



NATIONAL
FOOD
PROCESSORS
ASSOCIATION

December 22, 2003

FSIS Docket Room
Docket No. 03-032N
U.S. Department of Agriculture
Food Safety and Inspection Service
Room 102 Cotton Annex
300 12th Street, SW
Washington, DC 20250-3700

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[Docket No. 03-032N] Risk Analysis at FSIS: Standard Operating Procedures; 68 FR 61183; October 27, 2003

Dear Ms. Riley:

The National Food Processors Association (NFPA) is the voice of the \$500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers.

NFPA provides the following comments on the FSIS Standard Operating Procedures (SOP) for Risk Analysis.

NFPA has long been an advocate of the use of sound science as the basis for setting public policy. We support risk analysis as the appropriate process for prioritizing resources and focusing attention on those areas where solid evidence of true risks exists. We applaud the Agency for developing this framework to define the roles and interactions of risk assessors, risk managers, and risk communicators within the Agency. In particular, we commend the Agency for recognizing the importance of including stakeholders such as industry in the process. Although this may indeed slow the process, as the SOP indicates, the process is incomplete without stakeholder input, and consequently it may ultimately be less effective

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In general, we found the SOP to be well thought out and clearly set forth. FSIS appears to have captured the correct balance of interaction among risk assessors, risk managers and risk communicators. There is appropriate “functional separation” between risk assessors and risk managers, which should ensure objectivity and credibility (yet still provide) adequate direction for the risk assessment.

FSIS has indicated in the SOP that it will seek input on how and when to best involve risk communicators and consequently stakeholders throughout the risk analysis process. We believe stakeholder input is particularly important at the following steps in the process:

- Setting the risk analysis agenda. While clearly it is the role of the Agency to set the agenda through prioritization of food safety problems, stakeholders should be consulted on their priorities and to provide their views on the Agency’s proposal. Although protection of public health should be the primary consideration in prioritization, the availability of data and risk management options will also play a role, as will many other factors. It will be important that the agenda be transparent and include a rationale for the prioritization so that stakeholders can clearly understand the Agency thought process when presenting their own priorities. We recommend that FSIS develop a draft agenda on an annual basis and publish it (or note its availability) in the *Federal Register* for public comment. Each year the Agency should summarize progress made in the previous year and explain any additions to the agenda or changes in priority. The final agenda should be published within three months of the draft.
- Determine whether or not to conduct a risk assessment. After formulating the risk management questions, the Risk Assessment Division prepares a risk assessment proposal. At this point it is presented to the risk managers and risk communicators (according to the SOP) to determine whether or not a risk assessment is the best approach. We believe that this should be a function of the risk managers, and that risk communicators need not be involved (in fact, Table 1 does not list this step as a role of the risk communicator). The SOP indicates that the Agency should invite public comment after having decided to proceed with a risk assessment or with another approach. We believe that this is the correct point at which stakeholder input should be sought and that this is the role for the Agency risk communicators. We recommend that this be listed as a separate step in the risk analysis process, and that the role and responsibility be assigned to the Office of Communications and Outreach (OCO).

