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Descriptive Designation for Raw Meat and Poultry Products Containing Added Solutions; Final Rule

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317 and 381

[Docket No. FSIS–2010–0012]

RIN 0583–AD43

Descriptive Designation for Raw Meat and Poultry Products Containing Added Solutions

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending its regulations to require the use of a descriptive designation as part of the product name on the labels of raw meat and poultry products that contain added solutions and that do not meet a standard of identity. The descriptive designation will have to include the percentage of added solution, and the individual ingredients or multi-ingredient components in the solution listed in descending order of predominance by weight. The print for all words in the product name, including the descriptive designation, must appear in a single easy-to-read type style and color and on a single-color contrasting background. The print may appear in upper and lower case letters, with the lower case letters not smaller than one-third (⅓) the size of the largest letter. The percent solution must appear as a number (*e.g.,* 15, 20, 30) with the percentage sign (%) and may be declared with the word ''containing'' or ''contains.'' Under this final rule, the word ''enhanced'' is not allowed in the product name. The Agency is also removing the standard of identity regulation for ''ready-to-cook poultry products to which solutions are added''.

DATES: Effective Date: January 1, 2016.

Applicability Date: The regulation that prescribes that the product name appear with the lower case letters not smaller than one-third (⅓) the size of the largest letter in the product name (9 CFR 317.2(e)(2)(iv) and 381.117(h)(4)) will be applicable on January 1, 2018.

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

SUPPLEMENTARY INFORMATION:

Executive Summary

This rule requires a descriptive designation as part of the product name for raw meat and poultry products that contain added solutions. The Agency proposed changes to the labeling of these products on July 27, 2011, in response to two petitions that requested that the Agency prevent consumers from being misled by the on-going marketing of added solution poultry products.

FSIS, in response to the petitions and after evaluating its experience in reviewing labels, determined that some added- solution product labels that follow current labeling guidance and comply with current regulations are misleading because they do not clearly and conspicuously show that the product contains an added solution, and that, without updated labeling regulations that require the conspicuous labeling of the added solution, consumers likely cannot distinguish between raw single-ingredient products versus similar raw products containing added solution.

Under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), the labels of meat and poultry products must be truthful and not misleading, and the labels must accurately disclose to consumers what they are buying when they purchase any meat or poultry product. The FMIA and PPIA give FSIS broad authority to promulgate rules and regulations necessary to carry out the provisions of the Acts.

To increase consumer awareness of the added solution and the amount of the added solution in raw meat and poultry products, FSIS proposed that the common or usual name of the product include the percentage and the ingredients of the added solution. In addition, the Agency proposed that the print for all of the words in the name, including the percentage and ingredients in the solution, appear in a single font size, color, and style of print and appear on a single-color contrasting background.

This final rule requires a descriptive designation as part of the product name, not as part of the common or usual name of the product. FSIS made this change to make clear that the descriptive designation is required to be part of the product name but does not need to be on the same line as the rest of the name. The descriptive designation can be above, below, or next to the product name (without intervening text or graphics) on the principle display panel. FSIS also made this change to make this labeling rule more consistent with the rule concerning the labeling of mechanically tenderized beef products. This rule adopts all of the proposed rule's provisions for the listing of the individual ingredients or multi-ingredient components in the solution in descending order of predominance by weight, with the clarification that the added solution percentage must be a number and a percent symbol (*e.g.,* 15%), and that upper- and lower-case lettering may be used, provided that the lower-case lettering is not smaller than one-third (⅓) the size of the largest letter in the product name. The requirements concerning type style, color, and background for the product name (including the descriptive designation) are consistent with those in the proposed rule. The final rule also prohibits the use of the word ''enhanced'' in the product name (including the descriptive designation) of meat and poultry products containing added solutions that do not meet a standard of identity.

The final rule will result in one-time costs to establishments and retail facilities that produce and package raw meat and poultry products that contain added solutions and that do not meet a standard of identity. All of the costs pertain to the label modification procedures for the affected products, and are quantified below.

TABLE 1—SUMMARY OF COSTS AND BENEFITS

	Lower bound	Upper bound
Costs		
Annualized Cost (3% Discount Rate, 10 Year)	$5,897,722	$9,555,104
Annualized Cost (7% Discount Rate, 10 Year)	6,895,066	11,170,937
Benefits		
• 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 preferences and dietary needs through the added solutions descriptive designation. 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.		
• More complete label information may help consumers make more informed decisions leading to an increase in consumer welfare.		

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. 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 product 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 part 381, subpart N). On July 27, 2011, FSIS published a proposed rule to amend the meat and poultry regulations to establish a common or usual name for raw meat and poultry products that contain added solutions that do not meet a standard of identity (76 FR 44855). As FSIS explained in the proposed rule (76 FR 44856), the poultry products regulations include labeling requirements for ready-to-cook, bone-in poultry carcasses and parts with added solutions that increase the weight by approximately 3 percent over the raw product after chilling and washing (9 CFR 381.169). However, since 9 CFR 381.169 was codified on May 16, 1972 (37 FR 9706), and subsequently amended on October 7, 1974 (39 FR 36000), poultry processors developed new technologies that could incorporate more solution into products. In an effort to keep pace with industry practice and prevent false or misleading labeling, FSIS issued labeling guidance for raw bone-in poultry products that contain more than the 3 percent solution permitted by 9 CFR 381.169, and for boneless poultry products that contain added solutions. Policy Memo 042, ''Raw Bone-in Poultry Products Containing Added Solutions,'' (issued February 1982) provided that solutions may be added to raw bone-in poultry and poultry parts at various levels if the product name contained an appropriate qualifying statement. Policy Memo 044A, ''Labeling of Raw Boneless Poultry and Poultry Parts to Which Solutions are Added,'' (issued September 1986) provided for the addition of solution at any level to raw boneless poultry and poultry parts if the addition and the amount of solution were identified. FSIS also issued Policy Memo 066C, ''Uncooked Red Meat Products Containing Added Substances,'' (November 2004) to provide similar guidance for red meat products that contain added solutions.

As discussed in the proposal (76 FR 44856), the intent of the policy memoranda guidance was to assist industry in developing truthful, easy-to-read labeling information about the solutions added to products, so that consumers would be aware of the added solutions and could make informed purchasing decisions. However, it came to the Agency's attention from petitions, comments submitted by the public, and FSIS review of labels, that some product labels are misleading because they do not clearly and conspicuously identify that the raw meat or poultry products contain added solution, and that products that contain added solution have the same product name as products that do not contain added solution. For example, the name for both a single-ingredient chicken breast and a chicken breast with added solution is ''chicken breast,'' even though one is 100 percent chicken, and the other is not. Although the labeling of the product must include a qualifying statement that reflects the fact that the product contains added solution, this fact may not be readily apparent to consumers because the statement is not part of the product name (76 FR 44857). The petitions discussed in the proposed rule are found at *http://www.fsis.usda.gov/wps/portal/searchhelp/sitemap/!ut/p/a0/04_Sj9CPykssy0xPLMnMz0vMAfGjzOINAg3MDC2dDbz8LQ3dDDz9wgL9vZ2dDdx9jfQLsh0VAcILpdM!/?1dmy&current=true&urile=wcm%3Apath%3A%2Ffsis-content%2Fobsolete-archives%2Fproposed-rules%2Ffederal-proposed-rules-archive-2011.*

Therefore, to ensure that labels adequately inform consumers that those 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 proposed to establish a common or usual name for such raw products. FSIS proposed 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.

After the publication of the proposed rule, the Agency received a letter requesting a 60-day extension of the comment period, and the information, data, and evidence the Agency

considered in developing the proposed rule. On November 8, 2011, in response to the request to extend the comment period, the Agency reopened the comment period for 60 days (76 FR 69146). The Agency's letter responding to the request for additional information, including links to data and specific labels of concern is posted on its Web site at *http://www.fsis.usda.gov/wps/wcm/connect/cf80e9a5-7e39-470f-90c9-0911402268b0/2010-0012_Response_to_AMI_508.pdf?MOD=AJPERES.*

After review and consideration of all the comments submitted, FSIS is amending and clarifying the July 2011 proposed amendments. As is explained above, this rule is necessary because we have found that under current regulations, some product labels are misleading because they do not clearly and conspicuously identify to consumers that the raw meat or poultry products contain added solution. Therefore under, this final rule, such labels would be misbranded.

In response to comments, rather than requiring the added solution information as part of the common or usual name, the final rule requires a product name with a descriptive designation that clearly indicates that the product contains added solutions. The descriptive designation will need to appear as part of the product name on the principal display panel and may be above, below, or next to the product name (without intervening text or graphics).

All of the print and color requirements in the final rule, *i.e.,* a single easy-to-read type style and color and single-color contrasting background are consistent with those from the proposed rule and are applicable to the product name and the descriptive designation. However, in the final rule, FSIS made changes to the regulatory text to clarify that the percentage of added solution must be represented by a number and a percent symbol (*e.g.,* 15%), not words (*e.g.,* fifteen percent), and provide that upper and lower case lettering may be used for the in the product name, provided that the lower case lettering is not smaller than one-third (⅓) the size of the largest letter. Some added solution product labels may comply with current guidance for the labeling these products (Policy Memorandum 042, ''Raw Bone-In Poultry Products Containing Solutions;'' Policy Memorandum 044A, ''Raw Boneless Poultry Containing Solutions;'' and Policy Memorandum 066C, ''Uncooked Red Meat Products Containing Added Substances''). The labeling guidance provides that added solution statements must be one-fourth (¼) the size of the largest or most prominent letter in the product name. To reduce costs to establishments that produce added solutions products, the applicability date for the one-third (⅓) size requirement for the descriptive designation is January 1, 2018.

The Agency is also providing for the use of the words ''containing'' or ''contains'' (*e.g.,* ''containing 15% added solution of water and salt'') and prohibiting the use of the word ''enhanced'' in the product name (including the descriptive designation) of meat and poultry products containing added solutions that do not meet a standard of identity. The amendments and clarifications are discussed in further detail below in the summary of and response to comments.

