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January 6, 2006

05-013N
05-013N-7
Mark D. Dopp

FSIS: Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
300 12th St., SW
Room 102 Cotton Annex
Washington, DC 20250

Re: Docket No. 05-013N; Meeting to Discuss Possible Changes to the Regulatory Jurisdiction of Certain Food Products Containing Meat and Poultry

Dear Sir/Madam:

The American Meat Institute (AMI or the Institute) submits the following comments regarding the above-referenced notice published by the Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA) (collectively the agencies). 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. The Institute provides legislative, regulatory, public relations, technical, scientific, and educational services to the meat and poultry packing and processing industry.

All of AMI's general members are subject to the Federal Meat Inspection Act, the Poultry Products Inspection Act, or both. Many AMI members also produce products subject to the Federal Food, Drug, and Cosmetic Act. Although AMI represents many of the largest meat packing and processing companies in the country, more than 75 percent of AMI members are small businesses. For these reasons, AMI has a direct interest in the agencies' review of the regulatory inspection requirements of the Acts and the FDCA.

The agencies have presented several possibilities in the notice and are to be commended for again examining these amenability issues in the wake of the significant changes that have occurred in the regulatory system recently. In that regard, AMI favors changes that would move some products that have been inspected by FSIS to FDA jurisdiction, such as when the meat or poultry component of a product has already been subject to FSIS inspection. A more complete discussion of AMI's views on the issues presented follows.

Background

The issues and questions raised by the agencies in the *Federal Register* publication are not new. More than 20 years ago FSIS published an analysis of the Acts' exemption provisions and stated that "FSIS inspection of many processed products involved the reinspection of previously inspected meat and poultry product. In many instances, the processing plant is simply handling and repackaging the meat and poultry product with additional formulation."[1] FSIS went on to say, as part of a discussion about pizza, canned soups, and refined fats and oils, that "[T]here is a strong similarity between the processing of these products and their associated health risks with similar products non-meat or poultry ingredients, but regulated by the Food and Drug Administration."[2]

Slightly more than a decade later the Research Triangle Institute (RTI) completed a report, *Review of USDA Meat and Poultry Inspection Exemption Policies.* RTI concluded that a "study of exemption history revealed the USDA product exemption policies have been applied unevenly and inconsistently since passage of the Wholesome Meat Act in 1967 and the Wholesome Poultry Products Act in 1968."[3]

The FMIA defines a meat food product and allows the Secretary of Agriculture to exempt from inspection products that "contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat food industry, and which are exempted from definition as a meat food product by the Secretary under such conditions as he may prescribe to assure that the meat or other portions of such carcasses contained in such product are not adulterated and that such products are not represented as meat food products."[4] This definition makes clear that a meat product can be exempt by meeting either one of the two criteria. In that regard, the minimal, and arguably, arbitrary amounts established by FSIS many years ago in order to

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[1] *An Analysis of Exemption Provisions of the Meat and Poultry Inspection Laws*, United States Department of Agriculture, Food Safety and Inspection Service, (March 1983) at i.
[2] *Id.* at ii.
[3] *Review of USDA Meat and Poultry Inspection Exemption Policies*, Research Triangle Institute, January 1994, at x.
[4] 21 U.S. C. sec. 601(j). A similar definition exists for poultry.

qualify for the "relatively small proportion" provision may not reflect accurately the appropriate measures to determine exemption from inspection under that clause.

The Acts also exempt products that are not historically considered by consumers to be a product of the meat or poultry industry. Interestingly, many products offered today to consumers were not even contemplated when that exemption concept was developed, raising questions as to whether those products can be characterized as products historically considered to be products of the meat or poultry industry and, therefore, whether they should be exempt from inspection. These earlier analyses raise legitimate questions about the appropriateness of FSIS' conclusions that certain products should be subject to FSIS inspection.

Product Jurisdiction should be divided using Objective Criteria such that Inspection Resources are allocated most effectively to Benefit Consumer Safety and Public Health.

The starting point for a discussion about amenability is that it is not about food safety. Whether under FDA or FSIS jurisdiction, food products are produced in accordance with processes that ensure their safety. Rather, the primary issue presented is whether the exemptions in place, as well as those being considered, allow inspection resources to be allocated and focused as effectively and efficiently as possible -- avoiding duplicative regulation -- so that consumer safety and public health are enhanced. Interestingly, the notice supports the conclusion that the current criteria used by the agencies are antiquated and lack cohesiveness.

To that end, rather than engaging in arbitrary jurisdictional decision-making, the agencies should develop, for public discussion, objective criteria to guide amenability determinations. These criteria should include 1) whether the product's components have been previously inspected, 2) the nature of any risk presented concerning a particular product or product category, and 3) marketing and consumer expectations with respect to the product.

In that regard, prior FSIS inspection of a meat or poultry ingredient is a logical and sustainable dividing line in determining whether FDA or FSIS should have jurisdiction over the product. Previous FSIS inspection of a component or components (*e.g.* when a product contains a previously FSIS inspected meat component in combination with FDA inspected ingredients) should obviate the need for inspection again by FSIS when the meat component(s) are combined, such as in a kit. This conclusion is particularly applicable when the meat product component is Ready-to-Eat (RTE). Duplicative inspection by FSIS in these cases is unnecessary and could be

counterproductive because it can divert inspection resources away from where they likely would be more efficiently allocated.

