

Conduct of Quantitative Microbial Risk Assessments by U.S. Food and Drug Administration's Center for Food Safety and Applied Nutrition: Lessons Learned

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Introduction

During the past two years, the U.S. FDA's Center for Food Safety and Applied Nutrition (CFSAN) has been at the forefront of using new techniques in quantitative microbial risk assessment to evaluate issues related to the microbiological safety of various foods. This has included developing and disseminating the "Draft Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods" and "Draft Risk Assessment on the Public Health Impact of *Vibrio parahaemolyticus* in Raw Molluscan Shellfish." In addition to these major undertakings, the CFSAN has also been working with the USDA Food Safety and Inspection Service (FSIS) to expand and enhance the usefulness of its previously published risk assessment, "Salmonella Enteritidis Risk Assessment: Shell Eggs and Egg Products," and the Food and Agriculture Organization and the World Health Organization to develop a series of international microbial risk assessments.

In developing its quantitative microbial risk assessments, the FDA has attempted to advance the field, both in relation to scientific rigor used to conduct the work and the efforts it has placed to assure effective communication of the results to all interested parties. It made a concerted effort to follow both the principles and spirit of the frameworks developed by scientific bodies such as Codex Alimentarius Committee on Food Hygiene (CCFH), the International Commission on Microbiological Specifications for Foods, (ICMSF), and the U.S. National Advisory Committee on Microbiological Criteria for Foods (NACMCF) for the conduct of microbial risk assessments. Of particular concern to the CFSAN was assuring that the risk assessments were "transparent". Transparent is a term that was introduced into the risk analysis lexicon to articulate the need for risk assessors to fully disclose the assumptions, data, and judgments used in their work in order to provide others with the opportunity to evaluate fully the results and conclusions reached. However, the CFSAN feels strongly that the concept of transparency should not be limited to the simple inclusion of data in a microbial risk assessment. Instead, its risk assessment teams attempt to focus on the overall goal for conducting an assessment, i.e., the communication of scientific information and analysis to risk managers and other interested parties who have to use the assessments to make decisions. Realization of that goal requires that the information provided by the risk assessment teams must be scientifically accurate and in a form that can be readily understood. As a means of achieving this goal, FDA devoted a substantial amount of time and effort to assure effective communication by explaining in sufficient detail its assumptions, derivations and interpretations without reverting to jargon. It also introduced the use of communication tools such as "Interpretive Summary", which provided an abbreviated plain language version of the risk assessment that could be understood readily by

non-technical readers.

The Process

In keeping with the recommendations of the CCFH, ICMSF, and NACMCF, the quantitative microbial risk assessments conducted by the CFSAN have attempted to involve interested parties to the greatest degree practicable. It is important that process used to seek this involvement be outlined since a number of “lessons learned” over the course of the past two years are directly related to this effort.

1. Upon deciding to conduct the *L. monocytogenes* and *V. parahaemolyticus* risk assessments, the CFSAN announced its intentions via two means. The first was through formal announcement via the Federal Register, the venue to posting official documents for the United States government. These announcements included the purpose and scope of the risk assessments and provided an initial request for data pertinent to the assessment. The second “announcement” was to include both risk assessments as priority projects in our annual listing of major goals of the CFSAN’s food program. This communicated to the public the fact that the agency considered these priority projects of major significance.
2. The CFSAN sought an initial peer review of its planned approach to the assessments by twice going to the NACMCF. The first time, the risk assessment teams outlined their general approaches to the risk assessments including key assumptions and modeling techniques that they intended to employ. The second time, the teams had the committee review the data sets that were being employed, the assumptions that were used in addressing issues related to uncertainty, and specific modeling approaches that were used at various sections of the assessment. Both meetings with the NACMCF were open to the public and the FDA once again asked for additional scientific data pertinent to the two risk assessments.
3. Upon completion of the initial “running” of the risk assessment models there was a presentation to a limited number of individual representing a cross section of the agency’s “stakeholders.” The suggestions and questions related to the risk assessment, particularly in terms of the effectiveness of the presentation of the results were used to guide the drafting teams that developed the risk assessment reports.
4. Upon completion of the initial draft of the risk assessment reports, a panel of scientists who were either Federal government employees or who where “Special Government Employees” were asked to provide a final preliminary peer review of the reports. This review was limited to government employees to help insure that the results of the assessment were not released prematurely since by this stage there was a high degree of interest among a variety of interested parties.
5. The draft risk assessments were released to the public on January 19, 2001 both in hard copy, as a CD-ROM disk, and as a down-loadable PDF file. All references cited in the risk assessments were made available as part of a public docket. A 120-day period for public comments was established and all interested parties were encouraged to review the reports and provide comments on the approaches and data sets employed and the conclusions reached by the public to the public. In addition, the public was again encouraged to submit any additional scientific data that was pertinent.