- **Conduct the risk assessment.** NFPA believes that the role of stakeholders in the risk assessment process should be much more prominent than proposed in the SOP. The SOP notes the need for communication among the risk managers, risk assessors and risk communicators at various stages of development of the risk assessment. We believe that for a risk assessment to incorporate realistic assumptions, to reflect industry practices, and to minimize the need for significant revision it is often necessary to discuss the pathways, approaches and assumptions early in the risk assessment process and at various stages as it proceeds. This can be done using web pages, as the SOP suggests, with announcements in the Constituent Update when changes are posted. We also recommend the Agency consider informal discussions with appropriate stakeholders throughout the process. We have concerns about the statement that data from industry have the potential for bias. In our view, just as it is with the interpretation of data, the potential for bias exists within the actual data. Consequently, it is important for data to be collected and presented in a transparent manner so that any biases, statistical or otherwise, can be recognized and decisions can be made on how the data should best be used. We recommend that this sentence be rewritten to state, "The implications of various available data sets should be discussed and any biases that could impact how the data are used be identified."
- **Evaluate the output.** The SOP indicates that after the risk assessment is concluded it will be presented to the Office of Policy and Program Development (OPPD) and, as appropriate, the Office of Field Operations (OFO). This would be followed by a public meeting, at which the risk assessment would be presented to stakeholders. We recommend that the Agency announce the availability of the risk assessment several weeks prior to a public meeting so that stakeholders can review the document and come prepared with questions for clarification, as well as provide time for more insightful comments. We also recommend that the Agency post its response to the comments when it refines its draft risk assessment.
- **Peer review.** The peer review process is an important step where stakeholders play a role. The comments provided during the public meeting are considered to be part of the peer review process. The SOP notes that "the Agency believes it is important that scientific review also be sought." We recommend that this sentence be revised to read, "The Agency believes it is important that additional expert scientific review also be sought," to avoid the implication that the comments at the public meeting are not based on a scientific review.
- **Cost-benefit analysis.** The SOP rightfully notes that methods used to determine the parameters for, and the outputs of, the cost-benefit analysis should be subject to discussion with stakeholders. In many instances industry or other stakeholders can provide data that can assist in more accurate analyses. It would also be appropriate to have discussion on the cost-benefit analysis approaches at the public meeting on the risk assessment or at another public meeting.

The Agency described possible direct and indirect costs to the producer. However, the Agency did not specifically mention any consideration of the direct or indirect cost to the consumer as a result of implementation of mitigation strategies. It is implied in the SOP that such costs are not ultimately borne by the consuming public. We recommend the economists work closely with the risk managers, risk assessors and the industry to characterize any associated cost that may be passed on to the public as a result of implementing each mitigating strategy.

- Select risk management options. After the risk assessment has been peer reviewed, revised and finalized, the risk managers determine the appropriate risk management option(s). The SOP suggests that once these have been chosen, a public meeting or other such announcement should be considered. NFPA concurs with this approach. Although public meetings are not always necessary, if the food safety issue is of such significance that a risk assessment has been conducted, it is appropriate that the risk management strategies developed based on the risk assessment be conveyed to stakeholders. At a minimum the approach to be taken should be publicly announced. We further recommend that, for transparency, a document should be developed that outlines all risk management options considered and rejected; risk management options selected; and the rationale for the selection above other options. Moreover, the SOP lists considerations that risk managers will consider when choosing a mitigation strategy; to provide transparency in risk management, the Agency should provide an evaluation of each option against this list.
- Monitoring and reassessment. NFPA strongly supports Agency evaluation of the management measures that have been implemented. NFPA recommends that after OPPD has chosen a policy option the Agency outline the method and scope of monitoring and evaluation to be used to determine the effectiveness of the management measure implemented. The evaluation method should be included in an announcement and be discussed at a public meeting to discuss the risk management options previously suggested. We recommend that the results of such evaluations be shared with stakeholders and input be solicited on any changes being considered. Where appropriate, this should also involve a re-evaluation of the cost-benefit analysis.

We recommend that the title of Table 1 be revised to note that it describes “Risk Analysis: Roles and Responsibilities within FSIS,” as the role of stakeholders is not included. Further, we recommend that the SOP contain a flow diagram of the process with the steps that provide for stakeholder involvement clearly identified. A diagram such as the one presented at the public meeting would be very helpful in clearly summarizing the entire process.

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Thank you for the opportunity to provide input into the Agency's Standard Operating Procedures for Risk Analysis at FSIS. We strongly support the Agency's attempt to provide more transparency and structure to the process.

Sincerely,

A handwritten signature in cursive script, reading "Rhona S. Applebaum". The signature is written in black ink and is positioned above the printed name and title.

Rhona S. Applebaum, Ph.D.

Executive Vice-President and Chief Science Officer