calendar days of the date on which the GSM receives the request for a hearing. The hearing will be an informal procedure. The exporter or the exporter's assignee and/or its counsel may present any relevant testimony or documentary evidence to the GSM. A transcript of the hearing will not ordinarily be prepared unless the exporter or the exporter's assignee bears the costs involved in preparing the transcript, although the GSM may decide to have a transcript prepared at the expense of the Government. The GSM will make a decision regarding the appeal based upon the information contained in the administrative record. The GSM will endeavor to issue his or her written decision within 60 calendar days of the date of the hearing or the date of receipt of the transcript, if one is to be prepared, whichever is later.

(4) The decision of the GSM will be the final determination of CCC. The exporter or the exporter's assignee will be entitled to no further administrative appellate rights.

(c) *Failure to comply with determination.* If the exporter or the exporter's assignee has violated the terms of this subpart or the payment guarantee by failing to comply with a determination made under this section, and the exporter or the exporter's assignee has exhausted its rights under this section or has failed to exercise such rights, then CCC will have the right to take any measures available to CCC under applicable law.

(d) *Exporter's obligation to perform.* The exporter will continue to have an obligation to perform pursuant to the provisions of these regulations and the terms of the payment guarantee pending the conclusion of all procedures under this section.

§ 1493.195 Miscellaneous provisions.

(a) *Maintenance of records and access to premises.* For a period of five years after the date of expiration of the coverage of a payment guarantee, the exporter or the exporter's assignee, as applicable, must maintain and make available all records pertaining to sales and deliveries of and extension of credit for agricultural commodities exported in connection with a GSM–102 payment guarantee, including those records generated and maintained by agents, intervening purchasers, and related companies involved in special arrangements with the exporter. The Secretary of Agriculture and the Comptroller General of the United States, through their authorized representatives, must be given full and complete access to the premises of the exporter or the exporter's assignee, as applicable, during regular business hours from the effective date of the payment guarantee until the expiration of such five-year period to inspect, examine, audit, and make copies of the exporter's, exporter's assignee's, agent's, intervening purchaser's or related company's books, records and accounts concerning transactions relating to the payment guarantee, including, but not limited to, financial records and accounts pertaining to sales, inventory, processing, and administrative and incidental costs, both normal and unforeseen. During such period, the exporter or the exporter's assignee may be required to make available to the Secretary of Agriculture or the Comptroller General of the United States, through their authorized representatives, records that pertain to transactions conducted outside the program, if, in the opinion of the Director, such records would pertain directly to the review of transactions undertaken by the exporter in connection with the payment guarantee.

(b) *Responsibility of program participants.* It is the responsibility of all exporters, U.S. and foreign financial institutions to review, and fully acquaint themselves with, all regulations, Program Announcements, and Notices to Participants relating to the GSM–102 program, as applicable. All exporters, U.S. and foreign financial institutions participating in this program are hereby on notice that they will be bound by this subpart and any terms contained in the payment guarantee and in applicable Program Announcements.

(c) *Submission of documents by principal officers.* All required submissions, including certifications, applications, reports, or requests (*i.e.,* requests for amendments), by exporters or exporters' assignees under this subpart must be signed by a principal of the exporter or exporter's assignee or their authorized designee(s). In cases where the designee is acting on behalf of the principal, the signature must be accompanied by: wording indicating the delegation of authority or, in the alternative, by a certified copy of the delegation of authority; and the name and title of the authorized person or officer. Further, the exporter or exporter's assignee must ensure that all information/reports required under these regulations are submitted within the required time limits.

(d) *Officials not to benefit.* No member of or delegate to Congress, or Resident Commissioner, shall be admitted to any share or part of the payment guarantee or to any benefit that may arise there from, but this provision shall not be construed to extend to the payment guarantee if made with a corporation for its general benefit.

(e) *OMB control number assigned pursuant to the Paperwork Reduction Act.* The information collection requirements contained in this part (7 CFR Part 1493) have been approved by the Office of Management and Budget (OMB) in accordance with the provisions of 44 U.S.C. Chapter 35 and have been assigned OMB Control Number 0551–0004.

Dated: June 24, 2011.

Suzanne E. Heinen,

Acting Executive Vice President, Commodity Credit Corporation and Acting Administrator, Foreign Agricultural Service.

[FR Doc. 2011–18403 Filed 7–26–11; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 319 and 381

[Docket No. FSIS–2010–0012]

RIN 0583–AD41

Common or Usual Name for Raw Meat and Poultry Products Containing Added Solutions

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to amend its regulations to establish a common or usual name for raw meat and poultry products that do not meet standard of identity regulations and to which solutions have been added. Products with added solutions are sometimes referred to as ''enhanced products.'' The Agency is proposing that the common or usual name for such products include an accurate description of the raw meat or poultry component, the percentage of added solution incorporated into the raw meat or poultry product, and the individual ingredients or multi-ingredient components in the solution listed in the descending order of predominance by weight. FSIS is also proposing that the print for all words in the common or usual name appear in a single font size, color, and style of print and that the name appear on a single-color contrasting background. In addition, the Agency is proposing to remove the standard of identity regulation for ''ready-to-cook poultry products to which solutions are added.''

DATES: Submit comments by September 26, 2011.

ADDRESSES: FSIS invites interested persons to submit relevant comments on the implementation of this proposed rule. Comments may be submitted by either of the following methods:

- Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to *http://www.regulations.gov*. Follow the online instructions at that site for submitting comments.
- Mail, including floppy disks or CD–ROMs, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, Room 2–2127, George Washington Carver Center, 5601 Sunnyside Avenue, Beltsville, MD 20705–5273.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2010–0012. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *http://www.regulations.gov.*

Docket: For access to background documents or comments received, go to the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Ms. Rosalyn Murphy-Jenkins, Director, Labeling and Program Delivery Division, Office of Policy and Program Development, FSIS, USDA, (301) 504–0879.

SUPPLEMENTARY INFORMATION:

Background

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 601–695) and Poultry Products Inspection Act (PPIA) (21 U.S.C. 451–470) (''the Acts'') provide that the labels of meat and poultry products must be approved by the Secretary of Agriculture, who has delegated this authority to FSIS, before these products can enter commerce. The Acts also prohibit the distribution in commerce of meat or poultry products that are adulterated or misbranded.

