



United States Department of Agriculture

Food Safety and
Inspection Service

May 27, 2016

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

Phillip H. Kimball
Executive Director
North American Meat Processors Association
1910 Association Drive
Reston, VA 20191

Dear Mr. Kimball:

The Food Safety Inspection Service (FSIS) has completed its review of the petition submitted on behalf of the North American Meat Processors Association asking that the Agency define the term “pasteurization” as it applies to meat and poultry products. In addition, the petition requests that FSIS allow for the use of the claim “pasteurized” on the labels of meat and poultry products that are “fully cooked or that have otherwise been processed in a manner that has effectively eliminated potential public health risks from pathogenic organisms.” The petition asserts that this could be carried out immediately through the “issuance of routine label approvals” and that FSIS should issue guidance to clarify its policy as related. To support the requested action, the petition references and includes a scientific paper published by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) addressing the issue of establishing the equivalence of alternative methods of pasteurization.¹

After careful consideration of the petition and supporting information, we have decided to grant your petition in part. As discussed below, FSIS intends to update its guidance in the *FSIS Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat Products* to define “pasteurization.” However, instead of immediately approving use of the claim “pasteurized” in the labeling of certain products, as requested in the petition, FSIS does not intend to begin to approve use of the “claim” pasteurized in the labeling of meat and poultry products until it has issued guidance on use of the claim.

Your petition also described a second category of product where you state that “additional work needs to be done to establish acceptable parameters for pasteurization claims.” This response addresses our position on those products, also.

¹ NACMCF Executive Secretariat, “Requisite Scientific Parameters for Establishing the Equivalence of Alternative Methods of Pasteurization,” *Journal of Food Protection*, Vol. 69, No. 5, 2006, Pages 1190-1216.

Existing Definitions for “Pasteurized and Common Use of the Term as Applied to Meat and Poultry Products

Section 403(h)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) provides that a food may be represented as “pasteurized” only if the food has been subjected to a safe process or treatment that is prescribed as pasteurization for such food in a regulation issued under the FD&C Act or if the food has been subjected to a safe process or treatment that meet certain statutory criteria (21 U.S.C. 343(h)). The criteria in the FD&C Act that are relevant to the processing of meat and poultry products are that the process: (1) is reasonably certain to achieve destruction or elimination in the food of the most resistant micro-organisms of public health significance that are likely to occur in the food, and (2) is effective for a period that is at least as long as the shelf life of the food when stored under normal and moderate abuse conditions.

The 2006 NACMCF journal article that you submitted in support of your petition, NACMCF defined “pasteurization” as “any process, treatment, or combination thereof, which is applied to food to reduce the most resistant microorganism(s) of public health significance to a level that is not likely to present a public health risk under normal conditions of distribution and storage.” NACMCF also stated that, in addition to traditional thermal pasteurization, other treatments could satisfy this definition of pasteurization for certain foods with adequate validation through the use of processing authorities, challenge studies, predictive modeling, or safe harbors.

Of FSIS-regulated products, existing regulations require pasteurization only for egg products distributed for consumption. FSIS defines “pasteurization” for these products as an operation in which “every particle of all products is rapidly heated to a required temperature and held at that temperature for a required minimum holding time” (9 CFR 590.570). This process destroys *Salmonella* but does not cook the eggs or affect their color, flavor, nutritional value or use. For the dairy industry, the Food and Drug Administration (FDA) defines “pasteurization” as “the process of heating every particle of milk or milk product as required in properly designed and operated equipment” (21 CFR 1240.61). In both cases, pasteurization is regulatory, based on thermal inactivation of recognized pathogens of concern that may be present throughout a specific product, and may be in conjunction with voluntary use of the word “pasteurized” on the product labeling.

Currently, the term “pasteurization” is most commonly used by the meat and poultry industry to describe the “surface kill step” immediately before or just after packaging of RTE products. Typically, heat (in various forms) is applied to the RTE product or package surface to destroy contaminants found on or close to the surface of the RTE product. In addition, “steam pasteurization,” the process of applying steam to the surfaces of freshly slaughtered livestock carcasses, is commonly used to reduce the risk of pathogenic bacterial contamination at the slaughter level. However, although both of these processes have been shown to effectively reduce targeted pathogenic bacterial

populations on or just below the product's surface, neither process by itself is consistent with the term "pasteurization" as prescribed in section 403(h)(3) of the FD&C Act or as defined by NACMCF because they do not reduce pathogens to safe levels.

