USDA Perspective: Need for Prioritizing Potential Risks from Contaminants in Food

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Overview

- Background need for a science-based process/framework for prioritizing risks from chemical and microbial contaminants in food
- USDA's Food Safety and Inspection Service (FSIS) approach for:
  - Microbiological contaminants
  - Chemical/residue contaminants

FSIS

The Food Safety and Inspection Service (FSIS) is the public health agency in the U.S. Department of Agriculture responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged.

Microbiological

Listeria monocytogenes (Lm) as an example

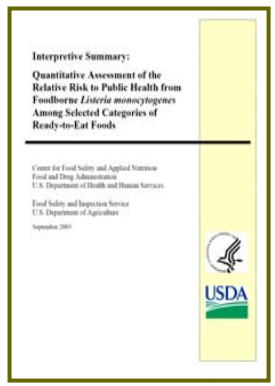
Setting the Risk Assessment Agenda

- Identify Food Safety Problem
- Prioritization based on factors such as:
  - Foodborne outbreaks
  - Epidemiological and clinical findings
  - Public health concern
  - New scientific findings
  - Surveillance and monitoring information
  - Changes in industry practices
- Public input important; mechanism for public access regarding status of agenda
- Prioritization can change

Food Categories

SEAFOOD
Smoked Seafood (finfish and mollusks)
Raw Seafood (finfish, mollusks, and crustaceans)
Preserved Fish (dried, pickled, and marinated finfish)
Cooked Ready-to-Eat Crustaceans (shrimp and crab)
PRODUCE
Vegetables (raw)
Fruits (raw, dried)
DAIRY
Fresh Soft Cheese (queso fresco, queso de Crema, Queso de Puna)
Soft Unripened Cheese, >50% moisture (cottage cheese, cream cheese, ricotta)
Soft Ripened Cheese, >50% moisture (brie, camembert, feta, mozzarella)
Semi-soft Cheese, 39-50% moisture (blue, brick, Monterey, muenster)
Hard Cheese, <39% moisture (cheddar, Colby, parmesan)
Processed Cheese (cheese foods, spreads, slices)
Pasteurized Fluid Milk
Unpasteurized Fluid Milk
Ice Cream and Other Frozen Dairy Products
Cultured Milk Products (yogurt, sour cream, buttermilk)
High Fat and Other Dairy Products (butter, cream, other miscellaneous milk products)
MEAT
Frankfurters (reheated)
Frankfurters (not reheated)
Dry/Semi-Dry Fermented Sausages
Deli Meats (cooked, ready-to-eat)
Pâté and Meat Spreads
COMBINATION FOODS
Deli-type Salads (fruit, vegetable, meat, pasta, egg, or seafood salads)

Food Categories used in the 2003 FDA FSIS Quantitative Lm Risk Assessment



Risk Ranking: Predicted Median Cases of Listeriosis for US Population

Relative Risk Ranking	Predicted Median Cases of Listeriosis for 23 Food Categories					
	Per Serving Basis[a]			Per Annum Basis[b]		
		Food	Cases		Food	Cases
1	High Risk	Deli Meats	7.7×10^{-8}	Very High	Deli Meats	1598.7
2	High Risk	Frankfurters, not reheated	6.5×10^{-8}	High Risk	Pasteurized Fluid Milk	90.8
3	High Risk	Pâté and Meat Spreads	3.2×10^{-8}	High Risk	High Fat and Other Dairy Products	56.4
4	High Risk	Unpasteurized Fluid Milk	7.1×10^{-9}	High Risk	Frankfurters, not reheated	30.5
5	High Risk	Smoked Seafood	6.2×10^{-9}	Moderate Risk	Soft Unripened Cheese	7.7
6	High Risk	Cooked Ready-to-Eat Crustaceans	5.1×10^{-9}	Moderate Risk	Pâté and Meat Spreads	3.8
7	Moderate Risk	High Fat and Other Dairy Products	2.7×10^{-9}	Moderate Risk	Unpasteurized Fluid Milk	3.1
8	Moderate Risk	Soft Unripened Cheese	1.8×10^{-9}	Moderate Risk	Cooked Ready-to-Eat Crustaceans	2.8
9	Moderate Risk	Pasteurized Fluid Milk	1.0×10^{-9}	Moderate Risk	Smoked Seafood	1.3

