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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317

[Docket No. FSIS-2008-0017]

RIN [0583-AD45]

Descriptive Designation for Needle- or Blade-Tenderized
(Mechanically Tenderized) Beef Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat inspection regulations to require the use of the descriptive designation "mechanically tenderized," "blade tenderized," or "needle tenderized" on the labels of raw or partially cooked needle- or blade-tenderized beef products, including beef products injected with a marinade or solution, unless the products are to be fully cooked or to receive another full lethality treatment at an official establishment. Under these final regulations, the product names of the affected products will have to include the descriptive designation "mechanically tenderized," "blade tenderized," or "needle tenderized" and an accurate description of the beef component. The print for all words in the descriptive

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designation and the product name will have to be 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 (1/3) the size of the largest letter. In addition, the labels of raw and partially cooked needle- or blade-tenderized beef products destined for household consumers, hotels, restaurants, or similar institutions will have to bear validated cooking instructions. The instructions will have to specify the minimum internal temperatures and any hold or "dwell" times for the products to ensure that they are fully cooked.

FSIS is amending the regulations because of scientific evidence that mechanically tenderized beef products need to be fully cooked in order to reduce the risk of pathogenic bacteria that may be transferred to the interior of the meat during mechanical tenderization.

FSIS is also announcing the availability of updated guidance for the use of federally inspected establishments in developing validated cooking instructions for mechanically tenderized product.

DATES: The effective date is [INSERT DATE 365 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. As discussed

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below in the preamble, FSIS has established this effective date based on the potential public health benefits.

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SUPPLEMENTARY INFORMATION:

Executive Summary

Mechanically tenderizing beef with a needle or blade has the potential to transfer pathogens that may occur on the exterior of the product into its interior. In such circumstances, it is important that the interior of the beef product be fully cooked. Not all mechanically tenderized products are readily distinguishable from non-tenderized products. Recent outbreak data indicate that consumers and food service facilities sometimes do not cook mechanically tenderized raw beef products to a temperature and for a time sufficient to destroy harmful bacteria that may have been transferred to the tenderized interior of the product. FSIS has, therefore, determined that labeling to state that the beef product is tenderized, along with validated cooking instructions, are necessary to provide

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consumers and food service workers the essential information to safely prepare the product.

On June 10, 2013, FSIS proposed new labeling requirements for raw or partially cooked needle- or blade-tenderized beef products, including beef products injected with a marinade or solution (78 FR 34589). Having reviewed and considered all comments received on the proposal, FSIS is finalizing all the proposed regulatory requirements with minor changes.

FSIS is requiring the labels of raw or partially cooked needle- or blade-tenderized beef products, including beef products injected with marinade or solution, to bear a descriptive designation that clearly indicates that the product has been mechanically tenderized, unless such product is destined to be fully cooked or to receive another full lethality treatment¹ that renders the product ready-to-eat, as defined in 9 CFR 430.1, in an official establishment.² To provide flexibility and respond to comments, FSIS is requiring in the final rule that the terms "needle tenderized" or "mechanically tenderized" be used as the descriptive designation for needle tenderized

¹Examples of full lethality treatments other than cooking that render a product ready-to-eat can include high pressure processing and irradiation, provided the establishment has supporting documentation that shows the treatment achieves at least a 5-log reduction for Salmonella and Shiga Toxin-producing E.coli organisms (including E.coli O157:H7), and applies the treatment consistent with its critical operational parameters.

² Any slaughtering, cutting, boning, meat canning, curing, smoking, salting, packing, rendering, or similar establishment at which inspection is maintained under (FSIS) regulations (9 CFR 301.2).

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beef products and the terms "mechanically tenderized" or "blade tenderized" be used as the descriptive designation for blade tenderized beef products.

In addition, to ensure that the descriptive designation is readily apparent on the label, FSIS is requiring the print for all words in 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 1/3 the size of the largest letter.

FSIS also is requiring that labels of raw and partially cooked needle- and blade-tenderized beef products destined for household consumers, hotels, restaurants, and similar institutions include cooking instructions that have been validated to ensure that any pathogens that may be on or in the product are destroyed. To clarify requirements and respond to comments, FSIS is providing in the final rule that these validated cooking instructions may appear anywhere on the product label.

FSIS proposed to use the January 1, 2016, uniform compliance date as the effective date of this final rule (79 FR 34597). However, according to the uniform compliance

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date final rule,³ if any food labeling regulation involves special circumstances that justify a compliance date other than the uniform compliance date, FSIS will determine an appropriate compliance date and will publish that compliance date in the rulemaking (79 FR 71008). Because of the potential public health benefits of this rule, the effective date of this rule will be [INSERT DATE 365 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Had the final rule published on December 31, 2014, the effective date would have been January 1, 2016, according to the uniform compliance date for food labeling regulations final rule. By establishing a compliance date of [INSERT DATE 365 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER] FSIS is providing establishments with the same 365-day compliance period that they would have had if the final rule had published on December 31, 2014. Therefore, this rule will not be subject to the 2018 uniform compliance date for new meat and poultry product labeling regulations. In addition, FSIS will delay enforcing the labeling requirements for beef products with added solutions⁴ until the effective date of this final rule.

³ On December 1, 2014, FSIS issued a final rule that established January 1, 2018, as the uniform compliance date for new meat and poultry product labeling regulations that are issued between January 1, 2015 and December 31, 2016 (79 FR 71007).

⁴ 79 FR 79044; Dec. 31, 2014

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Finally, after consideration of the difference between branded (sold in multiple stores) and private labels (sold in only stores with the label name), FSIS reevaluated the label design costs to industry. Based on this analysis, FSIS increased estimated costs associated with the final rule. Even so, FSIS predicts the final rule to have a positive net benefit. In Table 1 (below), FSIS estimates the quantifiable benefits, costs, and net benefits of the final rule.

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Table 1: Summary of Estimated Costs and Benefits

Estimated Quantified Benefits, Costs, and Net Benefits^a	
Benefits ^b	\$688,286 (\$430,178 to \$1,606,000)
Costs ^c	\$476,932 to \$784,053
Net Benefits	-\$95,768 to \$211,353 (-\$357,163 to \$3,022,369)
Non-Quantified Benefits and Costs	
Benefits	<ul style="list-style-type: none"> • Avoided pain and suffering associated with prevented non-fatal foodborne illnesses • Increased producer surplus to producers who sell intact beef or other meats consumers may substitute for mechanically-tenderized beef • Cost savings accruing to food service establishments that will more readily obtain the information on whether beef product has been mechanically tenderized, which will better enable them to comply with State law
Costs	<ul style="list-style-type: none"> • Cost to validate cooking instructions • Loss in producer surplus to producers who sell mechanically tenderized beef. • Loss in consumer surplus to consumers who start cooking their beef to a higher temperature, which they prefer less than cooking rare. • Loss in consumer surplus to consumers who either spend more time cooking or wait longer to eat in food service settings. • Loss in consumer surplus to consumers who might substitute other meats or other cuts of meat, which they prefer less. • Time cost associated with revised cooking procedures and training on thoroughly cooking mechanically tenderized beef products in the food service industry.

^a Annualized over 10 years at a 7 percent discount rate.

^b Assumes that on the low end, 15% of consumers and food service providers will use validated cooking instructions and using the lower bound of the credibility interval from Scallan while on the high end, 56% of consumers and food service providers and using the upper bound of the credibility interval from Scallan will use validated cooking instructions, with an average estimate of 24% for consumers and 24% for food service providers.

^c The upper and lower bound estimated costs fall to \$407,946 and \$670,643 when annualized with a 3 percent discount rate.

Source: FSIS Policy Analysis Staff

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Background

As explained in the proposed rule, consumers consider product tenderness to be a key factor when purchasing meat products. Thus, the tenderness of a roast or steak is a key selling point for the meat industry (78 FR at 34591).

Mechanically tenderized product is product that has been pierced with a set of needles or blades, which breaks up muscle fiber and tough connective tissue, resulting in increased tenderness. As was also explained in the proposed rule, such product may also be injected with a solution or marinade.

In 2009, the Safe Food Coalition sent a petition to the Secretary of Agriculture to request, among other issues, regulatory action to require that the labels of mechanically tenderized beef products disclose the fact that the products have been mechanically tenderized. The petition stated that, (1) consumers and restaurants do not have sufficient information to ensure that these products are cooked safely because FSIS does not provide recommended cooking temperatures for mechanically tenderized products, (2) the recommended cooking temperatures for intact products are not appropriate for non-intact, mechanically tenderized products, and (3) a labeling requirement for mechanically tenderized products

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is critical for consumers and retail outlets, so that they have the information necessary to safely prepare these products.

In June 2010, the Conference for Food Protection (CFP) petitioned⁵ FSIS to issue a mandatory labeling provision for mechanically tenderized beef that would require labels to specify that a cut has been mechanically tenderized. The petition stated that mechanically tenderized beef, especially when frozen, could be mistakenly perceived by consumers to be a whole, intact muscle cut. The petition asserted that without clear labeling, food retailers and consumers do not have the information necessary to prepare these products safely. According to the petition, if labeling does not indicate that the product is mechanically tenderized, consumers are not aware of the potential risk created when these products are less than fully cooked. The petition stated that mandatory labeling of these products would reduce the number of foodborne illnesses in the United States. In April 2014, CFP expressed their support of FSIS moving forward with final rulemaking at a meeting for the Conference of Food Protection.

⁵ The incoming petition is available on FSIS's Web site at http://www.fsis.usda.gov/wps/wcm/connect/7da02e44-712f-4779-aa10-fb1760493261/Petition_CFP_071710.pdf?MOD=AJPERES.

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Published research suggests that pathogens can be translocated from the surface of mechanically tenderized beef products to the interior of the products during processing because of the piercing of the beef by the needle or blade.⁶ The potential for this translocation of pathogens suggests that the interior of mechanically tenderized beef would have to be more fully cooked than a piece of intact beef with a similar amount of pathogens on the surface.⁷ Mechanically tenderized meat products are widely available to consumers in the marketplace (78 FR at 34591).

Since 2000, the Centers for Disease Control and Prevention (CDC) has received reports of six outbreaks determined to be attributable to needle- or blade-tenderized beef products prepared in restaurants and consumers' homes. These outbreaks included a total of 176 Escherichia coli (E. coli) O157:H7 cases that resulted in 32 hospitalizations and 4 cases of hemolytic uremic syndrome (HUS).⁸

In addition, in 2012, 18 cases of food-borne illness caused by E. coli O157:H7 were reported as part of a

⁶Luchansky, JB, Phebus RK, Thippareddi H, Call JE 2008. Translocation of surface-inoculated Escherichia coli O157:H7 into beef subprimals following blade tenderization. J. Food Prot. 2008 Nov.; 71(11) : 2190 - 7.

⁷Sporing, Sarah B. 1999. Escherichia coli O157:H7 Risk Assessment for Production and Cooking of Blade Tenderized Beef Steak. Thesis. Kansas State University.

⁸Compilation of USDA-FSIS Data, 2010.

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Canadian outbreak. During the food safety investigation associated with the outbreak, it was determined that a few cases were likely associated with the consumption of mechanically tenderized beef which had been tenderized at the retail level.⁹ On May 21, 2014, the Canadian Food Inspection Agency announced that it was amending its regulations to mandate Canadian establishments that produce mechanically tenderized beef to label those products as “mechanically tenderized” and provide cooking instructions. The Canadian regulations were effective on August 21, 2014, and are consistent with this final rule.

Proposed Regulatory Requirements

The Federal Meat Inspection Act (FMIA) gives FSIS broad authority to promulgate rules and regulations necessary to carry out its provisions (21 U.S.C. 621). To prevent meat or meat food products from being misbranded, the meat inspection regulations require that the labels of meat products contain specific information and that such information be displayed as prescribed in the regulations (9 CFR Part 317). Under the regulations, the principal display panel on the label of a meat product must include, among other information, the name of the product.

⁹ Catford, A., Lavoie, M., Smith, B., Buenaventura, E., Couture, H., Fazil, A., and J.M. Farber. 2013. “Findings of the Health Risk Assessment of Escherichia coli O157 in Mechanically Tenderized Beef Products in Canada.” Int. Food Risk Anal. J. 3:2013.

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In proposed 9 CFR 317.2(e)(i), FSIS proposed new requirements for raw or partially cooked needle- or blade-tenderized beef products, including beef products injected with a marinade or solution. FSIS proposed that the product name for these beef products include the descriptive designation "mechanically tenderized" and an accurate description of the beef component.

In proposed 9 CFR 317.2(e)(3)(ii), FSIS proposed that the print for all words in the product name be in the same style, color, and size and on a single-color contrasting background.