Under the Acts, a meat or poultry product is misbranded, among other circumstances, if its labeling is false or misleading in any particular or it is offered for sale under the name of another food (21 U.S.C. 601(n)(1), 453(h)(1), 601(n)(2), and 453(h)(2)). A meat or poultry product that is not subject to a standard of identity (9 CFR Part 319 and Part 381 Subpart P) is also misbranded ''* * * unless its label bears the common or usual name of the food, if any there be * * *'' (21 U.S.C. 601(n)(9)(A) and 453(n)(9)(A)). The FMIA and PPIA give FSIS broad authority to promulgate such rules and regulations as are necessary to carry out the provisions of the Acts (21 U.S.C. 621 and 463(b)).

To prevent meat and poultry products from being misbranded, the meat and poultry products inspection regulations require that the labels of meat and poultry products contain specific information and that such information be displayed as prescribed in the regulations (9 CFR part 317 and 381 subpart N). Under the regulations, the principal display panel on the label of a meat product and the label of a poultry product must, among other information, show the name of the product. For products that purport to be or are represented by a regulatory standard of identity, the name of the product on the label must be the name of the food specified in the standard. For any other product, the name on the label must be ''the common or usual name of the food, if any there be.'' If there is no common or usual name, the name on the label must be a ''truthful, descriptive designation'' (9 CFR 317.2(c)(1) and 381.117).

FSIS poultry products regulations (9 CFR 381.169) provide that solutions may be added to ready-to-cook, bone-in poultry carcasses and parts, increasing the weight by approximately 3 percent over the weight of the raw product after chilling and washing. Poultry products with solutions that have been added in accordance with this regulation must be labeled with a conspicuous, legible, and descriptive name, including terms that concisely describe the method of addition and function of the added material. The regulation requires that all major terms in the product name be printed with the same prominence, except that the words that describe the function of the added materials (such as ''injected for Flavored Basting'') may be more prominent. A qualifying statement that identifies the percentage of added solution must be printed at least one-fourth the size of the most prominent letter in the product name. The ingredients in the solution must be identified in the qualifying statement and must be displayed with a minimum size requirement of one-eighth the size of the most prominent letter in the product name. In addition, 9 CFR 381.169 contains labeling compliance quality control criteria that must be approved by the Administrator.

Since 9 CFR 381.169 was codified on May 16, 1972 (37 FR 9706), and subsequently amended on October 7, 1974 (39 FR 36000), several changes have taken place that have diminished the relevance of 9 CFR 381.169 in preventing the labels of poultry that contain added solutions from being false or misleading. Poultry processors have developed technologies, such as using injectors to inject solutions deep into the muscle tissue, that incorporate more than 3 percent solution into products. While the practice of adding liquid solution was initially used to flavor the raw poultry product without significantly increasing the product's net weight, the addition of the increased levels of solution has resulted in increasing the total weight of the finished product. Also, with the May 30, 2000, publication of the Elimination of Requirements for Partial Quality Control Programs Final Rule (65 FR 34381), the quality control criteria used to monitor the percent added solution per 9 CFR 381.169(c) are no longer in effect.

To provide labeling guidance for ready-to-cook, bone-in poultry products with solutions above 3 percent and for boneless poultry products with any amount of added solution, neither of which are covered under 9 CFR 381.169, the Agency issued Policy Memo 042, Raw Bone-In Poultry Products Containing Solutions (February 1982) and Policy Memo 044A, Raw Boneless Poultry Containing Solutions (September 1986). FSIS also issued Policy Memo 066C, Uncooked Red Meat Products Containing Added Substances (November 2004) to provide similar guidance for the labeling of ''enhanced'' uncured meat products. The Policy Memos are available on the FSIS Web site at *http://www.fsis.usda.gov/OPPDE/larc/Policies/Policy_Memos_082005.pdf.*

The intent of labeling guidance provided in the policy memoranda was to provide guidance to industry to develop truthful, easy-to-read labeling information concerning the solutions added to products so that consumers could make informed purchasing decisions. However, it has come to the Agency's attention, through the petitions discussed below, comments submitted by the public, and FSIS review of labels, that some product labels may not clearly and conspicuously identify that the raw meat or poultry products contain added solution.

Under FSIS's current regulatory approach, raw products that contain added solution and products that do not contain added solution may have the same product name. For example, the name for a single-ingredient chicken breast and a chicken breast with added solution is ''chicken breast,'' even though one is 100 percent chicken

breast and one may be 60 percent chicken breast and 40 percent solution. Although the labeling of the product must include a qualifying statement that reflects the fact that the product contains added solution, this may not be readily apparent to consumers because the statement is not part of the product name. For example, through label review, FSIS has found that it is common for product labels to contain product names in bold fonts with strong contrasting backgrounds, with the qualifying statement on added solution printed in tall, narrow, or slanted fonts at the smallest height permitted, and on background of poor color contrast. While such labeling may be consistent with existing Agency guidance, it may not clearly identify to consumers that the products contain added solutions.

Petitions and Public Comments Related to Products That Contain Added Solution

Since 2007, FSIS has received two petitions related to products that contain added solution. In July 2007, the Truthful Labeling Coalition (TLC) submitted a petition to the Agency requesting that it ''prevent the ongoing marketing of so-called 'enhanced' (added solution) fresh poultry products in all situations where ingredients added to such products are not being adequately labeled to prevent the consuming public from being misled.''

Included in the TLC petition were two consumer research studies.[1] [2] Though these studies are not generalizable, they provide anecdotal evidence that consumers read and use labels, and that users of ''enhanced'' chicken are not aware that it contains additives until specifically directed to look at the label. According to the Sorenson study, even after looking at the label of an ''enhanced'' chicken product, about 20% participants in the study that purchase the chicken failed to realize that the chicken contains additives.'' In addition, almost one-third of these participants indicated that they ''care a lot that their chicken contains additives,'' and after being informed about the additives, these participants said they probably or definitely would not buy it again. Participants in the study were also presented with the following label descriptions that communicated additive ingredients in chicken: ''Contains up to 15% water, salt, and sodium phosphate,'' ''Enhanced with up to 15% solution of water, salt, and sodium phosphates,'' ''Contains up to 15% chicken broth,'' and ''Enhanced with up to fifteen percent chicken broth.'' Respondents considered the wording ''Contains up to 15% water, salt, and sodium phosphates'' as most accurately communicating additive ingredients in chickens.

