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05-013N
05-013N-15
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March 3, 2006

Docket Clerk
U.S. Department of Agriculture
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300 12th Street, SW.
Room 102 Cotton Annex
Washington, DC 20250

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
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[Docket No. 05-013N] Meeting to Discuss Possible Changes to the Regulatory Jurisdiction of Certain Food Products Containing Meat and Poultry; 70 *FR* 67490; November 7, 2005

Dear Sir or Madame:

The Food Products Association (FPA) is the largest trade association serving the food and beverage industry in the United States and worldwide. FPA's laboratory centers, scientists and professional staff provide technical and regulatory assistance to member companies and represent the food industry on scientific and public policy issues involving food safety, food security, nutrition, consumer affairs and international trade.

FPA appreciates this opportunity to comment on this joint Agency effort to rectify long term inconsistencies in regard to the regulatory jurisdiction of certain food products that contain meat or poultry ingredient(s). Many FPA members are subject to the regulatory oversight of both the FDA and the FSIS due to the broad range of products they manufacture, including many that would be impacted by the jurisdictional shifts recommended by the FDA-FSIS working group. Thus, FPA and its members have a keen interest in this subject, especially since this effort provides an excellent opportunity to not only clear away jurisdictional confusion, but also to contribute to improved public health protection that would result from better focusing of limited inspection resources where food safety risks are the greatest.

Optimized allocation of limited USDA inspection resources within the existing statutory constraints of the meat and poultry inspection statutes is a primary focus of our comment

This written submission supplements and expands on comments made during the December 15, 2005 public meeting on this topic. It includes opening general observations followed by more detailed responses to the questions posed by the two Agencies in the *Federal Register* notice referenced above.

Highlights of FPA Comments

- We commend the Agencies for undertaking this effort to rectify amenability anomalies that have existed for many years.
- Safety is not the issue here. American consumers have ample reason to be highly confident in the safety, wholesomeness and proper labeling of meat- and poultry-containing food products, whether they are manufactured under the regulatory purview of FSIS or FDA.
- We believe that, in large measure, subjecting previously FSIS-inspected meat or poultry to subsequent FSIS inspection is unnecessary and is an inefficient use of limited inspection resources, which could be utilized in areas posing a more significant public health risk.
- Though FSIS has made very substantial strides in recent years to move away from command-and-control regulatory oversight, FSIS inspection remains much more intense and prescriptive than FDA inspection. As a result, the cost to the public for FSIS inspection is substantially more than for FDA oversight.
- In the absence of a clearly defined need for the greater level of inspectional intensity inherent in the FSIS inspection system, options for jurisdictional discretion provided within the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) should be exercised to their fullest.
- It makes sense to transfer from FSIS to FDA inspectional jurisdiction those products that contain previously FSIS-inspected meat or poultry ingredients, and for which there is no reasonable expectation that a daily FSIS inspection presence is required to assure their safe manufacture.
- For the same fundamental reasons, it does not make sense to suddenly subject to daily FSIS inspection any products that have been safely produced under FDA oversight for some time with no known consumer concern about the regulatory jurisdiction of such products.
- This regulatory jurisdiction effort provides an excellent opportunity to free up FSIS inspection resources from areas that clearly do not require the intensity of inspection inherent in the FSIS inspection system and which could be shifted to areas identified by the Agency that potentially could benefit from a greater level of inspection resources.
- There can be no clearer representation to a consumer as to whether or not a product is an FSIS-inspected meat or poultry product than the presence or absence of the USDA inspection legend on the label. For products shifted from FSIS to FDA inspection, the absence of the USDA mark of inspection, rather than required alteration of the traditional product name,

should be a more than adequate indication to any interested consumer that the product is not represented as a product of the meat or poultry industry.