In proposed 9 CFR 317.2(e)(3)(iii), FSIS proposed that the labels of raw and partially cooked needle- or blade-tenderized beef products destined for household consumers, hotels, restaurants, or similar institutions include validated cooking instructions. FSIS also proposed that the validated cooking instructions include the cooking method, inform consumers that these products need to be cooked to a specified minimum internal temperature, state whether the product needs to be held for a specified time at that temperature or higher before consumption to ensure destruction of potential pathogens throughout the product, and contain a statement that the internal temperature should be measured by a thermometer.

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FSIS explained in the proposed rule that should the rule be implemented, raw or partially cooked beef products subject to this rule whose labels do not include the descriptive designation ``mechanically tenderized,`` and such products destined for household consumers, hotels, restaurants, or similar institutions whose labels do not include validated cooking instructions, would be misbranded because the product labels would be false or misleading, because the products would be offered for sale under the name of another food, and because the product labels would fail to bear the required handling information necessary to maintain the products' wholesome condition (21 U.S.C. 601(n)(1), 601(n)(2), and 601(n)(12)) (78 FR 34595).

FSIS also announced in the proposal that it had posted on its Web site draft guidance on developing validated cooking instructions for mechanically tenderized product.

Final Rule:

FSIS is finalizing the proposed regulations with minor changes to provide additional clarification and flexibility. In response to comments, this final rule requires the descriptive designation "mechanically tenderized" or "needle tenderized" be used on raw or partially cooked needle tenderized beef products and the descriptive designation "mechanically tenderized" or "blade

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tenderized" be used on raw or partially cooked blade tenderized beef products. By permitting the terms "needle tenderized" and "blade tenderized" to be used as the descriptive designation, FSIS is providing additional flexibility to establishments to use more specific terms regarding the method of mechanical tenderization as part of the product name.

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. Thus, for a steak that has been tenderized, the common or usual name would be "steak." It would not be "mechanically tenderized steak." However, the descriptive designation needs to be in close proximity to the common or usual name. The descriptive designation may be above, below, or next to the rest of the product name (without intervening text or graphics) on the principal display panel. In response to comments on the proposed rule on mechanically tenderized beef products and on the proposed rule for raw meat and poultry products containing added solutions (76 FR 44855), this final rule provides that the print for all words in the product name and descriptive designation on raw or partially cooked mechanically tenderized products must appear in a single easy-to-read type style and color and on a single-color

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contrasting background. In addition, the final rule allows additional flexibility by providing that the print may appear in upper and lower case letters, with the lower case letters not smaller than 1/3 the size of the largest. These requirements are consistent with those in the final rule for raw meat and poultry products containing added solutions.¹⁰

In response to comments, the final rule also clarifies that validated cooking instructions may appear anywhere on the product label and that a descriptive designation will not be required for mechanically tenderized beef products destined for a full lethality treatment at an official establishment.

FSIS has carefully considered the available information on mechanically tenderized beef and has concluded that, without specific labeling, consumers and industry may be purchasing and preparing raw or partially cooked mechanically tenderized beef products without knowing that these products have been needle- or blade-tenderized. Because illnesses could be reduced if the Agency required more specific labeling, the final rule requires the product name of raw or partially cooked,

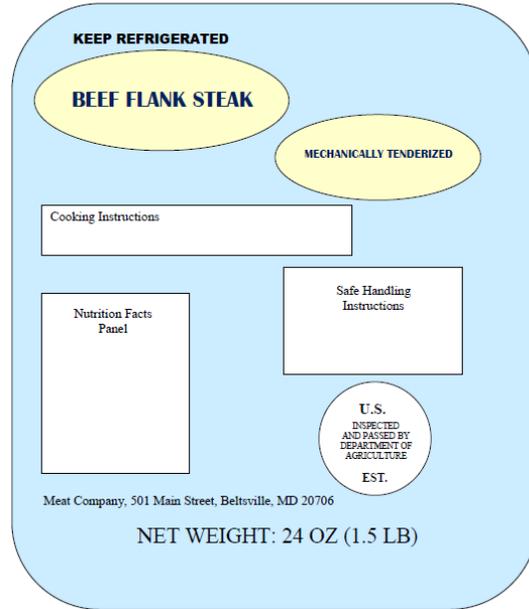
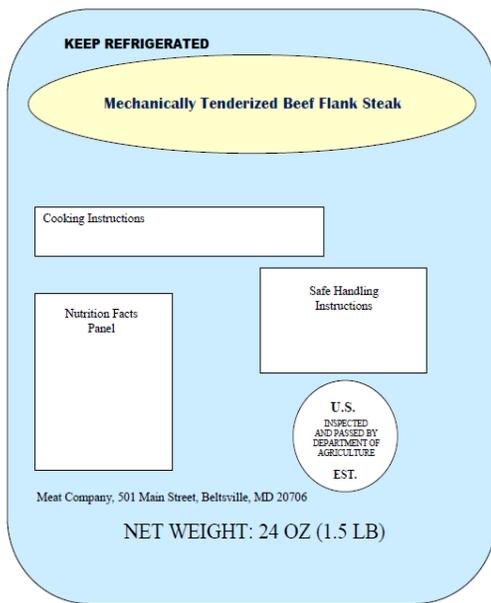
¹⁰ Except that the applicability date for raw meat and products containing added solutions that prescribes that the descriptive designation appear with the lower case letters not smaller than 1/3 the size of the largest letter will be delayed until January 1, 2018.

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mechanically tenderized beef products include the name of the beef component and a descriptive designation that the product has been "mechanically tenderized," "needle tenderized," or "blade tenderized," unless the product is destined to be fully cooked or to receive another full lethality treatment in an official establishment. The descriptive designation will provide household consumers, official establishments, restaurants, and retail stores with the information they need to distinguish a cut of beef that is an intact, non-tenderized product, from a non-intact, mechanically tenderized product.

Based on the requirements in 9 CFR 317.2(c)(1), all of this information will need to appear on the principal display panel of the immediate container. FSIS is requiring that the descriptive designation be a part of the product name so that the statement is prominently placed on the label and with such conspicuousness as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use (see 21 U.S.C. 601(n)(6)).

Examples of labels for mechanically tenderized beef product



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Note: Validated cooking instructions may appear anywhere on the label.

The descriptive designation will only apply to raw or partially cooked beef products that have been needle-tenderized or blade-tenderized, including beef products injected with marinade or solution. Other tenderization methods, such as pounding and cubing, change the appearance of the product, putting consumers on notice that the product is not intact. Moreover, most establishments already label cubed products as such.

FSIS is requiring the terms "mechanically tenderized," "needle tenderized," or "blade tenderized" because they accurately and truthfully describe the nature of the product. These terms also clearly differentiate needle- or blade-tenderized beef products from non-tenderized, intact beef products.

As explained in the proposed rule, under current regulations, to prevent raw and partially cooked meat products from being misbranded, the labels of all meat products, including those that have been mechanically tenderized, must bear safe handling instructions as prescribed in 9 CFR 317.2(1). Although the safe handling instructions in the regulations include "cook thoroughly," the regulations do not require that these instructions

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specify a dwell time or internal temperature parameters necessary to ensure that the product is fully cooked.

The safe preparation of this product requires that consumers know to handle the mechanically tenderized product differently than product in which there is potential for transfer of any exterior contamination into the interior of the beef product.

Some consumers of beef products consider a product to be thoroughly cooked product even if it has been prepared to a degree of doneness that is not sufficient for safety.^{11, 12, 13} Moreover, because mechanically tenderized beef products have the same appearance as intact beef products, household consumers, hotels, restaurants, and similar institutions may incorrectly assume that products that in fact have been mechanically tenderized products can be prepared similarly to intact products (i.e., that it is okay to cook them to be "rare" or "medium-rare"). Thus, in addition to a descriptive designation that identifies that needle- or blade-tenderized beef products have been mechanically tenderized, under this final rule, FSIS is requiring that labels of raw and partially cooked needle-

¹¹ Lorenzen, C.L., T.R. Neely, R.K. Miller, J.D. Tatum, J.W. Wise, J.F. Taylor, M.J. Buyck, J.O. Reagan, and J.W. Savell. 1999. "Beef Customer Satisfaction: Cooking Methods and Degree of Doneness Effects on the Top Loin Steaks." *J. Animal Science* 77:637-644.

¹² Savell, J.W., Lorenzen, C.L., Neely, T.R., Miller, R.K., Tatum, J.D., Wise, J.W., Taylor, J.F., Buyck, M.J., Reagan, J.O. 1999. "Beef Customer Satisfaction: Cooking Methods and Degree of Doneness Effects on the Top Sirloin Steaks." *J. Animal Science* 77:645-652.

¹³ Neely, T.E., Lorenzen, C.L., Miller, R.K., Tatum, J.D., Wise, J.W., Taylor, J.F., Buyck, M.J., and Savell, J.W. 1999. "Beef Customer Satisfaction: Cooking Method and Degree of Doneness Effects on the Top Round Steak." *J. Animal Science* 77:653-660.

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or blade-tenderized beef products destined for household consumers, hotels, restaurants, and similar institutions include cooking instructions that have been validated to support claims that potential pathogens throughout the product would be destroyed.

FSIS is requiring that the validated cooking instructions include, at a minimum: (1) the method of cooking; (2) a validated minimum internal temperature that would destroy pathogens throughout the product; (3) a statement as to whether the product cooked in the manner described also needs to be held for a specified time at the specified temperature or higher before consumption; and (4) instruction that the internal temperature should be measured by use of a thermometer. The cooking instructions included on the label should be practical and easily followed by consumers. In response to comments discussed below, the final rule provides that validated cooking instructions may appear anywhere on the product label.

Consistent with the regulation on Hazard Analysis and Critical Control Point (HACCP) validation (9 CFR 417.4), to validate the cooking instructions, the establishment will be required to obtain scientific or technical support for the judgments made in designing the cooking instructions, and in-plant data to demonstrate that it is, in fact,

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achieving the critical operational parameters documented in the scientific or technical support. Just as establishments have to validate their HACCP plans' adequacy in controlling food safety hazards identified during the hazard analysis, so too, under this final rule, establishments that produce raw or partially cooked mechanically tenderized beef products will have to validate their recommended cooking instructions. The scientific support would need to demonstrate that the cooking instructions provided can repeatedly achieve the desired minimum internal temperature and time at that temperature and would need to support that the product is fully cooked to destroy pathogens present in the product. The in-plant data would need to demonstrate that the establishment is, in fact, achieving the critical operational parameters documented in the scientific or technical support. For additional information on validation see the Federal Register notice on HACCP Systems Validation (77 FR 27135; May 9, 2012).¹⁴

In response to comments, FSIS has revised its guidance for developing validated cooking instructions for mechanically tenderized products. The Agency has posted the revised guidance on its Significant Guidance Documents Web

¹⁴ Available at . <http://www.fsis.usda.gov/wps/wcm/connect/d000cb67-23bc-4303-8f7b-71dcba5e7cd7/2009-0019.pdf?MOD=AJPERES>

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page. This guidance represents current FSIS thinking. Establishments could collect their own scientific data to support the cooking instruction, use a study from an outside source, or use the revised guidance provided by FSIS. An establishment could use the recommended cooking instructions from the revised guidance on its product labels, without having to conduct additional experiments or provide any further scientific support, if the products it is producing are similar to those in the guidance.

If establishments are unable to use the specific examples in the revised guidance (e.g., because the product is a different thickness or is to be cooked using a method different from one previously studied), the revised guidance also contains instructions on how to develop such support.

Summary of and Response to Comments

In the proposal, FSIS requested comment on specific issues: how it defined "mechanically tenderized," whether the definition should be incorporated into the regulations, whether the term should include products that have been vacuum tumbled or formed, whether the term would be understood by consumers, on how the proposed labeling changes would impact restaurants and other food service operations, and on the cost estimates outlined in the

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proposal. FSIS received 122 comments in response to these and other issues in the proposed rule. A majority of the comments (approximately 75) were form letters submitted by individuals. The remaining comments were from individuals, consumer advocacy groups, organizations representing the meat industry, meat processors, retail trade associations, and an organization representing food and drug officials.

FSIS did not receive any comments on whether it should require fully cooked needle- or blade-tenderized beef products to have the descriptive designation on their labels, on how food service workers will likely respond to the proposed labeling changes, on the number of cuts per establishment that would require validated cooking instructions, or on estimated costs for developing validated cooking instructions.

FSIS has summarized and responded to the relevant issues raised by commenters below.

