GMA

The Association of Food, Beverage and Consumer Products Companies

GUIDELINES FOR VALIDATION OF CONSUMER COOKING INSTRUCTIONS FOR NOT-READY-TO-EAT (NRTE) PRODUCTS

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INTRODUCTION

Unlike ready-to-eat (RTE) food products, which are safe to consume regardless of the form purchased by consumers (e.g., frozen, refrigerated, canned), not-ready-to-eat (NRTE) products require cooking by consumers for safety. While most RTE meat and poultry products are covered by specific lethality performance standards in Food Safety and Inspection Service (FSIS) regulations, NRTE products are not, since they contain at least one ingredient for which the elimination of vegetative pathogens such as *L. monocytogenes* and *Salmonella* cannot be assured by the manufacturer. Entree-type products containing RTE (fully cooked) meat or poultry combined with a component that has not received a heat treatment for pathogens such as *L. monocytogenes* may be considered NRTE by FSIS, provided that certain explicit labeling expectations are met, including validation of the cooking instructions provided on the label. Testing the validity of the consumer cooking directions for NRTE products, especially frozen NRTE products, is an important and effective tool for ensuring the safe consumption of these products by consumers. After several foodborne illness outbreaks due to undercooked frozen, raw, breaded poultry products in the last few years, FSIS issued a notice in late 2006 regarding such NRTE products available for retail sale. Included in the notice was a charge to companies to validate the cooking instructions provided to the consumer. Interest in these and similar frozen products intensified during the summer of 2007 when frozen NRTE products containing RTE meat or poultry components such as pot pies and pizzas were implicated in foodborne illness outbreaks. The FDA currently has no specific regulations addressing NRTE products falling 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, as used by the consumer based on manufacturer preparation instructions, are safe.

A protocol for the validation of consumer cooking instructions will facilitate industry efforts to ensure the adequacy of those instructions for NRTE foods. Of particular concern are those products with microwave cooking instructions, since non-uniform heating of foods in microwave ovens has been implicated as a key factor in undercooked food products. This non-uniform heating leads to cold spots in the product, which may allow the survival of pathogens such as *Salmonella* that could potentially be present in components of NRTE foods. With frozen uncooked, breaded poultry products and with frozen meat and poultry pot pies, improper microwave cooking by the consumer has been identified as a factor in the illnesses.

It is important that cooking instructions are written so the consumer can easily follow them. One way to help assure 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, difficult to use, or, when 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. These guidelines acknowledge the value of including visual 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.

PURPOSE AND SCOPE OF THE GUIDELINES

These guidelines are intended for manufacturers of retail NRTE products (both FSIS- and FDA-regulated) that, by definition, require a pathogen lethality treatment (cooking) by consumers before consumption in their homes. Use of these guidelines will help assure that the cooking instructions are capable of achieving a time/temperature combination sufficient to reduce the number of vegetative pathogens that might be present in NRTE food products to a safe level. It should be emphasized that these guidelines cover foods that require **cooking** by the consumer, rather than just heating or warming, before consumption. The distinction is that a cooking step is required to kill pathogenic microorganisms that may be present in NRTE foods (e.g., many frozen entrees), while a heating step warms an RTE food to meet consumer expectations for palatability, but is not required for food safety.

All labeled cooking instructions provided to the consumer 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 when product or packaging design changes are made that may adversely impact any of the conditions originally validated.

These guidelines can be applied to any NRTE product (frozen or not frozen) that bears specific cooking instructions on its label; however, to date NRTE-related food safety problems 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.

These guidelines cannot cover in detail all methods of preparation for all types of NRTE products. Rather, these guidelines highlight myriad issues that should be considered when conducting validation studies. There are many acceptable procedures for validation of cooking instructions; these guidelines should not be construed as setting a standard that limits industry's ability to employ other science-based validation methodologies.

In many cases, testing of worst case scenarios for every conceivable variable will be incompatible with a palatable finished product, and will represent unrealistic situations. Therefore it will be incumbent on manufacturers to consider all the variables in the document and then assure that validation testing adequately addresses those variables most meaningful to achieving the required lethality for their products.

DETERMINING APPROPRIATE LETHALITY REQUIREMENTS

There are a variety of sources of lethality information upon which validation testing can be based including regulatory guidance, published scientific papers, and product-specific microbiological inactivation studies.

Regulatory Guidance

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 and FSIS' Appendix A: Compliance guidelines for meeting lethality performance standards for certain meat and poultry products. These are summarized in Table 1. In general, a temperature of 160°F (165°F for products containing poultry that is not fully cooked) should provide adequate lethality to assure the safety of products cooked by consumers, as would temperature and time combinations equivalent to this temperature with no holding time. Manufacturers can use these time/temperature guidelines as a basis for validation of their cooking instructions. These temperatures provide a margin of safety with respect to expected levels of pathogens in raw meat and seafood; therefore it may be possible to justify lower time/temperature combinations. Nevertheless, it may be prudent to provide a greater safety margin for consumer cooking than for lethality delivered at a manufacturing site (NACMCF, 2007).

Published Scientific Studies

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 for destruction of specific pathogens of concern may be obtained from the scientific literature, e.g., Doyle and Mazzotta, 2000; Doyle et al., 2001. When using time-temperature lethality values from literature studies, it is important to assure that key parameters of the products studied are consistent with those of the product for which cooking instructions are being validated.

Product-Specific Microbiological Inactivation Studies

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. Procedures to determine D- and z-values are beyond the scope of this document but are well covered in the literature. Other types of microbial inactivation studies are discussed below in Type of Validation Required.

Impact of sanitary conditions

It is very important to note that the failure to control sanitary conditions within NRTE manufacturing establishments can adversely impact the adequacy of otherwise properly validated cooking instructions. Instructions validated to inactivate a specified number of organisms will be ultimately inadequate if sanitary conditions within the processing facility allow contamination with or growth of pathogens to numbers greater than those considered during the 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 within the manufacturing facility.

TYPE OF VALIDATION REQUIRED

Product Temperature

The simplest way to determine that the cooking instructions provide adequate lethality is to determine the temperature of the product after it is cooked following the directions on the label. Determining appropriate temperatures was addressed in the section Determining Appropriate Lethality Requirements.

It is important to note that 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 due to the types and numbers of pathogens to be inactivated. Different target lethalities may also be justified when manufacturers 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 justify their scientific adequacy if questioned by regulatory agencies.

Microbiological Inactivation Studies

In some cases, microbiological inactivation studies may be a desirable or necessary adjunct to temperature studies in the validation process. The purpose of these studies is to determine whether pathogens intentionally introduced into sample 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 not consistently achieved the target temperature or has demonstrated wide variability. Inactivation studies should be conducted using the pathogen of concern in the product under consideration. *L. monocytogenes* may be used as the test organism, even when it is not the pathogen of concern, since it tends to have higher heat resistance than other vegetative pathogens. A cooking procedure designed for *L. monocytogenes* inactivation will provide adequate lethality for other vegetative pathogens. Guidelines for conducting inactivation studies for *L. monocytogenes* are described by Scott et al. (2005). The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) is developing guidance on parameters for inoculated pack/challenge study protocols, which, when finished, should provide appropriate guidance for validation of cooking instructions through microbiological challenge testing.

Justification for the log reduction targeted for microbiological inactivation should be provided. One such approach has been described (GMA/FPA, 2007). 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 lower reductions may be scientifically justified as providing appropriate public health protection. For example, procedures that result in < 1 viable cell per serving, <1% probability of one or more cases of illness per year, or probability of yearly illness of less than 10^{-5} have also been useful measures

(GMA/FPA, 2007). As previously mentioned, it may be necessary to collect and maintain data on the numbers of the pathogen(s) of concern in the product or its ingredients to demonstrate on an ongoing basis that the chosen log reduction is appropriate.

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.

NUMBER OF SAMPLES TO TEST

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. One approach would be to conduct preliminary tests to identify the most significant variables and then conduct additional tests with worst case examples of those variables. More samples are recommended for products with greater variability in key parameters (for example, a product with non-uniform pieces of NRTE meat), as this variability should be accounted for in the validation test.

It is recommended that multiple (e.g., three separate) lots of product be tested to account for variability among lots. For some products it may be necessary to consider variability in contamination due to seasonality or regionality. While testing three separate lots may be desirable, typically with new products only one lot is available and the cooking instructions are developed based on test samples. However, even with limited lots to test, it may be possible to know something about the expected variability of the production line and product. This may be based on multiple lots of products prepared in a test kitchen, knowledge of variability based on similar types of products, etc. The cooking instructions should be revised if validation testing suggests this is necessary to achieve appropriate lethality.

