

Risk Analysis at FSIS: Standard Operating Procedures

Introduction

Risk analysis has become the basis for a significant part of the work of the Agency, therefore the need for a framework for its conduct has become apparent. In particular, the roles and responsibilities of the three collaborative but separate functional groups that make up the risk analysis team (risk assessors, communicators and managers) need to be defined and procedures describing when and how these groups interact need to be outlined. It is important to include stakeholders and take into account their views at different stages of the risk analysis process. Stakeholders are interested groups that may be affected by the outcome of the risk analysis activity and include consumer groups, industry, academic research groups and other government agencies.

This document is intended to outline the process of risk analysis as it is performed at FSIS and to clearly define the roles of various participants. The roles and responsibilities of the three groups involved in risk analysis are presented in Table 1. It is important to realize that the process of risk analysis at FSIS is evolving. This is an attempt to summarize its current form.

Points in the process that may prove important for the inclusion of stakeholders are clearly defined and mechanisms by which the Agency may engage its stakeholders are suggested. It is important to acknowledge that effective communication with stakeholders, especially at multiple steps of the risk analysis process, will slow down the time to completion of projects. Some slowing must be accepted, however, because thorough risk communication must be balanced against the need for timely scientific guidance. Finding this balance will be a challenge for the Agency; however, further developing risk communication and public involvement is a very important aspect of risk analysis, since it is one of the primary methods by which regulatory authorities can ensure transparency. Transparency is critical for credibility and scientific accountability. For example, assumptions, data inferences, and conclusions must be explicitly documented in a risk assessment, and risk management decisions and competing concerns must be clearly articulated.

Risk Analysis: Definitions and Roles

Risk analysis is a process that requires the efficient interaction of three groups, each responsible for different functional tasks. These three groups are the risk assessors, the risk communicators, and the risk managers. It is necessary to have a functional separation between risk assessment and risk management, that is; the individuals who prepare the risk assessment should not normally be the same individuals responsible for risk management. This is essential in order to maintain the scientific integrity of the risk assessment process and to avoid undermining the objectivity and the credibility of the conclusions. However, there should be frequent interaction between risk managers and

risk assessors in order to ensure that the assessment will meet the needs and answer the concerns of the risk managers, and in order to arrive at effective risk management decisions.

Risk Assessment

Risk assessment has come to be recognized around the world as a systematic way to organize information and help establish priorities. In *Risk Assessment in the Federal Government; Managing the Process*, the seminal book of risk assessment and risk management¹, risk assessment is defined as “*the qualitative or quantitative characterization of the potential health effects of particular substances on individuals or populations*”. This report states that risk assessments may include a hazard identification, dose-response assessment, exposure assessment and risk characterization. Similarly, the Codex Alimentarius Commission has defined risk assessment as “*a scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.*”²

Risk assessment is intended to inform and assist the decision making process with scientific analyses of food safety issues and the likely impact on public health of proposed risk management strategies. The types of questions risk assessors may be asked to answer, and the form in which the assessors answer these questions, will vary from project to project. The conventional types of risk assessment outputs will be discussed in greater detail later in this document.

At FSIS, risk assessments are conducted by the Risk Assessment Division of the Office of Public Health and Science (OPHS). The Risk Assessment Division is comprised of two groups: the Regulatory Affairs and Exposure Modeling Branch and the Technical Analysis and Evaluation Branch. The Regulatory Affairs and Exposure Modeling Branch is responsible for (1) providing leadership within OPHS for the integration of risk assessments into regulatory actions, risk management decisions, and educational campaigns; (2) providing the Division with expertise in systems modeling and exposure assessment; and (3) communicating risk assessment results to various stakeholders and participating in outreach activities. The Technical Analysis and Evaluation Branch identifies, collects and analyzes data for incorporation into risk assessments in order to provide the scientific and public health underpinnings for risk assessment activities.

Risk Communication

A 1989 report by the National Research Council³ described risk communication as “*an iterative process of exchange of information and opinion among individuals, groups, and institutions.*” It further states that risk communication “*involves multiple messages about the nature of risk and other messages, not strictly about risk, that express concerns,*

¹ Risk Assessment in the Federal Government; Managing the Process, National Research Council; National Academies Press, 1983.