A. Broadly Opposed to the Proposal

Comment: An individual stated that all of the proposed changes are unnecessary because the safe handling instructions required in 9 CFR 317.2(1) clearly state that raw beef products, including those that are tenderized, must be cooked thoroughly before being consumed. As an alternative to the proposed labeling changes, several

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organizations representing the meat industry suggested that FSIS focus its resources on improving the safe-handling instructions.

Response: FSIS disagrees that the changes are unnecessary. As FSIS stated in the preamble to the proposed rule, the literature suggests that many consumers are aware of the safe handling instruction labels (see 78 FR at 34592). However, the same literature also suggests that only a portion of consumers reported reading these instructions on raw meat product labels and changing their meat preparation methods because of the labels.¹⁵ Furthermore, although the required safe-handling instructions include "cook thoroughly" in raw and partially cooked beef products, the regulations do not require that these instructions specify the dwell time or internal temperature parameters required to support that the product is fully cooked. In addition, despite the safe handling instructions to "cook thoroughly," consumers, restaurants, and retail stores do not always cook these products fully by using a temperature-and-time combination sufficient to destroy harmful bacteria that may be in the product. They may incorrectly assume that it is safe to cook these

¹⁵ Yang, *et al* (1999) show that 15% of consumers changed their behavior based on reading safe handling instruction labels. ("Evaluation of Safe Food-Handling Instructions on Raw Meat and Poultry Products," *J of Food Protect.* 63: (1321-1325.)

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products "rare" or "medium-rare." CDC and other governmental investigators reported that failure to fully cook a mechanically tenderized raw or partially cooked beef product was likely a significant contributing factor in several of the outbreaks.^{16,17,18} In addition, consumer preference for steaks that are not thoroughly cooked¹⁹ along with the time span of the illness reports suggests undercooking was likely a significant contributing factor in the other investigations as opposed to post-cooking cross-contamination in which illnesses would be more likely to occur at the same time. FSIS has, therefore, determined that labeling to indicate that the beef product is mechanically tenderized, along with validated cooking instructions, is necessary to help inform consumers and industry of a key feature of the product and to instruct them that such products need to be thoroughly cooked.

In addition, in January, 2014, FSIS sought input from the National Advisory Committee on Meat and Poultry

¹⁶ Swanson, L. E., Scheftel, J.M., Boxrud, D.J., Vought, K.J., Danila, R.N., Elfering, K.M., and Smith, K.E. 2005. "Outbreak of Escherichia coli O157:H7 infections associated with nonintact blade-tenderized frozen steaks sold by door-to-door vendors." J. Food Prot 68:(1198-1202).

¹⁷ Haubert, N., Cronquist, A., Parachini, S., Lawrence, J., Woo-Ming, A., Volkman, T., Moyer, S., Watkins, A. 2006. Outbreak of Escherichia coli O157:H7 Associated with Consuming Needle Tenderized Undercooked Steak from a Restaurant Chain. Presented at the International Conference on Emerging and Infectious Diseases. March 19-22, 2006. Atlanta, GA.

¹⁸ Culpepper W, Ihry T, Medus C, Ingram A, Von Stein D, Stroika S, Hyytia-Trees E, Seys S, Sotir MJ. 2010. Multi-state outbreak of Escherichia coli O157:H7 infections associated with consumption of mechanically-tenderized steaks in restaurants--United States, 2009. Presented at International Association for Food Protection; August 1-4, 2010; Anaheim, CA.

¹⁹ Reicks, A.L., Brooks, J.C., Garmyn, A.J., Thompson, L.D., Lyford, C.L., Miller, M.F. 2011. "Demographics and beef preferences affect consumer motivation for purchasing fresh beef steaks and roasts." Meat Science. 87: 403-411.

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Inspection²⁰ to fully explore whether there is a need for enhancing the safe food handling label on meat and poultry packages (78 FR 77643; Dec. 24, 2013). The Committee recommended that FSIS pursue changes to the existing safe handling instructions. FSIS has initiated a project to research how we might modify the current safe-handling instruction requirements to improve consumer food safety behaviors.

Comment: Several comments stated that the proposed labeling changes will be ineffective in influencing consumer behavior to reduce relative risk. Moreover, an organization representing meat and poultry processors and a trade association stated that the Agency failed to provide any data to support that the proposed labeling changes can or will positively impact public health; thus, creating an unnecessary burden on industry.

Response: FSIS recognizes that not all consumers will change their behavior in response to the presence of the descriptive designation "mechanically tenderized," "needle tenderized," or "blade tenderized," and validated cooking instructions on the product label. However, FSIS disagrees that the labeling changes will not positively impact public

²⁰ For more information on the National Advisory Committee on Meat and Poultry Inspection, visit <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/advisory-committees/nacmpi>.

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health. Public health is characterized on a population level. As discussed below, on the basis of available studies on the impacts of food product labels on consumer behavior, FSIS used 24 percent as the primary estimate for the impact of labels on consumer behavior. Therefore, FSIS estimates that 24 percent of consumers that previously cooked mechanically tenderized beef to a lower temperature will change their behavior and cook that product to the endpoint temperature that appears in the cooking instructions, which is equivalent to 210 illnesses averted or prevented per year, with a range of 131 to 489 (See Table 5).

B. Defining "Mechanically Tenderized"

Comment: An organization representing the meat industry and a retail trade association characterized the Agency's proposed use of the term "mechanically tenderized" as overly broad and inaccurate. Both commenters stated that adding solutions by needle injection does not "mechanically tenderize" the product. A trade association requested that vacuum-tumbled products not be considered "mechanically tenderized."

Consumer organizations requested that "mechanically tenderized" product include vacuum-tumbled, vacuum-marinated, marinade-injected, and enzyme-formed beef

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products. An individual and a meat processor requested that mechanically tenderized product include products that are vacuum-tumbled because they stated the potential health risk to consumers is similar to that for needle- or blade-tenderized beef products. One consumer advocacy group remarked that, although enzyme-formed beef is now required to be labeled "formed," the designation does not inform the consumer on how the meat should be prepared or on the higher risk of exposure to pathogens that these products present.

Several meat processors and trade associations stated that use of the descriptive designation "mechanically tenderized" on the label will be misunderstood by consumers as a negative term and, therefore, may discourage customers from purchasing such beef products, resulting in a negative economic impact to small businesses. In addition, several organizations representing the meat industry requested that FSIS conduct targeted consumer research to determine whether the public perceives the descriptive designation "mechanically tenderized" as negative before finalizing the proposed changes.

As alternatives to "mechanically tenderized," commenters suggested "tenderized and packaged,"

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"tenderized," "marinated," "injection marinated," "solution enhanced," "cubed," and "blade tenderized."

Response: After review and consideration of the alternative descriptive designations provided by commenters, FSIS is finalizing the proposed regulations with minor changes. FSIS has concluded the descriptive designations "mechanically tenderized," "needle tenderized," and "blade tenderized" accurately and truthfully describe the nature of the product. Additionally, these term clearly and completely identify the preparation process that the product underwent, as required by 9 CFR 317.2(e). FSIS has previously described mechanically tenderized beef products in a similar manner, notably in its Federal Register notice, HACCP Plan Reassessment for Mechanically Tenderized Beef Products (May 26,2005; 70 FR 30331). Moreover, comments and other data do not support that the descriptive designations "mechanically tenderized," "needle tenderized," or "blade tenderized" would be misunderstood by consumers, restaurants, retail stores, and official establishments or that the other alternatives would be better understood by these parties. Furthermore, FSIS's definition of "mechanically tenderized" for raw and partially cooked beef products is consistent with that contained in the Canadian Food and Drug

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Regulations.²¹ To provide flexibility, FSIS is requiring the terms "needle tenderized" or "mechanically tenderized" be used as the descriptive designation for needle-tenderized beef products and the terms "mechanically tenderized" or "blade tenderized" be used as the descriptive designation for blade-tenderized beef products. The terms "needle tenderized" and "blade tenderized" merely provide more specific information on the mechanical methods used to tenderize the product. The terms "needle tenderized" and "blade tenderized" are not interchangeable. Only blade-tenderized product will be allowed to bear that descriptive designation, and only needle-tenderized product will be allowed to bear that descriptive designation. "Mechanically tenderized" could be used on either needle- or blade-tenderized product.

Even though vacuum-tumbled or enzyme-formed beef products are processed in a manner that may introduce pathogens (if present) below the product's surface, this final rule will not apply to them. FSIS regulations (9 CFR 317.8(b)(39)) already require labeling for meat products

²¹Section B.01.001(1) of the Canadian Food and Drug Regulations defines "mechanically tenderized beef" as uncooked solid cut beef that is prepared in either of the following ways:(a) the integrity of the surface of the beef is compromised by being pierced by blades, needles or other similar instruments; or (b) the beef is injected with a marinade or other tenderizing solution (P.C. 2014-478; May 1, 2014).

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that are formed or re-formed with an enzyme binder as part of the product name, e.g., "Formed Beef Tenderloin." As such, formed beef products are already labeled in a manner that distinguishes them from other products. In addition, FSIS has concluded that there is not sufficient data to understand whether the risk that pathogens may be introduced into product as a result of vacuum tumbling or enzyme formed beef product is similar to that associated with needle- and blade-tenderized beef.

As stated in the preamble of the proposal, FSIS will conduct a public education campaign to explain the significance of the terms "mechanically tenderized," "needle tenderized," and "blade tenderized" to consumers (78 FR at 34593). Thus, FSIS disagrees that additional consumer research is needed before moving forward with a final rule.

C. How the New Information Appears on the Label

Comment: Several consumer advocacy groups requested that the descriptive designation appear on the label in distinguishing typeface. Other consumer advocacy groups suggested that the descriptive designation be added to the package as a brightly-colored sticker, separate from the existing label, placed on the front of the packaging. Several meat processors and organizations representing the

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meat industry requested that the descriptive designation be permitted to appear on the label in a smaller font size than that of the product name. A trade association opposed the addition of the descriptive designation to the product name because it has found that consumers pay the least attention to tenderization information when it is included in the product's name. Noting that other FSIS labeling requirements to enhance food safety (for example, the safe handling instructions) effectively convey useful information that is not part of the product name, a meat processor and several trade associations requested that, rather than in the product name, the descriptive designation be permitted to appear elsewhere on the label.

Response: To make the descriptive designation readily apparent on the label but provide flexibility and address the comments discussed above, FSIS is requiring that the print for all words in the product name and descriptive designation appear in a single easy-to-read type style and color and on a single-color contrasting background. In addition, the print may appear in upper and lower case letters, with the lower case letters not smaller than 1/3 the size of the largest letter.

Establishments or retail stores will be permitted to add the required information to existing label designs, or

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they can apply a separate sticker with the required information to existing labels. Regardless, the product name must contain the term "mechanically tenderized," "needle tenderized," or "blade tenderized" as an accurate description of the beef component of the product.

The labels of raw and partially cooked mechanically tenderized beef products as required in this final rule will be considered to be generically approved. The labels will not have to be submitted to FSIS for approval prior to their use, provided that they meet the requirements in this rule, display all mandatory features in a prominent manner in compliance with part 317, and are not otherwise false or misleading in any particular manner (9 CFR 412.2).

Comment: A retail trade association requested that FSIS provide options for the descriptive designation for those labels that are under a certain size (e.g., if a label has less than or equal to six (6) square inches of available printing).

Response: FSIS is not aware of any raw or partially cooked mechanically tenderized beef product marketed in a package too small (i.e., with less than six square inches of available labeling space) to accommodate the requirements of this final rule.

D. Mandatory Labeling for Restaurants

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Comment: So that restaurant patrons can make informed decisions as to how their beef product should be prepared, several individuals requested that restaurants be required to disclose on their menus when products are made from mechanically tenderized beef. A trade association recommended that FSIS align any proposed labeling requirements for restaurants with the Food and Drug Administration (FDA). A consumer advocacy group urged FSIS, in partnership with retail or restaurant associations, to develop an "information system" targeted at those preparing mechanically tenderized beef products served at restaurants.

Response: FSIS expects that, by requiring the use of the descriptive designation "mechanically tenderized," "needle tenderized," or "blade tenderized," and validated cooking instructions, food service personnel will be able to identify mechanically tenderized beef as such and to safely prepare the product using the cooking instructions provided on the label.

Food service personnel should contact their local or State health department for information on the rules and regulations governing the preparation of food in restaurant, retail, or institutional settings.

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FSIS plans to share issues raised in comments received on restaurant menu labeling in response to the proposed rule with FDA.

E. Estimated Costs and Benefits of the Proposed Rule

Comment: An industry trade association stated that FSIS failed to assign a dollar value to many of the purported benefits and costs discussed in the proposed rule.

