How the FDA Ensures Quality in Its Risk Assessments

Suzanne Fitzpatrick, Ph.D./Antonia Mattia, Ph.D.
FDA/CFSAN/OFAS
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The views presented are those of the authors and do not necessarily represent the views or policies of the U.S. Food and Drug Administration.
Risk Managers Consider Regulatory Risk Assessment (RA) and More

- Preliminary risk management activities
  - identify food safety issue
  - develop risk profile
  - establish goals for risk management
  - decide on need for risk assess.
  - establish risk assess. policy
  - commission risk assess.
  - consider risk assess. results
  - rank risks (if necessary)

- Identification and selection of risk management options
  - identify possible options
  - evaluate options
  - Select preferred option(s)

- Implementation of risk management decision
  - validate control(s) where necessary
  - implement selected control(s)
  - verify implementation

- Monitoring and review
  - monitor outcomes of control(s)
  - review control(s) where indicated

RA
Regulatory Risk Assessment

- Conducting risk assessment in a regulatory agency IS NOT the same as doing it in industry or academia.
  - There are legal requirements.
  - There are policy requirements.
  - There are technical requirements.
  - There are reporting requirements.

All of this in addition to the need to do good science with limited data and few resources!
Quality at FDA

• Science - both its quality and integrity- is the touchstone of everything that FDA does.
• In carrying out its mission to protect and promote public health, FDA uses the best available scientific and technological information to make decisions on the products it regulates.
• High-quality data and a scientific review process that is thorough, unbiased, and transparent are critical to FDA’s ability to reach sound decisions.
• Result is public trust in FDA’s assessments.
Sources of Quality Data for RA

- Published literature (systematic review and meta-analysis)
- In-house research & surveys
- Surveillance & outbreak investigations
- Government surveys
- Commissioned studies
- Expert elicitation

- Data calls via Federal Register Notice
- Industry provided data
- Informal; educational site visits

The specific inputs needed for a risk assessment will depend on the specific questions the model is designed to answer.
Transparency

• Use publicly available data
• Make all the data available when the RA is published.
Requested data/information:

- Pathogen and filth prevalence and levels
- Production, storage, handling and processing practices and conditions.
- Effectiveness of process treatments
- Supplier specifications & audit practices
- Food manufacturing practices
- Use & consumption

which provided number of people in food and how changed if various qualitative and immediately based on available information in a range of decision, not to commence assessment or, whether or not immediate and final decision. In some that no further.

The risk profile of pathogen and filth in spices for FDA to use plans to reduce the level of spices containing pathogens and/ or filth in spices. The purpose of the risk profile is to ascertain the current state of knowledge about spices contaminated with microbiological pathogens and/or filth, and the effectiveness of current and interventions to prevent human
Meetings: Interagency Risk Assessment - Listeria monocytogenes in Retail Delicatessens

This Notice document was issued by the Food Safety and Inspection Service (FSIS)

For related information, Open Docket Folder

Action
Notice of public meeting.

Summary
The Food Safety and Inspection Service (FSIS) and the Food and Drug Administration/Center for Food Safety and Applied Nutrition (FDA/CFSAN) are holding a public meeting on May 22, 2013, to present the background, approach, scope, and findings of the draft "Interagency Risk Assessment—L. monocytogenes in Retail Delicatessens." The purpose of this draft quantitative risk assessment (QRA) is to evaluate the public health impact of changes in retail delicatessen (deli) practices and potential interventions to reduce or prevent L. monocytogenes contamination in ready-to-eat (RTE) foods that are sliced, prepared, or packaged in retail facilities. FSIS and FDA invite interested individuals, organizations, and other stakeholders to participate in the meeting and to provide comments on the draft QRA.

Dates
The public meeting will be held on May 22, 2013 from 8:45 a.m. to 4:15 p.m. EDT. Submit either electronic or written comments to FSIS June 24, 2013.

A copy of the agenda will be made available for viewing prior to the meeting on FSIS’s Web site at www.fsis.usda.gov/News/Meetings_&_Events/
Conducting External Peer Review
1983 NRC “Red Book”

- Maintain a clear distinction between science and risk management.
- Make the risk assessment document publically available before finalizing.
- Subject risk assessment to external peer review.
- Develop joint risk assessments if more than one agency is involved.

- Since 1983, related NRC publications built upon these foundation recommendations for quality risk assessments.

“Red Book” Recommendations: Application to Risk Assessment (1)

- FDA’s risk assessment on inorganic arsenic in rice
- Maintain a clear distinction between science and risk management
  - Risk Assessment, Risk Management and Risk Communication Teams initially met for scoping and problem formulation, then worked separately
- Make the risk assessment document publically available before finalizing
  - The risk assessment was made public on April 1, 2016 and comments were requested from the public
• FDA’s risk assessment on inorganic arsenic in rice
• Subject risk assessment to external peer review
  • Document went thru internal peer review by other federal agencies, then external peer reviewers by experts selected in a transparent manner by an outside contractor with no input from FDA
  • Report of the Peer Review Committee was made public
• Develop joint risk assessments if more than one agency is involved
  • FDA continues to work closely with EPA as it evaluates inorganic arsenic as part of its IRIS program
The Future....

Investment in assuring the quality of risk assessments is time-consuming and costly...

...but it’s critical for the advancement and use of risk assessments in FDA’s decision-making and rule-making processes.
Acknowledgement

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The End