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November 16, 2001

FSIS Docket Clerk
United States Department of Agriculture
Food Safety and Inspection Service
300 12th Street SW
Room 102 Cotton Annex
Washington, DC 20250

RE: FSIS Docket No. 01-030N

To Whom It May Concern:

The American Meat Institute (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 U.S. All of our member companies operate under federal inspection. AMI appreciates the opportunity to comment on the above-captioned notice.

The final regulation, "Retained Water in Raw Meat and Poultry Products: Poultry Chilling Requirements," 66 *Fed. Reg.* 1479, January 9, 2001, requires that establishments produce raw meat and poultry products with either no retained water or only the amount of water that is an unavoidable consequence of processes used to meet food safety standards. Establishments must prepare and have on file a written data collection protocol and the data for determining unavoidable moisture retention. If any water is retained, the maximum percentage of retained water must be specified on the principal display panel of the product label.

AMI members have a direct interest in providing unadulterated products in compliance with food safety requirements to consumers. AMI supports efforts to standardize moisture retention in meat and poultry products. AMI would like to reiterate its concerns, as expressed in the industry petition to postpone the effective date of regulations limiting, and requiring labeling for, retained water in raw meat and poultry products.

The time given to comply with the new retained water regulations is insufficient. AMI, along with others, requested an extension of the effective date until at least August 1, 2004. As articulated in the petition, failure to extend the implementation date likely will cause severe adverse economic consequences, as many meat and poultry companies will be unable to collect data and develop new labels before January 9, 2002.

As the petition outlined, and as the comments below will reiterate, the implementation date chosen by the agency is not realistic, and will if adhered to, result in a number of establishments being unable to comply and facing a Hobson's choice of processing product out of compliance or not operating. The agency can obviate that dilemma by granting an extension as requested.

There is insufficient implementation time given to protocol development, data collection, laboratory capacity, and labeling execution.

The agency has greatly underestimated the time needed for final rule implementation. The process of protocol development and data collection necessary for compliance is extremely lengthy. For an establishment to be in compliance with the regulation, four consecutive tasks must be completed. The nature of these tasks, in combination with the industry's limited resources, makes the January, 2002, implementation date impossible to meet. In that regard, to comply with the final rule, the establishment must:

1. Develop a protocol to determine the amount of unavoidable absorbed moisture retained;
2. Initiate "No Objection" protocol;
3. Ascertain the amount of moisture retained by product at the time of packaging; and
4. Obtain new labels and redesign packages to bear the required moisture content declaration.

To achieve industry wide compliance, the petition estimated that the effective date of the final rule would need to be extended to August 2004. Under a best case scenario the timetable would be as follows:

- Protocols submitted by November, 2001;
- Protocols receive "No Objection" (NO) letter by December, 2001;
- Data collection on absorption started by January, 2002;
- Data Collection on absorption (to reflect seasonal variation) completed by January, 2003;
- Data collection on moisture retention, by item, completed by February, 2003;
- All printing plates changed by April, 2004; and
- All labels printed by August 2004.

Protocol Development

On November 2, 2001, FSIS issued compliance guidelines and sample protocols to assist meat and poultry companies in developing protocols. Significantly, it has taken the agency 11 months to put together a sample protocol. Establishments now have a model protocol to follow and the agency could start receiving protocols from the industry as early as November 15, 2001. Because of unfortunate tampering incidents with mail in the past month, mail delivery to the agency has been slowed, lengthening the time to send correspondence to the agency. Under the regulation, FSIS has 30 days to review and comment on a protocol. However, because the agency may lack adequate resources to review the approximate 400 protocols they will be receiving from the meat and poultry industry, it is very likely the protocol review will take more than 30 days. Under a best case scenario, and allowing time for review and mail delivery, the earliest time for establishments to receive their NO letter is December, 2001.

Once the establishment has received its NO letter, the second stage of compliance is the collection and analysis of data in accord with the approved protocol. Although establishments should be able to commence their testing within 30 days of receiving their NO letter, receiving results from laboratories is likely to be difficult. Laboratory facilities are ill equipped to handle the enormous numbers of tests associated with the regulation for the 400 affected establishments.

