

I. Background

FSIS is the public health regulatory agency in the USDA that is responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and accurately labeled and packaged. FSIS develops and implements regulations and policies to ensure that meat, poultry, and egg product labeling is not false or misleading. Under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, 607) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, 457), 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.

Pursuant to its authority under the FMIA and PPIA, FSIS has established a framework of regulations and policies within which to judge whether labels and other labeling of meat and poultry products are not false or misleading.

To guide manufacturers in the development of labeling that FSIS is likely to determine to be not false or misleading with regard to the voluntary claim "natural," FSIS first issued policy guidance in the form of Standards and Labeling Policy Memorandum (Memo) 055, dated November 22, 1982. Policy Memo 055 stated that the term "natural" may be used in the labeling of meat and poultry products provided that the applicant for such labeling demonstrates that:

(1) The product does not contain any artificial flavor or flavoring, coloring ingredient, or chemical preservative (as defined in 21 CFR 101.22), or any other artificial or synthetic ingredient; and

(2) The product and its ingredients are not more than minimally processed. Minimal processing may include: (a) Those traditional processes used to make food edible, to preserve it, or to make it safe for human consumption, e.g., smoking, roasting, freezing, drying, and fermenting, or (b) those physical processes that do not fundamentally alter the raw product or that only separate a whole, intact food into component parts, e.g., grinding meat, separating eggs into albumen and yolk, and pressing fruits to produce juices. Relatively severe processes, e.g., solvent extraction, acid hydrolysis, and chemical bleaching, would clearly constitute more than minimal processing.

Policy Memo 055 also provided that the use of an ingredient that has undergone more than minimal processing in general precludes a product in which the ingredient is used from bearing an unqualified "natural"

claim. Policy Memo 055 stated that FSIS will evaluate label submissions on a case-by-case basis, however, and may approve a label if the manufacturer of the product demonstrates that the use of such an ingredient does not significantly change the character of the product provided the "natural" claim is clearly and conspicuously qualified to identify the ingredient.

Policy Memo 055 also provided that all products that claim to be "natural" or a "natural" food should be accompanied by a brief statement that explains what is meant by the term "natural," i.e., that the product is a "natural" food because it contains no artificial ingredients and is only minimally processed. In addition, the 1982 policy also stated that the decision of the Agency to approve or deny the use of a "natural" claim may be affected by the specific context in which the claim is made. For example claims that a product is a "natural" food, e.g., "natural" chili, would be unacceptable for a product that contains beet powder, an ingredient that has a "natural" source but that artificially colors the finished product. However, "all natural ingredients" might be an acceptable claim for such a product.

Since 1982, FSIS has updated its guidance on the use of "natural" claims to reflect case-by-case decisions made by the Agency and to revise references to regulations. In August 2005, FSIS rescinded Policy Memo 055 and incorporated its policy on "natural" claims into an entry in its Food Standards and Labeling Policy Book (the Policy Book) (available on the FSIS Web site at: http://www.fsis.usda.gov/OPPDE/larc/Polices/Labeling_Policy_Book_082005.pdf). The 2005 Policy Book entry modified FSIS's "natural" policy to add a note that acknowledged that "[s]ugar, sodium lactate (from a corn source) [at certain levels], and natural flavorings from oleoresins or extractives are acceptable for 'all natural' claims."

In late 2006, FSIS received information that raised questions about its initial judgment that the use of sodium lactate at levels consistent with those approved for flavoring (i.e., up to two percent of product formulation) was consistent with the meaning of "natural." More specifically, the information provided to the Agency indicated that sodium lactate, as well as potassium lactate and calcium lactate, may provide an antimicrobial effect at levels that have been approved for flavoring. The Agency concluded that listing "sodium lactate (from a corn source)" in the 2005 entry may have been in error. In December 2006, FSIS

modified the "natural" claims entry in the Policy Book to remove the 2005 reference to sodium lactate. The current entry in the Policy Book provides that the use of sodium lactate or any ingredient known to have multiple technical effects in products labeled as "natural" will be evaluated on a case-by-case basis at the time of label approval to assess whether the intended use, level of use, and technical function of the ingredient are consistent with the 1982 policy.