² Procedural Manual of the Codex Alimentarius Commission, Eleventh Edition

³ Improving Risk Communication; National Research Council; National Academies Press, 1989.

opinions, or reactions to risk messages or to legal and institutional arrangements for risk management". Similarly, risk communication has been defined by Codex Alimentarius Commission as *"the interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perception among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decision."*⁴ There are many means by which risk communication can occur including but not limited to:

- Intra-agency meetings, briefings and reports between risk managers and risk assessors (or other offices within FSIS),
- Federal Register notices intended to inform stakeholders or to solicit information or feedback from them,
- Public Meetings, often with the intent of both informing and soliciting feedback from stakeholders,
- Food Safety Education Campaigns
- Web-based updates
- Press releases and other information materials
- Presentations to outside groups.

The Office of Public Affairs, Education and Outreach (OPAEO) has a major role in risk communication because it is responsible for communicating with the public about agency activities and safe food handling practices through a variety of means, including public meetings, correspondence, press releases, speeches, consumer publications and educational campaigns, a newsletter to educators, and a toll-free hotline. Due to the continuous and multifaceted nature of risk communication, the actual communication of information may be carried out by numerous individuals throughout the agency, including scientists and policy makers. However, OPAEO coordinates risk communication activities within the Agency, with other government agencies, and with the public to ensure that messages are coordinated and effectively presented. This office also advises senior management on risk communication strategies and advises risk assessors and managers regarding information risk communicators will need to emerge from the risk assessment.

As was previously stated, the need for timely assessment and interventions must be appropriately balanced with public involvement. As we develop the process of risk analysis at FSIS, we will seek input on how and when to best involve risk communicators and consequently stakeholders throughout the risk analysis process.

Risk Management

Risk management has been defined in the 1983 National Research Council report⁵ as *"the process of evaluating alternative regulatory options and selecting among them."* This

⁴ Principles and Guidelines for the Conduct of Microbiological Risk Management, CX/FH 01/7, July 2001

⁵ Risk Assessment in the Federal Government; Managing the Process, National Research Council; National Academies Press, 1983

report also states that a risk assessment may serve as one of the foundations upon which risk management decisions are based. Risk management as defined by Codex Alimentarius Commission is *“the process, distinct from risk assessment, of weighting policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and option controls.”*⁶

Within FSIS, OPPD, working with the other offices as appropriate, are the risk managers. They identify the food safety problem and formulate the risk management questions to be answered by the risk assessment. Risk managers determine whether to have a risk assessment conducted or use other options, involve stakeholders at relevant steps, and coordinate and interact with risk assessors during the risk assessment process. Based on the risk assessment, risk managers weigh risk management options, select the risk management decision, and communicate and implement the selected risk management decision. Risk managers consider the scientific and technical evidence from the risk assessment, and the social, and economic factors and strive to reduce, eliminate, or control risks to public health. When choosing mitigations, risk managers also consider the uncertainty associated with risk assessment outputs. Risk managers also monitor and review the management decision at several points during implementation to assess their effectiveness.

Risk managers are the primary users of risk assessment outputs although risk assessment output can be used by risk communicators to better target education programs. Since risk managers generally know when the priorities and timelines associated with rulemaking change (based on internal and external pressures, changing events, etc.) they are responsible for keeping the risk assessors and risk communicators informed and apprised of these changes. Both OPPD and OPHS will cooperatively adjust timelines to ensure that goals are met.

Risk Analysis: The Process

Setting the Risk Analysis Agenda

The first step in setting the risk analysis agenda is prioritization of the issues (or food safety problems) that are of interest to the Agency. This is done by risk managers, communicators, assessors and other Agency officials. Food safety problems may be well recognized and long standing or new or emerging problems. The importance of any issue, and therefore, its place in the risk analysis agenda, can be influenced by many factors. These factors can include but are not limited to:

- Foodborne outbreaks, epidemiological and clinical findings
- Public concern
- Court cases or other litigious issues

⁶ Principles and Guidelines for the Conduct of Microbiological Risk Management, CX/FH 01/7, July 2001

- New scientific findings
- International issues
- Agency resources
- Regulatory Agenda
- Surveillance and monitoring information
- Changes in industry practices

Due to the variety of the influential factors listed above, a number of groups including consumer groups, industry and other groups within the executive and legislative branches of government can have an effect on the priorities and the risk analysis agenda of the Agency. Ultimately, however, it is the role of the risk managers to finalize this prioritization.

