alien remains eligible for admission as an E–2 CNMI Investor.

(xii) *Extensions of stay.* Requests for extensions of E–2 CNMI Investor nonimmigrant status may be granted in increments of not more than two years, until the end of the transition period. To request an extension of stay, an E–2 CNMI Investor must file with USCIS an application for extension of stay, with required accompanying documents, in accordance with the instructions on Form I–129. To qualify for an extension of E–2 CNMI Investor nonimmigrant status, each alien must demonstrate:

(A) Continuous maintenance of the terms and conditions of E–2 CNMI Investor nonimmigrant status;

(B) Physical presence in the CNMI at the time of filing the application for extension of stay; and

(C) That he or she did not leave during the pendency of the application.

(xiii) *Change of status.* An alien eligible for E–2 CNMI Investor status on the transition program effective date, but who obtains another valid nonimmigrant status, may apply to change nonimmigrant status to E–2 CNMI Investor in accordance with paragraph (e)(21) of this section and within the period of time provided by paragraph (e)(23)(v).

(xiii) *Expiration of transition period.* Upon expiration of the transition period, the E–2 CNMI Investor nonimmigrant status will automatically terminate.

(xiv) *Fee waiver.* An alien applying for E–2 CNMI Investor nonimmigrant status is eligible for a waiver of the fee for Form I–129 based upon inability to pay as provided by 8 CFR 103.7(c)(1).

* * * * *

PART 274a—CONTROL OF EMPLOYMENT OF ALIENS

3. The authority citation for part 274a continues to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1324a; 8 CFR part 2.

4. Section 274a.12 is amended by:

a. Removing the ''or'' at the end of paragraph (b)(20);

b. Removing the period at the end of paragraph (b)(21) and adding a ''; or'' in its place;

c. Adding a new paragraph (b)(22); and by

d. Adding a new paragraph (c)(12) to read as follows:

§ 274a.12 Classes of aliens authorized to accept employment.

* * * * *

(b) * * *

* * * * *

(22) An alien in E–2 CNMI Investor nonimmigrant status pursuant to 8 CFR 214.2(e)(23). An alien in this status may be employed only by the qualifying company through which the alien attained the status. An alien in E–2 CNMI Investor nonimmigrant status may be employed only in the Commonwealth of the Northern Mariana Islands for a qualifying entity. An alien who attained E–2 CNMI Investor nonimmigrant status based upon a Foreign Retiree Investment Certificate or Certification is not employment-authorized. Employment authorization does not extend to the dependents of the principal investor (also designated E–2 CNMI Investor nonimmigrant) other than those specified in paragraph (c)(12) of this section;

* * * * *

(c) * * *

(12) An alien spouse of a long-term investor in the Commonwealth of the Northern Mariana Islands (E–2 CNMI Investor) other than an E–2 CNMI investor who obtained such status based upon a Foreign Retiree Investment Certificate, pursuant to 8 CFR 214.2(e)(23). An alien spouse of an E–2 CNMI Investor is eligible for employment in the CNMI only;

* * * * *

Janet Napolitano,

Secretary.

[FR Doc. E9–21967 Filed 9–11–09; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317 and 381

[Docket No. FSIS 2006–0040A]

Product Labeling: Use of the Voluntary Claim ''Natural'' in the Labeling of Meat and Poultry Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food Safety and Inspection Service (FSIS) is issuing this Advance Notice of Proposed Rulemaking (ANPR) to assist the Agency in defining the conditions under which it will permit the voluntary claim ''natural'' to be used in the labeling of meat and poultry products. After considering comments on the ''natural'' claim submitted by the public in response to a **Federal Register** notice that the Agency issued on December 5, 2006, and the comments presented at a public meeting held by the Agency on December 12, 2006, FSIS has decided to solicit additional public input. FSIS has concluded that a further solicitation of comments could produce information that would help to clarify and resolve the issues surrounding the ''natural'' claim. Moreover, additional comment will help FSIS to assess how best to coordinate its regulation of ''natural'' claims with the standards for voluntary marketing claims developed by the Agricultural Marketing Service (AMS), particularly with AMS's ''naturally raised'' marketing claim standard.

DATES: Comments are due by November 13, 2009.