Interventions to Reduce Risk

- Combinations of interventions appear to be much more effective than any single intervention in mitigating the potential contamination of RTE product with L. monocytogenes and reducing the subsequent risk of illness or death
  - Testing and sanitation of food contact surfaces
  - Pre-and post-packaging interventions
  - Use of growth inhibitors/product reformulation

Lm Control Measures

- Established three alternative control measures:
  - Post-lethality treatment and antimicrobial agent/process with sanitation (Alternative 1)
  - Post-lethality treatment (Alternative 2a) or antimicrobial agent/process with sanitation (Alternative 2b); and
  - Sanitation alone (Alternative 3)

Risk Based Verification Sampling

- Generate a ‘risk ranking’ for all RTE establishments making post-lethality exposed product:
  - Alternative they opt to use to control Lm
    - 2003 FSIS Lm Risk Assessment
  - Product type: potential for Lm to grow
    - 2003 FDA FSIS Risk Ranking
  - Compliance history of the establishment
  - Volume of production
  - Voluntary measures chosen by the establishment

Risk-Based Inspection

- Risk varies across products produced at various establishments
- Exposure: Characteristics that contribute to presence and amount of hazard in a serving of food
  - Product supports the survival and growth of a pathogen
  - Process specifics (time and temperature conditions; line speed)
  - Interventions in place
  - Test and hold programs and testing
  - Disposition of the product
  - Empirical indicators include microbial test results
- Exposure: Number of servings that contain a likely amount of hazard
  - Production volume

Risk-Based Resource Allocation

- Definitive drivers of risk must be identified and, ultimately, understood quantitatively.
- Valid descriptions of establishments according to those risk factors are needed.
- Eventually, a global model, one tracking all pathogens and processes will allow FSIS to allocate resources of all types (sampling and inspection) according to the risk to human health. In the mean time, we build mechanistic models for each pathogen and process pair (Lm in RTE).

Chemical/Residue

National Residue Program (NRP) as an example

National Residue Program (NRP)

- The foundation of the NRP was a government action to control the occurrence of toxic chemicals in the food supply that resulted from the agricultural and industrial use of new chemicals.
- Purpose of the NRP is twofold:
  - First is to determine what toxic chemicals are present in meat, poultry, and egg products (exposure assessments).
  - Second is to keep the meat, poultry, and egg products free from toxic chemicals before reaching consumers.

USDA/FSIS Emphasis

Once these compounds have been identified, FSIS will:

- Prioritize what chemicals to monitor in the NRP based on risk
- Determine if risk management actions need to be taken

Considerations for Ranking of Compounds for NRP

- Public Health
  - Acute or chronic toxicity concern
  - Impact on new and existing human diseases
  - Development of resistance & impact on human health
- Duration and usage
- FSIS historical testing information
  - Number of animals treated
  - No. of violations reported
- Availability of laboratory resources
- Withdrawal time