Response: FSIS made every effort to quantify all known costs and benefits of the proposed rule. However, because of the uncertainty in determining producer and consumer response to the proposed rule, FSIS acknowledges that it was unable to monetize some potential costs and benefits. FSIS did not forecast, nor did it receive data to quantify, in the final rule the loss to producers that sell mechanically tenderized beef products, the loss to consumers when cooking the products to a higher temperature, the loss to consumers who may substitute products that they may like less than mechanically tenderized products because of cooking the mechanically tenderized beef product to a higher temperature, or the loss to food service providers that change their processes.

Comment: Several meat processors and organizations representing the meat industry stated that FSIS

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underestimated the costs to industry to comply with the proposed labeling requirements.

Response: FSIS based the proposal's mid-point label design modification costs estimate (\$310 per label) on the most detailed study available on the costs associated with the labeling of consumer products, the March 2011 FDA report.²² However, after consideration of the differences between branded and private labels, FSIS updated the cost estimates after determining that 60 percent of the private label modifications would be uncoordinated changes. The cost for a minor uncoordinated label is \$4,380 per label (with a range of \$2,417 and \$7,330), an increase from \$310 per label in the proposal estimate. Even with the increased estimate, FSIS predicts the final rule to have a positive net benefit (see Table 5).

In addition, the effective date allows establishments time to use existing labels and will, therefore, result in minimal loss of inventory of labels.

F. High Pressure Processing

Comment: An individual requested that mechanically tenderized beef subjected to High Pressure Processing (HPP)

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).

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be exempted from the mandatory labeling requirements outlined in the proposal.

Response: Any mechanically tenderized beef product treated at an official establishment with an intervention or process, including HPP, that has been validated to achieve at least a 5-log reduction for Salmonella and Shiga Toxin-producing E. coli (STEC) organisms (including E. coli 0157:H7) would not be subject to the requirements in this final rule because it has received a full lethality treatment.

In response to this comment, FSIS has modified the proposed codified language (9 CFR 317.2(e)(3)(i)) to clarify that a descriptive designation will not be required on mechanically tenderized beef products destined to receive a full lethality treatment at an official establishment.

G. Validated Cooking Instructions/Associated Guidance

Comments: According to commenters, consumers may serve the cooked, mechanically tenderized products without the benefit of a stand time, thereby becoming vulnerable to foodborne illness. Therefore, several comments urged FSIS to require cooking instructions with an endpoint temperature of 160 degrees Fahrenheit. Many comments requested that the method of cooking not appear within the cooking instructions, to prevent confusion among consumers.

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Likewise, rather than requiring the four elements proposed, several organizations representing the meat industry and a retail trade association stated that the validated cooking instructions should be required to include only two elements - an internal temperature at which pathogens can effectively be destroyed and the recommended use of a meat thermometer to verify this temperature.

Response: FSIS disagrees that the inclusion of the method of cooking within the cooking instructions will confuse consumers. Based on the Agency's experience addressing questions from consumers and based on consumer information from outbreak investigations, FSIS has concluded that the most explicit way to inform consumers as to how to prepare a product that is safe for consumption is to include the cooking method by which the endpoint temperature is achieved within the cooking instructions. Consistent with HACCP requirements, FSIS is providing establishments the flexibility to design cooking instructions. However, in response to comments from consumer groups, FSIS revised its compliance guidance to include a recommendation that if establishments use one of the temperature and time combinations from the FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts,

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and Steaks²³ with a temperature less than 145 degrees Fahrenheit and a rest time longer than three minutes (for example, 144 degrees Fahrenheit for four minutes, 143 degrees Fahrenheit for five minutes), then they should consider whether it is practical for consumers to achieve the longer rest time.

The first draft of the compliance guideline for validating cooking instructions recommended establishments consider, among other factors, the state of the product at the start of cooking (e.g., frozen vs. refrigerated vs. room temperature), product thickness, type of cut, rotation of product, method of cooking to include a cold spot determination, and number and location of temperature measurement sites during cooking to ensure the cooking instructions consistently achieve the desired endpoint temperature. However, new research demonstrates the importance of turning steaks multiple times during cooking to ensure consumers consistently achieve the desired endpoint temperature throughout the steak.²⁴ Accordingly, FSIS has revised its guidance to recommend that establishments design cooking instructions for steaks to include turning the product at least twice.

²³ Available at <http://www.fsis.usda.gov/wps/wcm/connect/6d2ee972-3fd1-4186-b1e7-656e7a57beb2/time-temperature-table-042009.pdf?MOD=AJPERES>.

²⁴ Gill, C.O., Yang, X., Uttaro, B., Badoni, M. and Liu, T.. 2013. "Effects on survival of *Escherichia coli* O157:H7 in non-intact steaks of the frequency of turning over steaks during grilling." *Journal of Food Research*. 2(5): 77-89.

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Comment: Several commenters indicated that steaks are more commonly merchandised by weight in ounces, rather than by thickness.

Response: FSIS has revised its compliance guidance for validated cooking instructions to recommend that if an establishment packages products by portion size (e.g., 10, 12, or 14 ounces), it should determine the variability in thickness of products packaged at that portion size and conduct the validation study using a product that represents the thickest product. The guidance now states that products from at least three lots should be measured to determine the worst case scenario.

Comment: Several consumer groups requested that FSIS recommend (within the guidance document) that the statement "fully thaw before cooking" appear on product labels. The commenters cited research that showed that frozen or partially thawed patties took longer to cook to the desired internal temperature of 160 degrees Fahrenheit than fully thawed patties.

Response: FSIS agrees that research has found that patties cooked from the frozen state take longer to achieve the target endpoint temperature than those that have been

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thawed.²⁵ Moreover, research with patties has shown that temperatures tend to be more consistent across patties that are cooked from the thawed rather than the frozen state.²⁶ Thus, FSIS has revised its guidance to include a recommendation that the instructional statement “fully thaw before cooking” appear on the labels of mechanically tenderized beef products.

Comment: An organization representing the meat industry argued that there is not enough space on most mechanically tenderized beef product labels for the level of detail proposed for cooking instructions.

Response: As stated above, FSIS is not aware of any raw or partially cooked mechanically tenderized beef product marketed in a package too small to accommodate the requirements of this final rule, including those for validated cooking instructions. Based on this concern, FSIS has clarified in the final rule that validated cooking instructions may appear anywhere on the product label.

H. Risk of Illness Related to Mechanical Tenderization

Comment: Several meat processors and organizations representing the meat industry stated that the proposed

²⁵ Luchansky, J.B., Porto-Fett, A.C.S., Shoyer, B.A., Phillips, J., Chen, V., Eblen, D.R., Cook, V., Mohr, T.B., Esteban, E. and Bauer, N. 2013. “Fate of Shiga Toxin-producing O157:H7 and non-O157:H7 *Escherichia coli* cells within refrigerated, frozen, or frozen then thawed ground beef patties cooked on a commercial open-flame gas or a clamshell electric grill.” Journal of Food Protection. 76(9): 1500-1512.

²⁶ Berry, B.W. 2000. “Use of infrared thermography to assess temperature variability in beef patties cooked from the frozen and thawed states.” Foodservice Research International. 12(4): 255-262.

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changes are unnecessary and will not function to promote public health because the risk of illness associated with mechanical tenderization is "very low," and "generally equivalent" to that associated with intact cuts of beef. To support these claims, several comments referenced the Agency's 2002 risk assessment, preliminary information provided by FSIS concerning its 2010 work, and the 2013 Canadian risk assessment. Many comments requested that FSIS conduct (and make available to the public) a comparative risk assessment for intact and non-intact beef using current data before finalizing the rule.

Response: The proposed and final benefit analysis used the recently published study by the Centers for Disease Control and Prevention that attributed foodborne illnesses by pathogens to general types of foods.²⁷ This study, along with reports of outbreaks attributable to mechanically tenderized products, allowed FSIS to base its estimate predicting 1,965 illnesses from mechanically tenderized products on analysis of recently observed illness data.

The FSIS attribution analysis is based on the latest published estimates of illness from the Centers for Disease Control and Prevention and for this pathogen product pair

²⁷ Painter, J., R. Hoekstra, et al. 2013. "Attribution of foodborne illnesses, hospitalizations, and deaths to food commodities by using outbreak data, United States, 1998–2008." *Emerg Infect Dis* 9(3): 407-415.

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allows an estimate of the current risk of illness. No updates to this dataset became available between the proposed and final rule, and therefore, no corresponding changes to the attribution analysis were necessary. The details of this analysis are included in this final rule.

Comment: Several meat processors and organizations representing the meat industry stated that additional labeling is unnecessary because present day intervention strategies, like applying interventions directly before tenderization and following best manufacturing practices, have effectively lowered the risk associated with mechanically tenderized beef products since the outbreaks cited in the proposal.

Response: In the 11-year study cited in the proposed rule, outbreaks of E. coli O157:H7 accounted for 4,844 illnesses.²⁸ The Centers for Disease Control and Prevention estimate 63,153 illnesses from E. coli O157:H7 occur annually. Over an 11-year period this amounts to nearly 700,000 illnesses. Reported outbreaks account for less than 1 percent of these. Thus, the absence of outbreaks in the time after the period studied by Painter, et al., which captured outbreaks through 2008, would not be sufficient to

²⁸ Painter, J., R. Hoekstra, et al. 2013. "Attribution of foodborne illnesses, hospitalizations, and deaths to food commodities by using outbreak data, United States, 1998–2008." Emerg Infect Dis 9(3): 407-415.

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conclude that mechanically tenderized beef has ceased to pose a risk. Since 2008, an additional 2009 outbreak has been attributed to blade-tenderized steaks, which resulted in 10 hospitalizations and one death. Additionally, the 2013 Canadian risk assessment, cited by some commenters, reports a Canadian outbreak attributed to mechanically tenderized beef occurring in 2012. Therefore, data continue to support the need for the rule.

Comment: An organization representing the meat industry and a meat processor opposed the Agency's approach of combining mechanically tenderized product not containing added solutions with mechanically tenderized product injected with a marinade or solution, because, in their assessment, mechanically tenderized products injected with a solution pose a clearly different risk profile.

Response: Production of both mechanically tenderized product not containing added solutions and mechanically tenderized product injected with a marinade or solution involve piercing the surface of the product, which allows translocation of bacteria that may reside on the surface into the interior of the product. The 2013 Canadian risk assessment noted above includes both types of products in its analysis but does not distinguish between the two types in its reported results in which it concludes that the risk

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of illness from mechanically tenderized products is higher than for non-tenderized products. Therefore, FSIS concludes that its approach is consistent with available data.

I. Mandatory Labeling for Other Species

Comment: Several comments requested that FSIS require similar mandatory labeling for mechanically tenderized pork and poultry products.

Response: FSIS considered the option to amend the labeling regulations to include a new requirement for labeling all mechanically tenderized meat and poultry products. However, FSIS has concluded that there is not sufficient data on the production practices and risks of consuming mechanically tenderized poultry products or mechanically tenderized meat products, other than beef, to proceed with this option. For example, there have been no known outbreaks for mechanically tenderized poultry or non-beef products.

Implementation Issues

The final new descriptive designation requirement will apply to all raw or partially cooked needle- or blade-tenderized beef products going to retail stores, restaurants, hotels, or similar institutions or to other official establishments for further processing other than

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cooking. The final requirements for validated cooking instructions will apply to raw or partially cooked mechanically tenderized beef products destined for household consumers, hotels, restaurants, or similar institutions. If a second establishment repackages the product for household consumers, hotels, restaurants or similar institutions, the second establishment will be responsible for applying the validated cooking instructions to the product label. If retail stores repackage the product, they will be required to include the descriptive designation and validated cooking instructions from the official establishment on the retail label.

Under the final rule, establishments or retail stores may add the required information to existing label designs, or they can apply a separate sticker with the required information to existing labels. Under the provisions for generic approval in 9 CFR 412.2(a)(1), the modifications made to the labels for needle- or blade-tenderized beef products from official establishments are generically approved.

To inform consumers that the nature of needle- or blade-tenderized beef is not the same as that of an intact cut of beef, to make them aware that the consequences of the tenderization process may include the intake of

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bacteria, and to assure consumers that these products can be prepared safely, FSIS plans to conduct consumer education and awareness efforts as part of its implementation strategy. The Agency will develop webinars and PowerPoint presentations for industry to assist establishments and retail facilities in complying with the new labeling requirements. FSIS staff will also be available to answer questions pertaining to the labeling of mechanically tenderized beef products.

