



United States Department of Agriculture

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Food Safety and  
Inspection Service

1400 Independence  
Avenue, SW,  
Washington, D.C.  
20250

JUL 15 2019

Ms. Laura MacCleery  
Policy Director  
Center for Science in the Public Interest  
1220 L Street NW  
Washington, DC 20005

Dear Ms. MacCleery,

The Food Safety and Inspection Service (FSIS) has completed its review of the December 2016 petition submitted by the Center for Science in the Public Interest (CSPI), requesting that FSIS create regulations requiring warning labels on “processed” meat and poultry products.<sup>1</sup> The petition proposes warning labels that advise consumers that frequent consumption of these products may increase their risk of colon and rectal cancer.

The petition relies on scientific studies asserting links between the consumption of processed meat with increased risk of certain types of cancer. It states that there is a low awareness among American consumers of this risk, and that the risk identified in the studies obligates the USDA to require a warning statement on processed meat and poultry product labels.

After careful consideration, FSIS has decided to deny the petition without prejudice. FSIS considers these products safe to consume and not misbranded for failure to display the warning labels sought in the petition. Further, the requested warning label could be misleading in that it would fail to provide information that consumers would need to place the asserted risk in proper context.

FSIS’s authority to regulate meat and poultry product labeling comes from the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 466 *et seq.*). These Acts direct the Secretary of Agriculture to maintain inspection programs designed to assure consumers that meat and poultry products are safe, wholesome, not adulterated, and properly marked, labeled, and packaged. These Acts also provide that the labels of meat and poultry products must be approved by the Secretary of Agriculture, who has delegated this authority to FSIS, before these products can enter commerce.

Products are “misbranded” under the Acts when their labeling fails to include a required labeling feature (*see* 21 U.S.C. 453(h) and 601(n) and 9 CFR 317.2 and

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<sup>1</sup> The petition defines processed meat and poultry products as those “produced by smoking, curing, salting, and/or the addition of chemical substances such as nitrate and nitrite to preserve the meat and enhance its flavor.”

Part 381, Subpart N). FSIS currently requires up to eight pieces of information on all product labels: the product name, FSIS inspection legend with establishment number, handling statement, net weight statement, ingredients statement, address line, nutrition facts, and safe handling instructions. The regulations require additional information on labels for certain products. This information is authorized by specific provisions of the FMIA (21 U.S.C. 601(n)(1), (5), (9), and (12)) and PPIA (21 U.S.C. 453(h)(1), (5), (9), and (12)).

Products also are misbranded under the Acts if their labeling is “false or misleading in any particular” (21 U.S.C. 601(n)(1) and 453(h)(1)). FSIS considers a product to be misbranded not only if its label includes representations that are false, but also if its label fails to inform consumers of consequences that may result from using or consuming a product, whether under the conditions of use prescribed by its labeling or under conditions that are customary or usual. In this regard, the petition asks FSIS to require that processed meat and poultry products include a warning statement stating that “[f]requent consumption of processed meat [or poultry] products may increase your risk of developing cancer of the colon and rectum.” The petition cites several extant FSIS labeling requirements as being similar to the warning labels it seeks. However, as is discussed below, these current requirements are significantly different from the statement the petitioner requests. We also find that processed meat and poultry products as currently labeled are not misbranded for failing to warn consumers of alleged correlations between long-term consumption and increased risk of certain types of cancer.

The petition first refers to 9 CFR 316.10(d) and 317.17, which require that meat products cured without nitrates or nitrites be labeled as “uncured,” and include the statements “No Nitrate or Nitrite Added” and “Not Preserved - Keep Refrigerated Below 40° F.” These labeling features are based on FSIS’s authority to require that each ingredient in a product be listed (21 U.S.C. 601(n)(9)), and on our authority to require labeling that will inform the public of the manner of handling required to maintain a product in a wholesome condition (21 U.S.C. 601(n)(12)). The statement “Not Preserved - Keep Refrigerated Below 40° F” is intended to inform consumers of the proper method of handling and storing products not preserved by curing, in order to protect against the growth of pathogenic bacteria like *Clostridium botulinum*. The PPIA contains similar statutory authority (*see* 21 U.S.C. 453(h)(9) and (12)).

