Lynn **Kosty** <lkosty@meatami.com>
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To: John **F.** Morrall III/OMB/EOP@EOP

cc:

Subject: COMMENTS - Report to Congress on the **Costs** and Benefits **of** Federa l Regulations

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Dear Mr. Morrall:

Attached you will find the American Meat Institute's comments on the Office of Management and Budget's "Report to Congress on the Costs and Benefits of Federal Regulations." AMI appreciates the opportunity to provide input on this important document.

Please feel free to contact me at: 703/841-2400 with any comments or questions you may have.

Sincerely,

Lynn **L.** Kosty
Director, Regulatory Affairs
American Meat Institute

Make plans now to be at the 2002 AMI Annual Convention and Innovation Showcase in New Orleans, LA, October 24-26, 2002.
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AMERICAN MEAT INSTITUTE

May 28,2002

VIA ELECTRONIC MAIL

Mr. John Morrall
Office of Information and Regulatory Affairs
Office of Management and Budget
NEOB, Room 10235
725 17th Street, NW
Washington, DC 20503

RE: Comments On Draft Report to Congress on the Costs and Benefits of Federal Regulations.

Dear Mr. Morrall:

The American Meat Institute (AMI) appreciates the opportunity to provide comments on the Office of Management and Budget's (OMB) "Draft Report to Congress on the Costs and Benefits of Federal Regulations." AMI is the nation's oldest and largest trade association representing packers and processors of beef, pork, lamb, veal, turkey, and processed meat products. Our member companies produce more than 90 percent of these products in the United States. AMI actively works with government officials to create regulatory systems that are beneficial to consumers and feasible for the industry.

OMB has requested input from stakeholders on regulations "that are outdated, duplicative, ineffective, or unnecessary." Accordingly, AMI submits the attached regulations and regulatory requirements as those in greatest need of reform or repeal. We appreciate the opportunity to participate in this important endeavor to ensure that regulations are effective and meaningful. Please contact me with any comments or concerns you may have.

Sincerely,

Mark D. Dopp
Senior Vice President of Regulatory Affairs and General Counsel

Federal Meat Inspection Act and Poultry Products Inspection Act
Hazard Analysis Critical Control Point - Pathogen Reduction Rule

Regulating Agency:	Food Safety and Inspection Service (FSIS)
Citation:	9 C.F.R. Sections 417.2(a)(1); 417.1; 417.3(b)(3); 417.6(e).
Authority:	21 U.S.C. Section 601 *et seq.* and 451 *et seq.*

Description of the Problem: The Food Safety and Inspection Service (FSIS or the agency) published the Pathogen Reduction/HACCP rule in July 1996. In implementing that rule, however, FSIS has repeatedly deviated from HACCP principles as articulated by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), instead administering an inspection system that has come to be known as "regulatory HACCP." In so doing, FSIS has mandated critical control points and has enforced the unwarranted withholding and suspension of inspection services at numerous plants, to the detriment of consumers and the regulated industry. A petition was filed on December 30, 1999, to amend several sections of the HACCP rule to make the rule consistent with the NACMCF's recommendations.

Proposed Solution: The petition recommended the following regulatory changes.

- The HACCP rule should be amended to account for other programs, such as SSOPs and GMPs when assessing the adequacy of HACCP systems (417.2(a)(1)).
- The definition and interpretation of a food safety hazard should be amended to reflect a more precise definition adopted by the National Advisory Committee on Microbiological Criteria for Foods to prevent the inclusion of hazards not reasonably likely to occur in a quantity or a type that will result in human health problems in a HACCP plan (417.1).
- The rule should be amended to establish when product is shipped, giving consideration to the fact that product may leave an establishment and remain under the control of the establishment (417.3.(b)(3).
- The provision regarding inadequate HACCP plans should be amended to require actual shipment of adulterated product, rather than production or shipment. Such a change would allow a plant to take appropriate corrective action on adulterated product, before shipment, in a manner consistent with its HACCP plan (417.6(e)).

Economic Impact: Making the aforementioned changes will make meat and poultry production and processing systems more effective in producing safe and wholesome products and will reduce the cost inefficiencies introduced by the agency's imposition of a rule that is inconsistent with the scientific recommendations of the agency's own advisory committee.

Federal Meat Inspection Act and Poultry Products Inspection Act Rules of Practice

Regulating Agency: Food Safety and Inspection Service (FSIS)

Citation: 9 C.F.R. Sections 500.6; 500.4; 500.3; and 500.7.

