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Docket Clerk U.S. Department of Agriculture Food Safety and Inspection Services Patriot's Plaza 3 1400 Independence Avenue, S.W. Room 8- 163B Washington D.C., 20250-3700

RE: U.S. Department of Agriculture's Descriptive Designation for Needle or Blade Tenderized (Mechanically Tenderized) Beef Products

Executive Summary:

STOP Foodborne Illness – a national non-profit organization dedicated to consumer protection from foodborne pathogens – finds this proposal to be much-needed step forward to provide improved and more accurate information to consumers regarding mechanically tenderized beef products. While we support many of FSIS' proposals and thinking on the subject, and applaud the Agency for putting forth this proposal, there are serious areas of concern raised within this proposed rule we would like to address. Particularly, STOP finds the definition and scope of the items to be labeled to be too narrow; with a need for <u>all</u> mechanically tenderized, vacuum tumbled, vacuum marinated, marinade injected, and enzyme-formed beef products to be labeled. If these products are not labeled with easily identifiable, consumer-friendly terms and appropriate cooking methods to kill pathogens, consumers will remain at the same level of risk they are today, and thus reduce the potential life-saving power of this rule. In our common goals of ever-advancing awareness and food safety, we urge FSIS to act upon these weaknesses in the proposed rule and make the appropriate corrections swiftly.

Comments:

STOP Foodborne Illness greatly appreciates the opportunity to comment on the Food Safety and Inspection Services' Descriptive Designation for Needle or Blade Tenderized (Mechanically Tenderized) proposed rule. [Docket No. FSIS – 2008- 0017, Regulatory Information Number 0583- AD45].

STOP Foodborne Illness (STOP) is a national non-profit public health organization that for two decades has worked with and for consumers; particularly those who have been impacted by a

foodborne illness. STOP's membership includes over a thousand victim advocates who strive for sound public policy improvements to a system that too often fails those it is tasked with protecting.

As a long-time member of the Safe Food Coalition, STOP is aware of the increased risk to consumers from mechanically tenderized beef products and applauds the Agency for taking this important step to increase transparency about the potentially-risky practice and to accurately label these products. STOP strongly supports the concept of an updated labeling system – particularly one that provides consumers with important food safety and handling instructions.

While it is FSIS' responsibility to ensure there is no adulterated product in the marketplace, this is not a perfect system, and consumers – the last barrier to foodborne illness protection – need appropriate information and cooking guidelines to ensure a completely functioning food safety system. As noted by FSIS, these products "are typically indistinguishable in appearance" from their intact counterparts, although have significant differing physical qualities.¹

We support various parts of the proposal, including the need for validated, practical and likely to be followed cooking instructions, clearly identifiable and apparent descriptive designation, and educational outreach campaigns to inform consumers.

We note, however, five key areas in which we have major concerns and offer the following comments regarding those apprehensions, along with potential solutions to be included in the subsequent draft of the proposed rule.

(1) The definition of mechanical tenderization should be robust and include vacuum tumbled, vacuum marinated, marinade injected, and enzyme-formed beef products.

As noted above, consumers cannot visually distinguish between intact and non-intact, mechanically tenderized products. FSIS also acknowledges that consumers also cannot readily distinguish between vacuum tumbled, vacuum marinated, marinade injected, and enzyme-formed beef products.² In a proposal aimed at increasing transparency, increasing decision-making abilities, and decreasing consumer illnesses it is inconsistent to label one potentially risky item and not another. This is also counterintuitive as FSIS undergoes an educational campaign to explain these differences and elucidate risk. With an effective and wide spread educational campaign to be undertaken, the consumers and FSIS would be best served if it were all-inclusive – sending a clear, uncomplicated message.

Although enzyme-formed beef is already labeled in retail locations (denoted as "formed" product), the designation does <u>not</u> indicate to the lay-consumer how the meat should be prepared or that there is a higher risk of exposure to pathogens with these products. With a distinct label (see point #4) disclosing the entirety of non-intact meat sources and how they must be cooked,

¹ Federal Register. Vol. 78: 111 (p. 34591). 10 June 2013. Proposed Rules.

² Ibid.

consumers will be considerably better informed – enabling them to safely prepare their food – and therefore should be included within the final proposal.

(2) Labels denoting mechanical tenderization should be placed on <u>all</u> mechanically tenderized meat and poultry products, not just beef.

Just because there have been "no known outbreaks for mechanically tenderized poultry or nonbeef products"³ does not mean there have not been illnesses from these products; something FSIS acknowledges.⁴ It is highly likely that the pathogens from the surface of a cut of pork or piece of poultry are pushed to the interior of the product from the piercing of needles and blades, just as they can be with mechanically tenderized beef products.

