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American Association of Meat Processors
American Meat Institute
Eastern Meat Packers Association
National Chicken Council
National Food Processors Association
National Meat Association
National Turkey Federation
North American Meat Processors Association
Southeast Meat Association
Southwest Meat Association

FSIS Docket Clerk
Room 102, Cotton Annex Building
300 12th Street S.W.
Washington, D.C. 20250-3700

Re: FSIS: Next Steps, Docket No. 00-47N

The undersigned trade associations respectfully submit these comments in response to the Food Safety and Inspection Service's (FSIS or the agency) "Next Steps" initiative. We commend FSIS for undertaking this necessary initiative. As Administrator Billy commented at the recent public hearing, we are only beginning to transition to a scientific, risk-based inspection system designed to achieve measurable public health improvements.

To aid the transition, there are improvements to be made by industry and the agency. Industry must expand its use of modern technologies and procedures to enhance product safety. For some, this means rededicating themselves to the HACCP principle of prevention – taking charge of their own operations with an eye towards continual improvement. For others, it means a more open relationship with the agency in terms of sharing procedures and findings.

These changes in industry must occur in conjunction with a corresponding change by the agency. HACCP is a new approach, radically different from the "command and control" style under which FSIS and its predecessor agencies have operated since the enactment of the Meat Inspection Act of 1906. FSIS needs to better embrace the HACCP model developed by the National Advisory Committee for Microbiological Criteria for Food and the promise embodied in the agency's own Pathogen Reduction:HACCP regulations. Changes in emphasis and in the very manner of regulating are necessary to effect true progress.

In making the transition to a scientific, risk-based regulatory system with measurable public health implications, there are a host of issues to be resolved. The comments below identify and address the more significant issues. If we work together to achieve resolution of the major issues, lesser matters can be more easily dealt with.

Hazard and Risk

To implement a risk-based approach, FSIS must differentiate between those matters that have a significant influence on public health and those that do not. The primary focus of a risk-based regulatory system should be on controlling agents that pose significant risk to consumers, rather than on controlling all hazards equally, regardless of the risk posed by a biological, chemical, or physical agent. Unfortunately, the current agency interpretation of the HACCP regulations does not encourage or permit the flexibility to focus on "risk;" rather the agency's current focus is on whether an agent is a "hazard."

As the agency transitions to a risk-based inspection system, a clear understanding of the relationship between hazard and risk is essential. Unless an understanding of this relationship is recognized and applied as an integral component of inspection activities, misunderstandings between FSIS and the industry are certain to occur.

The agency's current broad interpretation of "hazard" may, in fact, result in situations where actions taken could undermine the concept of a risk-based system. Risk reduction is best accomplished when the focus of government and industry is on those activities that address significant risks to public health. It follows then, that the system will be weakened if agency and industry reactions to low/no risk situations are of equal magnitude to those of higher risk. If an agent is labeled as a "hazard reasonably likely to occur," then from the current regulatory perspective, it automatically becomes as important as all other hazards, regardless of the risk (or lack thereof) posed. This philosophy undermines the intent of a risk-based system.

To that end, the Codex Alimentarius Commission defines risk as: "A function of the *probability* of an adverse health effect and the *severity* of that effect consequential to a hazard(s) in food." (Anon., Procedural Manual: Eleventh Edition, Codex Alimentarius Commission, FAO/WHO (2000)(emphasis added).) It is clear from this definition that *hazard* refers only to *potential* of a biological, chemical or physical agent to cause harm, but *risk* is related to the *probability* of an adverse effect actually occurring. Although some have expressed concern that risk is too complex a concept to be addressed on a routine basis, that is not the case. Indeed, we each employ such rational thinking to some degree in practically everything we do, *e.g.*, driving with seat belts or riding a motorcycle without a helmet.

In fact, prior to HACCP, the FSIS inspectors employed a simple procedure to evaluate the risk associated with a non-conformance prior to determining actions to be taken. This risk-based approach was outlined in the "Deficiency Classification Guide," which enabled inspectors to classify each non-conformance as "Critical," "Major," or "Minor" based on the response (certain, likely, or potential) to the following three questions:

1. Will the deficiency result in adulterated or misbranded/mislabeled product?
2. Will the adulterated or misbranded/mislabeled product reach consumers?
3. Will the product have a detrimental effect upon consumers?

Presumably, agency and industry expectations for the type and extent of corrective actions and follow-up activities were determined on the basis of the qualitative evaluation of risk associated with the non-conformance. In our view, this is what should happen in a risk-based system.

