities
  – Highlighted concerns
• Met with USDA Office of the Chief Scientist
• Food industry coalition developed to address issues with Meat Institute a primary leader
• Public meeting later this year
Labeling

- Nutrition Facts Panel
- Product Date Labeling and Food Waste
- Product Claims
  - Genetically Modified Organisms, “Natural”, "Healthy"
- Warnings
  - Proposition 65
- Other Labeling
  - CSPI Petition, Sodium Reduction Targets
Nutrition Facts Panel: Key Changes

- Mirrors, to the extent possible, FDA Final Rule
- Removes declaration of “Calories from fat”;
- Requires labeling of *trans 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**

Serving Size: 2/3 cup (55g)  
Servings Per Container: About 8

<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>10%</td>
</tr>
</tbody>
</table>

| Daily Value*       | 2%           | 10%                  |

### New Label

**Nutrition Facts**

8 servings per container  
Serving size: 2/3 cup (55g)

<table>
<thead>
<tr>
<th>Amount per serving</th>
<th>Calories 230</th>
<th>% Daily Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Fat</strong></td>
<td>8g</td>
<td>10%</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>
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<td>Sugars</td>
<td>1g</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Protein</strong></td>
<td>3g</td>
<td>10%</td>
</tr>
</tbody>
</table>

| Daily Value*       | 2%           | 10%            |

**Vitamin A**  10%  
**Vitamin C**  8%  
**Calcium**  20%  
**Iron**  45%

*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>Total Fat</th>
<th>Less than</th>
<th>65g</th>
<th>80g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sat Fat</td>
<td>Less than</td>
<td>20g</td>
<td>25g</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>Less than</td>
<td>300mg</td>
<td>300mg</td>
</tr>
<tr>
<td>Sodium</td>
<td>Less than 2,400mg</td>
<td>2,400mg</td>
<td>2,400mg</td>
</tr>
<tr>
<td>Total Carbohydrate</td>
<td>300g</td>
<td>375g</td>
<td></td>
</tr>
<tr>
<td>Dietary Fiber</td>
<td>25g</td>
<td>30g</td>
<td></td>
</tr>
</tbody>
</table>

**Vitamin D**  10%  
**Calcium**  20%  
**Iron**  45%  
**Potassium**  6%

*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

**Serving size**
1 cup (255g)

<table>
<thead>
<tr>
<th>Calories</th>
<th>Per serving</th>
<th>Per container</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>220</strong></td>
<td>10g</td>
<td>440</td>
</tr>
</tbody>
</table>

**% DV**

<table>
<thead>
<tr>
<th>Total Fat</th>
<th>6%</th>
<th>13%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saturated Fat</td>
<td>10%</td>
<td>20%</td>
</tr>
<tr>
<td>Trans Fat</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>5%</td>
<td>10%</td>
</tr>
<tr>
<td>Sodium</td>
<td>10%</td>
<td>21%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total Carb.</th>
<th>13%</th>
<th>25%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dietary Fiber</td>
<td>21%</td>
<td>43%</td>
</tr>
<tr>
<td>Total Sugars</td>
<td>8%</td>
<td>16%</td>
</tr>
<tr>
<td>Incl. Added Sugars</td>
<td>9%</td>
<td>18%</td>
</tr>
</tbody>
</table>

**Protein**

<table>
<thead>
<tr>
<th>Protein</th>
<th>25%</th>
<th>50%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin D</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcium</td>
<td>15%</td>
<td>30%</td>
</tr>
<tr>
<td>Iron</td>
<td>6%</td>
<td>10%</td>
</tr>
<tr>
<td>Potassium</td>
<td>10%</td>
<td>20%</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 1 PINT</td>
<td>3 SERVINGS 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

12 OUNCES 120 CALORIES
20 OUNCES 200 CALORIES
Nutrition Facts Panel Revisions

• FSIS Comments due April 19, 2017
• FDA’s updated labels must be on packages by July 26, 2018
  – July 26, 2019 for manufacturers with less than $10 million in annual food sales.
• Nutrition Facts Label Compliance
• Uniform Compliance Date
PRODUCT DATE LABELING AND FOOD WASTE
The Dating Game:
How Confusing Food Date Labels Lead to Food Waste in America