Detailed FPA Comments

Historical Considerations

Before we respond to the questions raised in the recent *Federal Register* notice, we would like to share some historical perspective on this issue. The issue of USDA versus FDA jurisdiction has been studied and discussed on a number of occasions, each time with a slightly different focus relevant to contemporary issues and concerns. It is interesting to note that, despite multiple efforts to clear up the confusion and inconsistencies, no significant changes in regulatory jurisdiction have resulted from those efforts in the past 25 years.

In today's climate, with broad recognition of the need for risk-based allocation of inspection resources, the effective use of limited inspection resources must be a primary consideration as the two Agencies reexamine this issue once more. We applaud the Agencies' initiative.

We hope the current initiative, as opposed to those in the past, will result in significant change, not just to reduce confusion and achieve greater consistency, but, more significantly, to better focus limited inspection resources for the greatest good. FPA believes that a review of past regulatory jurisdiction reform efforts reveals some common themes.

In March of 1983, FSIS issued a report titled, "An Analysis of Exemption Provisions of the Meat and Poultry Inspection Laws." That report included the following:

> The Food Safety and Inspection Service (FSIS) is conducting a number of studies to determine what changes could be made in its operations to alleviate regulatory burdens upon industry and to minimize taxpayers' expense while still ensuring that consumers receive wholesome, unadulterated, and properly labeled meat and poultry products.

In this report, issued nearly twenty-five years ago, the Agency concluded that "FSIS's continuous inspection of the preparation of ..." pizza, canned soups and refined fats and oils " ... appears unnecessary ..." Also:

> There is a strong similarity between the processing of these products and their associated health risks with similar products containing non-meat or poultry ingredients, but regulated by the Food and Drug Administration.
>
> For these products, compliance with the continuous inspection requirements under the FMIA and PPIA appears an inappropriate allocation of limited USDA and industry resources. The preparation of pizza and canned soups involves the use of previously inspected meat/poultry items which are added to another product or repackaged.

While not a focus of the report, the Agency viewed the placing of certain products under FDA's regulatory authority as one limited alternative to legislation it was seeking at the time for less-than-continuous inspection.

In 1991, Congress directed USDA to conduct two studies, one of which was to reevaluate "... the criteria it uses to exempt food products with a meat or poultry component from Federal inplant inspection requirements." FSIS contracted with Research Triangle Institute (RTI) to conduct the studies. In February of 1994, FSIS released a report titled, "Analysis of the Congressionally-mandated Inspection Exemption Study." In the Executive Summary of that analysis of the findings of the RTI study, prepared by the FSIS Policy Analysis Unit, FSIS committed to "adjust" the "relatively small proportion" statutory exemption criterion.

Among the findings from a dozen years ago, well before the Agency and the industry implemented HACCP for all meat and poultry operations, were the following:

> The ability of FSIS to make risk-based allocations of inspection resources is limited partly by statutory provisions that require inspection be performed in ways which may not be consonant with modern production system hazards and also by a policy of granting exemptions to products and establishments that is not consistently based on risk.
>
> These limitations have presented barriers to innovation in the Federal meat and poultry regulatory program and have hampered efforts to improve its effectiveness. For example, many plants or products receive more inplant inspection than the risk they present requires. Some receive less.

The report stated that the "relatively small proportion" exemption has been used to exempt products from inplant inspection "... as a practical way of focusing limited inspection resources on the meat and poultry manufacturing establishments that Congress intended the legislation to cover." The report also stated that "(I)t is only by exempting such products from inplant inspection that FSIS has sufficient resources to focus on higher-risk products." In addition the report stated that "...there is no evidence that foods exempted from USDA inplant inspection on the basis that they contain very small amounts of meat or poultry have presented any public health problem or adversely affected the regulated industry."

The report stated that the RTI study "...pointed up the need for a reevaluation of the exemption threshold for various products which contain only a small proportion of meat and poultry..." and that FSIS "...agrees that a reevaluation of product exemption thresholds is warranted."

