United States Department of Agriculture

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

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Advancing Analysis Workshop
Washington, DC – June 18, 2013

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
- Collaborat 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

NRP

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

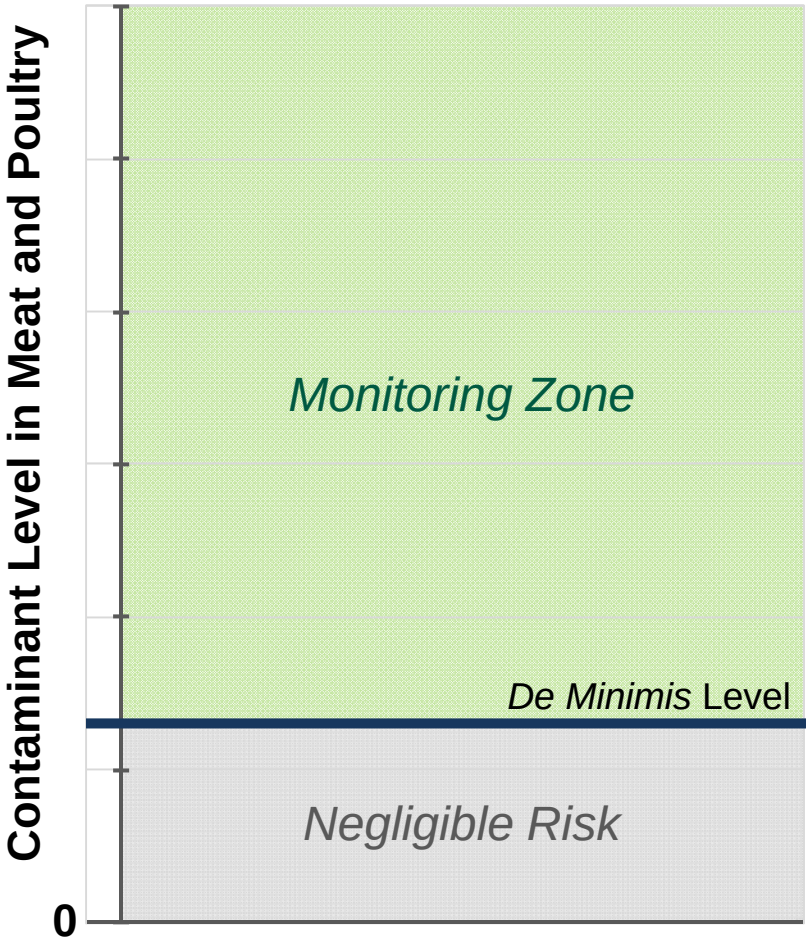
Other chemical hazards

- 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



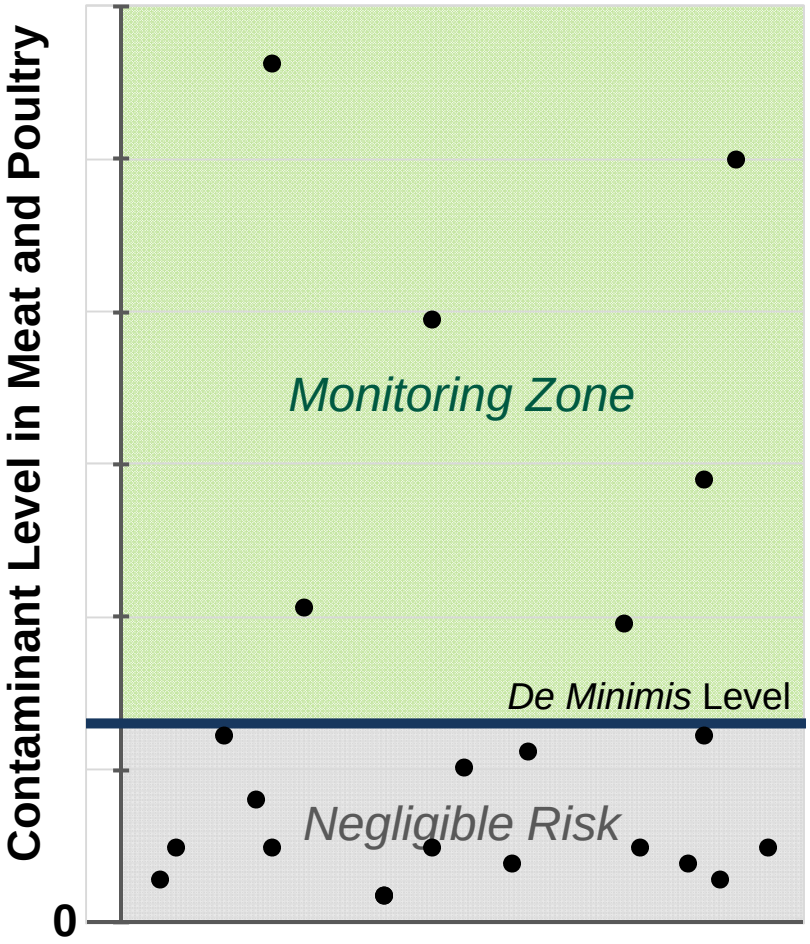
Step 1: Derive a *de minimis* level

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

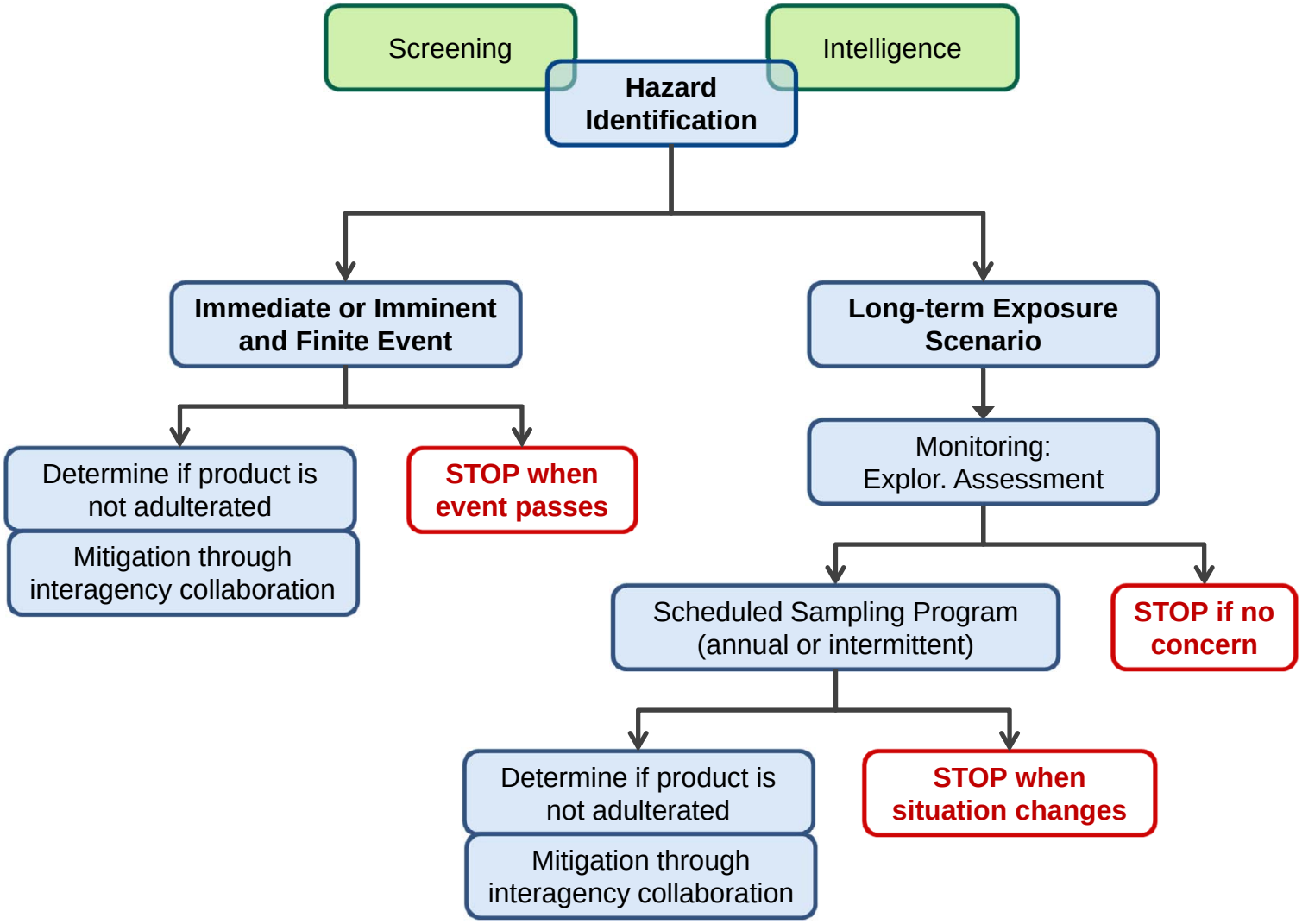


Step 2: Collect contaminant monitoring data as part of an exploratory assessment in the NRP*