The TLC petition also pointed out health concerns associated with the addition of salt to these products. TLC submitted a comparison of the sodium content in 4 ounces of a single ingredient, raw poultry product (45 mg sodium) to 4 ounces of a poultry product with added solution (370 mg sodium), more than an eightfold increase in the amount of sodium. TLC argued that many consumers do not realize that there may be a significant difference in sodium content between a single-ingredient, raw product and a similar-looking product with added solution.

In March 2009, the California Agricultural Commissioners and Sealers Association submitted a petition to revoke FSIS's September 9, 2008, Final Rule, ''Determining Net Weight Compliance for Meat and Poultry Products'' (73 FR 52189), which eliminated wet tare provisions for determining the net weight of packaged meat and poultry products. The petition suggested that meat and poultry products with added solution were misleading to the consumer because added liquids represent a high percentage of product weight. The petition stated that in 2006, California Weights and Measures officials conducted a study that indicated that, in California alone, consumers spent an estimated $246 million on solutions added to ready-to-cook poultry. The petition further stated that, assuming California has approximately 12% of the U.S. market share, the nationwide impact is projected at a cost of $2 billion annually for just the added solution.

In addition, after FSIS held a public meeting on December 12, 2006, to solicit public input on ''natural'' claims, the Agency received more than 12,000 comments from a write-in campaign sponsored by TLC that objected to the use of ''natural'' claims in the labeling of poultry product with added solutions (71 FR 70503). The Agency received similar comments in response to its September 14, 2009, Advance Notice of Proposed Rulemaking, ''Product Labeling: Use of the Voluntary Claim 'Natural' in the Labeling of Meat and Poultry Products'' (74 FR 46951). Although the current proposed rule does not address ''natural'' claims in product labeling, we note that almost all of the comments submitted as part of the TLC write-in campaign also requested that FSIS require poultry products with added solution to bear a prominent label that clearly reflects the products' true composition. This proposed rule addresses the labeling of products that contain added solution and does not affect FSIS's ''natural'' claims policy. The Agency intends to pursue separate rulemaking to address issues associated with ''natural'' claims.

Proposed Amendments

After considering the comments submitted in response to the 2006 public meeting and the 2009 advanced notice of proposed rulemaking, and the information presented in the petitions described above, along with the Agency's experience in reviewing labels of meat and poultry products with added solution, the Agency has tentatively concluded that without specific, clear, and conspicuous information about the percentage of added solution incorporated into the product, the labeling of these raw meat or poultry products that do not meet a standard of identity is likely to be misleading to consumers.

As noted above, raw products that have added solution and single-ingredient raw products currently have the same product name, and the qualifying statement required for products with added solution may not be readily apparent to consumers. Thus, the labeling of meat and poultry products with added solution that do not meet a regulatory standard of identity often does not adequately reveal a significant material fact about the nature of the product.

FSIS agrees with the petitions discussed above, the comments submitted in response to the 2006 public meeting on ''natural'' claims, and the 2009 Advance Notice of Proposed Rulemaking on ''natural'' claims that without adequate information, consumers likely cannot distinguish between single-ingredient raw meat and poultry products versus similar raw meat and poultry products containing added solution that do not meet a standard of identity. The added solution in a raw meat and poultry product is a characterizing component of the product, and, as suggested by the consumer research discussed above, is likely to affect consumers' purchasing decisions. Furthermore, as noted in the TLC petition, the presence of added solutions affects the product's nutrition profile because there may be a significant difference in sodium content between a single-ingredient raw product

[1] Russell Research, Fresh Chicken Study Final Report, June 2006.

[2] ''Enhanced'' Chicken, Consumer Research, November 2004, SAI Project #04177, Sorensen Associates, Minneapolis, Minnesota (888–616–0123), Portland, Oregon (800–542–4321).

and a similar-looking product containing added solution. The effect of excess sodium may be compounded if consumers unknowingly purchase a product with added solution, believe it to be a single-ingredient product, and add salt during preparation or prior to consumption.

Therefore, to ensure that labels adequately inform consumers that raw products that do not meet a standard of identity in 9 CFR part 319 or 9 CFR part 381, subpart P, contain added solutions, the Agency is proposing to establish a common or usual name for such raw products. FSIS is proposing that the common or usual name of such product consist of the following: an accurate description of the raw meat or poultry component; the percentage of any added solution incorporated into the raw meat or poultry product (total weight of solution ingredients divided by the weight of the raw meat or poultry without solution or any other added ingredients, multiplied by 100) using numerical representation and the percent symbol ''%;'' and the common or usual name of all individual ingredients or multi-ingredient components in the solution listed in descending order of predominance by weight. For example, an applicable product could be labeled as ''chicken breast—40% added solution of water, salt and sodium phosphate'' or ''chicken breast—40% added solution of water, teriyaki sauce, and salt.'' If the poultry component of a poultry product is represented by a standard cut for raw poultry prescribed in 9 CFR 381.170, the common or usual name of the product would include the name of the standard poultry cut, the percentage of added solution, and the common or usual names of the ingredients in the solution.

Under this proposal all of the letters in the name would be required to appear in a single font size, color, and style of print and appear on a single-color contrasting background, as opposed to the smaller type and differing style that is currently permitted for the qualifying statement. This approach will clearly disclose that the product has been formulated with added solution, and it will clearly distinguish raw meat and poultry products that have added solution from single-ingredient raw meat and poultry products.

The Agency would like to receive any consumer research information that evaluates whether the proposed product name requirements described above would better inform consumers and affect their purchasing habits.

Under the current regulations, as noted above, the product label is required to show the product name, which, for a non-standardized product with a common or usual name, would be the common or usual name of the food (9 CFR 317.2(c)(1) and 381.117). Thus, if finalized, the common or usual name for raw meat and poultry products containing added solution subject to this proposed rule would be different from the name for similar raw products without added solution. If this proposal is finalized, raw products containing added solution subject to the rule that are not labeled with the prescribed common or usual name would be considered misbranded because their labeling would be false or misleading and they would be offered for sale under the name of another food (21 U.S.C. 601(n)(1), 453(h)(1), 601(n)(2), and 453(h)(2)).