Finally, in a section of the report titled "Applying Risk-Based Inspection Principles to the Exemption Issue," it is stated that the Agency decided that "...its exemption policies need to be evaluated further and revised where necessary to focus primarily on the risk to public health presented by product processes or establishments."

As correctly noted in the RTI Study of 1993, FSIS does not have statutory authority to grant exemptions from inspection based solely on the degree of risk associated with certain categories of products. However, this should not preclude the Agency from considering risk, as well as USDA's stated intent to move toward risk-based allocation of its inspection resources, in amenability policy decisions where an expansive interpretation of the statutory exemption provisions so permits.

Inspection Intensity

By law, FSIS provides inspection for the slaughter of meat and poultry producing animals as well as certain other products manufactured with meat and poultry ingredients. FDA inspects all food products that are not inspected by FSIS. Significant implications for the public and for food manufacturers derive from determinations about which Agency provides regulatory oversight for a particular product. For the products at issue, these implications do not relate to food safety. The safety of these products should not be in question regardless of which Agency provides oversight. In fact, game products, which the consumer clearly recognizes as meat products, fall under FDA jurisdiction, although they may be voluntarily inspected by USDA.

FSIS deserves substantial credit for the significant strides it has taken in recent years to move away from its historical prescriptive, command-and-control regulatory oversight philosophy. Nevertheless, by statute and by regulation, FSIS inspection remains much more intense and prescriptive than inspectional oversight inherent in the FDA inspection philosophy.

As a result, the cost to the public for FSIS inspection is substantially more than for FDA oversight. It is readily apparent to all that funding for the daily presence of one or more inspection personnel in FSIS-inspected processing establishments vastly exceeds the funds required for periodic investigator visits deemed necessary for adequate oversight of FDA-regulated facilities.

Yet the higher costs to the public are not the only added costs of FSIS versus FDA inspection. FSIS-inspected establishments also incur substantial direct and indirect costs not borne by FDA-regulated facilities. These costs include required reimbursement for overtime or holiday inspection service and the expense of obtaining prior label approval.

There are also costs for daily interactions with in-plant inspection personnel, a substantial portion of which have no direct bearing on public health.

There are also added indirect costs to FSIS-inspected establishments, such as the inability to operate if overtime inspection is not available, and the longer time it takes to bring new products to the marketplace. There can also be costs associated with delays in implementing a new technology, such as when a new technology review is required in order to consider any potential impact of the new technology on the inspection process.

The Goal of This Regulatory Jurisdiction Exercise

According to the recent *Federal Register* notice, the primary objective of this jurisdictional reconsideration is to achieve greater consistency and predictability regarding product amenability. Intended or not, it appears the recommendations of the joint Agency working group could also have been intended to result in an approximately equal exchange of establishments between the Agencies so that in the end the relative inspection resource needs of the two Agencies would be little changed.

FPA suggests that such an outcome would represent a failure of FDA and FSIS to utilize this opportunity to simply and effectively broaden the implementation of risk-based inspection for

the enhancement of our nation's public health. The goal of this initiative should not be a reciprocal shift of regulatory oversight. Rather, the goal should be to utilize available information to help categorize the intensity of inspection most appropriate for the types of meat- and poultry-containing products under discussion. These findings should then be the basis for shifts in inspection jurisdiction that will maximize risk-based inspection to the greatest extent allowable under existing statutory constraints. Consequently, we suggest that in the absence of a clearly defined need for the greater level of inspectional intensity inherent in the FSIS inspection system, options for jurisdictional discretion provided within the FMIA and PPIA should be exercised to their fullest.

Statutory Exemption Provisions

Under the FMAI and the PPIA, there are two primary grounds for exempting meat- and poultry-containing products from FSIS inspection. The first is that a product contains meat "only in a relatively small proportion." Though the Agency has historically interpreted this to mean approximately 2 or 3 percent meat or poultry, the threshold level is not mandated by statute and could be modified administratively by FSIS. Indeed this provision of the FMIA and the PPIA readily could be interpreted by reasonable individuals to encompass products with a significantly greater percentage of meat or poultry as routinely eligible for exemption from FSIS inspection.