It is important to realize that this agenda needs to be flexible because priorities can change. Some of the influential factors listed, such as outbreaks and new scientific findings, can occur after an agenda for a fiscal year is set but may be significant enough to demand new attention be given to an issue previously considered a low priority. Maintaining public access to relevant information, including the current risk analysis agenda, status of various projects on the agenda, related Federal Register Notices, reports from National Advisory Committee on Microbiological Criteria for Foods, past public meeting transcripts as well as upcoming public meetings will be important in achieving this objective. A critical mechanism for achieving this public access is the FSIS web page.

Formulate the Risk Management Questions, Issues, and Intent

For each food safety issue which is determined by consensus to be of high priority within the Agency, OPPD risk managers meet to discuss and formulate the food safety issue or problem, questions, objectives and goals. OPPD may involve OFO in these discussions but in any event should always offer the opportunity for such engagement. Risk managers then present a written list of risk management questions and needs to OPHS for discussion. This meeting can include risk communicators and other technical experts. After the risk management questions have been formulated such that they are mutually understood by OPPD, who is asking them, and OPHS who will answer them, they should be sent to the appropriate Deputy Administrators for review and sign off. A proposal that sets out how the issues and questions from the risk managers will be addressed is prepared by the Risk Assessment Division of OPHS.

Develop a Proposal to Address the Risk Management Questions

A risk assessment proposal is prepared by the Risk Assessment Division of OPHS, with input from groups including members of OPPD and other divisions within OPHS. The risk assessment proposal should:

- Summarize the risk management questions presented to OPHS by OPPD and other FSIS programs as appropriate.

- Explain the public health and regulatory context for the food safety issue. This will include: (1) a description of the hazard in the food commodity of concern, (2) an overview of the public health problem including the current number of cases per year, the severity of the associated illness, epidemiological evidence of foodborne transmission, populations of interest etc., (3) a summary of the regulatory status of the pathogen in the commodities of concern or other existing Agency mitigations such as directives that have been issued, and (4) a summary of existing scientific guidance provided by groups such as the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) and the National Academy of Sciences (NAS).
- Specify the type of risk assessment to be performed based on the risk management questions and the availability of information. The scope (e.g., farm to table risk assessment, process model, etc.) and nature of the risk assessment will be determined. The risk assessment proposed may be (1) a quantitative risk assessment, (2) a qualitative risk assessment, (3) a safety assessment, (4) a relative risk ranking, or (5) a hazard ranking.
- The expected outputs of the risk assessment should be clearly presented so that the risk managers can determine whether the proposal can adequately address their questions.
- Develop the conceptual model. The conceptual model illustrates the relationship among key parameters in a food system. It may be a graphical (e.g., process diagram, decision-tree diagram, etc.), or a mathematical representation and usually depicts the stages of a food safety system such as production, processing, preparation, and consumption, as well as factors that affect the increase or decrease in the amount of hazard throughout these steps.
- Specify the mechanism for scientific peer review.
- Summarize both the available data and the data gaps. Various groups within OPHS (e.g., Biosciences Division or the Residue Branch) should review and comment on this section depending on their expertise.
- Outline the deliverables, a timeline for completion of each deliverable, and the team member responsibilities.
- Include references of the available data and other pertinent information.

Determine Whether or not to Conduct a Risk Assessment.

Once the risk assessment proposal is completed, it should be presented to the risk managers and risk communicators for review and sign-off. There are a variety of options for risk managers to choose from at this point including: (1) developing a research agenda to address data-gaps. (This will require some coordination between FSIS and other agencies such as FDA or ARS); (2) developing public education campaigns/programs; (3) conducting a risk assessment; and (4) implementing temporary actions or interventions. It is possible a combination of approaches may be chosen such as to begin a risk assessment but implement temporary interventions.

