Food Safety and Inspection Service (FSIS)
Labeling Policy Guidance
Uncooked, Breaded, Boneless Poultry Products

Purpose of the Guidance

The intent of this document is to provide guidance to the industry on the modifications that are necessary for the labeling of uncooked, breaded (both pre-browned and not pre-browned), boneless poultry products that also may be stuffed or filled, char-marked, or artificially colored, in accordance with the letter to the manufacturers of these types of products posted on the FSIS website on March 20, 2006 (see the following web link: http://www.fsis.usda.gov/OPPDE/larc/Policies/Letter_to_Industry_on_Frozen_Uncooked_Poultry.pdf). Products of these types are similar to the products associated with the recall that was posted on the FSIS website on March 10, 2006, involving frozen, stuffed chicken entrees.

As explained in the recall notice, the frozen state, labeling, and cooked appearance of the uncooked chicken products may have caused consumers to believe that they were precooked. Thus products may not have been cooked by consumers to a safe internal temperature. FSIS is concerned that the labeling of products of this type be adequate to inform the public of the manner of handling required to maintain the products in a wholesome condition and to prepare them safely. Moreover, the cooking instructions need to be validated to address the intended use by the consumer. While consumers may be directed to cook the products to an internal temperature of 165 degrees Fahrenheit (F), if they are directed to use a cooking method that is not practical or not likely to achieve the necessary level of food safety (e.g., cooking frozen product in a toaster oven or microwave oven), the cooking instructions may not be valid.

As a result of the recall, the letter noted above was posted on the FSIS website and sent directly to manufacturers of these products and similar products recommending that labels be modified to emphasize that such products are not cooked. A statement on the principal display panel of the packaging, such as "*Uncooked: For Safety, Must be Cooked to an Internal Temperature of 165 degrees F as Measured by Use of a Thermometer,"* is an appropriate way to help consumers understand the need for the safe preparation of the products on their part. The cooking instructions should also be revised commensurate with validation that lethality is achieved with all the methods of cooking preparation that are declared on the labels. By improving the cooking instructions, as well as documenting that cooking methods are validated as part of the official labeling record, a situation like the one that that led to the recent recall could be avoided.

Additional guidance was made available in the March 2006 Report of the Subcommittee on Consumer Guidelines for the Safe Cooking of Poultry Products of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). This report should serve as a guide on how an establishment can make the necessary modifications to

product labeling and for cooking method validation such that the subject products can be assured to result in safe and wholesome products, and that the revised labeling is not misleading. The report can be found on the FSIS website at: www.fsis.usda.gov/PDF/NACMCF_Report_Safe_Cooking_Poultry_032406.pdf

I. Suggestions on the Modifications of Affected Labeling

Consumer-Packaged Product and Products Directed to Food Preparation Establishments

- The principal display panel of labels should bear prominent and clear terms that convey that the product contains raw or uncooked poultry, i.e., "raw," "uncooked," or "not ready to eat." Based on the recommendations of the NACMCF, the term "ready to cook" should not be used unless used in conjunction with a term such as one of those listed above.

Consumer-Packaged Product

- Only validated cooking instructions should appear on labeling. The cooking instructions should include, at a minimum, (1) the method of cooking, (2) an endpoint temperature of 165 degrees F or higher, and (3) instruction that the endpoint temperature is measured by use of a thermometer.

Products Directed to Food Preparation Establishments

- For food products directed to food preparation establishments, i.e., hotels, restaurants, and institutions (HRI), FSIS will accept references to the Food Code or equivalent State and local requirements as adequately addressing the need for adequate cooking. Because the food preparation establishments have standard operating procedures, e.g., cooking procedures consistent with Food Code or State standards, there is no need for further evidence of validation regarding the cooking instructions. In these instances, a statement of limited use should be applied to the labeling of these products, stating that the product is for preparation at food preparation establishments or specific restaurants. Examples of such statements are "For preparation by a food preparation establishment," "for HRI use only," or "Made exclusively for XYZ restaurants only." This statement should appear on the label as well as the label application form.