When the rule becomes effective, FSIS inspection program personnel will verify that establishments meet the labeling requirements in this rule. FSIS inspection program personnel review labels and compare them to actual product formulations to verify that, when applicable, the processes used in the production of the product are listed accurately on the label; that the label is not misleading; and that the label is otherwise in compliance with all labeling requirements. If the label does not meet the labeling requirements in this rule, the product will be misbranded (under 21 U.S.C. 601(n)(1), 601(n)(2), 601(n)(6) or 601(n)(12)). FSIS will inform the establishment that it needs to make corrections to its label. In limited circumstances, if the label is particularly problematic (e.g., the label presents potential health, safety, or

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dietary problems for the consumer), FSIS would rescind the label's approval under 9 CFR 500.8.

Descriptive Designations on Intact Product

Note that intact beef products may bear a descriptive designation of "intact," consistent with 9 CFR 317.2(e). However, such a descriptive designation is not required. If producers want to use such a descriptive designation on labels of intact product to distinguish it from non-intact product, FSIS would allow the designation and would not consider it a special statement requiring label submission to FSIS and FSIS review prior to using the label. Rather, FSIS would generically approve the labels with the statement based on the provisions for generic approval in 9 CFR 412.2(a)(1).

Executive Order 12866 and Executive Order 13563

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 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

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designated a "significant regulatory action," though not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

FSIS updated the Preliminary 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 more up-to-date model from the secondary cost analysis in the proposed rule to estimate the cost of label changes for the industry. The label design costs were determined utilizing a March, 2011, FDA report that provides a model for determining label design costs.

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- Also, FSIS adjusted the percentage of coordinated and uncoordinated label changes which resulted in greater proportion of labels incurring additional costs.

Baseline

The Final Report of the Expert Elicitation on the Market Shares for Raw Meat and Poultry Products Containing Added Solutions and Mechanically Tenderized Raw Meat and Poultry Product, February 2012 (February 2012 Report),²⁹ estimates that there are 555 official establishments that produce blade-, needle-, and both blade- and needle-tenderized beef products.³⁰ In terms of assigned HACCP processing size, the 555 establishments are comprised of 251 very small, 291 small, and 13 large establishments. Total U.S. beef production was 24.3 billion pounds in 2010.³¹ The February 2012 Report estimates that the proportion of beef products that is mechanically tenderized is about 10.5 percent of total beef products sold, or 2.6 billion pounds. Of these products, an estimated 318 million pounds were brand-name-packaged by the establishment for retail sales; 640 million pounds were

²⁹ Muth, Mary K., Ball, Melanie, and Coglaiti, Michaela Cimini February 2012.: RTI International Final Report – Expert Elicitation on the Market Shares for Raw Meat and Poultry Products Containing Added Solutions and Mechanically Tenderized Raw Meat and Poultry Products, Table 3-11 on p. 3-17.

³⁰ The February 2012 report estimates that 490 establishments produce products that are both mechanically tenderized and containing added solutions.

³¹ Based on slaughter volumes multiplied by average carcass weights in the Expert Elicitation on the Market Shares for Raw Meat and Poultry Products Containing Added Solutions and Mechanically Tenderized Meat and Poultry Products, RTI International, February 2012.

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private-label-packaged by the establishment for retail sales; 1,594 million pounds were packaged by the establishment for food service, and 479 million pounds were packaged in retail operations.³²

Retail establishments would be involved in repackaging products to be sold at retail. FSIS did not estimate the number of retail establishments that would be involved with repackaging raw or partially cooked mechanically tenderized beef products or the number of labels they would require to be in compliance with this rule.³³ However, in the Agency's estimation, very few retail facilities are producing mechanically tenderized beef. FSIS requested comments on the number of retailers who would be involved with repackaging raw or partially cooked mechanically tenderized beef products, but received none.

The new descriptive designation requirement will apply to all raw or partially cooked needle- or blade-tenderized beef products going to retail stores, restaurants, hotels, or similar institutions, or other official establishments for further processing, unless such product is destined to be fully cooked or receive another full lethality treatment at an official establishment. The requirements for

³² Ibid. Table 3-8 Proportions of Mechanically Tenderized-only Beef Product pounds by Packaging and Labeling Type on p. 3-13, and Table 3-14 Estimated Pounds of Mechanically Tenderized-only Beef Products by Packaging and Labeling Type (Millions), p. 3-18.

³³ FSIS believes that the number of retailers involved in repackaging mechanically tenderized beef is small and declining, with large retailers and warehouse clubs moving toward ordering case-ready packaged beef products.

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validated cooking instructions will apply to raw or partially cooked mechanically tenderized products destined for household consumers, hotels, restaurants, or similar institutions. If a second establishment repackages the product for household consumers, hotels, restaurants, or similar institutions, the second establishment will also be responsible for applying the validated cooking instructions to the product label. If retail stores repackage the product, they will have to include the descriptive designation and validated cooking instructions from the official establishment on the retail label.

Expected Cost of the Final Rule

This final rule requires all official establishments that produce raw or partially cooked mechanically tenderized beef products to modify their product labels to include the term "mechanically tenderized," "needle tenderized," or "blade tenderized" as part of the products' descriptive name and to add validated cooking instructions to the labels of all raw or partially cooked needle- or blade-tenderized beef products destined for household consumers, hotels, restaurants, or similar institutions. To incorporate this information, establishments may add the required information to existing label designs with minor changes.

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Cost Analysis

IRI scanner data indicate that there are 4,148³⁴ raw beef labels in retail, approximately 11.55 percent (or 479) of which are private label, with the remainder (3,669) 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 FSIS's 2012 expert elicitation (see Table 2, below) to calculate that 46 percent (22% / [16% + 22% + 10%]) of retail labels may be private label. In this case, there are an estimated 3,152 private retail labels and 6,821 (3,669 + 3,152) total retail labels. Next, these estimates must be adjusted upward to account for food service labels (because the IRI scanner data do not capture food service labels); based on the contents of Table 2, about 52 percent of all mechanically tenderized beef

³⁴IRI scanner data was used to calculate the number of raw meat 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.

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products are for food service. From this, FSIS estimates about 52 percent of beef labels are for food service and the remaining 48 percent of labels are for retail, yielding estimates of 8,616 (4,148/48.14%) to 14,169 (6,821/48.14%) raw beef product labels in the marketplace.

Table 2: Percent of Mechanically Tenderized Only and Mechanically Tenderized and Enhanced Beef Products by Packaging and Labeling Type

Packaging or Labeling Type	Mechanically Tenderized Only (pounds)	Share of Mechanically Tenderized Only	Mechanically Tenderized and Enhanced (pounds)	Share of All Mechanically Tenderized
Brand Name Label for Retail Sales	318	10%	829	16%
Private Label for Retail Sales	640	21%	934	22%
Foodservice	1,594	53%	2,075	52%
Retail	479	16%	206	10%

Source: 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 3-14 and 3-16. Available at: http://www.fsis.usda.gov/wps/wcm/connect/3a97f0b5-b523-4225-8387-c56a1eece189/Market_Shares_MTB_0212.pdf?MOD=AJPERES

Using the 10.5-percent estimate for the share of beef products that are mechanically tenderized but do not contain added solutions³⁵, and the 8,616 to 14,169 estimated range for number of beef labels (with brand and private allocations as shown in the previous paragraph), the estimated number of labels for mechanically tenderized beef products without added solutions is 905 (800 brand and 104 private) to 1,488 (1,316 branded and 172 private), as shown in Table 3.

³⁵ From Muth, Mary K., Ball, Mary K., and Coglaiti, Michaela Cimini February 2012.: RTI International Final Report – Expert Elicitation on the Market Shares for Raw Meat and Poultry Products Containing Added Solutions and Mechanically Tenderized Raw Meat and Poultry Products, Table 3-6. In this report, products containing added solution are referred to as “enhanced.”

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There are an additional 15.8 percent (or 1,338 to 2,199) of all beef products that are mechanically tenderized and also contain added solutions. The cost of label changes for these products is included in another FSIS final rule, finalized in December of 2014, which requires label changes for products with added solutions. These costs were overestimated by using a 12 month compliance period, although changes are required in some cases by January 1, 2016, and in other cases by January 1, 2018. For the products required by the added solutions rule to have label changes by January 1, 2016, if such label changes have not already been completed, this rule will delay by a few months the imposition of labeling change costs. For products required by the added solutions rule to have label changes by January 1, 2018, this rule's requirements related to mechanical tenderization would generate non-negligible costs because the shortening of the compliance period (from 36 months as required by the added solutions rule alone to 12 months as required by this rule). However, the added solutions rule's estimates captured the difference in cost from the 12 and 36 month compliance periods by overestimating the cost of labeling

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changes for these products under a 12 month compliance period.³⁶

Table 3: Relabeling Cost for Beef Only Mechanically Tenderized, 12-Month Compliance Period

Lower Bound	Branded		Private		Cost		
	800		104		Lower	Mid	Upper
Coor Chg	88	11%	5	5%	\$15,857	\$28,916	\$41,042
Uncoor Chg	712	89%	99	95%	\$1,961,931	\$3,555,341	\$5,949,920
Total Lower Bound Cost					\$1,977,789	\$3,584,257	\$5,990,962
Annualized Cost (3% DR, 10 Year)					\$225,104	\$407,946	\$681,868
Annualized Cost (7% DR, 10 Year)					\$263,171	\$476,932	\$797,176
Upper Bound	Branded		Private		Cost		
	1,316		172		Lower	Mid	Upper
Coor Chg	145	11%	9	5%	\$26,069	\$47,538	\$67,473
Uncoor Chg	1,171	89%	163	95%	\$3,225,318	\$5,844,804	\$9,781,374
Total Upper Bound Cost					\$3,251,387	\$5,892,342	\$9,848,847
Annualized Cost (3% DR, 10 Year)					\$370,060	\$670,643	\$1,120,957
Annualized Cost (7% DR, 10 Year)					\$432,640	\$784,053	\$1,310,518
Minor Coordinated					\$170	\$310	\$440
Minor Uncoordinated					\$2,417	\$4,380	\$7,330

This final rule will require the product name to include the descriptive designation "mechanically tenderized," "needle tenderized," or "blade tenderized."

³⁶ If any label changes for mechanically tenderized beef products with added solutions have already been completed in response to the added solutions rule, a second label revision is required to achieve compliance with this rule. The cost of a second label revision for mechanically tenderized beef products with added solutions was not captured in the added solutions rule.

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The number of labels was not tracked by the FSIS Labeling Submission and Approval System,³⁷ which replaced the Agency's earlier Labeling Information System Database, because many mechanically tenderized beef products are single-ingredient products, and establishments may be eligible for generic approval of these labels. FSIS does not have data on partially-cooked mechanically tenderized beef products but thinks that the amount of these products is small and therefore has not included them in the cost calculations.

This cost analysis uses the mid-point label design modification costs for a minor coordinated label change and a minor uncoordinated label change, as provided in a March 2011 FDA report.³⁸ This report defines a minor change as one in which only one color is affected and the label does not need to be redesigned. We conclude that the labeling change that will be required by this final rule is a minor change because the words "mechanically tenderized," "needle tenderized," or "blade tenderized" need to be added to the label, which is comparable to the addition of an ingredient to the ingredient list and the addition of validated

³⁷ Labeling Submission and Approval System (LSAS) replaced the Labeling Information System Database. LSAS, an electronic system designed to expedite many aspects of the prior label approval system by offering electronic submission and status checks for labels and Generic Label Adviser to assist establishments in determining whether labels can be approved generically or require sketch approval.

³⁸ 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).

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cooking instructions is comparable to minimal changes to a facts panel (e.g. nutrition facts, supplement facts, or drug facts).

For comparison purposes, in 2011, the Food and Drug Administration estimated that the required labeling costs for its final rule³⁹ on the labeling of bronchodilators were deemed minor. The FDA required revisions to the ``Indications,`` ``Warnings,`` and ``Directions`` sections of the Drug Fact label. Using the RTI labeling model described in the March 2011 report, the FDA concluded that the revisions would be deemed minor. FSIS assumes that the addition of validated cooking instruction is similar to the aforementioned changes to the drug fact panel, and is therefore deemed minor.

FSIS anticipates that 11 percent of branded label (a label bearing the "brand" or name of the manufacturer of the product) changes will be coordinated. Five percent of the private label (a label branded by a contract manufacturer for a retailer under the name of the retailer rather than that of the manufacturer) changes will be coordinated and that 95 percent of the private label

³⁹ Labeling for Bronchodilators To Treat Asthma; Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use (76 FR 44475; Jul. 26, 2011); available at <http://www.gpo.gov/fdsys/pkg/FR-2011-07-26/pdf/2011-18347.pdf>.