Since the close of this final peer review of the risk assessments, the CFSAN has read each of the public comments, added the new data to its databases, and modified the risk assessment models as appropriate. The risk assessments are currently being recalculated and the “final” versions of the risk assessments are targeted for release during the summer of 2002.

Lessons Learned

While the CFSAN made every attempt to develop risk assessments in a transparent manner that brought the best available science to bear on the questions posed by the risk managers, there were a number of times where communications or expectations impeded the completion of the projects. The experiences gained as a result of these risk assessments prompted the CFSAN to develop a framework that it will use to select future risk assessment so that they provide the CFSAN risk managers with the information that they need to reach informed decision. A copy of this recently completed document of the framework is provided in Appendix 1. A brief summary of some of the issues addressed in the development of the framework is provided below. For ease of review, the subjects covered have been grouped into five topics: (1) commissioning a risk assessment, (2) interaction between risk managers and risk assessors during the conduct of a risk assessment, (3) acquiring input from interested parties, (4) peer review, and (5) reporting the results.

1. **Commissioning a risk assessment.** This is perhaps the most critical step in the conduct of a risk assessment because it establishes what the question(s) that the risk assessment will address, the resources that will be brought to bear, and the expectations that the risk managers have in relation to both the product that will be produced and the timeframe in which the activity can be completed. To a large degree, the challenges faced in this process seem to be related to the understanding that the risk managers have regarding the conduct of a detailed quantitative microbial risk assessment, which is not surprising considering the emerging nature of the techniques. A key initial question that needs to be asked is whether a risk assessment should be done, and there is not complete agreement on even the usefulness of the process. In some instances risk managers expressed the opinion that they did not feel that the process did not add significantly to the decision making process and actually decreased their degrees of freedom because it reduced their options when attempting to negotiate with various stakeholders. Conversely, consumer groups expressed concern that the conduct of a risk assessment was being used as a means of delaying dealing with food safety concerns. There was general concerns among a number of different groups concerning the time and resources that were needed to conduct a quantitative microbial risk assessment, and the conclusion was that they should be reserved for issues where the science is complex or there is substantial differences of opinion concerning the interpretation of the scientific data among the various interested parties.

The commitment of staff time to the conduct of a risk assessment was an ongoing issue since the projects were much more resource intensive than the risk managers

initially anticipate both for the individual directly involved and for the risk managers that much interact with the risk assessment teams on a routine basis. This is compounded by the fact that it is difficult to assess the resource needs until the risk assessment teams have actually begun the process. However, the need to have a formal mechanism for establishing resource commitments is critical, and the commitment of the resources needs to span the duration of the project or limitation associated with personnel need to be known ahead of time so that their contributions can be staged appropriately. To this end, it is critical to have a project coordinator who is capable of negotiating and managing for resources. The issue of personnel availability has been an issue in virtually all risk assessments in which the authors have been involved both nationally and internationally.

The critical aspect of this phase of the risk assessment is defining the question that the risk assessors are being asked to investigate. This process was severely hampered by a general lack of knowledge of what a risk assessment can and cannot do among the risk managers. This was compounded by a propensity on the part of the risk managers to have the risk assessments be as detailed as possible in order to differentiate subpopulations among manufacturers or product identities. A critical responsibility on the part of the risk assessors is work with the risk managers to articulate their needs in a form that can be actively modeled. Likewise, the need to communicate to the risk managers in non-jargon language is a requirement for success. The recommendations in relation to the development of the risk assessment questions is that this should be the first priority, that it will require an iterative process, with the assessor reviewing the status of available information and working with the risk managers to define questions that are meaningful and practical. Once agreed upon, the risk assessment charge should be developed as a formal document and periodically reviewed to see if the project is faithful to the original intent.

