AMERICAN MEAT INSTITUTE

October 31, 2005

Docket Clerk – Docket No. 05-024N
USDA, Food Safety and Inspection Service
300 12th Street, SW
Room 102
Cotton Annex
Washington, DC 20250

05-024N
05-024N-18
Robert A. Seward II, Ph.D.

Re: Docket No. 05-024N, Notice of a Section 610 Regulatory Flexibility Act Review of the Pathogen Reduction/Hazard Analysis Critical Control Point (HACCP) Systems Final Rule

Dear Sir/Madam:

The American Meat Institute (AMI) submits the following comments regarding the above-referenced final rule. AMI represents the interests of packers and processors of beef, pork, lamb, veal and turkey products and their suppliers throughout North America. Together, AMI's members produce 95 percent of the beef, pork, lamb, and veal products and 70 percent of the turkey products in the United States. AMI provides legislative, regulatory, public relations, technical, scientific, and educational services to the meat and poultry packing and processing industry.

AMI and its members have long supported the use of HACCP systems to control food safety hazards and endorsed the concepts behind the Pathogen Reduction/Hazard Analysis Critical Control Point (HACCP) Systems Final Rule (HACCP Rule, or the rule) issued by the Food Safety and Inspection Service (FSIS, or the agency). While the use of HACCP systems by meat and poultry establishments has decreased the prevalence of food safety hazards such as *Listeria monocytogenes* in ready-to-eat (RTE) meat and poultry products, *Salmonella* in beef, and *Escherichia coli* O157:H7 in raw ground beef, its effective use by FSIS has been diminished through distortion and extension of the fundamental scientific HACCP principles for regulatory purposes.

The regulatory consequences of this misuse of scientific HACCP, and the principles on which HACCP is based, have had significant negative consequences for the meat and poultry industry, and especially those small and very small establishments with limited resources necessary to respond to the demands of regulatory HACCP initiatives. The negative consequences associated with the HACCP Rule are a function of the complexity of the rule, but also from the use of the rule by FSIS to extend its command and control over the processing sector. As technologies and the economics associated with production practices have changed, and knowledge about the relative risks of foodborne hazards has increased, the use of the HACCP Rule by the agency has progressed toward more control, minimizing the positive affects of the changes in production practices and increased knowledge about relative risks.

AMI appreciates the opportunity to file comments on the regulations established by the HACCP Rule, particularly as the rule relates to small and very small meat and poultry establishments. These comments support the continuation of the rule, but describe extensions of the rule that have occurred through FSIS publications that have had negative consequences for businesses without measurable benefits. The complexity of the rule has been broadened by lack of definitive statistical criteria for regulatory expectations, lack of definitions for terminologies used by FSIS in interpretative documents, lack of transparency in pre-publication development of policies, and extension of regulatory initiatives into the minutia of HACCP without measurable benefits.

Regulatory HACCP vs. Scientific HACCP

The HACCP Rule, if based and implemented on scientific principles of hazard analysis and the use of validated critical control points (CCPs) to control hazards reasonably likely to occur (RLTO), would have served the agency, industry and consumers well by optimizing control over foodborne hazards. Unfortunately, the agency has chosen to expand the rule through a broader, non-scientific interpretation of HACCP principles to extend regulatory control over the processing sector. The agency has not been as transparent as possible during its expansion of the rule to broaden its control and regulatory impact on meat and poultry processors of all sizes.

The HACCP Rule stated that "All slaughter and processing plants will be required to adopt the system of process controls to *prevent* food safety hazards known as HACCP." FSIS' conclusion that HACCP plans can "prevent" all hazards is inconsistent with the scientific principles of HACCP that state that HACCP plans typically help to reduce and control hazards, and in fewer instances, where there are kill steps, to eliminate hazards. Under the regulations in 9 CFR 417, critical limits must be designed to satisfy FSIS regulations that call for the prevention of hazards even though this may not be scientifically possible in all instances where a hazard may be RLTO, or deemed to be RLTO by FSIS without scientific data to support that contention.

Under the HACCP Rule, FSIS sends conflicting messages on the expectations for documenting the potential hazards at each step in the hazard analysis. For example, establishment #1 may determine that the science (*e.g.*, testing data, literature review, monitoring data) supports the conclusion that the hazard is not RLTO. However, some FSIS inspection staff dictates that if FSIS believes that a hazard exists because of what has happened elsewhere at establishment #2, establishment #1 will be questioned indefinitely about their hazard analysis, and asked to provide even more data, to justify why a particular hazard is not RLTO at a specific process step. This clearly is contrary to what is intended in the HACCP Rule that each establishment is responsible for writing its own HACCP plan according to its own scientific assessment of risks. When FSIS begins to dictate hazard RLTO and CCPs, this adds burdens to all establishments, but particularly very small and small establishments because the establishments must now invest time and labor into not only development of additional hazard control steps, but also all of the validation and verification activities, all without any science-based reasons.

An outgrowth of the HACCP Rule is the creation of numerous performance standards. FSIS stated that developing HACCP systems around verifiable, objective performance standards is the most effective way for establishments to consistently produce safe, unadulterated meat and poultry products. As part of the rule, FSIS stated that they wanted to *minimize* regulatory burdens on the industry, and that the performance criteria would be implemented on the basis of a statistical evaluation of the prevalence of bacteria in each establishment's products measured against the nationwide prevalence of the bacteria in the same products. Industry contends that FSIS places maximum regulatory burdens on industry through HACCP and performance standard regulatory enforcement actions, not the *minimal* regulatory burdens suggested in their

policy. Furthermore, performance standards need to be based on a set of scientific principles, and as discussed in greater detail in a separate section of these comments, the FSIS performance standards stemming from the HACCP Rule have not met the scientific criteria endorsed by experts internationally.

FSIS published guidance (*e.g.*, FSIS Directive 5000.1) for their inspection staff on how they are to protect the public health by properly verifying an establishment's compliance with the pathogen reduction, sanitation, and HACCP regulations. These procedures are prescriptive and involve verifying sanitation performance standards (SPS) in 9 CFR 416.2-416.5 involving grounds and pest control, construction, lighting, ventilation, plumbing and sewage, sewage disposal, water supply and water, ice, and solution reuse requirements, dressing rooms and lavatories, equipment and utensils, sanitary operations, and employee hygiene. FSIS has not clearly defined the science behind these regulations to clarify when specific violations can lead to a regulatory control action such as a noncompliance record (NR) or Notice of Intended Enforcement (NOIE) stating that a meat or poultry product is adulterated and has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. Inspection personnel are only required to be of the opinion that conditions *may have* caused product to be contaminated with filth or cause product to be unsafe. FSIS gives their inspectors the right to use professional knowledge and judgment in making the determination whether the sanitation performance standard requirements are met. There is no visible or transparent process in place to measure the abilities of inspection staff to correctly make such judgments, nor a set of scientific criteria used by inspection staff to judge establishments against SPS.