ADDRESSES: Comments may be submitted by one of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to *http://www.regulations.gov* and, in the ''Search for Open Regulations'' box, select ''Food Safety and Inspection Service'' from the agency drop-down menu, and then click on ''Submit.'' In the Docket ID column, select FDMS Docket Number FSIS–2006–0040A to submit or view public comments and to view supporting and related material available electronically. This docket can be viewed using the ''Advanced Search'' function in Regulations.gov.

Mail, including floppy disks or CD–ROMs, and hand or courier-delivered items: Send to FSIS, OPPD, Docket Room, U.S. Department of Agriculture, Food Safety and Inspection Service, 5601 Sunnyside Avenue, Room 2–2127, Beltsville, Maryland 20705.

All submissions received by mail and electronic mail must include the Agency name and docket number FSIS–2006–0040A. All comments submitted in response to this notice will be available for public inspection in the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday. The comments also will be posted to the regulations.gov Web site and on the Agency's Web site at: *http://www.fsis.usda.gov/regulations_&_policies/2009_Notices_Index/index.asp.*

FOR FURTHER INFORMATION CONTACT: Sally Jones, Acting Director, Labeling and Program Delivery Division, Office of Policy and Program Development USDA, FSIS, 5601 Sunnyside Avenue, Beltsville, Maryland 20705, (202) 205–0623, e-mail: *Sally.Jones@fsis.usda.gov.*

SUPPLEMENTARY INFORMATION:

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/Policies/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

functional effects on a case-by-case basis at the time of label evaluation.

The public meeting on ''natural'' was held on December 12, 2006, in Washington, DC (transcripts available for viewing by the public in the FSIS docket room and on the FSIS Web site at *http://www.fsis.usda.gov/PDF/Natural_Claims_Transcripts.pdf*). The comment period on the petition and the claim ''natural'' closed on January 11, 2007, but FSIS re-opened and extended the comment period to March 5, 2007 (72 FR 2257).

IV. Issues Raised by the Comments and Other Issues Associated With FSIS's ''Natural'' Policy

FSIS received over 12,000 comments on issues discussed in the December 2006 **Federal Register** notice and at the December 2006 public meeting. The Agency also received petitions requesting that it take action with regard to ''natural'' claims that differ from the action requested in the Hormel petition. Because the actions requested in these petitions raise the same issues as those raised by the comments, FSIS will address these petitions as if they were comments.

Most of the comments were identical letters submitted electronically by individuals that identified themselves as members of the Truthful Labeling Coalition (TLC), a coalition of chicken producers and private citizens concerned about the labeling of fresh poultry. These comments objected to the use of flavoring, tenderizing, and seasoning solutions to enhance poultry products bearing the ''natural'' claim. The TLC also submitted a petition dated July 27, 2007, that requests that FSIS take immediate action to prohibit the use of ''natural'' claims on the labels on poultry products enhanced with flavorings and other solutions.

FSIS received 92 comments and three petitions that raised additional issues associated with ''natural'' claims. The comments and petitions were submitted by industry, trade associations representing industry, animal welfare advocacy organizations, private citizens, consumer advocacy organizations, researchers, consultants, and law firms representing industry.

The comments expressed divergent views on what the claim ''natural'' as applied to meat and poultry products should mean and, in general, focused on particular ingredients, processing methods, and animal production practices that individual commenters felt should or should not be permitted for meat or poultry products labeled as ''natural.'' In addition, several comments disagreed with the request in the Hormel petition that FSIS establish a codified definition for ''natural.'' These comments suggested alternative approaches for addressing issues surrounding ''natural'' claims.

The comments indicate that there is an overall lack of consensus on both the general or common understanding of what the claim ''natural'' means to the industry and to the public and on the approach that FSIS should take to address issues associated with the use of ''natural'' claims on the labels of meat and poultry products. Nonetheless, FSIS has concluded that a further solicitation of comments could produce information that would help to clarify and resolve the issues surrounding the ''natural'' claim. Therefore, to better focus the public input submitted in response to this ANPR, FSIS is requesting comments on the issues described below.

1. The Need for Rulemaking

The comments submitted in response to the December 2006 **Federal Register** notice and presented at the 2006 public meeting indicate that there is significant disagreement on whether FSIS should resolve issues surrounding ''natural'' claims through the rulemaking process.

Some comments agreed with the Hormel petition and supported rulemaking to clarify and codify requirements for the use of ''natural'' claims. The comments stated that the only way to resolve issues associated with ''natural'' claims is to issue clear rules that can be applied consistently. Some comments stated that issues on whether certain ingredients should be allowed in meat or poultry products labeled as ''natural'' should be resolved through a transparent rulemaking process.