The Agency seeks to ensure that the common or usual name consistently conveys to consumers that these products contain added solutions. Various methods are used to add solutions to meat and poultry products (e.g., injecting, marinating, or tumbling). The term ''enhanced'' is commonly used to describe products with added solutions, regardless of the method used to incorporate solution into the product, and was the term used in the petitions submitted to the Agency. However, FSIS recognizes that the term ''enhanced'' could imply a judgment about the value of the product. As such, the Agency did not propose to include the term ''enhanced'' in the common or usual name for products containing added solutions.

In addition, FSIS is proposing that the common or usual name of such products that contain added solution include the common or usual name of individual ingredients or multi-ingredient components in the solution listed in descending order of predominance. FSIS is proposing to require this information in the product name to ensure that consumers are aware of the ingredients in the solution. FSIS is proposing that the common or usual names of applicable multi-ingredient components, rather than the components' individual ingredients, may be listed in the common or usual name to simplify the product name for raw products that may contain numerous ingredients. FSIS requests comment on whether the common or usual name of a multi-ingredient component in the product name sufficiently alerts consumers concerning the content of the added solution. FSIS acknowledges that many solutions include salt and requests comment on whether consumers are aware of that. Under this proposal, when the common or usual name includes the individual ingredients in the solution, those ingredients would not need to be listed in a separate ingredients statement on the label. However, when the common or usual name includes multi-ingredient components, all ingredients in the product would be required to be declared in a separate ingredients statement on the label. Regulations currently require that ingredients in the ingredients statement on the label be listed in descending order of predominance (9 CFR 317.2(c)(2),(f) and 381.118(a)(1)).

Raw products are products that have not received any type of heat treatment or full lethality treatment to destroy harmful bacteria. FSIS agrees with the petitions and comments that without adequate information, consumers have difficulty distinguishing between single-ingredient raw meat and poultry products and raw meat and poultry products containing added solution.

FSIS has not received information indicating that consumers lack adequate ingredient information for fully cooked or partially heat-treated products containing added solution. An example of a partially heat-treated product containing added solution is a raw chicken strip with an added solution that is breaded, and then immersed in hot oil to set the breading. This product and other similar products would not be subject to the common or usual name requirements proposed in this rulemaking because FSIS has tentatively concluded that consumers are unlikely to be misled into thinking that these are single-ingredient products based on the product appearance. For example, breaded products are obviously not single-ingredient. Furthermore, the petitions and comments submitted on products containing added solution expressed concern that without adequate labeling consumers would have difficulty distinguishing raw products with solutions from single-ingredient raw products. They did not express the same concern regarding partially heat-treated or cooked products. FSIS requests comments on whether it should establish a common or usual name for non-standardized fully cooked or partially-heated treated products that contain added solutions.

Under this proposed rule, meat and poultry products that comply with a standard of identity in the regulations will continue to be labeled as the named food specified in the standard. For example, ''corned beef,'' which includes curing solution, is allowed up to a 10 percent gain from the fresh weight of the uncured beef in accordance with the 9 CFR 319.100 standard of identity for

corned beef. Products that comply with this standard would be named and labeled as ''corned beef.'' However, if a product similar to ''corned beef'' includes a solution amount that is greater than the standard allows, the product is no longer a standardized product and, under this proposed rule, it must be labeled with the common or usual name, ''corned beef containing up to 15% of a solution.'' The name would follow the labeling requirements for font size, color, and style and background color as proposed.

This proposed rule is only applicable to raw meat and poultry products that, after post-evisceration processing, have solutions added. Raw, single-ingredient meat and poultry products that retain water as the result of post-evisceration processing are subject to the retained water regulations (9 CFR 441.10). The regulations at 9 CFR 441.10 also address retained water as a result of the use of anti-microbial solutions (66 FR 1766). This proposal addresses most other added solutions.

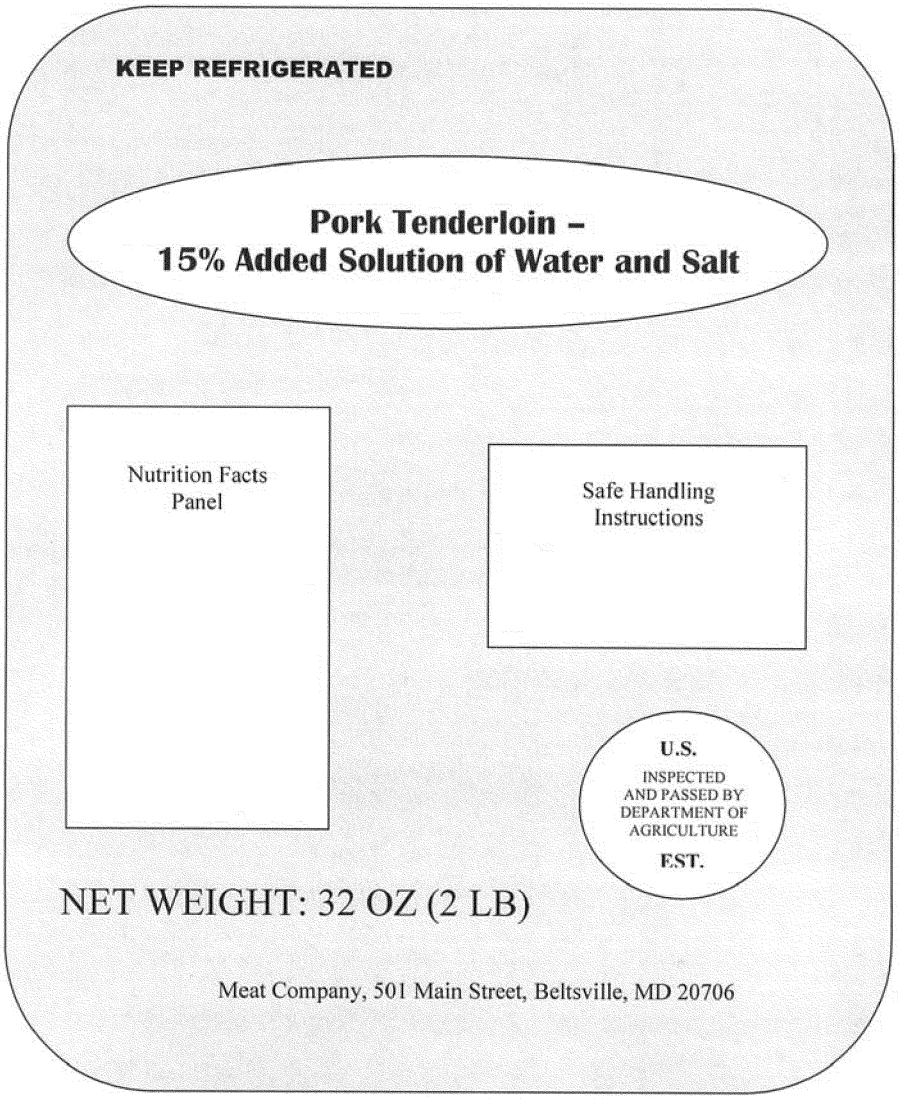
FSIS Directive 7620.3, ''Processing Inspectors' Calculations Handbook,'' provides instructions to inspection personnel concerning the method to use in determining the percent pickup of solutions added to raw poultry and meat products. The National Institute of Standards and Technology (NIST) Handbook 133 provides instructions to personnel concerning the method to use in determining the net weight of enhanced products. Should this rule become final, FSIS personnel will continue to follow Directive 7620.3 when enforcing these labeling requirements and the NIST Handbook 133 in order to determine the net weight of these products.