Authority: 21 U.S.C. Section 601 *et seq.* and 451 *et seq.*

Description of the Problem: The Food Safety and Inspection Service (FSIS or the agency) published, on November 29, 1999, rules of practice regarding enforcement actions pertaining to, among other things, the HACCP/Pathogen Reduction rule promulgated in July 1996.

The rules include procedures to be followed when there are other circumstances that may warrant some form of enforcement action, including alleged inspector harassment or refusing to destroy condemned product. The rules also establish the procedures to be followed when the agency believes it has the authority to withdraw a company's grant of inspection. Some of those provisions, however, are legally questionable because they are outside the scope of the authority granted to FSIS by the Federal Meat Inspection Act and the Poultry Products Inspection Act (the Acts). AMI, along with two other trade associations, on December 15,2000, filed a petition requesting that the agency amend the rules of practice to conform to the Acts. Unfortunately, the Rules provide that FSIS may impose suspensions and withholding actions in several instances not authorized by the Acts. Moreover, the Rules identify a number of circumstances in which the agency is empowered, contrary to its statutory authority, to seek withdrawal of an establishment's grant of inspection.

Proposed Solution: The petition recommended the following regulatory changes.

- Amend section 500.6 by deleting subsections (a) through (f) and subsection (h) and redesignating subsection (g) as subsection (a) and redesignating subsection (i) as subsection (b).
- Amend section 500.4 by deleting subsections (d) and (e).
- Amend section 500.3 by deleting subsections (a)(1)-(2) and redesignating subsections (a)(3)-(a)(7) as subsections (a)(1)-(a)(5) respectively.
- Amend section 500.7 by deleting subsections (a)(1)-(4) and redesignating subsection (a)(5) as subsection (a) and amending it to read as follows: "(a) the FSIS Administrator may refuse to grant Federal inspection because an applicant is unfit to engage in any business requiring inspection as specified in section 401 of the FMIA of section 18(a) of the PPIA."

Economic Impact: Making the aforementioned changes will provide the necessary due process protections guaranteed by the Constitution and bring the agency's rules of practice into compliance with the authorizing statutes.

Packers and Stockyard Act and Meat and Poultry Inspection Act: Animal Identification and Trace Back

Regulating Agency:	Grain Inspection Packers and Stockyard Administration and the Food Safety and Inspection Service
Citation:	9 C.F.R. Parts 201.49, 201.86, 201.94 and 201.95, and 9 C.F.R. Part 310.2
Authority:	7 U.S.C. *181 et seq.* and 21 U.S.C. 601 *et seq.*

Description of the Problem: The animal identification and trace back systems defined in existing regulations are out-dated and fail to embrace technological and operational advances made in animal identification and trace back. In that regard the acts are overly prescriptive regarding accomplishing animal identification and trace back. Specifically, the Acts' prescriptive regulations confine establishments to antiquated systems that often increase food safety risks because of unnecessary handling of contaminated animal hides and identification tags. Furthermore, the regulations do not discriminate between meaningful animal identification, *e.g.*, country-of-origin and vaccination tags, and meaningless tags, *e.g.*, feedlot identification tags.

Packers and Stockyard Act regulations (9 CFR 201.49 (a)) require that livestock weighed for purchase or sale must have serially numbered scale tickets generated; and, if hot carcass weights are used for purchase, the scale must be linked to a printer to generate scale tickets with dates, names of buyers & sellers, number of head, kind of livestock, weights & the individual responsible. The identity of the consignment is required until inspection has been completed (9 CFR 201.86 (d)), information must be made available to USDA (9 CFR 201.94), and records must be available (9CFR 201.95).

In 9 CFR 310.2, FSIS regulations require linking the head, tail, tongue, thymus gland and viscera, and all blood or other parts destined for food or medicine, to the carcass and the animal from which it was derived, until post-mortem inspection is done; this includes retention of ear tags, back tags, implants and other ID devices attached to the animals in such a way as to relate them to the carcass; the back tag must be bagged and attached to the carcass until removed with viscera for inspection; brucellosis and tuberculosis ear tags, and herd ID tags should be bagged and attached to the carcass until removed with the viscera for inspection. Part 310.2 (b4) does allow the FSIS circuit supervisor to recognize an alternative method if the method allows carcass identification in association with the corresponding devices during post-mortem inspection; however, this recognition does not take place in practice, nor is not applied equally across all sectors of the industry because of individual preferences and tolerances.