Other comments objected to rulemaking to address issues associated with ''natural'' claims. Several comments suggested that FSIS decline to codify the definition of ''natural,'' as requested in the Hormel petition, and maintain a flexible policy on the use of ''natural'' claims instead. Sara Lee, a manufacturer of meat and poultry products, submitted a petition requesting that FSIS adopt a flexible policy on ''natural'' claims that provides for case-by-case consideration of the use of the claims on the labeling of meat and poultry products as opposed to a static, fixed definition adopted through notice-and-comment rulemaking.

The comments that opposed rulemaking stated that determining whether a ''natural'' claim on the label of a meat or poultry product is not false or misleading often depends on the context in which the claim is used. According to the comments, because the number of uses of the claim ''natural'' that are not false or misleading cannot be captured in a single, static regulation, FSIS must maintain a flexible policy that will allow the Agency to evaluate a proposed use of the claim on a case-by-case basis.

Some comments stated that a codified definition of ''natural'' is unnecessary and would restrict FSIS's ability to update its ''natural'' claims policy to address new technologies and changes in consumer expectations. Several comments noted that prior attempts by other Federal agencies to establish regulations to define ''natural'' as it applies to foods have proven unsuccessful.

To address these concerns, it would be possible for FSIS to continue to resolve issues surrounding ''natural'' claims by maintaining its current approach based on the current, or a revised, guidance document.

As many of the comments noted above indicate, determining whether a ''natural'' claim on the label of a meat or poultry product is not false or misleading may often depend on the context in which the claim is used. Thus, these comments seem to suggest that FSIS should not define natural by adopting a rigid, static definition, but instead consider an approach that would allow manufacturers of meat and poultry products to use the ''natural'' claim on their labels in a manner consistent with Agency guidance as long as they explain clearly on the label why their proposed use of a ''natural'' claim appropriately applies to their particular product. The ''natural'' claim and explanation would continue to be subject to premarket, case-by-case approval by FSIS.

This approach would give manufacturers of meat and poultry products flexibility to use a ''natural'' claim to reflect specific characteristics of different products, so long as they accurately explain on the label why this term fairly characterizes their product. The information provided on the product label would allow consumers to determine whether the ''natural'' claim, as explained or qualified by the product label, is consistent with the characteristics that the consumer expects from a ''natural'' meat or poultry product.

2. Sodium Lactate and Other ''Multi-Functional'' Ingredients and Food Safety

FSIS received several comments on the use of sodium lactate and other multi-functional ingredients in ''natural'' meat and poultry products. As discussed above, in late 2006, FSIS

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

expressed the view that poultry products containing added solutions (i.e., ''enhanced'' poultry) should not be labeled as ''natural'' because, according to the comments, ''natural'' products are not injected with solutions containing water, salt, flavorings, seasonings, tenderizing agents, and water-binding ingredients, such as the seaweed extract carrageenan. As noted above, the TLC also submitted a petition dated July 27, 2007, requesting that FSIS take immediate action to prohibit the use of ''natural'' claims on the labels of ''enhanced'' poultry products. The petition includes results from consumer surveys that, according to the petition, demonstrate that a majority of consumers believe that ''enhanced'' products should not be labeled as ''natural.''

Other comments suggested that FSIS establish two categories for ''natural'' claims associated with raw poultry products. The comments proposed that raw, single-ingredient poultry products that are not otherwise marinated, seasoned, injected, or otherwise ''enhanced'' could be labeled as ''natural,'' while raw poultry products that have been enhanced with ''natural'' ingredients could bear claims such as ''Made with All Natural Ingredients'' or ''Enhanced with All Natural Ingredients.''

''Enhanced'' products are products to which marinades/flavoring/tenderizing solutions have been added. Enhanced poultry products are widely sold and may bear ''natural'' claims because all of their ingredients are ''natural.'' On a commercial scale, manufacturers of poultry products are not likely to use a bowl, pan, or any of the other common household methods used by consumers to marinate poultry.