In its 1994 report, FSIS noted that this exemption was " ... a practical way of focusing limited inspection resources on the meat and poultry manufacturing establishments that Congress intended the legislation to cover." It further noted that "It is only by exempting such products from in plant inspection that FSIS has sufficient resources to focus on higher-risk products." Also in the report FSIS agreed with its contractor's recommendation that " ... a reevaluation of the product exemption thresholds is warranted."

By raising the threshold for the relatively small proportion exemption, the Agencies could maximize this existing statutory option for shifting oversight of certain products to a more appropriate intensity of inspection. Indeed, the poultry regulations and Agency policy for meat products allow higher percentages of certain meat or poultry components (e.g., 15% poultry meat in institutional packs [9CFR 381.15(b)(2)]) to be exempt.

The second primary basis for exemption is for products that " ... historically have not been considered by consumers as products of the meat food industry." As with the "relatively small proportion" exemption, regulatory discretion is available in defining the most appropriate scope of this statutory provision; its meaning is not cast in stone.

We believe that maximizing limited inspection resources should be the most important factor as FSIS and FDA decide which products should be inspected by which Agency. This will require the liberal exercise of these two exemption provisions.

We concur with the 1994 finding in the FSIS report that the threshold limits for exemption should be reviewed. No matter what percentage might be picked as a more appropriate threshold

for exemption, there will always be a basis for questioning why a product with 1% more meat or poultry than the cutoff would not be equally suitable for exemption. No matter what decisions are made about historical consumer considerations there will always be virtually identical products that might fall on the other side of the fence. For this reason, rather than focusing solely on trying to draw black or white distinctions between products that are and are not amenable to FSIS inspection, we suggest the Agencies first consider the level of inspection intensity appropriate for a particular category of products, and then determine if the statutory exemption provisions would allow for efficient and effective regulatory oversight of those products by FDA rather than FSIS.

In addition to the two primary grounds for exemption, there are two additional provisions in the statutes that are pertinent to all products being considered for exemption. The first allows the Secretary of Agriculture to prescribe conditions to assure that the meat or poultry ingredients of exempted products are not adulterated. This condition is readily met by a requirement that the meat or poultry ingredients are derived from animals that were slaughtered under FSIS inspection and that when such ingredients are subsequently used in further processed products, those processing operations are subject to FDA inspection (and all requirements of the Federal Food, Drug, and Cosmetic Act) as well as State inspection.

The second provision is that the exempted products "are not represented as meat food products." Historically, FSIS has relied on product naming conventions to provide this assurance that an exempted product is not being represented as a meat or poultry food product. However, in order to advance the purposes of this regulatory jurisdiction effort, it is critical that an alternative means for meeting this statutory provision is identified. FPA believes that the USDA inspection legend rather than the product name is a much better and clearer indicator of whether or not a product is represented as a meat or poultry food product.

Historical practice would dictate that the names of many currently amenable products would have to be changed to deemphasize their meat or poultry content if oversight of their manufacture was shifted to FDA. However, for marketability and other reasons, it is critical that exempted products be allowed to continue to use product names by which they have been recognized by consumers while under FSIS inspection. To do otherwise would be to deceive consumers into thinking that the products have changed in some significant manner, when they have not. Labeling applied historically to products that contained non-amenable levels of meat or poultry, e.g., beef flavored or flavored with chicken, would clearly not be appropriate for products that contain previously amenable levels of meat. This problem was clearly recognized more than 20 years ago when, in a 1983 FSIS report on amenability issues, it was correctly noted that

> If the Department moves to completely exempt a wide variety of the products discussed .... the product labels should not be changed. It would appear unreasonable to require that "sausage pizza" be labeled as "pizza garnished with sausage" or "pizza flavored with sausage" or even "pizza with a sausage topping." Similarly, it would be absurd to label a frozen TV chicken dinner as a "dinner (flavored, garnished or seasoned) with chicken."