Under the current HACCP system, unfortunately, this essential understanding has been lost so that from a regulatory perspective, all hazards, and thus all deviations, are treated alike, often creating situations where a non-conformance that would result in no measurable risk to consumers must be addressed identically with non-conformances of a

critical nature. The foundation of a risk-based system must be clearly focused on public health risks and we encourage the agency to take serious action only in situations where the public health is truly at "risk."

Performance Standards versus Performance Guidelines

Perhaps no issue of HACCP implementation is more controversial than microbiological performance standards. This controversy must also be resolved before the transformation to a scientific, risk-based regulatory system. The current FSIS performance standards, which operate as immutable rules of law with draconian regulatory sanctions, are not scientifically justifiable; rather, they should be replaced by performance guidelines, which, when not met, serve as an indicator of the need for further agency oversight and suggest corresponding actions by the establishment that may be necessary.

As an initial matter, we understand that FSIS not only desires, but needs, some objective measure to verify that the new system is helping to meet public health goals. In a perfect world, the single most relevant measure of effectiveness would be a beneficial reduction in illnesses caused by meat or poultry. However, the science is simply not sufficiently advanced at present to allow correlation between pathogen levels on product and public illnesses. The information needed and corresponding techniques for such an analysis should be established as quickly as possible through cooperative efforts with the National Academy of Sciences, the Centers for Disease Control and Prevention, the Food and Drug Administration, and other public health agencies.

In seeking a surrogate measure of HACCP effectiveness, FSIS adopted microbiological performance standards, such as *Salmonella* incidence in raw products. However, as the agency admitted when adopting the *Salmonella* performance standards, there is no scientific evidence to establish such a link. Nor has the scientific linkage been established through evidence gathered since HACCP implementation first began.

Thus, although we understand the agency's need for an objective measure, we disagree with the current regulatory implications of failure to comply with a performance standard. If the current standards are not a scientific means of measuring public health improvements, they should not be the sole basis for severe sanctions due to non-compliance.

This is not to say that microbiological goals have no place. In fact, incidence rates have declined since the adoption of the HACCP regulations and, as a general matter, are continually improving. However, the predicament remains where establishments may not be able to comply through no fault of their own. This dilemma can only worsen if new, more stringent standards are added. Using the *Salmonella* standard for ground beef as an example, why should a beef grinding operation be closed if the actual cause of the failure is due to the *Salmonella* levels of its incoming raw materials? Because the prevalence of *Salmonella* in raw product may indicate potential for involvement in food-borne illness, the failure to comply with the microbiological goals indicates that there is a need for further investigation to determine the cause of the non-compliance and, when

appropriate, a need for the establishment to take preventive actions. We consider the best application of such microbiological performance goals as guidelines for determining a need for investigation and should be so viewed by FSIS.

As to the matter of adoption of any performance guidelines, they should be established on the basis of sound science, with full consideration of all relevant information. Adopting an average incidence level, however appealing and simplistic, may not represent all circumstances. For example, the agency adopted the ground beef *Salmonella* performance standard of 7.5% by averaging *Salmonella* incidence levels among the grinders selected for the sample. However, the baseline data showed a standard deviation of 3.1 percent. From a statistical perspective, the magnitude of the standard deviation suggests that the prevalence rate in the sampled plants is unlikely to represent the prevalence rate of all plants, thus casting doubts on the statistical validity of the ground beef standard. Likewise, in adopting this standard, FSIS had no data as to the incidence levels of *Salmonella* that may be associated with incoming beef trimmings. Yet, according to industry data, the *Salmonella* prevalence on trimmings from slaughtering establishments varies greatly according to the geographic location of the slaughterer up to an incidence level almost equal to that for the finished ground beef. Microbiological goals must be established on the basis of all relevant information if they are to be accorded respect.

A scientific, risk-based agency, even a regulatory one, should tend away from legalistic, rigid standards in the absence of a clear scientific link between microbial incidence and food-borne illnesses. Instead, sound performance guidance can act as an indicator for additional steps that plants may need to take to improve safety in conformance with the guidelines.

Joint Training

From the time of the HACCP rulemaking, there have been repeated requests for joint training of agency and industry. Although such suggestions have not been adopted previously, joint training is an essential component of any "Next Steps" initiative. Indeed, when employed, joint training has greatly enhanced the smoothness of HACCP implementation. In the agency's initial HACCP pilot program in 1990-1991, joint training was identified as the single most helpful aspect of the pilot. Likewise, in the current HACCP implementation, state government officials were trained jointly with the state inspected facilities and that effort has been remarkably successful.