Laboratory Capabilities and Data Collection and Analysis

Based on the draft model protocol issued by FSIS on July 5, 2001, and the number of affected establishments, approximately 240,000 tests for *Salmonella* will have to be conducted by the industry to comply with the retained water regulation. According to the protocol, five groups of 10 carcasses must be selected to determine moisture absorption during chilling. Additionally, five groups of 10 carcasses must be selected and analyzed for *Salmonella*. Because this sampling and analysis must be done for each of the four variations in the chilling process, 200 samples will have to be analyzed for *Salmonella* in a week. There must be three replicates of the testing for different processing days, so the proposal requires that 600 *Salmonella* samples be analyzed per protocol per establishment. If 400 protocols are ultimately to be submitted, this means 240,000 *Salmonella* tests will be conducted by the industry.

It is simply a fact that there is insufficient laboratory capacity to handle such a load. Given current laboratory capabilities, it would take at least 12 months to complete the required data collection and analysis to determine the amount of absorbed moisture unavoidably occurring as a consequence of the process used to meet a food safety requirement. 66 *Fed Reg.* at 52719 (Oct. 17, 2001).

In addition to laboratory capacity problems, seasonal variation and the naturally occurring variability in moisture will almost assuredly delay data collection. FSIS has recognized that "there is more than one level of naturally

occurring water” based on seasonal variation; therefore, an establishment must know what the maximum amount of retained water will be, regardless of the time of the year, for appropriate moisture declaration on all packaging. Notice 22-01, section X (Attachment 4) 66 *Fed Reg.* at 52719 (Oct. 17, 2001). For seasonal testing to occur, at a minimum, a one-year testing period is necessary to enable establishments to ensure that moisture level declarations on labeling are accurate, despite seasonal variation. In short, a one-year data collection period will enable the industry to ascertain the amount of moisture absorption that is an unavoidable consequence of the process used to meet food safety standards.

Moisture Retained in Packaging

Once the establishment has determined how much moisture is an unavoidable consequence of meeting food safety requirements, it must determine how much moisture is retained in the product at the time of packaging. *The amount of water retained at packaging almost always will be less than the amount absorbed, and, in many cases, significantly less.*

Determining the amount of moisture at the time of packaging can only occur after the plant determines which chilling method results in the lowest moisture absorption levels. Once determined, representative samples will be taken to determine the naturally occurring moisture; and similar sampling and analysis will be conducted on the product as packaged. If 400 protocols are submitted, multiplied by the number of “major” raw products, the resulting number is 3,600. Taking a minimum of 10 samples in duplicate to calculate the naturally occurring moisture and the moisture-before-packaging results in 72,000 samples. Finally, for statistical significance, there must be at least three repetitions of this data, resulting in a total of 216,000 samples. This sampling and data analysis will require at least two, if not three months, bringing the project timeline to February 2003.

Labeling Implementation

The final step in retained moisture compliance is labeling implementation. For any label changes to occur, new plates have to be created; and then the labels must be printed and shipped. Because more than 6,500 labels will need to be revised and suppliers have the capacity to create about 450 new labels per month, it will take a minimum of 14.4 months before all of the plates have been tooled, which yields a reasonable implementation date of no earlier than August, 2004. Given the above discussed timeline, it is clear that the agency has not allowed the industry sufficient time to prepare for the implementation of the retained water regulation.

The Compliance Date would be Inequitable

Many facilities do not have on-site laboratories and therefore are dependent upon commercial laboratories to conduct all of their analyses. Due to the massive number of tests to be conducted industry wide, establishments relying on other laboratories may be further delayed in data collection and analysis than those who can conduct their tests in-house. It would be unfair to provide less than one year to conduct all testing caused by the delays in the labs. To level the playing field everyone should have sufficient time to conduct the requisite testing and analysis.

Extending the Compliance Date would not Adversely Affect Consumers.

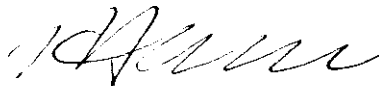
Postponing the rule's effective date of the retained water regulation will have no adverse affect on consumers. The only way the consumer would be adversely affected by the implementation of this regulation would be if it were implemented too soon, which would force many meat and poultry establishments to close and result in increased prices for consumers. If no extension is granted, the industry will simply have to cease production, resulting in loss of jobs and adversely affecting the viability of many companies.

Summary

As demonstrated by the above discussion, it is virtually impossible for all meat and poultry companies to be in compliance with the moisture before the August 2004, date requested in the petition. Given the realities associated with protocol development, data collection, data analysis, and label retooling, it is critical that the agency adjusts the effective date of the new labeling requirement. Absent an extension, implementing the rule could result in an economic disaster and the essential closing of an industry.

AMI appreciates the opportunity to submit these comments. If you have any questions about these comments, AMI's position, or anything else regarding this matter, please contact me.

Sincerely,



Mark D. Dopp