Summary of and Response to Comments

FSIS received a total of 889 comments. These were from consumers; a coalition representing poultry producers and consumers; consumer advocacy organizations; health organizations; dieticians; State and county departments of agriculture, weights and measures; trade associations that represent meat and poultry processors; an association of agricultural commissioners and sealers; a trade association that represents ingredient manufacturers; a trade association that represents food retailers and wholesalers; and poultry, beef, and pork products manufacturers. The majority of comments were identical form responses submitted electronically by individuals that identified their organization as the coalition of poultry producers and consumers or one of the poultry producers that belong to the coalition.

A. General Support for the Proposed Common or Usual Name Requirements

The majority of comments generally supported the proposed amendments. Many commenters agreed that the current labels for meat and poultry products containing added solutions are misleading. Many commenters stated that the current solution statement is too small to read, and that other claims or statements on the product label make it difficult for consumers to differentiate between single-ingredient products and those with added solutions. One meat association acknowledged that containing statements can appear in fonts that are tall, slanted, and difficult to read. Many commenters stated that product labels should be truthful, clear, easy to read (*e.g.,* clear font, size, color, and style), and easily understandable, so that consumers can compare products and make informed choices. These commenters stated that the proposed regulations accomplish these goals. Additionally, these commenters stated that the proposed regulations would ensure fair competition among retailers and manufacturers.

B. Opposition to the Proposed Common or Usual Name Requirements

Comment: Several commenters stated that the petitions submitted by the Truthful Labeling Coalition (TLC) (with attached research studies) and the California Agriculture Commissioners and Sealers Association (CACSA) did not support the need for the proposed amendments, and that the research was limited and not compelling.

Response: FSIS acknowledged in the proposed rule that findings included in the TLC petition were not generalizable but constituted anecdotal evidence that consumers read and use labels (76 FR 44857). The Sorensen Associates Research, included with the TLC petition, found that consumers of ''enhanced'' chicken products were not aware that the ''enhanced'' product contained additives until they were specifically directed to look at the label. Even after looking at the label, nearly 1 out of 5 ''enhanced'' chicken buyers didn't realize that the chicken contained additives. The CACSA petition stated that in 2006, California Weights and Measures officials conducted a study that indicated that consumers, because they pay for the solution added to products, pay an estimated $246 million for the added solution in California alone. CASCA then estimated, assuming that California has an approximate market share of 12 percent, that the impact to consumers nationwide is projected at $2 billion annually. Also, information from FSIS's Labeling and Program Delivery Staff's (LPDS), formerly the Labeling and Program Delivery Division (LPDD), review of labels and compliance activities indicated that some product labels do not clearly and conspicuously identify that the raw meat or poultry products contain added solution even though they meet current regulatory requirements and follow current guidance. The findings, projected costs from the CACSA petition, and label approval and compliance information were the best data available to the Agency.

Comment: Several meat and poultry companies argued that the proposed requirements would obscure the identity of the meat or poultry component of their products and submitted labels to illustrate this point.

Two companies conducted consumer surveys to compare consumer understanding of labels that meet the current labeling requirements versus those that meet the proposed labeling requirements. The two companies stated that the surveys demonstrated that consumers preferred the current added-solution product labeling to the proposed required labeling.

One consumer survey compared a current meat with added solution label with a meat with added solution label meeting the proposed requirements. The results of the 66 respondent survey showed that the 79 percent of respondents agreed that the ''current'' label and the ''proposed'' label were ''easy to understand.'' The results also showed that eighteen percent of the panelists responded that the current label ''could be confusing,'' in comparison with twenty-three percent of the respondents that stated the proposed label was ''confusing'' (a five percent increase).

The other consumer survey was conducted online with a panel of 857 respondents. The overall results of this survey showed that 65 percent of the respondents preferred the current ''large'' font size label.

Response: The majority of the label examples submitted to illustrate that the proposed amendments would obscure the identity of the meat or poultry component of their products did not accurately reflect the proposed requirements. The common or usual names included superfluous text (*e.g.,* ''tenderness and juiciness improved''), spelled out percentages (*e.g.,* ''twelve percent''), and contained only uppercase letters.

The one consumer survey did not accurately represent the proposed requirements, and the ''current'' label's containing statement was considerably larger than the ¼ size provided in labeling guidance and, therefore, may have been more conspicuous to survey participants than product labels currently available at retail.

Another consumer survey, conducted online, did not offer respondents labels that accurately represented the current labeling guidance versus the proposed labeling requirements. The company presented two versions of four different added solution product labels, fresh chicken breast, frozen chicken wing sections, pork loin, and beef. Respondents were asked to compare the labels that meet the current labeling guidance with the labels that meet the proposed requirements. Three of the four current labels appeared to have containing statements larger than the minimum of ¼ size permitted under the current regulation (9 CFR 381.169) and labeling guidance. The containing statement on three of the four labels that represented the proposed requirements is in upper case letters, which is not a proposed requirement. FSIS proposed to require the added solutions statement in the common or usual name. However, in response to these comments, the Agency is amending this final rule to provide that a descriptive designation that clearly indicates that the product contains added solution will be required on the label as part of the product name, but not as a part of the common or usual name. In addition, the product name (including the descriptive designation) may appear in upper and lower case letters, with the lower case letters not smaller than one-third (⅓) the size of the largest letter (9 CFR 317.2(e)(2)(iii) and 381.117(h)(3)). Current labeling guidance for added solutions statements provide for a one-fourth (¼) size requirement in comparison to the largest letter in the product name. However, the one-third (⅓) size requirement is based on several regulatory requirements (9 CFR 319.104 and 319.105) and is consistent with the requirements in the Descriptive Designation for Needle- or Blade-Tenderized (Mechanically Tenderized) Beef Products final rule.

FSIS is also amending this final rule to require that the percent solution must appear as a number (such as, 15, 20, 30) and the percent symbol (%) (9 CFR 317.2(e)(2)(i) and 381.117(h)(1)). These amendments will ensure that the descriptive designation is easy to recognize and understand, and that the meat or poultry component of the product is not obscured. Also, the product name (including the descriptive designation) must be printed in a single easy-to-read type style and color and must appear on a single-color contrasting background, which will ensure the overall prominence of the descriptive designation on the label (9 CFR 317.2(e)(2)(v) and 381.117(h)(5)).

Examples of labels that met the proposed labeling requirements were included in the proposed rule (76 FR 44860 and 44861). Label examples are included again in this final rule as guidance (Figures 1, 2, and 3). The label in Figure 1 is an example of a product with a descriptive designation that includes a multi-ingredient component. The ingredients of the component are not declared in the descriptive designation but are declared in a separate ingredients statement along with all of the ingredients in the product (9 CFR 317.2(e)(2)(iii) and 381.117(h)(3)). The label in Figure 2 is an example of a product with a descriptive designation that includes the term ''contains'' and lists the individual ingredients in the added solution in descending order of predominance by weight (9 CFR 317.2(e)(2)(i), 317.2(e)(2)(ii), 381.117(h)(1), and 381.117(h)(2)). The label in Figure 3 is an example of a descriptive designation that includes the term ''flavored with'' and lists the individual ingredients in the solution in descending order of predominance by weight (9 CFR 317.2(e)(2)(ii) and 381.117(h)(2)).

Comment: One commenter agreed that it is important to inform consumers when differences exist between single-ingredient raw meat and poultry products and similar raw meat and poultry products containing added solutions, but it did not agree with establishing a common or usual name to describe these differences. The commenter stated that there should be a general common or usual naming convention for all meat and poultry products. In addition, the commenter stated the proposed requirements would change the product names and ingredient declarations of secondary products in which these added solution products are used, resulting in complicated naming conventions for ordinary foods and expanding ingredient declarations.

Response: The intent of this rule is to ensure that consumers have specific, clear, and conspicuous information about the percentage of added solution. As discussed above, although FSIS proposed to require that the percentage and ingredients of the added solution as part of the common or usual name, in response to comments, in this final rule, FSIS is requiring a descriptive designation as part of the product name, consistent with prior labeling guidance FSIS has provided in Policy Memoranda. The declaration of the secondary product's name and the product's ingredients will continue to follow the applicable labeling regulations.

C. Comments Opposed to Removing Ready-To-Cook Poultry Products Regulatory Requirements (9 CFR 381.169) and Rescinding Policy Memoranda for Products With Added Solutions

Comment: Several commenters opposed removing the regulatory requirements and policy guidance for products with added solutions (9 CFR 381.169; Policy Memorandum 042, ''Raw Bone-In Poultry Products Containing Solutions;'' Policy Memorandum 044A, ''Raw Boneless Poultry Containing Solutions;'' and Policy Memorandum 066C, ''Uncooked

Red Meat Products Containing Added Substances''). These commenters were specifically concerned about removing the requirement in 9 CFR 381.169(a) that states that the added materials shall increase the weight of the poultry product by approximately 3 percent over the weight of the raw product, and the policy guidance limiting the amount of solution used in products labeled with the terms ''basted,'' ''marinated,'' or ''for flavoring,'' because removing these provisions would result in the unbridled addition of solutions. The commenters also objected to removing the regulatory requirement in 9 CFR 381.169(c) for processors to control the finished product within a range of three-tenths of 1 percent accuracy, using an approved plant control procedure.

Response: As discussed above, FSIS explained in the proposed rule (76 FR 44856) that after the regulation for ready-to-cook, bone-in poultry (9 CFR 381.169) was codified and amended in the 1970's, poultry processors developed technologies, such as injecting solutions deep into muscle tissue, that increased the amount of solution that could be incorporated into products. Therefore, to provide labeling guidance for ready-to-cook, bone-in poultry products that contained more than the approximate 3 percent added solution and ready-to-cook, boneless poultry products with added solution, the Agency issued Policy Memoranda for the industry to develop truthful, easy-to-read labeling information so that consumers could make informed purchasing decisions. The Agency also later issued labeling guidance for raw red meat products with added solutions. The regulatory requirements provided in 9 CFR 381.169(c) for processors to control the finished product within a specified range are only applicable to ready-to-cook, bone-in poultry products with approximately 3 percent added solution. Raw meat and ready-to-cook, boneless poultry products that contain added solutions, and ready-to-cook, bone-in poultry products that contain more than approximately 3 percent added solution follow the labeling guidance provided in the Policy Memoranda.