FACTORS AFFECTING THE VALIDATION TEST

There are a variety of product factors that can affect the validity of cooking instructions, and all that are 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 utilize 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.

Product and Package Factors

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. To account for variation among samples within one lot, such as sample weight, cooking instructions should be based on the heavier samples in the lot. A maximum-sized piece (such as one that exceeds the product specification by 1/8” in all dimensions) may be appropriate to use in tests with some foods. Ideally, samples for testing should be from pilot scale-up rather than bench-top formulations to more accurately portray the product the consumer will be cooking, but this may not be needed, especially if there is experience with similar types of products. There tend to be more inconsistencies with scale-up products than with bench-top formulations, so it is possible that bench-top formulated product would reach an adequate temperature throughout, while the same product produced in large batch quantities might be less uniform, resulting in less uniform heating.

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 requiring thawing prior to cooking, should be in their frozen state (0°F - 10°F) when testing begins. Even if the instructions require thawing before cooking, it may be worthwhile to consider additional tests to assess the impact on cooking adequacy if the consumer does not fully thaw the product prior to cooking. Alternatively, two sets of validated cooking instructions could be provided: one for preparation of thawed product and one for preparation of frozen product. Frozen products are more likely to heat unevenly, especially in microwave ovens, than products that are refrigerated prior to cooking and, as such, have a greater likelihood of having cold spots that could allow pathogens to survive.

Type of Cooking Device

Cooking directions are typically provided to the consumer for a variety of cooking devices. Depending upon the product, there could be instructions for microwave ovens, conventional or toaster ovens, and even for stovetop cooking. Of particular concern are microwave ovens, which have been a factor in cases of salmonellosis resulting from improper cooking of frozen NRTE breaded poultry products and, more recently, frozen NRTE pot pies containing RTE meat and poultry. Because of the fundamental differences in the way foods heat (i.e., the kinetics of heat transfer) in the various cooking devices, especially 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. As such, this protocol addresses each cooking device separately.

Microwave Ovens

Microwave Oven Wattage

A fundamental step in validation studies involving microwave ovens is the determination of each oven’s wattage. In some cases, the input wattage of the microwave is listed on the back or side of the microwave. This is usually somewhat higher than the output wattage, upon which the validation testing will be based. The output wattage of microwave ovens should be measured using the IEC (International Electrotechnical Commission) method (IEC 60705 ed. 3.2, 2006 - Household microwave ovens - Methods for measuring performance). This method will determine the actual output wattage, which will likely differ from the manufacturer’s stated output wattage.

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:

1. Tests can be run with the lowest wattage oven only. Validated instructions that ensure the required product temperature can be reached in the lowest wattage oven will be more than adequate to ensure that temperature is also reached in any higher wattage oven a consumer might use. However, when this validation procedure is followed, it is also advisable to apply these instructions to product cooked in the highest wattage oven to ensure the product maintains acceptable quality and is deemed safe for the consumer (for example, to assure the product will not ignite or become a burn hazard due to the higher wattage). The difference in time required to reach a target temperature for a low, 600 wattage microwave versus a high, 1200 wattage microwave could be several minutes. In some cases the time may be halved for a high wattage microwave (e.g., to achieve the results of a 10-minute cook in a 600 watt microwave may require only a 5-minute cook time in a 1200 watt microwave). Thus, providing consumers with a single cook time based on a low wattage microwave oven may prove unacceptable, if consumers using higher wattage ovens will be unhappy with the quality of the cooked product. To balance the need to maintain optimal quality while assuring safety, cooking instructions may need to be developed and validated for microwave ovens of different wattage ranges as discussed below.

2. Validation tests can be conducted on a range of consumer microwave oven wattages. For example, tests can be performed with microwave ovens that have the lowest wattage in several ranges (e.g., 600-800, >800-1100, and >1100), to ensure cooking instructions are adequate for safety, regardless of the wattage of a consumer's microwave oven. This method accounts for the variability in product temperature due to microwave wattage, and should address the potential quality issues associated with the previous method. This approach will generally result in multiple microwave cooking times on the label for several wattage ranges. Depending on the product, two or three wattage ranges may be used for validation.

3. Validation can also be conducted using the most common wattage used by consumers (~1100 watts). This approach is currently widely used for some products. However, in this situation in particular, additional information may need to be provided to consumers to assure they do not consume insufficiently cooked product. This could be achieved by placing a statement on the packaging indicating that the cooking instructions are for microwave ovens of a specified wattage and that more time may be required if a lower wattage oven is used. It may be prudent to determine the amount of additional time the consumer should use.

Rotation of Product, Magnetron Power Output, and Number of Units being Cooked at One Time

Ideally, units that do and do not have features such as carousels to rotate product during cooking should be included in the test. Carousels have been shown to generally improve uniformity of product heating. However, this may not be the case for product placed in the exact center of the carousel, since it remains in the same place during rotation (Geedipalli et al., 2007). If this is found to be a significant factor during validation testing, it may be appropriate to note in the cooking instructions that product should not be centered on the carousel. Since not all microwaves are equipped with carousels, instructions often include manual product rotation. Any directions provided for manual rotation of the product during cooking should be based on validated test results.

As the magnetron heats up, the amount of power it generates for cooking decreases (as much as 20% in some cases). Some companies take a conservative approach to validation testing by conducting all tests, including the first one of the day or session, in a warm microwave oven (e.g., preheat using 1-2 liters of hot water for at least 1 minute). Others attempt to assure that power loss is not excessive over a series of tests by incorporating a “wait time” between tests, e.g., 30 minutes has been recommended (Datta and Davidson, 2000), which also helps to maintain a relatively constant power output for each test. One specific approach (R.F. Schiffmann Associates, Inc., personal communication) used by some firms is as follows:

1. Conduct IEC 60705 power output test. Record data.
2. Pre-warm the oven by heating a 1000 ml cold water load for 15 minutes. (This will stabilize the power output for the tests to follow.) Remove water from the oven and discard. Wipe down interior of oven to remove any condensed water vapor. Allow oven to cool to room temperature – about 20 minutes. Leave the oven door open while it cools. Cool the turntable under tap water, drain, dry and replace in oven for the next use.
3. Run first test. At end of test remove turntable and cool as above, replace in oven. Feel walls, ceiling and floor of oven. If warm, wipe down with cold, wet sponge and dry. If very warm, use a fan to assist in cooling. The oven should be ready to use again in 15 minutes.
4. Repeat the sequence for each test. If using more than one oven in the test, rotate between ovens. In other words, if using three ovens, run the tests in the sequence: 1,2,3,1,2,3… That way each oven will cool down between each test before being used again. Also, it allows more tests to be conducted in a shorter period of time.
5. It is critical that the ovens be pre-warmed and that they all have IEC power output results that are within 10% of each other. The power output will vary from day to day.

Manufacturers should consider the need to provide appropriate instructions on products for which they could reasonably expect consumers to microwave multiple units simultaneously. If instructions are provided for cooking multiple units (e.g., packages) simultaneously in the microwave, these must be validated. Tests should be conducted with the units at different locations and with different orientations, unless the worst-case location and orientation are determined for a specific oven. However, since there will likely be many potential orientations and a large variation in appliance performance, in most instances the issue of cold spots in the oven resulting in cold spots in the product will be addressed through the hold time at the end of the cook rather than determining worst-case location and orientation.

Cold Spot Determination and Heating Uniformity in Product

In order 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 temperature for a minimum period of time adequate for the appropriate log reduction of the pathogen(s) of concern. As is clear from prior discussion, gaining this assurance can be particularly challenging for foods cooked in microwave ovens due to the likelihood of non-uniform heating, which commonly will result in some localized areas of the product, or cold spots, where temperatures can be significantly less than those of surrounding areas. Thermal imaging may be useful in identifying cold spots, as well as hot spots. As noted below, the location of cold spots within a microwave-cooked food product is dependent on many variables, including placement in the oven. Determining the cold spot in product cooked in a microwave oven is further complicated by the fact that uniformity of heating is more dependent on the formulation of the food than is the case for cooking in a conventional oven, and the cold spot can shift as the product heats up (Datta and Davidson, 2000). For safety assurance, the product temperature may need to be taken in multiple places in each sample to detect a cold spot.

A profile of the product can be developed using a mathematical simulation of the heating process that takes into consideration the various characteristics of the product (size, shape, dielectric properties, and so forth). This simulation could provide insight into the probable location of cold spots, and could thus reduce the number of trials needed to understand the heating patterns for the product during microwave cooking (Datta and Davidson, 2000).

For most cooking methods, the cold spot is usually found in the very center of the product, or in the center of any large pieces in the product. This may or may not be true for products cooked in microwave ovens. Since microwaves are absorbed better at higher temperatures, it becomes harder for the microwaves to penetrate the product as its temperature rises. This could lead to a cold spot in the exact center of the food product (Datta and Davidson, 2000).