Under the HACCP Rule, and its broadened use by FSIS, processing plants of all sizes are impacted by the agency's requirements that CCPs be developed and written into a HACCP plan even where there is no scientific justification, *i.e.*, forcing a regulatory CCP where there is no evidence that a science-based CCP exists. This can have a significant impact on all businesses as they are forever in a no-win situation trying to meet regulatory requirements for validating the CCP that is required by FSIS, but not based on science. As a result of FSIS compliance reviews on CCPs and their validation, there can be NRs or NOIE written, appeals made, attempts made at preventative and corrective actions (even though the attempts are in response to regulatory requirements, not grounded in scientific findings) and other resource-draining responses by industry, particularly burdensome to small and very small businesses with resources already tapped to address real food safety monitoring issues.

Simply stated, if there is no CCP to control a hazard, then an establishment should not be expected to have one, *e.g.*, a raw ground beef grinding establishment that receives beef trimmings and grinds the trimmings to raw ground beef has no CCP that has been scientifically validated for effective control of *E. coli* O157:H7. FSIS has established regulatory requirements such as 1) an establishment should have documented, verified and validated expectations for trimming suppliers (*i.e.*, particular production practices that include a pathogen reduction step), and 2) an establishment should verify what the trimming suppliers are doing, even though the suppliers are operating in federally-inspected facilities already inspected by FSIS. While the regulatory requirements for establishments' control over suppliers of beef trimmings may be worthwhile (and such requirements are always documented in product specifications), they are not science-based CCPs and should not be regulated under the HACCP Rule as is currently practiced by the agency. The FSIS requirements such as those discussed above are costly and burdensome for establishments, particularly small and very small establishments, because paperwork and routine visits to suppliers to verify that the specifications are being met takes significant resources; the benefits from these HACCP Rule extended requirements certainly do not justify the costs.

The science behind the day-to-day implementation and the regulatory extensions (*e.g.*, notices and directives) of the HACCP Rule has proven to be lacking in several other key areas. One area of concern is the lack of definition of the statistics behind the regulatory HACCP initiatives. The United States Department of Agriculture (USDA) has used the wording "statistical based sampling and testing" in their policies, press releases and directives. However, USDA has not fully delineated the statistical limitations of sampling and testing plans, nor linked the limitations of these plans to the performance standards, particularly the zero tolerance performance standards.

Regardless of how low the prevalence of *E. coli* O157:H7 or *L. monocytogenes* becomes, and the lack of discrimination (*i.e.*, contaminated vs. not contaminated) of sampling and testing at these low prevalence levels, FSIS continues to use single verification samples to assess the acceptability of HACCP systems and the safety of the products, without any discussion on the lack of statistical significance of the verification sampling programs. Whether a microbial pathogen, or a chemical such as a prion molecule, the agency has shown almost no regard for using statistics as a rational means to allocate resources based on science. This can create wasted resources for all businesses, particularly small and very small operations where sampling and testing programs are designed out of necessity to use outside laboratories and thus, add significant costs. Such sampling and testing are needed to satisfy regulatory HACCP requirements, but statistically afford no greater assurance of safety than appropriate monitoring of science-based CCPs.

In the section of FSIS Directive 5100.1 describing the assessment of the establishment's generic *E. coli* process, the directive indicates that the Enforcement, Investigation and Analysis Officer (EIAO) should perform statistical tests to define any correlations among the assembled data sets. The directive states that if there are no significant correlations, the EIAO need not pursue this analysis any further. The directive provides no indication as to what "statistical tests" are being done by the EIAO, nor does it explain (or provide references for) the criteria used to establish "significant correlation." In the section on assessing the reassessment requirements, the directive provides questions that the EIAO could ask. One such question is "If the establishment considered *E. coli* O157:H7 as a hazard likely to occur in the grinding process, are the CCPs designed to control the pathogen?" As mentioned above, there is no known science-based CCP to control *E. coli* O157:H7 in a raw ground beef grinding process (except for finished-product irradiation which has no acceptance by consumers currently for widespread application).

There are other examples where the scientific justification or rationale is not provided by FSIS to support their regulatory control initiatives related to the HACCP Rule. In the section of FSIS Directive 5100.1 regarding verification (and at several other points in the directive), the directive uses the terminology "science-based" without defining this term. This is followed by a list of questions that take the form of "is there a rationale for …" without any definition for "rationale." FSIS should define and clarify the terms, "science-based" and "rationale," along with the words "statistical validity" and "critical thinking."

The failure to ensure that regulatory initiatives associated with HACCP Rule are substantiated and justified through science places enormous burdens on establishments, particularly small and very small establishments that must contend with regulatory requirements that are difficult to achieve, refute, argue and defend, but must be met according to inspection staff.

Implementation of the HACCP Rule

In the Backgrounder on the rule, FSIS stated that the use of microbiological performance standards is part of a fundamental shift in FSIS regulatory philosophy and strategy, from command and control (telling how) to performance standards (expressing the objectives without specifying the means). As much as FSIS has spoken about changes to the inspection system, there is a lack of evidence that they have moved away from command and control inspection where the use of NRs, 30-day letters and NOIE are used as regulatory enforcement tools.

The inspection staff, by-and-large the same inspection staff that was in existence before the HACCP Rule, still operates primarily under command and control, rather than a cooperative, educational process with the establishments producing meat and poultry products. Although the agency has implemented training for inspection staff, the training cannot be sufficient to fully educate and train inspection staff on all of the complexities of microbiology, chemistry, validation, modeling and the other components of a food safety system that supports compliance with the HACCP Rule. Furthermore, there is no transparent process for the review of the performance of FSIS field inspection staff to determine to what extent the training and education is returning benefits equal to the costs.

FSIS inspectors often rely on generic regulations that become catch-alls rather than request and use specific regulations that substantiate science-based decisions for taking regulatory action. For example, 9 CFR 416.2 is commonly cited in regulatory actions. This regulation states that the grounds about an establishment must be maintained to prevent conditions that could lead to insanitary conditions or adulteration of product. This vague statement results in enforcement action without any scientific justification or measurement of consistency in interpretation and application by FSIS. Documentation standards for FSIS inspectors should be equivalent to those expected from industry. FSIS should monitor inspection activities more closely than is currently done, ensuring that science-based decision making is taking place, and that justification for regulatory actions is supported by facts and less by opinion.

In the HACCP Rule, FSIS stated that they were working with industry, academia and other governmental agencies to *develop and foster* measures that can be taken on the farm and through distribution and marketing of animals to reduce food safety hazards associated with animals presented for slaughter. Industry has yet to see the development and fostering of measures on the farm and throughout distribution and marketing of animals. What has occurred is increased regulatory oversight on live animals destined for slaughter without measured benefits for consumers relative to food safety. There have been a lack of validated on-the-farm, distribution and marketing measures *developed and fostered* by FSIS as proposed in 1996.