With this in mind, FPA suggests that the product name is not the best indicator of whether a particular product is "represented" to the consumer as a meat or poultry food product as opposed to a food product containing meat or poultry as an ingredient. Rather, we believe the best such indicator will be the presence or absence of the USDA mark of inspection. Regardless of product name, products deemed by the Federal government to be meat food products will bear the USDA inspection legend; products deemed nonamenable will not. While we believe that the presence or absence of the mark of inspection is insignificant in regard to consumer purchasing decisions for formulated food products, any consumer interested in that distinction will have a ready means for knowing which Agency exercises regulatory oversight for any particular product.

Our Recommendations

We believe that in large measure, subjecting previously FSIS-inspected meat or poultry to subsequent FSIS inspection is unnecessary and is an inefficient use of limited inspection resources. With this in mind, it makes sense to transfer from FSIS to FDA inspectional jurisdiction those products which contain previously FSIS-inspected meat or poultry ingredients and for which there is no reasonable expectation that a daily FSIS inspection presence is required to assure their safe manufacture.

For the same fundamental reason, it does not make sense suddenly to subject to daily FSIS inspection any products that (with no known consumer concern about regulatory jurisdiction) over a substantial period of time have been safely produced under FDA oversight. Bagel dogs can be used to illustrate this point. USDA-inspected hot dogs are the predominant ingredient. The hot dogs are then enrobed in a pastry wrap. The resultant bagel dogs have been successfully and safely produced under the oversight of FDA for more than 25 years. (The preamble to the *Federal Register* notice states that the determination that bagel dogs were nonamenable was made in 1979.) In our view, this argues forcefully for maintaining these products under the FDA's purview. It also suggests that corn dogs could also be adequately and effectively inspected by FDA.

Consumers' "Need to Know"

Some commenters at the recent public meeting suggested that consumers would be alarmed if they learned that the manufacture of any food product was shifted from the daily inspection regimen of FSIS to a much lower frequency of inspection under FDA. If presented out of context, the implication that such a product would receive "less Federal inspection," probably could evoke that reaction from consumers.

However, if all the facts were laid out, we believe that many more consumers would be incredulous to learn that many times more public funds are expended on FSIS inspection of certain meat or poultry products than is needed to assure an equivalent level of food safety for virtually identical products overseen by FDA.

Some commenters also suggested that product labels should inform consumers whether a particular product is inspected by FDA or by FSIS. As previously noted, we believe that consumers are highly unlikely to make purchasing decisions for processed food products based on which regulatory agency oversaw its manufacture. Nevertheless, the solicited information is readily available to any interested consumer in the form of the FSIS inspection legend. Products manufactured under FSIS inspection bear the mark of inspection. Products manufactured under FDA inspection do not.

We submit that this statutory requirement for meat and poultry products to bear the appropriate mark of inspection provides the very best indication for consumers as to whether or not a particular product is represented as a product of the meat or poultry industry. Thus it is also the very best means for assuring compliance with the additional statutory restriction on exempted meat or poultry containing products – that they not be represented as products of the meat or poultry industry. Historically, FSIS has utilized the product name as the primary basis for this determination. We believe that the absence of the mark of inspection is a much clearer and effective indicator of products that are not represented as products of the meat or poultry industry. The use of product names for this purpose has always been subject to confusion or ambiguity; the presence or absence of the mark of inspection is clear and definitive.