For years, meat and poultry product manufacturers have used various techniques to infuse marinade and other solutions containing flavorings, seasonings, tenderizing agents, water, salt, and other ingredients, such as starches and seaweed extractives, that help hold the moisture in the product. FSIS labeling policies have been updated over time in light of techniques in commercial operations where flavoring and seasoning marinades and solutions are added to poultry and meat products using tumbling and ''needling'' mechanisms. For example, to ensure that the labeling of meat and poultry products to which solutions are added bears a truthful, descriptive product designation as provided in 9 CFR 317.2(c)(1) and 9 CFR 381.117(a), the traditional product name must be supplemented with an adjacent qualifier that informs the consumer of the presence of the solution in the product. Examples of such statements are ''Chicken Breast with up to 15% of a Flavoring Solution'' and ''Turkey Cutlets Enhanced with 10% of water, salt, spices, and carrageenan.'' In addition, FSIS's regulations require that all ingredients added to poultry and meat products be listed in the ingredients statement on labeling (9 CFR 317.2, 9 CFR 381.118).

Thus, the labels of ''enhanced'' meat and poultry products are required to contain information to inform consumers that the product contains added solutions. However, many comments submitted on this issue, as well as the TLC petition, maintain that this required supplemental labeling feature does little to prevent consumers from believing that they are purchasing fresh, single-ingredient chicken because it is typically not prominently displayed on the product label.

6. ''Natural'' and Animal Production Conditions

Several comments stated that ''natural'' claims on the labels of meat and poultry products should reflect the conditions under which animals used to produce these products were raised. Most of these comments stated that meat and poultry products from animals that have been genetically altered, treated with hormones, or fed prophylactic antibiotics should not qualify to be labeled as ''natural.'' The comments also asserted that products from animals raised under intensive confinements that were unable to engage in their natural behavior should not be labeled as ''natural.'' FSIS received these types of comments from both consumers and producers of meat and poultry products.

In addition, Farm Sanctuary, a farm animal advocacy organization, petitioned the Agency to prohibit the claim ''natural'' on all meat and poultry products or, in the alternative, to work with USDA's Agricultural Marketing Service (AMS) to codify an expanded definition of ''natural'' that addresses the treatment and living conditions of animal raised for food before their slaughter. The petition includes the results of a nation-wide consumer survey that, according to the petition, indicates that consumers are confused about what ''natural'' claims on the labels of meat and poultry products mean and believe that the claim relates to the treatment of an animal while alive.

Several comments suggested that FSIS work with USDA's AMS to develop a ''naturally raised'' claim for meat and poultry products that reflects the animal production practices. Other comments, as well as the Farm Sanctuary petition, asserted that establishing separate claims for ''natural'' and ''naturally raised'' would be confusing to consumers, and that FSIS, in consultation with AMS, should establish a single ''natural'' claim that encompasses the treatment and living conditions of animals raised for food prior to slaughter, as well as post-slaughter processing.

FSIS has regarded the claim ''natural,'' when used on the labels of meat and poultry products, as one that is intended to reflect the characteristics of the finished product and, unlike the claim ''naturally raised,'' one that is not intended to encompass animal production practices. AMS as well has viewed ''natural'' as a distinct and different claim from its ''naturally raised'' marketing claim because ''natural'' has been considered as a post-harvest processing claim, while ''naturally raised'' has been viewed as a claim that pertains to pre-harvest production practices.

On January 21, 2009, AMS published in the **Federal Register,** a voluntary standard for ''naturally raised'' livestock and meat marketing claims (74 FR 3541). The standard addresses the circumstances in which a ''naturally raised'' claim could be made for the production of livestock used in meat and meat products. The naturally raised marketing claim standard states that livestock used for the production of meat and meat products have been raised entirely without growth promotants and antibiotics (except ionophores used as a coccidiostatic for parasite control), and have never been fed animal by-products derived from the slaughter/harvest process or from animal waste.

AMS and FSIS are carefully evaluating the comments submitted to FSIS and AMS addressing this issue, including the views expressed at the recent public meeting on animal raising claims (73 FR 60228, October 10, 2008). Several participants at the public meeting urged the agencies to work together on labeling claims such as ''natural'' and ''naturally raised,'' and AMS and FSIS are, in fact, collaborating to achieve a consistent USDA approach to these issues.

AMS' voluntary standard for ''naturally raised livestock'' was adopted to establish conditions for the raising of livestock that AMS will verify to increase the value of the livestock and of the meat and meat products derived from them. After consideration of the comments received with regard to the AMS ''naturally raised'' standard and of the views expressed at the public

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

for raw meat and poultry products enhanced with ''natural'' ingredients to be allowed to bear an ''all natural ingredients'' claim instead of a ''natural'' product claim.