Proposed Solution: All carcasses are identified by a carcass ID number that, in turn, is linked to an incoming animal. Carcasses, viscera, and other parts of the animal destined for food or medicines *are* linked through ID systems through completion of post-mortem inspection. All slaughter establishments conform to the Packers & Stockyards Act, which requires carcass identification to the last point of production or purchase; beyond that, there is no national, uniform animal ID system. There should be a flexible regulatory policy identifying what information is needed without prescribing how those needs are met. **This** approach will allow for the development **and** use of technological (*e.g.*, computer-based systems, microchip technology) innovations that will improve animal trace back capabilities in cost-efficient ways. Until a national ID **system** is in place, **from** birth to slaughter, regulations should focus on tags that have consistent, standardized meaning, *e.g.*, country-of-origin and vaccination tags. There should not be any requirement for other non-uniform, local tags that provide no meaningful information regarding animal identification and have no national basis for regulation.

Federal Meat Inspection Act and Poultry Products Inspection Act
Post-Modem Inspection: Extent and Time of Post-Mortem Inspection - *Staffing* Standards

Regulating Agency: Food Safety and Inspection Service (FSIS)

Citation: **9** CFR **310.1**

Authority: **21** U.S.C. **451** ***et seq.*** and 21 **U.S.C.** 601 ***et seq.***

Description of the Problem: The Food Safety and Inspection Service **(FSIS** or the agency) regulations pertaining to staffing standards were established many years ago and are based on the number of carcasses processed hourly at an establishment **(9** CFR 310.1(a)), and indirectly, the inspectors union's workload management expectations. However, the upper limits on carcasses per hour (line speed) can now be exceeded based on new technologies and improved operations at facilities. Due to the regulatory limit, there is no opportunity to take advantage of these new technologies and improved operations, which prevents establishments from improving efficiencies and capitalizing on investments.

Proposed Solution: Rewrite the staffing regulations such that they *are* formula based, or otherwise open-ended to accommodate technological advancements in operational efficiencies. **An** alternative is to separate staffing from line speeds. Inspection staffing should be based on establishment historical performance relative to compliance with regulatory requirements. Those establishments with a history of non-compliance might receive a higher level of staffing to assist the establishments in improving compliance. This approach would benefit the consumer and help raise the performance **of the** entire industry.

Agricultural Marketing Service
Ground Beef Purchasing Specifications

Regulating Agency: Agricultural Marketing Service (AMS)

Citation: Technical Data Supplement (TDS) for the Procurement of Frozen Ground Beef Items (TDS-136, June 2000)

Authority: Agricultural Marketing Act of 1946

Description of the Problem: More than 126 million pounds of commodity ground beef, ground pork, and ground turkey are purchased annually by AMS for the National School Lunch Program and other federal feeding programs. Revisions to the AMS ground beef purchase specifications in June, 2000, were developed without consultation with industry and established unrealistic microbiological criteria. The new specification established a zero tolerance for both *E. coli* O157:H7 and *Salmonella* in raw, ground beef. Although the best technology available can reduce these contaminants significantly, zero tolerance is impossible and unrealistic (with the exception of irradiation that was excluded – see below). In addition, the TDS requires slaughter establishments supplying raw materials to grinding operations to use an "FSIS recognized" microbial intervention as a critical control point. However, AMS explicitly excluded the use of irradiation, a proven intervention that could achieve the zero tolerance standard. When AMS published the TDS it stated that the specification was interim and would be revised for the 2001-2002 school; which did not happen. Modifications for the 2002-2003 school year are expected to be minor and do not address the scientific issues surrounding the zero tolerance requirements. These zero tolerance requirements are not science-based and make supplying these products to AMS essentially a game of chance relative to the presence or absence, or detection or non-detection, of low levels of these potential pathogens. This uncertainty eliminates some suppliers from the market, thereby limiting supply to AMS and increasing prices paid by the agency.

Proposed Solution: AMS published a revised TDS document, TDS-136, June, 2001, for public comment; but this revised document was hastily withdrawn four days after its publication following a public outcry from those concerned that somehow food safety was being jeopardized. The revised TDS took an innovative approach to the microbiological specifications, an approach that was science-based and would drive continuous improvement. The new microbiological specifications would take advantage of statistical process control (SPC) techniques to ensure that AMS would purchase meat and poultry products from the very best suppliers, while at the same time, allowing those at the bottom tier the opportunity to improve their performance and enter the supply chain. This SPC approach is science-based, and has been proven effective in controlling risks throughout the world and in the U.S. This new, science based approach should be adopted by AMS for purchase specifications and replace the current "quality-by-chance" purchasing program.