Tool for Ranking Criteria

- Score for Acute or Chronic Toxicity Concerns (“T”) (FDA)
- Predicted or actual score for “FSIS Historical Testing Information on Violations” (“V”) (FSIS)
- Score for “Impact on new and existing human disease” (“D”) (CDC)
- Relative Public Health Concern Score (R)

$$R = V*[(D+3*T)/4]$$

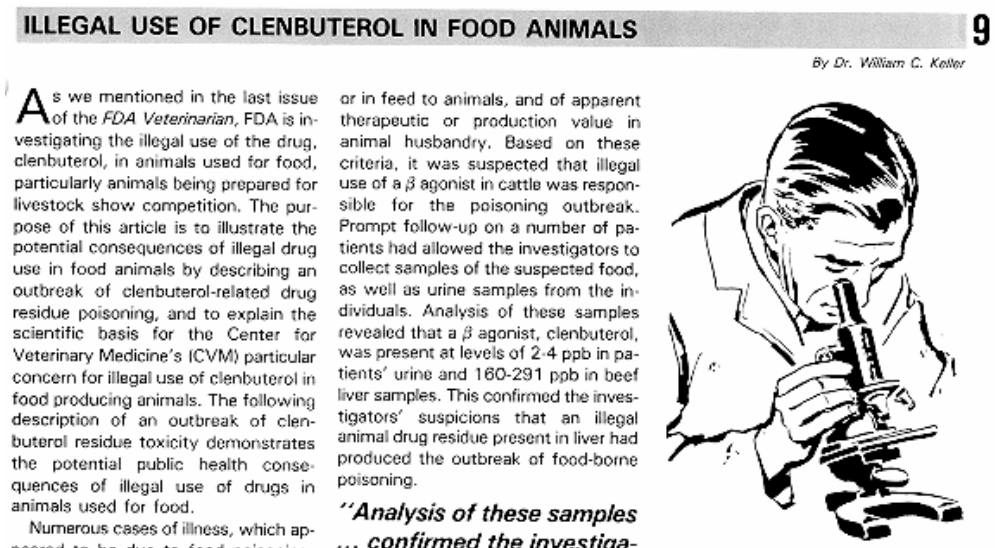
- Professional judgment is always an important consideration in ranking the compounds

Considering Toxicity for Ranking

- Acute effects:
  - Anaphylactic reactions e.g., Penicillins
  - Neuromuscular effects e.g., Organophosphates
  - Potentially life threatening e.g., Clenbuterol
- Subchronic toxicity:
  - Adrenal damage e.g., Carbadox and olquindox
- Chronic toxicity:
  - Carcinogenicity e.g., Nitroimidazoles and Nitrofurans

Clenbuterol

- In one 6 month period in 1993 more than 1,200 hospitalizations and 3 deaths in France and Spain were reported to have resulted from eating beef livers contaminated with the illegal growth promotant clenbuterol.
- These patients were reported to complain of tremor, headaches, tachycardia, atrial fibrillation and dizziness 1-3 h after eating veal liver.



ILLEGAL USE OF CLENBUTEROL IN FOOD ANIMALS 9

By Dr. William C. Keller

As we mentioned in the last issue of the *FDA Veterinarian*, FDA is investigating the illegal use of the drug, clenbuterol, in animals used for food, particularly animals being prepared for livestock show competition. The purpose of this article is to illustrate the potential consequences of illegal drug use in food animals by describing an outbreak of clenbuterol-related drug residue poisoning, and to explain the scientific basis for the Center for Veterinary Medicine's (CVM) particular concern for illegal use of clenbuterol in food producing animals. The following description of an outbreak of clenbuterol residue toxicity demonstrates the potential public health consequences of illegal use of drugs in animals used for food.

Numerous cases of illness, which appeared to be due to food poisoning, or in feed to animals, and of apparent therapeutic or production value in animal husbandry. Based on these criteria, it was suspected that illegal use of a β agonist in cattle was responsible for the poisoning outbreak. Prompt follow-up on a number of patients had allowed the investigators to collect samples of the suspected food, as well as urine samples from the individuals. Analysis of these samples revealed that a β agonist, clenbuterol, was present at levels of 2-4 ppb in patients' urine and 160-291 ppb in beef liver samples. This confirmed the investigators' suspicions that an illegal animal drug residue present in liver had produced the outbreak of food-borne poisoning.

"Analysis of these samples ... confirmed the investiga-

The End

Thank you very much