WELCOME TO ReFED
A data-driven guide for businesses, government, funders, and nonprofits to collectively reduce food waste at scale
Together, we can reduce U.S. food waste by 50% by 2030.
Product Date Labeling Initiatives

- “BEST if Used By” – quality phrasing
- “Use By” – safety phrasing
- Urging widespread industry adoption
- Consumer education planned to coincide with new Nutrition Facts labels – summer 2018
Federal Activities

• FSIS Draft Guidance “Best if Used By”
  – Comments due March 7

• Legislation
  – Mandatory “Best if Used By” and “Expires On” introduced in last Congress
  – Expect similar legislation introduced this Congress
    • “Best if Used By” and “Use By”
PRODUCT CLAIMS
GMO Labeling

National Bioengineered Food Disclosure Standard

- Secretary of Agriculture – Two years to promulgate standard
- 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
GMO Labeling

• Food derived from an animal is not considered "bioengineered" solely because the animal consumed GMO feed.
• Products sold in restaurants and other “similar retail food establishments” are exempt.
• 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

- 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
“Natural” Labeling

• New GMO law does not address “natural.”

• FDA Request for Information – comments filed April 2016

• FSIS regulatory agenda -- proposed “natural” rule for meat and poultry in August 2017
“Healthy”

- FDA Request for Information
  - Redefine to align with 2015-2020 Dietary Guidelines for Americans and the updated Nutrition Facts label
- Public meeting on March 9
- Comments due April 26, 2017
WARNINGS
Proposition 65

• Nitrites in combination with amines and amides – OEHHA Carcinogen Identification Committee (CIC) voted unanimously not to list
  – IARC monograph on red and processed meat – expected this summer (July or August)
  – CIC chairman referenced the red and processed meat issue
Evaluations of Red and Processed Meat:
International Agency for Research on Cancer

- Working with American Meat Science Association on Lexicon project
- Monitoring scientific community for updates
- Communicating with stakeholders about need for additional processed meat and poultry research
- Monograph expected in 2017
Evaluations of Red and Processed Meat: National Toxicology Program

Request for Information:

• Consumption of red meat: cancer and non-cancer health hazard evaluations.
• Consumption of processed meat: cancer and non-cancer health hazard evaluations.
• Consumption of meat cooked at high temperatures: cancer and non-cancer health hazard evaluations.
Evaluations of Red and Processed Meat: World Cancer Research Fund

Animal foods

Limit red meat and avoid processed meat

Limit intake of red meat and avoid processed meat

Public health goal

Population average consumption of red meat to be no more than 300 g (11 oz) a week, very little if any of which to be processed

Personal recommendation

People who eat red meat to consume less than 500 g (18 oz) a week, very little if any to be processed

1. Red meat refers to beef, pork, lamb, and goat from domesticated animals including that contained in processed foods
2. Processed meat refers to meat preserved by smoking, curing or salting, or addition of chemical preservatives, including that contained in processed foods

Limit intake of red meat & avoid processed meat

View our recommendations

RELATED TOPICS
CONTINUOUS UPDATE PROJECT (CUP)
SECOND EXPERT REPORT
“Other” Labeling

• CSPI Petition
  “USDA WARNING: Frequent consumption of processed meat products may increase your risk of developing cancer of the colon and rectum. To protect your health, limit your consumption of such products.”

• Voluntary Sodium Reduction Targets
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
What’s Next? TBD

- Guidance was close to being issued at close of Obama Administration
- Expect continued pressure from consumer groups
- Dietary Reference Intakes for Sodium and Potassium
QUESTIONS?

sbackus@meatinstitute.org or 202-587-4220
Top of Mind Regulatory Issues

Norm Robertson
VP, Regulatory Services
The Meat Institute
Meat Industry Summit, April 5, 2017
Labeling