The expected risk assessment outputs must meet two criteria in order to be useful to risk managers: (1) the risk assessment outputs must be applicable to the development of cost and benefit analyses and (2) they must fit within the statutory framework for the regulation of meat, poultry, and egg products. The risk managers review the proposal and determine whether it will serve the needs of the Agency. Having seen the proposal that specifies the issues and questions of the risk managers, risk managers may find that they need to refine or change their risk management questions. In this case, a collaborative process may need to occur where parts of the proposal may change as well. The proposal is modified based on the discussions between risk assessors and risk managers.

After having decided to either proceed with a risk assessment or to proceed with another approach, the Agency should invite public comment at this time and revisit its decision based on the input obtained. If a risk assessment is to be conducted, the proposal should be presented to the public and a call for data (based on data gaps outlined in the proposal) should be made. If another option is to be pursued, it will similarly be considered for announcement either via the Federal Register or a public meeting.

Conduct the Risk Assessment

The risk assessment is a scientifically based process consisting of many steps and is performed by a team with expertise in data analysis including predictive microbiology, modeling, and statistics. The risk assessment team is usually staffed by members of the Risk Assessment Division (RAD) of OPHS but on occasion will include others from within OPHS or FSIS who have the appropriate expertise. On occasion, FSIS may secure the services of external experts through other contracts, cooperative agreements, or Intergovernmental Personnel Acts (IPAs). In such cases, a member of RAD will be responsible for ensuring funding and monitoring the work to be performed.

The steps of risk assessment usually include: (1) further development of the conceptual model, (2) collection and analysis of data, (3) identification of data gaps, (4) modeling and (5) analysis of uncertainty and variability. The scope of the risk assessment proposed will dictate the nature of the modeling to be performed.

It is important to note that at various stages of development of the risk assessment, communication among the risk managers, assessors, and communicators will be necessary. For instance, after the development of the conceptual model, the Risk Assessment Division should present the proposed approach to OPPD to ensure that it will facilitate the development of risk management strategies by OPPD. Similarly, during or after the data analysis phase of the risk assessment, gaps, limitations, or inconsistencies among the data should be discussed with OPPD. The implications of various available data sets should be discussed; for instance, data from industry has the potential for bias. At this stage it may be necessary for OPPD and OPHS to reconsider the type of model to be developed given the available data, or at the very least, limitations of the model should be clearly articulated to risk managers. Risk managers may be asked to select between two or more model options by the risk assessors. They may also be asked to furnish

potential assumptions to each step of the model including “what if” scenarios. Similarly, if problems develop with a proposed assessment approach, or if the Agency’s priorities and timelines change, the risk assessors may need to change the methodology. This type of decision or complication should be discussed while the risk assessment is still in progress. It is possible some of the issues that arise during a risk assessment should also be shared with various stakeholders outside of the Agency, and mechanisms for this should be considered such as maintaining web-pages describing risk analyses projects in progress.

The final report must effectively communicate the findings of the risk assessment. It should clearly describe the methodology used, assumptions made, sources of uncertainty and variability, and the impact of all of these on the outputs. A sensitivity analysis must be conducted to determine what factors have the largest influence on the risk assessment. The report should be written so that a technically trained third party could reproduce the results. An executive summary will also need to be prepared in order to communicate the intent, methods and results of the risk assessment.

Evaluate the Output

After completion, the draft risk assessment report will be presented to OPPD, and as appropriate, OFO. This presentation will describe the RAD’s approach toward answering the risk management questions, the outputs obtained, assumptions used, and the limitations and uncertainties of the risk estimates.

This should be followed by a public announcement and meeting for the various stakeholders at which the risk assessment would be presented by appropriate personnel from OPHS, OPPD and OPAEO. This presentation will also describe the RAD’s approach toward answering the risk management questions, the outputs obtained, assumptions used, and the limitations and uncertainties of the risk estimates. This will provide the Agency with the opportunity to receive public comment on the draft assessment. Based on the comments received, the draft assessment can be further refined prior to, or concomitant with, submission of the document for peer-review. Due to the technical nature of the assessment, and its intended use, any communication with the public will occur via a team consisting of appropriate personnel from OPHS, OPPD and OPAEO.

