Addressing Chemical Contaminants without Established Regulatory Limits in Meat, Poultry, and Egg Products: the De Minimis Level Approach

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Overview

- Introduction to FSIS
- National Residue Program for Meat, Poultry, and Egg Products (NRP)
- Tentative proposal to address currently unregulated chemical hazards through a *de minimis* level approach
- Cadmium example
- Applying the mark of inspection
What is FSIS?

- The Food Safety and Inspection Service (FSIS):
  - Is a public health regulatory agency within the United States Department of Agriculture (USDA)
  - Is responsible for the safety of domestic and imported meat, poultry, and egg products
  - Consists of ~8,000 inspection personnel, plus 10 district offices, 3 laboratories (chemical and microbial), and headquarters staff
FSIS scope

- Inspect slaughter and processing establishments
- Perform in-plant sampling and laboratory testing for microbial pathogens and chemical residues and contaminants
- Establish science-based policies to prevent foodborne illness
- Reach out to consumers to improve food-handling and cooking practices
- Respond to foodborne outbreaks; managing product recalls
- Collaborate with Federal (FDA, EPA, CDC), State, and international partners
National Residue Program (NRP)

Risk-based approach to residue testing in the U.S. National Residue Program for Meat, Poultry, and Egg Products (NRP)

- **Hazard identification**
  - Veterinary drugs
  - Pesticides
  - Other chemical hazards

- **Public health prioritization of chemical hazards**

- **Scheduling and sampling algorithms**
  - When and where to take samples

- **Multiple testing programs**
  - Scheduled, random sampling
  - Inspector-generated sampling
  - Exploratory assessments
Veterinary drugs and pesticides

- FDA and EPA register or approve veterinary drugs and pesticides for certain uses
  - Toxicity and potential for human exposure are assessed and tolerances (maximum residue levels) are set for certain commodities

- FSIS uses these tolerances to determine if a meat, poultry, or egg product should be considered adulterated
  - Tolerances are legally binding
  - When the observed residue is greater than the tolerance, product is considered adulterated

- Veterinary drugs and pesticides have been the historical focus of the FSIS residue program
Other chemical hazards

- Some contaminants are ubiquitous in the air, water, and soil and are likely present in our food as well
  - Presence can be the result of natural process or of human activity
  - Exposure to humans cannot be “controlled” by eliminating some or all approved uses (unlike for veterinary drugs and pesticides)

- No tolerances or legally permissible levels for these chemical hazards are available for meat, poultry, and egg products

- The following is a conceptual framework proposal for FSIS to address the presence of environmental contaminants in meat, poultry, and egg products
Tentative proposal

- For potential chemical hazards not currently regulated by FDA or EPA, FSIS may identify a *de minimis* level in FSIS-regulated products.

- FSIS cannot determine that products containing levels above the *de minimis* level are not adulterated.

- FSIS may decide not to apply the Mark of Inspection to such products.
Step 1 – *De Minimis* level

**Step 1: Derive a *de minimis* level**

The *de minimis* level is a negligible risk level derived from reasonably conservative estimates.

This level is based on:

- Toxicity of the contaminant
- Meat/poultry consumption data
- Expected meat/poultry contribution to total exposure
Step 2 – Monitoring

Step 2: Collect contaminant monitoring data as part of an exploratory assessment in the NRP*

* If an immediate or imminent public health problem is likely, FSIS may move directly to Step 3
Step 3 – Risk management

- Immediate or imminent and finite health hazard event
  - E.g. a specific herd or flock is exposed to a certain contaminant
  - Acute health effects are possible
  - FSIS can address these types of events immediately by withholding the Mark of Inspection from product exceeding the *de minimis* level

- Long-term, low levels of a contaminant in FSIS-regulated product, potentially leading to harmful chronic exposure
  - Set up a data gathering program (exploratory assessment)
  - Determine whether *de minimis* level is routinely exceeded
  - If necessary: make sampling part of the regular NRP, adjust *de minimis* level as needed, and withhold Mark of Inspection as appropriate
Screening

Hazard Identification

Intelligence

Immediate or Imminent and Finite Event

Determine if product is not adulterated

Mitigation through interagency collaboration

STOP when event passes

Long-term Exposure Scenario

Monitoring: Explor. Assessment

Scheduled Sampling Program (annual or intermittent)

Determine if product is not adulterated

Mitigation through interagency collaboration

STOP when situation changes

STOP if no concern
Why derive a *de minimis* level?

- **Public Health Context**
  - How concerning (or not) are our monitoring results?