Relationship to on-going FSIS risk-based inspection initiative

Our suggestions regarding an expansive exercise of the exemption provisions in the meat and poultry inspection acts are very much consistent with our support for FSIS' stated intent to move forward with an enhanced risk-based inspection system that allows for the risk-based allocation of limited inspection resources. That effort is intended primarily to promote public health protection by focusing FSIS inspection oversight on areas that present the greatest risk to public health. The reexamination of jurisdictional boundaries now under consideration provides an excellent opportunity to shift resources from areas that need less intensive coverage to areas that could benefit from a greater level of inspection resources. Any shift of products from FSIS to FDA jurisdiction will free up FSIS inspection resources. Where history shows that specific products or closely comparable processed products have been safety overseen by FDA, such a shift is a move toward the objectives of risk-based inspection and risk-based allocation of limited inspection resources. Any shift in the opposite direction, in the absence of some food safety justification, is a step in the wrong direction – entailing the use of more inspection resources than are necessary and consequently deflecting resources away from recognized needs based on risk.

Response to Questions Posed

The following are our responses to the specific questions posed by the Agencies in the November 7 *Federal Register* notice.

- **Is the approach that is suggested by the agencies a reasonable one? If not, why not?**

  FPA appreciates the effort undertaken by the joint working group to identify many long term inconsistencies in the designation of products as amenable or not amenable to FSIS inspection. We concur with the working group determination that while many of the case-by-case jurisdictional decisions might have made sense at the time, for many years a closer examination of the characteristics of these products has exposed many situations that cannot be justified. However, FPA believes that the effort has not fully captured the opportunities available to define a logical and rational policy on amenability. For example, the express basis for the determination that meat topped pizzas could be exempted from FSIS inspection is equally applicable to a broad range of formulated meat and poultry products, e.g., soups, frozen entrees, wraps and other product lines as discussed below. Furthermore, we believe there is inadequate justification for shifting products that have been successfully and safely overseen by FDA to FSIS inspection.

  But for the tremendous disparity of inspection resources expended by the two sister Agencies to assure the safety of food products under their regulatory oversight, drawing a line of demarcation between amenable and non-amenable products would be much less demanding, since the consequences of falling on one side or the other would be relatively minor. However, this is not the case; the consequences are huge – both for the government and for the impacted industry. It is primarily for this reason that amenability decisions, to the extent allowed by statutory exemption provisions, should be made on the basis of the most effective and efficient utilization of limited inspection resources.

  FPA and its members strongly hold that this should not be an exercise in simply exchanging the regulatory oversight for the manufacture of certain groups of products between the two Agencies so that in the end approximately the same number of plants remain under the jurisdiction of each Agency. This should be about the Federal government taking advantage of this opportunity to use its limited food inspection resources in the most efficient manner possible. Where history has shown or strongly suggests that the less intensive level of inspection provided by the FDA provides an equal assurance of public health protection, the Agencies should exercise the maximum flexibility under the law to exempt food products that contain previously FSIS-inspected meat or poultry ingredients from the more rigorous, but no more protective umbrella of FSIS inspection.

- **Are there other food products or product categories that have been the subject of historical regulatory jurisdictional decisions by FSIS, which were based on a consumer perception factor that should be considered by the agencies?**

  As noted above, FPA believes that many products not mentioned in the November 7 *Federal Register* notice are equally suitable candidates for a shift in inspectional oversight from FSIS to FDA. There are two primary grounds for exemption: "contain meat or poultry only in relatively small proportion" and "historically not perceived by consumers as products of the meat or poultry food industry." We believe both should be broadly applied. The rationale referenced by the Agencies for shifting meat topped pizzas to the FDA purview is, in our opinion, just as applicable to a host of other further processed products. The same distinction between flavoring and characterizing ingredient could be made for many soups, certain refrigerated entrees and meals, turnovers and pocket type meals, egg rolls made with pork or other meat or poultry ingredients, etc. Kit type assembled products are another excellent candidate for clear exemption from the FSIS inspection. FPA has previously made known to FSIS our position that FSIS inspection of assembly operations involving packaged meat or poultry components that were previously inspected by FSIS would be an exceptional waste of limited inspection resources.