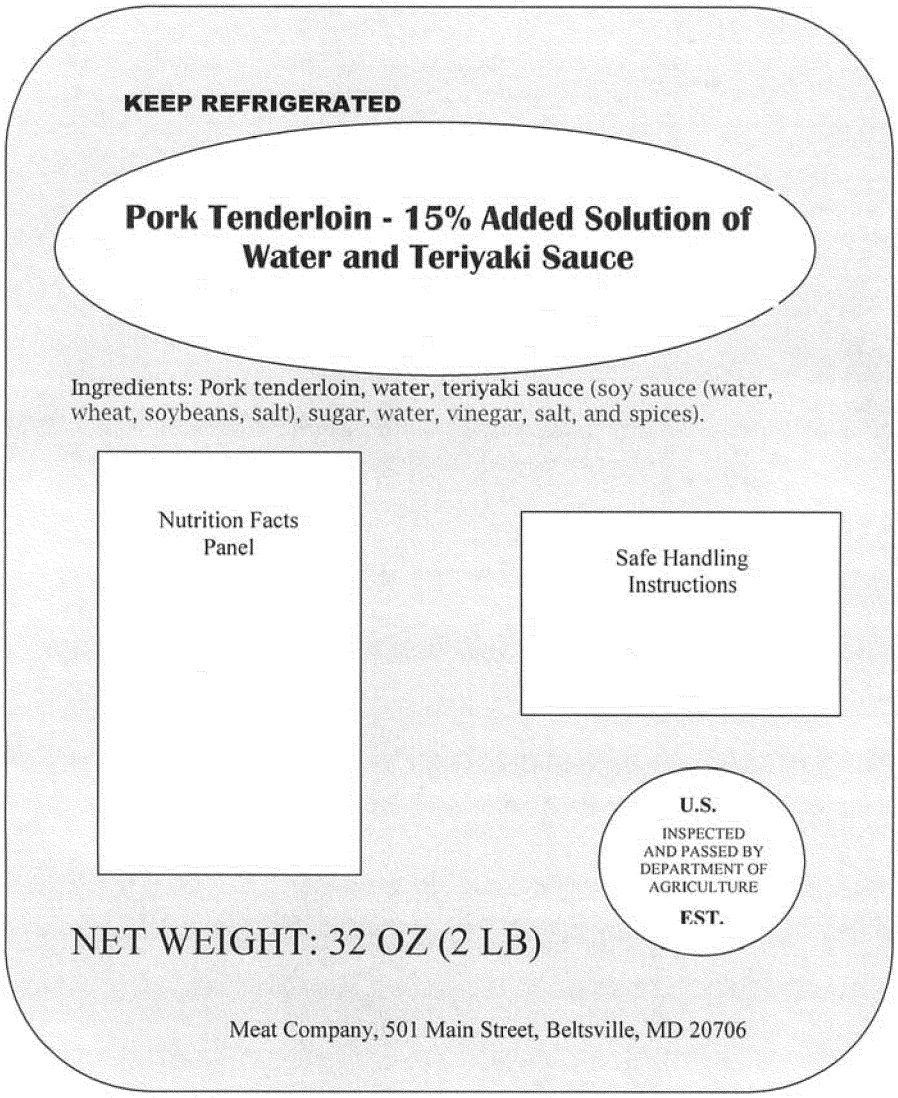
In addition to proposing a common or usual name for raw meat and poultry products containing added solution, FSIS is proposing to remove 9 CFR 381.169, the standard for ''ready-to-cook poultry products to which solutions are added.'' The Agency has evaluated the provisions in 9 CFR 381.169 and has determined that the provisions are not necessary. If this proposal is finalized, 9 CFR 381.169 will not be necessary because the labeling of all poultry and meat products containing added solution will be required to comply with the common or usual name requirements. Likewise, when these proposed amendments are finalized, Policy Memos 042,044A, and 066C will be rescinded and references to these policy memoranda will be deleted from the FSIS Food Standards and Labeling Policy Book. FSIS is requesting comments on removing all of the regulatory requirements in 9 CFR 381.169.

The misbranding provisions of the Acts apply to all meat and poultry products, including products that are not subject to the inspection provisions of the Acts (21 U.S.C. 623(d) and 464(e)). Thus, if finalized, these proposed regulations will apply to raw meat and poultry products containing added solutions that do not meet a regulatory standard of identity and that are sold for retail sale, institutional use, or further processing. If retail facilities, such as grocery stores, produce such products, the proposed labeling requirements would apply to those products. The proposed regulations would also apply to raw meat and poultry products containing added solutions that have been sliced or cut up and re-packaged at retail or another official establishment.

These proposed amendments, if finalized, will become effective on January 1, 2014, the compliance date provided by the Uniform Compliance Date for Food Labeling Regulations (75 FR 71344).