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changes will be uncoordinated with the required changes.⁴⁰

A coordinated label change is one that occurs when a regulatory label change takes place along with other labeling changes planned by the firm. Moreover, this allows time to use existing labels and results in minimal losses of inventories of labels. An uncoordinated label change occurs when establishments make non-regulatory labeling changes because of an ingredient change or product reformulation; promotional text or graphics purposes; brand images or graphics update, science update, package changes (because of changes in the size, type or vendor); corporate contact, distributor, or country of origin update; and product claims addition or deletion. These labeling changes may be minor, major or extensive, and they may also apply to changing or adding a package insert. Uncoordinated label changes costs include (not necessarily in this order) administrative activities, recordkeeping activities, analytical testing, graphic design alteration, market testing, prepress activities, engraving new plates, and printing and manufacturing labels.

⁴⁰ According to the 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), Table 3-1, Assumed Percentages of Changes to Branded and Private-label UPCs that Cannot be Coordinated with a Planned Change, for private labels for food that has a compliance period of 30 months, it is assumed that 60% of the changes are not coordinated. Thus, 40% of the changes are coordinated. Private labels are not frequently changed. As such, the cost is much higher than for branded labels.

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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. Using these costs for the number of minor coordinated and uncoordinated changes in branded and private labels, Table 3, FSIS estimates that the one-time total cost of modifying labels for all federally inspected processors is \$3,584,257 to \$5,892,342 as an upper and lower bound mid-point estimate. Over a ten-year period, the upper and lower bound annualized cost for the industry is \$407,946 and \$670,643 at a 3-percent discount rate over ten years and \$476,932 and \$784,053 at a 7-percent discount rate over ten years.

This final rule will require validated cooking instructions on the labels of packages for beef that is only mechanically tenderized and beef that is both mechanically tenderized and contains added solutions. Establishments may also incur costs to validate the required cooking instructions for raw and partially cooked needle- or blade-tenderized beef products. These costs may be incurred to ensure that the cooking instructions are adequate to destroy any potential pathogens that may remain in the beef products after being tenderized. Most cooking

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instruction validations will be contracted out to universities or conducted by trade associations or large establishments. FSIS estimates that a validation study will cost between \$5,000 and \$10,000 per product line with one formulation. Most studies will validate cooking instructions for beef products with two formulations: injected with or without solution; therefore, the total cost per validation study will be between \$10,000 - \$20,000.⁴¹ However, industry cost will likely be relatively small because FSIS is issuing guidance along with this final rule that establishments can use to develop cooking instructions. For purposes of this analysis, FSIS assumes that the costs of developing validated cooking instructions will be minimal because FSIS assumes that most establishments will follow FSIS's guidance. FSIS requested data on the costs of developing validated cooking instructions; however, none were received.

Various types of time costs are associated with this rule. For example, there may be costs due to changes in cooking procedures, as kitchen staff may prepare products differently once the product is labeled to indicate that it has been mechanically tenderized and once the labeling includes validated cooking instructions (e.g., staff may

⁴¹ Per telephone conversation with the Grocery Manufacturers Association Director of Science Operations, Food Protection.

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place a product in foil and keep it in a warm oven until it reaches the rest time established in the validated cooking instructions). The changes could potentially lead to training costs for kitchen staff to properly prepare mechanically tenderized beef products.

There may be additional wait time for consumers in both food service settings and at home before eating their meals due to increased cooking or holding product. In the absence of data with which to reliably estimate the time cost associated with this rule, we have not attempted to quantify this cost.

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 expenditure since inspectors periodically perform tasks to verify the presence of mandatory label features and to ensure that the label is an accurate representation of the product. The Agency's cost to develop guidance material that establishments can use to develop cooking instructions will be minimal because such guidance exists and can be modified and posted on the FSIS Web site in fewer than six staff-hours.

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Expected Benefits and Miscellaneous Impacts of the Final Rule

The Agency has determined that the final new labeling requirements will improve public awareness of product identities. The final rule will clearly differentiate non-intact, mechanically tenderized beef products from intact products, thereby providing truthful and accurate labeling of beef products.

As stated earlier, tenderness is a key factor in deciding to purchase a beef product. Yet it is not often easy to distinguish the more tender from the less tender, and especially the blade-tenderized from the non-tenderized beef products. The mandatory descriptive designation "mechanically tenderized," "needle tenderized," or "blade tenderized" on the labels of the needle- or blade-tenderized or similar products will inform consumers of the additional product attributes when they are making their purchase decisions.

Although the benefits of having such additional information cannot be quantified, providing better market information to consumers could promote better competition among establishments that produce beef products. In addition, if the new label causes a divergence in price between intact and mechanically tenderized beef, there

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would be a number of changes in consumer and producer surplus. Consumers who purchase mechanically tenderized beef in the absence of the rule, and would continue doing so in its presence, would gain surplus if the price for mechanically tenderized beef were to decrease, while consumers purchasing intact beef in the absence of the rule would experience a loss of surplus because of the increase in price for intact beef. Some producers of intact beef or other meats will realize a surplus increase if consumers substitute such products for mechanically tenderized beef.

FSIS has concluded that labeling information on needle- or blade-tenderized beef products may help consumers and retail establishments better understand the product they are purchasing. This knowledge is the first step in helping consumers and retail establishments become aware that they need to cook these products differently than intact beef products before the products can be safely consumed. Additionally, by including cooking instructions, the food service industry and household consumers will be made aware that a mechanically tenderized beef product or injected beef product needs to be cooked to a minimum internal temperature and may need to be maintained at this temperature for a specific period of time to sufficiently

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reduce the presence of potential pathogens in the interior of the beef product.

Additionally, the Food Code for the food service industry, which most states have adopted into State law, recommends cooking mechanically tenderized and injected meats to a minimum temperature of 145°F for a minimum of 3 minutes. In the absence of readily available information on the label as to how to cook the beef product and whether it is intact or mechanically tenderized, the food service industry likely now spends time determining whether the beef products it purchases have been mechanically tenderized. The final rule will require that raw or partially-cooked mechanically tenderized beef be labeled to indicate that it has been tenderized and to include validated cooking instructions. Therefore, the final rule will save the food service industry time to meet State requirements based on the Food Code. In addition, the new labeling requirements will lead to improved public health as a result of less mistakes in the food service industry meeting the State requirements to adequately cook mechanically tenderized beef products.

In addition, in this final analysis, FSIS did not include benefits associated with reduced illness associated with mechanically tenderized product prepared at food

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service establishments. First, FSIS recognizes that even when the food service industry can more readily determine whether beef has been mechanically tenderized, consumers may continue to request that the product be served to degree of doneness that is less than fully cooked. In most States, as long as the restaurant has noted on the menu the risk of consuming meat products that are undercooked, the food service establishment may serve the product less than fully cooked and be in compliance with State law. In addition, FSIS does not have data to estimate the percentage of total food service establishments that currently may not have sufficient information concerning whether beef product they serve is mechanically tenderized or currently may not have adequate cooking instructions for such product. Therefore, FSIS cannot effectively estimate the percentage of product that will be routinely prepared differently at food service establishments as a result of this rule.

FSIS generated an estimate of the annual number of illnesses from mechanically (needle- or blade-) tenderized beef steaks and roasts and mechanically tenderized beef steaks and roasts that contain added solutions that could potentially be avoided as a result of this final rule. FSIS evaluated the effect of additional cooking of non-

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intact product by first determining the implied concentration of organisms prior to cooking given current information, then determining the effect of adding additional cooking. Additional cooking is modeled to a minimum temperature of 160°F. Current cooking practices as captured in the EcoSure dataset do not specifically include the time from when the final cooking temperature was recorded to when consumption occurred. It is likely that product in this data set encountered a range of dwell times. FSIS recommends in its guidance concerning steaks and roasts a cooking temperature of 145°F with 3 minutes dwell time for cooking steaks and whole roasts because data support that this would be equivalent to cooking at 160°F without holding a product at that temperature for any dwell time. FSIS's guidance concerning cooking steaks and whole roasts is located at <http://blogs.usda.gov/2011/05/25/cooking-meat-check-the-new-recommended-temperatures/>. If consumers adopt the cooking practices and temperature and dwell time combinations recommended in the guidance, the results would be comparable to their cooking product to 160°F but not holding product at that temperature for any dwell time.^{42, 43}

⁴² Equivalency in cooking temperatures and times can be estimated using D and Z-values. The D-value is a measure of how long bacteria must be exposed to a particular temperature to effect a 1 log₁₀ reduction. The Z-value is a measure of how much

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Therefore, FSIS used the results from the risk analysis that estimate the benefits of consumers cooking mechanically tenderized product to 160°F without a dwell time because they are equivalent to 145°F with 3 minutes of dwell time and because the Agency did not have information about dwell time from the risk analysis.

The CDC recently completed an analysis attributing foodborne illnesses to their sources. Painter, et al., examined outbreak data from 1998 through 2008 and identified 186 outbreaks of E. coli O157 resulting in 4,844 illnesses during that period.⁴⁴ As a consequence of this analysis, Painter, et al., attributed 39.4% of illnesses or 1,909 (4,844 x 0.394) to beef.

Of the 6 outbreaks in tenderized products described in the preamble of the proposed rule (78 FR at 34592), 5 occurred during the time frame analyzed by Painter, et al. These 5 outbreaks (occurring between 2000 and 2007) resulted in 151 illnesses. Thus, approximately 7.9%

temperature change is necessary to effect a 1 log₁₀ change in the D-value. Although these values have not been measured for E. coli O157:H7 in steaks, they have been measured in ground beef. At 158°F (70°C) E. coli O157:H7 had a D-value of about 3.3 seconds, at 144.5°F (62.5°C) the D-value was 52.8 seconds. Three minutes at 145°F would be equivalent to more than 10 seconds at 160°F. Using the Z-value for E. coli O157:H7 in ground beef yields similar estimates. The Z-value was given as 9.8°F (5.43°C). Changing the temperature from 160°F to 145°F would then represent an increase in D-value of about 1.5 log₁₀. Thus, 3 minutes at 145°F would be equivalent to 5.7 seconds at 160°F. In either case, three minutes at 145°F is more than equivalent to an instantaneous temperature (< 1 sec) at 160°F..

⁴³ Murphy, R. Y., E. M. Martin, et al. (2004). "Thermal process validation for Escherichia coli O157:H7, Salmonella, and Listeria monocytogenes in ground turkey and beef products." J Food Prot 67(7): 1394-1402.

⁴⁴ Painter, J., R. Hoekstra, et al. (2013). "Attribution of foodborne illnesses, hospitalizations, and deaths to food commodities by using outbreak data, United States, 1998–2008." Emerg Infect Dis 9(3): 407-415.

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(151÷1,909) of E. coli O157 illnesses are attributable to tenderized beef product.

Painter, et al.'s work includes the illnesses associated with outbreaks, which constitute only a fraction of the overall E. coli O157 illnesses that occur each year. For an estimate of overall illness numbers, we turn to another CDC study, whose authors estimate that there are 63,153 annual illnesses in the United States attributable to E. coli O157 from all sources.⁴⁵ To determine the annual number of illnesses from E. coli O157 (STEC O157), CDC begins with the annual incidence of STEC O157 infections reported to CDC's Foodborne Diseases Active Surveillance Network (FoodNet) sites from 2005 to 2008. This value is adjusted up using an under-diagnosis multiplier that is based on the following factors:

1. Whether a person with diarrhea seeks medical care. CDC bases this on unpublished surveys of persons with bloody or non-bloody diarrhea conducted in 2000-2001, 2002-2003, and 2006-2007. CDC estimates that about 35% of persons with bloody diarrhea (about 90% of STEC O157 illnesses) would seek medical care and about 18% of persons with non-bloody diarrhea would seek medical care.

⁴⁵ Scallan, E., R. M. Hoekstra, et al. (2011). "Foodborne illness acquired in the United States--major pathogens." Emerg Infect Dis 17(1): 7-15.

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2. Whether a person seeking medical care submits a stool specimen. This is also based on unpublished surveys of persons with bloody or non-bloody diarrhea conducted in 2000-2001, 2002-2003, and 2006-2007. CDC estimates that about 36% of persons with bloody diarrhea seeking medical care and about 19% of persons with non-bloody diarrhea seeking medical care would submit stool specimens.

3. Whether a laboratory receiving a stool specimen would routinely test it for STEC O157. This is based on a published study from the FoodNet Laboratory Survey.⁴⁶ CDC estimates that 58% of laboratories would routinely test for STEC O157.

