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6200 Aurora Ave., Suite 200W, Des Moines, IA 50322-2864

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Assuring the Safety of Not-Ready-to-Eat (NRTE) Products: Industry Guidelines for Validation of Consumer Cooking Instructions

LLOYD HONTZ*, VIRGINIA N. SCOTT and YUHUAN CHEN
Grocery Manufacturers Association, 1350 I St., NW, Washington, D.C. 20005, USA

SUMMARY

Not-ready-to-eat (NRTE) prepared food products typically contain one or more components that are uncooked or only partially cooked. Consequently, the ultimate safety of these products depends on their being cooked by the consumer prior to consumption. It is the obligation of the food processor to assure that the cooking instructions provided to the consumer on the label of these products are adequate for their intended purpose.

In recent years, a number of cases of foodborne illness associated with such products have brought increased recognition within the industry about the importance of the cooking instructions provided with these products and growing concern by regulatory agencies about their adequacy. A proactive industry initiative has led to the development and dissemination of substantive guidelines that will help processors validate the safety of their products when their cooking instructions are properly followed by consumers. This guidance document does not dictate exactly how validation must be performed; rather, it discusses the wide range of factors, especially for microwave ovens, that should be considered when validation testing is performed. Broad industry adoption and adherence to the guideline recommendations should help assure the adequacy of labeled cooking instructions for NRTE products and the ongoing safety of this category of convenience foods.

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*Author for correspondence: Phone: 202.639.5924; Fax: 202.639.5991
E-mail: lhontz@gmaonline.org

INTRODUCTION

Consumers today enjoy a vast selection of convenient and nutritious foods that can be quickly prepared in the home by consumers. While some ready-to-eat (RTE) meals, entrées and snacks can be safely eaten in the form in which they are purchased, other foods, classified as not-ready-to-eat (NRTE) products, must be cooked by consumers before they are consumed. It is the obligation of the food processor to ensure that the consumer knows that cooking, rather than just heating or warming for palatability, is necessary for these products and that the cooking instructions provided to the consumer are adequate for their intended purpose.

In recent years a number of cases of foodborne illness associated with NRTE products have brought increased recognition by industry of the importance of the cooking instructions for these products and a growing concern by the regulatory agencies about their adequacy *(2, 6, 7, 8, 9, 14)*. A proactive industry initiative by the Grocery Manufacturers Association (GMA) has led to substantive guidelines that will aid processors in validating that the cooking instructions on the label, when properly followed by consumers, will result in safe products. This article highlights GMA's "Guidelines for Validation of Consumer Cooking Instructions for Not-Ready-to-Eat (NRTE) Products" ("the guidelines" or "the guidance document," hereafter) that were finalized in July 2008 *(5)*. The guidance document discusses the wide range of factors, especially for microwave ovens, that should be taken into account when validation testing is performed. Topics addressed in the guidelines include Purpose and Scope; Determining Appropriate Lethality Requirements; Type of Validation Required; Number of Samples to Test; Factors Affecting the Validation Test, including Product and Package Factors and Type of Cooking Device (Microwave Ovens, Conventional and Toaster Ovens, Fryers, Stovetops). For microwave ovens, information is provided on the following subjects: Microwave Oven Wattage, Rotation of Product, Magnetron Power Output, Number of Units Being Cooked at One Time, Cold Spot Determination and Heating Uniformity in Product, Temperature Determination, and Labeling Products for Microwave Cooking. The guidelines also cover Evaluating the Results of the validation tests. Broad industry adoption and adherence to the guideline recommendations should help assure the continued safety of this category of convenient food products.

Cooking for safety is required for NRTE foods because these products typically contain at least one ingredient for which the processor cannot ensure the elimination of vegetative pathogens, such as *Listeria monocytogenes* and *Salmonella*, during their manufacture. Many NRTE products contain an RTE (or fully cooked) meat or poultry component combined with one or more other ingredients that are uncooked or only partially cooked and that therefore have not received heat treatment adequate to eliminate vegetative pathogens.