II Procedures for Submitting Labels for Approval

- Submittals of modified labeling that respond to the March 20 Letter should be submitted to the Agency in the usual manner. Labels may be submitted individually or, to help establishments that may have several labels that need to be modified, label submissions may be presented as a

"blanket" sketch submissions. A "blanket" sketch submission consists of a completed FSIS Form 7234-1 to which is attached at least one representative label that indicates the proposed modifications, i.e., a prominent statement on the PDP designating the product as raw, uncooked, or not-ready-to-eat, and the planned modifications of the cooking instructions, or a statement of limited use if the product is designated for use at a food preparation establishment, and a listing of all other product labels that will be revised in the same manner (in duplicate). Such blanket sketch submissions are being accepted by the Agency as a means of accommodating manufacturers of the types of products in question when the only changes to the subject labels are those that are the subject of the March 20 Letter.

- The Agency understands that establishments may have existing stocks of labels for the affected products on-hand. Existing stocks can be used by November 1, 2006, without submitting to the Agency for a temporary approval. However, every effort should be made to submit revised labeling to the Agency in accordance with the dates noted below.

Dates by Which Labels Need to be Submitted

- All products packaged and labeled for consumer retail purchase, i.e., those sold directly to consumers and prepared by consumers, should be submitted to the Agency for sketch approval by May 1, 2006, in accordance with the March 20 Letter.

- Manufacturers of products to be prepared by food preparation establishments, such as a hotels, restaurants, or institutions, need to submit a listing of the labels and the planned changes, (i.e., one representative label that includes the terms or statements about being uncooked product and validated cooking instructions or examples of statements of limited use) to the Agency by July 1, 2006.

- FSIS recognizes that labeling for the subject products that bear Child Nutrition (CN) statements must be submitted directly to the Food and Nutrition Service (FNS) for evaluation prior to submission to FSIS. Because such labels cannot be submitted as a blanket approval, individual label submittals must be prepared. For that reason, labels for the subject products that bear CN statements must be submitted to FNS by June 1, 2006. After the labels have been evaluated by FNS, they need to be sent to FSIS for sketch approval.

- All labels (i.e., for consumer packaged retail products, products for food preparation establishments, and products bearing CN statements) that have been sketch-approved by FSIS (either through a blanket approval or individual label approvals) should be in final form no later than September 30, 2006.

- The Office of Field Operations (OFO) will not be taking enforcement action on the labeling changes expected to be initiated by May 1, 2006, until FSIS issues specific verification procedures in an FSIS Notice expected in early September 2006. Meanwhile, FSIS will convey the labeling implementation strategy to the District Offices, who will inform field personnel about the implementation strategy.

QUESTIONS AND ANSWERS CONCERNING THE REVISION OF LABELING OF UNCOOKED, BREADED, BONELESS, POULTRY PRODUCTS THAT MAY BE STUFFED OR FILLED, CHARMARKED OR ARTIFICIALLY COLORED

1. Will all types of products need the label changes described in the March 20, 2006 letter to industry concerning uncooked breaded, poultry products that is posted on FSIS website?

   The types of products include uncooked, raw or not ready to eat, breaded (both pre-browned and not pre-browned), boneless poultry products that also may be stuffed or filled, char-marked, or artificially colored. The frozen state, labeling, and cooked appearance of these uncooked poultry products may cause consumers to believe that they are ready to eat. Examples of such products include but are not limited to: breaded chicken patties, breaded, pre-browned, chicken cordon bleu, chicken Kiev, chicken stuffed with broccoli and cheese, turkey patties, and chicken nuggets.

2. Does this action apply to both refrigerated and frozen products?

   Yes, the food safety concern regarding the adequacy of the labeling for uncooked, raw or not ready to eat, breaded, boneless poultry products that also may be stuffed or filled, charmarked, or artificially colored, exists whether the product is frozen or refrigerated.

3. Will the labels for single ingredient products, such as leg quarters, drumsticks, chicken wings, or other whole muscle products, or poultry products with added solution but no breading, that have a cooked appearance, need to be revised?

   The products to which the March 20, Letter relates are frozen or refrigerated, breaded, boneless not-ready-to-eat poultry with a cooked appearance. If a product is other than breaded, boneless not-ready-to-eat poultry, the Letter does not apply. However, if the product is not-ready-to-eat and has a cooked appearance or it is not obvious that the product is raw, the product should bear special labeling alerting the user that the product is not-ready-to-eat. The labeling should bear safe handling instructions if the poultry component is not ready to eat; a prominent statement on principal display panel indicating product is not-ready-to-eat, e.g., "Cook thoroughly" or "Raw," validated cooking instructions that have been shown to be understood by the food preparers and that are sufficient to destroy

pathogens to result in a microbiologically safe product and if nutrition facts are present, the serving size should be based on the ready to cook reference amount customarily consumed (9 CFR 381.412).