- Generic approval expansion and the backlog
  - FSIS identified unnecessary sketch submission contributing significantly to the backlog
  - Multiple labels submitted individually for approval of common claim – rather than blanket or single submission
  - Submission for supplier updates, *e.g.*, new supplier of grass fed animals, *etc.*
    - See December 12, 2016 NAMI memo
Labeling

• Transfer of labeling and approvals from one EST to another
  – Can generically approve, based on another EST approval – provided all supporting info available
  – Can transfer labeling with another EST number in the legend, provided it is to be covered with pressure sensitive legend with producing EST number
• See Q&A from FSIS, Q’s 12 and 34 respectively, here:
Labeling

• Instructional and disclaimer statements on raw beef
  – Voluntary, not compulsory
  – Use of these statements limits where product may move
    • Only to Federal Establishments with a validated lethality process
    • State inspected facilities, ID Warehouses, retail - not acceptable
  – Commonly misunderstood by FSIS field personnel as required when untested beef trim is produced
  – To test, or not to test, dictated by customer needs
  – Untested trim:
    • Not required to move only to lethality process
    • Should not be presumed adulterated
Labeling

• Use by/Sell by dating – not a regulatory issue!
  • Exception is poultry dating regulation – 9 CFR 381.126
    – Validation only required if tied to hazard analysis
  • E.g., supportive of Listeria alternative chosen
    – An issue of quality and brand protection
    – Can become regulatory if dates are changed without supportable basis
      • 9 CFR 317.8, “misleading” angle
    – “Best if used by” guidance currently out for comment
Labeling

• Protective covering policy update – still waiting!!
  – Current policy understanding varies widely within FSIS, leading to inconsistent application at field level
  – Multiple individual packages in protective covering without full labeling individually requires limited use statements
  – Product remaining in unlabeled protective covering cannot be labeled at downstream Federal Establishments, unless exposed, or further processed in some way
Labeling

- **Sample and Experimental products**
  - Sample requirements - same as any inspected production
    - HACCP, SSOP, under inspection, compliant labeling, etc.
      - Can be given to general public without restriction
  - Experimental production – limited use
    - Done outside inspection requirements
    - Primarily for sensory evaluation panel use
      - Must be maintained under control of producing establishment
        » Control can be via a proxy with supportive documentation
Common inadequacies identified regarding initial validation – typically through the FSA process:
- No or inadequate decision making documents for monitoring and verification procedures and frequencies
- “Cherry picking” – determination of critical parameters
- Less than 5.0 log lethality processes
  - If validated for something less than 5.0 log, burden to demonstrate adequacy falls on the establishment
HACCP - Implementation

• Inadequate 9 CFR 417.3 corrective action
  – 417.3(a) – in response to a deviation
    • Failure to identify appropriately the cause
      – *e.g.*, lack of trimming versus where the contamination occurs
      – Adding more trimmers down the line versus eliminating cause
      – Proposed preventive measures not linked to cause
  • Turning four parts of 417.3(a) into “yes/no” questions
  • Failure to take/document actions to demonstrate control reestablished after a deviation
  • Failure to demonstrate all product affected by the deviation are “unadulterated” by the deviation – back to the last check
HACCP - Implementation

• Reassessment
  – Must include reason for change or no change in the record of reassessment
    • Except for annual reassessment with no changes
  – Changes that *could* affect the hazard analysis or alter the HACCP plan
    • Often raised as an additional issue when other noncompliance is identified - supportive of stronger action
    • Triggers in 417.4(a)(3) necessitating reassessment are very broad – most companies have vulnerability in this area
      – changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.
HACCP - Implementation

• Common inspection overreach examples
  – Thawing versus tempering
    • Requiring companies to identify tempering as a step
      – If tempering done in cooler, the step is cooler storage
  – Flow chart and hazard analysis matching
    • Requiring a “one for one” match between the two
      – steps with common hazard analysis findings may be grouped in flow chart and/or hazard analysis – supported in AskFSIS
HACCP - Implementation

• Common inspection overreach examples
  – Requiring separate HACCP plans for intact and non-intact products that are raw, not ground
    • Regardless of intact status, products remain raw, not ground
    • Regulation does not even require HACCP plans to be established by the 9 HACCP process categories
      – A company could have a single plan for multiple categories or 100 different plans for 100 different products under a single category – although we do not recommend these approaches
HACCP - Implementation