FSIS does not believe, and the comments did not provide any evidence, that the terms ''marinated,'' ''basted,'' and ''for flavoring,'' provided in Policy Memoranda imply to today's consumers a specific level of added solution in the product. This final rule establishes consistent regulatory requirements for a descriptive designation as part of the product name for all raw meat and poultry products containing added solutions that do not have a standard of identity (9 CFR 317.2(e)(2) and 381.117(h)), regardless of the amount of solution or other information provided on the label. For this reason, the requirements in 9 CFR 381.169 are no longer needed, and will be deleted with this final rule. In addition, when this rule becomes effective, FSIS will eliminate the Policy Memoranda that provides labeling guidance for meat and poultry products with added solutions. The terms ''marinated,'' ''basted,'' ''for flavor,'' and ''flavored with,'' may be used with any level of solution, provided that the product labeling contains a descriptive designation. The final rule includes an example of added solution product label (Figure 3) that uses the term ''flavored with'' in the descriptive designation.

Comment: The commenters that opposed removing 9 CFR 381.169 and the FSIS Policy Memoranda for products with added solution wanted the Agency to retain the requirement of the method of solution introduction and the function of the added materials. In addition, approximately 133 comments that had been submitted as part of a write-in campaign stated that FSIS should require that the method by which solutions are added to the product be included in the product name.

Response: As discussed above, FSIS is deleting 9 CFR 381.169 because it contains regulatory requirements that are outdated and inconsistent with industry practice. Also, FSIS has never required the method of addition or function of the added solution in the labeling of meat products or boneless poultry products. Companies use various methods to add solutions to meat and poultry products, and the solutions can have various functions. The Agency does not have any data suggesting that including the method of addition and function of the added solution in the product name provides useful information to consumers. Therefore, FSIS has concluded that the product name does not have to refer to the method of addition or the function of the added solution.

Comment: Some commenters were concerned that when Policy Memorandum 066C, ''Uncooked Red Meat Products Containing Added Substances,'' is rescinded, it will eliminate the limit on the addition of enzyme solutions (3 percent) to meat products.

Response: The 3 percent limit for tenderizing solutions is a regulatory requirement (9 CFR 424.21 and 381.87(b)(25)) that is not affected by this final rule.

Comment: Several commenters stated that many products with added solutions currently in the marketplace do not meet regulatory requirements or comply with labeling guidance. The commenters stated that the LPDS should be reviewing and ensuring the accuracy of labels during label review.

Response: The LPDS reviews labels that are submitted to ensure compliance with the labeling regulations in 9 CFR parts 317 and 381. However, as provided by 9 CFR 412.2, FSIS authorizes establishments to use generically approved labels without submitting them for approval. Generically approved labels must bear all applicable mandatory labeling features in a prominent manner in compliance with part 317 or part 381, and is not otherwise false or misleading. Inspection program personnel periodically review products with these labels to ensure compliance with labeling requirements. When the LPDS receives a labeling complaint and determines that a label is false or misleading, FSIS contacts the company and advises it to make corrections. If the company does not make corrections, FSIS may rescind or refuse label approval under 9 CFR 500.8, ''Procedures for Rescinding or Refusing Approval of Marks, Labels, and Containers.''

D. Use of the Term ''Enhanced''

Comment: Several commenters stated that FSIS should not allow the use of the term ''enhanced'' in the product name of raw meat or poultry products that contain added solutions. These commenters stated that the term ''enhanced'' suggests the meat is a higher quality or that the meat has been improved by added solutions when it actually may contain increased levels of sodium, which is a concern for consumers trying to limit their sodium intake. These commenters also asserted that the word ''contains'' does not imply a judgment about the product. One commenter recommended that FSIS prohibit the use of the word ''enhanced'' (or similar terms) anywhere on products containing added solutions.

One commenter argued that the term ''enhanced'' should be permitted because the added solution results in a product that is juicier and has an improved value, quality, desirability, and attractiveness over non-enhanced products.

Response: FSIS agrees that the term ''enhanced'' suggests that the product has been increased or improved in value, quality, desirability, or attractiveness, based on the Merriam-

Webster dictionary definition.[1] A product with added solution may or may not be ''juicier'' when consumed, depending on the way it is cooked or used. Whether or not a product with added solution is of improved value, quality, desirability, or attractiveness is dependent on individual preference. FSIS stated in the proposed rule that it recognized that the term ''enhanced'' could imply a judgment about the value of the product; for this reason, the Agency did not propose to include the term ''enhanced'' in the common or usual name for products containing added solutions (76 FR 44858). The Agency has concluded the term ''enhanced'' is not appropriate in the product name (including the descriptive designation) for raw meat and poultry products containing added solution and is stating in the regulatory text that the term ''enhanced'' must not be used in the product name of meat and poultry products containing added solutions that do not meet a standard of identity. The term ''enhanced,'' however, can be used elsewhere on the label, *e.g.,* in a starburst, or in advertising language.

The Agency agrees that the word ''contains'' does not imply a judgment about the product, and, to provide additional clarification and flexibility to producers, FSIS is clarifying in this final rule that the words ''containing'' or ''contains'' may be used in the descriptive designation of raw meat and poultry products containing added solutions, *e.g.,* ''containing 15% Added Solution of Water and Salt,'' or ''contains 15% Added Solution of Water or Teriyaki Sauce.'' Other terms that may be used in the descriptive designation include ''basted'' or ''marinated,'' as listed in the foregoing sections.

E. Comments on Sodium and Salt

Comment: Many commenters expressed the opinion that the current labeling of products with added solutions does not sufficiently alert consumers to the fact that the products contain added solutions, or the fact that salt is almost always included in the added solutions. One commenter recommended that the labels of products with added salt and sodium solutions contain a disclosure statement such as ''Contains SALT: See sodium content on the Nutrition Facts Panel.'' Another commenter recommended that a similar statement be displayed on raw, partially-heat treated, and fully cooked meat and poultry products with added solutions.

However, other commenters indicated that the appropriate place for nutrition information, and where consumers will look for that information, is the Nutrition Facts panel. Additionally, some commenters stated that the proposed amendments would provide improved consumer awareness of the added ingredients, and that consumers would look at the ingredients statement for ingredients of concern, such as salt.

Response: FSIS agrees that the Nutrition Facts panel is the appropriate place for the sodium content to be displayed and is where consumers will look for that information. This conclusion is supported by the 2010 Food and Health Survey conducted by the International Food Information Council (IFIC) Foundation,[2] which found that 68 percent of consumers use the Nutrition Facts panel to obtain nutrition information. Additionally, the survey reported that, when asked which specific elements consumers use on the Nutrition Facts panel, 63 percent of consumers mentioned the statement of sodium content. FSIS also agrees that the proposed amendments will alert consumers to products containing added solutions, and that, being so alerted, consumers are likely to look at the Nutrition Facts panel and the ingredients statement where all ingredients must be listed.

F. Comments on Fully-Cooked or Partially Heat-Treated Products Containing Added Solutions

Comment: A few commenters stated that FSIS should establish common or usual name requirements for non-standardized fully-cooked or partially-heat treated products that contain added solutions. One of the commenters argued that consumers need this information to make informed choices, because consumers will not be aware that a solution was added that could make up a significant portion of the product weight or contain significant amounts of other ingredients.

Other commenters stated that FSIS should not establish a common or usual name for non-standardized fully cooked or partially-heat treated products that contain added solutions. The commenters stated that consumers understand that fully cooked or partially heat-treated products are not single-ingredient products, and that the required qualifiers, *e.g.,* ''Breaded,'' ''Coated,'' and ''Glazed,'' alert consumers to any added ingredients in the products or that the products have been further processed in some way. One commenter expressed concern that it would not be appropriate to require that the common or usual name for these types of products include a listing of ingredients. One commenter suggested that FSIS, in the regulatory text, specifically exclude these products.

Response: FSIS agrees with the commenters that non-standardized fully-cooked or partially heat-treated products, which are typically breaded, coated, and glazed, are obviously not single-ingredient products, and that consumers understand that these products may contain ingredients that affect the products' weight. These commenters support the Agency's tentative conclusion, stated in the proposed rule (FR 76 44858), that consumers are unlikely to be misled into thinking that non-standardized fully cooked or partially-heated treated products that contain added solutions are single-ingredient products.

The regulatory text clearly states that the requirements are for raw meat and poultry products that contain added solutions and that do not meet a regulatory standard (9 CFR 317.2(e)(2) and 381.117(h)). Therefore, the Agency sees no need to add regulatory text to exclude fully-cooked or partially-heat treated products that contain added solutions.

G. Comments on Retail Labeling of Products With Added Solutions

Comment: A trade association that represents food retailers and wholesalers commented that the proposed rule would impose a burden on the supermarket industry. The association stated that retailers would be affected directly because it is not feasible to calculate marinade absorption rates at the retail level because they do not operate in the same manner as a Federal establishment and do not have precise marination times, temperatures, or solution composition; that retail signage would have to be altered; and that retailers would have to redesign labels at a very significant cost. The trade association also stated that the $1,557 per label cost estimate was too low.

Response: As discussed in the proposed rule (76 FR 44859), 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)). Therefore, these regulations 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

[1] *http://www.merriam-webster.com/dictionary/enhance.*

[2] Available at *http://www.foodinsight.org/Content/3651/2010FinalFullReport.pdf.*

processing. Retail stores must comply with amendments in this final rule, including determining marinade absorption rates, redesigning labels, and altering retail signage.

FSIS requested comment on the number of retail facilities that produce product containing added solution and the volume of such product that would be subject to the proposed requirements (76 FR 44862). The Agency did not receive any comments addressing the number of facilities or the volume of product produced at retail. As discussed in the ''Cost and Benefits'' section below, to acquire a better cost estimate, the Agency utilized the March 2011 FDA labeling cost model and contracted for an expert elicitation on the market shares for raw meat and poultry products containing added solutions, including products produced at retail, and has adjusted the per-label cost estimate to $310 per label for a coordinated minor change and $4,380 for an uncoordinated minor change. The expert elicitation concluded that very few products containing added solutions are produced at retail establishments (<5%). FSIS believes the revised label change cost, provided from the March 2011 labeling cost estimate, is a superior estimate as it represents the most detailed study available on the costs associated with labeling of consumer products. FSIS included the expected costs borne by the retailers in the final estimate.