However, it is also advisable to ensure that the surface of product cooked in a microwave oven has achieved an adequate temperature. While a lower surface temperature would not be expected for other cooking methods, this can be a consideration for microwave cooked foods because of the room-temperature environment to which the product surface is exposed and the fact that evaporation of water from the surface could leave fewer water molecules there to create heat (Datta and Davidson, 2000).

However, it is critical to understand that the location of the cold spots is not always easily predicted; that is, it should not be presumed that the cold spot will be on the surface of the product or in the exact center of the product. Product formulation can also greatly affect the location of cold spots. High water and salt contents decrease microwave penetration, leading to a surface-heating phenomenon, and making it more difficult for microwaves to penetrate to the center of the product (Fakhouri and Ramaswamy, 1993). A high fat content will actually improve the heating uniformity and increase the heating rate, while a high protein content will do the opposite (Fakhouri and Ramaswamy, 1993). The shape of the product also affects the heating distribution, as a curved shape focuses microwaves, causing the center to heat more quickly (Heddleson and Doores, 1994). Thus, the determination of the potential cold spots in a product heated in a microwave is much more complex than in a conventional heating device, in which the temperature rises by conduction of heat from the outside of the product to the inside. This further emphasizes that multiple temperature probe points are essential for cold spot detection.

A specified holding time between cooking steps or at the end of cooking is a common feature of microwave cooking instructions that allows temperatures in different parts of the product to equilibrate. This holding time is frequently an integral part of the lethal process, to allow the product temperature to rise after microwave cooking due to latent heat effect and to ensure temperature reaches the target throughout the product. It has also been observed that post-heating holding times have increased the destruction of pathogenic microorganisms (Heddleson et al., 1994). The number of degrees of temperature rise during the hold time depends on several factors, including, but not limited to, the type of product, how high the temperatures around the cold spots are, and how well the product conducts heat to other areas. It is desirable to achieve lethality without relying on holding time where possible. If cooking instructions specify a holding time, the validation test should follow these instructions. However, it may be desirable to obtain data with shorter hold times to understand the robustness of the cooking process; this may provide useful information with respect to emphasizing certain points in the consumer instructions. Such data may be available from studies used to establish the cooking instructions.

Temperature Determination

For foods having multiple components, the temperature should be documented for all components that require a lethality treatment, including at least the surface of any component that contacts another component that requires a lethality treatment (e.g., the surface of an RTE chicken component that comes in contact with NRTE vegetables).

The temperatures can be monitored while the product is cooking using a microwave oven modified to accommodate fiber optic sensors. Alternatively, immediately after removing the product, multiple temperature probes can be inserted at specified locations. As previously mentioned, thermal imaging technology may prove valuable for this purpose by identifying potential cold spots.

With either method, it is recommended that the temperature be monitored at or determined for multiple sites on any product. Care should be taken to assure that the time required to set up the temperature sensor(s) does not unduly impact the validation test and that the methodology does not impair rotation during cooking.

Probing with a thermometer to determine post-cooking temperature should occur immediately after the product is removed from the microwave oven or after a specified holding time, according to the cooking instructions being validated. The temperature should be taken at different depths at the same location in a thick product such as lasagna, or probes can be placed in numerous spots and different depths. Alternatively, once the coldest spot in this type of product has been located, the temperature at that spot can be monitored until the maximum temperature is attained. Use of a data logger to continuously monitor temperature from the time of removal of product from the oven until the maximum temperature is attained will provide data that can be used to determine integrated lethality. Integrated lethality that includes time in the microwave oven can be determined when using fiber optic probes connected to a data logger.

Note: No matter what method of temperature measurement is employed during validation testing, it is important that the temperature measuring device(s), whether a thermometer, thermocouple, fiber optic sensor, etc., is properly calibrated prior to use. Even the most carefully controlled tests can yield erroneous results if the temperature data gathered during the test is inaccurate.

For more specific information on cooking food in the microwave oven, see the *Handbook of Microwave Technology for Food Applications* (Datta and Anantheswaran, 2001).

Labeling Products for Microwave Cooking

While this document deals with the scientific basis for cooking instruction validation, the importance of human factors in cooking instruction communication cannot be denied. It is critical that the instructions provided to the consumer are clear, complete and well designed. Labeling issues relevant to NRTE food products are addressed in ”Recommended Guidelines for the Labeling of Microwave Cooking Instructions” developed by an American Frozen Food Institute working group (AFFI, 2008).

<u>Conventional and Toaster Ovens</u>

When testing the validity of consumer cooking instructions for a conventional oven, one should consider gas ovens, electric ovens and convection ovens. All products should be prepared as per the instructions given to the consumer. Once the food is cooked, the temperature should be determined to assure adequate lethality. It may be desirable to perform the tests with and without preheating the oven, as the consumer may not always preheat the oven as per the directions. However, including preheat directions on products with cooking times validated without preheating will likely lead to overcooked product for most consumers. Conversely, validation of cooking instructions in a preheated oven could be problematic for consumers that cook the product in a non-preheated oven. This is a case where inclusion of visual cues alongside the cooking instructions might help alert consumers that additional cooking time is required before serving, if failure to preheat causes the product not to conform to those cues after the labeled cooking time.

If possible, it is also advisable to perform tests in a variety of different brands of conventional ovens to account for variability among ovens when validating cooking instructions. This will help facilitate the development of a cooking time range that will encompass cooler running ovens as well as hotter ovens when set at the same baking temperature.

While product heating non-uniformity is of less concern for conventional ovens than for microwave ovens, there still may be variations in temperature distribution within test ovens. As such, prior to commencing validation testing, these cold spots should be identified, if present in test ovens, and the product should be placed in the cold spots during the validation test to ensure that even there it reaches the temperature necessary for adequate lethality. Validation test results may suggest the need to specify the location in the consumer's oven where the product should be placed for cooking.

The amount of product cooked at the same time in the conventional oven also needs to be considered, as cooking time may need to be extended if multiple servings are cooked at once. If cooking instructions are written for cooking multiple units, validation must occur for each set of multiples, i.e., 15 versus 30.

The type of pan used should also be considered, as darker metals tend to heat more efficiently than lighter ones. For some products, it will be important whether the product is covered or not covered while it cooks. If so, the validation tests and the labeled cooking instructions should take this into account.

For a solid product cooked in a conventional oven, the cold spot will most likely be in the geometric center of the food (Datta and Davidson, 2000). When validating cooking instructions for non-uniformly shaped food, temperatures may need to be checked at multiple locations to ensure that a time/temperature combination sufficient to kill any pathogenic organisms of concern is reached. Those locations would include the center as well as any particularly thick parts of the food product. If heating a sheet full of variably-sized pieces (e.g., chicken nuggets), it would be advisable to take the temperatures of several of the pieces; for example, several nuggets in the center of the sheet. Where feasible, some manufacturers measure the temperature in all individual pieces. If that is not possible, they prefer to monitor pieces from representative areas of the entire baking sheet, e.g., middle, sides, corners, etc.

For validation of cooking instructions for toaster ovens, ovens of different sizes should be tested. Cooking instructions that are validated as adequate for both the smallest and the largest toaster ovens available to consumers should also be adequate for ovens of intermediate sizes. However, some manufacturers prefer to test their products in small, medium and large ovens due to the degree of variability they have found. The number of units of products being cooked at one time must also be taken into consideration when validating this method.

Fryers

Though fryers are used most commonly in restaurants and other institutions, some consumers do have fryers in their homes, to prepare products such as frozen, battered, NRTE poultry, seafood, etc. It is important that such products are adequately cooked to assure their safe consumption.

When validating instructions for the fryer, one significant variable is the volume of the product fried relative to the quantity of cooking oil. This ratio determines in part how much the oil temperature drops when product is placed in the fryer, how long it takes the temperature to return to the set temperature, and whether or not the entire surface area of each piece being fried is exposed to the hot oil. Thus, for validation testing purposes, the largest volume of product expected to be fried at one time should be used.

As soon as the product is removed from the fryer, product temperature should be logged frequently, e.g., every five seconds, for at least two minutes or until the target lethality temperature is reached in the thickest part of each product piece, or near a large bone for bone-in product. The number of pieces to be probed depends upon the type of product and the number of pieces likely to be fried at one time. For example, fewer chicken filets would have to be probed than for a ground chicken product such as a chicken nugget.

If the product has a tendency to clump during frying, it may be necessary to validate the cooking adequacy for clumped product. Alternatively, cooking instructions could specify to consumers that care should be taken to prevent product clumping during frying.