This authority also supports FSIS’s safe-handling instructions mandated on raw meat and poultry products. The safe handling final rule relied on 21 U.S.C. 601(n)(12) and 453(h)(12) to mandate a statement informing the public how to maintain these products in a wholesome condition.<sup>2</sup> Specifically, the safe-handling instructions inform consumers that some products may contain bacteria capable of causing illness if they are mishandled or cooked improperly. Consumers are advised to keep the raw products refrigerated or frozen, separate them from other foods, cook them thoroughly, and keep hot foods hot (*see* 9 CFR 317.2(l) and 381.125(b)).

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<sup>2</sup> *Mandatory Safe Handling Statements on Labeling of Raw Meat and Poultry Products*, (59 FR 14528, Mar. 28, 1994).

FSIS's 2015 rule requiring a descriptive designation on raw or partially cooked needle- or blade-tenderized beef products is also based on our safe handling authority.<sup>3</sup> The descriptive designation provided consumers with information necessary to distinguish needle- or blade-tenderized beef products from intact, non-tenderized product, and handle and prepare them safely. Mechanical tenderization improves the tenderness of less tender, and typically less expensive, beef cuts, and such products are typically indistinguishable in appearance from whole, intact products. FSIS found that needle- or blade-tenderizing was a characterizing feature of such products and therefore was a material fact that needed to be disclosed.

In contrast, the warning statement sought in the petition is not intended to inform consumers about proper handling or cooking. Although some of the studies cited in the petition state that cooking certain processed meat and poultry products at high temperatures can cause carcinogenic compounds to form, the studies and the petition acknowledge that the mechanisms giving rise to the purported increased cancer risk are currently unknown. In any case, the petition does not seek labeling requirements on how to cook or handle processed meat or poultry products. Also, unlike mechanical tenderization, consumers can readily determine that a product has been smoked, cured, or otherwise processed under the definition provided in the petition, either from the appearance of the product or from labeling regulations already in place. For example, all multi-ingredient product labels must contain an ingredients statement with the common or usual name of each ingredient in the product (9 CFR 317.2(f) and 381.118). Additionally, any meat product prepared by salting, smoking, drying, etc., must be so described on the label unless the name of the product or the manner of packaging shows that the product was subjected to such preparation (9 CFR 317.2(e)(1)). Curing agents must also be identified on the product label (9 CFR 317.17).

The petition also cites irradiation as an example of labeling that informs consumers about material facts that would not otherwise be apparent, arguing that the health risks of processed meat and poultry products are similarly not apparent and should be addressed through labeling. We disagree with this comparison. FSIS required foods exposed to ionizing radiation to be labeled as such in 1999.<sup>4</sup> This rule was published after the U.S. Food and Drug Administration (FDA) approved, in December 1997, a food additive petition for the use of ionizing radiation on meat food products under FSIS jurisdiction.<sup>5</sup> The FDA specified that labeling requirements regarding the use of ionizing radiation would be determined by FSIS under its labeling authority through the FMIA. The FDA defined ionizing radiation used to treat food as a food additive, as defined by the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 321(s)). FSIS later proposed requiring that the use of ionizing radiation be disclosed on product labels, including in the ingredient statements of multi-ingredient products containing irradiated meat or poultry.<sup>6</sup> FSIS considers food additives to be ingredients, which are required to be listed on meat and poultry products labels under 21 U.S.C. 453(h)(9) and 601(n)(9). This authority also supported a 2001 rule, cited by the petition, requiring that the source of natural sausage casings be included on the label if the casings came from a species different from the ones used to make the product.<sup>7</sup>

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<sup>3</sup> *Descriptive Designation for Needle- or Blade-Tenderized (Mechanically Tenderized) Beef Products*, (80 FR 28155, May 18, 2015).