H. Use of the Term ''Natural''

Comment: Numerous consumers commented that products with added solutions should not be labeled as ''natural.'' Several commenters wanted FSIS to take immediate action or quickly move forward on a proposed rule.

Response: Products with added solutions may meet the current FSIS labeling policy guidance for the term ''natural'' if (1) the product does not contain any artificial flavor or flavoring, coloring ingredient, or chemical preservative (as defined in 21 CFR 101.22), or any other artificial or synthetic ingredient; and (2) the product and its ingredients are not more than minimally processed (the practice of marinating or tenderizing products prior to consumption is a minimal process).

The Agency is developing a proposed rule to define the ''natural'' claim in response to comments received on the 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).

I. Compliance Date and Label Review Time

Comment: One commenter stated that the proposed January 1, 2014, compliance date was excessive and unnecessary. The commenter believed that immediate action should be taken, and that the effective date of the final rule could be 30–60 days after publication of the final rule because labeling changes can be easily implemented by industry at a minimal cost.

Another commenter stated that processors need ample time to get through their label inventories and requested that the status of products in-commerce on the effective date of the final rule be clarified by the Agency.

Response: The January 1, 2014, uniform compliance date was applicable for meat and poultry product labeling final rules published between January 1, 2011 and December 31, 2012. On December 31, 2012, FSIS published a final rule establishing January 1, 2016, as the uniform compliance date for meat and poultry product labeling regulations issued between January 1, 2013, and December 31, 2014 (77 FR 76824). Therefore, the effective date of this final rule is January 1, 2016. However, as discussed above, the Agency is providing an applicability date of January 1, 2018 for the one-third (⅓) type size requirement for the descriptive designation to provide additional time and flexibility for establishments to make labeling changes. Based on current guidance for the labeling of these products, many establishments likely use one-fourth (¼) type size for the descriptive designations or qualifying statements for products with added solutions. Establishments may continue to do so until January 1, 2018.

Comment: Several commenters expressed concern that the proposed amendments would overly burden the Agency's label approval process, especially since the proposed labeling changes could not be generically approved within the parameters of 9 CFR 317.5 and 381.133.

Response: On November 7, 2013, FSIS published the final rule, ''Prior Label Approval System: Generic Label Approval'' (78 FR 66826) that expands the circumstances in which FSIS generically approves meat and poultry labels. The labels of meat and poultry products containing added solutions can be generically approved, *i.e.,* the labels do not have to be submitted to FSIS for approval, provided that they display all mandatory features in a prominent manner in compliance with part 317 or part 381, and are not otherwise false or misleading in any particular (9 CFR 412.2). In addition, in May 2012, the Agency launched the Label Submission and Approval System (LSAS). The LSAS will have a significant impact on the speed and accuracy of label review.

J. Comments on Costs and Benefits of the Proposal

Comment: A number of commenters suggested that FSIS underestimated the costs to the industry of the proposed amendments and did not accurately identify the proportion of products with added solution in the marketplace.

Response: FSIS used the more up-to-date model [3] from the secondary cost analysis in the proposed rule to estimate the cost of label changes for the industry. Although a few commenters provided additional cost estimates for label plates, FSIS did not receive any additional numbers that contradict the cost estimates presented in the proposed rule. FSIS continues to believe that these cost estimates are accurate because they represent the most detailed study available on the costs associated with the labeling of consumer products.

In the proposed rule, FSIS estimated that the proportion of products containing added solutions to be about 39 percent of all raw meat and poultry products sold (76 FR 44862). This percentage was based on FSIS's label review process estimates and the pounds of poultry, beef, and pork consumed by households. The sources cited for the pounds of poultry, beef, and pork consumed by household were the U.S. Poultry & Egg Association: Poultry Statistics, 2007; the Economic Research Service, USDA, U.S. Beef and Cattle Industry: Background Statistics and Information, 2007; and the National Pork Producers Council: Background Statistics and Information, 2007. However, the source of the information for the pounds of poultry, beef, and pork consumed by households should have been ''Livestock, Dairy, and Poultry Outlook,'' Dec. 17, 2009. The proposed rule also stated that the number of pounds of poultry consumed by households was 49.2 billion (76 FR 44862), that number, based on the corrected source information, should have been 42.7 billion pounds.

For a better estimate of the amount of product with added solution purchased, FSIS contracted for an expert elicitation on the market shares for raw meat and poultry products containing added

[3] 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).

solutions. The results of that elicitation showed that the amount of product with added solution purchased is approximately 60 percent of the total. The cost analysis in this final rule uses this market share analysis.

Comment: A number of commenters suggested that the costs associated for the rule would be borne by the consumer in a time of economic uncertainty. Conversely, a number of commenters also suggested that consumers unfairly pay a premium price for products with added solutions. Some commenters suggested that this rule will place products with added solutions at a competitive disadvantage to products without the solution.

Response: The overall impact of the final rule on costs to the consumer is expected to be minimal. The estimated additional cost per package is between $0.0013 and $0.003. Thus, the increase in cost of buying two packages per week is between $.13 and $0.36 per year, and the consumer will only pay a portion of the this cost based on the relative elasticity of demand. Given the high elasticity of demand for this product because of the availability of close substitutes, the minimal cost imposed may be borne more by the producers than the consumers.

FSIS has no data to determine that this rule places products with added solutions at a competitive disadvantage to products without the solution and has no evidence to suggest that the market for these products will be adversely impacted.

Comment: One commenter suggested that the current labeling practices will result in higher health care costs.

Response: This rule does not provide new nutrition information. FSIS did not quantify the health care costs and benefits of this rule.

K. Miscellaneous Comments

Comment: One commenter recommended that all of the proposed requirements apply to meat and poultry products that meet standards of identity.

Response: As explained in the preamble to the proposed rule, under this 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 would need to be labeled with a descriptive designation.

Standard of identity regulations provide requirements for added solutions for standardized products. Therefore, consumers likely understand and are aware that products with a standard of identity, such as corned beef or poultry roast, include solutions. The intent of this final rule is to eliminate confusion between single-ingredient products and those similar types of products that contain additional ingredients and solutions. Therefore, the Agency will not include products with a standard of identity in this rulemaking.

Comment: FSIS received numerous comments on an array of issues including: Country of origin labeling for all meat, poultry, fruits, and vegetables; the labeling of genetically modified foods; organic claims; concerns over raising conditions of animals and the use of hormone implants; pesticides and herbicides; mandatory nutrition labeling for liquor products; mandatory declaration of potassium and phosphorus in the Nutrition Facts panel; healthy eating; and nutrition education.

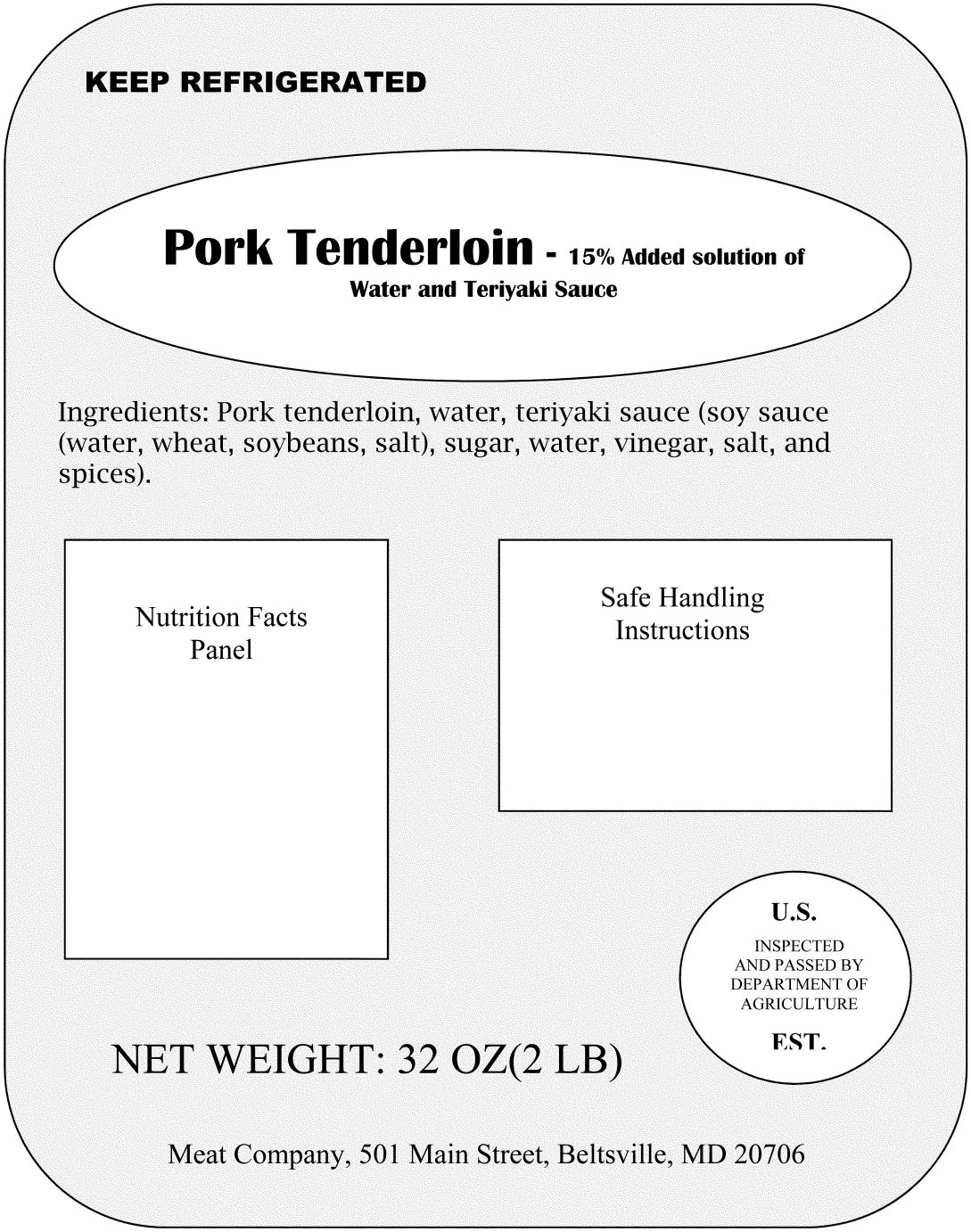
Response: These comments are outside the scope of this rulemaking.