4. Why do the labels for the products described above need to be revised?

   FSIS is concerned that the labeling of products of this type should be revised to adequately inform consumers and food preparers about the uncooked nature of the products and of the manner of handling required to maintain the products in a wholesome condition and to prepare them safely; i.e., provide a lethal heating step to achieve a microbiologically safe product.

5. Why does FSIS want to take this action so quickly?

   It is clear from the recent events that labels for uncooked, breaded, boneless poultry products on the market today may not be understood or followed by consumers. This lack of understanding may result in consumers not cooking the products to the minimum internal temperature (165 degrees F) necessary for the destruction of foodborne bacteria and viruses, even though the cooking instructions on the product labeling tell them to do so.

6. Does this guidance only affect the labeling of retail product labels or are all product labels of the type described above, even those destined for food preparation establishments such as hotel, restaurants and institutions, as defined by the Food Code, need to be revised?

   No, there is no distinction between the labeling needed for consumer packaged retail products; and food preparation establishments, such as hotels, restaurants or institutions or other food preparers, because the same food safety concerns exist.

7. If an official establishment is selling its uncooked or not-ready-to-eat breaded, boneless, poultry product to a food preparation establishment that already has specific cooking instructions for that product, is it necessary that cooking instructions be added to the label?

   It depends on whether the product has the potential of being released into commerce. If a federal establishment can ensure that given the circumstances of its relationship with a food preparation establishment and there is no real chance of the product getting into commerce, the Agency will consider whether or not the cooking instructions for that product are necessary. In all cases, a specific statement of limited use, e.g., "For preparation by a food preparation establishment only, according to the food code or equivalent; " "Prepared exclusively for XYZ Restaurants; " or "For HRI use only," will be required to ensure the product is confined to the food preparation industry only.

8. What types of terms or statements should be included when revising labels for uncooked breaded, boneless poultry product labels to convey to consumers that these products are not ready to eat?

   Although the statement in the Letter to Industry, i.e., "Uncooked: For Safety, Must be Cooked to an Internal Temperature of 165 degrees F as Measured by a Thermometer" clearly conveys that the product is not-ready-to-eat and needs to be cooked before it can be safely consumed, other statements may be used on the principal display panel as well. The three key elements for an effective statement are: (1) terms that reflect that the product is not ready to eat, for example, "Uncooked," "Raw," "Raw - Cook Thoroughly," "Raw, See Cooking Instructions;" (2) a specific endpoint internal temperature, i.e., 165 degrees F or higher; and (3) a direction to measure the endpoint safe minimum temperature by a food thermometer. Statements that include these three key elements need to appear on the principal display panel of consumer packaged products in order to give consumers consistent and prominent information about the nature of the product.

9. Where does the statement that will convey that the product is uncooked or partially cooked need to appear on the label?

   Such statements need to appear on the principal display panel of the product label. The principal display panel of the package should be the focal point for certain safety information to make it clear that the product is not ready to eat.

10. When do affected establishments need to submit revised labels to the Agency?

    Establishments need to submit labeling for consumer packaged retail products by May 1, 2006. Products prepared for food preparation establishments (not sold directly to the consumer) need to submit by July 1, 2006. For labels bearing a child nutrition (CN) statement, labeling must be submitted to the Food Nutrition Service (FNS) by June 1, 2006, and then subsequently sent for approval by FSIS.

11. Why do CN labels have a different deadline date for submission of revised labeling?

    That is because labels bearing CN statements require evaluation by FNS for each label submitted. FNS needs adequate time to handle the expected increase in label rescissions, requests for temporary approval and new label submissions. The extended date for submitting such labeling to FNS is June 1, 2006. The date by which modified labels need final label approval is September 30, 2006. Labels for FNS evaluation should be directed to USDA, FNS, CND, 3101 Park Center Drive, Alexandria, VA 22302, Attn: CN Label Reviewer, Phone: 703-305-2609

12. If a company believes that its current labeling is sufficient to meet the criteria in the March 20 Letter, do they need to resubmit their labels to the Agency by one of the dates cited above?

    Yes, if a company has reevaluated their current labeling and feels that it is sufficient to inform the consumer that cooking is required for safety (and the cooking instructions are validated), then they should resubmit their labeling to the Agency for consideration of sketch approval. In other words, establishments cannot self-determine that the labeling is sufficient.