• Common inspection overreach examples
  – Suggesting appendix A & B use is limited and Applicable to only Beef and poultry, not pork or non-meat components
  • These validated guidelines can be applied to any component of, or finished FSIS inspected product
    – FDA does not always agree, consider if dual jurisdiction EST
    – Don’t forget the poultry lethality tables: https://www.fsis.usda.gov/wps/wcm/connect/9ab2e062-7ac8-49b7-aea1-f070048a113a/RTE_Poultry_Tables.pdf?MOD=AJPERES
  – Suggesting if using appendix B option 2, the critical limit must include 120 to 80 in 1 hour or less
  • Although it must be considered and addressed in some way, it does not need to be part of the critical limit
SSOP - Implementation

- Routine reevaluation, under 416.14
  - No specific triggers
  - Not required after any particular finding
  - Should be done anytime effectiveness is in question
    - Recurring findings not prevented by corrective action
    - Recurring findings with no procedure to prevent
  
*Failure to document routine reevaluation can be easily characterized negatively by the agency, even though not required expressly by the regulation*
FSIS Sampling

• MT-65 sampling
  – Should be of raw materials used to produce non-intact product, when raw materials not subject to MT-60 sampling at harvester
  – Inspection should not sample finished non-intact product under MT-65
    • Sample taken from single vacuum bag – given appropriate information maintained by company
      – Information from supplier (i.e., comingling, intended use, intervention(s))
FSIS Sampling

• Sample discard criteria
  – Routine raw beef sampling (MT- 60, 65, 43)
    • Discard if > 1 day in mail
    • Discard if > 15° C
    • Discard if days to ship after collection > 4
    • Discard if insufficient tissue
  – Follow up raw beef sampling (MT- 44, 44T, 52, 53)
    • Discard if > 15° C or insufficient tissue
    • NO DISCARD related to number of days in mail or days held before shipping
Company Sampling

• Key – always consider what will or must be done when results are received – before sampling!

• Companion Sampling when FSIS samples
  – Typically not a good idea
    • FSIS positive, company negative, positive trumps negative
    • FSIS negative, company positive, positive trumps negative
    • Both negative – no benefit, both positive – no benefit
  – Exception – FSIS non-food-contact environmental *Listeria monocytogenes* sampling – 5 sample composites
    • take and hold mirror samples of same sites to be run individually, if FSIS sample is positive – can help narrow scope of investigation and corrective action.
Company Sampling

- *Listeria spp.* (*L. spp.*) or *Listeria monocytogenes* (*Lm*)?
  - For environmental and food-contact-surface samples – *L. spp.* makes more sense
    - Seeking vulnerabilities – more likely to detect
    - More likely to detect vulnerability = more likely to prevent adulteration from occurring
  - For product sampling – *Lm* makes more sense
    - If *L. spp.* positive on product with no attempt to confirm for *Lm* (or analysis stopped at *presumptive*) product presumed to be adulterated
Animal Handling

- Headquarter level appeal granted - supports signs of a possible return to sensibility does not equate to the determination an animal has regained consciousness and an egregious noncompliance has occurred
  - Not a noncompliance unless the animal regains consciousness (i.e., comes out of a state of surgical anesthesia)
Food Safety Modernization Act

• Does the FSMA apply to federal establishments?
  – YES, it can!!
    • Dual Jurisdiction establishments
      – Preventive controls required for FDA regulated production
        » HACCP, plus more
    • Box in-Box out, FDA regulated products
      – If only storing and distributing FDA products requiring refrigeration
        » Implement temperature controls for pathogens
        » Monitor, document, and take corrective actions when problems occur
        » GMPs (21 CFR 117.10 to 117.110) – similar to 9 CFR 416 sanitation performance standard regulations, but more prescriptive

• If receiving FDA products for inclusion into USDA products, FSMA is not applicable
Thank You for Attending!

• Additional Questions?
• Contact information:
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  – (510)575-0211 (Direct line for Norm)
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