In a 1998 Key Facts publication, FSIS stated that the HACCP regulations "provide enormous flexibility for the industry to develop and implement innovative measures for producing safe foods." Industry has not yet seen the measures of progress on this initiative. Only in 2003 did FSIS create an Office of New Technology, and there have been examples of relatively straightforward interventions (*e.g.*, higher levels of organic acids, hydronium ion formulations, chlorine dioxide, carcass irradiation, use of common antimicrobials in meat products) taking months, if not years to move through (and in most cases become stalled in) the approval system that was supposed to "remove unnecessary obstacles." Ultimately this prevents small and very small businesses easy access to validated hazard control measures that can be built into formulations or operations to help reduce risks.

Besides the agency's claim that they would remove unnecessary obstacles to innovation, FSIS stated in the HACCP Rule that they would reorganize to implement a modernized system of inspection and begin a <u>public</u> process to develop and evaluate new approaches to inspection, anticipating a major redeployment of its inspection resources to successfully implement HACCP

and better target food safety hazards during transportation, storage and retail sale. Industry has not seen any public process toward developing a modernized inspection system, nor significant redeployment. In fact, new FSIS positions have focused on production processes, rather than transportation, storage and retail sale. The regulatory authority of FSIS, not risk-based inspection across the entire food chain, is driving FSIS policies and programs. Without understanding the larger, broader picture relative to risks in the food chain, the continued focus on the processing sector will not deliver equivalent continuous improvement in public health. This regulatory bias toward processing establishments can result in resource drains on the processing establishments, especially small and very small establishments, without significant gains in public health. If the authority to move into other areas of the food supply system to reduce risks is not within FSIS, the monetary resources supporting less significant regulatory policies at FSIS should be reallocated to the appropriate agencies, *e.g.*, state and local governments.

As implementation of the HACCP Rule has matured, FSIS has extended the rule in various ways. For example, in HACCP plans the corrective actions taken in response to a deviation should and must be documented. However, the agency has begun to require that HACCP plans include the name of the person who is responsible for taking the corrective action, something that is inconsequential to the corrective action since numerous persons could take a corrective action; if a specific name is not identified, the establishment would receive a NR or NOIE for not having an effective HACCP system. It is this type of extension into the minutia of HACCP for which FSIS continues to develop regulatory requirements, all of which place greater documentation, monitoring and recordkeeping requirements on establishments of all sizes without any demonstrable (measurable) benefits. The small and very small establishments become increasingly burdened by inconsequential regulatory requirements with no proven or substantiated benefits. FSIS, to date, has not been required to measure the impact of their ever-increasing number of regulatory requirements.

FSIS inspectors extend their inspection processes based in the HACCP Rule to establishment procedures and records that are outside of regulatory review. These procedures are not pre-requisite programs noted in the SSOP or HACCP plans, but are necessary for ensuring product consistency and operational efficiency. The FSIS inspection staff will attempt to regulate these programs and adherence to these programs by the establishment even though they are not components of the HACCP Rule or any other FSIS regulation. This type of inspection makes it difficult for establishments, particularly very small and small establishments, to develop and implement such programs because the programs will be under the scrutiny of the inspection staff with the likely attempted regulatory control and resulting resource drain in responding to FSIS.

FSIS inspection staff can migrate to enforcement in areas of the establishment they have the greatest comfort level and experience. In RTE establishments for example, there are instances where inspection staff will focus more time in the raw material management areas than in the cook operation because they have greater familiarity in that area, even though the further processing CCPs are the key to management of food safety hazards by the establishment. The circuit and district review processes should evaluate the number of regulatory actions taken in raw versus RTE areas in such situations to determine if the balance coincides with risk, and whether the information provided in the regulatory documentation fully supports the deficiency noted. Very small and small establishments in particular, have limited resources; and if they are spending an inordinate amount of time addressing raw material issues unrelated to hazard control, this diminished the time they can spend focusing on more critical areas of operation.

The extension of the HACCP Rule into requirements for meat and poultry processors has not only traveled backwards to requirements for raw materials, but also forward into distribution and

management of products at retail and food service facilities. FSIS has set expectations associated with the HACCP Rule for processors to predict, gauge and even monitor their products as these products move into distribution and retail and food service outlets. Processors are expected to ensure that the many end users manage these products appropriately. The processors, especially small and very small establishments, have little control over products once they leave the control of the processing establishment. When necessary as judged by a farm to table risk assessment or other epidemiological data, FSIS should explore additional regulatory means to monitor retail and food service establishments for their controls over meat and poultry food products. Processors should not be required to manage products through these outlets through extension of the HACCP Rule.

Just as frustrating to establishments of all sizes are the layer upon layer of inspection and sampling and testing, and the lack of acceptance of USDA inspection at one facility by another USDA inspected facility, both operating and inspected under the HACCP Rule. When plants successfully produce product under the HACCP Rule at one federally-inspected establishment, FSIS should accept that product as safe, wholesome and unadulterated when received at another establishment with records indicating adequate temperature control during the interim storage and transportation. However, as indicated elsewhere in these comments, receiving establishments are required to implement numerous verification and even validation measures to double-check what has been verified and validated at the supplier by both the manufacturer and the FSIS inspection staff. This duplicative inspection process has not demonstrated any measurable food safety impact, yet adds additional costs and resource drains on the receiving establishments, especially small and very small establishments.

Implementation of the HACCP Rule has led to an overly complex and duplicative inspection process by FSIS, in more ways than multiple inspections at multiple plants as described above. The layers of inspection at a single facility are numerous and can include local inspection, circuit inspection, Consumer Safety Officers, EIAOs, Intensified Verification Testing, Food Safety Assessment (FSA), RTEALL sampling programs for *L. monocytogenes* and RTE001 sampling programs for *L. monocytogenes*. When you are a small or very small establishment particularly, (although the burden on large establishments also is great), the repeated, overlapping inspection and reviews can tap all resources, particularly when each layer of inspection has as their objective, to find and report problems. None of the layers of FSIS inspection has as their primary objective an educational one, *i.e.*, how can the agency help share best practices and work cooperatively with the establishment to improve the food safety systems. For FSIS inspection staff, the goal appears to be finding problems and placing the burden on the establishment to fix whatever issue the inspection staff believes is important at that time, without prioritization or reality checks on resource optimization.

Validation of Critical Control Points

As the HACCP Rule has matured in its implementation, so have the inquiries and requirements related to validation of CCPs. That there is more emphasis on validation by itself is not unreasonable or unwise; but what is unreasonable and unproductive is the expectation for an establishment to respond to an inspector's comment that what the establishment is providing as validation documentation is *inadequate* without the inspector providing any definitive statement as to what is *adequate* – so the plant has to guess at what will satisfy the inspection staff while the inspection staff can continuously say that whatever is supplied is inadequate. Thus, what the establishment faces is a moving, or non-existent or ill-defined target. The repeated attempts to satisfy the inspection staff without a clearly articulated end-point is a tremendous burden on all establishments, but even more so for small and very small establishments that either have limited

internal resources or must hire relatively expensive outside consultants to attempt to find the answer that will be satisfactory to the individual inspection staff employee.