Agency Action in Response to the Petition

We have considered the information in your petition, the supporting documentation, and the various definitions of pasteurization described above and agree with your assertion that the term "pasteurized" should not be limited to heat treated liquid foods. We also believe that use of the claim "pasteurized" in the labeling of meat and poultry products should be consistent with existing definitions for pasteurized. Therefore, we have decided to define the term "pasteurized" as applied to RTE meat and poultry products as, "any process, treatment, or combination thereof, that eliminates or reduces the number of pathogenic microorganisms to achieve at least a 5-log reduction of *Salmonella* on or in meat or poultry products in the final finished package. In cases where the products are known to be positive for *Listeria monocytogenes* (*Lm*) because they test positive or cross over a surface that is positive for *Lm*, the process would need to achieve a 5-log reduction of *Lm* on or in meat or poultry products in the final package to make them safe for human consumption. This process should be effective for a period that is at least as long as the shelf life of the food (as determined by the manufacturer) when it is stored under normal and moderate abuse conditions." We intend to update the guidance in the *FSIS Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat Products* to include this definition. With adequate validation,² pasteurization processes may include alternative technologies other than traditional cooking (e.g., High Pressure Processing (HPP)). FSIS will not, however, consider irradiation a pasteurization process or treatment. Although the effect is similar to pasteurization, FSIS considers ionizing radiation a food additive under 9 CFR 424.22.

FSIS will not allow the claims "pasteurization," "pasteurized," or "steam pasteurization" on the labels of not-ready-to-eat (NRTE) products (e.g., carcasses, subprimals, and trimmings) destined for consumers or for further processing. FSIS is not aware of any pasteurization processes for livestock carcasses (or subprimals) that have been validated to achieve a 5-log reduction for *Salmonella*, which is what would be needed to eliminate or reduce the number of pathogenic microorganisms on or in the product to make it safe for human consumption. Even if steam pasteurization could achieve a 5-log reduction for *Salmonella*, labeling any NRTE meat product destined for further processing as "pasteurized" could present a food safety risk due to the potential for recontamination

² Regardless of the lethality process or treatment used, all establishments that produce ready-to-eat meat and poultry products must provide supporting documentation that the process for their ready-to-eat products achieves the required or recommended reduction of pathogens. This supporting documentation must be provided as part of an establishment's hazard analysis decision-making documents, and validation data must be included in its HACCP records (9 CFR 417.5(a)(1) and (2) and 417.4(a)).

and growth of pathogens during subsequent processing steps like grinding.³ Furthermore, use of the claim “pasteurized” on NRTE meat and poultry product labeling may be confusing or misleading to consumers because of their pre-existing perception that pasteurized products (e.g., dairy products) are produced in a manner that eliminates any dangerous bacteria. The petition did not include, and FSIS is not aware of, any data to demonstrate consumer expectations of the term “pasteurized” on NRTE product labels.

The updated guideline will make clear that establishments would be permitted to use the claim “pasteurized” on the labels of RTE meat and poultry products that have not been post-lethality exposed, or those that are post lethality exposed and receive a treatment that achieves a 5-log reduction of *Salmonella*. It also applies to products that are known to be contaminated because they test positive for *Lm* or pass over a surface that tests positive for *Lm* and receive a 5-log treatment after they are packaged. In this case, the process would need to achieve a 5-log reduction of *Lm* instead of *Salmonella* because the product was contaminated with *Lm*. Products with a raw appearance that have been treated with a lethality process that renders the product RTE, and that are not post-lethality exposed, e.g., “steak tartare” subjected to a HPP treatment that is sufficient to eliminate the number of pathogenic microorganisms to make the product safe for human consumption and that is effective for at least as long as the product shelf life, would also be included.

Once the updated guideline is made available to the public, FSIS agrees that allowing the claim could be accomplished through the Agency’s prior label approval system. Under 9 CFR 412.1(c)(3), all labels bearing “special statements and claims” (a processing method claim, in this case “pasteurized”) must be submitted to FSIS for prior approval. Sufficient information supporting the claim would have to accompany the label application. For example, for a post-lethality exposed product to be labeled “pasteurized,” the supporting information would have to include evidence that the post-lethality pasteurization process achieves at least a 5-log reduction in *Lm*.

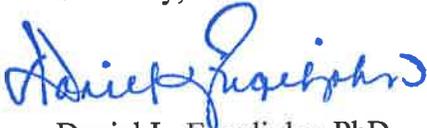
FSIS will approve these claims if the documentation supports that the claim is truthful and not misleading. Because of the scientific nature of these types of claims, the Labeling and Program Delivery Staff will make its label approval determination in consultation with the Risk Innovations and Management Staff. Both staffs will review the documentation to determine whether the process creates a risk to the health or safety of inspection program personnel, creates a food safety concern, or is inconsistent with FSIS’s regulations.

FSIS routinely works with foreign and domestic regulatory agencies to ensure that the regulations governing the labeling of meat and poultry products are as consistent as possible.

³ The Canadian Food Inspection Agency has recalled ground beef from a facility with steam pasteurization capability after linking *E. coli* O157:H7 to the consumption of ground beef produced in that establishment.

For the reasons discussed above, we are granting your petition in part. In accordance with FSIS regulations, the petition was posted on the FSIS website, and the Agency intends to post this response as well.

Sincerely,



Daniel L. Engeljohn, PhD
Assistant Administrator
Office of Policy and Program Development