4. How sensitive the testing procedure is. CDC used a laboratory test sensitivity rate of 70% based on studies of Salmonella.^{47, 48}

CDC also adjusted the value for geographical coverage of the FoodNet sites and for the changing United States population for the years 2005-2008.

The value was also adjusted down for the following factors:

⁴⁶ Voetsch, A. C., F. J. Angulo, *et al.* (2004). "Laboratory practices for stool-specimen culture for bacterial pathogens, including *Escherichia coli* O157:H7, in the FoodNet sites, 1995-2000." *Clin Infect Dis* 38 Suppl 3: S190-197.

⁴⁷ Chalker, R. B. and M. J. Blaser 1988. "A review of human salmonellosis: III. Magnitude of *Salmonella* infection in the United States." *Rev Infect Dis* 10(1): 111-124.

⁴⁸ Voetsch, A. C., T. J. Van Gilder, *et al.* (2004). "FoodNet estimate of the burden of illness caused by nontyphoidal *Salmonella* infections in the United States." *Clin Infect Dis* 38 Suppl 3: S127-134.

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1. The proportion of illnesses that were acquired outside of the United States. Based on the proportion of FoodNet cases of STEC O157 infection who reported travel outside the United States within 7 days of illness onset (2005–2008), CDC estimated that 96.5% of illnesses were domestically acquired.

2. The proportion of STEC O157 outbreak-associated illnesses that was due to foodborne transmission. Based on reported outbreaks CDC estimated that 68% were foodborne.⁴⁹ The overall effect of the upward and downward adjustments is a multiplier of 26.1 that is applied to the reported number of illness which is then adjusted down by about 35% to account for domestically acquired foodborne illness.

CDC's credible interval surrounding this point estimate ranges from 17,587 to 149,631.⁵⁰ The estimated annual illnesses due to mechanically tenderized product is given by 63,153 (annual estimated illnesses of E. coli O157:H7⁵¹) × 0.394 (proportion of E. coli O157:H7 illnesses attributable to beef⁵²) × 0.079 (proportion of beef attributable illnesses due to tenderized product⁵³) = 1,965.

⁴⁹ Rangel, J. M., P. H. Sparling, *et al.* (2005). "Epidemiology of Escherichia coli O157:H7 outbreaks, United States, 1982-2002." *Emerg Infect Dis* 11(4): 603-609.

⁵⁰ Scallan, E., R. M. Hoekstra, *et al.* (2011). "Foodborne illness acquired in the United States--major pathogens." *Emerg Infect Dis* 17(1): 7-15.

⁵¹ *Ibid.*

⁵² Painter, J., R. Hoekstra, *et al.* (2013). "Attribution of foodborne illnesses, hospitalizations, and deaths to food commodities by using outbreak data, United States, 1998–2008." *Emerg Infect Dis* 9(3): 407-415.

⁵³ 151 outbreak illnesses attributable to tenderized beef out of 1,909 outbreak illnesses attributable to all beef (151 / 1,909 = 0.079).

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This gives a range of estimated annual illnesses from 547 (= 17,587 x 0.394 x 0.079) to 4,657 (= 149,631 x 0.394 x 0.079).

An analysis of the NHANES 2005–2006 Dietary Interview, Individual Foods, First Day, and Second Day files estimated approximately 11.7 billion servings annually of steaks and roasts. FSIS contracted with Research Triangle Institute to estimate market shares for mechanically tenderized beef and mechanically tenderized beef with added solutions.⁵⁴ After accounting for the proportion of all beef that was ground, FSIS estimates that 21.0% of non-ground product is mechanically tenderized only and that 31.6% of non-ground product was mechanically tenderized with added solutions. Thus, FSIS estimates that mechanically tenderized beef accounts for 6.2 billion servings annually. FSIS also estimates that the frequency of illness for mechanically tenderized product is $1,965 \div 6.2$ billion or 320 illnesses per billion servings, with a range from 88 (= $547 \div 6.2$ billion) to 751 (= $4,657 / 6.2$ billion) illnesses per billion servings.

⁵⁴ Muth, M. K., M. Ball, et al. (2012). Expert Elicitation on the Market Shares for Raw Meat and Poultry Products Containing Added Solutions and Mechanically Tenderized Raw Meat and Poultry Products. Research Triangle Park, NC 27709, RTI International, 3040 Cornwallis Road.

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The dose-response function for a pathogen associates an average dose with a corresponding frequency of illness. For E. coli O157:H7 the dose-response function is characterized by a linear part in which the predicted probability of illness per serving across all exposures is proportional with respect to an average dose and by a non-linear part in which the predicted probability of illness is not proportional to dose.

In the case of E. coli O157 illnesses attributable to mechanically tenderized beef, the frequency of illness is very low; therefore the mean dose across the population of servings that could account for this frequency of illness is also low. For one set of parameters the dose response function for E. coli O157:H7 corresponds to an average dose of 0.0001 E. coli O157:H7 bacteria per serving with a frequency of illness of 320 per billion.⁵⁵ This average dose is more than 5 log₁₀ below the point at which the dose response function becomes non-linear. This makes the average dose an appropriate surrogate for the distribution of all doses.⁵⁶ At the lower end of the range of illnesses, a dose of 0.000028 E. coli O157:H7 bacteria per serving

⁵⁵ Powell, M., USDA-FSIS. 2002. "Comparative Risk Assessment for Intact (Non Tenderized) and Non-Intact (Tenderized Beef): Technical Report". [fsis.usda.gov](http://www.fsis.usda.gov). Retrieved April 27, 2011, from: http://www.fsis.usda.gov/wps/wcm/connect/7afddc93-f812-42fb-92b7-52455124bbe0/Beef_Risk_Assess_ExecSumm_Mar2002.pdf?MOD=AJPERES

⁵⁶ Williams, M. S., E. D. Ebel, et al. (2011). "Methodology for determining the appropriateness of a linear dose-response function." *Risk Anal* 31(3): 345-350.

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corresponds to a frequency of illness of 88 per billion servings. At the upper end of the range of illnesses, a dose of 0.00024 E. coli O157:H7 bacteria per serving corresponds to a frequency of illness of 751 per billion servings. Both of these values also fall well below the point at which the dose response function becomes non-linear.

From a post-cooking dose of 0.0001, a pre-cooking dose of E. coli O157:H7 bacteria can be calculated by determining the average contamination level needed to survive cooking. The 2007 EcoSure consumer cooking temperature audit⁵⁷ involved the collection of data from primary shoppers of over 900 households geographically dispersed across the country. Participants were asked to record the final cooking temperature and name or main ingredient of any entrée they prepared during the week of the study. Of the 3,257 recorded consumer cooking temperatures in the database for all products, 318 recorded consumer cooking temperatures ranging from 82°F to 212°F for beef (not ground). Table 4 shows the number of observations for each recorded cooking temperature.

⁵⁷ EcoSure-EcoLab. (2007). "EcoSure 2007 Cold Temperature Database." [FoodRisk.org](http://foodrisk.org/exclusives/EcoSure/). Retrieved May 26, 2010, from <http://foodrisk.org/exclusives/EcoSure/>.

Table 4: Final recorded consumer cooking temperatures for beef (not ground) in 2007 EcoSure consumer cooking temperature audit (EcoSure-EcoLab, 2007).

Final cooking temperature	Observations	Percent
80-89	1	0.3%
90-99	3	0.9%
100-109	6	1.9%
110-119	11	3.5%
120-129	19	6.0%
130-139	27	8.5%
140-149	38	11.9%
150-159	54	17.0%
160-169	61	19.2%
170-179	31	9.7%
180-189	45	14.2%
190-199	14	4.4%
200-209	7	2.2%
210-219	1	0.3%

Sixty-seven (21%) of the recorded cooking temperatures were below 140°F and 159 (50%) of the temperatures were below 160°F. A 2010 USDA Agricultural Research Service (ARS) study by Luchansky, et al.,⁵⁸ looked at the relationship between final cooking temperatures and log₁₀ reductions for mechanically tenderized beef. An additional ARS study by Luchansky, et al.,⁵⁹ also examined the relationship between final cooking temperatures and log₁₀ reductions for chemically injected beef (mechanically tenderized beef with added solutions). Equations derived

⁵⁸ Luchansky, J. B., A. C. Porto-Fett, et al. (2012). "Fate of Shiga toxin-producing O157:H7 and non-O157:H7 Escherichia coli cells within blade-tenderized beef steaks after cooking on a commercial open-flame gas grill." J Food Prot **75**(1): 62-70.

⁵⁹ Ibid.

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from these studies combined with the distribution of final cooking temperatures shown in Table 4 estimate that an average pre-cooking dose of 0.0432 E. coli O157:H7 bacteria per serving⁶⁰ would result in an average post-cooking dose of 0.0001. Thus, a pre-cooking dose of 0.0432 corresponds with the estimate of 1,965 illnesses. Given the current cooking distribution, about 93% of the 1,965 illnesses are attributed to cooking temperatures below 160°F and about 7% to cooking temperatures equal to or greater than 160°F.

To evaluate the effect of using a higher minimum cooking temperature, FSIS modified the distribution derived from the EcoSure (2007) data set so that all of the observations that were originally below 160°F were set to 160°F. FSIS then calculated a new predicted number of illnesses using this modified cooking temperature distribution with the pre-cooking dose of 0.0432. This changed the post-cooking average dose from 0.0001 E. coli O157:H7 bacteria per serving to an average dose of 0.0000073, which corresponds to a frequency of illness of 23 per billion. With this change, the predicted number of

⁶⁰ The previous estimate for an average pre-cooking dose was 0.0188 E. coli O157:H7 bacteria per serving. Both estimates were derived using an attribution estimate of 1,965 illnesses and cooking data from the 2007 EcoSure study. The previous estimate, however, used data from two ARS studies (Luchansky 2011 and Luchansky 2012) provided to FSIS prior to their publication. After their publication, we substituted the data as published. This had the effect of decreasing the effect of cooking. Thus, in the previous submission, cooking to 160°F resulted in a decrease from 1,965 illnesses to 78 illnesses. With the change to the published data, cooking to 160°F results in a decrease from 1,965 illnesses to 144 illnesses. The change of the pre-cooking dose from 0.0188 to 0.0432 is a result of this recalculation.

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illnesses decreases from 1,965 to 144. Thus, if all consumers cook all mechanically tenderized beef to at least 160°F, the resulting total number of illness will be 144. Analogous calculations yield illness estimates of 40 and 341 illness, respectively, if the baseline annual illness totals are 547 and 4,657 (the lower and upper values of illnesses that could be attributed to mechanically tenderized beef when we consider the original uncertainty in CDC estimates of all foodborne O157 illnesses (from 17,587 to 149,631)).

The annual estimated number of illnesses averted or prevented is estimated at 1,821 (1,965 illnesses less 144 illnesses), with a range of 507 illnesses (547 illnesses - 40 illnesses) to 4,316 illnesses (4,657 illnesses - 341 illnesses), if mechanically tenderized and mechanically tenderized beef containing added solution is cooked to a minimum temperature of 160°F (which is equivalent to cooking to a minimum internal temperature of 145°F with 3 minutes of dwell time). However, FSIS knows that not all consumers will change their behavior based on reading the labels and, therefore, the Agency has estimated the uncertainty surrounding the number of illnesses that will be averted by obtaining ranges for consumer response rate, as well as using the range for the estimated number of illnesses if

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all consumers cooked the product at a minimum recommended temperature.

To determine this, FSIS used studies on the impacts of food product labels on consumer behavior. These studies estimated the proportion of consumers changing their behavior in response to the presence of cooking instructions (safe-handling instructions) ranging from 15 to 19 percent.⁶¹ In a study of the nutrition fact panel on food products, the American Dietetic Association (ADA) conducted a survey which indicated that 56 percent of the people interviewed claimed to have modified their food choices after using this nutrition fact labeling (American Dietetic Association, 1995).⁶² Finally, the Food Marketing Institute (FMI) in early 1995 indicated that the nutrition fact label may be causing some dietary change. Fifteen percent of the shoppers indicated that they had stopped buying products they had regularly purchased, after reading the label.⁶³ We use the range (15 to 56 percent) as the estimate for the impact of labels on consumer behavior in

⁶¹ Yang states that 15% (51% of respondents seen the Safe Handling Instruction labels x 79% remembered reading the labels x 37% changing their behavior after seeing and reading the labels), and Bruhn states that 17% (60% of respondents seen the labels x 65% said that their awareness was increased x 43% said that they changed their behavior). Ralston states that 19% (67% of respondents seen the label x 29% who changed their behavior).