Joint training offers significant benefits:

- Joint training can help communication between FSIS and the industry by ensuring a common language. To be blunt, there has been frustration among our members over HACCP implementation. This frustration is based, in large part, on differences in training. Industry taught HACCP as a risk management system, whereas, FSIS appears to have focused on HACCP as a hazard management system. These differing perspectives have made communication difficult,

because the same words have different meanings based on the training received. We believe this frustration is shared by many FSIS in-plant inspectors.

- Joint training can provide a forum for both parties to discuss and resolve concerns or misconceptions. This can also provide a greater understanding of the thought processes and priorities of the agency and the regulated industry.

- Joint training can instill needed confidence that all understand and approach HACCP from the same perspective, so that regulatory decisions are perceived as being, and in reality are, based on science and the logical application of HACCP principles.

- Joint training can provide an opportunity for those in industry and the agency to "catch-up" with current HACCP interpretations as the Next Steps initiative proceeds. There are both company personnel and FSIS inspectors who are not yet comfortable with HACCP, especially regarding those issues that arise when HACCP theory is put into practice. Joint training can serve as a "refresher" course.

Obviously, to achieve these benefits, there must be agreement on the principles to be taught. That is why the issue of whether HACCP is to be a hazard management system or a risk management system must be resolved before training proceeds. For the reasons stated above, as well as the reasons provided by the undersigned at numerous public meetings and in the HACCP petition, HACCP must be treated as a risk management system if it is to survive.

Sharing Information

Beyond training, there is the need to share ideas and information. Many in the industry have a wealth of scientific data that could be shared once there is confidence that: (1) the information will be used to advance public health, not as the basis for a regulatory reaction, and (2) there would not be indiscriminate public dissemination.

In that regard, we wish to comment briefly on *Listeria* testing of product contact areas and other establishment testing. Notwithstanding the widespread use of microbial testing by establishments, most of these programs are not incorporated in the establishment's SSOP or HACCP system. The principal concern most often expressed is that sharing such data with the agency may trigger an inappropriate regulatory response – where the mere finding of an organism immediately results in a regulatory response against the establishment rather than an inquiry as to what occurred and what can be done to prevent recurrence. A positive finding of *Listeria* should not be the principal regulatory event. Instead, the regulator should be concerned with what the establishment does in response to the finding. A feeling of trust that FSIS will use the industry data in a confidential, reasonable manner will help eliminate hesitancy in sharing an establishment's microbiological program results.

Field Implementation

The final issue for comment involves current and future implementation in the field. Many of the issues discussed above, especially those dealing with HACCP as a risk management system, have initial application to the FSIS in-plant inspector, because that is where regulatory decisions are first rendered.

The industry petition provides a number of recommended revisions to the HACCP regulations. However, merely revising language is not enough; the changes must be implemented in the field. In this regard, FSIS should adopt a thought process similar to that incorporated in the agency's Deficiency Classification Guide to ensure regulatory actions are appropriately based on risk.

FSIS is and will remain a *regulatory* agency, and in this regard, we understand enforcement actions will be taken in response to incidents of non-compliance. However, serious enforcement actions should be taken only in response to serious non-compliances; specifically, those non-compliances that directly and adversely affect public health.

In addition, FSIS should adopt a corporate decision making model, where consideration is given to all views and perspectives expressed from within the agency. This corporate style will require a change in the perceived roles of all branches of the agency, especially compliance personnel. Compliance officials have been trained to investigate and document violations of the regulations, with the bulk of their work involving economic and aesthetic non-compliances with little or no public health implications. Given this experience, they often perceive the establishment as an intentional wrongdoer that should be punished, both to penalize the company and to deter others. However, in the public health context, the "intentional" wrongdoer is, at most, a rarity. Non-compliances in the food safety area pose different issues. To be sure, no establishment should operate if, by so doing, it poses a demonstrable public health risk. However, in instances of food safety non-compliances, punishment is not automatically warranted if there was no intent. Likewise, absent intent, how can any punishment imposed on one establishment deter others? In these situations, the regulatory response should be of the type envisioned by HACCP – prevention.

Finally, we recommend that FSIS adopt a more formal and open dispute resolution process. Violence simply has no place in any workplace – it cannot and will not be condoned by anyone in our industry. The tragedy of last year compels us all to learn from the incident so that it will never be repeated. In this regard, we understand that the Under Secretary for Food Safety and the agency have committed to establishing an "ombudsman" process, and are working on the issue internally, as well as with an outside non-profit organization, to arrive at a solution. We urge FSIS to proceed with this process and establish an ombudsman position as quickly as possible.

Conclusion

We appreciate the opportunity to comment on the Next Steps initiative. The proposed transition to a scientific, risk-based regulatory agency is critical to further progress in HACCP implementation – but only if the transition is based on science, common understanding, and communication.

Respectfully submitted,

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