Proposed Rules

Federal Register
Vol. 66, No. 201
Wednesday, October 17, 2001

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 381 and 441

[Docket No. 01–030N]

RIN 0583–AC87

Announcement of and Request for Comment on Industry Petition to Postpone the Effective Date of Regulations Limiting and Requiring Labeling for Retained Water in Raw Meat and Poultry Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Opportunity to comment.

SUMMARY: The Food Safety and Inspection Service (FSIS) is requesting comment on a petition that asks FSIS to postpone until August 1, 2004, the effective date of new regulations that limit water retained by raw meat and poultry products from post-evisceration processing to the amount that is unavoidable in meeting applicable food safety requirements, such as the pathogen reduction requirements for *Salmonella*, and require labeling for the amount of water retained. The regulations were published in the final rule ''Retained Water in Raw Meat and Poultry Products; Poultry Chilling Requirements,'' in the **Federal Register** on January 9, 2001.

The petitioners, four trade associations representing the meat and poultry industries, assert that the postponement is necessary because affected companies will not be able to comply with the regulations until they have completed several steps for which the Agency did not allow sufficient time. The petitioners maintain that: Because of the time necessary to obtain Agency review of industry data collection protocols for determining minimum retained water in products, some companies will not be able to begin data collection under the protocols until late in 2001; because of insufficient laboratory capacity in the industry and because of the need to determine seasonal variation in moisture content of poultry and the relation between water retention controls and *Salmonella* levels on raw product, data collection on water absorbed during chilling processes, and then on water retention in individual raw products at packaging, cannot be completed until early 2003; and once retained water levels have been determined, changes to plates for printing labels and the labeling of the many products affected by the final rule cannot be completed until mid-2004. The petitioners elaborate on these points in their petition and supporting documentation. Finally, they argue that if no extension were granted, the economic consequences would be severe. Much of the industry would have to shut down because of the inability to ship product that is not misbranded.

DATES: Comments must be received on or before November 16, 2001.

ADDRESSES: Submit one original and one copy of written comments to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 300 12th Street, SW., Room 102 Cotton Annex, Washington, DC 20250. Please refer to docket number 01–030N in your comments. All comments submitted in response to this proposal, as well as research and background information used by FSIS in developing this document, will be available for public inspection in the FSIS Docket Room between 8:30 a.m. and 1 p.m., and 2 p.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Dr. Daniel L. Engeljohn, Director, Regulations and Directives Development Staff, OPPDE, FSIS, U.S. Department of Agriculture, Washington, DC 20250–3700; (202) 720–3219.

SUPPLEMENTARY INFORMATION:

Background

For many years, meat and poultry slaughtering establishments have conducted carcass-chilling operations differently. In livestock slaughtering establishments, carcasses undergo a final wash after slaughter and dressing to remove remaining consumer protection defects before being air-chilled in large coolers. In the coolers, a water mist is typically applied to the carcasses to minimize shrinkage and promote rapid heat loss. Water mist systems must be operated in a manner that does not result in meat carcasses weighing more than their pre-chilled weight.

Most poultry processors chill poultry using the water immersion chilling method, which is faster and more cost efficient than air chilling, but results in absorption and retention of water both in the skin and in the tissue under the skin. Because immersion chilling is considered an efficient way to lower the internal temperature of poultry, FSIS has permitted the retention of some water in poultry. But because a product containing excessive water may be considered adulterated, FSIS has consistently required that the retention of water in meat and poultry be minimized and has enforced regulations limiting the retained water percentage in the carcasses.

In 1994, a group of poultry consumers and red meat producers sued the USDA in U.S. District Court (*Kenney, et al.* v. *Glickman*), alleging that poultry products containing absorbed water were both economically adulterated and misbranded within the meaning of the Poultry Products Inspection Act (PPIA). They also disputed the differences in regulations concerning water retention by meat and poultry.

In July 1997, the Court found that the presence of absorbed water in poultry did not mean that the product was necessarily economically adulterated or misbranded under the PPIA. However, the Court set aside the regulations specifying water absorption and retention limits for whole poultry. The court noted that the record of the rulemaking in which those levels were established did not explain how the particular water retention levels were determined, why water retention in poultry cannot be reduced below current levels, or why meat and poultry levels should be treated differently.

In September 1998, responding to the Court's ruling and rulemaking petitions filed with the Agency by several livestock industry associations, FSIS issued a proposed rule that would restrict the amount of water that could be retained by raw meat and poultry carcasses and parts. Specifically, the Agency proposed revising the moisture absorption and retention regulations by limiting the amount of water retained by

raw meat and poultry carcasses and parts as a result of post-evisceration processing to the amount unavoidable in achieving a food safety objective.

