

Supplemental Q's and A's to Address Products Affected by FSIS Notice 75-06 Verification Instructions for Changes in Label Requirements for Uncooked and Raw, Frozen, Breaded, Boneless Poultry Products

This is additional information intended to assist in clarifying information set forth in [FSIS Notice 75-06](#), issued on November 13, 2006. Other Q's and A's are currently posted on FSIS website at: http://www.fsis.usda.gov/PDF/Labeling_Policy_Guidance_Uncooked_Breaded_Boneless_Poultry_Products.pdf.

New Questions/Answers

1. Does the endpoint internal temperature, 165 degrees Fahrenheit (F), apply to all uncooked poultry products that require cooking for safety before being consumed? Also, does the guidance supersede any performance standards?

The endpoint safe minimum internal temperature of 165 degrees F applies to all poultry products, including those to which this guidance is focused, i.e., uncooked boneless, breaded poultry products that may be stuffed or filled, artificially colored or charmarked, such as Breaded Chicken Cordon Bleu, Chicken Patties, and Turkey Nuggets. Cooking poultry products to a safe minimum internal temperature of 165 degrees F will meet the performance standards for poultry products that are in the Federal poultry regulations. The guidance does not supersede the performance standard or any time and temperature guidance provided for manufacturers preparing cooked products, e.g., Appendix A (Compliance Guidelines for Meeting Lethality Performance Standards for Certain Meat and Poultry Products).

2. My establishment produces a not-ready-to-eat entree that contains a fully cooked, breaded boneless, chicken nugget. Does the labeling guidance for uncooked, breaded, boneless poultry products apply to the labeling of this product?

No, the guidance does not apply. Although the meal may be not-ready-to-eat, it contains a fully cooked breaded, boneless poultry product. Because the poultry product was cooked to an internal temperature that renders the poultry portion ready-to-eat before being incorporated into the meal, the labeling does not need to be revised per the labeling guidance.

3. What are some distinctions an establishment may use when validating cooking instructions for products that contain raw or partially cooked poultry products

described in [FSIS Notice 75-06](#) versus those for other not-ready-to-eat (NRTE) products?

The distinction relates to how the cooking instructions on the label for products *that are for sale to the consumer* must be validated. For products that are produced specifically for food preparation operations (e.g., hotels, restaurants, school lunch programs, and other institutions), this distinction does not apply.

To explain further, products covered by Notice 75-06, which appear to be ready-to-eat but are not, must be labeled with cooking instructions for the consumer indicating that the product must be cooked to an internal temperature of 165 degrees F, and the cooking instructions on the package must be validated as reaching this internal temperature.

For other not ready-to-eat products (those not covered by Notice 75-06), the cooking instructions on the label for products for sale to the consumer may be based on the final internal temperature, or they may be based on a combination of an internal temperature and holding time to achieve the appropriate lethality. These combinations can be found in [Appendix A, Compliance Guidelines for Meeting Lethality Performance Standards for Certain Meat and Poultry Products](#) or in [Time and Temperature Tables for Cooking Ready-to-Eat Poultry Products](#), which supplements Appendix A with updated information. For example, based on *Time-Temperature Tables for Cooking Ready-to-Eat Poultry Products*, a product could be cooked to 160 degrees F and held at that temperature for 14.5 seconds to achieve the same lethality as cooking to 165 degrees F.

4. What type of information does my establishment need to include in the labeling record to demonstrate that the cooking instructions on the label of an uncooked breaded poultry product have been validated?

The purpose of validation is to demonstrate that an intervention or lethality step (cooking) achieves the intended goal. For cooking, the process is to be validated as achieving a required \log_{10} reduction of a particular pathogen. Supporting documentation for the validated cooking instruction process should 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 used to demonstrate that the cooking instructions are practical and effective in achieving the desired lethality include a regulatory document or a processing authority document; or a peer-reviewed scientific journal article that presents a time, temperature, and other critical factors for the cooking of that particular food item (e.g., specifying the cooking equipment such as a microwave, oven, broiler, toaster oven, stove top, etc.). It is important that all the instruction parameters for processing the product in question match the supporting documentation used.

5. Because microwave instructions on labels seem to be of much concern, what type of information does an establishment need to consider as part of its validation data if microwave cooking instructions are included on the label of a product that contains raw or partially cooked poultry?

For microwave cooking instructions intended for the consumer, the processor would validate that the product would reach a safe minimum internal temperature of 165 degrees F throughout, which would achieve the required \log_{10} reduction of Salmonella. Although the consumer is instructed to take the product temperature, the Agency realizes that this will not be done in most instances. In determining the time for the product to reach a safe minimum internal temperature of 165 degrees F, the processor should consider the wattage of the microwave, and the number and location of sites to measure temperature. The following questions may assist establishments when developing validation data for the microwave instructions to consumers:

- 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 degrees F throughout the product as measured by a food thermometer?
- 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?
- 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 degrees F throughout the product?
- Are there data to support that the consumer will prepare the product as instructed (i.e., that the instructions are practical)?
- Do the labeled cooking instructions contain multiple steps that might not be easily followed by consumers?
- Do the validation data documented by the processor use the same wattage and power level as are specified in the instructions on the package?