Tied directly with FSIS' proposed educational campaign, adding the additional labels to all meat products sends a more transparent message. Since the poultry and pork products are unlabeled – and a label of "intact" is not required on intact product^5 – FSIS and producers run the risk of misleading the consumer, having them falsely believe the mechanically-tenderized pork or poultry they purchase is intact.

In a contemporary food safety era where regulatory agencies are looking at food safety from a proactive and preventative standpoint, it seems contradictory to not take a precautionary approach to protect public health from likely risks, especially when they are easy and relatively inexpensive. STOP takes serious concern with the Agency's thinking on this matter. **Do consumers need to become ill before a label is placed on these products?**

For the aforementioned reasons, STOP supports Option 1 and Option 2.

We recognize that is not an outlined option within this proposal, but believe that even without hard scientific data, this is a logical, proactive, and precautionary measure – and information consumers deserve to have access to. Further study can later be conducted by FSIS and independent researchers, and the proposal can be revised at a later date, if need be, based on scientific findings.

(3) Effective education is critical to the success of the proposed labeling changes.

STOP supports an extensive educational campaign to explain the significance of the new "mechanically tenderized" designation and its additional impact on at-home safety measures. This campaign must include readily-accessible signs in the meat department and on refrigeration cases containing these products with visually appealing, easy-to-follow, pictorial, take-home multi-lingual explanations and web-based learning tools.

³ Federal Register. Vol. 78: 111 (p. 34593). 10 June 2013. Proposed Rules.

⁴ Federal Register. Vol. 78: 111 (p. 34595). 10 June 2013. Proposed Rules.

⁵ Federal Register. Vol. 78: 111 (p. 34595). 10 June 2013. Proposed Rules.

While FSIS deems the terms "mechanically tenderized" and "intact" to be non-technical,⁶ STOP believes they are essentially meaningless to the lay consumer and not likely to be understood without *significant* educational outreach. A public information campaign will be necessary to fully educate the public about the increased risk. We urge the Agency to work in partnership with retail associations to develop in-store messaging (see above) and install end-caps or display cases containing instant-read thermometers in close proximity, so that consumers are easily able to purchase these products and the food safety message is emphasized with easy-to-execute, concrete, actionable steps.

The explanations should also be included in the packaging of at-home-tenderization products. And these tools should be addressed in consumer literature within the educational campaign.

Within the language of the new labels, STOP strongly urges the Agency to make minor adjustments to ensure thorough consumer understanding. In addition to the current proposed language, consumers should be directed to (1) take the temperature *at the thickest point* of the piece of meat or poultry and (2) to use a *calibrated* thermometer.

(4) The label should be readily distinguishable from the manufacturer's label.

STOP and our members strongly support additional labeling, but note the label for mechanically tenderized products should be separate, different, brightly colored and easily distinguishable from the product's general label. Hiding pertinent information in plain sight does not follow the spirit of this rule based on increasing transparency, awareness, and consumer safety.

FSIS' current proposal suggests including the new designation in a smaller typeface below the brand name and meat identifier on the existing label. The Agency has also requested comment on whether it should allow producers to choose a method of labeling that best suits their unique product packaging. STOP urges the Agency to select a single, easily-distinguishable, standardized method for labeling and require it on all mechanically tenderized product to make the labeling clearer for consumers. The label should be a brightly colored sticker, separate from the existing label, which should be placed on the front of the packaging. STOP makes this request based on the presumption that consumers are more likely to take notice of a separate sticker, rather than words in the same type-face and color scheme as the original label.

(5) To account for potential cold spots within frozen product, the additional label should indicate an instant read temperature of 160°F without any added rest time.

In recent years there has been a strong shift towards more frozen foods, readily-accessible and easy-to-prepare meals,⁷ more meat consumption,⁸ and more mechanically tenderization to meet a

⁶ Federal Register. Vol. 78: 111 (p. 34593). 10 June 2013. Proposed Rules.

⁷Transparency Market Research (2013). Frozen Food Market (Vegetables & Fruits, Potatoes, Ready-to-eat Meals,

Meat, Fish/Seafood and Soups) - Global Industry Analysis, Size, Share, Growth, Trends and Forecast, 2013 - 2019. ⁸ Daniel, C.R., Cross, A.J., Koebnick, C., Sinha, R. (2011). Trends in meat consumption in the USA. *Public health nutrition*, *14*(4), 575-583.

desired tenderness and quality for a reasonable cost.⁹ Further, consumers often buy a product and freeze all or a portion of it at home, turning a point-of-sale refrigerated product into a frozen state prone to cold spots (see below).