FSIS also proposed revisions to the poultry chilling regulations to improve consistency with the Agency's Pathogen Reduction/Hazard Analysis and Critical Control Points (PR/HACCP) regulations, eliminate ''command-and-control'' features, and reflect current technological capabilities and good manufacturing practices. Some of the regulatory provisions that were to be eliminated or replaced with performance standards were those specifying the manner in which opening cuts are to be made in poultry before evisceration, chilling equipment features, fresh water replenishment rates for continuous chillers, the type of giblet wrap to be used, and the method for thawing frozen poultry to be used in further processed products.

On January 9, 2001, FSIS published a final rule in the **Federal Register** (66 FR 1750) promulgating regulations that limit the amount of water that could be retained by raw, single-ingredient, meat and poultry products as a result of post-evisceration processing, such as carcass washing and chilling. Under the regulations (codified at 9 CFR 441.10), which become effective January 9, 2002, raw livestock and poultry carcasses and parts will not be permitted to retain water resulting from post-evisceration processing unless the establishment preparing those carcasses and parts demonstrates to FSIS, with data collected under a written protocol, that any water retained in the carcasses and parts is an inevitable consequence of the process used to meet applicable food safety requirements. The protocol and data collected under it must be available for review by FSIS. The labels of products covered by the rule must bear statements on their labels indicating the maximum percentage of retained water in the products. The final rule also revises the poultry chilling regulations (in 9 CFR 381.65, 381.66) as proposed, with technical adjustments made in response to comments. On June 29, 2001, FSIS issued instructions to its personnel (FSIS Notice 22–01) on procedures, including those for review of data collection protocols, that are to be followed during the period before the new water retention regulations become effective.

Since publication of the final rule, FSIS has met on several occasions with representatives of the regulated industry, has responded to requests for clarifications and further information, and has exchanged correspondence with the industry on various matters relating to the final rule. During this time, some industry representatives have consistently expressed doubts about the ability of companies to comply with the provisions for retained water minimization by the effective date.

In a July 16, 2001, letter to the Secretary of Agriculture, the National Cattlemen's Beef Association (NCBA) stated that NCBA had been informed by representatives of the poultry industry that they were considering seeking an extension of the implementation deadline. Citing the chronicle of litigation, industry petitions, and regulatory proposals on retained water from 1994 till the present, NCBA characterized the process leading to the final rule as ''painfully slow.'' NCBA maintained that the beef industry had worked hard to bring fairness to the issue and was ready for the meat and poultry industry to comply with the new regulations, and that the association could not support an extension.

Petition

FSIS received a petition dated August 17, 2001, signed by the following organizations: The American Meat Institute, National Chicken Council, National Food Processors Association, and the National Turkey Federation. The petition requests that FSIS postpone until August 1, 2004, the effective date of the new regulations that limit and require labeling for the amount of water retained by raw meat and poultry products from post-evisceration processing (9 CFR 441.10).

The petitioners assert that postponement of the effective date is necessary because affected companies will not be able to comply with the regulations until they complete several steps for which the Agency allowed insufficient time. First, the petitioners state that the time necessary to obtain Agency review of industry data collection protocols for determining minimum retained water in products will mean that some companies will not be able to begin data collection under the protocols until late in 2001. Second, they state that, because of insufficient laboratory capacity in the industry, data collection on water absorbed during chilling processes and then on water retention in individual products at the time of packaging, cannot be completed until early in 2003. In this connection, they note that a one-year data collection period will be necessary to determine seasonal variation in the moisture content of poultry and the relation between water retention controls and *Salmonella* prevalence on raw products. Finally, they state that changes to plates for printing labels and the labeling of the many products affected by the final rule cannot be completed until mid-2004.

The petitioners elaborate on these points in their petition and supporting documentation. They present an ''optimistic timeline'' that begins with the submission of industry protocols for FSIS review by September 15, 2001, and ends with the printing of all new retained-water labels by August 1, 2004, cautioning that the timeline assumes no significant problems at any stage that would introduce delays. ''Given the realities associated with this optimistic timeline,'' they say, ''it is critical that the agency adjust the effective date to allow for a realistic implementation of the new labeling requirement.'' They say it is possible that some establishments or labels will not be in compliance with an August 1, 2004, implementation date, and that the Agency should invoke the regulatory provisions for temporary label approvals (9 CFR 381.132(f)) in that eventuality.

The petitioners conclude their petition by forecasting an extremely severe economic impact if an extension is not granted because of the inability of the poultry industry to avoid shipping product that is misbranded under the PPIA. Misbranded product cannot bear the mark of inspection and thus cannot be shipped (21 U.S.C. 457(d), 458(a)(2)). An establishment that cannot ship product is closed, for practical purposes. ''In fact,'' the petitioners emphasize, ''if no extension is granted, industry would simply have to cease production, throwing thousands of people out of work and resulting in the bankruptcy of virtually all companies.''