<sup>4</sup> *Irradiation of Meat Food Products*, (64 FR 72150, Dec. 23, 1999).

<sup>5</sup> *Irradiation in the Production, Processing and Handling of Food*, (62 FR 64107, Dec. 3, 1997).

<sup>6</sup> *Supra* Note 5 at 72166; see also 9 CFR 424.22(c)(4).

<sup>7</sup> *Labeling of Natural or Regenerated Collagen Sausage Casings*, (66 FR 40843, Aug. 6, 2001).

The requirement that each ingredient be listed already applies to meat and poultry products, whether they are processed or not. The requirement to list ingredients does not support or authorize warning statements.

### Material Misrepresentation

The petition argues that processed meat and poultry products are misbranded absent a warning label. It relies on FSIS's response to another petition, in which we cited the FFDCA (21 U.S.C. 321(n)), which we consider to further explain the terms "false" or "misleading" in our determination that a product may be misbranded if it fails to inform consumers of consequences that may result from using or consuming a product.

The FDA has relied on 21 U.S.C. 321(n) to require warnings regarding acute health risks posed by certain food products and containers. Because we look to 21 U.S.C. 321(n) to inform our interpretation of the terms "false" or "misleading," it is helpful to consult regulations promulgated by the FDA under this authority. For example, the FDA relied on this provision to require a statement on unpasteurized juice warning of the dangers of harmful bacteria to certain at-risk populations.<sup>8</sup> The FDA also relied on section 321(n) to require a label on certain high-protein food products marketed for weight loss, after receiving reports that such products had been associated with several cardiac deaths.<sup>9</sup> Additional warning statements or notices must appear on dietary supplements containing iron or iron salts, self-pressurized food containers, and foods containing psyllium husk.<sup>10</sup> These labeling statements address serious public health risks that may result from one or several uses of a product and are only required under exceptional circumstances. We agree with this approach.

Like the FDA, FSIS has the authority to require that product labels disclose material facts to prevent them from being misbranded. But this authority does not mandate that FSIS require every labeling statement or feature that some may consider material. Specifically, the Agency is unlikely to find that reports of human health risks associated with long-term consumption of products under our jurisdiction are material facts that must be disclosed on the label when several factors other than consumption of the product are also known to contribute to these risks. It is difficult to include all of the facts necessary to place a warning in its proper context, such as the effect of different cooking methods, the level of exposure arising from different products, and individual risk factors like genetic predisposition, lifestyle, and diet. Warning statements that omit this type of information have the potential to be misleading to consumers. Furthermore, this type of labeling may distract consumers from important information related to acute health risks, such as the presence of allergens and the need to cook and handle products safety.

FSIS can issue general consumer information and conduct outreach activities to promote food safety and public health. Notably, the Agency already informs consumers that cooking bacon at higher temperatures may be more hazardous than less well-done bacon, due to the formation of

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<sup>8</sup> *Food Labeling: Warning and Notice Statement; Labeling of Juice Product*, (63 FR 37030, July 8, 1998).

<sup>9</sup> *Food Labeling; Protein Products; Warning Labeling*, (49 FR 13690, Apr. 6, 1984).

<sup>10</sup> Each of the warnings or notice requirements in this paragraph is designated in 21 CFR 101.17.

nitrosamines, most of which are known carcinogens in test animals.<sup>11</sup> We also publish specific information on food safety issues for at-risks populations.<sup>12</sup>

For these reasons, FSIS is denying your petition. Because our denial is without prejudice, you may submit a revised petition that contains additional information to support the requested action. In accordance with our petition regulations, we have posted your petition on the FSIS website (9 CFR 392.6). We intend to post this response as well.

Sincerely,



Roberta Wagner  
Assistant Administrator  
Office of Policy and Program Development

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<sup>11</sup> *Bacon and Food Safety*, available at: [https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/meat-preparation/bacon-and-food-safety/ct\\_index](https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/meat-preparation/bacon-and-food-safety/ct_index).

<sup>12</sup> *At-Risk Populations*, available at: <https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/at-risk-populations>.