- **Screening-Level Tool**
  - Which potential hazards to focus resources on?
  - What level of quantitation should laboratories target?

- **Risk Management**
  - Is the product safe, wholesome, and not adulterated?
  - Is mitigation or other interagency action necessary?
Deriving a *de minimis* level (I)

Toxicological Starting Point × Allocation fraction ÷ Consumption

- Calculation is similar to the “safe concentration” approach used by FDA/CVM for animal drugs
- Concept is similar to the Maximum Contaminant Level Goals (MCLGs) set by EPA under the Safe Drinking Water Act (SDWA)
Deriving a *de minimis* level (II)

1. Selection of a toxicological starting point, often a health-based guidance value (HBGV)
   
   *e.g. RfD, ADI, TDI, NOAEL/LOAEL, LD$_{50}$, etc.*

2. Based on relative source contribution data, products of interest (e.g. meat and poultry) are allocated an “allocation fraction,” which is essentially a “slice” of the total acceptable exposure (HBGV)

3. Consumption analysis for products of interest

4. Calculation yields a *de minimis* level
De minimis levels and monitoring

- If no data on contaminant levels are available, FSIS can conduct exploratory monitoring of edible tissues
- Unlike veterinary drugs and pesticides, dosage and application rates cannot be controlled for environmental contaminants
- Slight individual excursions above the de minimis level are not necessarily a cause for concern
  - Health-based guidance values (HBGV) incorporate safety factors
  - When the de minimis level is based on a chronic HBGV, average contaminant levels across an entire species or production class are more relevant than individual values
- Monitoring high outliers can help identify localized pre-harvest environmental conditions leading to high chemical burdens
Example: Cadmium

- Cadmium is a naturally-occurring heavy metal. It also is a byproduct of mining and smelting.
- Exposure primarily comes from the diet (leafy greens, potatoes, grains, nuts, meats, shellfish), smoking, and occupational exposure.
- The most important health effect from cadmium ingestion is renal damage.
- FSIS has been analyzing beef, pork, and chicken muscle and kidney tissue for cadmium for several years now.

\[
\frac{H B G V \times f_{allocation}}{C_{meat}}
\]

Picture credit: Heinrich Pniok (Alchemist-hp)
Input Values

- Several health-based guidance values exist for cadmium
  - U.S. Agency for Toxic Substances and Disease Registry (ATSDR)
  - Joint WHO/FAO Expert Committee on Food Additives (JECFA)

- Fraction of cadmium exposure allocated to meat and poultry
  - Data from Egan et al. (2007) based on Total Diet Study (TDS)
  - Fraction of cadmium allocated to meat, poultry, and fish ranges from 1.0 to 4.4 percent, depending on age and gender

- Average daily consumption values for meat and poultry
  - 2003–2008 NHANES/WWEIA surveys using DEEM-FCID
  - Includes consumption of all edible tissues from beef, chicken, goat, game, pork, rabbit, sheep, turkey, other poultry, fish
**Potential de minimis levels**

- 1.6 ppb (using ATSDR Minimal Risk Level) and 13 ppb (using JECFA Tolerable Intake)
- Average consumption of meat with these levels leads to
  - 3.6 ng/kg bw/day cadmium exposure (ATSDR)
  - 30 ng/kg bw/day cadmium exposure (JECFA)
- Mean cadmium exposure from all sources (non-smokers) estimated at 300–350 ng/kg bw/day (Choudhoury et al. 2001)
- Most recent FSIS data showed 2–3 percent cadmium detection rate (limit of quantitation: 10 ppb)
- Organ meat needs to be considered separately due to much lower consumption and much higher cadmium levels (99.8 percent of kidneys contained detectable cadmium)
Applying the Mark of Inspection

- A *de minimis* level paired with the distribution of contaminant levels in the product can be used to support a risk management decision.
- Important factors to consider for any contaminant:

<table>
<thead>
<tr>
<th>U.S. population total exposure:</th>
<th>Relative contribution from FSIS-regulated products to total exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Near or exceeding HBGV or acute exposure concerns</td>
<td>HIGH</td>
</tr>
<tr>
<td>High Priority</td>
<td>Medium Priority</td>
</tr>
<tr>
<td>Below HBGV and no acute exposure concerns</td>
<td>Medium Priority</td>
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Conclusion

- When tolerances are not available, a separate approach is provided for environmental contaminants to determine monitoring levels for the NRP.

- This is a proposal for a three-step process:
  - Derive a *de minimis* level
  - Collect monitoring data
  - Determine risk management approach

- This proposal is part of broader improvements to the NRP.
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Questions?

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