The petitioners do not address the technical revisions of the poultry chilling regulations. FSIS therefore assumes that they do not object to the January 9, 2002, effective date for those revised regulations.

Questions

FSIS is seeking public comment on the industry petition. To help in deciding this matter, FSIS would appreciate any additional information not already made available to the Agency. In particular, responses to the following questions relating to the petition would be appreciated:

1. Did the Agency allow the regulated industry sufficient time—one year from publication of the final rule—to prepare for implementation? Explain why the time for implementation was adequate or inadequate.

2. Is available laboratory capacity sufficient or insufficient to enable the

industry to comply with the new regulations by the effective date?

3. Is there additional information on the time necessary to produce new labels for retained-water products that the Agency should consider?

4. Would postponement of the effective date be fair or unfair to anyone and, if so, how?

5. Would postponement of the effective date of the new retained water regulations (9 CFR 441.10) affect consumers and, if so, how?

Text of the Petition

Citizen's Petition to Extend the Effective Date of 9 CFR 441.10.

The undersigned associations, on behalf of their members, respectfully submit this Citizen's Petition to extend the effective date of the Food Safety and Inspection Service's (FSIS or the agency) final regulation entitled ''Retained Water in Raw Meat and Poultry Products: Poultry Chilling Requirements,'' 66 FR 1479 (January 9, 2001) (to be codified at 9 CFR 441.10).

This regulation is scheduled to become effective on January 9, 2002. Simply put, it is impossible for our members to comply with the regulation by that date. This petition sets before the agency the obstacles preventing January 2002 compliance, obstacles which are out of our members' control. Even with the smoothest of implementations, the earliest date for compliance is August 1, 2004.

A. Action Requested

We respectfully request that the effective date of the moisture regulation be extended until August 1, 2004.

B. Statement of Grounds

To achieve compliance with the regulation, establishments need to complete four separate tasks—tasks that must be done consecutively, not concurrently:

1. The establishment has to determine the amount of absorbed moisture that is an unavoidable consequence of meeting a food safety requirement. To determine this level, the regulation requires that the establishment develop a protocol. Until FSIS accepts a protocol, an establishment cannot begin to collect the data.

2. After receiving a ''No Objection'' letter from the agency, an establishment would initiate the procedure to determine the unavoidable amount of absorbed moisture.

3. Once the establishment has validated the amount of moisture that is unavoidable, there remains the matter of ascertaining the amount of moisture retained by product at time of packaging.

4. Finally, the establishment must work with its suppliers to obtain new packages bearing the required declaration.

Only after these four steps have been completed can there be compliance. Unfortunately, each step poses a variety of difficulties that simply cannot be overcome to meet the effective date set by FSIS, even if companies act in the most expeditious manner.

1. Protocol Approval

Upon publication of the final rule, we immediately began a complete review of the new requirements and planned for the ambitious undertaking of converting labels to be in compliance with the new required label declaration. Following extensive industry technical meetings, it became apparent that there were significant questions not addressed by the final rule for which clarification is necessary before implementation can commence. We have, and will continue to work closely with the agency to ensure compliance with the final rule.

The first task is to develop the protocol to ascertain the amount of moisture unavoidably absorbed by the product as a consequence of a process used to meet food safety standards. As promulgated, the regulation imposes the ''command and control'' requirement that such protocols must be submitted to FSIS. Only protocols receiving a ''No Objection'' letter could be used to ascertain the moisture absorption.

In light of this requirement, we contacted FSIS as soon as the regulation was published to obtain guidance on what would be required in such protocols. A meeting, prompted by significant questions raised by industry as to practical compliance with the new rule, was held at the FSIS Technical Service Center in February. There were a host of issues surrounding the protocols, as well as general regulatory compliance with the rule. Many of these issues have been resolved, such as what food safety standard would be appropriate to use in determining unavoidability. However, several key issues remain unresolved, such as the use of thighs to determine compliance. We hope that, with further dialogue, industry and the agency will work to a cooperative and timely resolution of these issues, thereby paving the way for complete implementation.

Having discussed the agency's expectations regarding the protocol in February, we agreed to submit generic protocols for agency review and comment in order to obtain guidance on what the agency wanted in the protocol. On May 21, 2001, four generic protocols were submitted to FSIS. (Attachment 1). Notwithstanding the good faith efforts to submit protocols in compliance with the regulatory requirements, FSIS responded on July 5, stating: ''None of the protocols fully addressed the data collection and information required by the regulations.'' Letter from Phillip S. Derfler, Deputy Administrator, FSIS. (Attachment 2). In lieu of comments on the draft protocols, FSIS developed its own model protocol. Unfortunately, we have unresolved questions with the model. Believing it is more expedient to resolve any uncertainties before having our members submit protocols, we submitted a request for clarification on August 3, 2001. (Attachment 3). That request is still pending.