Compliance With This Final Rule

To facilitate Agency verification of compliance with regulatory labeling requirements, FSIS requires that establishments make labeling records available to any authorized USDA official upon request (9 CFR 320.4). Inspection program personnel will perform labeling verification activities to ensure that establishments are complying with the requirements of this final rule. FSIS also performs verification and post-market surveillance activities in-commerce to ensure that meat and poultry product labels comply with all applicable regulations. The Agency will provide guidance on its Web site to assist establishments in meeting the requirements in this final rule. Figures 1 and 2 (below) are examples of labels of pork product containing added solutions and Figure 3 (below) is an example of poultry product containing added solution, all three examples meet the labeling requirements of this final rule.

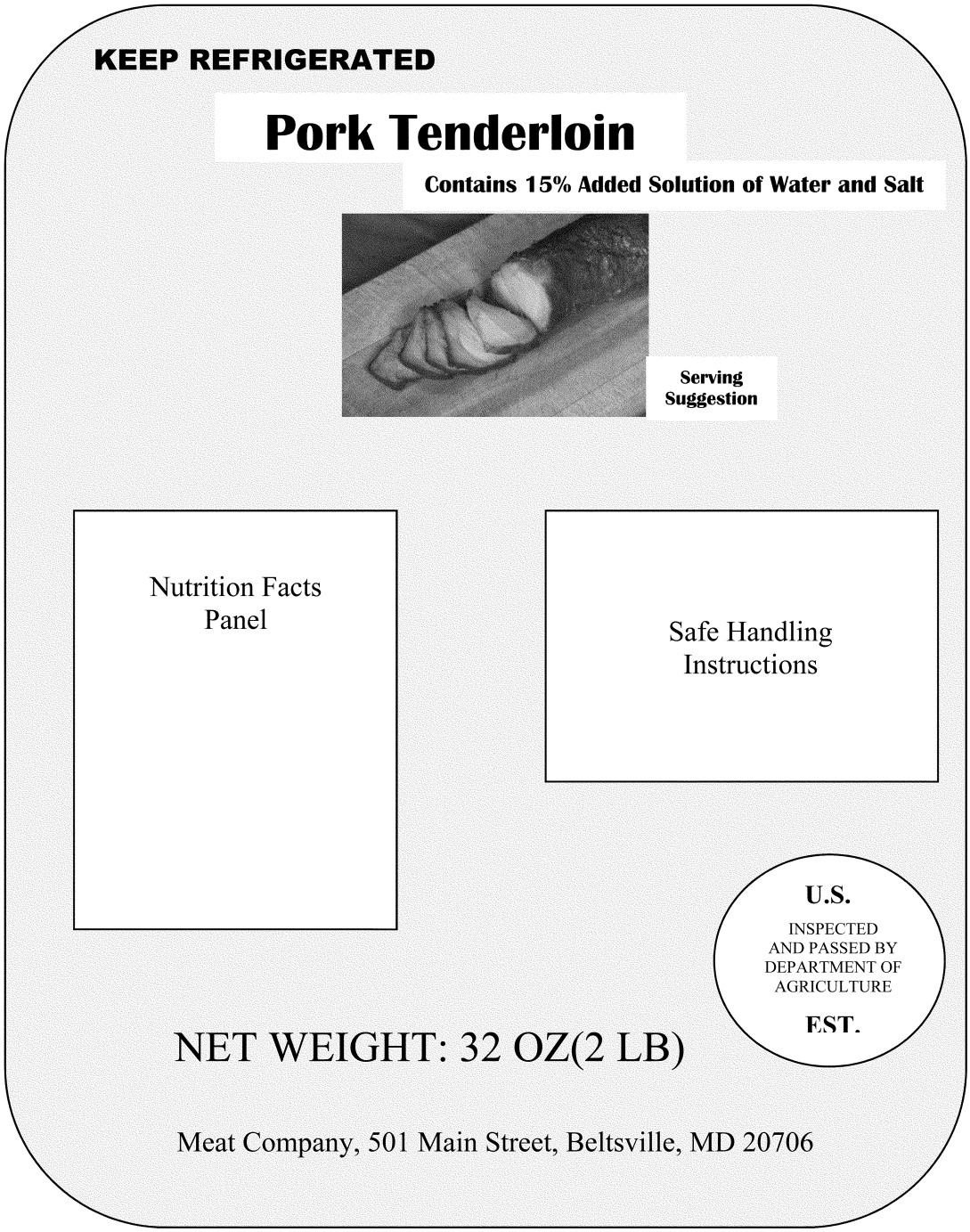
BILLING CODE 3410–DM–P

Figure 1. Label example - The product name includes a descriptive designation at one-third (1/3)[4] the size of the largest letter (9 CFR 317.2(e)(2)(iv)), a multi-ingredient component (Teriyaki Sauce), all ingredients in the product are declared in a separate ingredients statement (9 CFR 317.2(e)(2)(iii)).



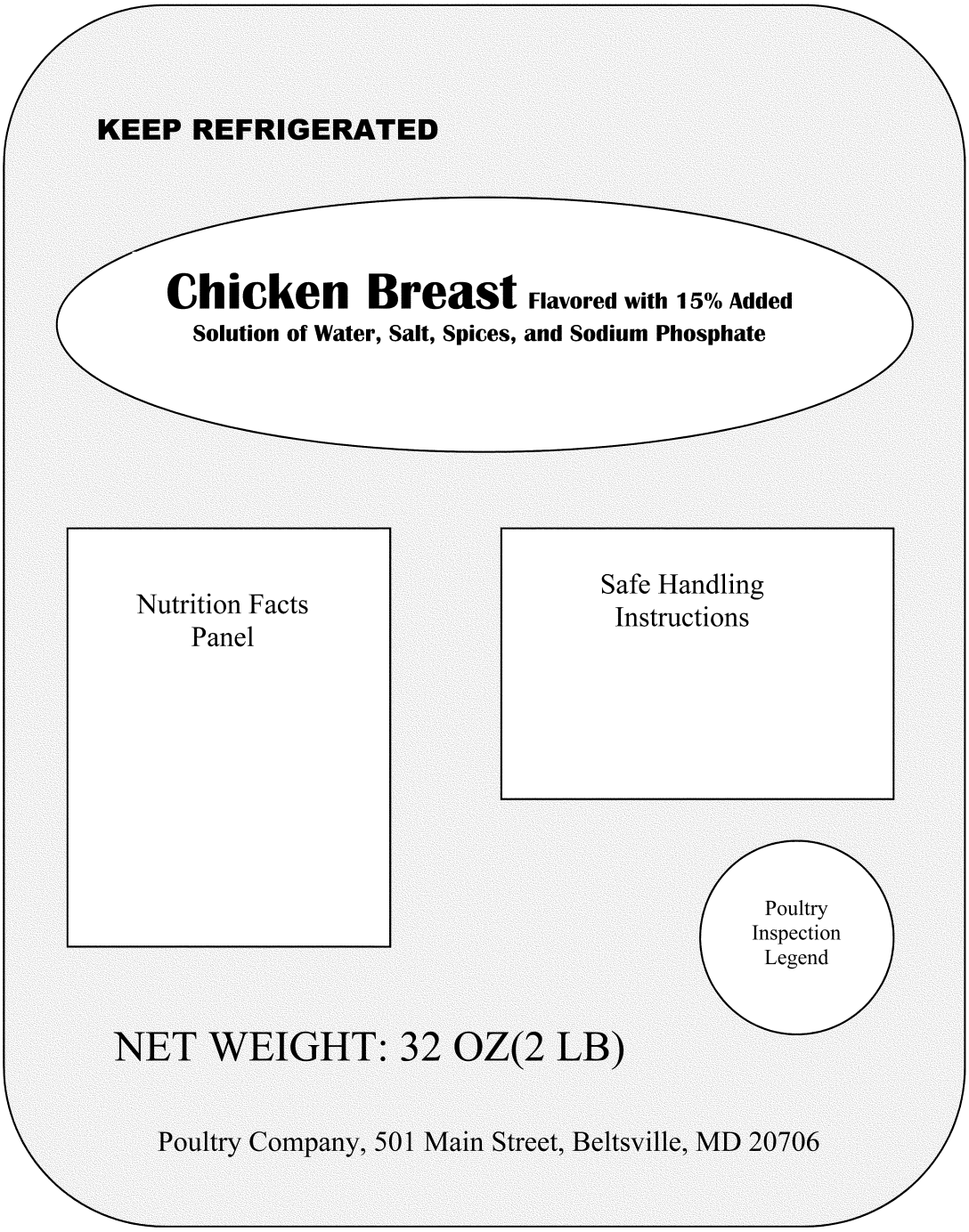
[4] Label shown using the one-third (1/3) font size requirement applicable January 1, 2018.

Figure 2. Label example – The product name includes a descriptive designation at one-third (1/3)[5] the size of the largest letter (9 CFR 317.2(e)(2)(iv)), includes the word "contains" (9 CFR 317.2(e)(2)(i)), the individual ingredients in the solution listed in descending order of predominance by weight (9 CFR 317.2(e)(2)(ii), followed by a vignette of the product.



[5] Label shown using the one-third (1/3) font size requirement applicable effective January 1, 2018.

Figure 3. Label example – The product name includes a descriptive designation at one-third (1/3)[6] the size of the largest letter (9 CFR 381.117(h)(4)), includes the term "flavored with," the individual ingredients in the solution listed in descending order of predominance by weight (9 CFR 381.117 (h)(2)).



[6] Label shown using the one-third (1/3) font size requirement applicable effective January 1, 2018.

BILLING CODE 3410–DM–C

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. This final rule has been reviewed under E.O. 12866. The Office of Management and Budget (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 OMB.