⁶² America's Eating Habits: Changes and Consequences. U.S. Department of Agriculture, Economic Research Service, Food and Rural Economics Division. Agriculture Information Bulletin No. 750

⁶³ Food Marketing Institute (FMI) states that of the 43 percent of the shoppers interviewed, who had seen the label, 22 percent indicated it had caused them to start buying and using food products they had not used before, and 34 percent said they had stopped buying products they had regularly. We use the higher percentage of 15% (43% x 34%) in our estimate. FMI and Prevention Magazine Report Shopping for Health: Balancing Convenience, Nutrition and Taste, 1997

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retail and food service, with our primary estimate equaling the average of available estimates, or 24 percent.

In addition, the RTI study indicates that the market share for mechanically tenderized beef and beef containing added solution is estimated at 48 percent at retail.⁶⁴

Table 5 shows the estimated reduction in illness numbers based on these assumptions for consumer and food service provider behavior. To derive the estimated number of illnesses averted and focusing first on inputs derived from Scallan, et al.'s primary estimate, the range for the estimate would be 131 illness (1,821 illnesses (mid-point estimate from the risk analysis) x 48% (retail share of mechanically tenderized beef market) x 15% (lower end of the range for percent of consumer using validated cooking instructions) to 489 illness averted (1,821 illnesses (mid-point estimate from the risk analysis) x 48% (retail share of mechanically tenderized beef market) x 56% (upper end of the range for percent of consumers using validated cooking instructions)). The primary estimate is 210 illnesses.

⁶⁴ RTI, pp. 3-12 and 3-14

Table 5: Response Rate and Resulting Averted Illnesses from Retail			
	Lower	Primary	Upper
Estimated Preventable Illnesses	507	1,821	4,316
Response to Label	15%	24% ¹	56%
Share of Mechanically Tenderized Beef in Retail	48%		
Total Estimated Illnesses Averted - Lower Bound	37	58	136
Total Estimated Illnesses Averted - Primary	131	210	489
Total Estimated Illnesses Averted - Upper Bound	311	497	1,160
Expected Benefits - Lower Bound	\$119,770	\$191,631	\$447,140
Expected Benefits - Primary	\$430,178	\$688,286	\$1,606,000
Expected Benefits - Upper Bound	\$1,019,577	\$1,631,324	\$3,806,422

¹ The average of the percentages of consumer response rate: Yang 15%, Bruhn 17%, Ralston 19%, American Dietetic Association 56%, and FMI 15% as discussed in the benefits section.

Using the FSIS estimate for the average cost per case for an E. coli O157:H7 illness of \$3,281,⁶⁵ the expected benefits from this final rule are \$688,286 per year (with a range of \$430,178 to \$1,606,000). Using the credible interval from Scallan, et al., provides expected benefits of \$191,631 per year for 58 illnesses prevented (with a

⁶⁵ The FSIS estimate for the cost of E. coli O157:H7 (\$3,281 per case, - 2010 dollars) was developed using the USDA, ERS Foodborne Illness Cost Calculator: STEC O157 (June 2011). <http://webarchives.cdlib.org/sw1rf5mh0k/http://www.ers.usda.gov/Data/FoodborneIllness/> (archived link – calculator currently being updated). FSIS updated the ERS calculator to incorporate the Scallan (2011) case distribution for STEC O157. Scallan E. Hoekstra, Angulo FJ, Tauxe RV, Widdowson MA, Roy SL, et al. (2011) “Foodborne Illness Acquired in the United States—Major Pathogens.” Emerging Infectious Diseases .

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range of \$119,770 to \$447,140) for the lower bound of the credible interval and expected benefit of \$1,631,324 per year for 497 illnesses prevented (with a range of \$1,019,577 to \$3,806,422) in the upper bound of the credible interval. This estimate for the average cost of an E. coli O157:H7 illness is derived by using the 2010 version of ERS Cost calculator (for E. coli) and replacing the case numbers with new case numbers based on Scallan's report.

For E. coli, FSIS adjusted Scallan's case distribution to fit the ERS Cost Calculator because Scallan reported each illnesses in three categories (doctor visits, hospitalization, and death) while the ERS Cost Calculator for E. coli O157 has seven severity categories. By changing only the case numbers, FSIS kept all other assumptions in the ERS Cost Calculator. ERS updated the dollar units to 2010 dollars and FSIS is using these estimates.

These estimates represent a minimal estimate for an average cost of illness because they only include medical costs and loss-of-productivity costs. They do not include pain and suffering costs.

FSIS believes that consumers prefer lower cooking temperatures and therefore they may substitute other meat choices rather than cooking at a higher recommended

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temperature included in cooking instructions. This welfare loss associated with substituting to less-preferred meats or cooking to temperatures that are higher than ideal (from a taste perspective) was not quantified in the analysis.

Conclusion

The upper and lower bound cost to produce labels for mechanically tenderized beef is a one-time cost of \$3,584,257 and \$5,892,342. The upper and lower bound annualized cost is \$476,932 and \$784,053 for 10 years at a 7-percent discount rate or \$407,946 and \$670,643 over 10 years at a 3-percent discount rate.

The expected number of illnesses prevented would be 210 per year, with a range of 131 to 489, if the predicted percentages of beef steaks and roasts are cooked to an internal temperature of 160° F (which is equivalent to 145° F and 3 minutes of dwell time). These prevented illnesses amount to \$688,286 per year in benefits with a range of \$430,178 to \$1,606,000. The expected annualized net benefits, given the lower and upper bound cost estimate are -\$95,768 to \$211,353 as reflected in Table 6.

Using the lower end of the credible interval from Scallan, et al., provides an expected number of illness prevented of 58 per year, with a range of 37 to 136, as discussed earlier. These prevented illnesses amount to

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\$191,631 in benefits, with a range of \$119,770 to \$447,140. The expected annualized net benefits for the lower end of the Scallan's credible interval, given the lower and upper bound cost are -\$592,422 to -\$285,301.

Using the upper end of the credible interval from Scallan, et al., provides an expected number of illnesses prevented of 497 per year, with a range of 311 to 1,160 as discussed earlier. These prevented illnesses amount to \$1,631,324 in benefits, with a range of \$1,019,577 to \$3,806,422. The expected annualized net benefits for the upper end of the Scallan's credible interval given the upper and lower bound costs are \$847,270 to \$1,154,391.

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Table 6 - Estimated Net Benefits

Scallan Midpoint Credible Interval				
	Benefits	Cost	Lower Bound Net Benefits	Upper Bound Net Benefits
Midpoint	\$688,286		\$211,353	-\$95,768
Lower	\$430,178	\$476,932	-\$46,754	-\$353,875
Upper	\$1,606,000	\$784,053	\$1,129,067	\$821,946
Scallan Lower Credible Interval				
Midpoint	\$191,631		-\$285,301	-\$592,422
Lower	\$119,770	\$476,932	-\$357,163	-\$664,284
Upper	\$447,140	\$784,053	-\$29,792	-\$336,913
Scallan Upper Credible Interval				
Midpoint	\$1,631,324		\$1,154,391	\$847,270
Lower	\$1,019,577	\$476,932	\$542,645	\$235,524
Upper	\$3,806,422	\$784,053	\$3,329,490	\$3,022,369

In addition to the quantified net benefits mentioned above, the rule will generate the unquantifiable benefits of increased consumer information and market efficiency, an unquantified consumer surplus loss and an unquantified cost associated with food service establishments changing their standard operating procedures.

As mentioned above, FSIS is using an estimate of the number of establishments producing needle- or blade-tenderized beef products and the number of labels that will be modified as a result of this final rule.

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Additionally, FSIS did not estimate the number of validation studies that will be necessary to develop cooking instructions for raw and partially cooked needle- or blade-tenderized beef products. FSIS requested comments on the number of validation studies; however, no data was received.

Alternatives

FSIS considered several alternatives to the final rule:

Option 1. Extend labeling requirements to include vacuum tumbled beef products and enzyme-formed beef products.

FSIS considered the option to amend the labeling regulations to include a new requirement for labeling all vacuum tumbled and enzyme-formed beef products. But, as discussed earlier, FSIS does not have, nor was it provided with, sufficient data on the production practices and risks of consuming vacuum-tumbled and enzyme-formed beef products to proceed with this option.

Option 2. Extend the labeling requirements to all needle- or blade-tenderized meat and poultry products. FSIS

considered the option to amend the labeling regulations to include a new requirement for labeling all mechanically tenderized meat and poultry products. However, as

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discussed above, FSIS does not have, nor was it provided with, sufficient data on the production practices and risks of consuming mechanically tenderized poultry products or mechanically tenderized meat products, other than beef, to proceed with this option.

Option 3. Validated cooking instructions for needle- or blade-tenderized beef, needle-injected beef, and all beef containing solutions. FSIS considered the option of amending the labeling regulations to require validated cooking instructions for needle- or blade-tenderized beef, needle-injected, and all beef containing solutions.

However, FSIS did not find any outbreak data for products that contain added solutions but are not injected. In addition, if products are marinated but not injected, the pathogen remains on the surface of the product and would typically be eliminated, even if the product is cooked to rare temperatures. Therefore, FSIS does not have any data necessary to substantiate the need for this alternative.

Executive Order 12988, Civil Justice Reform

This proposed 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

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administrative proceedings will be required before parties may file suit in court challenging this rule.

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 impact on a substantial number of small entities in the United States. This determination was made because the rule will affect the labeling of about 10.5% of 24.3 billion pounds of beef products. Over 97 percent of the 555 Federal establishments that produce mechanically tenderized beef products could possibly be affected by this final rule are small or very small according to the FSIS HACCP definition. There are about 251 very small establishments (with fewer than 10 employees) and 291 small establishments (with more than 10 but less than 500 employees). Therefore, a total of 542 small and very small establishments could possibly be affected by this rule. The FSIS HACCP definition assigns a size based on the total number of employees in each official establishment. The Small Business Administration definition of a small business applies to a firm's parent company and all affiliates as a single entity.

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These small and very small manufacturers, like the large manufacturers, will incur the costs associated with modifying product labels to add on the labels "mechanically tenderized," "needle tenderized," or "blade tenderized," and validated cooking instructions needed to ensure adequate pathogen destruction.

Based on the upper bound estimated number of labels that will be required by the establishments, the cost will add an average of \$0.0038 per package (\$5,892,342 /951,000,000 packages of needle- or blade-tenderized beef).⁶⁶ The average cost per establishment will be \$10,616 per establishment (\$5,892,342/555). Also, small and very small establishments will tend to have a smaller number of unique products and will therefore have a smaller number of labels to modify, resulting in less labeling cost.

The labeling costs discussed above are one-time costs. FSIS believes these one-time costs will not be a financial burden on small entities.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the

⁶⁶ FSIS estimates that the annual quantity of mechanically tenderized beef at is about 951 million packages (2.6 billion pounds of mechanical tenderized beef produced/2.735 average weight of a retail package according to the National Cattlemen's Beef Association).

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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.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, "Consultation and Coordination with Indian Tribal Governments." Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian

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tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

FSIS has assessed the impact of this rule on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation under E.O. 13175. If a Tribe requests consultation, FSIS will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified herein are not expressly mandated by Congress.

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.

USDA Nondiscrimination Statement

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Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce it on-line through the FSIS Web page located at: <http://www.fsis.usda.gov/federal-register>.

FSIS also will 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 our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an e-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/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password-protect their accounts.

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List of Subjects in 9 CFR Part 317

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

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

Part 317 Labeling Marking Devices and Containers

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

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

2. Amend § 317.2 by adding and reserving paragraphs (e)(1) and (2), and adding a new paragraph (e)(3) to read as follows:

§ 317.2 Labels: definition; required features.

* * * * *

(e) * * *

(3) Product name and required validated cooking instructions for needle- or blade-tenderized beef products.

(i) Unless the product is destined to be fully cooked or to receive another full lethality treatment at an official establishment, the product name for a raw or partially cooked beef product that has been mechanically tenderized, whether by needle or by blade, must contain the term "mechanically tenderized," "needle tenderized," or "blade

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tenderized," as a descriptive designation and an accurate description of the beef component.

(ii) The product name 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 1/3 the size of the largest letter.

(iii) The labels on raw or partially cooked needle- or blade-tenderized beef products destined for household consumers, hotels, restaurants, or similar institutions must contain validated cooking instructions, including the cooking method, that inform consumers that these products need to be cooked to a specified minimum internal temperature, whether the product needs to be held for a specified time at that temperature or higher before consumption to ensure that potential pathogens are destroyed throughout the product, and a statement that the internal temperature should be measured by a thermometer. These validated cooking instructions may appear anywhere on the label.

* * * * *

Done, at Washington, DC on:

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Alfred V. Almanza

Acting Administrator.