This burden becomes even more dramatic when a single establishment faces numerous layers of inspection, each with their own ideas on what may or may not be satisfactory, since each inspector has their own unique interpretation of what the HACCP Rule and its corollaries require, *i.e.*, the lack of a well-defined set of validation criteria for CCPs is compounded by the fact that there is a lack of consistency amongst the FSIS inspection staff in managing issues such as validation. When asked for technical guidance, some inspectors may help while others indicate that "HACCP belongs to the plant and we are not going to tell you how to handle this concern." Satisfying one inspector may not satisfy another layer of inspection that occurs subsequently. Differences of opinions and expectations are permitted in the FSIS inspection force; the establishments pay the consequences with pressures to respond to the varied needs of different inspection staff.

An example of how FSIS has broadened the HACCP Rule to create regulatory requirements that are costly, duplicative and inconsequential is the requirement that companies have been expected to "validate" RTE products that have been formulated with an antimicrobial and purchased or received from another USDA-inspected plant. FSIS has concluded that a letter of guarantee and the USDA mark of inspection are "not enough" according to the validation/records section of the HACCP Rule. The same is true for suppliers' letters of guarantee on packaging film and ingredients. These are examples of an unnecessary, duplicative regulatory requirement, *i.e.*, products being produced under the HACCP Rule at one establishment being somehow subject to a regulatory requirement for validation at a receiving company, or assigning a hazard to packaging materials that have never been implicated in foodborne illnesses or never come in contact with food.

Industry agrees with the International Committee on Microbiological Specifications for Foods (ICMSF) that food safety management systems based on preventing hazards through Good Hygiene Practices (GHP) and HACCP are much more effective in ensuring safe foods than is end-product testing. In fact, these international experts expressed concern over the "continued indiscriminate use of microbiological testing of the end product." ICMSF concluded that microbiological testing can be useful in management of food safety, but tests should be selected and applied with the knowledge of their limitations. As FSIS continues to expand on the HACCP Rule, end-product testing has increased without the recognition of its limitations in terms of predicting whether a lot of food is safe and its tremendous impact on operations of plants of all sizes, but particularly on small and very small establishments that customize production for niche markets, just-in-time deliveries, and who have limited storage and production capacities.

As a result of the HACCP Rule and its corollaries, industry is required to establish control measures that result in processes and products that meet performance standards established by regulatory authorities, regardless of whether the performance standards are achievable with existing technologies (*e.g.*, zero tolerance for *E. coli* O157:H7 in raw ground beef components). This creates situations where the science clearly establishes the inability to be in compliance, yet regulatory HACCP demands "artificial compliance," that is, where control measures reduce levels as low as possible, or below detectable levels, even though clearly a zero tolerance in not achievable. Thus, the challenge becomes one of validating that a control measure achieves an unattainable goal. Clearly, this is not an approach that any scientist wishes to undertake; but often the regulatory approach to HACCP leaves industry with no other option. For many small and very small businesses, creating the explanations and justifications to deal with regulatory

compliance to unattainable standards is costly and is dependent upon these businesses finding external consultants qualified and creative enough to meet the regulatory challenges.

Other complicating factors surrounding validation include the variation in acceptance by local regulatory authorities of published literature as satisfactory validating documentation and the lack of sufficient scientific knowledge and training by those in decision-making positions within the regulatory field operations staff. A regulatory authority needs only to question the legitimacy of the published validation documentation, without providing a rationale for its questioning, or without providing an expectation for what is required to address its question. That is, the establishment can be left guessing as to what is required to satisfy a local authority, and have no guarantee that the validation data, even if peer reviewed and published in a scientific journal, will prevail in satisfying a regulatory authority. As a result, acceptance of validation data is somewhat arbitrary, as regulatory authorities have not established, in most cases, specific criteria for acceptable, published literature. Industry contends that until such criteria are established, or a set of published validation documents is recognized for specific CCPs, the ambiguities and inconsistencies will persist as challenges for industry, especially small and very small establishments.

Verification

Single verification samples pulled by the agency are used to judge the acceptability of the product, raw materials or food contact surfaces (FCS), despite the fact that there is no statistical confidence surrounding such verification samples in predicting the safety of the product, raw materials or FCS – yet the agency expects plants to justify their sampling plans using statistics without any specifics from the agency on the stringency that is required. FSIS needs to publicly state the limitations of sampling and testing plans to ensure safety when the prevalence of pathogens becomes very low (*e.g.*, <5%).

As the HACCP Rule has been extended into the minutia of the regulatory HACCP process, the paperwork and recordkeeping have become more excessive, without measurable benefits to food safety and public health. For example, rather than a signature verifying that a verification activity has occurred, some FSIS inspectors have indicated that a "result" of the verification action must be written down as well as the person who did the verification. This type of micro-managing of the HACCP system that is supposed to "belong to the establishment" creates waste at both the establishment and inspection levels, draining resources from more important activities in both sectors.

Additional FSIS Actions to Measure Compliance with the HACCP Rule

FSIS has expanded their inspection processes as a result of implementation of the HACCP Rule. These expanded processes include extensive, multi-week FSA and other visits by EIAOs. These expanded assessments of HACCP systems and broader food safety systems can be beneficial, especially if approached in a cooperative, educational fashion in contrast to a regulatory, compliance approach. Unfortunately, the implementation of the FSA and EIAO visits have been very burdensome to plants of all sizes; although the initial focus has been on larger, high volume plants, the burden on small and very small plants will increase substantially as the FSA are conducted in every federally-inspected establishment. For example, a FSA in one establishment where the FSA reviewed five production systems, the cost of inventory control, down-time labor, storage and other requirements totaled nearly $175,000.

There is a disconnect between the classification of establishments as very small, small and large (done on the basis of number of employees) and the regulatory considerations related to the

HACCP Rule. Large establishments do not necessarily produce higher volumes of products than small establishments; however in many instances the regulatory requirements, *e.g*., sampling and testing schemes for *L. monocytogenes*, are related arbitrarily to plant size. The focus on establishments with high volume production as part of the regulatory policies associated with the HACCP Rule has not been based on scientific data showing a correlation between production volume and food safety risks. In fact, the agency admitted that FSIS has not been able to correlate risk of product contamination with production volume. Additionally, the agency's own economic assessment indicated that nearly 60 percent of all of the establishments that could be potentially affected by performance standards associated with the HACCP Rule are classified as small, and that small facilities produce a significant volume of RTE products.

Industry has had mixed success in ensuring that adequate notification is provided before sampling of products and FCS occurs. The suggestion that somehow establishments can selectively reduce the likelihood of pathogens on a given day following advanced notification of the intent to sample is simply false and unfounded. FSIS has not provided any science-based evidence that advance notification of their intent to sample has a significant effect on sampling results for a federally-inspected establishment. Scheduled sampling should be coordinated with the establishment in order to minimize disruption to the business while allowing a random sampling by FSIS. A reasonable time would be at least seven business days in order to minimize shorting customer orders when the establishment holds product that is under FSIS verification testing. Failure to provide adequate advance notification of the intent to conduct verification sampling and testing creates complex problems for plants of all sizes, but can be especially troublesome for small and very small plants with limited resources. These problems include raw material supply, operational scheduling of labor and unit operations, meeting customer orders, product storage and shelf life, and control of allergens through scheduling of production.