<u>Stovetops</u>

Stovetop cooking directions could encompass several different cooking methods. These include frying, sautéing, steaming, boiling in a bag, or heating a liquid product in a saucepan. Temperature should be monitored in a variety of locations during cooking, depending upon the product, to assure that the target lethal temperature is attained.

When validating cooking directions for pieces of meat cooked in a frying pan, the variables that need to be considered include whether the stove is gas or electric, the size of the burner, the type of frying pan being used, whether the pan is covered or uncovered during and/or after cooking, the heat setting of the burner, the placement of the pieces in the frying pan, and how many pieces are being cooked at one time. A pan made of the lowest-conductive metal available to consumers could represent a worst-case scenario. Alternatively, depending on the product, a pan that conducts heat well could result in rapid browning, leading the consumer to remove the product before it is thoroughly cooked. Since browning is a visual cue commonly used by consumers, this could lead to undercooking. The potential for such issues should be addressed during validation of cooking instructions.

If a cold spot is identified in the pan, then product pieces should be cooked there. Validation testing should also account for cooking as many pieces at one time as an impatient consumer might do, since this will likely lower the overall temperature of the frying pan. Alternatively, inclusion of visual cues of adequate cooking (e.g., cook until meat juices run clear, cook until fish flesh is opaque and flakes easily) might be more straightforward and more beneficial to consumers. The target lethal temperature should be determined in the thickest parts of the pieces. However, for precooked or RTE meats, it may be possible to justify achieving the target lethal temperature only on the surface of the pieces where recontamination would be most likely to occur. Also, this could apply for intact whole muscle meat where the interior is expected to be sterile.

When validating cooking directions for a product contained in a boiling bag, both gas and electric stovetops should be used. The bag should be placed in the water when boiling bubbles start to float up and steam is visible above the water, but before a rapid boil has been reached. This will validate the applicability of the instructions in the event a consumer did not wait for the water to reach a rapid boil before placing the bag in the water. The target lethal temperature should be determined in the center of the bag.

Regarding validation of cooking directions for an NRTE food product with a liquid component such as a soup, stew or stir fry product with sauce that is to be cooked directly in a saucepan or fry pan, directions that specify a clear visual cue, such as bringing the product to a rapid boil, should be sufficient to achieve adequate lethality of any vegetative pathogens in the product. However, if a specific heating time, rather than a rapid boil, is specified then the target lethal temperature should be determined near the top and at the center of the liquid, as the heat is coming from the bottom of the pan. Again, this may not be necessary if cooking instructions specify bringing the product to a rapid boil.

EVALUATING THE RESULTS

For validation that cooking instructions deliver a target temperature, a minimum target temperature with or without a holding time is identified prior to the test. The target temperature, once achieved, will result in a safe product. Generally, if all of the temperatures taken from the test are at or above the target, the cooking instructions are adequate (provided these temperature locations represent the coldest spot in the product) and no further analysis is required. However, for microwave ovens in particular, further statistical analysis might be necessary in some cases. For example, extreme variation in microwave oven validation temperatures may suggest that, even though all the individual data points are at or above the minimum target temperature, additional statistical evaluation of the adequacy of the cooking instructions may be desirable.

For all cooking methods, a statistical analysis of the data points may be used when not all the data are at or above the target temperature. When temperature data are normally distributed, one approach is to calculate the Z value for the data using the formula

$$Z = (\text{average temperature} - \text{target temperature}) / \text{standard deviation}$$

from all data for a product cooked using a specified set of consumer directions. The probability that a random temperature value would be less than the target temperature can be determined from a statistical table (Table 2). For example, a Z equal to or higher than 2.33 means that 99% of the temperatures are at or above the target, but about once in every 100 times a random temperature would be less than the target. The impact of this on public health will depend on how much below the target temperature this is and how much lethality (how many log reductions) would be achieved compared to the expected initial number. Working with a statistician to interpret the data is recommended when in-depth data analysis is necessary to determine the adequacy of the cooking instructions.

In the event that end-point product temperatures measured at various parts of the product or statistical analyses of data show that the cooking instructions do not deliver the target temperature consistently with an acceptable level of variation, several approaches may be taken to further evaluate the adequacy of the cooking instructions. One approach is to collect time/temperature data throughout the cooking process and calculate integrated lethality based on the data. This approach would require knowledge of the D- and z-values of the pathogen of concern in the test product or one with similar characteristics. A second approach is to conduct a microbiological inactivation study, as discussed previously.

Upon completion of data collection and analysis, a report should be written and maintained to support the adequacy of the cooking instructions. The report should include all information on how the tests were conducted, the results of the tests and conclusions with respect to the validity of the cooking instructions.

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Table 1. Recommended Cooking Time and Temperature for Various Products [a]

Product	Temperature (°F)	Time	References
Poultry	165[b]	–[c]	NACMCF (2007)
Poultry	160	–	FSIS Appendix A (1999)
Cured and smoked poultry	155	–	FSIS Appendix A (1999)
Meat patties[d]	160	–	9 CFR 318.23(b)
	155	16 sec	
	151	41 sec	
Cooked beef, roast beef, and cooked corned beef[d]	160	–	FSIS Appendix A (1999)
	158	–	
	155	22 sec	
	150	67 sec	
	145	4 min	
Fish and meat	145	15 sec	FDA Food Code (2005)
Patties and injected meats; comminuted fish and meat; eggs	158	–	FDA Food Code (2005)
	155	15 sec	
	150	1 min	
	145	3 min	
Whole meat roast including beef, corned beef, lamb, pork, and cured pork	158	–	FDA Food Code (2005)
	155	22 sec	
	151	54 sec	
	145	4 min	
Microwave cooking for raw animal foods	165	2 min[e]	FDA Food Code (2005)

[a] These time and temperatures may be used as a safe harbor, as the parameters are recognized in FSIS regulations or guidance, FDA's *Food Code*, or NACMCF guidance.
[b] For consumer cooking
[c] No holding time required
[d] selected time/temperature combinations; others are available
[e] Standing time (covered) after cooking to 165°F

Table 2. Z Table (Areas Under the Normal Curve)