- 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?
 - 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?
 - 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?
 - 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 degrees F throughout the product or meet the validated cooking instructions)?
 - 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?
6. Are labels of poultry products that are covered by Notice 75-06 required to bear a “Do Not Microwave” statement or similar statement discouraging the use of a microwave?

No. Labels of poultry products covered by the Notice are not required to bear a “Do Not Microwave” statement or similar statement discouraging the use of a microwave. However, FSIS plans to conduct food safety assessments at all establishments producing uncooked, breaded, boneless poultry products that appear cooked. Establishments that produce consumer-sized products that do not bear on their labels a “Do Not Microwave” or similar statement may be subject to a food safety assessment sooner rather than later. During the FSAs, EIAOs will thoroughly assess the validation for the cooking instructions.

7. If an establishment wishes to add a “Do Not Microwave” or similar statement on its labels, must it resubmit its labels to the LCPS for approval?

No. Pursuant to 9 CFR 381.133(b)(9)(vi), modifications to cooking instructions may be generically approved.

8. Notice 75-06 states that establishments should have data that support that microwave cooking instructions are practical and likely to be followed by the consumer. What type of data are acceptable?

Product manufacturers of raw or partially cooked poultry products should document in their labeling records their rationale and basis for believing that labeled cooking instructions are practical and easily followed by targeted consumers. The absence of consumer complaints either in writing or through a toll-free consumer hotline may serve as a basis for believing that labeled cooking instructions are practical and easily understood. Although not required, firms may also elect to conduct consumer surveys or other direct consumer follow-up to monitor how well consumers are able to follow labeled cooking instructions.

9. Notice 75-06 lists two types of documentation that may be adequate to support validated cooking instructions: (1) a regulatory document or processing authority document; and (2) a peer reviewed scientific journal article. Are there other types of documentation that will be deemed adequate?

The types of documentation listed in the Notice are only examples of adequate documentation. The agency will consider other types of documentation that may be relied upon to demonstrate that cooking instructions are practical and effective in achieving desired lethality. Such other types of documentation may include challenge studies or an establishment's actual product cook tests.

10. If an establishment relies on its own product cook tests for its validated cooking instructions, must the cook tests be approved by a process authority?

No. Establishments may rely on their own product cook tests, provided that the conditions studied in the validation testing support the parameters stated in the labeled cooking instructions.

11. Must cooking instructions advise consumers where to place the thermometer in the product (i.e., coldest/thickest part), or how many temperature readings to take?

No. However, if a product label includes cooking instructions that advise consumers where to place the thermometer, or how many temperature readings to take, the validation data must support those parameters.

12. Must cooking instructions advise consumers whether product should be cooked from a frozen state or from a thawed state?

No. If the cooking instructions advise consumers that product should be cooked from a frozen or thawed state, however, the validation data should support those parameters. Validation studies based on starting with frozen product may support cooking instructions that provide for cooking from a frozen or thawed state. However, validation based on thawed product would not support cooking instructions that allowed microwaving of frozen product.

13. Do the questions on supporting documentation for validation procedures described in Notice 75-06 also apply to validation of cooking instructions for not-ready-to-eat (NRTE) products that contain fully cooked poultry components?

No. NRTE products that contain fully cooked meat or poultry components along with other ingredients that require cooking by consumers are not the subject of this notice.

14. If FSIS determines that an establishment has not updated its labeling records in accordance with Notice 75-06, or that it is not using new labels, will the Agency grant the establishment a temporary label approval to exhaust its label inventory until it can make the appropriate modifications?

FSIS is unlikely to grant a temporary label approval if it determines that an establishment is using labels that do not meet basic regulatory requirements for advising consumers that the product is not ready to eat (e.g., use of the terms “uncooked”, “raw,” or “not ready to eat” on the PDP; clear instructions on the PDP to cook to a minimum internal temperature of 165 degrees F; and a clear recommendation on the PDP that the endpoint temperature be measured by the use of a food thermometer). However, when the labels do meet these basic expectations, but there are questions regarding the adequacy of the establishment’s supporting documentation for its cooking instructions, the Agency will consider granting a temporary label approval on a case-by-case basis.

15. Notice 75-06 implies that the *principal display panel (PDP)* of the revised labels for consumer-sized retail packages must bear “practical cooking instructions describing validated cooking methods appropriate for consumer use.” Does this mean that the cooking instructions need to appear on the PDP?

While practical cooking instructions are required on the labels of the consumer-sized retail packages of the products in question, as stated above, the cooking instructions are not required to appear on the PDP.

16. If a company has done its own cooking validation, is it the agency’s expectation that each individual product must be tested, or can like items be grouped together?

Like items can be grouped together provided the facility has incorporated the rationale behind the grouping methodology as part of the validation information.