Although these NRTE products are not subject to specific lethality requirements as are many RTE products, USDA's Food Safety and Inspection Service (FSIS) has certain explicit expectations for these products, including validation of the cooking instructions provided on product labels *(12, 13)*. The Food and Drug Administration (FDA) currently has no regulations or written policies that specifically address the NRTE products that fall under its jurisdiction. However, FDA fully expects NRTE products to be safe. Manufacturer validation of cooking instructions is a key step in ensuring that products prepared by the consumer according to the manufacturer's preparation instructions are safe to eat.

After several foodborne illness outbreaks linked to undercooked frozen, raw breaded poultry products, FSIS in late 2006 issued a notice *(12)* instructing NRTE food processors to validate the cooking instructions they provide to consumers. Regulatory interest in these and similar frozen products intensified during the summer of 2007 when frozen NRTE products, such as pot pies and pizzas made with RTE meat or poultry components, were implicated in foodborne illness outbreaks.

Even before the illness outbreaks of 2006 and 2007, GMA had recognized that a protocol for the validation of consumer cooking instructions for NRTE foods would facilitate industry efforts to ensure the adequacy of those instructions and could lessen the potential for new and possibly restrictive regulations for these products. As a result, GMA staff, with valuable assistance from the GMA Consumer Cooking Instruction Validation Task Force, developed guidance on this issue. For the guidance document to reflect input from, and be relevant to, the broadest audience possible, drafts were circulated to allied trade associations, as well as to FSIS and FDA, for review and comment.

OVERVIEW OF THE GUIDELINES

These guidelines are intended for manufacturers of FSIS- and FDA-regulated retail NRTE products that, by definition, require a pathogen lethality treatment (cooking) by consumers before being consumed. They are not intended for RTE products that are simply heated or warmed for palatability.

The guidelines recommend that all labeled cooking instructions should be validated to confirm and document that they will provide adequate lethality to destroy any pathogenic organisms of concern that might be present. Cooking instructions should be reassessed and revised if necessary when product or packaging design changes are made that may adversely impact any of the conditions originally validated.

Rather than exhaustively detailing how validation testing should be performed for all methods of preparation and all types of NRTE products, these guidelines highlight the many issues that manufacturers should consider when conducting validation studies. The guidelines emphasize that cooking instruction validation can be performed in many different ways. Thus, it is very important to note that the guidelines are not intended to set a standard that limits or restricts industry's ability to employ other science-based validation methodologies.

These guidelines apply to both frozen and refrigerated NRTE products; however, it is appropriate to note that to date food safety problems for this category of foods have consistently involved frozen products. Consequently, frozen NRTE products, especially those bearing microwave cooking instructions, can be expected to be a focal point for attention by the regulatory agencies.

It is recognized that validation testing based on worst case scenarios for every conceivable variable that could be encountered in cooking NRTE products represents a situation that is highly unlikely to occur in the home. Furthermore, it would almost certainly result in overcooked and

unpalatable finished products that would not be commercially viable. Thus, the guidelines stress that it is up to manufacturers to fully consider all the variables mentioned in the document and then assure that validation testing adequately addresses those variables most meaningful to achieving the required lethality for their products.

Validation strategies

There are at least two strategies for conducting cooking instruction validation studies. The simplest way to determine that the cooking instructions provide adequate lethality is to identify a target time/temperature combination that has been scientifically determined to be adequate to eliminate the appropriate level of the pathogen of concern (see lethality requirements) and to confirm that the test product reaches the target time/temperature after it has been cooked following the directions on the label. If the target time/temperature associated with the required lethality for the product is attained, then the instructions are validated.

Alternatively, microbiological inactivation studies may be a desirable or necessary cooking instruction validation strategy. The purpose of these studies is to determine whether pathogen(s) of concern intentionally introduced into the product to be tested are inactivated when the product is cooked according to the instructions. Microbial inactivation studies may be most appropriate for those products with a higher risk of microbial contamination (for example, products containing NRTE meat or poultry) or in cases where validation testing of product temperatures alone has shown that the target temperature has not been achieved consistently or has demonstrated wide variability. Additional recommendations on inactivation studies are included in the guidelines *(5)*, as are references to other sources of information *(10)* pertinent to validation studies.

Justification for the log reduction targeted for microbiological inactivation should be provided. In the absence of regulatory guidelines, a 5-log reduction of the pathogen of concern (often *Salmonella*) has generally been acceptable for most products. Nevertheless, under some circumstances more modest reductions may be scientifically justified as adequate for public health protection. The guidelines suggest that consultation with the relevant regulatory agency may help manufacturers to anticipate the amount and type of data needed to demonstrate that the selected parameters provide adequate lethality for appropriate pathogens.