* 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
Intelligence
Hazard Identification
Immediate or Imminent and Finite Event
Long-term Exposure Scenario
Determine if product is not adulterated
Mitigation through interagency collaboration
STOP when event passes
Monitoring: Explor. Assessment
Scheduled Sampling Program (annual or intermittent)
STOP if no concern
Determine if product is not adulterated
Mitigation through interagency collaboration
STOP when situation changes

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)

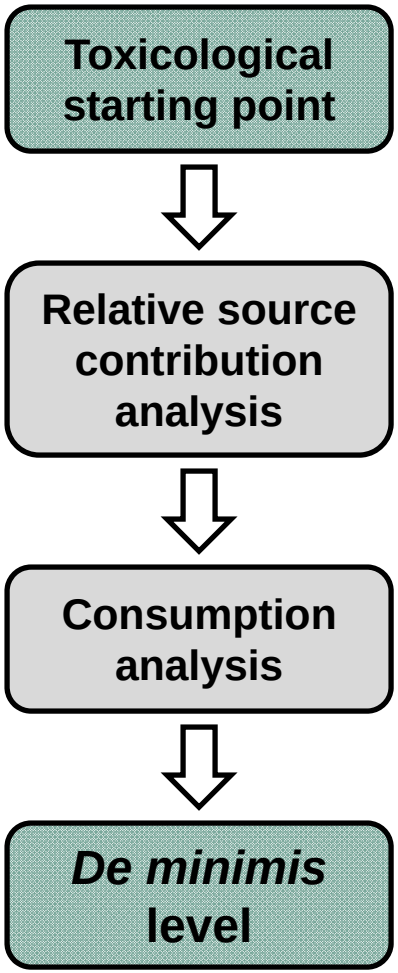
1. Selection of a toxicological starting point, often a health-based guidance value (HBGV)

   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

$$\frac{HBGV \times f_{allocation}}{C_{meat}}$$

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:

U.S. population <u>total</u> exposure:	**Relative contribution from FSIS-regulated products to total exposure**	
	HIGH	**LOW**
Near or exceeding HBGV *or* acute exposure concerns	High Priority	Medium Priority
Below HBGV and no acute exposure concerns	Medium Priority	Low Priority

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

Acknowledgements

- Dr. Patty Bennett
  USDA, Food Safety and Inspection Service, Office of Public Health Science

- Dr. Kerry Dearfield
  USDA, Food Safety and Inspection Service, Office of Public Health Science

Questions?

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