II. Hormel Petition

On October 9, 2006, Hormel Foods submitted a petition to FSIS requesting that the Agency initiate rulemaking to establish a codified definition for the voluntary claim "natural" and to delineate the conditions under which the claim can be used on the labels of meat and poultry products. The petition requests that, consistent with FSIS's longstanding policy on "natural," a meat or poultry product should not be labeled as "natural" unless (1) it does not contain artificial flavorings, artificial coloring ingredients, other artificial or synthetic ingredients, or chemical preservatives; and (2) it is not more than minimally processed. The petition further states that issues of consumer confidence and consistency in labeling dictate that exceptions for specific chemical preservatives and synthetic ingredients should not be allowed. The petition focused on the 2005 Policy Book entry's references to the use of sodium lactate (from a corn source).

A copy of the 2006 Hormel petition is available for viewing by the public in the FSIS docket room and on the FSIS Web site at: http://www.fsis.usda.gov/Regulations_& Policies/Petition_Natural_Label_Claims/index.asp.

III. Federal Register Notice and Public Meeting

The use of the claim "natural" is a marketing issue of significant interest to FSIS, to industry, and to the public. Therefore, on December 5, 2006, FSIS published in the **Federal Register** a notice to inform the public of the October 2006 petition from Hormel and to announce a public meeting to discuss the petition (71 FR 70503). The notice also requested comments on the petition and on the use of the claim "natural" in general. The notice explained that FSIS had removed the 2005 reference to sodium lactate (from a corn source) from its "natural" claims policy and that with respect to "natural" claims FSIS would consider the use of sodium lactate and other ingredients with multiple

received information to indicate that sodium lactate, as well as potassium lactate and calcium lactate, may provide antimicrobial effects at levels approved for their flavoring effect. FSIS also received comments suggesting that additional multi-functional ingredients, such as sodium citrate, distilled vinegar, fruit juice concentrates, and sea salt, may present similar issues for the Agency's "natural" policy. Like sodium lactate, these substances serve technical purposes that at certain levels and under certain conditions would preclude the use of "natural" labeling under the Agency's policy on the claim.

Several comments stated that FSIS should not preclude products containing ingredients that have multi-functional effects from qualifying for the "natural" claim. The comments maintained that the term "chemical preservative" as used in FSIS's natural policy refers to synthetic or artificial preservative, not natural ingredients with preservative effects. The comments asserted that sodium lactate (from a corn source) and certain other lactates are "natural" ingredients that should be permitted in meat and poultry products labeled as "natural" regardless of their technical effects.

Some comments stated that ingredients that have both flavoring and antimicrobial effects are greatly needed in the manufacturing of large food quantities to enhance both food safety and quality. The comments stated that ingredients that have both flavoring and antimicrobial effects provide food processors with interventions that are needed to help ensure public health. Other comments acknowledged that while antimicrobial agents can serve important food safety purposes, these ingredients nonetheless raise concerns as to whether they can be used in products labeled as "natural."

An issue raised by the comments, therefore, is whether it would be appropriate in approving "natural" claims to distinguish ingredients used for their antimicrobial effects to inhibit the growth of pathogenic organisms, such as *Listeria monocytogenes*, from those used for preservative effects. This distinction is implicit in the definition of "chemical preservative" in 21 CFR 101.22(a)(5) and in FSIS's definition of "chemical preservative" in 9 CFR 301.2, which provide that a "chemical preservative" is "any chemical that, when added to a food, tends to prevent or retard deterioration thereof * * *."

The preservative technical effect is to retard or prevent deterioration of food, and this effect is achieved by preventing the outgrowth of microorganisms that produce off-odors and discolor food as

the food ages. Based on data that FSIS has received, however, some companies add substances with antimicrobial effects to their products not to achieve effects on spoilage organisms but to impart flavor and to inhibit the outgrowth of the pathogen *Listeria monocytogenes* that may be present in the product.

These companies submitted data to demonstrate that the ingredient's primary purpose is for flavoring, with a potential added benefit of preventing the outgrowth of *Listeria monocytogenes*, and not to prevent or retard deterioration of the product. The data submitted show that products containing the ingredient have the same "sell by/use by" date as products with the same formulation except the antimicrobial ingredient, and that both products have a similar outgrowth of spoilage organisms over time. These companies have argued, therefore, that under these circumstances, the product should be eligible to bear the "natural" claim.