The final rule will apply to all in-commerce raw meat and poultry products containing added solution that do not meet a standard of identity. The labeling requirements would apply to such products that are produced at federal establishments, retail facilities, such as grocery stores, and products produced in countries deemed equivalent under 9 CFR 327.2 and 381.196.

FSIS updated the Regulatory Impact Analysis to take into account recently updated source data and modified timelines for implementation of the final rule. The changes to the costs and benefits sections incorporate the following factors:

- Information Resources, Inc., (IRI) scanner data was used to calculate the number of raw meat and poultry products in the retail market and the number of private and branded products. IRI gathers data by scanners in supermarkets, drugstores, and mass merchandisers and maintains a panel of consumer households that record purchases at outlets by scanning UPC codes on the products purchased.
- FSIS used the FDA March 2011 labeling cost model [7] from the secondary cost analysis in the proposed rule to estimate the cost of label changes for the industry. FSIS believes the FDA March 2011 labeling cost model represents the most detailed study available on the costs associated with labeling of consumer products and reflects more recent data than the primary analysis used in the proposed rule, and therefore is used in the final rule.
- In response to the change in compliance period when calculating the relabeling cost, FSIS adjusted the percentage of coordinated and uncoordinated label changes.

Need for the Rule

Under FSIS's current regulatory approach, some raw products are not conspicuously identifying that they contain added solution. A survey [8] submitted during the comment period found that only 40 percent of all consumers are aware that the products they purchase may contain added solutions, and therefore, FSIS assumes that current regulations are insufficient to fully inform consumers about the nature of the product they purchase. It is important for consumers to have readily available information on meat and poultry products with added solutions as 87 percent of chicken purchasers care if their chicken contains additives (Sorensen, November 2004).[9] Fifty-four percent of the respondents in this study indicated they felt deceived at the disclosure that some chicken products include additives and 10 percent indicated they felt angry. This research has some limitations such as no reported peer review and some methodological weakness. The research did not provide information on response rate or sample selection which could contribute to survey bias. On the other hand, this study is strengthened by the diversity of the six primary sampling units [10] and a significant sample size; moreover, its results are similar to those of other consumer studies.[11]

FSIS, in response to stakeholder petitions and after evaluating its experience in reviewing labels, determined that some added-solution product labels that follow current labeling guidance and comply with current regulations are misleading because they do not clearly and conspicuously show that the product contains an added solution, and that, without updated labeling regulations that require the conspicuous qualifying statement, consumers likely cannot distinguish between raw single-ingredient products versus similar raw products containing added solution. A market failure exists when raw products with added solutions are misbranded and information is not readily available for the consumer. This market failure results from inadequate information in misbranded products and information asymmetry between producers and retail consumers and leads to suboptimal equilibrium quantities for both products containing solutions and products not containing solutions because consumers cannot readily identify the differences between the two groups. 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. The new regulation presented in the final rule addresses the market failure by requiring that all labels for these types of products provide clear and conspicuous labeling.

Baseline

FSIS contracted for an expert elicitation on the market shares for raw meat and poultry products containing added solutions (February 2012 report).[12] The February 2012 report, using FSIS data on the number of establishments that produce each type of product by species and establishment size and the 2010 total volume,[13] provided estimates of numbers of establishments that produce products with added solutions only (*i.e.,* without mechanical tenderization) and establishments that produce mechanically tenderized products with added solutions and estimates of the total volume of these products.

[7] FDA March 2011 labeling cost model: A copy of the document is available in the FSIS Docket Room, Patriots Plaza 3, 355 E. Street SW., Room 8–164, Washington, DC 20250–3700.

[8] Label Contaminant Statement Package Test: Study Results, Prepared for: Tyson Foods, Inc. by Lunt Associates. Question 10. May 2011.

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

[10] The research in the Sorensen Study was conducted in six primary sampling units; Atlanta, Chicago, San Francisco, Kansas City, Dallas and Seattle.

[11] Label Contaminant Statement Package Test: Study Results, Prepared for: Tyson Foods, Inc. by Lunt Associates. May 2011.

[12] Expert Elicitation on the Market Shares for Raw Meat and Poultry Products Containing Added Solutions and Mechanically Tenderized Raw Meat and Poultry Products. Final Report. Research Triangle Institute. February 2012. Available at: *http://www.fsis.usda.gov/wps/wcm/connect/3a97f0b5-b523-4225-8387-c56a1eeee189/Market_Shares_MTB_0212.pdf?MOD=AJPERES.*

[13] FSIS data estimated the 2010 total volume by multiplying slaughter volumes by average carcass weights.

TABLE 1—ESTIMATED NUMBER OF ESTABLISHMENTS THAT PRODUCE EACH TYPE OF PRODUCT BY SPECIES AND ESTABLISHMENT SIZE [14]

Species	Product	Very small	Small	Large	Total
Beef	Containing added solutions only [15]	181	218	21	420
	Mechanically tenderized with added solutions	251	218	21	490
Pork	Containing added solutions only	285	439	34	758
	Mechanically tenderized with added solutions	256	293	27	576
Lamb and Goat	Containing added solutions only	24	29	0	53
	Mechanically tenderized with added solutions	35	34	0	69
Chicken	Containing added solutions only	282	371	131	784
	Mechanically tenderized with added solutions	267	346	116	729
Turkey	Containing added solutions only	80	123	21	224
	Mechanically tenderized with added solutions	75	127	21	223

Note: Establishments may produce multiple types of products and species and, therefore, may be represented in more than one row of the table.

The February 2012 report also provided updated estimates for the proportion of products containing added solutions. The preliminary regulatory impact analysis estimated that the proportion of products containing added solutions was 39 percent (76 FR 44855–44865). Based on the findings of the February 2012 report, FSIS estimates that approximately 60 percent of all raw meat and poultry products sold contain added solutions. The proportions and volumes for specific product classes are found in Table 2.

TABLE 2—PROPORTION OF RAW PRODUCTS CONTAINING ADDED SOLUTIONS IN MILLIONS OF POUNDS BY SPECIES

Product category	Volume produced (2010) [1]	Proportion of product containing added solutions (%) [2]	Estimated amount of raw product containing added solutions (volume * proportion)
Beef	24,300	21	5,127
Pork	21,400	57	12,134
Lamb and Goat	185	30	55
Chicken	49,400	78	38,532
Turkey	7,000	74	5,194
Total	102,285	60	61,042

[1] Numbers derived from FSIS data, as reported in the Expert Elicitation on the Market Shares for Raw Meat and Poultry Products Containing Added Solutions and Mechanically Tenderized Raw Meat and Poultry Products. Final Report. Research Triangle Institute. February 2012. Section 3.2.1 Available at *http://www.fsis.usda.gov/wps/wcm/connect/3a97f0b5-b523-4225-8387-c56a1eeee189/Market_Shares_MTB_0212.pdf?MOD=AJPERES.*

[2] *Id.,* Table 3.6. Derived by summing median estimates for ''enhanced only'' and ''mechanically tenderized and enhanced.''

* Totals in Estimated Amount do not necessarily add up due to rounding in Proportion of Product Containing Added Solutions.

Currently, although labeling regulations and guidance state that the labeling of products must include a qualifying statement that reflects the fact that the product contains added solution, the statement may not be readily apparent to consumers. This is because the statement is not conspicuous. For example, through label review, FSIS has found product labels contain product names in bold fonts with strong contrasting backgrounds, with the qualifying statement on added solution printed in 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 regulations and guidance, it does not clearly identify to consumers that the product contains added solutions. This rule addresses these issues.

The final rule will apply to all in-commerce raw meat and poultry products containing added solution that do not meet a standard of identity. These products will require a new label in order to comply with the final rule.

A March 2011 FDA report [16] 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

[14] Expert Elicitation on the Market Shares for Raw Meat and Poultry Products Containing Added Solutions and Mechanically Tenderized Raw Meat and Poultry Products. Final Report. Table 3–11 and 3–16. Available at: *http://www.fsis.usda.gov/wps/wcm/connect/3a97f0b5-b523–4225–8387-c56a1eeee189/Market_Shares_MTB_0212.pdf?MOD=AJPERES.*

[15] The expert elicitation report referred to products ''containing added solutions'' as ''enhanced.''

[16] 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).

package surface area. FSIS estimates the cost of label modification to accommodate the requirements of this final rule to fall into the minor category.

The March 2011 FDA Report divides the minor category into minor coordinated and minor uncoordinated changes based on the assumption that all products are typically relabeled at least as often as every 3 to 4 years. The cost estimate is $310 per label (with a range of $170 to $440) for minor coordinated changes and $4,380 per label (with a range of $2,417 to $7,330) for minor uncoordinated changes.[17] The model, defined in the report, assigns additional costs, *e.g.* labor, to any change that does not fall into this 3 to 4 year period and is designated to be an uncoordinated change that requires additional cost attributes.

This rule will affect foreign establishments that manufacture and export raw meat or poultry products containing added solutions to the United States, the same as it affects U.S. establishments. The labeling costs for the affected foreign establishments are captured in the total costs outlined later in this analysis. However, these products are not typically imported; based on label review data,[18] the amount of raw meat and poultry products containing added solutions imported into the United States is estimated to be less than 1 percent of the products imported into the United States. For the purposes of this analysis, FSIS assumes that the majority (>99.0 percent) of the affected products are domestically produced.

Regulatory Alternatives

We have identified three regulatory options for this rule.

1. Require or propose the use of ''enhanced'' in the containing statement;
2. The final rule, except no requirement on background color for the qualifying statement;
3. Amend FSIS regulations to establish a common or usual name for raw meat and poultry products that contain added solutions; and
4. The final rule.

1. Require the Use of ''Enhanced'' in the Containing Statement

Under this alternative, FSIS would require the word ''enhanced'' in the qualifying statement, or propose the use of the term ''enhanced'' in the containing statement, *e.g.,* ''enhanced with a 15% solution . . .''

FSIS did not select this alternative to require the word ''enhanced'' in the qualifying statement because the word implies that the product is improved by the addition of the solution. The intent of this rule 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. The cost for this alternative is the same or slightly less than the preferred alternative; however benefits for consumers may be reduced as a result of decreased transparency of products with and without added solutions.

In addition, consumer research (Sorensen, November 2004)[19] 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) than the use of the description ''contains up to 15% water, salt, and sodium phosphates.''