Assuming the agency responds promptly to our request for clarification (e.g. September 1, 2001), our members can begin to draft the protocols. We estimate that such drafting will be relatively simple once the outstanding questions are resolved. Assuming two weeks for drafting and submission, FSIS will begin receiving protocols from the majority of the industry on or about September 15th.[1]

Under the regulation, FSIS has 30 days to review and comment on a protocol. However, we respectfully submit that the agency lacks adequate resources to review the estimated number of protocols in a timely manner. The National Chicken Council estimates that its members will submit at least 265–300 protocols and the National Turkey Federation estimates approximately 80 protocols. This number does not include protocols from poultry slaughter establishments that may not be a member of either association. Likewise, it does not include any protocols submitted by red meat companies. We do not know how much staff time FSIS has allocated to the review, but we anticipate that completion of the review of approximately 400 protocols will take over thirty days.[2]

Although the regulation provides for passive ''approval'' of the protocols (i.e., if no objection is raised within the 30 days, the agency cannot subsequently raise an objection), we respectfully disagree that this will be how the matter will be implemented in the field. In this regard, we direct your attention to FSIS Notice 22–01; specifically, the Retained

[1] We understand that some companies have already submitted protocols that have been reviewed by the agency. However, the majority of broiler establishments and almost all turkey establishments have not yet done so.

[2] We note that it took FSIS six weeks to review four generic protocols and develop one of its own.

Moisture Checklist for IICs.[3] Item 2 on this checklist requires the IIC to identify the date of the FSIS No Objection Letter. If 30 days have passed and no letter has been received, we believe many, if not most, IICs will not permit the establishment to proceed in light of the instructions contained in the Notice. Moreover, we remain concerned that the agency may indeed suggest changes to a protocol after the thirty-day period has passed. Hence, some legal counsel have advised members not to initiate any protocol until a No Objection letter has actually been received.

We can only speculate as to the time it will take for FSIS to complete the review. Assuming that FSIS anticipated 300 protocols (because it estimated there are approximately 300 establishments covered by the rule, 66 Fed. Reg at 1,768, colt 3) and established a 30 day review period, it seems that 400 protocols would take 40 days. Adding five days for mail delivery, the earliest time for all establishments to have received the No Objection letter is November 1, 2001.

2. Collection and Analysis of Data

a. Laboratory Capacity

Once the establishment receives its No Objection letter, the second task is to conduct the protocol. Although the establishment should be ready to commence the study within 30 days (e.g. December 1, 2001), the sheer volume of the sampling will cause bottleneck delays at the laboratories—delays beyond an establishment's control.

Assuming all establishments follow the Model Protocol[4] contained in the FSIS July 5 letter, the establishment is to select five groups of 10 carcasses to determine moisture absorption during the chilling process. In addition, under section 7.2 of the Model, the establishment is to randomly select five groups of 10 carcasses from the flocks selected for moisture absorption testing. This latter sample set is to be analyzed for *Salmonella.* The *Salmonella* sampling and analysis is to be done for each of the four variations in chiller factors; in other words, 200 samples are to be analyzed for *Salmonella* that week. Moreover, under the Model Protocol, there must be three replicates of the testing for different processing days. Thus, the draft proposal calls for 600 *Salmonella* samples to be analyzed per protocol. If 400 protocols are ultimately submitted, this means 240,000 *Salmonella* tests are to be conducted by the industry. To put this number in context, in the first two years of HACCP implementation, FSIS only conducted 44,272 *Salmonella* analyses[5] or approximately 18% of the total FSIS expects the industry to conduct before the January 9, 2002, effective date.

Put bluntly, there is insufficient laboratory capacity to handle such a sampling and testing overload. We have spoken with several of the major private laboratories that can perform *Salmonella* analyses. According to Dr. Paul Gerhardt of the National Food Laboratories, his laboratory can handle 700 samples per week at the current time (or 36,400 per year, about 15% of the total required). To be sure, existing laboratory capacity could be increased, but this would take six months lead-time and ''contractual assurance of testing.'' (Attachment 5.) Dr. Gerhardt's conclusion is supported by other private laboratories with which we have spoken.

Dr. William Brown of ABC Research, one of the major laboratories analyzing meat and poultry products, estimated that his laboratory could handle approximately 150 additional samples per day or 39,000 in 12 months. Dr. Brown also cautioned that such a massive testing program could result in a shortage of laboratory supplies, thereby increasing cost of these materials and the analyses themselves. (Attachment 6.)