While FSIS evaluates this and other issues discussed in this notice and the comments submitted in response to it, the Agency will continue to evaluate and approve "natural" claims in the labeling of products that contain multi-functional ingredients on a case-by-case basis. Firms seeking FSIS approval of a "natural" claim for a product that includes a multi-functional ingredient like sodium lactate would need to substantiate the claim with, among other evidence, a showing that the ingredient is not being used to extend the product's shelf life.

3. Separate Claims for "Natural" Products and "Natural Ingredients"

Several comments suggested that FSIS establish criteria for separate and distinct claims for (a) "natural" products and (b) products with "natural ingredients." According to these comments, meat and poultry products that meet the conditions specified in the "natural" claims entry in the Policy Book should be permitted to bear the claim "natural" on their labels, while meat and poultry products that simply contain no artificial or synthetic ingredients should be permitted to bear the claim "natural ingredients" on their labels. Some comments suggested that FSIS permit meat and poultry products that contain ingredients that comply with FDA's definition of "natural flavor" or "natural flavoring" in 21 CFR 101.22(a)(3) to bear the claim "natural ingredients" regardless of the ingredient's technical effects or whether the ingredient is considered to be "minimally processed."

4. "Non-Traditional" Food Processing Methods

Several comments noted that many types of processing methods that are in use today did not exist 25 years ago when FSIS first established its policy on "natural." The comments stated that many of these processing methods, such as steam pasteurization, ultra pasteurization, modified atmosphere packaging, and high pressure processing, enhance the safety and quality of meat and poultry product without altering the basic nature of the food and thus should be permitted to be used on products labeled as "natural." The comments suggested that FSIS consider a meat or poultry product to be "minimally processed" based on the processing method's impact on the food rather than the complexity of the processing technology and equipment. Several comments supported allowing the use of high pressure processing on meat and poultry products labeled as "natural."

Other comments questioned whether advanced processing technologies, such as high-pressure pasteurization, should be considered minimally processed regardless of their effects on the composition of the finished product. Some comments presented results from focus groups and consumer surveys that, according to the comments, indicate that the consumers do not have a clear understanding of what "minimally processed" means. The comments suggested that FSIS either clarify what minimally processed means or eliminate the minimal processing component of its "natural" claims policy.

While it considers the comments submitted on this issue, FSIS will continue to evaluate the use of "non-traditional" processing methods on products labeled as "natural" on a case-by-case basis. FSIS is likely to find that a product that has undergone a "non-traditional" processing method to be "minimally processed" if the manufacturer of the product demonstrates: (1) That the processing method functions in a manner that is similar to one of the traditional processes described in "natural" claims entry of the Policy Book, and (2) that a meat or poultry product that has been subjected to the non-traditional process has the same basic characteristics as a product that has not undergone such a process.

5. "Enhanced" Products

FSIS received over 12,000 electronic form letters from individuals stating that they are members of the TLC that

meeting on “raising” claims held by the two agencies, AMS and FSIS have mutually determined that the application of the “naturally raised” claim to meat and meat products warrants further evaluation by the agencies as well as further input from all interested parties. FSIS, in cooperation with AMS, will evaluate the “naturally raised” claim in the context of its consideration of the broader issues presented by “natural” claims on meat and poultry products. Accordingly, FSIS does not intend, at this time, to approve “naturally raised livestock” claims for meat or meat products based solely on the AMS certification to its “naturally raised” standard. Nonetheless, FSIS will evaluate all requests for “naturally raised” claims on a case-by case basis.

AMS and FSIS continue to believe that certification by AMS to the “naturally raised” standard provides appropriate support for claims for livestock and thus can enhance the value of such livestock when marketed by producers. Accordingly, AMS will continue to offer livestock producers the opportunity to use the “naturally raised” claim, verified by AMS, to market their animals.