2. Final Rule, Except No Requirement on Background Color for the Qualifying Statement

Under this alternative, the color and style of the product's qualifying statement is not required on a single-color contrasting background. FSIS would still require the qualifying statement to 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.

FSIS did not select this alternative because the benefits would likely be reduced. A benefit of this rule is to help consumers determine whether products containing added solutions are suitable for their personal preference and dietary needs. Removing the requirement for background color choice would decrease transparency, as a result of the reduction in contrast, to consumers.

The cost for this alternative is slightly less than the preferred alternative because some existing labels already meet these requirements. FSIS does not have supporting data to estimate the precise number of labels in compliance with this alternative, but we expect the number is minimal. FSIS expects reduced benefits from this alternative as consumers are less likely to distinguish products with and without added solutions, resulting in less informed decisions. Consumers would not fully benefit from improved consumer awareness and understanding that raw meat or poultry products may contain added solutions.

3. Amend FSIS Regulations To Establish a Common or Usual Name for Raw Meat and Poultry Products That Contain Added Solutions

Under this alternative, the common or usual name for a raw meat or poultry product that contains an added solution would need to include the percentage of added solution, and list the individual ingredients or multi-ingredient components of the solution in descending order of predominance by weight. Also, FSIS considered finalizing the proposed provisions that would require that the print for all words in the common or usual name appear in a single font size, color, and style of print. As discussed above, after considering the comments, FSIS concluded that the proposed requirements were more onerous and stricter than necessary. Therefore, FSIS did not select this alternative and made changes to the proposed rule to provide more flexibility and more consistency with other labeling regulations.

4. The Final Rule

Under this alternative, FSIS would require that the qualifying statement includes 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.

FSIS selected this alternative because it is preferred to the other alternatives and is likely to improve consumer awareness and understanding that the raw meat or poultry product contains an added solution. The percentage of the solution and the ingredients of the solution included in a qualifying statement is information consumers need to make informed purchasing decisions.

Expected Cost of the Final Rule

The final rule will result in one-time costs to establishments and retail facilities that produce and package raw meat and poultry products containing added solutions. Producers may bear most of the cost burden, not the consumers, given the high elasticity of demand for this product because of the availability of close substitutes. All of the costs pertain to the label modification procedures for the affected products. The estimated cost of modifying labels is determined by the number of label plates or digitized label

[17] FDA March 2011 labeling cost model: A copy of the document is available in the FSIS Docket Room, Patriots Plaza 3, 355 E. Street SW., Room 8–164, Washington, DC 20250–3700.

[18] Source: FSIS Labeling and Program Delivery Staff.

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

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.

Market Share

FSIS has updated the estimates for the proportion of products containing added solutions to reflect the data received in the February 2012 report. Based on the findings of the report, FSIS estimates that approximately 61.0 billion pounds or 60 percent of the 102.3 billion pounds of meat and poultry products produced by federally inspected establishments in the U.S. contain added solutions (Table 2). The February 2012 report applies the estimate to the estimated pounds of enhanced-only products and mechanically tenderized and enhanced products by species, packaging, and labeling type. Based on this data, FSIS is able to estimate (Table 3) the breakdown by percentage of labels for products containing added solutions in the marketplace.[20]

TABLE 3—PERCENT OF ENHANCED-ONLY AND MECHANICALLY TENDERIZED AND ENHANCED PRODUCTS BY SPECIES, PACKAGING, AND LABELING TYPE

Packaging or labeling type	Beef (percent)	Pork* (percent)	Lamb and goat* (percent)	Chicken (percent)	Turkey (percent)	All*[1] (percent)
Brand Name Label for Retail Sales	21	35	34	36	38	35
Private Label for Retail Sales	22	31	27	22	22	24
Foodservice	51	30	38	37	35	37
Retail	6	5	2	5	5	5

[1] Unweighted average.
* Totals do not necessarily add up due to rounding.

Costs for Label Modification

IRI scanner data indicate that there are 13,697[21] raw meat and poultry labels in retail, 16.39 percent (or 2,245) of which are private label, with the remainder (or 11,452) branded. Although IRI's geographic coverage—which includes the largest urban areas in the U.S. and a few whole states—may yield a reasonable estimate of the universe of branded retail labels, a substantial number of chains that are large enough to have their own private labels but that only serve small or medium-sized cities may be missed. For this reason, the IRI results will be used as a lower bound on the number of retail labels affected by this rule. To estimate an upper bound, we make use of the estimates in Table 3, to calculate that 37.5 percent (24%/[35% + 24% + 5%]) of retail labels may be private label. In this case, there are an estimated 6,871 private retail labels and 18,323 (11,452 + 6,871) total retail labels. Because the IRI scanner data do not capture food service labels, these estimates must be adjusted upward; based on the contents of Table 3, about 37 percent of all meat and poultry products are for food service. From this, FSIS estimates about 37 percent of meat and poultry labels are for food service and the remaining 63 percent of label are for retail, yielding estimates of 21,741 (13,697/63%]) to 29,084 (18323*/63%) raw meat and poultry product labels in the marketplace. The market share of raw meat and poultry products that contain added solutions is estimated to be 60 percent. Therefore, FSIS estimates approximately 13,045 (21,741 * 60%) to 17,450 (29,084 * 60%) unique labels for meat and poultry raw products containing added solution in-commerce.

This cost analysis uses the label design modification costs for a minor coordinated label change and a minor uncoordinated label change as defined in the March 2011 FDA Report.[22] The use of the label design modification costs for minor coordinated and uncoordinated label changes are further supported by the 2-year compliance increments defined in the FSIS regulation titled ''Uniform Compliance Date for Food Labeling Regulations.''[23] That regulation helps 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. In other words, the ''Uniform Compliance Date for Food Labeling Regulations'' increases the number of establishments that can incorporate new requirements as a coordinated change, which reduces the cost of complying with the final regulation. (For example, FSIS is simultaneously developing a final rule that would require additional labeling for beef products that are mechanically tenderized. The cost associated with the labels for mechanically tenderized beef products containing added solutions are lessened if both rules' changes are required as of the same Uniform Compliance Date.)

The labeling cost model states that the allocation of label changes between coordinated and uncoordinated depends on the compliance period allowed by the regulation under consideration. For some products affected by this rule, the only necessary label change is an increase in the formatting of the descriptive designation so that the size of the smallest letter is at least one-third, rather than just one-fourth, the size of the largest letter; the cost impact for such products would be appropriately analyzed using the model's results for a 36-month compliance period (100% of branded and 57% of private label changes able to be coordinated). On the other hand,

[20] Expert Elicitation on the Market Shares for Raw Meat and Poultry Products Containing Added Solutions and Mechanically Tenderized Raw Meat and Poultry Products. Final Report. Tables 3–15 and 3–16. Available at: *http://www.fsis.usda.gov/wps/wcm/connect/3a97f0b5-b523–4225–8387-c56a1eeee189/Market_Shares_MTB_0212.pdf?MOD=AJPERES.*

[21] Information Resources, Inc, (IRI) scanner data was used to calculate the number of raw meat and poultry products in the retail market. IRI gathers data by scanners in supermarkets, drugstores, and mass merchandisers and maintains a panel of consumer households that record purchases at outlets by scanning UPC codes on the products purchased.

[22] 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).

[23] 77 FR 76824.

many products—including the ones currently labeled with term ''enhanced''—will be subject to a 12-month compliance period (for which the model shows 11% of branded and 5% of private label changes can be coordinated). In the absence of data on the portion of products that will need to have label changes in 12 months and the portion that will need to have label changes in 36 months, we present results using only the 12-month estimates, acknowledging that this approach leads to an overstatement of the actual rule-induced costs.

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) and $4,380 per label (with a range of $2,417 and $7,330) for a minor uncoordinated change.[24] Using these costs for the number of minor coordinated and uncoordinated changes in branded and private modified labels from Table 4, FSIS estimates that the one-time total cost of modifying labels for all federally inspected processors is between $52 and $84 million as lower and upper bound estimates. Over a ten year period, the lower and upper bound annualized cost for the industry is $5.9 and $9.6 million at a 3 percent discount rate (DR) over ten years and $6.9 and $11 million at a 7 percent DR over ten years.

The relabeling cost estimate is an overestimate for several reasons beyond those already discussed. The model used to calculate the cost for updating food labels encompasses all food labels products, including FDA food labels. Information from FSIS's Labeling and Program Delivery Staff's (LPDS) determined label changes for FSIS products occur more frequently than the model indicates, resulting in an overestimate of costly uncoordinated changes. Additionally, the relabeling estimate includes all unique labels with added solutions while many products with added solutions are already in compliance with regulations provided in this rule. For these reasons, FSIS considers the relabeling cost estimate an overestimate.

TABLE 4—RELABELING COST FOR MEAT AND POULTRY PRODUCTS WITH ADDED SOLUTIONS, 12 MONTH COMPLIANCE PERIOD

Lower bound	Branded		Private		Cost		
	10,907		2,138		Lower	Mid	Upper
Coor Chg	1,200	11%	107	5%	$222,129	$405,059	$574,922
Uncoor Chg	9,707	89%	2,031	95%	28,371,037	51,412,967	71,154,236
Total Lower Bound Cost					28,593,166	51,818,026	71,729,158
Annualized Cost (3% DR, 10 Year)					3,254,360	5,897,722	8,163,928
Annualized Cost (7% DR, 10 Year)					3,804,695	6,895,066	9,544,503
Upper bound	**Branded**		**Private**		**Cost**		
	7,670		3,464		Lower	Mid	Upper
Coor Chg	1,944	11%	173	5%	359,879	656,250	931,452
Uncoor Chg	15,727	89%	3,291	95%	45,964,902	83,295,933	139,397,075
Total Upper Bound Cost					46,324,781	83,952,183	140,328,526
Annualized Cost (3% DR, 10 Year)					5,272,502	9,555,104	15,971,635
Annualized Cost (7% DR, 10 Year)					6,164,118	11,170,937	18,672,547
Minor Coordinated					170	310	440
Minor Uncoordinated					2,417	4,380	7,330

The cost of modifying the labels is small relative to the total volume of meat and poultry products. On a per pound basis, the upper bound one-time cost for this rule is $.0014/per pound ($83 million/61.0 billion pounds). Further, the 2010 National Meat Case Study[25] found that the average number of pounds per package in the market place is 2 pounds. In the study, chicken and pork packages tended to be slightly heavier at 2.5 and 2.1 pounds respectively. Therefore, by applying a range of 1.5 to 2.5 pounds per package to the low and high range mid-point cost estimates, the estimated additional cost per package is between $.0013 and $.003. This cost is only incurred once and would be even smaller if annualized (per package) over future years.