Mr. Kurt Westmoreland of Silliker Laboratories Group, one of the largest laboratories, commented that, even though Silliker has eleven laboratories, the volume of tests required ''would be very difficult to complete within the time frame.'' Moreover, this additional *Salmonella* testing would displace ''other much needed food safety based testing.'' Although Mr. Westmoreland did not anticipate higher costs for the supplies given his laboratory's buying power, he too was concerned as to the availability of testing supplies. (Attachment 7.)

Beyond private laboratories, several of our members with their own laboratories have estimated the time it would take to analyze the additional *Salmonella* samples generated by the Model Protocol. According to Dr. Neal Apple, Vice President of Tyson Corporate Laboratory and Research Services, it would take his laboratory approximately 10.5 months to conduct the 42,000 *Salmonella* analyses his company anticipates would be required under the Model Protocol, ''[b]arring any sample submission or testing problems.'' Even this would ''generate a considerable amount of overtime for our laboratory group and contribute to decreasing the technical flexibility that the laboratory currently has.'' Statement of Dr. Neal Apple. (Attachment 8.)[6]

Dr. Lee G. Johnson, Chief Microbiologist, ConAgra Refrigerated and Prepared Foods, anticipates it will take six months at the very least, with eight months being more realistic, to complete the analysis for its establishments. Statement of Dr. Lee G. Johnson. (Attachment 9.) Dr. Johnson also raises the issue of whether there will be enough testing reagents and supplies available to conduct the analyses. A shortage of these materials caused by excess demand would delay the analyses even further.

Mr. Jason Tisch, Assistant Manager, Deibel Laboratories (Cargill) frankly admitted his laboratory would be forced to contract out the additional volume generated by the protocols and it would still likely take 10.5 months to complete the necessary analysis. In addition, the added tests ''will limit the amount of research and development currently being conducted'' by the laboratory. Statement of Jason Tisch. (Attachment 10.)

Obviously, the above does not even address the significant testing costs.[7]

As the statements of the laboratory managers demonstrate, available laboratory resources, private or corporate, cannot handle in an expeditious fashion the workload generated by the *Salmonella* testing requirement. It is a matter of capacity. Moreover, available capacity cannot easily be expanded: Not all laboratories are structured to conduct pathogen testing; the laboratories may be in the plant (with exposure to other raw product and cross contamination); or, the employees may not be trained in handling such biological hazards. As Dr. Gerhardt pointed out (Attachment 5), not only will it take time to significantly expand capacity, but laboratories would expect ''contractual assurances of future testing,'' assurances that may not be forthcoming given that the testing here would be a one time occurrence. Nor, as Mr. Westmoreland cautioned, is it advisable to shift existing resources from current pathogen testing currently

[3] This Notice, issued June 29. 2001, also codified the agency's position on many issues discussed at the February meeting in Omaha. (Attachment 4.).

[4] The FSIS Model Protocol was an enclosure to the July 5th Derfler letter (our Attachment 2).

[5] http://www.fsis.usda.gov/ophs/haccp/salmcomp.htm.

[6] Interestingly, this company would be required to analyze approximately the same number of samples as FSIS analyzed in all of 1998 and 1999.

[7] At approximately $30 per sample for *Salmonella,* the costs are $7.2 million, assuming the costs of the reagents/supplies do not increase, a potential problem noted by Dr. Brown (Attachment 6).

used to maintain and enhance food safety. Hence, the new requirement can only be fulfilled through excess capacity which will result in longer turnaround times.

In short, barring any problems whatsoever we estimate it will take the majority of establishments approximately 12 months from the time a ''No Objection'' letter is issued, to complete the required data collection to determine the amount of absorbed moisture unavoidably occurring as a consequence of the process used to meet a food safety requirement. This brings us to December 1, 2002, as the best case scenario.[8]

b. Seasonality

Even though the above demonstrates the impossibility of conducting all the necessary analyses in less than one year, there is another factor which supports conducting the analysis over a year's time—seasonal variation.

i. Naturally occurring, variability in moisture. On the issue of moisture variation, as FSIS has recognized, there may be ''more than one level of naturally occurring water'' based on seasonal differences. Notice 22–01, section X (Attachment 4). Although an establishment may choose to have different declarations based on seasonal variation, it is essential that, in determining the appropriate moisture level to declare on the labels, the establishment know what the maximum amount will be, regardless of what time of year it occurs.

To confirm the FSIS conclusion as to seasonal moisture variability, we have received some data from our members concerning moisture levels. Because we do not have data on moisture levels per se, our members have provided us with data comparing the live weight of the birds to the finished yield. As the attached data (Attachment 11) show, the yield was low during the summer months, even though bird weight remained constant. In the winter months the bird weight varied, but yield remained constant. A likely cause of this variability in yield during the summer (without a corresponding variation in weight) is that moisture content of the birds is low in the summer. When the temperature cools, the moisture content is no longer a variable and the establishment can control yield better, notwithstanding fluctuations in live weight.