7. Establish a Uniform Federal Definition of “Natural”

Many comments, as well as the petition submitted by Sara Lee, suggested that USDA and FDA work together to create a consistent meaning for the “natural” claim for both agencies. Some comments proposed that both FSIS and FDA define “natural” based on the conditions that were first described in FSIS Policy Memo 055. Other comments proposed that FSIS model its “natural” policy after FDA’s definition of “natural flavor” in 21 CFR 101.22(a), which does not include a “minimally processed” component. One comment encouraged FSIS to coordinate with FDA in the development of its “natural” claims policy but stated that it is not imperative for the two agencies to have the same policy. One comment also suggested that FSIS work with the Alcohol and Tobacco Trade and Taxation Bureau (ATTB), in consultation with the Federal Trade Commission (FTC), to develop a single working definition of the term “natural” for food and beverage products.

8. Carbon Monoxide

Although FSIS did not receive comments on this issue, some processing establishments and producers have expressed interest in using carbon monoxide in modified atmosphere packaging systems for meat products labeled as “natural.” Carbon

monoxide is used to stabilize the naturally occurring red color pigment of meat. Proponents of this technology have expressed support for the use of carbon monoxide in “natural” products because carbon monoxide is a naturally occurring gas and acts to form a naturally occurring red meat color that dissipates after the product is removed from packaging.

Although carbon monoxide is a Generally Recognized as Safe (GRAS) and suitable substance in modified packaging systems, FSIS considers the use of this technology as inconsistent with its policy on “natural.” The Agency’s view has been that the process used to add carbon monoxide to product packages represents more than minimal processing. FSIS continues to believe that the control system required in modified atmosphere processing using carbon monoxide, such that no more than 0.4% carbon monoxide is added, is too complex to support a “natural” claim.

V. Issues for Comment

FSIS issued the December 5, 2006, **Federal Register** notice and held the December 12, 2006 public meeting, to solicit public comments on what the voluntary labeling claim “natural” should mean when applied to meat and poultry products to inform the development of a proposed rule regarding the “natural” claim. However, the comments demonstrate that there is a lack of industry and public consensus on the meaning of “natural.” Therefore, FSIS is not prepared at this time to issue a proposed rule to establish a regulatory definition for the claim. Instead, the Agency is publishing this ANPR to solicit further public comment. During the pendency of this process, the Agency will continue to apply its “natural” claims policy described in the Policy Book.

To inform this process, FSIS requests comments on the following issues raised in this document.

1. Alternatives to Rulemaking

- In light of the concerns expressed by the comments that disagreed that FSIS should establish a codified definition for “natural,” the Agency requests comments on whether it should proceed to develop a proposed regulation, or use this proceeding to develop an updated “natural” claims policy.

- If commenters think that FSIS should not promulgate a rule to define “natural,” the Agency requests comments on whether it should continue to resolve issues associated with “natural” claims by relying on the

existing or a revised policy document on “natural” claims, and if so, whether it should consider adopting the more flexible approach described earlier in this document in which, instead of defining “natural,” the Agency would approve the labels of meat or poultry products bearing a “natural” claim if the claim is accompanied on the label by a truthful statement that clearly explains what “natural” means as applied to a particular product.

2. Sodium Lactate and Other Multifunctional Ingredients

- FSIS requests comments on whether it should develop a policy on “natural” claims in which the Agency would continue to distinguish products that use ingredients for their antimicrobial effects to inhibit the growth of pathogenic organisms, such as *Listeria monocytogenes*, from products that use the same ingredients for preservative effects when evaluating labels that contain “natural” claims.

- FSIS also requests comments on whether it would be more appropriate for the labeling of a meat or poultry product that contains multi-functional ingredients derived from “natural” sources, such as sodium lactate from a corn source, to bear an “all natural ingredients” claim rather than a “natural” claim.

3. “Non-Traditional” Food Processing Methods

- Given the advances in food processing and packaging technologies that have occurred since Policy Memo 055 was first issued, FSIS requests comments on whether it should continue to permit more complex processes to be used on meat and poultry products labeled as “natural” if the process does not change the basic characteristics of the product.

- The Agency also requests comments on whether some of the more complex processes qualify as “minimal processing” under the Agency’s established “natural” policy, and, if not, whether the Agency should revise the policy to allow the use of such processes on products labeled as “natural.”

4. “Enhanced” Products

- Given the significant interest in the use of “natural” claims in the labeling of “enhanced” products, FSIS requests comments on whether it should approve a “natural” claim on meat and poultry products that have been enhanced with solutions that contain “natural” ingredients.

- FSIS also requests comments on whether it would be more appropriate