Z = (Ave T - Target T)/SD, where T = temperature and SD = standard deviation

Z	0.00	0.01	0.02	0.03	0.04	0.05	0.06	0.07	0.08	0.09
-3.5	0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	0.0002
-3.4	0.0003	0.0003	0.0003	0.0003	0.0003	0.0003	0.0003	0.0003	0.0003	0.0002
-3.3	0.0005	0.0005	0.0005	0.0004	0.0004	0.0004	0.0004	0.0004	0.0004	0.0003
-3.2	0.0007	0.0007	0.0006	0.0006	0.0006	0.0006	0.0006	0.0005	0.0005	0.0005
-3.1	0.0010	0.0009	0.0009	0.0009	0.0008	0.0008	0.0008	0.0008	0.0007	0.0007
-3.0	0.0013	0.0013	0.0013	0.0012	0.0012	0.0011	0.0011	0.0011	0.0010	0.0010
-2.9	0.0019	0.0018	0.0018	0.0017	0.0016	0.0016	0.0015	0.0015	0.0014	0.0014
-2.8	0.0026	0.0025	0.0024	0.0023	0.0023	0.0022	0.0021	0.0021	0.0020	0.0019
-2.7	0.0035	0.0034	0.0033	0.0032	0.0031	0.0030	0.0029	0.0028	0.0027	0.0026
-2.6	0.0047	0.0045	0.0044	0.0043	0.0041	0.0040	0.0039	0.0038	0.0037	0.0036
-2.5	0.0062	0.0060	0.0059	0.0057	0.0055	0.0054	0.0052	0.0051	0.0049	0.0048
-2.4	0.0082	0.0080	0.0078	0.0075	0.0073	0.0071	0.0069	0.0068	0.0066	0.0064
-2.3	0.0107	0.0104	0.0102	0.0099	0.0096	0.0094	0.0091	0.0089	0.0087	0.0084
-2.2	0.0139	0.0136	0.0132	0.0129	0.0125	0.0122	0.0119	0.0116	0.0113	0.0110
-2.1	0.0179	0.0174	0.0170	0.0166	0.0162	0.0158	0.0154	0.0150	0.0146	0.0143
-2.0	0.0228	0.0222	0.0217	0.0212	0.0207	0.0202	0.0197	0.0192	0.0188	0.0183
-1.9	0.0287	0.0281	0.0274	0.0268	0.0262	0.0256	0.0250	0.0244	0.0239	0.0233
-1.8	0.0359	0.0351	0.0344	0.0336	0.0329	0.0322	0.0314	0.0307	0.0301	0.0294
-1.7	0.0446	0.0436	0.0427	0.0418	0.0409	0.0401	0.0392	0.0384	0.0375	0.0367
-1.6	0.0548	0.0537	0.0526	0.0516	0.0505	0.0495	0.0485	0.0475	0.0465	0.0455
-1.5	0.0668	0.0655	0.0643	0.0630	0.0618	0.0606	0.0594	0.0582	0.0571	0.0559
-1.4	0.0808	0.0793	0.0778	0.0764	0.0749	0.0735	0.0721	0.0708	0.0694	0.0681
-1.3	0.0968	0.0951	0.0934	0.0918	0.0901	0.0885	0.0869	0.0853	0.0838	0.0823
-1.2	0.1151	0.1131	0.1112	0.1093	0.1075	0.1056	0.1038	0.1020	0.1003	0.0985
-1.1	0.1357	0.1335	0.1314	0.1292	0.1271	0.1251	0.1230	0.1210	0.1190	0.1170
-1.0	0.1587	0.1562	0.1539	0.1515	0.1492	0.1469	0.1446	0.1423	0.1401	0.1379
-0.9	0.1841	0.1814	0.1788	0.1762	0.1736	0.1711	0.1685	0.1660	0.1635	0.1611
-0.8	0.2119	0.2090	0.2061	0.2033	0.2005	0.1977	0.1949	0.1922	0.1894	0.1867
-0.7	0.2420	0.2389	0.2358	0.2327	0.2296	0.2266	0.2236	0.2206	0.2177	0.2148
-0.6	0.2743	0.2709	0.2676	0.2643	0.2611	0.2578	0.2546	0.2514	0.2483	0.2451
-0.5	0.3085	0.3050	0.3015	0.2981	0.2946	0.2912	0.2877	0.2843	0.2810	0.2776
-0.4	0.3446	0.3409	0.3372	0.3336	0.3300	0.3264	0.3228	0.3192	0.3156	0.3121
-0.3	0.3821	0.3783	0.3745	0.3707	0.3669	0.3632	0.3594	0.3557	0.3520	0.3483
-0.2	0.4207	0.4168	0.4129	0.4090	0.4052	0.4013	0.3974	0.3936	0.3897	0.3859
-0.1	0.4602	0.4562	0.4522	0.4483	0.4443	0.4404	0.4364	0.4325	0.4286	0.4247
-0	0.5000	0.4960	0.4920	0.4880	0.4840	0.4801	0.4761	0.4721	0.4681	0.4641
+0	0.5000	0.5040	0.5080	0.5120	0.5160	0.5199	0.5239	0.5279	0.5319	0.5359
0.1	0.5398	0.5438	0.5478	0.5517	0.5557	0.5596	0.5636	0.5675	0.5714	0.5753
0.2	0.5793	0.5832	0.5871	0.5910	0.5948	0.5987	0.6026	0.6064	0.6103	0.6141
0.3	0.6179	0.6217	0.6255	0.6293	0.6331	0.6368	0.6406	0.6443	0.6480	0.6517
0.4	0.6554	0.6591	0.6628	0.6664	0.6700	0.6736	0.6772	0.6808	0.6844	0.6879
0.5	0.6915	0.6950	0.6985	0.7019	0.7054	0.7088	0.7123	0.7157	0.7190	0.7224
0.6	0.7257	0.7291	0.7324	0.7357	0.7389	0.7422	0.7454	0.7486	0.7517	0.7549
0.7	0.7580	0.7611	0.7642	0.7673	0.7704	0.7734	0.7764	0.7794	0.7823	0.7852
0.8	0.7881	0.7910	0.7939	0.7967	0.7995	0.8023	0.8051	0.8078	0.8106	0.8133
0.9	0.8159	0.8186	0.8212	0.8238	0.8264	0.8289	0.8315	0.8340	0.8365	0.8389
1.0	0.8413	0.8438	0.8461	0.8485	0.8508	0.8531	0.8554	0.8577	0.8599	0.8621
1.1	0.8643	0.8665	0.8686	0.8708	0.8729	0.8749	0.8770	0.8790	0.8810	0.8830
1.2	0.8849	0.8869	0.8888	0.8907	0.8925	0.8944	0.8962	0.8980	0.8997	0.9015
1.3	0.9032	0.9049	0.9066	0.9082	0.9099	0.9115	0.9131	0.9147	0.9162	0.9177
1.4	0.9192	0.9207	0.9222	0.9236	0.9251	0.9265	0.9279	0.9292	0.9306	0.9319
1.5	0.9332	0.9345	0.9357	0.9370	0.9382	0.9394	0.9406	0.9418	0.9429	0.9441
1.6	0.9452	0.9463	0.9474	0.9484	0.9495	0.9505	0.9515	0.9525	0.9535	0.9545
1.7	0.9554	0.9564	0.9573	0.9582	0.9591	0.9599	0.9608	0.9616	0.9625	0.9633
1.8	0.9641	0.9649	0.9656	0.9664	0.9671	0.9678	0.9686	0.9693	0.9699	0.9706
1.9	0.9713	0.9719	0.9726	0.9732	0.9738	0.9744	0.9750	0.9756	0.9761	0.9767
2.0	0.9772	0.9778	0.9783	0.9788	0.9793	0.9798	0.9803	0.9808	0.9812	0.9817
2.1	0.9821	0.9826	0.9830	0.9834	0.9838	0.9842	0.9846	0.9850	0.9854	0.9857
2.2	0.9861	0.9864	0.9868	0.9871	0.9875	0.9878	0.9881	0.9884	0.9887	0.9890
2.3	0.9893	0.9896	0.9898	0.9901	0.9904	0.9906	0.9909	0.9911	0.9913	0.9916
2.4	0.9918	0.9920	0.9922	0.9925	0.9927	0.9929	0.9931	0.9932	0.9934	0.9936
2.5	0.9938	0.9940	0.9941	0.9943	0.9945	0.9946	0.9948	0.9949	0.9951	0.9952
2.6	0.9953	0.9955	0.9956	0.9957	0.9959	0.9960	0.9961	0.9962	0.9963	0.9964
2.7	0.9965	0.9966	0.9967	0.9968	0.9969	0.9970	0.9971	0.9972	0.9973	0.9974
2.8	0.9974	0.9975	0.9976	0.9977	0.9977	0.9978	0.9979	0.9979	0.9980	0.9981
2.9	0.9981	0.9982	0.9982	0.9983	0.9984	0.9984	0.9985	0.9985	0.9986	0.9986
3.0	0.9987	0.9987	0.9987	0.9988	0.9988	0.9989	0.9989	0.9989	0.9990	0.9990
3.1	0.9990	0.9991	0.9991	0.9991	0.9992	0.9992	0.9992	0.9992	0.9993	0.9993
3.2	0.9993	0.9993	0.9994	0.9994	0.9994	0.9994	0.9994	0.9995	0.9995	0.9995
3.3	0.9995	0.9995	0.9995	0.9996	0.9996	0.9996	0.9996	0.9996	0.9996	0.9997

APPENDIX

COOKING INSTRUCTION VALIDATION EXAMPLES

The following are representative examples of industry validation tests for food products, including approaches to interpretation of results. These examples include some approaches that may not follow all elements of these validation guidelines, but are nonetheless effective for their intended purpose.

Example 1

VALIDATION OF STOVETOP COOKING INSTRUCTIONS:

SKILLET MEAL

Skillet Meal Validation

HANDLING STATEMENTS: KEEP FROZEN COOK THOROUGHLY

COOKING INSTRUCTIONS (To Prepare Entire Package)
You Need
6 Large Eggs
1 Tablespoon cooking oil or non-stick spray

For Food Safety and Quality Purposes, this product must be cooked to a minimum internal temperature of 160°F prior to eating.

Since stove tops and skillets vary, heat and cook times may require adjusting.

1. Beat 6 eggs in a small bowl and set aside (egg substitute can also be used).
2. Preheat a large (12-inch), non-stick skillet with 1 tablespoon of oil (or non-stick spray) over medium-high heat; then pour in the pouch contents.
3. Heat with occasional stirring for 7 minutes, then push mixture to one side of the skillet and pour beaten eggs into the other half; scramble eggs until cooked (2-3 minutes).
4. Stir the scrambled eggs and mixture together until evenly blended, remove from heat and top with cheese, if desired. Season to taste and serve immediately.

Serving Suggestions
You can customize the flavor by adding garnishes such as ketchup, hot sauce, salsa, sour cream, or tomato.

Skillet Meal Validation

PRODUCT PERFORMANCE REPORT **DATE: May 4, 2007**

OBJECTIVE: To validate heating instructions developed for the [skillet meal] to make sure a temperature of at least 160°F is achieved in product components.