• Finally, because of the large number of comments that objected to the addition of ingredients to meat and poultry products labeled as ''natural,'' FSIS requests comments on whether the claim ''natural'' should refer only to raw, single-ingredient meat and poultry products, i.e., cuts of meat and poultry and ground meat and poultry.

5. Natural and Naturally Raised

• Given the number of comments that suggested that the claim ''natural'' as applied to meat and poultry products should encompass the conditions under which the source animals for these products were raised, FSIS requests comments on the issue and on how FSIS and AMS can best achieve a consistent approach to the claims ''natural'' and ''naturally raised.''

• FSIS also requests comment on whether the Agency should adhere to its traditional view that the claim ''natural'' relates only to the finished meat or poultry product and not factor in how the source livestock or poultry are raised.

6. Carbon Monoxide

• FSIS requests comments on whether the Agency's position regarding the use of carbon monoxide in the packaging of meat products is appropriate and should continue to be applied in evaluating requests for approval of ''natural'' claims.

7. Economic Effects

• FSIS requests comments on the potential economic effects and burdens of the various approaches on the use of ''natural'' claims that were presented in this document.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that minorities, women, and persons with disabilities are aware of this document, FSIS will announce it online through the FSIS Web page located at *http://www.fsis.usda.gov/regulations_&_policies/2009_Notices_Index/index.asp*. FSIS will also 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, recalls, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade and farm groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is available on the FSIS Web page. Through the Listserv and the Web page, FSIS is able to provide information to a much broader and more diverse audience. In addition, FSIS offers an e-mail subscription service that provides automatic and customized access to selected food safety news and information. This service is available at *http://www.fsis.usda.gov/news_and_events/email_subscription/*. Options range from recalls to export information to regulations, directives and notices.

Customers can add or delete subscriptions themselves, and have the option to password-protect their accounts.

Done at Washington, DC, on September 9, 2009.

Alfred V. Almanza,

Administrator.

[FR Doc. E9–22036 Filed 9–11–09; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[REG–116614–08]

RIN 1545–BH90

Disregarded Entities and Excise Taxes

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: In the Rules and Regulations section of this issue of the **Federal Register**, the IRS is issuing temporary regulations clarifying that a single-owner eligible entity that is disregarded as an entity separate from its owner for any purpose, but regarded as a separate entity for certain excise tax purposes, is treated as a corporation for tax administration purposes related to those excise taxes. Those regulations also make conforming changes to the tax liability rule for disregarded entities and the treatment of entity rule for disregarded entities with respect to employment taxes. The regulations affect disregarded entities in general and, in particular, disregarded entities that pay or pay over certain federal excise taxes or that are required to be registered by the IRS. The text of those temporary regulations also serves as the text of these proposed regulations.

DATES: Written or electronic comments and requests for a public hearing must be received by December 14, 2009.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–116614–08), room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG–116614–08), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS REG–116614–08).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Michael H. Beker, (202) 622–3070; concerning the submissions of comments and requests for a public hearing, Richard Hurst, (202) 622–2949 (TDD telephone) (not toll-free numbers) and his e-mail address is *Richard.A.Hurst@irscounsel.treas.gov.*

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

Temporary regulations in the Rules and Regulations section of this issue of the **Federal Register** amend 26 CFR part 301. The temporary regulations clarify that a single-owner eligible entity that is disregarded as an entity separate from its owner for any purpose, but regarded as a separate entity for certain excise tax purposes, is treated as a corporation for tax administrative purposes related to those excise taxes (that is, excise taxes reported on Form 720, ''Quarterly Federal Excise Tax Return;'' Form 730, ''Monthly Tax Return for Wagers;'' Form 2290, ''Heavy Highway Vehicle Use Tax Return;'' and Form 11–C, ''Occupation Tax and Registration Return for Wagering;'' excise tax refunds or payments claimed on Form 8849, ''Claim for Refund of Excise Taxes;'' and excise tax registrations on Form 637, ''Application for Registration (For Certain Excise Tax Activities).'' The temporary regulations also make conforming changes to the tax liability rule for disregarded entities in § 301.7701–2(c)(2)(iii) and the treatment of entity rule for disregarded entities with respect to employment taxes in § 301.7701–2(c)(2)(iv)(B). The text of those temporary regulations also serves as the text of these proposed