Federal Meat Inspection Act and the Poultry Products Inspection Act Performance Standards for Processed Meat and Poultry Products

Regulating Agency: Food Safety and Inspection Service (FSIS)

Citation: Proposed rule: FSIS Docket No. 97-013P

Authority: 21 U.S.C. 451 *et seq.* and 21 U.S.C. 601 *et seq.*

Description of the Problem: The proposed rule, as written, discourages companies from testing for ***Listeria,*** making it is plausible that implementing the rule as written would adversely affect public health. Moreover, the proposed level of testing lacks scientific basis and encourages companies currently conducting a large sampling program to decrease testing. There are also significant concerns concerning the economic impact the proposed regulation would have, particularly on small businesses. One large company has conservatively estimated its costs of implementing the rule at $30 million. Simply aggregating the costs likely to be incurred by the four or five largest processors easily exceeds the $100 million threshold, qualifying this as a major regulation in need of a comprehensive cost/benefit analysis per Executive Order 12866. In that regard, the proposal has the following flaws:

1) The agency fails to demonstrate how this regulation will have a significant, positive impact on consumer health.

2) The proposal misuses the concept of the Hazard Analysis and Critical Control Point (HACCP) system.

3) The proposal grossly underestimates the economic impact on industry.

4) Consistent with the September 20,2001, OIRA memorandum, the risk-assessment conducted by the Food and Drug Administration (FDA) and FSIS on ***Listeria monocytogenes,*** which was released in draft months after this proposal was issued, could help serve as the foundation for a regulation such as this one.

Proposed Solution: Voluntary environmental testing (product contact and non-product contact surfaces) as part of a total ***Listeria monocytogenes*** (*Lm*) control program should be encouraged, as well as voluntary finished product testing to verify that HACCP systems are controlling and eliminating product contamination. Unfortunately, the proposed rule is counterproductive to that objective. Indeed, not only will the proposal not benefit public health, it will conflict with HACCP principles and would impose substantial and unnecessary costs on the industry without enhancing food safety. OMB should take a close look at this proposed regulation and work with the Food Safety and Inspection Service to develop a more meaningful final rule that will enhance food safety and further protect public health.

Federal Meat Inspection Act and Poultry Products Inspection Act
Policy on Beef Products Contaminated With *E. coli* O157:H7

Regulating Agency: Food Safety and Inspection Service

Citation: Docket No. 97-068N - Policy on Beef Products Contaminated With *E. coli* O157:H7; and Directive 10,010.1 - Microbiological Testing Program for *Escherichia coli* O157:H7 in Raw Ground Beef.

Authority: 21 U.S.C. 601 *et seq.*

Description of the Problem: On January 19, 1999, FSIS expanded its policy regarding raw beef products contaminated with E. *coli* O157:H7 (*E. coli*). Although intact products, *i.e.* "beef products in which the meat interior remains protected from pathogens migrating below the exterior surface," are not considered. adulterated if *E. coli* is present, non-intact products, *i.e.*, beef products that have been injected or mechanically tenderized are considered adulterated if *E. coli* is found and the product has not been processed into a ready-to-eat item. In addition, intact cuts that are to be further processed into non-intact cuts (*e.g.* beef trim) before distribution will be treated as non-intact cuts. E. *coli* should not be an adulterant in fresh beef products. The incidence of E. *coli* in raw beef is so low that sampling and testing cannot reduce the public health risk significantly. No sampling program exists that will ensure that the pathogen is not in the product.

Proposed Solution: The *E. coli* policy can be improved by the following: 1) removing the non-intact whole muscle cuts (tenderized steaks, *etc.)* from the policy, *2)* maintaining the current "point source" contamination policy, and 3) modifying FSIS Directive 10,010.1 *Microbiological Testing Program for Escherichia coli* O157:H7 *in Raw Ground Beef,* to allow carcass testing at a rate of one per 300 carcasses, to remove the six-month penalty provision, and to provide eligibility for reduced sampling through the distribution chain (from slaughter through retail/foodservice).

Federal Meat Inspection Act and Poultry Products Inspection Act *Salmonella* Performance Standards

Regulating Agency:	Food Safety and Inspection Service (FSIS)
Citation:	9 C.F.R. 310.25(b) and 9 C.F.R. 381.94(b)
Authority:	21 U.S.C. 601 *et seq.*

Description of Problem: As part of its 1996 HACCP pathogen reduction rulemaking FSIS established performance standards for *Salmonella*. Notwithstanding the questionable scientific validity of the performance standards, FSIS move forward with its program of sampling carcasses and ground product and the enforcement scheme attendant to it. Litigation ultimately ensued after FSIS sought to close a plant that failed the standard, asserting that failing to meet the standard meant the plant was not sanitary. In December 2001 the United States Court of Appeals for the Fifth Circuit ruled that FSIS did not have the statutory authority to close the plant in question because the *Salmonella* performance standard did not measure plant sanitation and absent that connection the agency lacked the statutory authority to take a withholding action.