An extension of the effective date to permit a one year collection period would enable establishments to ensure that the moisture level declarations placed on labels will be valid no matter what seasonal variations there are in moisture.

ii. Salmonella incidence variability. To better ensure compliance with the agency's performance standards, several of our members conduct their own Salmonella testing. Based on the data provided to us by establishments, it is clear that even at establishments with an overall low *Salmonella* incident rate, the incidence rate is not consistent throughout the year. For some establishments there is a higher incident rate in the summer months. Indeed, the data forms a rough bell curve when plotted by months. (Attachment 10). However, we have received data from other establishments that show *Salmonella* incidence rises in the fall/winter. (Attachment 13).

The amount of unavoidable moisture is tied to achieving a food safety requirement; specifically, the Salmonella performance standard. If Salmonella incidence varies during the year, it is important to ensure that controls on the moisture levels do not restrict the establishment's ability to achieve compliance with this food safety standard.

In sum, a data collection period of one year will assist us in better ascertaining the amount of moisture absorption that is an unavoidable consequence of the process used to meet a food safety standard. However, we wish to re-emphasize that a one-year data collection period is unavoidable in any event due to the restrictions imposed by laboratory capacity.

3. Determining Amount of Moisture Retained in Products

Once the establishment has determined the amount of moisture absorption that is unavoidable, it will proceed to the third task—to determine how much moisture is retained at time of packaging. For all items, the amount retained will be less than the amount absorbed and, in many cases, significantly less.

This calculation will be done by taking representative samples of whole birds and parts to determine the average naturally occurring moisture, such as with the oven drying method. The establishment must then conduct similar sampling and analysis on the product as it will be packaged. An establishment would not conduct this sampling until it has determined which chiller method results in the lowest absorption; otherwise, it would be required to conduct this sampling/analysis for each of the four variations, increasing costs and straining laboratory capacity.

We conservatively estimated the number of moisture retention tests that must be conducted. In that regard, we multiplied the number of estimated protocols submitted (400) by the number of major raw products.[9] We then multiplied the resulting number (3,600) by the number of samples in a set (we estimate that 10 samples would be the minimum amount to provide statistically significant results). This total of 36,000 was doubled (because an establishment must ascertain the naturally occurring moisture and the moisture content before packaging) and then multiplied by three repetitions (which we took from the FSIS model protocol for absorption). This results in a total of 216,000 moisture samples. Although many of our members will conduct the analysis in house, we expect it will take at least two, if not three, months to conduct the sampling and analyze the data. This process brings us to February, 2003, at the very earliest.

4. Labeling Implementation

According to the above time line, it will be February of 2003 before all establishments will know the amount of retained moisture, as contemplated by the regulation. Only then can establishments begin their fourth and final task, to make label changes. There are two steps in implementing any label change: New plates have to be created and the actual labeled packages have to be printed/shipped.[10] The majority of the labels are printed on the film package and not affixed by sticker.[11] This is because the processing and storage of the products, such as frozen turkeys, makes it impossible for an adhesive to remain on the film. Based upon an informal survey of our members, we estimate more than 6,500 labels (5,600 broiler labels and 950 turkey labels) will need to be revised to declare moisture. See Statements of Stephen Pretanik (attachment 14—broiler labels) and J. Roy Escoubas (attachment 15—turkey labels). To estimate the necessary time to perform such modifications, Mr. Escoubas contacted the principal packaging

[8] Please note, this does not factor in any additional time for data analysis. Nor does it account for the possibility that additional tests may need to be conducted.

[9] Whole birds; halves; quarters; breast (with and without skin); wings; legs: drumsticks; and ground.

[10] During the data collection period, our members could work on redesigning labels to expedite the process. However, until the retained moisture level is ascertained, the plates cannot be tooled.

[11] The discussion herein will focus on obtaining retail labeled packages. Labels of products intended for institutions and/or further processing are normally printed on the shipping container or affixed by a sticker. These labels will not pose the difficulties generated by retail product.

suppliers to the industry. The suppliers estimated that they have a capacity to design and tool a maximum of 450 new product labels per month. See Escoubas Statement. (Attachment 15). Taking the total number of labels and dividing by the excess capacity of 40, we estimate it will take 14.4 months before the plates have even been tooled. This means actual printing could not begin on all labels until April 1, 2004.

Finally, at this point, labels bearing the required declaration will be printed. Recognizing that there can be a ''rolling'' plate change/printing schedule, where labels are printed as soon as plates are ready, there would clearly need to be some period for printing after the last plate has been finalized. We estimate four months. Accordingly, as a matter of printing capacity, labels bearing the moisture declaration will not appear on all products until August 1, 2004.