FSIS Budgetary Impact of the Final Rule

This final 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.

Expected Benefits of the Final Rule

FSIS anticipates benefits for the consumer such as improved consumer awareness and understanding that raw meat or poultry products may contain added solutions. This may increase consumer welfare.

The rule will likely improve 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. As noted in the need for rule sections, nearly 60 percent of consumers are unaware that meat and poultry products contain added solutions. Therefore, 60 percent of consumers purchasing a chicken containing 15 percent added solution are unaware they are purchasing a product that is 85 percent chicken and 15 percent added solution. Providing truthful and

[24] All costs are shown in 2010 Dollars.

[25] 2010 National Meat Case Study Executive Summary. Accessed here: *http://www.beefretail.org/CMDocs/BeefRetail/research/2010NationalMeatCaseStudy.pdf.*

accurate information on the label allows consumers to compare value among such products and make a more informed purchasing decision.

Consumers can better determine whether products containing added solutions are suitable for their personal preferences and dietary needs through the added solutions qualifying statement. 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. For example, a raw chicken breast containing added solutions averages an additional 333 mg of sodium than chicken without added solutions, (122mg–455mg).[26] High intakes of sodium are directly associated with elevated blood pressure leading to risks of cardiovascular disease (CVD) and stroke.[27] While some research [28] suggests a U-shape relationship between sodium and health with favorable sodium intake between 2,645 and 4,945 mgs, a Nutrition Impact Model developed by Tim Dall estimates 1.5 million fewer cases of hypertension with a potential annual savings of $2.3 billion if adults with uncontrollable hypertension reduced their daily sodium intake by 400 mg.[29]

Additionally, it is estimated that there are about 3 million pre-hypertensive and hypertensive persons in the US population.[30] A consumer research study indicates that 39% of consumers read but do not understand current labels,[31] and an FDA consumer study estimates that 49% of consumers would read and be able to understand new labels.[32] Considering that difference and the estimates of pre-hypertensive and hypertensive adults in the U.S. population, about 1 million individuals may be able to better understand and apply the new label information and, thereby, be better able to stay within their dietary salt intake requirements.

More complete label information should increase consumer welfare. Based on 2009–2010 National Health and Nutrition Examination Survey data, NHANES, 46 percent of consumers rarely or never read food labels when buying raw meat, poultry or fish products.[33] Of the consumers who rarely or never using food labels, 21 percent specified they are not checking food labels because they did not know what to look for. Results from the 2008 Health and Diet Survey indicated 29 percent of respondents who never read food labels are not using labels because it is hard to understand. The new requirements in this rule may make it easier for consumers to understand the label and identify what to look for. Providing more complete label information, currently unavailable in the marketplace, will reduce transaction costs for consumers trying to satisfy individual dietary or other preferences. Consumers with complete information will be better able to discriminate between products with added solutions and those without and select the products they prefer, resulting in an increase in consumer welfare.

Regulatory Flexibility Analysis

The FSIS Administrator certifies that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601–602), the final rule will not have a significant economic impact on a substantial number of small entities in the United States.

There are about 6,099 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 the classifications outlined in the Pathogen Reduction; Hazard Analysis Critical Control Point (HACCP) final rule (61 FR 38819). Hence, more than 90 percent of the federal establishments [34] that produce meat and poultry products with added solutions which could possibly be affected by this rule are small or very small according to the FSIS HACCP definition.

In the cost analysis above, FSIS estimated that the total upper and lower bound one-time cost for the industry is about $52 to $84 million. This results in an average one-time cost per establishment of about $8496 ($52 million/6,099 establishments) to $13765 ($84 million/6,099) or $967 to $1567 annualized (3 percent, 10 years). The small and very small establishments produce less output and fewer unique labels, and therefore their average one-time cost per establishment will be lower. Thus, 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.

Executive Order 13175

This final rule has been reviewed in accordance with the requirements of Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments.'' FSIS has concluded, on the basis of its evaluation, that this final rule will not have substantial and direct effects on Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power or responsibilities between the Federal Government and Indian Tribes. Nonetheless, FSIS will include Tribes and intertribal organizations, involved in or interested in the meat and poultry sectors, in the Agency's outreach efforts associated with implementation and administration of this final rule.

Executive Order 12988 Civil Justice Reform

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this 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.

[26] U.S. Department of Agriculture, Agricultural Research Service. 2013. USDA National Nutrient Database for Standard Reference, Release 26. Nutrient Data Laboratory Home Page, available at: *http://ndb.nal.usda.gov/ndb/*.

[27] Institute of Medicine (IOM) of the National Academies. ''Sodium Intake in Populations: Assessment of Evidence (2013), Chapter 4: Sodium Intake and Health Outcomes,'' Washington, DC: National Academies Press; 2013. pp.57.

[28] N. Graudal, G. Jurgens, B. Baslund, M.H. Alderman. Compared With Usual Sodium Intake, Low- and Excessive-Sodium Diets Are Associated With Increased Mortality: A Meta-Analysis. *American Journal of Hypertension,* 2014; DOI: *10.1093/ajh/hpu028*.

[29] Dall, T.M., V.L. Fulgoni III, Y. Zhang, K.J. Reimers, P.T. Packard, and J.D. Astwood. 2009. Potential health benefits and medical cost savings from calorie, sodium, and saturated fat reductions in the American diet. American Journal of Health Promotion. 23 (6), 12–22.

[30] Estimate is derived using U.S. Census Bureau, 2013 population estimates and studies that indicate that about 31% of American adults have high blood pressure (CDC. *Vital signs: awareness and treatment of uncontrolled hypertension among adults—United States, 2003–2010. MMWR.* 2012;61(35):703–9) and an additional one in three have prehypertension (Go AS, Mozaffarian D, Roger VL, *et al. Heart disease and stroke statistics—2013 update: a report from the American Heart Association. Circulation.* 2013;127:e6–245).

[31] Label Contaminant Statement Package Test: Study Results, Prepared for: Tyson Foods, Inc. by Lunt Associates. Question 10. May 2011.

[32] FDA. ''Consumer Behavior Research 2008 Health and Diet Survey'' Topline Frequencies. Question C3. Available at: *http://www.fda.gov/Food/FoodScienceResearch/ConsumerBehaviorResearch/ucm193895.htm.*

[33] NHANES. 2013 ''Questionnaires, Datasets, and Related Documentation'' Center for Disease Control and Prevention. Accessed on 6/16/2014. Available at: *http://www.cdc.gov/nchs/nhanes/nhanes_questionnaires.htm.*

[34] Expert Elicitation on the Market Shares for Raw Meat and Poultry Products Containing Added Solutions and Mechanically Tenderized Raw Meat and Poultry Products. Final Report. Table 3–11. Available at: *http://www.fsis.usda.gov/wps/wcm/connect/3a97f0b5-b523-4225-8387-c56a1eeee189/Market_Shares_MTB_0212.pdf?MOD=AJPERES.*

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or record keeping requirements included in this final rule have been submitted for approval to the Office of Management and Budget (OMB). This information collection request is at OMB awaiting approval. FSIS will collect no information associated with this rule until the information collection is approved by OMB.

Copies of this information collection assessment can be obtained from Gina Kouba, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW., Room 6083, South Building, Washington, DC 20250–3700; (202) 690–6510.

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

FSIS will announce this rule online through the FSIS Web page located at *http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/interim-and-final-rules.*

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. 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/wps/portal/fsis/programs-and-services/email-subscription-service.* 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.

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

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 amending 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 paragraph (e)(2) to read as follows:

§ 317.2 Labels: definition; required features.

* * * * *

(e) * * *

(2) The product name for a raw meat product that contains added solution and does not meet a standard of identity in 9 CFR part 319 must contain a descriptive designation that includes:

(i) 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). The percentage of added solution must appear as a number (such as, 15, 20, 30) and the percent symbol (%). The percentage of added solution may be declared by the words ''containing'' or ''contains'' (such as, ''contains 15% added solution of water and salt,'' or ''containing 15% added solution of water and teriyaki sauce'').

(ii) The common or usual name of all individual ingredients or multi-ingredient components in the solution listed in descending order of predominance by weight.

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

(iv) The product name and the descriptive designation must be printed in a single easy-to-read type style and color and must appear on a single-color contrasting background. The print may appear in upper and lower case letters, with the lower case letters not smaller than one-third (⅓) the size of the largest letter.

(v) The word ''enhanced'' cannot be used in the product name.

* * * * *

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. Amend § 381.117 by adding paragraph (h) to read as follows:

§ 381.117 Name of product and other labeling.

* * * * *

(h) The product name for a raw poultry product that contains added solution and does not meet a standard of identity in this part must contain a descriptive designation that includes:

(1) 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). The percentage of added solution must appear as a number (such as, 15, 20, 30) and the percent symbol (%). The percentage of added solution may be declared by the words ''containing'' or ''contains'' (such as, ''contains 15% added solution of water and salt,'' or ''containing 15% added solution of water and teriyaki sauce'').

(2) The common or usual name of all individual ingredients or multi-ingredient components in the solution listed in descending order of predominance by weight.

(3) When the descriptive designation includes all ingredients in the solution, a separate ingredients statement is not required on the label. When the descriptive designation 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.

(4) The product name and the descriptive designation must be printed in a single easy-to-read type style and color and must appear on a single-color contrasting background. The print may appear in upper and lower case letters, with the lower case letters not smaller than one-third (⅓) the size of the largest letter.

(5) The word ''enhanced'' cannot be used in the product name.

§ 381.169 [Removed and Reserved]

■ 5. Remove and reserve § 381.169.

Done at Washington, DC, on December 23, 2014.

Alfred Almanza,

Acting Administrator.

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