Lethality requirements

Before beginning a validation study, it will be necessary to determine the target lethality value for the specific NRTE product. The guidelines review the various sources of lethality information upon which validation testing can be based, including regulatory guidance, published scientific papers, and product-specific microbiological inactivation studies.

Safe harbor times and temperatures are available for certain products in regulations and/or in regulatory guidance documents such as FDA's Model Food Code *(15)* and FSIS' Appendix A: Compliance guidelines for meeting lethality performance standards for certain meat and poultry products *(11)*. Many studies published in peer-reviewed scientific journals provide times and temperatures for cooking products to eliminate target pathogens or provide data on the heat resistance of pathogens expressed as D- and z-values. Summary information on such time-temperature recommendations or on heating values that can be used to determine time-temperature combinations adequate to destroy specific pathogens of concern may be obtained from the scientific literature *(3, 4)*. When literature values do not adequately address product parameters, it may be necessary to develop information on the heat resistance of specific pathogens in specific food products.

The target lethality may be different for NRTE products containing NRTE meat or poultry components versus those containing RTE meat or poultry components along with some other uncooked ingredients. In some cases, a lower target lethality may be justified for a product containing RTE meat or poultry because of the types and numbers of pathogens to be inactivated. Lower target lethalities may also be supportable for manufacturers that elect to implement incoming ingredient controls and/or environmental and in-process microbiological control programs. Under these circumstances, firms must continually document adherence to these specified conditions and must be prepared to demonstrate their scientific adequacy if questioned by regulatory agencies.

Importance of sanitary operating conditions

The guidelines emphasize that failure to control sanitary conditions within NRTE manufacturing establishments can adversely affect the adequacy of otherwise properly validated cooking instructions. Instructions validated to inactivate a specified number of organisms will be inadequate if sanitary conditions within the processing facility allow contamination with pathogens or growth of pathogens to numbers greater than those considered during validation testing. Thus, it is important to assure that the target lethality selected for validation testing takes into consideration the sanitary conditions in the plant. Then, on an ongoing basis, manufacturers must assure that proper attention is paid to sanitation, including verification that sanitary conditions are being maintained.

Number of samples to test

The Task Force determined that while it would be convenient to set a minimum number of samples that should be tested in a validation study, there is simply too much variation in the range of products and their heating characteristics to permit this. Rather, the guidelines stress that the number of samples to be tested should be sufficient to provide reasonable assurance that the cooking instructions, if followed, will result in a safe product. This number will depend on the food and the method of heating, with fewer replicates needed for methods that provide more uniform heating. The number of samples tested must be sufficient to capture the variability in product heating and determine which factors are most responsible for this variability. More samples are recommended for products with greater variability in key parameters (for example, a product with non-uniform sized pieces of NRTE meat). In addition, the guidelines recommend that multiple (e.g., three separate) lots of product be tested to account for variability among lots.

Factors affecting the validation test

A variety of product factors can affect the validity of cooking instructions, and all factors pertinent to the cooking method should be accounted for in the

validation study. The details of the validation study depend upon the method of cooking and the product. In many cases, it may be appropriate to consult a statistician to assure that the study fully considers all variables that might significantly affect the adequacy of the final temperature achieved throughout the product during the cooking process.

Each product type (including composition, size, shape, components, distribution, or package configuration) should be tested, unless worst-case conditions can be logically applied to cover multiple product variables. In general, testing should be performed with heavier samples in the lot or with maximum-sized pieces (e.g., ones that exceed the product specification by 1/8" in all dimensions).

The initial temperature of tested product should be the lowest expected at the time of preparation in a typical consumer's home. Thus, frozen products, unless they bear clear instructions that thawing is required prior to cooking, should be in their frozen state (0°F - 10°F) when testing begins.

Type of cooking device

Cooking directions are often provided to the consumer for a variety of cooking devices, such as microwave ovens, conventional or toaster ovens, and stovetops. Because of the fundamental differences in the way foods heat (i.e., the kinetics of heat transfer) in the various cooking devices, especially in microwave ovens, and the impact of the number of units being cooked at a time, the type of cooking device will certainly affect the design of the validation study. The guidelines provide specific information on validation testing for conventional and toaster ovens, fryers, and stovetops. However, validation testing for microwave ovens warrants the greatest attention in the guidelines.