BILLING CODE 3410–DM–P


KEEP REFRIGERATED
Pork Tenderloin –
15% Added Solution of Water and Salt
Nutrition Facts
Panel
Safe Handling
Instructions
U.S.
INSPECTED
AND PASSED BY
DEPARTMENT OF
AGRICULTURE
EST.
NET WEIGHT: 32 OZ (2 LB)
Meat Company, 501 Main Street, Beltsville, MD 20706



BILLING CODE 3410–DM–C

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this proposed rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted, (2) no retroactive effect will be given to this rule, and (3) no retroactive proceedings will be required before parties may file suit in court challenging this rule.

Executive Orders 12866 and 13563 and the Regulatory Flexibility Act

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order (E.O.) 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Section 4 of E.O. 13563 emphasizes flexible approaches, including ''provision of information to the public in a form that is clear and intelligible.'' This proposed rule has been reviewed under Executive Order (E.O.) 12866. OMB has determined that it is a significant regulatory action under section 3(f) of E.O. 12866 and, therefore, it has been reviewed by the Office of Management and Budget.

FSIS estimated that the proportion of products containing added solutions is about 39 percent of all raw meat and poultry products sold. Based on FSIS's label review process estimates, 30 percent of the 49.2 billion pounds of poultry [3] consumed by households (14.8 billion pounds), 15 percent of the 27.3 billion pounds of beef [4] consumed by households (4.1 billion pounds), and 90 percent of the 21 billion pounds of pork [5] consumed by household (18.9 billion pounds) contain added solutions. As a result, approximately 37.8 billion pounds, or about 39 percent of the 97.5 billion pounds of meat and poultry products consumed by households in the U.S. contain added solutions.[6] FSIS requests comments on these estimates.

This rule will affect foreign establishments that manufacture and export products containing added solutions to the United States, because foreign establishments that manufacture and export products containing added solutions to the United States will be required to follow these same labeling requirements. FSIS requests information on the number of foreign establishments that may be affected by this proposed rule.

If finalized, the proposed regulations will apply to all raw meat and poultry products containing added solution that do not meet a standard of identity that are produced at federal establishments. The proposed labeling requirements also apply to such products that are produced at retail facilities, such as grocery stores. FSIS requests comment on the number of retail facilities that produce product containing added solution and the volume of such product that would be subject to these regulations.

Alternatives considered:

1. No Action.

FSIS considered taking no action but did not select this alternative because of evidence (Sorenson, November 2004) [7] that consumers view information about these additives as important factors in their purchasing decision.

2. Propose to require the word ''enhanced'' in the product's common or usual name, or propose the use of the term ''enhanced'' in the containing statement, e.g., ''enhanced with a 15% solution * * *''.

FSIS did not select the alternative of proposing to require the word ''enhanced'' in the product's common or usual name because the word implies that the product is improved by the addition of the solution. The intent of this proposal is to increase transparency to consumers, not to suggest that the product is either better or worse than a raw product without the added solution.

In addition, consumer research (Sorenson, November 2004) [8] showed that the containing statement, ''enhanced with up to 15% solution of water, salt, and sodium phosphates'' was preferred by fewer study participants (about 10% fewer) [9] than the use of the description ''contains up to 15% water, salt, and sodium phosphates.''

3. Propose to require that the common or usual name of the product include an accurate description of the raw meat or poultry component, the percentage of added solution, and the common or usual names of the ingredients in the solution, with all of the print in a single font size, color, and style on a single-color contrasting background (the proposed amendments).

FSIS selected this alternative because it is likely to improve consumer awareness and understanding that the raw meat or poultry product contains an added solution. FSIS believes proposing to require the percentage of the solution and the ingredients of the solution as part of the common or usual name is information consumers need to make informed purchasing decisions.

Expected Cost of the Proposed Rule

The proposed rule will result in one-time costs to establishments and retail facilities that produce and package enhanced products pertaining to modifying labels of products. The estimated costs of modifying labels are determined by the number of label plates or digitalized label templates required to be modified and the average cost of modifying labels. This methodology provides an estimated cost for all labels of products with added solution in commerce, including those for retailers and foreign entities that sell meat and poultry in the United States. Based on the Agency's Labeling Information System database, FSIS estimates that there were approximately 121,350 [10] raw meat and poultry product unique labels submitted by official establishments and approved by the Agency in 2009. Therefore, FSIS estimates that there are 46,990 (121,350 * 39%) unique labels for meat and poultry raw products containing added solution in commerce.

The Agency is providing a primary cost analysis based on the costs published in the December 29, 2010, final rule, ''Nutrition Labeling of Single-Ingredient Products and Ground or Chopped Meat and Poultry Products'' (75 FR 82148). In May 2011, the Food and Drug Administration (FDA) published a report, ''Model to Estimate Costs of Using Labeling as a Risk Reduction Strategy for Consumer Products Regulated by the Food and Drug Administration, FDA.'' A secondary cost analysis based on the FDA report is also provided for comment. FSIS requests comment on which cost analysis should be used for the economic analysis of the final rule.

Primary Cost Analysis

The primary cost estimate for label modification reflects administrative activities, graphic design, prepress activities, and plate engraving costs and excludes nutrient analysis costs and all other types of analysis. The mid-point label design modification cost is an estimated $1,557 per label (75 FR 82148). This estimate assumes separate label costs for every unique product containing added solution. Because subsidiary establishments are owned by parent companies, and subsidiaries

[3] U.S. Poultry & Egg Association: Poultry Statistics, 2007.

[4] Economic Research Service, USDA. U.S. Beef and Cattle Industry: Background Statistics and Information, 2007.

[5] National Pork Producers Council: Background Statistics and Information, 2007.

[6] Totals do not necessarily add up due to rounding.

[7] See footnote 2, page 8.

[8] See footnote 2, page 8.

[9] The Sorenson study did not report statistical significance.

[10] Source: FSIS Labeling and Program Delivery Division, Labeling Information System Database, 2009.

would likely use the same label, this estimate probably overestimates the total cost. Using this estimate, total costs of modifying labels for all federally inspected processors is $73 million as a central estimate (46,990 * $1,557 label modification cost).