SAMPLE IDENTIFICATION:
Sample # XXXX1 (Potatoes, Smoked Sausage, Onions, Red and Green Bell Peppers)
Sample # 7XXXX (Potatoes, Sausage, Bacon, Red and Green Bell Peppers)
Sample # XX5XX (Potatoes, Sausage, Bacon)
Sample # XXXX9 (Potatoes, Sausage, Red and Green Bell Peppers)

METHODOLOGY:
Three samples of each product variable were prepared following the preparation directions exactly. The samples were removed from the freezer (5-7ºF) and prepared immediately. Two samples of each product were prepared on an electric range and one sample on a gas range for each variable.

Temperatures were taken with a calibrated thermometer (+ 1ºF prior to test) in five places throughout the skillet for each component and were recorded within 90 seconds after preparation was completed.

RESULTS AND CONCLUSIONS:
All of the four skillet sample variables, when prepared according to package directions, met the target temperature. Results are listed below.

Skillet Meal Validation

SAMPLE # XXXX1
(POTATOES, SMOKED SAUSAGE, ONIONS, RED AND GREEN BELL PEPPERS)

TEST 1: (GE ELECTRIC RANGE)

	1	2	3	4	5
A	Sausage: 172°F	Potato: 161°F	Egg: 165°F	Sausage: 170°F	Egg: 167°F
B	Potato: 165°F	Egg: 161°F	Sausage: 185°F	Egg: 177°F	Sausage: 170°F
C	Egg: 165°F	Potato: 170°F	Sausage: 172°F	Egg: 168°F	Potato: 161°F

TEST 2: (GE ELECTRIC RANGE)

	1	2	3	4	5
A	Potato: 165°F	Egg: 178°F	Sausage: 172°F	Potato: 168°F	Egg: 176°F
B	Egg: 176°F	Potato: 175°F	Sausage: 165°F	Egg: 174°F	Sausage: 165°F
C	Sausage: 172°F	Potato: 175°F	Sausage: 165°F	Egg: 179°F	Egg: 178°F

TEST 3: (TAPPAN GAS RANGE)

	1	2	3	4	5
A	Sausage: 176°F	Potato: 167°F	Egg: 169°F	Pepper: 178°F	Egg: 186°F
B	Potato: 185°F	Egg: 186°F	Sausage: 178°F	Pepper: 179°F	Sausage: 176°F
C	Egg: 173°F	Potato: 173°F	Sausage: 178°F	Egg: 175°F	Potato: 185°F

SAMPLE # 7XXXX
(POTATOES, SAUSAGE, BACON, RED AND GREEN BELL PEPPERS)

Test 1: (GE ELECTRIC RANGE)

	1	2	3	4	5
A	Sausage: 178°F	Potato: 169°F	Egg: 165°F	Sausage: 172°F	Egg: 167°F
B	Potato: 168°F	Egg: 167°F	Sausage: 167°F	Egg: 177°F	Sausage: 175°F
C	Egg: 165°F	Pepper: 167°F	Potato: 180°F	Pepper: 167°F	Pepper: 170°F

Test 2: (GE ELECTRIC RANGE)

	1	2	3	4	5
A	Potato: 167°F	Egg: 180°F	Sausage: 180°F	Pepper: 177°F	Potato: 170°F
B	Potato: 168°F	Egg: 167°F	Sausage: 184°F	Pepper: 181°F	Sausage: 181°F
C	Egg: 173°F	Potato: 182°F	Sausage: 181°F	Egg: 167°F	Potato: 173°F

Test 3: (TAPPAN GAS RANGE)

	1	2	3	4	5
A	Sausage: 180°F	Potato: 178°F	Egg: 180°F	Pepper: 177°F	Egg: 184°F
B	Potato: 173°F	Egg: 170°F	Pepper: 181°F	Egg: 171°F	Sausage: 171°F
C	Egg: 170°F	Pepper: 165°F	Sausage: 172°F	Egg: 168°F	Potato: 167°F

Skillet Meal Validation

SAMPLE # XX5XX
(POTATOES, SAUSAGE, BACON)

Test 1: (GE ELECTRIC RANGE)

	1	2	3	4	5
A	Egg: 177°F	Potato: 171°F	Egg: 175°F	Sausage: 181°F	Egg: 167°F
B	Potato: 202°F	Egg: 199°F	Sausage: 184°F	Egg: 177°F	Sausage: 175°F
C	Egg: 167°F	Potato: 171°F	Sausage: 184°F	Potato: 170°F	Egg: 170°F

Test 2: (GE ELECTRIC RANGE)

	1	2	3	4	5
A	Egg: 168°F	Potato: 170°F	Egg: 168°F	Sausage: 160°F	Egg: 168°F
B	Potato: 172°F	Egg: 160°F	Sausage: 170°F	Egg: 168°F	Sausage: 172°F
C	Egg: 170°F	Potato: 161°F	Sausage: 172°F	Potato: 170°F	Egg: 170°F

Test 3: (TAPPAN GAS RANGE)

	1	2	3	4	5
A	Potato: 190°F	Egg: 198°F	Sausage: 188°F	Potato: 204°F	Sausage: 188°F
B	Potato: 177°F	Egg: 167°F	Sausage: 184°F	Egg: 176°F	Sausage: 172°F
C	Egg: 199°F	Potato: 177°F	Sausage: 184°F	Potato: 171°F	Egg: 175°F

SAMPLE # XXXX9
(POTATOES, SAUSAGE, RED AND GREEN BELL PEPPERS)

Test 1: (GE ELECTRIC RANGE)

	1	2	3	4	5
A	Sausage: 165°F	Pepper: 165°F	Egg: 174°F	Sausage: 171°F	Egg: 168°F
B	Potato: 160°F	Potato: 166°F	Egg: 172°F	Pepper: 162°F	Sausage: 177°F
C	Egg: 167°F	Potato: 171°F	Sausage: 177°F	Potato: 170°F	Egg: 169°F

Test 2: (GE ELECTRIC RANGE)

	1	2	3	4	5
A	Sausage: 176°F	Pepper: 167°F	Egg: 188°F	Sausage: 171°F	Egg: 165°F
B	Potato: 171°F	Potato: 171°F	Pepper: 169°F	Pepper: 160°F	Sausage: 177°F
C	Egg: 176°F	Egg: 195°F	Sausage: 167°F	Egg: 184°F	Egg: 167°F

Test 3: (TAPPAN GAS RANGE)

	1	2	3	4	5
A	Sausage: 183°F	Pepper: 187°F	Egg: 172°F	Sausage: 172°F	Egg: 175°F
B	Potato: 201°F	Potato: 195°F	Pepper: 172°F	Pepper: 184°F	Sausage: 178°F
C	Egg: 178°F	Potato: 195°F	Sausage: 178°F	Potato: 187°F	Egg: 194°F

Example 2

VALIDATION OF MICROWAVE COOKING INSTRUCTIONS:

FROZEN MEAL

Frozen Meal Microwave Oven Validation

Product Sku:
Effective Date:
Page 1 of 1

Product Name:

Storage: Frozen

Serve: Hot

KEEP FROZEN UNTIL READY TO USE.
MICROWAVE COOKING INSTRUCTIONS:
The following instructions are based on an 1100 watt oven set on HIGH. Due to differences in the microwave ovens, heating times may vary.

Recommended Preparation:

From Frozen:

1. Remove from carton; puncture film.
2. Microwave for 2 minutes on HIGH.
3. Remove film and stir.
4. Microwave on HIGH an additional 1 minute. Let stand 1 minute before serving.

CAUTION: PRODUCT WILL BE HOT. COOL 1 MINUTE BEFORE EATING. ENJOY!
DO NOT USE IN TOASTER OVEN. DO NOT REUSE BOWL.

VALIDATION FORM FOR COOKING INSTRUCTIONS

Product Name & SKU:	[Frozen Meal]
Date:	
Oven Type (include brand, model, & serial number):	NA
Or	
Microwave Type (include brand, model, serial number, & wattage):	General Electric Model # JE1860-BH04 Serial # ZL 900 716 U December 2006 Wattage: 1100
Verified Microwave Output	1100 Watts
Thermometer / Probe	Thermapen 5 Probe Thermometer (-58-572°F) Thermoworks Serial # EO652100 Calibrated (+1ºF) and verified prior to use
Calibration Method and Date	SOP-912; November 30, 2007
Copy of validated cooking instructions to be put on the label:	Preparation instructions were developed using an 1100 watt microwave oven set on HIGH. Due to differences in microwave ovens, heating times may need adjustment. 1. Remove from carton; puncture film. 2. Microwave for 2 minutes on HIGH. 3. Remove film and stir. 4. Microwave on HIGH an additional 1 minute. Let stand 1 minute, before serving. KEEP FROZEN UNTIL READY TO USE. CAUTION: PRODUCT WILL BE HOT. COOL ONE MINUTE BEFORE EATING. ENJOY! DO NOT USE IN TOASTER OVEN. DO NOT REUSE BOWL.
Starting (>24 hr) Equilibrated Temperature.	12°F out of freezer

Test 1:
Date:
Microwave Used: GE   Wattage: 1100
Cook Time: 2 min., stir, 1 min.
Stand Time: 1 min.

