# FSIS NOTICE	75-06	11/13/06

VERIFICATION INSTRUCTIONS FOR CHANGES IN LABEL REQUIREMENTS FOR UNCOOKED AND RAW, FROZEN, BREADED, BONELESS POULTRY PRODUCTS

NOTE: DO NOT IMPLEMENT UNTIL DECEMBER 1, 2006

I. PURPOSE

   This notice provides instructions for inspection program personnel to use for verifying that establishments that produce certain uncooked and raw, breaded, boneless poultry products that did not already have labels in compliance with the Food Safety and Inspection Service's (FSIS) labeling guidelines dated April 20, 2006 (see paragraph II), have revised their package labeling to be consistent with these guidelines. Specifically, FSIS inspection program personnel are to verify that these establishments have new labeling along with adequate validation to support the cooking instructions that they include on the labels that will be applied to these products.

II. BACKGROUND

   FSIS is responsible for verifying that product labels are not misleading, and that they adequately reflect practical instructions related to the proper use, cooking, and handling of a specific product. On March 10, 2006, FSIS posted a Class I recall notice announcing a voluntary recall of approximately 75,800 pounds of frozen, stuffed chicken entrees. The frozen and cooked appearance of the uncooked chicken products may have caused consumers to believe that these products were precooked, and that thus it was not necessary to cook the products to a safe minimum internal temperature of 165° F prior to consumption. The products are raw, however, and poultry products that consumers do not cook to a safe minimum internal temperature of 165° F (as measured by a thermometer) are considered unsafe and unfit for human consumption.

DISTRIBUTION: Inspection Offices; T/A Inspectors; TRA; TSC; Import Offices	**NOTICE EXPIRES:** 12/1/07	**OPI:** OPPED

On March 29, 2006, FSIS sent a letter directly to the manufacturers of uncooked poultry products. FSIS published the letter at:

http://www.fsis.usda.gov/OPPDE/larc/Policies/Letter_to_Industry_on_Frozen_Uncooked_Poultry.pdf.

In the letter, the Agency recommended that establishments modify the labels of products of this type to emphasize that the products are not cooked. FSIS made publicly available guidance contained in a 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) at:

http://www.fsis.usda.gov/About_FSIS/NACMCF_Subcommittee_Poultry_Cooking/index.asp

On April 20, 2006, FSIS provided the industry with guidance on necessary labeling modifications for this type of product through the posting of Labeling Policy Guidelines for Uncooked, Breaded, Boneless Poultry Products at:

http://www.fsis.usda.gov/PDF/Labeling_Policy_Guidance_Uncooked_Breaded_Boneless_Poultry_Products.pdf

The Agency informed industry that it needed to take immediate steps to have sketch approval for the labels of affected products.

III. INSPECTION PROGRAM PERSONNEL VERIFICATION RESPONSIBILITIES

A. Inspection program personnel are to verify that the establishments that did not have labels for the specific uncooked and raw poultry products in compliance with the FSIS guidelines have revised labels for consumer-sized retail packages and have received sketch approval from the FSIS Labeling and Consumer Protection Staff (LCPS).

B. Inspection program personnel are also to verify that the principal display panel of the revised labels for consumer-sized retail packages bears:

1. terminology that is consistent with the labeling guidance provided by FSIS and referenced above and includes a clear and concise statement that conveys that the product is not ready-to-eat by using terms such as "uncooked," "raw," or "not ready to eat;"

2. a clearly stated safe minimum internal temperature of 165 °F or higher, specifically for product for the consumer as opposed to product for food service operations that may prepare the product in accordance with the Food Code, equivalent state and local requirements, or with time/temperature combinations deemed equivalent;

3. a clearly stated recommendation that the endpoint internal temperature be measured by the use of a food thermometer; and

4. practical cooking instructions describing validated cooking methods appropriate for consumer use.

NOTE: If the label does not state "do not microwave" or some similar statement discouraging the use of a microwave for preparing the product, inspection program personnel should inform the District Office of this fact through the chain of supervision. The District Manager should then assign an Enforcement, Investigation and Analysis Officer (EIAO) to conduct a Food Safety Assessment (FSA) in the operation specifically to assess the validation of the cooking instructions. As noted below, the EIAO is to give special attention to the establishment's data that support that the microwave cooking instructions are practical and likely to be followed by the consumer (e.g., a report on file that contains the support and rationale for demonstrating how the establishment ascertained that the product as prepared by the consumer is safe, based on targeted consumer follow-up, consumer feedback, or complaints). These products, particularly when cooked by the consumer using a microwave, have resulted in numerous cases of foodborne illness. Although FSIS has approved labeling that includes microwave cooking instructions, FSIS expects that the validation support documentation on file at the establishment is obviously compelling in demonstrating that the products will be safe to consume as prepared by the consumer.

C. Inspection program personnel are also to verify that there is supporting documentation for the validated cooking instruction process to demonstrate that each method by which the product may be prepared by the consumer is adequate to achieve the lethality of pathogens of public health concern. The types of documentation that may be present, demonstrating that the cooking instructions are practical and effective in achieving the desired lethality, include:

1. a regulatory document or a processing authority document; or

2. a peer-reviewed scientific journal article that presents a time, temperature, and other critical factors for the cooking of that particular food item.