Peer Review

Peer review is an integral part of the risk analysis process at FSIS. In part, this review will be provided by the public during comment periods in response to announcements and public meetings; however, the Agency believes it is important that scientific review also be sought. For projects with less economic impact, peer review may consist solely of internal review or review by knowledgeable experts in sister agencies. For large assessments that will be used to inform regulations that have a significant economic impact, independent, external expert review will be considered. The mechanism for peer

review and a timeline for such a review will be specifically proposed in the proposal that specified the issues and questions of the risk managers.

There are a number of mechanisms which may be considered for peer review and input including:

- National Advisory Committee on Microbiological Criteria for Foods (NACMCF)
- National Academy of Sciences (NAS)
- Contractual arrangements with subject area experts
- IPAs with subject area experts
- Stakeholder organizations
- Other risk assessment groups (e.g., Risk Assessment Consortium).

After the peer review has been conducted the concerns and comments raised will be evaluated by the appropriate staff, and the Agency will need to decide what, if any, response or changes are warranted.

Cost-Benefit Analysis

Outputs of risk assessments are used in developing cost -benefit analyses. The benefits of food safety programs are measured by the degree to which foodborne illnesses and deaths are expected to decline after implementing mitigation strategies. By definition, this requires some knowledge of the current frequency of foodborne illness for comparison against the expected incidence of illness after implementation of mitigation strategies.

The risk assessment creates this needed “baseline” describing current conditions and helps risk managers to gauge the impact of the different mitigation strategies under consideration in a transparent framework. The risk assessment must clearly describe the uncertainty and variability associated with the human health outcomes to be expected from any mitigation. The expected reduction in illness, determined by the risk assessment, and the certainty in this reduction are critical factors to be used directly by economists and Agency personnel to estimate the benefits of a proposed mitigation. In a way, the economists’ role is to help communicate the results of the risk assessment to risk managers in a language they can understand: that is, quantifying, to the extent possible, the costs and benefits of their proposed actions in monetary terms.

In this process, risk assessment outputs are aligned with their expected direct costs (e.g., equipment that must be purchased, testing that must be conducted etc.) and indirect costs (e.g., loss of industry due to companies choosing to stop producing, loss of productivity due to extra cleaning/breakdown time or longer stabilization, lethality or other CCP application, etc) associated with each mitigation. The economist must work closely with risk assessors to determine if such cost estimates are realistic and identify how proposed actions might lead to other changes outside the realm of the risk assessment. These issues include the mitigation’s impact on small entities; on international trade; on product

variety; and on the extent and type of any other possible unintended outcomes. The knowledge and insight gained by risk assessors in their work can greatly assist economists and risk managers in identifying such issues. These considerations, plus their expected cost impacts, can then be more accurately weighed against potential benefits.

It should be noted that the methods used to determine parameters for, and the outputs of, the cost benefit analysis are also subject to discussion with stakeholders and need to be transparently reported.

As part of the Agency clearance process, the Office of Risk Assessment and Cost Benefit Analysis (ORACBA) reviews Regulatory Impact Analyses (RIA) for regulations of significant economic impact (\$100M) and therefore is likely to comment on the validity of models, assumptions, and other factors included in the risk assessment. ORACBA will perform these analyses before regulations are presented to the Office of Management and Budget (OMB). OMB similarly reviews the RIA for regulations prior to approving them.

Select Risk Management Options

After the risk assessment has been peer reviewed, revised to accommodate relevant concerns, and delivered in its final form, OPPD in consultation with OFO and the FSIS Administrator must consider the results while evaluating potential mitigation strategies. The mitigations can include one or a combination of the following:

- Establishment of a performance standard or other regulatory approach,
- Public education,
- Industry Guidance, and
- Adopting an intervention aimed at reducing risks.

Risk managers will consider a variety of issues when choosing a mitigation strategy. These considerations include:

- risk assessment output,
- Agency's public health goals,
- societal values,
- costs of regulatory action or inaction,
- international issues,
- technical feasibility/ monitoring or enforcement capabilities,
- unintended risks associated with the management strategies,
- practicality of implementation, and
- statutory mandates.

It is OPPD's responsibility to develop and recommend risk management options for Agency approval. Once a policy option or set of options has been chosen, a public meeting or other such announcement should be considered.

Implementation

Implementation is the method the Agency uses to act on its choice of management options. Mechanisms which facilitate implementation of policy options include but are not limited to: (1) notices/directives, (2) guidelines, (3) voluntary industry programs, (5) developing research agendas to address data-gaps, and (6) regulations. OPPD develops the regulations, performance standards, or notices in the process of rulemaking. After these are approved by the Agency and published in the Federal Register, OPPD develops a directive with input from OFO for use in the enforcement of the management option(s).

Monitoring and Reassessment

The Agency must evaluate the effectiveness of the management measures implemented as well as the impact on public health and on industry. If the selected option is found to not be effective at achieving the public health goal, the mitigation strategy and implementation methods may need to be re-evaluated.

Similarly, it may be necessary to refine or revise an assessment if enough new and relevant science is conducted. Any intent to conduct a reassessment or revise policy options will be made public as will the reasons for it.

Table 1: Risk Analysis: Roles and Responsibilities

Stage of Risk Analysis Process	Responsible Office
Setting the Risk Analysis Agenda: <ul style="list-style-type: none"> • Risk Analysis Agenda is established on a yearly basis. 	OPPD/OPHS/FSIS Administrators
Formulate the Risk Management Questions, Issues and Intent: <ul style="list-style-type: none"> • Develop and present written Risk Management Questions to OPHS. • Collaborative refinement of Risk Management Questions. • Administrative sign-off. 	OPPD OPPD/OPHS OPHS DA/ OPPD DA
Develop a Proposal to Address the Risk Management Questions: <ul style="list-style-type: none"> • Develop and present the risk assessment proposal to OPPD. 	OPHS
Determine Whether or not to Conduct a Risk Assessment: <ul style="list-style-type: none"> • Evaluate risk assessment proposal. • Collaborative refinement of the risk assessment proposal. • Commission the proposed risk assessment and/or choose other risk management options. • Administrative sign-off on decision/risk assessment plan. 	OPPD OPPD/OPHS OPPD OPHS DA/ OPPD DA
Conduct the Risk Assessment: <ul style="list-style-type: none"> • Further development of the conceptual model. • Collection and analysis of data. • Identification of data gaps. • Presentation of written “what if scenarios” for evaluation. • Modeling. • Provide estimates for “what if scenarios”. • Analysis of uncertainty and variability. • Risk Assessment Report. 	OPHS/OPPD OPHS/OPPD OPHS OPPD OPHS OPHS OPHS OPHS
Evaluate the Output: <ul style="list-style-type: none"> • Presentation and discussion of the risk assessment. • Evaluate the output of the risk assessment. • Public Announcement and possibly a Public Meeting describing risk assessment. 	OPHS/OPPD/OFO OPPD/OFO OPHS/OPPD/OC
Peer Review: <ul style="list-style-type: none"> • Commission/organize peer review. • Modify risk assessment according to comments received. 	OPHS OPHS/OPPD
Cost Benefit Analysis	OPPD

<ul style="list-style-type: none"> • Perform a cost benefit analysis based on the outputs. 	
<p>Select Risk Management Options</p> <ul style="list-style-type: none"> • Select risk management strategy. • Announce selected strategy and invite public comment. 	<p>OPPD/OFO/FSIS Administrator OPPD/OC</p>
<p>Implementation</p> <ul style="list-style-type: none"> • Implementation of the selected strategy. 	<p>OPPD/OFO/OPHS/OPAEO</p>
<p>Monitoring and Reassessment</p> <ul style="list-style-type: none"> • Refine or revise assessments as determined to be necessary. • Monitor the public health impact of implemented strategy. • Evaluate the effectiveness of implemented strategy. 	<p>OPHS/OPPD/OFO OPHS/OPPD OPPD/PEER</p>