- **How many firms or establishments would be affected for each product and product category? What is the volume of production for each product or product category?**

  It is difficult to quantify the number of firms, the number of products or the volume of products that might be impacted by the type of regulatory jurisdiction shifts that are envisioned by the FDA-FSIS working group. However, we believe that any jurisdictional changes should be based on their merits, not on the number of plants or inspection personnel impacted. If FSIS reinspection of meat or poultry ingredients previously inspected at another FSIS-inspected establishment is not needed to assure the safety of food products formulated from those ingredients, and if there is a plausible basis for applying an existing statutory exemption provision to those products, then oversight of their manufacture should be shifted to the FDA, regardless of the number of plants or inspectors impacted.

- **Would there be modifications in equipment, facility design, labeling, recordkeeping, or processing and reporting responsibilities that are needed in order for current operations to continue making the products that are the subject of the suggested changes, and what are they?**

  We believe that there would be few if any changes in manufacturing procedures or food safety practices for the vast majority of companies in the processed food industry due to shifts in regulatory jurisdiction, no matter which way the shift went. This is because food safety is paramount and is an absolute necessity for maintaining a brand name. Indeed food safety is good for business. Most of FPA's members that produce processed meat or poultry products also manufacture very similar items that do not contain meat or poultry. The manufacturing processes and the food safety and quality control practices that are utilized are

typically employed across the board. As such, there would be no changes for individual products that might shift regulatory oversight from one Agency to the other. However, we recognize that this response is very different from our response to the next question about operational costs, which are considerable in regard to dealing with the FSIS inspection system.

- **What would the administrative, operational, marketing, and labeling costs be associated with changes in product jurisdiction?**

  There would be labeling costs for shifts in either direction to either add the USDA inspection legend or to remove it. Since this is not a food safety matter, sufficient time (perhaps a year or more) should be allowed for using up existing labeling stock. However, the greatest increase in cost would be for the manufacturers of products shifted from FDA to FSIS inspection due to the need to comply with more intensive FSIS inspection, including substantial costs for dealing with non food-safety related matters. These costs were previously discussed in more detail under the heading of "Inspection Intensity." (See page 5)

  Another very significant issue could be preserving the ability of firms to conduct business internationally, as well as with the government, i.e., with the school lunch program and sales to the military. Government should find a solution to accommodate the requirements of foreign countries for USDA export certification without imposing additional costs for inspection. Failure to satisfy this potential problem could block market access or reduce domestic industry's ability to complete in the global marketplace. The USDA's Foreign Agriculture Service might be of assistance in resolving issues related to international expectations for export certification.

  Likewise, government assistance may be needed to assure that meat and poultry containing products can continue to be sold to the military or to the school lunch program with no greater level of inspection than is currently required for the sale of FDA-regulated products that do not bear the USDA mark of inspection. If necessary, amendment of regulations pertaining to inspection of product destined for such programs may be necessary.

- **What would be a reasonable process and time frame within which to implement any changes in jurisdiction?**

  This initiative may require a two-tiered process. Shifts from FSIS to FDA could be implemented relatively quickly, especially for the specific products already identified by the FDA-FSIS working group as worthy candidates for such a move. If our recommendations to significantly expand the types of products that should be shifted to FDA oversight would cause a significant delay in moving this effort forward, then we strongly urge the Agencies to consider a two-tiered approach. It is neither necessary nor appropriate to delay the shift in jurisdiction of products about which there is agreement until decisions about additional products can be finalized.

- **What would be consumers' views of the subject products under the suggested approach? More particularly, what effect would changing regulatory jurisdiction have on consumers' perceptions of the subject products? For example, what would consumers' reaction be to the fact that dried chicken soup mix is regulated by FDA?**

  As noted previously, we believe that the vast majority of consumers are very confident in the safety and regulatory oversight of our nation's food supply, including the further processed food products that contain previously FSIS-inspected meat or poultry ingredients and that are the subject of this initiative. When consumers visit their local grocery store, decisions about buying a pepperoni pizza versus a cheese pizza; chicken broth versus beef broth; cheese filled ravioli versus meat filled ravioli; vegetable soup versus vegetable beef soup; seafood dinner versus turkey dinner; packaged lettuce versus packaged lettuce with sliced ham strips, are based on taste preferences, cost, nutritional values, and the like, not on the presence or absence of the USDA mark of inspection.