Moreover, such an approach is consistent with a risk based inspection (RBI) system.[5] In an RBI system, risk likely decreases in operations where previously-inspected products (whether inspected by FDA or FSIS) are reassembled into products and this is particularly true if the products are frozen or have limited shelf lives. Put simply, application of extensive FSIS inspection resources for relatively low-risk operations such as these and others does not make sense. Because the overall impact on public health would be better served through a more effective allocation of resources, FDA should manage the inspection of these operations. FDA jurisdiction is appropriate in this circumstance because FSIS already has inspected the product's meat component and continuous inspection of low-risk operations is not cost effective and does not enhance public health.

The notice identifies several product categories that, because they have been developed or evolved in recent years, because of how they are marketed, or because of consumer expectations, should not be considered products of the meat or poultry industry and therefore subject to FDA jurisdiction. Simply put, and as the earlier referenced reviews suggested, there is little cohesiveness or logic involved in subjecting to FSIS inspection a number of products, particularly those that have been developed in the last 10 to 15 years. To that end it cannot be argued that they are products historically considered by consumers to be products of the meat and poultry industry because they did not exist when the applicable statutory language was crafted. Thus, for example, assembled kits with a meat component, wraps, among other products, have been successfully developed and marketed relatively recently and should be exempt from inspection as products not historically viewed as part of the meat industry.

The Agencies Should Reconsider the Levels of a Meat or Poultry Component that Trigger FSIS Inspection.

The agencies should, using all information available today, as well as the criteria developed as suggested above, consider carefully the *de minimis* standards that have been used in the past, and whether those standards are consistent with the statutory authority. In its 1983 analysis, FSIS referred to "minimal portions of meat/poultry" as the basis for one element of

[5] As evidenced by the discussion at the recent National Advisory Committee on Meat and Poultry Inspection Meeting and the efforts of the industry coalition examining risk based inspection, an RBI system would offer numerous benefits by more efficiently allocating limited resources and enhancing the public health. See NACMPI Fall Meeting, November 15-16, 2005, and see also *Industry Perspective on Risk-Based Inspection, its Components and it Execution by Industry and Regulatory Authorities*. December 2, 2005.

determining product exemption. The meat food product definition, as discussed above, however, allows exemptions for products that "contain meat or other portions of such carcasses only in a relatively small proportion." (Emphasis added). Because, from an amenability standpoint, the inspection system was last "revised" significantly nearly 40 years ago, the agencies should carefully consider the appropriateness of the two or three percent measure and whether that hard number approach is in keeping with the standard established by the statute, *i.e.*, "relatively small proportion." In short, it is time, keeping in mind the above-discussed discretion provided by the statute, to align inspection and food safety resources with risks in order to implement an RBI system and not be wedded to hard numbers.[6]

Subjecting Certain Products currently under FDA Jurisdiction to FSIS Inspection would Impose Substantial and Unnecessary Costs

There is little if anything in the notice or other available information that suggests that expanding FSIS inspection authority to cover certain products identified in the notice and traditionally inspected by FDA will benefit public health in any meaningful way. What those potential changes would almost certainly do is impose additional and unnecessary costs on the producers of those products. These added costs could drive some companies out of business, particularly smaller entities, and almost certainly would be passed on to consumers.

It is beyond dispute that FSIS regulatory requirements regarding facilities and inspection are different, and more costly, from those applicable to facilities producing FDA regulated products. In that regard, product labeling, marketing, and distribution practices would certainly be affected by any such jurisdictional reassignment. Specifically, the changes resulting from a shift to FSIS inspection would include, among other things:

(1) The need to obtain a grant of inspection;
(2) A change in packaging to include the mark of inspection;
(3) A need for labels to be approved by FSIS; and
(4) Overtime costs for inspectors would be incurred.

A conservative cost estimate for just one small company currently subject to dual jurisdiction that would be forced to incur added costs if certain items discussed in the notice were shifted to FSIS is approximately $100,000 annually. Notably, this figure does not include capital costs incurred if this change in jurisdiction occurred. These considerations support the conclusion

[6] Assigning a value of two or three percent to the meat or poultry component as a demarcation to separate FSIS and FDA responsibilities cannot be viewed as science- or risk-based.

that, absent a legislative mandate, FSIS should not assert jurisdiction over products historically not considered amenable to FSIS inspection.

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For the foregoing reasons AMI recommends that the agencies develop, utilizing the notable discretion afforded by the Acts and in cooperation with all stakeholders, objective criteria for determining jurisdiction and that those criteria be based on how best to provide effective inspection within the framework of a risk based inspection system. Moreover, given the absence of public health concerns, the agencies should not, absent a legislative mandate, subject product not traditionally deemed subject to FSIS inspection, to that agency's jurisdiction.

AMI appreciates the opportunity to submit these comments and would be pleased to meet with the agencies to discuss further the issues presented and these comments.

Sincerely,

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