



December 29, 2003

Docket Clerk
US Department of Agriculture
Food Safety and Inspection Service
Room 102, Cotton Annex
300 12th Street S.W.
Washington, DC 20250-3700

RE: Docket No. 03-032N: “Risk Analysis Standard Operating Procedures at the U.S. Department of Agriculture Food Safety and Inspection Service”

To Whom It May Concern:

The American Meat Institute (AMI) is the nation's oldest and largest meat packing and processing industry trade association. Our members slaughter and process over 90 percent of the nation's beef, pork, lamb, veal and nearly 75 percent of the turkey produced in the United States. AMI appreciates the opportunity to comment on development of Standard Operating Procedures (SOP) at the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS or the agency). AMI supports the use of Risk Analysis as a foundation for decision-making on regulatory policy at FSIS. Underlying this support is our belief that a scientifically-based risk assessment is paramount to development of sound inspection programs for the U.S. meat and poultry supply.

AMI has long held a position supporting the use of science-based risk analysis in establishing public policy related to the processing of meat and poultry products. We are pleased that FSIS has made the decision to establish a written protocol that will guide the agency in implementing the risk analysis process. We believe strongly that this process must be rigorous, credible, transparent, and based upon the most reliable, current and accurate information available regarding the hazard of concern. We offer the following comments and suggestions for consideration by the agency as it works to finalize the SOP process.

Early Engagement of Industry Experts is Critical to Achieving Transparency.

The SOP establishes the importance of transparency with the following quote: “*Transparency is critical for credibility and scientific accountability.*” AMI agrees that it is absolutely critical to achieve the highest degree of transparency possible, very early in the process. For example, in the step that outlines *The Development of a Proposal to Address the Risk Management Options* (pages 5 - 6 of the SOP) the agency should seek input and guidance from industry experts in the formulation of the conceptual model. Industry experts are most likely to have the knowledge to complete this task, as described in the SOP, since the task will require a working knowledge of the day-to-day operations of processing, distributing, and selling products to consumers. To develop the best and most current conceptual models, the agency should engage in informal discussions with specific industry experts or groups. In this regard, the American Meat Institute is willing to assist in any way possible.

We recognize that all stakeholders provide unique and important viewpoints on food safety and other critical issues that involve the inspection of meat and poultry. We strongly encourage the agency to recognize the value of early interaction with the most knowledgeable technical experts within the industry to gain their perspective on issues and procedures. In most cases, leading industry scientists are the most knowledgeable and have the greatest awareness of the food safety issues, because they are the technical experts responsible for designing and implementing food safety control programs, including HACCP and pre-requisite programs that ensure that safe products are produced every day. The risk analysis process will be greatly enhanced by early interaction with those who have the greatest understanding of the day-to-day operations and the interactions of these processes with potential risks.

Furthermore, AMI recommends that the agency use this SOP to establish a framework for how industry may share data to help inform the risk assessment process. Under Secretary for Food Safety Dr. Elsa Murano has publicly recognized that data from industry has significant value in helping the agency conduct risk assessments and evaluate risk management options, and she has requested publicly that industry strive to share that information with the agency. However, experience has shown that in some cases, when data has been offered by industry, the agency has refused to use the data or recognize its value. The SOP provides an opportunity for the agency to describe and define the parameters that are expected for data submission.

Public Announcement of the Risk Analysis Agenda Should be Defined.

Stakeholders need to be made aware of the risk analysis agenda on a regular basis. The SOP states that public access to the agency risk analysis agenda will be afforded through the FSIS web site; however, the SOP does not establish a routine method by which stakeholders will be apprised of the agenda and the agencies current efforts to realign priorities. AMI suggests that the agency establish a set timeframe for announcing the risk analysis agenda, much like the semi-annual regulatory agenda that is required via

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Executive Order 12866 "Regulatory Planning and Review." We recognize that priorities may change during the course of the year; however, this routine announcement process will enhance transparency and will provide stakeholders with ample time to plan for providing input to the process.

The SOP Should Provide Guidance on the Timeliness of Completion.

Undoubtedly, the agency will be under pressure to quickly complete the risk analysis process for a given hazard or process, once the hazard has been identified and the risk analysis process has commenced. AMI recognizes that efficiency and timeliness of completing tasks are critical. However, we recommend that the agency clearly establish, through this SOP, the process for establishing a realistic timeline for completion. This should be done as early as possible in the process. In many cases, the risk assessment will uncover the need to fill major data gaps and to address those areas where uncertainty can be significantly reduced through additional data collection and/or targeted research. In these cases, a modification of the timeline may be most appropriate to achieve an acceptable outcome.