As part of the extension of FSIS regulatory initiatives associated with the HACCP Rule, FSA have been initiated by FSIS as yet another in the multitude of inspection activities in establishments. FSA in meat and poultry plants reportedly have taken from as short as two weeks to nearly two months. The protracted time period to conduct FSA, whether two weeks or two months, is a significant resource drain on the establishment and where applicable, the corporate staff. The FSA, and its protracted timeframe, impacts production and the supplier-customer supply chain, and will be especially problematic for small and very small establishments with limited capacities to build and store inventories of raw materials and finished products.

FSIS also has changed their approach to issuing NRs as a result of inspections related to HACCP systems. AMI has learned that beginning in mid-2004, 30-day letters were being "phased out" by the agency and greater use of NOIE letters has ensued. AMI believes that a NOIE is not appropriate in instances where an EIAO concludes that there may be a food safety system issue, but there are no indications of product adulteration, misbranding, or unwholesomeness. Questions about the legitimacy of a NOIE can be raised when agency officials conclude such an action is necessary after days or weeks of a FSA, while production lots are being marked as inspected and passed by USDA. Such an approach calls into question the legitimacy of either the inspection process or the FSA. FSIS Office of Field Operations (OFO) has indicated that a NOIE may be written when the FSA team concludes that there is a systematic problem in a facility that suggests that products are being prepared, packed or held under insanitary conditions that may allow contamination with filth or may render the product injurious to health. Based on NOIE issued in the field, the conclusion that a systematic food safety problem exists in an establishment does not appear to be grounded in science in all instances.

The problem associated with the use of a NOIE at the conclusion of a FSA when it is not warranted is that it can inappropriately impact business for establishments; and this can be especially problematic for small and very small establishments with limited capacity to meet customer needs, to store product and to recover from negative reactions by customers to issuance of a NOIE. Although not a primary concern of the agency, FSIS should be aware that business relationships, *e.g*., loss of customer confidence and reduced or terminated ordering, can result when a NOIE is written and issued. Accordingly, issuance of a NOIE should not be the default result of a FSA, but should be limited to circumstances when an adulterant is actually detected in the product or there is a serious concern that the plant is not producing wholesome product.

Another burden placed on establishments as part of the extensive HACCP system assessment is the sheer number of inspection resources being committed to the FSA. Although the FSIS OFO indicated that the FSA should involve two, or three at most, FSIS employees, historically, there have been as many as six FSA team members in many establishments conducting FSA. As important as the number of FSIS staff, is the coordination of their activities with a defined team leader and coordinated work plan. Industry contends that in some circumstances, the FSA staff operates as individuals, with each staff person having their own views, their own agenda and their own approach to documenting and communicating purported non-compliance or other regulatory issues. Again, the OFO indicated that there is an expectation on behalf of the agency that the FSA staff will have a leader and a coordinated approach; however, there appears to be a disconnect in communication between what the FSA plan calls for and what is being done in the field.

As an outgrowth of the HACCP Rule, FSIS often spoke of moving toward a risk-based inspection program, allocating resources where there is the greatest risk. The progress toward this goal has been very slow despite recommendations from industry on means to expedite the process, and multiple offers from industry to participate in a transparent process to achieve the objectives of risk-based inspection. One of the factors that reportedly have been under consideration by the agency in determining risk is the number of NRs issued to an establishment. However, as industry has demonstrated through its own data gathering exercise, there is no relationship between NRs as currently issued, and food safety risk. What is relevant is that the number of NRs increases as the number of inspectors increases. In one instance the number of NRs increased six-fold during the seven weeks a FSA was in progress. While some NRs were warranted, other issues normally would have been covered with direct communication in a weekly meeting, for example. Again, whether a NR or a NOIE, the establishment must commit resources to respond to the issues laid out in the NR or NOIE, or to request an appeal. Some of these responses and the ensuing plans can take weeks or even months to document, implement, and monitor. Yet there are no systems in place at the agency to determine to what extent these NR or NOIE actions measurably improve food safety systems, HACCP systems or public health, or were even necessary or consistently applied across all establishments nationwide.

As mentioned above, an outgrowth of the HACCP Rule has been waves of new inspection teams and initiatives, the most recent being the FSA. To assess the benefits against the costs (for both industry and FSIS) of FSA, FSIS should increase the number of measurable factors to assess the effectiveness of the FSA and the staff that perform the FSA. Such measurements will drive continuous improvement and afford FSIS the opportunity to use facts to report the effectiveness of the FSA. For example, FSIS should consider the following factors for measurement and reporting: the time it takes to complete each FSA in days as well as hours, breaking out the in-plant activities and the external activities (*e.g.*, preliminary record review and post-FSA discussions and decision making); the number of NRs issued before (*e.g.*, per week for three months), during and after (*e.g.*, per week for three months) each FSA; the number of regulatory issues noted by each staff person during each FSA; the ultimate outcome of each FSA as linked

to the team leader; and the number and names of FSIS participants in each FSA. FSIS should consider requesting input from establishments following each FSA as to the positive and negative attributes associated with the FSA, and suggestions for improvements.

Regulatory Directives & Notices Extending the HACCP Rule

FSIS has extended its use of the HACCP Rule through numerous directives and notices. This process has not been transparent to the public. The language and intent of these publications often are not clear; and despite repeated requests by stakeholders to review these documents in advance of their publication, FSIS has not involved stakeholders in the review of the documents to better improve their clarity and usefulness. A few examples are discussed below to exemplify how FSIS has used notices and directives to extend the HACCP Rule and build more regulatory requirements and inspection without measures in place to assess whether these additional burdens on industry add any value to improving food safety or protecting human health.

Notice 68-05, *Verification Activities at Establishments that Transport or Receive Cattle Carcasses or Parts with Vertebral Columns that Contain SRMs* references procedures that need to be included in a HACCP system even though some of the procedures do not deal with a hazard RLTO. For example, HACCP plans are required to consider prions as a hazards RLTO, even though there essentially is a zero risk of infectious prions being present based on testing conducted by USDA itself on high-risk and low-risk cattle, and the Harvard BSE Risk Assessment. The use of HACCP plans in this manner and the regulatory requirements that accompany such uses, have no scientific basis, add no real public health benefit and undermine the value and scientific credibility of the HACCP Rule. Any establishment, including small and very small establishments involved in the slaughter of cattle over 30 months, or in processing carcasses with intact spinal columns, must commit significant resources to controlling this "regulatory hazard" without enhancing food safety or public health. These resources could be better spent on other operations that may contribute to food safety risks.