Proposed solution: The performance standard should be amended utilizing a microbiological organisms or organisms that accurately and adequately measure plant process control and sanitation.

Microbial Sampling of Ready-to-Eat Products "Zero Tolerance" for *Listeria monocytogenes*

Regulating Agency:	Food and Drug Administration (FDA) and Food Safety and Inspection Service (FSIS)
Citation:	21 C.F.R. § 109.3(d); FSIS Directive 10,240.2
Authority:	Food, Drug, and Cosmetic Act 21 U.S.C. § 402(a); Federal Meat Inspection Act 21 U.S.C. § 601(m); Poultry Products Inspection Act, 21 U.S.C. § 453(g)

Description of the Problem: Since 1985, FDA has maintained a "zero tolerance" policy for ***Listeria monocytogenes*** ***(L. monocytogenes)*** in ready to eat (RTE) foods, which are foods that may be consumed without further preparation by the consumer. FDA considers RTE foods to be adulterated under section 402(a) of the FFDCA if any ***L. monocytogenes*** is detected in either of two 25-gram samples. Since 1989 FSIS has maintained a similar "zero-tolerance" policy for RTE meat or poultry products. Meat or poultry products in RTE form in which any ***L. monocytogenes*** is detected are deemed adulterated under the Federal Meat Inspection Act and the Poultry Products Inspection Act, 21 U.S.C. §§ 601(m) and 453(g), respectively.

On August 6, 1998, the FSIS issued Directive 10,240.2, ***Microbial Sampling of Ready-To-Eat Products Produced by Establishments Operating Under A HACCP System*** (the Directive). The Directive outlined procedures for, among other things, inclusion of all pathogens and microbial toxins and clean-up to clean-up lot definition, but did not recognize the sporadic, environmental nature of some pathogens. On December 1, 2000, a revised Directive 10,240.2 went into effect. The revisions included realigning the testing programs into HACCP categories, eligibility for establishments conducting their own testing for reduced agency sampling, and follow-up agency sampling protocol. Establishments may randomly test one product per HACCP plan once a month or randomly test one product per HACCP plan every three months, coupled with ongoing product contact and non-product contact surface testing. Such testing must be included in an establishment's HACCP plan or SSOPs. Testing protocols, results, scientific justification for frequency, sampling methods, randomness, ***etc.***, must all be made available to inspection personnel. This directive provides the mechanism for further the reach of the enforcement of the FSIS zero tolerance policy by expanding the amount of sampling conducted beyond the current routine FSIS monitoring samples.

Major U.S. trading partners such as Canada, Denmark, the United Kingdom, Australia, and New Zealand have established flexible regulatory limits relative to ***L. monocytogenes*** in RTE foods. Regulators in these countries have recognized that, although eradication of ***L. monocytogenes*** in the food-processing environment is a commendable goal, it is not practical given the widespread and ubiquitous nature of the organism and in light of currently available technologies. These countries choose to focus limited regulatory resources on foods presenting a realistic risk of

listeriosis, which are distinguished from foods that do not support growth of the pathogen and that do not contain it at levels of public health consequence.

Proposed Solution: The U.S. "zero tolerance" approach for all RTE foods utilized by **FDA** and **FSIS** was a cautious enforcement policy based on the state of the science at the time of its creation. **A** substantial body of evidence now demonstrates that the policy is scientifically unsound as applied to **foods** that do not support growth of ***L. monocytogenes,*** a precondition to infectiveness. There is scientific agreement that **low** levels of ***L. monocytogenes*** are **not** uncommon in the food supply **and** that such **low** levels are routinely consumed without apparent harm. **A** health threat is presented, however, when the bacterium is permitted to multiply to high levels in foods that support its growth. The growth in **food** of pathogens such as *L. **monocytogenes*** is dependent upon a number of environmental and other parameters, including temperature, pH, water activity, oxygen content, and the presence of added substances or the use of processes with bacteriocidal activity. For those foods that do not support growth of the bacterium to levels that may cause illness, a new regulatory approach **is** needed to ensure that trade in foods is not needlessly restricted in a manner that does not yield a corresponding public health benefit.