Summary

As established by the above discussion and supporting documentation, it is simply impossible for companies to be in compliance with the moisture regulation until August 1, 2004. The time line once again:

- Protocols submitted by September 15, 2001
- Protocols receive No Objection letters by November 1, 2001
- Data collection on absorption started by December 1, 2001
- Data collection on absorption completed by December 1, 2002
- Data collection on moisture retention, by item, completed by February 1, 2003
- All plates changed by April 1, 2004
- All labels printed by August 1, 2004

Given the realities associated with this optimistic timeline, it is critical that the agency adjust the effective date to allow for a realistic implementation of the new labeling requirement.

Margin of Error

We cannot overemphasize that the above timeline presumes no significant problems. For example, if FSIS objects to many of the protocols, there will be delay as the agency and the establishments work to resolve any differences. There may also be delay in gathering the data at some establishments given the FSIS policy decision not to permit experimentation if the establishment has failed its most recent Salmonella performance standard series. Notice 22–01, section XII (Attachment 4). There may also be delay in obtaining new labels if FSIS mandates any new labeling requirement, such as mandatory nutritional labeling for single ingredient products, so as to require additional revisions of the labels after companies have begun printing the labels in compliance with the moisture regulation. It may be advisable to provide some margin for error in the revised effective date.

Obviously, we hope that the vast majority of labels would be in compliance by August 1, 2004. However, for the reasons discussed above, and for other unforeseen difficulties, there is a strong possibility that some establishments and/or product labels will not be in compliance by the revised date.[12] Accordingly, we respectfully request that FSIS acknowledge this potential and indicate that the provisions of 9 C.F.R. § 381.132(f) dealing with temporary label approvals would apply in such circumstances.

C. Environmental Impact

Petitioners are unaware of any adverse environmental impact that would result from an extension of an effective date for a mandatory label requirement. We do note that a viable effective date would minimize the amount of film labels that will have to be discarded.[13]

D. Economic Impact

Up until this point, we have not focused on the economic impact on the industry to comply with the regulation by the current effective date. Obviously, an impossibly short effective date could have an extremely adverse economic impact. In fact, if no extension is granted, industry would simply have to cease production, throwing thousands of people out of work and resulting in the bankruptcy of virtually all companies.

The closure of a company constitutes irreparable injury.[14]

E. Certification

The undersigned certifies that, to the best knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and other information known to the petitioners which are unfavorable to the petitioners.

Respectfully submitted

The American Meat Institute
The National Chicken Council
The National Food Processors Association
The National Turkey Federation

Submitted August 17, 2001

Description of Attachments

As mentioned, the petition is accompanied by 14 attachments, which are available for viewing in the FSIS Docket Clerk's Office at the location indicated in **ADDRESSES.** The attachments are as follows:

Attachment 1—May 21, 2001, letter to Mr. Philip S. Derfler, Deputy Administrator, OPPDE/FSIS, from National Turkey Federation and National Chicken Council, enclosing 2 proposed protocols for evaluating moisture retention in poultry products

Attachment 2—July 5, 2001, letter from Mr. Philip S. Derfler, Deputy Administrator, OPPDE/FSIS, to Mr. Stephen Pretanik, National Chicken Council, enclosing FSIS-amended generic protocol for evaluating retained water in single-ingredient poultry products

Attachment 3—August 3, 2001, letter to Mr. Philip S. Derfler, Deputy Administrator, OPPDE/FSIS, from Mr. Stuart E. Proctor, Jr., National Turkey Federation, and Mr. Steve Pretanik, National Chicken Council.

Attachment 4—FSIS Notice 22–01, 6/29/01, ''Procedures for FSIS Personnel during Pre-implementation Period for 'Retained Water in Raw Meat and Poultry Products; Poultry Chilling Requirements' ''

Attachment 5—August 14, 2001, letter from Paul N. M. Gerhardt, Ph.D. National Food Laboratory, Inc., ''to whom it may concern,'' on laboratory capacity limitations affecting microbiological testing of poultry product samples

Attachment 6—August 14, 2001, electronic mail message from William L. Brown, Ph.D., President, ABC Research Corporation, ''to whom it may concern,'' on laboratory capacity for microbiological testing of meat samples

Attachment 7—August 15, 2001, electronic message from Kurt Westmoreland, Silliker Laboratories Group, Inc., to Mr. Steve Pretanik, National Chicken Council, on laboratory capacity for

[12] This may be especially true for turkey products, many of which are sold during the holidays in November and December, only three months after the earliest possible compliance date.