AMI recognizes that, on very rare occasions, an issue may arise that poses a unique and new public health threat of significant consequence, and in this circumstance, timeliness of completion of the risk analysis process may override the desire for a complete treatment of scientific issues. However, we strongly believe that these are highly unique circumstances that are less likely to occur in today's modern food processing environments. For the vast majority of food safety issues that FSIS will encounter, we do not believe that urgency of completion exceeds the priority of adequately addressing major data gaps that will result in significant scientific uncertainty. As stated by one of the afternoon panelists during the FSIS public meeting on Risk Analysis on November 13, 2003;

“Efficiency and timeliness of risk assessment completion should never be more important than getting the science right.”

This quote should be considered seriously by the agency, and AMI would suggest that this concept is an inherent part of the agency's practice in the conduct of risk assessments. There must be a very well defined process for ensuring the risk assessment portion of the process is not “rushed” due to political or other pressures. The consequences of not using the best data available or allowing a risk assessment to be finalized with major data deficiencies can be enormous. The unintended consequences on industry, and society as a whole, are significant when risk assessments are finalized with known major data deficiencies.

Use of the Risk Assessment Models.

AMI recommends that the agency take full advantage of the risk assessment model as it provides the scientific basis for risk management decisions, both now and in the future. When political or other pressures result in risk management decisions being made in the absence of sound science, and through the use of assumptions that have a high likelihood of being superseded by facts at a later date, everyone loses. AMI

recommends that the agency establish a mechanism within the SOP that will provide for ongoing incorporation of enhanced knowledge in the risk assessment output. The SOP should also recognize that when the enhanced knowledge significantly affects the risk management outcomes, a mechanism must be in place to change the risk management strategies. This action will be in keeping with the desire by FSIS to have scientifically sound regulations for meat and poultry inspection.

Furthermore, AMI recommends that the agency use the risk assessment models as a tool to retrospectively evaluate the effectiveness of pre-existing regulations implemented prior to the establishment of the formal risk analysis process within the agency.

Sharing of Mathematical Algorithms.

AMI understands that development of a risk assessment is a complex endeavor. One of the central concepts of transparency is identical to that long employed in other areas of science. Scientific publications are transparent in that they are to contain a description of how an experiment was conducted to the extent that an informed reader should be able to reproduce the study. As risk assessments are essentially a scientific and mathematical endeavor, it is expected, for the sake of complete transparency, that the models developed should also be available for those that wish to reproduce the risk estimates.

AMI requests that FSIS provide risk assessment models in an electronic format that is accessible to the public and may be run on computers and software that is commonly available to the public. Simply providing printed computer code is not sufficient and does not meet the public expectation of transparency in the scientific process. Further, AMI requests that these models be provided well in advance of the process step whereby the agency begins to evaluate risk management options. This will provide the public with an opportunity to fairly evaluate the risk management options using the risk assessment models that have been developed by the agency. This provides the greatest opportunity for true transparency in the entire risk analysis process.

Selection of Risk Management Options Must be Transparent.

The SOP describes the process and issues that the agency will consider when selecting risk management options. At this point in the SOP, however, the agency seems to lose perspective on transparency by its position that the public will be informed only on the risk management decision made, and only after the decision is made. The risk management selection step (page 10 of the SOP) should be as transparent as the other steps of the risk analysis process. The agency should establish a procedure for informing

the public about proposed risk management options and the factors that were influential in the selection of the preferred options.

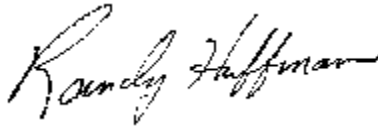
AMI agrees that it is the Office of Policy and Program Development's responsibility to develop and recommend risk management options (mitigation strategies) for Agency approval (or at least consideration). However, in our view it is imperative that this part of the risk analysis process be as transparent as the other steps in the process. The SOP lists the following as factors that Risk Managers will consider:

- 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.

As each of these factors will be considered for each risk management strategy, the agency should share a summary of these considerations in an open and transparent way. This should be done through a public forum. An explanation of how the agency intends to measure the various impacts that the mitigation strategy will have on the regulated industry should be included in this discussion. By embracing transparency in the risk management option selection step, the agency will increase the credibility and effectiveness of any final regulatory actions that may come of the risk analysis process.

We appreciate the opportunity to comment on this important initiative within the agency. AMI and its member companies stand ready to assist the agency in the process of implementing the Risk Analysis SOP. The concepts of risk analysis are aligned with industry's desire to have science-based regulations for the meat and poultry industry.

Respectfully submitted,



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