	A	B	C
1	Egg: 192°F	Saus: 187°F	Pot: 193°F
2	Egg: 194°F	Pot: 190°F	Egg: 191°F
3	Pot: 192°F	Egg: 175°F	Saus: 173°F

Test 2:
Date:
Microwave Used: GE   Wattage: 1100
Cook Time: 2 min., stir, 1 min.
Stand Time: 1 min.

	A	B	C
1	Egg: 188°F	Pot: 192°F	Saus: 180°F
2	Pot: 184°F	Egg: 197°F	Saus: 179°F
3	Saus: 187°F	Pot: 176°F	Egg: 180°F

Test 3:
Date:
Microwave Used: GE   Wattage: 1100
Cook Time: 2 min., stir, 1 min.
Stand Time: 1 min.

	A	B	C
1	Egg: 177°F	Egg: 183°F	Egg: 171°F
2	Saus: 176°F	Pot: 184°F	Egg: 186°F
3	Saus: 167°F	Pot: 175°F	Egg: 169°F

Test 4:
Date:
Microwave Used: GE   Wattage: 1100
Cook Time: 2 min., stir, 1 min.
Stand Time: 1 min.

	A	B	C
1	Egg: 189°F	Egg: 189°F	Saus: 179°F
2	Pot: 195°F	Pot: 196°F	Pot: 188°F
3	Saus: 180°F	Pot: 196°F	Egg: 173°F

Test 5:
Date:
Microwave Used: GE   Wattage: 1100
Cook Time: 2 min., stir, 1 min.
Stand Time: 1 min.

	A	B	C
1	Egg: 188°F	Egg: 187°F	Egg: 185°F
2	Pot: 182°F	Pot: 190°F	Saus: 183°F
3	Saus: 183°F	Pot: 171°F	Saus: 182°F

Test 6:
Date:
Microwave Used: GE   Wattage: 1100
Cook Time: 2 min., stir, 1 min.
Stand Time: 1 min.

	A	B	C
1	Egg: 186°F	Pot: 184°F	Saus: 178°F
2	Egg: 178°F	Pot: 182°F	Saus: 184°F
3	Egg: 192°F	Pot: 190°F	Pot: 189°F

Test 7:
Date:
Microwave Used: GE   Wattage: 1100
Cook Time: 2 min., stir, 1 min.
Stand Time: 1 min.

	A	B	C
1	Pot: 180°F	Saus: 177°F	Pot: 173°F
2	Saus: 175°F	Pot: 167°F	Egg: 167°F
3	Saus: 182°F	Egg: 175°F	Egg: 175°F

Test 8:
Date:
Microwave Used: GE   Wattage: 1100
Cook Time: 2 min., stir, 1 min.
Stand Time: 1 min.

	A	B	C
1	Egg: 188°F	Pot: 184°F	Egg: 175°F
2	Pot: 178°F	Egg: 181°F	Egg: 181°F
3	Saus: 180°F	Egg: 178°F	Saus: 169°F

Test 9:
Date:
Microwave Used: GE   Wattage: 1100
Cook Time: 2 min., stir, 1 min.
Stand Time: 1 min.

	A	B	C
1	Pot: 199°F	Egg: 189°F	Egg: 187°F
2	Saus: 178°F	Egg: 195°F	Saus: 194°F
3	Egg: 185°F	Pot: 182°F	Egg: 179°F

Test 10:
Date:
Microwave Used: GE   Wattage: 1100
Cook Time: 2 min., stir, 1 min.
Stand Time: 1 min.

	A	B	C
1	Egg: 174°F	Pot: 188°F	Saus: 177°F
2	Saus: 167°F	Egg: 192°F	Saus: 183°F
3	Egg: 187°F	Pot: 183°F	Egg: 185°F

Conclusion:
All temperatures exceeded 160°F; instructions validated

Person responsible & title (print):

Signature:

Example 3

VALIDATION OF MICROWAVE COOKING INSTRUCTIONS:

BREADED, MEAT-CONTAINING, INDIVIDUAL SNACK ITEM

Microwave Cooking Instructions Validation Protocol
for
Breaded, Meat-containing, Individual Snack Items

Cooking Instructions Being Validated
Place 6 units on microwaveable plate. Place in center of microwave. Microwave on high for 55 seconds. If not hot, microwave up to 10 seconds longer. Let stand 2 minutes.

Product Considerations
Products were tempered overnight (at a minimum) under conditions typical for consumer freezers (0°F).
Individual product units were weighed to insure they fell within the target weight range.
Plant-produced product was obtained for validation testing.

Microwave Ovens Used in Tests
The test ovens encompassed a range of age, cavity size, and brands, but were all 1000 watts.
Ovens selected included good and poor performing ovens based on past experience.

Test Criterion
All pieces must either reach a temperature of 160ºF or an analysis of time/temperature data must document the equivalent of 160ºF by the end of the 2-minute stand time.

Test Conditions
Pre-tests were run to determine the maximum number of pieces (6) to cook at one time to give best chance of successfully achieving required lethality.
Three different microwave ovens were used, with a minimum of two runs performed in each.
An apparatus containing multiple temperature probes attached to data loggers was used to monitor temperatures of each of 6 individual units for 2 minutes immediately upon removal from the microwave. From a lethality standpoint, this method conservatively measured only part of the heating profile. Lethality also accrued during the microwave cooking step and the time it took to place the items on the temperature probes, but was not counted in this protocol; thus the product units actually achieved more lethality than was measured by this method.
When the results of the first run (Run A) in the two better performing microwave ovens (Microwaves 1 and 2) indicated more than adequate lethality during the 2-minute hold, a decision was made to perform the second and third test runs in these ovens with a 50-second cook rather than a 55-second cook.
When the first and second runs (Runs A and B) in the worst performing microwave oven (Microwave 3) showed that the temperature of one probe in each run did not reach 160ºF during the 2-minute hold, the final run in Microwave 3 was conducted for 60 seconds. Data were then submitted for analysis.

Data Analysis
Inactivation studies were run to determine D and z values of different products. *Listeria monocytogenes* was chosen as the target organism since it is considered the most heat resistant vegetative pathogen reasonably likely to occur in this product. As illustrated in the Validation Data Results that follow, the data set(s) from any probe(s) that did not reach 160ºF and hold that

temperature for a minimum time were mathematically evaluated to assure that the lethality accumulated over the 2-minute stand time was at least equivalent to attaining and holding 160ºF for the required period of time. For this product, the D value required for 1-log reduction of *Listeria monocytogenes* at 160ºF is 2.33 seconds. A 5-log reduction requires 11.65 seconds at 160ºF. Thus successful validation for this product required either that probes reached and held 160ºF for at least 11.65 seconds, or the mathematical analysis yielded an equivalent accumulated lethality at lower temperatures. See Example 1 – Cumulative Lethality, which indicates that the cumulative lethality for the two probes that did not reach 160 ºF (probe 11 in Run A and probe 3 in Run B) both exceeded the required equivalent lethality value for safety.

<u>Cooking Instruction Considerations</u>

Package directions state that a 1000-watt microwave was used for testing.
A range of cooking times would be recommended if there had been great variability in cooking results among the microwave ovens. However, a single cooking time is used (as in this example) when the time required to achieve lethality in the poorest performing microwave oven also yielded acceptable product quality in the highest performing microwave oven.