Secondary Cost Analysis

This secondary cost analysis uses the mid-point label design modification costs for a minor coordinated label change, as provided in a March 2011 FDA report.[11] The Agency is requesting comment on whether these costs estimates are applicable to the amendments in this proposed rule. The mid-point label design modification costs for a minor coordinated label change is an estimated $310 per label (with a range of $170 to $440). A coordinated label change is when a regulatory label change is coordinated with planned labeling changes by the firm. In this case, only administrative and recordkeeping costs are attributed to the regulation and all other costs are not. Using this cost, FSIS estimates that the total costs of modifying labels for all federally inspected processors is about $14.6 million as a central estimate (46,990 labels * $310 label modification costs), with a range of approximately $8.0 to $20.7 million).

These estimated costs include the labeling costs of imported and retailer-produced raw imported meat and poultry products containing added solutions. Under either of the cost analyses presented above, the compliance cost of this proposed rule will be negligible as the cost of modifying labeling is small relative to the total sales of meat and poultry products. The 2-year compliance increments defined in the FSIS regulation titled ''Uniform Compliance Date for Food Labeling Regulations'' (75 FR 71344) will help affected establishments minimize the economic impact of labeling changes because affected establishments possibly could incorporate multiple label redesigns required by multiple Federal rules into one modification during the 2-year increments. Moreover, the ''Uniform Compliance Date for Food Labeling Regulations'' allows establishments time to use existing labels and would, therefore, result in minimal loss of inventory of labels, if any. The ''Uniform Compliance Date for Food Labeling Regulations'' also allows establishments to incorporate the new requirements as a coordinated change, which reduces the cost of complying with the proposed regulation.

FSIS Budgetary Impact of the Proposed Rule

This proposed rule will result in no impact on the Agency's operational costs because the Agency will not need to add any staff or incur any non-labor expenditures if the proposed rule is adopted.

FSIS is soliciting comments and data regarding any other potential costs that might result from finalization of this rule.

Expected Benefits of the Proposed Rule

The expected benefits of this proposed rule are:

- Improved public awareness of product identities by providing truthful and accurate labeling of meat and poultry products to clearly differentiate products containing added solutions from single-ingredient products.
- Consumers can better determine whether products containing added solutions are suitable for their personal dietary needs through increased product name prominence. For example, consumers' choices of meat and poultry products with added solutions with a high sodium content could have unintended health consequences if labels of these products were inadequate in revealing the information of added ingredients to the consumers.

This proposed action is not likely to result in a market demand shift, relative to other products, for meat and poultry products, with or without added solutions, because this proposed action is unlikely to influence consumers' preference for meat and poultry products in general. The proposed action, if adopted, will not add monetary benefits to the meat and poultry industry. Instead, the rule will make clearer product content information available to consumers of meat and poultry products with added solutions.

This rule may also help consumers reduce their sodium intake because the new product names will better alert consumers to the fact that the products contain added solutions. The prominence and design of the label on the front of the package may increase the likelihood that consumers review the nutrition facts panel, including information on sodium content, and make more healthful food choices. The benefits of improved market information are not quantifiable due to lack of data.

FSIS is soliciting comments and data that would permit the quantification of the expected benefits.

Regulatory Flexibility Analysis

The FSIS Administrator has made a preliminary determination that this proposed rule would not have a significant economic impact on a substantial number of small entities in the United States, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). There are about 5,719 small federally inspected establishments, of which 2,616 are small (with 10 or more but less than 500 employees), and 3,103 are very small (with fewer than 10 employees) based on Hazard Analysis Critical Control Point (HACCP) classification. Because only a portion of all meat and poultry products is sold with added solutions, a fraction of small and very small establishments will be impacted by this proposed rule at a negligible cost.

In the primary cost analysis above, FSIS estimated that the average one-time cost of modifying labels per unique label is about $1,557 and the total one-time cost for the industry is about $73 million (the secondary cost analysis total cost is $14.6 million). This results in an average one-time cost per establishment of about $11,969 ($73 million/6099 establishments). Because small and very small establishments produce less output and fewer unique labels, their average one-time cost per establishment will be lower. Therefore, FSIS believes that the cost to small and very small establishments of providing modified labels for the meat and poultry products with added solutions will be negligible. FSIS requests comment on the average number of labels of meat and poultry products with added solutions produced by small and very small producers and invites small and very small establishments to comment on the estimation of the compliance cost of the proposed rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995, the information collection or

[11] Model to Estimate Costs of Using Labeling as a Risk Reduction Strategy for Consumer Products Regulated by the Food and Drug Administration, FDA, March 2011 (Contract No. GS–10F–0097L, Task Order 5). The labeling model defines all labeling changes as minor, major, or extensive. A minor change is one in which only one color is affected and the label does not need to be redesigned. Examples of this type of change include changing an ingredient list or adding a toll-free number. A major change requires multiple color changes and label redesign. An example of a major change is adding a facts panel or modifying the front of a package. An extensive change is a major format change requiring a change to the product packaging to accommodate labeling information. An example of an extensive change is adding a peel-back label or otherwise increasing the package surface area. We, therefore, conclude that the labeling change that would be required by this proposed rule is a minor change. FSIS expects that all label changes resulting from this proposed rule will be coordinated with planned label changes.

recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB).

Title: Product Labeling Requirements for Meat and Poultry Containing Added Solutions.

Type of Collection: New.

Abstract: FSIS is proposing common or usual name labeling requirements for raw meat and poultry products that do not meet standard of identity regulations and to which solutions have been added. The proposed amendments will require establishments that manufacture products containing added solutions to modify or redesign the product label. The proposed amendments will be effective on the next compliance date provided by the Uniform Compliance Date for Food Labeling Regulations.

Estimate of Burden: FSIS estimates that it will take a respondent 75 minutes per response to comply with the information collection associated with product labeling requirements.

Respondents: Official establishments, retail stores, and foreign firms.

Estimated Number of Respondents: 6,100.

Estimated Number of Responses per Respondent: 8.

Estimated Total Annual Burden on Respondents: 61,000 hours.

Copies of this information collection assessment can be obtained from John O'Connell, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, 1400 Independence Avenue, SW., Room 6083, South Building, Washington, DC 20250.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of FSIS's functions, including whether the information will have practical utility; (b) the accuracy of FSIS's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to both John O'Connell, Paperwork Reduction Act Coordinator, at the address provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253. To be most effective, comments should be sent to OMB within 60 days of the publication date of this proposed rule.

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget.