D. Inspection program personnel should be aware that when verifying labels for products that are produced specifically for food preparation operations (e.g., hotels, restaurants, school lunch programs, and other institutions (HRI)) and that are not for retail sale, the establishment also needs to have revised labels that receive sketch approval from the FSIS, LCPS. Inspection program personnel are to verify that the labels include the following:

1. terminology on the principal display panel consistent with the labeling guidance, including a clear, prominent, and concise statement that conveys that the

product is not ready-to-eat, using terms such as "uncooked," "raw," or "not- ready-to-eat," and

      2. a statement that the product must be cooked to a safe minimum internal temperature of 165 °F or higher or to an equivalent lethality,

      3. language recommending that the safe minimum internal temperature be measured by the use of a food thermometer, and

      4. validated cooking instructions that describe the method of cooking.

      5. In lieu of doing D. 2. 3. and 4, above, establishments may use

      a. a statement on labeling that the product was prepared for a food preparation operation that will prepare the product in accordance with the Food Code or equivalent State and local requirements addressing the need for adequate cooking. For example, "Not for retail sale; Prepare in accordance with the Food Code cooking procedures." Such food preparation operations have standard operating procedures in place; thus there is no need for further evidence of validation regarding the cooking instructions; or

      b. a statement of limited use that states that the product is to be used at food preparation operations or specific restaurants. Examples of such statements are "For preparation by a food preparation operation," "for HRI use only," or "Made exclusively for XYZ restaurants only." Such statements should appear on labeling, as well as on the label application form.

    E. The labeling records are to include the revised label in its final form, and when cooking instructions are present on the label, the data used to validate that the methods of cooking are adequate to achieve the lethality of any pathogen that may be present in a raw product should also be included.

Refer any questions to the Technical Service Center (TSC) at 1-800-233-3935 (press 1 and listen for instruction for contacting labeling) or e-mail to FSISlabeling@fsis.usda.gov.

IV. INSTRUCTIONS FOR EIAOs

    A. Although any establishment may be subject to a FSA, District Managers should make establishments priorities for receiving a FSA when they present a high risk for producing product that is adulterated. Establishments that produce certain uncooked and raw, breaded, boneless poultry products, and particularly those that produce products with labeling that does not discourage the use of a microwave for consumer preparation, are to be given this type of priority. EIAOs should thoroughly assess the validation for the cooking instructions for these products.

    B. It is important that the essential instruction parameters for processing the product in question match the supporting documentation used. EIAOs are to assess whether the processor has validated that, by following the cooking instructions (including microwaving), the consumer will produce a product that attains at least a minimum internal temperature of 165 °F throughout and thus achieve the required $\log_{10}$

reduction of *Salmonella*. Although the consumer is instructed to use a thermometer to ensure that the product reaches this temperature, the Agency has data demonstrating that many consumers will not do so. Therefore the EIAOs should ask the following questions when checking the supporting documentation for cooking instructions including those labels with microwave instructions:

1. Do validation data documented by the processor demonstrate that the product, when cooked using the labeled cooking method, achieves a safe minimum internal temperature of 165 °F throughout the product as measured by a food thermometer?

2. Is the initial temperature of the product the same as that used in the processor's validation study? For example, if the validation study tests used frozen product, do the labeled cooking instructions state that the product should be cooked from the frozen state, or if the validation study tests used refrigerated product, do the labeled cooking instructions state that the product must be thawed?

3. Do the validation data documented by the processor demonstrate that the cooking instructions tell the consumer where to place the thermometer in the product (i.e., coldest/thickest part), and how many temperature readings to take, in order to ensure that there is a safe minimum internal temperature of 165 °F throughout the product?

4. Are there data to support that the consumer will prepare the product as instructed (i.e., that the instructions are practical)?

5. Do the labeled cooking instructions contain multiple steps that might not be easily followed by consumers?

(The following questions also apply if microwave cooking instructions are present as a method of cooking)

6. Do the validation data documented by the processor use the same wattage and power level as are specified in the instructions on the package?

7. If a company does not specify a microwave oven wattage or power level in the labeled cooking instructions, does the validation study support the adequacy of those instructions for the wide range of oven wattages and power levels that might be used by consumers? Do the validation data demonstrate that a specific wattage and power level are not necessary?

8. If the microwave instructions do not specify the need to cover or rotate the product, are there data to demonstrate that the microwaved product does not need to be covered or rotated during the microwaving process?

9. If the microwave instructions specify the need to cover or rotate the

product for a specified period of time, are there data to support that following those instructions will ensure that the safe minimum internal temperature of the product is equilibrated throughout the product?

10. Do the labeled cooking instructions include visual or other cues (e.g., "steaming hot throughout the product;" "cheese filling will be melted when fully cooked;" or "if any portion of the product is cold to the touch it indicates that the product may not be fully cooked throughout") to indicate that the product either did or did not cook properly (e.g., reach 165 °F throughout the product or meet the validated cooking instructions)?

11. What assurance does the establishment have that the labeled cooking instructions, especially more complex instructions (e.g., instructions to cook for 2 minutes on high, turn product, and cook for an addition 5 minutes on medium), can be readily followed by consumers?

V.   INSPECTION PROGRAM PERSONNEL ENFORCEMENT ACTION

If establishments that produce product covered in this notice have not updated the labeling record in accordance with this notice or are not using new labels, inspection program personnel are to issue a non-compliance record and notify LCPS. LCPS will consider rescinding any existing label approval for the product on the grounds that the label is misleading in that labeling does not adequately convey that the product is uncooked or raw, or that the cooking instructions on the label are not adequate to produce a safe product. Also, inspection program personnel can issue a non-compliance record under 417.4(a)(1) at the request of the EIAO because of inadequate validation of the cooking instructions.

Refer any questions to the TSC at 1-800-233-3935 (press 1 and listen for instruction for contacting labeling) or e-mail to FSISlabeling@fsis.usda.gov.

Assistant Administrator
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