- 2. Conducting the Risk Assessment.** The CCFH framework for the conduct of quantitative microbial risk assessments calls for a functional separation of the risk assessors and the risk managers. Practical experience has indicated that this is simultaneously impractical and absolutely necessary. Without ongoing input from the risk managers, the risk assessors tend to simplify the assumptions and parameters associated with the foods under consideration or lack some of the detailed knowledge pertaining to the food that is most likely to be available only from the risk managers. Conversely, there is a propensity on the part of a number of the risk managers to micro-manage the process, most often leading decisions that further increase the complexity of the models without significantly changing the ultimate outcome of the risk assessment. This becomes particularly important when the risk assessors perceive that the risk managers are attempting to influence the outcome of the risk assessment to match their preconceived notions of how the assessment should come out. We found that the best way of avoid most of this was to have regular meetings of the risk assessment teams with a corresponding team of risk managers. At these meetings issues related to assumptions, methods and models were discussed and decisions were generally reached by consensus. The roles and responsibilities of both groups should be clearly agreed upon before initiation of the

risk assessment. It was concluded that the risk managers must have the responsibility for making key decisions related to assumptions or data sets to be used, but the risk assessors had the responsibility for depicting in the risk assessment the impact that these decisions had on the reliability of the results. It is also worth noting that CFSAN employed a risk communication team that also participated in these meeting so that they could ultimate help with the communication phases of the risk assessment.

The CFSAN established an additional component within this mix to arbitrate those instances where consensus could be reached by the risk assessors and risk managers. This designated individual was a senior science policy official who, in consultation with the CFSAN senior management officials, would be responsible for making the decision. However, this was again done with the expectation that the impact of that decision would be articulated in the final risk assessment document.

- 3. Acquiring Data from Interested Parties.** A frustration that the CFSAN encountered when conducting both of its risk assessments was the poor response it received from the affected industry in relation calls for pertinent data. Our initial calls for data yielded virtually nothing even though we had informal knowledge that a substantial body of data was available. In part this was not surprising based on historical reluctance of industry to provide meaningful scientific data to a regulatory agency. It was only toward the end of the risk assessment development period, when industry became concerned that the information in the scientific literature did not adequately capture the current status of the industry that more information was provided or new studies undertaken. In the intervening period, the CFSAN has been working with the industry, particularly trade organizations, to find better ways of acquiring industry information that would be beneficial to the risk assessment process. We anticipate that responses will be better in the future as the industry becomes for comfortable with the risk assessment process.
- 4. Peer Review.** The CFSAN remains committed to extensive peer review of its major quantitative microbial risk assessments, but sees a need to streamline the process and ensure that the Center is getting from the reviews the information that is needed. The Center found the reviews from the NACMCF of limited usefulness in part because of the general lack of knowledge about the details of risk assessment modeling techniques among the members of the committee and the inexperience of the CFSAN risk assessment team in presenting the materials that needed responses in a clear manner. Future use of the NACMCF will likely improve as a result of those initial experiences. Release of information about the preliminary results of the risk assessments during the peer review process was problematic since this quickly lead to a discussion of the impact/interpretation of the results and not whether there were scientific modifications that were needed. While the CFSAN will continue to focus its primary peer review through a public comment period, its initial interim reviews are likely to employ employee mechanisms that permit more confidentiality.
- 5. Reporting the Results.** The CFSAN learned several lessons regarding the reporting

of the results of risk assessments of the magnitude and interest as the ones they have undertaken in the last few years. Critical to the process is effective communication at all levels, and most particularly in the presentation of the results. The risk assessment teams have a tendency to simply “provide the facts” and did not focus on the nuances of the messages being provided. Internal discussions on the extent to which the results should be interpreted took place. Ultimately it was decided that after the risk assessment team provided a draft report, a team of scientific writers and senior managers then worked with the document to provide it in a form that met the overall goal of providing the risk managers with the information that they needed to make informed decisions.

The other aspect of communication that became apparent as the risk assessment approached release is that the agency had to be ready to provide individuals who could meet with industry and the public to describe the risk assessments and the implications of their findings. We found that this required our risk assessors and risk managers to seek the advice of professional experts in the presentation of risk data. Pairs of risk managers and risk assessors were then made available to interested parties that wanted more information about the results. This approach proved to be highly successful.

Concluding Remarks

The lessons-learned highlighted above are only a small percentage of those that were considered by our task force as a result of the CFSAN initiating its first quantitative microbial risk assessments. We have attempted to take advantage of the challenges that we faced by learning from them. The Center is encouraged by the willingness of all parties to be involved in that process, including the willingness of our stakeholder groups to describe how they could be used more effectively. We have used the information gained as a result of these initial experiences to design a framework that we feel will enhance our ability to conduct quantitative microbial risk assessment more effectively and rapidly in the future. We hope our lessons-learned exercise will be useful to others that may be facing the same challenges in the future.