  Indeed, this position is supported by several prior studies conducted on behalf of USDA. The 1983 FSIS report, previously noted above, stated that several focus group interviews conducted for USDA on consumer perceptions of food grading revealed that, in regard to differences between inspection and grading, "... consumers had little knowledge of either concept." The report concluded that if products were exempt and did not have the USDA inspection legend, "...consumers would still purchase the products." In 1989, a focus group study commissioned by FSIS and conducted by RTI clearly showed that consumers did not recognize that many or most formulated meat or poultry products sold in ready-to-eat form were manufactured under FSIS regulatory jurisdiction. While these reports are somewhat dated, we are not aware of any information which suggests that consumer views on this point have changed over the years. We continue to believe that consumers today rightly have ample confidence that the products under discussion are safe for consumption whether or not their labels bear the USDA mark of inspection.

  In specific response to the question posed by the Agencies, we anticipate only a remote likelihood that a typical consumer contemplating the purchase of dried chicken soup mix would even notice that the container no longer bore the USDA inspection legend. Further, any consumer who did notice such a change would have no basis whatsoever to consider it less safe than the dried beef soup mix sitting next to it on the grocery shelf, which traditionally has not borne an inspection mark.

- **What effects would there be, if any, on the way the subject products are marketed?**

  FPA foresees no impact in the way products are marketed in the event of shifts in regulatory jurisdiction for certain meat- and poultry-containing products.

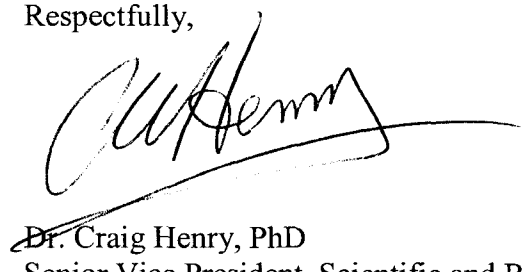
  One proviso here is that any products which are shifted from FSIS to FDA inspection must be allowed to utilize the same product names that they currently use. To require otherwise would be to greatly diminish the marketability of these products and deceive consumers into

thinking that the products for which they have developed a preference and a loyalty suddenly differ in some significant aspect. FDA should consider that established FSIS name as an appropriate common or usual name through a notice or Compliance Policy Guide, with no need for further rulemaking.

This very issue was discussed in the 1983 FSIS report previously mentioned. (See pages 7-8) In regard to labeling policy, that report correctly noted that if USDA completely exempted a wide variety of the products, the product labels should not be changed. The views expressed by the Agency over twenty years ago are equally relevant today. Products which are shifted from FSIS to FDA inspection oversight must be permitted to bear the product names that consumers have grown to recognize.

We thank you for this opportunity to comment on this important issue. We strongly encourage FSIS and FDA not to allow this issue to languish unresolved. Rather than further delay or postpone action to implement needed changes that have been recognized for decades, the Agencies should take this unprecedented opportunity to incorporate shifts in regulatory jurisdiction into ongoing efforts to focus limited inspection resources on the basis of risk. We welcome the opportunity to work with both Agencies to advance this effort for the improvement of public health.

Respectfully,



Dr. Craig Henry, PhD
Senior Vice President, Scientific and Regulatory Affairs
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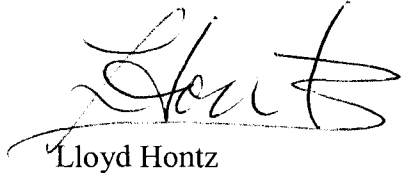

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