13. We have several labels that need to be revised according to the March 20, 2006, letter. Do we need to submit each label separately?

    Establishments do not need to send in every label in for sketch approval by the dates mentioned above. Establishments can submit a "blanket" sketch approval indicating the modifications they intend to make to the labels of products that are the subject of the letter. An example of one of the products with the proposed changes would need to be submitted attached to a completed FSIS Form 7234-1 (in duplicate).

14. Why are labels for products bearing CN statements excluded from blanket approvals?

    A blanket request is a label application for multiple label approvals sharing the same problem. All CN labels with proper documentation must be submitted to FNS prior to submission to FSIS. Acceptable label applications for FSIS evaluation contain a FNS sign-off. In order to remind industry of the proper label approval procedure for CN labels, a statement will be placed on all blanket requests indicating that CN labels are excluded and will also indicate that all CN labels must be submitted through FNS prior to submission to FSIS, LCPS. Labels for FNS evaluation should be directed to USDA, FNS, CND, 3101 Park Center Drive, Alexandria, VA 22302, Attn: CN Label Reviewer, Phone: 703-305-2609

15. Our establishment is prepared to make the necessary changes to its labeling; however, we have several hundreds of label on-hand. Will we need to get temporary approval on existing inventory of labels?

    The Agency understands that establishments may have existing stocks of labels on hand. Existing stocks must be used by November 1, 2006, without submitting for a temporary approval.

16. Can a pressure sensitive sticker that includes the necessary terms be used to update labels?

If a pressure sensitive sticker is used to modify current labeling, the sticker must be submitted for evaluation, as well. Once approved, the pressure sensitive sticker policy guidance on the FSIS website would be in effect; all existing stocks bearing a sticker with acceptable terminology may be used until stocks are exhausted.

17. Will my inspector take action against my labeling associated with this issue after May 1, 2006?

    The Office of Field Operations has been informed of the issue and will not take enforcement action on this issue until the Agency provides verification procedures through an FSIS Notice. It is anticipated that FSIS will publish an FSIS Notice in early September 2006, in order to ensure that labels are modified and applied to new production after November 1, 2006.

18. Does the statement of limited use that a food preparation establishment adds to labeling in lieu of cooking instructions need to be on the principal display panel?

    No, the statement of limited use does not need to appear on the principal display panel but may appear in a prominent manner anywhere on the label.

19. Do the cooking instructions need to be on the principal display panel (PDP)?

    No, the cooking instructions may appear anywhere on the label. However, on consumer packaged products, the endpoint internal temperature and the need to measure the endpoint internal temperature by use of a food thermometer need to appear on the principal display panel.

20. Is it necessary to revise the cooking instructions on uncooked, breaded, boneless poultry products if it does not include the internal temperature of 165 degrees F?

    Yes, as recommended by the NACMCF, a single minimum internal temperature of 165 degrees F for cooking without time limitation will ensure that the cooked poultry product is microbiologically safe. This temperature will destroy *Salmonella,* the most heat resistant pathogen of public health concern in raw poultry.

21. Why do the cooking instructions on these uncooked, breaded, boneless, poultry products need to be validated?

    Cooking instructions need to be validated to ensure that the method by which the product is prepared is adequate to achieve the lethality of any pathogens that may be present in a raw product. When validating the cooking instructions establishments should take into account how the consumer is likely to interpret the cooking instructions and what the consumer may actually do in preparing and cooking the product.

22. How can I assure FSIS that the cooking instructions have been validated? Does the validation data need to be included with the label submittal?

    Validation data should be included as part of the official labeling record for the product.

23. Why is it necessary to include cooking instructions on the label if the statement on the principal display panel includes both an endpoint temperature and the need to measure the temperature with a meat thermometer; e.g., *"Uncooked: For Safety, Must be Cooked to an Internal Temperature of 165 degrees F as Measured by Use of a Thermometer"*

    The cooking method by which the endpoint temperature is achieved needs to be included on the label in the cooking instructions because the consumer needs explicit information about the way to achieve a safe product for consumption.

24. If the statement on the PDP includes an internal temperature and the use of a thermometer to measure the temperature; does this information need to be included in the cooking instructions as well?

    Yes, the endpoint temperature and the need for a thermometer to ensure that the endpoint temperature is met, should also be included in the cooking instructions would further emphasize that 165 degrees F is necessary to achieve a microbiological safe product using the method described in the cooking instructions.