E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that minorities, women, and persons with disabilities are aware of this proposed rule, FSIS will announce it online through the FSIS Web page located at *http://www.fsis.usda.gov/regulations_&_policies/Federal_Register_Publications_&_Related_Documents/index.asp.*

FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. Through the Listserv and Web page, FSIS is able to provide information to a much broader and more diverse audience. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at *http://www.fsis.usda.gov/News_&_Events/Email_Subscription/.* Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Executive Order 13175

This proposed rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

USDA Nondiscrimination Statement

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (Not all prohibited bases apply to all programs.)

Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's Target Center at 202–720–2600 (voice and TTY).

To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue, SW., Washington, DC 20250–9410 or call 202–720–5964 (voice and TTY).

List of Subjects

9 CFR Part 317

Food labeling, Food packaging, Meat inspection, Nutrition, Reporting and recordkeeping requirements.

9 CFR Part 381

Food labeling.

For the reasons discussed in the preamble, FSIS is proposing to amend 9 CFR Chapter III as follows:

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

1. The authority citation for Part 317 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

2. Amend § 317.2 by redesignating paragraph (e) as paragraph (e)(1) and adding a new paragraph (e)(2) to read as follows:

§ 317.2 Labels: definition; required features.

* * * * *

(e) * * *

(2)(i) The common or usual name for a raw meat product that contains added solution and does not meet a standard of identity in 9 CFR part 319 consists of:

(A) An accurate description of the raw meat component;

(B) The percentage of added solution (total weight of the solution ingredients

divided by the weight of the raw meat without solution or any other added ingredients multiplied by 100) using numerical representation and the percent symbol ''%;'' and

(C) The common or usual name of individual ingredients or multi-ingredient components in the solution listed in descending order of predominance by weight (such as, ''pork tenderloin—15% added solution of water and salt'' or ''beef—15% added solution of water and teriyaki sauce'').

(ii) The common or usual name must be printed in a single font size, color, and style of print and must appear on a single-color contrasting background.

(iii) When the common or usual name includes all ingredients in the solution, a separate ingredients statement is not required on the label. When the common or usual name includes multi-ingredient components and the ingredients of the component are not declared in the product name, all ingredients in the product must be declared in a separate ingredients statement on the label as required in §§ 317.2(c)(2) and 317.2(f).

* * * * *

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

3. The authority citation for Part 381 continues to read as follows:

Authority: 7 U.S.C. 138F, 450; 21 U.S.C. 451–470; 7 CFR 2.7, 2.18, 2.53.

4. A new § 381.117(h) is added to read as follows:

§ 381.117 Name of product and other labeling.

* * * * *

(h) *Common or usual name for raw products containing added solution.* (1) The common or usual name for a raw poultry product that contains added solution and does not meet a standard of identity in 9 CFR part 381 consists of:

(i) An accurate description of the raw poultry component;

(ii) The percentage of added solution (total weight of the solution ingredients divided by the weight of the raw poultry without solution or any other added ingredients multiplied by 100) using numerical representation and the percent symbol ''%;'' and

(iii) The common or usual name of all individual ingredients or multi-ingredient components in the solution listed in descending order of predominance by weight (such as, ''chicken breast—15% added solution of water and salt'' or ''chicken breast—40% added solution of water, teriyaki sauce, and salt'').

(2) The common or usual name must be printed in a single font size, color, and style of print and must appear on a single-color contrasting background.

(3) When the common or usual name includes all ingredients in the solution, a separate ingredients statement is not required on the label. When the common or usual name includes multi-ingredient components and the ingredients of the component are not declared in the product name, all ingredients in the product must be declared in a separate ingredients statement on the label as required in § 381.118.

§ 381.169 [Removed and reserved]

5. Remove and reserve § 381.169.

Done at Washington, DC, on July 20, 2011.

Alfred Almanza,

Administrator.

[FR Doc. 2011–18793 Filed 7–26–11; 8:45 am]

BILLING CODE 3410–DM–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 40

RIN 3150–AI50

[NRC–2009–0079 and NRC–2011–0080]

Domestic Licensing of Source Material—Amendments/Integrated Safety Analysis

AGENCY: Nuclear Regulatory Commission.

ACTION: Extension of public comment period and public meeting.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its Title 10 of the *Code of Federal Regulations* (10 CFR) Part 40 regulations by adding additional requirements for source material licensees who possess significant quantities of uranium hexafluoride (UF6). The proposed rule and proposed guidance document were published in the **Federal Register** on May 17, 2011 (76 FR 28336), for public comment and an administrative correction to 76 FR 28336 was published in the **Federal Register** on June 1, 2011 (76 FR 31507). The Nuclear Energy Institute (NEI), in a letter dated June 21, 2011, requested the NRC to hold a public meeting on the proposed rule and draft guidance document and to extend the public comment period.

Based on NEI's request, the NRC will conduct a public meeting on August 17, 2011, to seek public input on the proposed rule and its associated draft guidance document. In addition, the NRC is extending the public comment period for the proposed rule and associated draft guidance document from 75 days to 115 days to allow the public ample opportunity to submit written comments.

DATES: Submit comments specific to the proposed rule and draft guidance document by September 9, 2011. Comments received after this date will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date.

The public meeting will be held on Wednesday, August 7, 2011, from 9 a.m. to 12 p.m. (eastern daylight time).

ADDRESSES: Please include the applicable Docket ID in the subject line of your comments. Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal rulemaking Web site, *http://www.regulations.gov.* Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed. The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed. You may submit comments on the proposed rule (Docket ID NRC–2009–0079) by any one of the following methods:

- *Federal Rulemaking Web Site:* Go to *http://www.regulations.gov* and search for documents filed under Docket ID NRC–2009–0079 for the proposed rule. Address questions about NRC dockets to Carol Gallagher, telephone: 301–492–3668; e-mail: *Carol.Gallagher@nrc.gov.*
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555–0001, ATTN: Rulemakings and Adjudications Staff.
- *E-mail comments to: Rulemaking.Comments@nrc.gov.* If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at 301–415–1677.
- *Hand deliver comments to:* 11555 Rockville Pike, Rockville, MD 20852, between 7:30 a.m. and 4:15 p.m. Federal workdays. (Telephone 301–415–1677)
- *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.

You may submit comments on the proposed draft guidance document (Docket ID NRC–2011–0080) by any one of the following methods: