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ENSURING EFFECTIVE COMMUNICATION BETWEEN RISK ASSESSORS AND RISK MANAGERS

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SUMMARY

The mission of the United States food safety regulatory agencies is to safeguard public health by ensuring the safety of food products in the United States. To accomplish this goal, these agencies are increasingly relying on a risk analysis approach to address complex food safety problems.

This document will discuss how US regulatory agencies balance the need to ensure the independence of risk assessors and risk managers, while yet maintaining essential frequent and transparent communication between the two groups. Two illustrative cases of coordinated risk assessment and management are included; these address Salmonella Enteritidis in shell eggs and Listeria monocytogenes in ready-to-eat foods.

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INTRODUCTION

The mission of the United States food safety regulatory agencies¹ is to safeguard public health by ensuring the safety of food products in the United States. To accomplish this goal, these agencies are increasingly relying on a risk analysis approach to address complex food safety problems.

Risk analysis is a powerful tool to enhance the scientific basis of regulatory decisions. It is accomplished through the efforts of risk assessment, risk management, and risk communication teams. **Risk assessment** is a systematic method of gathering information and predicting the likelihood of harm attributed to a specific hazard. **Risk management** includes all activities undertaken to control a hazard. **Risk communication** is the exchange of information and opinions about a hazard among interested parties. Effective communication is needed to ensure that the risk assessment adequately addresses the risk management problem(s) and thereby that the resulting risk management decisions are rational, defensible, and arrived at in an open and transparent manner that ensures trust in the decision-making process.

This document elaborates on the interaction necessary between the risk managers and the risk assessors² and provides two cases studies showing how U.S. food safety regulatory agencies have implemented this approach.

FUNCTIONAL SEPARATION OF RISK ASSESSMENT AND RISK MANAGEMENT

Tasks related to risk assessment and risk management activities should be performed in a coordinated manner by different people or functional groups, and ideally persons who perform the risk assessment should not also be responsible for making risk management decisions. Separation of responsibility helps to maintain the scientific integrity of the process and to avoid political pressures that would undermine the objectivity and the credibility of the conclusions. Furthermore, separation of activities helps to ensure that risk assessments are not biased by pre-conceived opinions related to management solutions. At the same time, there is a need for frequent interaction between risk managers and risk assessors to ensure that the assessment will meet the needs and answer the concerns of the risk manager; acknowledge any constraints that may impact on the risk assessment, and to assure that managers fully understand the results.

KEY CHARACTERISTICS OF RISK ANALYSIS

Risk analysis is powerful because it provides a framework for utilizing scientific data to answer risk management questions. Risk assessments are structured to clearly tell what we know and how well we know it. **Transparent** and **iterative** are two key characteristics that describe our approach to solving food safety issues using risk analysis.

Transparent. In **risk assessment**, transparency means that all assumptions, data, inferences, and conclusions are explicitly documented and made available for open review and discussion. In **risk management**, it means that the process is open and available for scrutiny by interested parties including those whose physical and economic health may be affected by the outcome of the risk management decisions. Transparency includes stating any biases that impact the risk analysis conclusions and decisions, providing clear and concise documentation, and using a participatory process.

Iterative. Risk assessment is a dynamic process involving cycles of increasingly refined risk description and exploration of risk management alternatives. Risk assessment for complex topics

¹ Six agencies in the United States federal government have primary responsibility for food safety: two agencies under the Department of Health and Human Services (HHS)--the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC); three agencies under the Department of Agriculture (USDA)-- the Food Safety and Inspection Service (FSIS), the Agricultural Research Service (ARS), and the Cooperative State Research, Education, and Extension Service (CSREES); and the Environmental Protection Agency (EPA).

² Also see the March 2000 WHO report, "The interaction between assessors and managers of microbiological hazards in food." The document is available on the internet at <http://www.who.int/fsf/mbriskassess/InteractionConsultationinKiel/index.htm>

should be an iterative process, and this requires communication and collaboration between the various teams and among individuals as the assessment is conducted.

As the risk assessment team presents initial risk descriptions, risk management strategies are explored and the potential effect of further analysis or focused research to reduce uncertainties are evaluated. Furthermore, as additional scientific knowledge, additional data, or improved modeling techniques become available, the assessment and its conclusions may have to be reevaluated or updated.

CONDUCTING THE RISK ASSESSMENT

The overall plan for conduct of a risk assessment must include the question(s) to be answered by the risk assessment, provide guidelines for dealing with uncertainties and value judgements, and make provisions for apportionment of adequate financial and personnel resources.

Risk assessors should focus on science-based evidence and analysis. Establishing the scope, range and policy of a risk assessment are interactive processes that require considerable, and ongoing, consultation and exchanges between risk managers, risk assessors, and other interested groups. The rationale for all judgements that are part of risk assessment should be clearly documented for inclusion in the published risk assessment report.

COMMUNICATING RISK ASSESSMENT RESULTS

Risk assessors must be aware of the importance of communicating insights gained during literature review, model building and analysis. It is important for risk managers to understand various aspects of risk assessment so they make appropriate regulatory decisions. These include the following:

- the degree of variability and uncertainty, and the confidence that the risk assessors have in the risk estimate
- the key sources of variability and uncertainty and their impacts on the analysis
- the critical assumptions and their importance to the estimate
- the unimportant assumptions and why they are unimportant
- the extent to which alternative, plausible assumptions or models could affect any conclusion

Risk managers should be made aware of key controversies concerning the data or assumptions used. In evaluating the results of a risk assessment, the risk manager determines whether the current level of risk is acceptable. In other words, is the risk of enough concern to warrant measures for reduction? If the risk is acceptable, no further action is required. If the risk is unacceptable managers need to consider appropriate interventions. In general, illness from microorganisms in food is not a new risk that we can choose to accept or reject, but a risk we have always experienced, although perhaps not at the current level. For these reasons microbiological risk assessment requires a more sophisticated approach than simply determining an acceptable level of risk. Some countries have set risk reduction goals with associated time frames in recognition of this difficulty.

RISK MANAGEMENT ACTIVITIES

One objective of risk management is optimizing the interventions necessary to prevent and control risks. It is aimed at selecting the option or options that achieve a chosen level of public health protection for the hazard in the commodity of concern as effectively and efficiently as possible, and within the technical feasibility of the industry.

The interaction between managers and assessors concerning development of risk management options or strategies depends on the scope of the risk analysis project. The risk assessors may be asked to simply provide explanatory narrative in support of risk estimates generated from the risk assessment process or may be asked to assist in compiling a list of options. Often the risk assessment is designed to identify the stage in the food chain where interventions will most effectively reduce the public health burden attributable to the specific food and pathogen in question. A risk assessment also may be initiated to examine the effectiveness of current controls or to evaluate a new technology for control. In

these cases the risk assessor may be asked to provide explanatory narrative and/or quantitative estimates in support of various interventions or controls.

MONITORING, REVIEW, AND RESEARCH

An essential part of risk analysis is gathering and analyzing data from a range of points in the food chain to ensure that food safety goals are being achieved over time. Reasons to revisit a risk assessment include the emergence of new problems, unsatisfactory epidemiological findings, or high variability in compliance with required performance/process criteria. In addition, risk managers may request the reevaluation of specific inputs to the risk assessment model, or may commission a new risk assessment. Both of these requests will involve interaction between risk managers and risk assessors in formulating the statement of the problem.

A risk assessment should be based on sound science. Where data are lacking, assumptions must be made, and risk managers contribute to those assumptions from their background experience and knowledge. It is likely that a risk assessment will raise uncertainties that might be addressed through further research. Thus, a risk assessment can be useful in identifying the research that will have the most impact on future regulatory decisions.

EXAMPLES OF EFFECTIVE COMMUNICATION BETWEEN RISK MANAGERS AND RISK ASSESSORS: TWO CASE STUDIES

CASE STUDY I: SALMONELLA ENTERITIDIS IN SHELL EGGS AND EGG PRODUCTS.

The National Egg Safety Action Plan requires the Department of Agriculture's Food Safety and Inspection Service (FSIS) to develop performance standards for shell egg packers and for egg products processors. A group consisting of risk managers and risk assessors from different program areas in FSIS was formed to accomplish this task. To evaluate the risk of pathogens in these products as part of the problem formulation stage of the risk analysis process, the group reviewed the literature on the pathogens of concern, prevalence studies on eggs and egg products, time and temperature challenge studies, and epidemiological data. Based on the available data and literature, the group determined that although *Salmonella* Enteritidis (SE) is the most prevalent pathogen in shell eggs, other *Salmonella* serotypes contaminate the product at different stages of processing. Risk managers and risk assessors then held a series of meetings to discuss revising a previous SE Risk Assessment (SERA) to develop performance standards for shell eggs and egg products.

These two groups have met continuously to discuss the goals of the risk assessment policy. For example: for the rule on shell egg refrigeration at 45° F, the risk managers asked the risk assessors to estimate the reduction of risk associated with refrigeration. The risk assessors ran a model to estimate the reduction in risk, and explained the results and attendant uncertainties to the risk managers. The risk managers used the result to determine the benefits of the proposed rule.

Upon completion of the revised risk assessment, the risk assessors and risk managers will review and discuss the assumptions, uncertainties and outcomes in the risk assessment. The risk managers will formulate options for performance standards, and select the performance standards that will give the greatest public health protection at the least cost to industry. The performance standards for eggs and egg products will be included in a proposed rule, which will be published in the Federal Register to obtain comments from all stakeholders. Also, a public meeting will be held to present the proposed rule and solicit comments.

CASE STUDY II: LISTERIA MONOCYTOGENES IN READY-TO-EAT FOODS.

Listeria monocytogenes (LM), a bacterium found in a variety of foods, causes about 2,500 illness and 500 deaths a year in the United States. The Secretary of Health and Human Services and the Secretary of Agriculture were directed to identify aggressive steps to significantly reduce the risk of illness and death from LM by 2005. A risk assessment was conducted to better understand both the health risks posed by this bacterium and the associated food vehicles that can transmit the pathogen. In

January 2001, FDA and USDA/FSIS released a draft assessment of the public health impact from LM in ready-to-eat foods and a draft risk management action plan targeted to reduce LM-illness.

FDA formed risk assessment, risk management and risk communication teams of regulatory officials and scientists to work on this problem. These teams met separately and together on a regular basis to exchange information and discuss progress, technical and scientific issues, and policy concerns. As part of a transparent process, public meetings were held to explain the scope of the assessment, data and assumptions and the modeling approach used. The opinions of an advisory committee and other subject matter experts including the interagency Risk Assessment Consortium were also actively sought throughout the conduct of the risk assessment. Notices were published in the Federal Register requesting the submission of research data. The risk assessment and risk management action plans were both issued as draft for public comment. Since the close of the comment period in mid July 2001, the agencies have been discussing the revisions to the assessment and action plan.

The results of the January 2001 risk assessment were used in the development of the action plan and in education and outreach efforts. For example, the risk assessment concluded that two important factors that affect consumer exposure to LM at the time of consumption are the refrigerator temperature and duration of food storage before consumption. Among the suggested action items in the plan, risk managers included the need for targeted research and enhanced consumer information and education efforts on those behaviors. The risk communication team developed a public health message that reminded consumers to: use perishable items that are precooked or ready-to-eat as soon as possible; clean their refrigerators regularly; and using a refrigerator thermometer to make sure that the refrigerator always stays at 4.5 degrees C or below.

Two important outcomes of the risk assessment are the initiation of research efforts based on the results of this risk assessment that will be used to refine future risk assessments, and the ad hoc Risk Analysis Working Group that has been formed in FDA's Center for Food Safety and Applied Nutrition to facilitate future complex quantitative microbial risk assessments. The Working Group is developing a very detailed description of the decision-based, systematic process that will be used in the future to initiate and conduct risk assessments within the risk analysis framework.

SUMMARY

To ensure that risk management decisions are rational, defensible, and arrived at in an open and transparent manner, active communication between risk assessors and risk managers is emphasized. In the United States, this interaction has led to successful development of an egg-safety action plan and draft action plan to reduce the risk of *Listeria monocytogenes* in ready-to-eat foods.

Prior to embarking on a risk assessment, risk assessors and risk managers meet to identify food safety problems and issues; clarify risk management questions and goals; and agree on the scope of the risk assessment. This required considerable consultation and active interchange of information, and will provide risk managers with an important tool to assist in making decisions on food safety issues. It is the responsibility of risk assessors to ensure that risk managers have an understanding of at least: the degree of variability, uncertainty, and confidence in the risk estimates; the key sources of variability and uncertainty and their impacts on the analysis; the critical assumptions and their importance to the risk estimates; the controversies (if any) concerning the data or assumptions used; and the extent to which alternative plausible assumptions or models could affect any conclusions. Effective communication of the risk assessment will help the risk manager select appropriate risk management options that adequately protect public health.