[13] Our members have informed us that approximately $8 million of label inventory would have to be destroyed if the effective date is unchanged.

[14] From a legal perspective, a product is misbranded if its label does not bear all mandatory information. Section 4(h)(12) of the Poultry Products Inspection Act. Upon the effective date of the moisture regulation, a moisture declaration is mandatory. Accordingly, any product whose label does not bear this information is misbranded. Misbranded product cannot bear the mark of inspection, and cannot be shipped. Sections 8(d) & 9(a)(2). If an establishment cannot ship product, it is, for all intents and purposes, closed.

microbiological testing of poultry product samples
Attachment 8—July 27, 2001, letter from Dr. Neal Apple, Vice President of Tyson Corporate Laboratory and Research, Tyson Foods, Inc., ''to whom it may concern,'' on laboratory capacity for microbiological testing of poultry product samples
Attachment 9—August 2, 2001, letter from Lee G. Johnson, Chief Microbiologist, Con Agra Refrigerated and Prepared Foods, ''to whom it may concern,'' on laboratory capacity for microbiological testing of product samples
Attachment 10—August 16, 2001, letter from Jason Tisch, Assistant Manager, Deibel Laboratories, on laboratory capacity for microbiological testing of poultry product product samples
Attachment 11—Line graphs showing monthly percentage variation of turkey pre-baste yield and monthly variation of poultry live weight yield in pounds
Attachment 12—Chart showing monthly variability in *Salmonella* incidence on poultry carcasses at some establishments
Attachment 13—Chart showing monthly variability in *Salmonella* incidence on poultry carcasses at some establishments, other than those represented the chart in Attachment 12
Attachment 14—Letter from Mr. Stephen Pretanik, Director of Science and Technology, National Chicken Council, ''to whom it may concern,'' reporting results of membership survey on labels affected by the retained water rule
Attachment 15—Letter from J. Roy Escoubas, Ph.D., Technical Enhancements, Inc., to Mr. Stuart Proctor, President, National Turkey Federation, reporting on number of new printing plates and labels needed to bring turkey processors in compliance with retained water regulations

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this notice, FSIS will announce it and provide copies of this **Federal Register** publication in the FSIS Constituent Update. FSIS provides a weekly FSIS Constituent Update, which is communicated via fax to over 300 organizations and individuals. In addition, the update is available on-line through the FSIS web page located at http://www.fsis.usda.gov. The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the Congressional and Public Affairs Office, at (202) 720–5704.

Done, at Washington, D.C.: October 12, 2001.

Thomas J. Billy,

Administrator.

[FR Doc. 01–26168 Filed 10–16–01; 8:45 am]

BILLING CODE 3410–DM–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 2

RIN 3150–AC07

Availability of Official Records

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations on availability of official records in three areas. The proposed rule would require those who submit documents claimed to contain proprietary or other confidential information to mark the information as specified to decrease the chances of inadvertent public release of the information by the NRC, codify NRC's current practices delineating the circumstances under which the agency will not return confidential documents that have been submitted to the NRC, and clarify that the NRC will make as many copies of copyrighted material submitted to the agency as it needs to perform its mission. The proposed rule is necessary to conform the NRC's regulations regarding the availability of official records to existing case law and agency practice.

DATES: The comment period expires December 31, 2001. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Mail written comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff. Deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:30 am and 4:15 pm on Federal workdays.

Comments also may be submitted via the NRC's interactive rulemaking Website (http://ruleforum.llnl.gov). This site provides the ability to upload comments as files (any format) if your Web browser supports that function. For information about the interactive rulemaking Website, contact Ms. Carol Gallagher, 301–415–5905 (e-mail *CAG@nrc.gov*). Comments received also may be viewed and downloaded electronically via this interactive rulemaking Website.

Except for restricted information, documents created or received at the NRC after November 1, 1999, also are available electronically at the NRC's Public Electronic Reading Room on the Internet at *http://www.nrc.gov/NRC/ADAMS/index.html.* From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. For more information, contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, 301–415–4737 or by email to *pdr@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Catherine M. Holzle, Senior Attorney, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–1560, email CMH@NRC.GOV.

SUPPLEMENTARY INFORMATION:

I. Background
II. Public Comments
III. Discussion
IV. Plain Language
V. Voluntary Consensus Standards
VI. Environmental Impact: Categorical Exclusion
VII. Paperwork Reduction Act Statement
VIII. Regulatory Analysis
IX. Regulatory Flexibility Certification
X. Backfit Analysis

I. Background

The NRC first published 10 CFR 2.790 on March 22, 1976 (41 FR 11810). This regulation established procedures governing the submission of proprietary information to the NRC. The regulation provided that material determined to be proprietary generally would be protected by the NRC and would not be released to the public. The agency then