As we've all unfortunately seen, frozen food products are often thawed outside of the refrigerator, which increases the likelihood of bacterial growth, like deadly STECs. Thawing completely is an extreme challenge, especially to do so properly in a short time period thus potentially leaving "cold spots" (less than recommended cooking temperatures), in otherwise cooked meats. FSIS recognizes in the proposal that mechanically tenderized product may have pathogenic bacteria far inside a piece of meat. All of these things combined together quite likely means more mechanically-tenderized, frozen, not-completely-thawed meat is being consumed than ever before.

Luchansky, reports that the "data also confirmed that both intrinsic and extrinsic factors, such as uneven heating and the sporadic presence of cold spots within patties on occasion allowed for fortuitous survivors, even after cooking to the endpoint patty temperatures recommend by USDA-FSIS and/or FDA."¹⁰ The problem is that the prescribed rest time, which normally allows the temperature to rise within products to attain complete cooking, does not generate enough heat to overcome cold spots that may be present in products that begin the cooking process in the frozen or partially frozen state. While the Luchansky study focuses on ground product, and we recognize that ground beef and mechanically tenderized steaks are not identical, they do share similar qualities of non-intact products and therefore believe this study should be taken into consideration.

STOP is further concerned about misunderstandings that could arise if the validated cooking instructions on each package of meat are different than what is recommended by FSIS. According to FSIS' proposal, companies could label their mechanically tenderized steak as requiring an instantaneous temperature of 160° F or any validated time and temperature that achieves the same temperature level. Temperatures below 145° F with long stand times may not reach temperatures high enough to eliminate fortuitous survivors, especially if not followed precisely.

Additionally, Luchansky's studies note that using different cooking appliances can have an "appreciable effect on the extent and rate that microbes are inactivated in foods" and suggest that the "potential for illness can be appreciably lessened by ensuring that all portions of each steak or piece of meat achieve the recommended end point temperature of 160 degrees Fahrenheit."¹¹ Luchansky's research group also states that given the nature of steaks and cooking processes, "it

⁹ FSIS's Checklist and Reassessment of Control of *E. coli* O157:H7 in Beef Operations (2008). http://www.fsis.usda.gov/wps/wcm/connect/9ce5ce22-f609-4990-bd9ace2c323d229b/Ecoli Reassement Checklist.pdf?MOD=AJPERES.

¹⁰ Luchansky, J.B., Porto-Fett, A.C.S., Shoyer, B.A., Phiilps, J., Chen, V., Eblen, D.R., Cook, L.V., Mohr, T.B., Esteban, E., 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 clamshell electric grill." *Journal of Food Protection* 76: 9(1500-1512).

¹¹ Luchansky, J.B., Porto-Fett, A.C.S., Shoyer, B.A., Call, J.E., Schlosser, W., Shaw, W., Bauer, N., Latimer, H. (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." *Journal of Food Protection* 75: (62-70).

is likely that not all portions of the meat achieved the target temperature... Thus, it may be necessary to evaluate slightly higher endpoint cooking temperatures, with or without a holding time, to ensure total elimination of ECOH and STEC." ¹² Furthermore, the infectious dose of an STEC is exceedingly small; just a few cells.¹³ Thus, any fortuitous survivors have the potential to cause extreme risk to human health, and must be wholly inactivated if present.

Mixing messages about cooking temperatures can be confusing to consumers, and in order to ensure consumers are probable to heed their instructions, labels must be easy and likely to follow, while providing the most protection possible.

In conclusion:

STOP Foodborne Illness applauds the Agency for its work on this much-needed labeling rule, and urges FSIS to proceed quickly with final rulemaking and labeling requirements. But not before making the abovementioned changes.

Given the current distribution of illnesses attributable to mechanically tenderized beef, and the cooking temperatures achieved at home (as noted in the EcoSure study), the Agency estimates there is the potential to eliminate 1,887 illnesses per year -- which FSIS notes is not only an economic burden, but as we well know causes much unquantified and unquantifiable pain and suffering. American consumers deserve to know what they are eating and how to protect themselves and their families from added risk and in a way that is easy-to-follow and explicit. With added information and education, we can work to reduce this economic and emotional burden.

¹² Luchansky, J.B., Porto-Fett, A.C.S., Shoyer, B.A., Call, J.E., Schlosser, W., Shaw, W., Bauer, N., Latimer, H. (2011). "Inactivation of shiga toxin-producing O157:H7 and non-O157:H7 shiga toxin-producing *Escherichia coli* in brine-injected gas-grilled steaks." *Journal of Food Protection* 74: (1054-1064).

¹³ Food Safety Authority of Ireland (2010). The prevention of verocytotoxigenic Escherichia coli (VTEC) infection: a shared responsibility, 2nd ed. Food Safety Authority of Ireland, Dublin.