An example of over-working the HACCP Rule is Notice 64-05, *Availability of Meat and Poultry Hazards and Control Guide*. This guide lists hazards and control steps for processing steps, yet attempts to state that the guide is "not intended to suggest where CCPs should be placed." However, the guide indicates that with its use, "FSIS personnel should be able to verify more effectively whether an establishment's food safety system has appropriately accounted for the hazards that are RLTO in its operations." This sets up a checklist mentality for inspection staff and forces establishment's to justify to inspection personnel why their HACCP plan does not account for every hazard listed in the guide. FSIS wants it both ways – the HACCP plan is owned by the establishment, but the HACCP plan must meet all of the regulatory considerations listed by FSIS. This two-sided approach makes compliance a constant resource drain, as not only does an establishment need to operate its own HACCP system, it must comply with, or defend against the FSIS regulatory HACCP criteria.

On May 26, 2005, FSIS published a Federal Register notice, *HACCP Plan Reassessment for Mechanically Tenderized Beef Products* (70 FR 30331). The notice requires establishments to consider *E. coli* O157:H7 as a potential hazard. This results in a requirement for a CCP, monitoring and verification sampling and testing. This is another instance where FSIS has made a determination that there is a hazard RLTO, without statistical or operational criteria to establish the opposite; this clearly is the opposite of what was intended in the HACCP Rule where establishments would decide whether or not a hazard is RLTO and would make their decision based on their rationale. FSIS actions suggest they believe they are more qualified to make the determination on both the hazard RLTO and the rationale, and can continue to question the establishment's rationale without clearly defining their expectations. A second example of this

would be the requirement to consider *E. coli* O157:H7 as a hazard RLTO in raw beef trimmings coming from a USDA-inspected facility where CCPs have been used already to control *E. coli* O157:H7 and the product has been inspected and passed by USDA (notice issued October 7, 2002 and re-emphasized in Directive 10,010.1, Revision1 issued on March 31, 2004). When transportation, storage and receiving temperature checks are acceptable, there should be no reason to consider *E. coli* O157:H7 a hazard RLTO; furthermore, there are no CCPs approved by FSIS for grinders to use to reduce or eliminate pathogens on trimmings or in ground beef, except for irradiation which is not used because of negative consumer reaction and lack of acceptance by retail and restaurant customers. Thus, to force suppliers to note *E. coli* O157:H7 as a hazard RLTO and use a "regulatory CCP" such as low temperature, simply distorts scientific HACCP as intended by the HACCP Rule into a form of regulatory HACCP without scientific foundation.

Notice 25-05, *Use of Microbial Pathogen Computer Modeling in HACCP Plans*, gives very specific instructions on the use of microbial pathogen computer modeling (MPCM) in HACCP plans, indicating that a microbiologist or trained process authority can make the determination on the adequacy of the MPCM for support of an element of a HACCP plan., but further states that MPCM programs do not replace microbial validation, experimental challenge studies, or the judgment of a trained and experienced microbiologist. The notice further states that risk assessments developed in establishments cannot be based on MPCM programs alone; however, numerous FSIS risk assessments used to set policy and performance criteria are based on similar predictive modeling programs complete with data gaps, assumptions and uncertainties. The double standard for use of predictive modeling has no explanation. Most FSIS inspectors and district staff are not career microbiologists or modeling experts and thus, should not be expected or relied upon to make decisions relative to the establishment's use of modeling in their validation. The HACCP Rule did not intend for local inspection staff to make judgments on the adequacy of MPCM for validation; this is clearly an establishment's responsibility to ensure their microbiologist or process authority is accurate in their use of the model.

FSIS Notice 28-02, *Actions to be Taken in Establishments Subject to Salmonella Testing*, states that inspection personnel at slaughter and grinding operations are to take certain actions if an establishment failed one or more sets of the *Salmonella* performance standard, and that after a third failure, the FSIS District Manager and Washington, D.C. staff would decide what, if any, actions were to be taken. The notice stated that failure "on the part of the establishment to prevent, eliminate, or reduce to an acceptable level food safety hazards, will result in enforcement actions." This language suggests that *Salmonella* in raw beef may be viewed by FSIS as a food safety hazard RLTO, which in turn suggests the need for a CCP for *Salmonella*. There is no scientific basis for this suggestion.

Additional examples of FSIS using the HACCP Rule to extend its regulatory control into non-HACCP related areas include components of Directive 5000.2, *Review of Establishment Data by Inspection Program Personnel*. This directive gives broad authority to inspection personnel for HACCP record review, including all decision making documentation (a broad, general concept) and all microbiological test results that may impact a hazard analysis, "whether or not such testing or monitoring is incorporated into an actual HACCP plan, referenced in a HACCP plan, or considered separate activities." This goes well beyond the HACCP Rule in extending inspection authority for record review and can potentially limit the benefits of establishments conducting their own internal microbiological testing, whether for diagnostic, research, trouble-shooting, or to meet customer specifications, since all testing could fall within the record review authority as described in the directive.

Directive 5100.1, *Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology*, is pertinent to the comments submitted herein because it

provides instructions to the EIAOs on methodology to be used when they conduct comprehensive FSA. The directive stops short of calling for a cooperative, educational approach to conducting FSA, an approach that could prove most beneficial to small and very small establishments that have limited resources in many instances to comprehend and react to the many directives and notices published by FSIS to extend the regulatory initiatives connected to the HACCP Rule. Directive 5100.1 states that the establishment should receive one to two weeks advance notice of the FSA "when possible" and that the EIAO will review six to eight months of FSIS data on the establishment before initiating the FSA. The request for the historical establishment records again places resource demands on the establishment; and in most instances, should not be necessary since all of the records have been reviewed, or could have been reviewed as part of the local inspection process leading to the mark of inspection being placed on all outbound products. This duplication of inspection as part of the HACCP Rule extended inspection processes is a repetitive burden on plants of all sizes.

With regard to the language of the publications that are used to extend the HACCP Rule, there are references to the use of "critical thinking" by the EIAO to analyze and assess findings to determine the adequacy of such issues as the establishment's food safety systems, and whether there is "a solid basis for taking an enforcement action." FSIS has not provided any details surrounding the criteria used for the basis for this "critical thinking," nor the checks and balances, and efficacy measurements, to assess the ability of an EIAO to use and deliver "critical thinking."

Performance Standards

As a component of the HACCP Rule, FSIS stated that developing HACCP systems around verifiable, objective performance standards is the most effective way for establishments to consistently produce safe, unadulterated meat and poultry products. Performance standards are complex in design when developed according to international, expert principles. Failure to use these guiding principles in the design of performance standards make them counter-productive and burdensome to meat and poultry establishments of all sizes. Performance standards not built on these scientific principles cannot be measured for their impact on public health goals or food safety objectives. Unfortunately, the FSIS performance standards have many shortfalls that to date have not been addressed by FSIS. The following discussion highlights some of these deficiencies to exemplify the redesign that should occur to have truly effective and meaningful performance standards as part of the HACCP Rule.