Factors to consider for microwave ovens

Products bearing microwave cooking instructions are of particular concern, since non-uniform heating of foods in microwave ovens has been implicated as a key factor in undercooked food products resulting in a number of cases of salmonellosis *(7, 8, 9)*. This non-uniform heating leads to cold spots in the product, which may allow the survival of pathogens such as *Salmonella* potentially present in components of NRTE foods. The guidelines cite microwave oven wattage, rotation of product, magnetron power output, number of units cooked at one time, cold spot determination and heating uniformity in product as key factors to be considered during validation of microwave cooking instructions.

Determination of the wattage for each oven used is a fundamental step in validation studies involving microwave ovens. In general, cooking instructions should be validated using a number of ovens that span the range of wattages commonly used by consumers. However, validation studies for microwave cooking instructions can be conducted in several different ways, including running tests with the lowest wattage oven only; conducting tests with a range of consumer microwave oven wattages; and performing tests with the most common wattage used by consumers (~1100 watts). Each method is addressed in the guidelines.

The guidelines cover many additional factors to be considered. Ideally, units that do and do not have certain features, such as carousels to rotate product during cooking, should be included in the tests. Any directions provided for manual rotation of the product during cooking should be based on validated test results. Manufacturers should consider the need to provide appropriate instructions on products for which they could reasonably expect consumers to microwave multiple units simultaneously. Examples are provided of various approaches manufacturers can take during validation testing to account for the fact that as the microwave magnetron heats up, the amount of power it generates for cooking decreases (as much as 20% in some cases).

Another critical matter addressed in the guidelines is cold spot determination and product heating uniformity. To assure the safety of NRTE foods cooked in a microwave oven, it is necessary to determine that all portions of the product have reached a given temperature for a minimum period of time adequate for the appropriate log reduction of the pathogen(s) of concern. As previously noted, gaining this assurance can be particularly challenging for foods cooked in microwave ovens because of the likelihood of non-uniform heating. Thermal imaging may be useful in identifying cold spots, as well as hot spots. For safety assurance, the product temperature may need to be measured in multiple places in each sample to detect a cold spot. The importance of proper calibration of temperature measuring devices used in the validation study is noted in the guidelines.

Clarity of instructions

In addition to the critical importance of validating the cooking times and/or temperatures, it is also very important that cooking instructions are written so the consumer can easily follow them. One way to help ensure this is to have a method for consumers to provide feedback, and to monitor this feedback for any indication that the cooking instructions are hard to understand or difficult to use, or that when they were followed, the product was still cold or otherwise not well cooked. Such feedback should be used to review the adequacy/clarity of the cooking instructions. The guidelines acknowledge the value of including visual or other cues, where appropriate, with cooking instructions, especially those for microwave ovens, to help consumers recognize when a product has not been adequately cooked for safety and therefore may require additional cooking time. Examples of such cues could include a statement within the instructions informing the consumer that if the bottom of the tray is cold after the prescribed cooking time, then the product should be cooked for additional increments of time until the tray is warm or hot, or a statement to the effect that when the product is properly cooked, it will be steaming.

Although this document deals with the scientific basis for cooking instruction validation, the importance of human factors in cooking instruction communication should not be overlooked. It is critical that the instructions provided to the consumer are clear, complete and well designed. For this reason, this guidance document also refers readers to a complementary document that addresses labeling issues relevant to NRTE food products. This document, "Recommended Guidelines for the Labeling of Microwave Cooking Instructions," was developed by an American Frozen Food Institute working group (*1*).

The guidelines also contain a table of recommended cooking time and temperatures for various products. In addition, an appendix of generic cooking instruction validation examples is included, along with some approaches to interpretation of results that were provided by GMA members based on their validation protocols. The examples include some approaches

that may not follow all elements of the validation guidelines, but are nonetheless effective for their intended purpose.

These guidelines have been widely distributed and are available at http://www.gmabrands.com/publications/121894_1.pdf. Broad industry adoption and adherence to the guideline recommendations should help assure the continued safety of this category of convenient food products.

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