When designing microbiological standards as performance standards, the principles for the establishment of microbiological criteria developed by the Codex Alimentarius (Codex) should be followed. These principles state that a performance standard should be used only where there is a definite need. Application of the standard should be practical and technically attainable by applying GHP and HACCP. Industry agrees with the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) conclusion that microbiological performance standards should be designed to effectuate a decrease in the presence of enteric pathogens with the goal of improving public health. In the design of performance standards, the stringencies of the standards should be proportional to the risk and the public health goals; and the degrees of uncertainty must be considered when setting the stringency required of the performance standard. NACMCF reported that the principles for linking public health goals to performance standards via a risk analysis process, articulated by ICMSF, should be followed. Performance standards should accomplish the intended purpose, *e.g.*, reducing foodborne illnesses. The Codex principles, and guidance provided by experts comprising NACMCF and ICMSF, have not been applied effectively in the design of FSIS performance standards. Industry agrees with the evaluation of performance standards completed by National Academy of Science Committee

(NAS) and their conclusion that improvements are needed in the design of performance standards, in particular, that FSIS needs to bring regulatory HACCP in line with science-based HACCP.

The food industry shares the views of the microbiological experts that comprise NACMCF with respect to the role of performance standards. NACMCF has supported the use of performance standards to define the expected level of control at one or more steps in a process. NACMCF reported that microbiological performance standards are a tool to advance the microbiological safety of food products by articulating to the industry the expected level of control through such systems as HACCP, Pre-requisite Programs, and Sanitation Standard Operating Procedures (SSOPs). The FSIS performance standards are limited in their ability to serve as such tools because of design flaws.

ICMSF concluded that while microbiological criteria have played an important role in defining acceptable microbiological quality, their use in testing of food has seldom proven to be effective for control of microbial hazards. Whether performance standards call for zero tolerance or establish an acceptable tolerance for pathogen prevalence, they translate into the requirement for microbiological testing by industry to verify compliance to FSIS regulations associated with the HACCP Rule. These requirements result in millions of dollars being spent on pathogen testing every year, with little or no recognition that scientifically, the low level of sampling that is affordable and practical, in combination with the low prevalence of foodborne pathogens, provides little assurance that pathogens, if present, will be detected.

Industry agrees that one of the most important factors in establishing performance standards for foods is to be able to measure the impact of the performance standard on public health. Without specific product-handling-illness linkages, it is nearly impossible to determine whether a performance standard truly is reducing foodborne disease related to a food product. For meat and poultry products, NACMCF concluded that existing public health statistics make it very difficult to specifically attribute reductions in enteric diseases to the performance standards enforced by FSIS. NACMCF noted that the underlying assumptions of the FSIS performance standards need to be reexamined, and recommended that before new standards are adopted for meat and poultry products, alternative approaches need to be examined; and FSIS should work in greater collaboration with the Centers for Disease Control and Prevention (CDC) to measure the impact of the performance standards on foodborne diseases. It is only in 2005 that progress is being made to better coordinate with CDC to help define food attribution; representatives of CDC have said that this is a five to ten-year program.

The FSIS approach to setting some performance standards (*e.g.*, lethality standards for ground poultry) has been to first define a *worst-case* raw product. NACMCF, NAS and the international experts of ICMSF disagree with this approach to establishing performance standards. These expert scientific panels agree that the use of single-value, worst-case estimates as a means of considering uncertainty should be avoided, particularly when more than one factor contributes to overall public health risk. In this regard, FSIS has not provided the scientific rationale for their selection of microbial loads for worst-case scenarios and their use in the design of performance standards. FSIS has stated that assumptions are "conservative but reasonable", and has stated that worst case levels are not expected to actually occur. The use of the term "reasonable" appears inconsistent with the FSIS statement that "there is not a high degree of confidence in the magnitude of the higher levels of *E. coli* O157:H7 that might exist," and that meeting the lethality standards means that only "small numbers of reference organisms would remain viable in a worst case finished product." FSIS needs to reconcile acknowledgement of survivors in a worst case scenario for adulterants such as *E. coli* O157:H7 for which there is a zero tolerance standard.

Another example of FSIS creating performance standards that were not designed under principles endorsed by the experts of ICMSF and NACMCF were those related to the HACCP-based Inspection Models Project (which despite its weaknesses in terms of the associated performance standards, is an excellent program designed to allocated inspection resources more effectively than traditional inspection). FSIS stated that, while no system is perfect, the models project was an effort to reduce and eliminate defects that pass through traditional inspection. Under the models project, performance standards were based on improving what was achieved under the existing traditional method of inspection. It seems that instead of being a science-based justification for the performance standards, plants entering the project must improve their process in order to meet new, arbitrary performance standards.

FSIS has not acknowledged nor publicly responded to the 2003 conclusion of NAS that food safety criteria, such as performance standards that are implemented in food plants, are in many cases, not directly linked to specific public health outcomes; and thus, it is difficult to identify the benefits that result from a particular performance standard. NAS, NACMCF, the experts comprising ICMSF, and industry have called for improved surveillance of foodborne illnesses and their root cause. In addition, NAS called for the use of more appropriate criteria (*e.g.*, food safety objectives, FSO) and analytical systems (*e.g.*, statistical process control) to improve the government's ability to make science-based decisions relative to the development and implementation of performance standards that will have the desired public health outcomes. Before the burden of the FSIS performance standards related to the HACCP Rule were placed on large, small and very small establishments, a transparent review of the performance standards should have taken place.

NAS concluded in 2003 that because it has taken a very long time to develop federal food safety regulations, and because of the myriad political, economic and social factors that affect them, some current regulations have been "left in the dust" by both science and existing processes to update antiquated regulations. Additionally, NAS reviewed the extent to which microbiological performance standards are appropriate means of ensuring the safety of selected products in a HACCP-based system, and evaluated the scientific bases for existing USDA or Food and Drug Administration (FDA) microbiological performance standards. NAS reported that the *Salmonella* performance standards for raw ground beef likely do not reflect the overall quality of a grinding operation, but likely reflect the raw materials used in the grinding operation; that the *E. coli* O157:H7 zero tolerance standard for raw ground beef seemingly has failed to reduce the public health consequences of this pathogen on an equal cost-benefit basis; that existing and proposed stabilization requirements are not justified scientifically; and that the use of worst case scenarios is not the best approach to establishing performance standards. FSIS has not made any adjustments to their performance standards as a result of the NAS report; although FSIS has indicated that perhaps the new stabilization standards would be somewhat more realistic. Inappropriate performance standards with weak or no scientific bases have resulted in millions of pounds of raw materials and finished products being destroyed.

Industry also agrees with the experts comprising ICMSF who concluded in 2002 that when establishing performance criteria, including performance standards, account must be taken of the initial levels of the hazard and changes of the hazard during production, processing, distribution, storage, preparation and use. ICMSF reported that performance criteria may be established for a wide variety of reasons, but are optimal when the risk to consumers is sufficiently high and compliance with the standard is essential for consumer protection. Industry would agree with this conclusion, but would argue that compliance with some performance standards, *e.g.*, zero tolerance for *E. coli* O157:H7 in raw ground beef (when the food industry interprets zero tolerance as establishing an expected level of control over a manufacturing process, then zero

tolerance represents a performance standard), is not achievable today, and thus, not the essential element for consumer protection (*i.e.*, cooking). FSIS has determined that zero tolerance is an appropriate performance standard for raw ground beef even though there is no means, except for thorough irradiation, to eliminate all pathogens from raw ground beef. There is no question that the reduction of *E. coli* O157:H7 must be a top priority for all manufacturers of raw ground beef; however, to require zero tolerance, a performance standard not meeting basic scientific principles for performance standards, has cost the industry and consumers needlessly. Industry applauds the Canadian government for its approach to *E. coli* O157:H7 in its "Policy on the Control of *E. coli* O157:H7 Contamination in Raw Beef Products." In its guidance policy, the Canadian Food Inspection Agency recognized that zero tolerance is not the correct approach, and established a statistical confidence of 95% for detecting *E. coli* O157:H7 as acceptable.

An example of the confusion that underlies FSIS performance standards related to the HACCP Rule is the lethality performance standard for fermented RTE products. Performance standards require that establishments meet a specific probability of surviving cells of *E. coli* O157:H7 in 100 grams of sample of the product (made from worst case raw materials) or use processes validated to achieve a five-log reduction of the pathogen throughout the product. Yet, there is a zero-tolerance standard for *E. coli* O157:H7 in fermented RTE meat products. This is, in effect, a duplicative set of performance standards where meeting one may not necessarily mean that the second would be met.

The HACCP Rule should have taken the federal inspection system closer to international standards to allow greater harmonization and easier, more efficient access for companies of all sizes to international markets. FSIS regulations pertaining to HACCP, particularly performance standards, do not yet achieve this objective. Internationally, performance criteria have been defined as the effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a performance objective or a FSO. A performance objective refers to the maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to a FSO or acceptable level of protection (ALOP), as applicable. The FSO is defined as the maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the ALOP. To date, FSIS, that claims to be a public health agency, has made no attempt to establish the ALOP for the United States for hazards of concern in meat and poultry products.

Internationally, application of risk analysis principles is sought when new regulations are developed. Under these principles, and in line with the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures, countries should base their regulatory actions, including the development of performance standards, on scientific risk assessment. NACMCF and ICMSF report that a country should be able to clearly link its targeted level of protection, based on a scientifically assessed risk level, to its regulatory goals and, in turn, to its standards and inspection system. FSIS has not dedicated time to publicly and definitively link its targeted levels of protection to its regulatory goals, inspection processes and performance standards.

Since 1989, FSIS has maintained a zero tolerance policy for *L. monocytogenes* in RTE meat or poultry products. FSIS should consider the expert evaluation on *L. monocytogenes* completed by ICMSF and reconsider their approach to performance standards for *L. monocytogenes* based on this expert evaluation and that of NAS. A substantial body of evidence now demonstrates that these zero tolerance policies are scientifically unsupportable, especially when applied to foods that do not support the growth of *L. monocytogenes*. Properly implemented, HACCP plans and prerequisite programs can substantially reduce the prevalence of *L. monocytogenes*. However,

these cannot assure the complete elimination of the pathogen from processing facilities. The WHO concluded, "The total elimination of *L. monocytogenes* from all food is impractical and may be impossible." NACMCF noted, "currently applied technology does not permit its eradication from the processing environment or from all finished product." ICMSF advised, "due to its widespread prevalence in the environment, eradication of *L. monocytogenes* from the food supply is impossible." Internationally, Canada, Denmark, the United Kingdom, Australia and New Zealand have established that zero tolerance is not an appropriate regulatory strategy for *L. monocytogenes*, and that a FSO of less than or equal to 100 *L. monocytogenes* per gram provides a higher level of protection than does a more strict tolerance of "not detected in 25 grams." FSIS has failed to accept the growing global recognition of the fallacy of a zero tolerance standard for all foods, and in fact, recently rejected an industry coalition petition to adopt a more scientific and global approach to *L. monocytogenes* in foods.

Economic Analysis

The costs associated with the HACCP Rule are enormous, and increasing every day as FSIS extends the HACCP policies into more-controlling and less impactful areas such as those described herein. In 2001, an industry survey indicated that the cost associated with validating a single CCP ranged from $5,000 for small plants to $360,000 for large plants, with an average of nearly $20,000 for all respondents. Costs associated with HACCP Rule policies related to *L. monocytogenes* also are higher than previous estimates made by FSIS since costs such as those associated with test and hold requirements, environmental testing shipping and storage were not included, or greatly under-estimated. For example, FSIS estimates of $3,400 for environmental testing for *Listeria* are very low; in fact, one large processor has costs near $30 million for the environmental monitoring program designed to meet regulatory expectations. Also, the labor costs associated with the numerous layers of FSIS inspection discussed herein have increased costs for establishments related to the HACCP Rule.

The economic impact analysis should be redone now that HACCP and all of its corollaries have been set in motion for over five years.

Conclusions

The HACCP Rule would have been more successful had FSIS used science-based principles to ensure that the HACCP-based policies, directives, notices and other publications met HACCP criteria endorsed by international experts. The greatest problem with the HACCP Rule is that regulatory HACCP, not science-based HACCP, has led to ever-increasing resource burdens on industry, especially small and very small establishments, without measurable impact on food safety or public health. While prevalence of some pathogens and diseases associated with these pathogens have decreased, these successes have resulted from the implementation of science-based HACCP plans by federally-inspected establishments to reduce the likelihood that pathogens will be present on meat and poultry products. The regulatory HACCP system continues to layer requirements and inspections on individual establishments without measurements to determine whether each new requirement and each layer of inspection, and how these are executed, add value to the objective of reducing risks. At the same time, the establishment must commit ever more monetary and human resources to respond to the regulatory initiatives without benefits to the consumer.

Embedded in the comments are many recommendations for FSIS that include the following:

- Align and base regulatory requirements on science-based HACCP principles

- Communicate in open dialogue with stakeholders (transparency) in advance of policy making, directives, notices and rules
- Establish measures for all elements of FSIS inspection, from individual inspection personnel to impact of regulations on public health
- Improve non-compliance management system with clear distinction between risks of higher and lower concern
- Require greater documentation and scientific justification for non-compliance documentation and rationale
- Take a farm to table approach to risk mitigation and assign resources appropriately
- Remove layered inspection of establishments with adequate local inspection
- Use the principles from NACMCF, NAS and ICMSF when establishing performance standards
- Link performance standards to public health objectives and outcomes
- Evaluate all existing performance standards, including zero-tolerance standards, against international standards
- Clarify statistics for FSIS verification sampling
- Provide adequate notification of the intent to conduct FSIS sampling and testing at establishments
- Establish cooperative panel of experts from stakeholder community to set and define validation criteria
- Establish educational mission as part of FSIS-industry relationship
- Accept products produced under FSIS inspection at one establishment into another FSIS-inspected establishment without validation and verification requirements except to ensure temperature control, and proper storage and distribution practices
- Conduct economic assessment of the HACCP Rule

Sincerely,

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