VALIDATION DATA RESULTS

MICROWAVE 1

Run A - 55 Seconds

Time (Sec.)	Probe 1 °F	Probe 3 °F	Probe 5 °F	Probe 7 °F	Probe 9 °F	Probe 11 °F
0	182.2	181.4	170.1	177.9	192.3	179.4
5	178.5	180.6	170.3	178.7	192.2	180.4
10	174.8	179.3	186.5	180.0	191.2	179.8
15	172.3	178.4	189.5	179.6	190.1	179.2
20	170.5	177.9	187.5	178.8	189.0	178.7
25	169.0	177.6	186.5	177.8	187.9	178.1
30	167.9	177.3	185.7	176.8	186.7	177.5
35	166.8	177.0	184.9	175.8	185.6	177.0
40	165.9	176.7	184.2	174.8	184.5	176.4
45	165.1	176.4	183.6	173.7	183.4	175.8
50	164.3	176.0	183.0	172.5	182.4	175.2
55	163.6	175.6	182.3	171.5	181.4	174.6
60	162.9	175.2	181.7	170.4	180.4	174.0
65	162.3	174.7	181.0	169.5	179.4	173.4
70	161.7	174.3	180.4	168.4	178.4	172.8
75	161.0	173.8	179.8	167.4	177.4	172.2
80	160.4	173.3	179.1	166.3	176.4	171.5
85	159.9	172.8	178.4	165.4	175.5	170.9
90	159.3	172.2	177.8	164.4	174.6	170.2
95	158.7	171.7	177.1	163.5	173.6	169.5
100	158.1	171.1	176.4	162.6	172.7	168.9
105	157.6	170.5	175.7	161.8	171.8	168.3
110	157.0	169.9	175.0	160.8	171.0	167.6
115	156.5	169.3	174.3	159.9	170.1	167.0
120	155.9	168.7	173.6	159.1	169.2	166.3

Run B - 50 Seconds

Time (Sec.)	Probe 1 °F	Probe 3 °F	Probe 5 °F	Probe 7 °F	Probe 9 °F	Probe 11 °F
0	196.7	170.9	200.9	191.5	178.4	179.0
5	198.6	167.1	201.9	191.4	180.4	180.9
10	198.2	164.6	201.2	190.1	180.0	181.1
15	197.3	163.1	200.2	188.5	178.9	180.6
20	196.2	162.1	199.1	186.8	177.7	179.8
25	195.0	161.4	198.1	185.1	176.3	178.8
30	193.6	160.9	197.1	183.5	175.0	177.7
35	192.3	160.5	196.1	182.0	173.8	176.6
40	190.9	160.1	195.2	180.5	172.5	175.4
45	189.6	159.8	194.4	179.0	171.3	174.4
50	188.2	159.5	193.5	177.7	170.2	173.3
55	186.8	159.3	192.6	176.3	169.0	172.2
60	185.5	159.1	191.8	175.0	168.0	171.1
65	184.2	158.9	190.9	173.8	166.9	170.2
70	182.8	158.6	190.1	172.6	165.9	169.2
75	181.6	158.5	189.2	171.4	164.8	168.2
80	180.2	158.2	188.4	170.3	163.9	167.3
85	179.0	158.0	187.5	169.2	162.9	166.4
90	177.7	157.8	186.7	168.1	162.0	165.5
95	176.4	157.5	185.8	167.1	161.0	164.7
100	175.2	157.3	184.9	166.0	160.1	163.8
105	174.1	157.0	184.2	165.0	159.2	163.0
110	172.9	156.7	183.4	164.1	158.4	162.2
115	171.8	156.5	182.5	163.1	157.6	161.3
120	170.7	156.1	181.7	162.2	156.7	160.6

Run C - 50 Seconds

Time (Sec.)	Probe 1 °F	Probe 3 °F	Probe 5 °F	Probe 7 °F	Probe 9 °F	Probe 11 °F
0	184.1	174.1	184.9	183.0	190.1	174.6
5	184.4	176.8	186.4	183.9	193.5	175.3
10	184.4	173.3	185.1	183.4	194.0	174.7
15	183.8	169.3	183.6	182.4	193.5	173.7
20	182.1	167.8	182.0	181.1	192.7	172.6
25	180.5	166.7	180.4	179.8	192.0	171.4
30	178.8	165.8	178.9	178.5	191.0	170.3
35	177.1	164.9	177.6	177.2	190.1	169.1
40	175.5	164.3	176.2	175.9	189.2	168.0
45	174.0	163.7	175.0	174.7	188.3	166.9
50	172.4	163.2	173.8	173.5	187.4	165.9
55	171.0	162.7	172.7	172.3	186.6	164.9
60	169.6	162.3	171.5	171.1	185.7	163.9
65	168.2	161.9	170.5	170.1	184.9	163.0
70	166.9	161.5	169.4	168.9	184.0	162.1
75	165.7	161.2	168.4	167.9	183.2	161.2
80	164.4	160.8	167.5	166.9	182.3	160.4
85	163.3	160.5	166.5	165.9	181.5	159.5
90	162.1	160.2	165.5	164.9	180.7	158.7
95	161.0	159.8	164.6	164.0	179.9	157.9
100	159.9	159.5	163.7	163.0	179.1	157.2
105	158.9	159.2	162.9	162.1	178.3	156.4
110	157.9	158.8	162.0	161.3	177.5	155.6
115	156.9	158.5	161.2	160.4	176.7	154.9
120	156.0	158.2	160.4	159.5	175.9	154.2

MICROWAVE 2

Run A - 55 Seconds

Time (Sec.)	Probe 1 °F	Probe 3 °F	Probe 5 °F	Probe 7 °F	Probe 9 °F	Probe 11 °F
0	199.7	205.8	197.5	154.7	200.4	193.2
5	200.7	205.3	200.6	160.1	201.8	193.6
10	200.0	204.1	200.7	160.9	200.8	193.3
15	199.0	202.6	199.9	161.0	199.4	192.6
20	197.8	201.1	198.9	161.0	197.9	191.8
25	196.5	199.6	197.7	160.8	196.5	190.7
30	195.3	198.2	196.4	160.4	195.0	189.7
35	194.0	196.7	195.1	160.0	193.5	188.5
40	192.7	195.3	193.9	159.5	192.1	187.5
45	191.4	194.0	192.6	159.0	190.8	186.3
50	190.2	192.6	191.4	158.5	189.4	185.2
55	189.0	191.3	190.2	157.9	188.2	184.1
60	187.9	190.0	189.0	157.4	186.9	183.0
65	186.7	188.7	187.9	156.8	185.6	182.0
70	185.6	187.5	186.7	156.2	184.4	180.8
75	184.5	186.3	185.6	155.6	183.2	179.7
80	183.5	185.1	184.5	155.1	182.1	178.7
85	182.4	184.0	183.4	154.5	181.0	177.7
90	181.3	182.9	182.3	153.9	179.9	176.6
95	180.3	181.7	181.3	153.4	178.8	175.5
100	179.4	180.7	180.3	152.8	177.6	174.5
105	178.4	179.6	179.3	152.2	176.6	173.4
110	177.4	178.5	178.3	151.7	175.5	172.3
115	176.5	177.4	177.3	151.1	174.5	171.4
120	175.5	176.4	176.4	150.6	173.5	170.4

Run B - 50 Seconds

Time (Sec.)	Probe 1 °F	Probe 3 °F	Probe 5 °F	Probe 7 °F	Probe 9 °F	Probe 11 °F
0	186.0	188.6	193.9	141.0	185.4	171.6
5	186.2	191.0	194.8	140.7	186.9	173.4
10	185.2	194.3	194.8	*165.78	187.3	174.0
15	184.9	194.3	194.2	163.7	187.2	174.1
20	183.2	193.6	193.4	161.4	186.8	173.9
25	181.7	192.8	192.5	159.5	186.2	173.6
30	180.0	192.0	191.5	158.0	185.5	173.1
35	178.4	191.0	190.5	156.7	184.7	172.5
40	177.0	190.1	189.4	155.6	183.9	172.0
45	175.5	189.1	188.3	154.4	183.0	171.4
50	174.1	188.1	187.2	153.5	182.1	170.8
55	172.7	187.1	186.1	152.6	181.2	170.1
60	171.4	186.1	185.1	151.8	180.3	169.5
65	170.0	185.0	184.0	150.9	179.3	168.9
70	168.8	184.0	182.9	150.2	178.5	168.2
75	167.6	183.0	181.8	149.5	177.5	167.5
80	166.5	182.0	180.8	148.8	176.6	166.9
85	165.4	181.0	179.8	148.1	175.7	166.2
90	164.2	180.0	178.7	147.5	174.8	165.6
95	163.2	178.9	177.7	146.9	173.9	164.9
100	162.1	177.9	176.7	146.3	173.0	164.2
105	161.0	177.0	175.7	145.7	172.1	163.6
110	160.1	176.0	174.7	145.1	171.2	162.9
115	159.1	175.0	173.8	144.6	170.3	162.3
120	158.1	174.0	172.8	144.0	169.4	161.6

* Temperature jump due to need to readjust Probe 7

Run C - 50 Seconds

Time (Sec.)	Probe 1 °F	Probe 3 °F	Probe 5 °F	Probe 7 °F	Probe 9 °F	Probe 11 °F
0	180.0	181.4	182.1	158.1	181.1	192.1
5	180.5	182.6	186.1	160.6	181.6	194.3
10	180.3	182.8	187.6	161.8	181.4	194.4
15	179.8	182.9	188.1	162.4	180.8	193.8
20	179.2	182.7	187.9	162.5	180.0	193.0
25	178.6	182.5	187.4	162.2	179.1	192.0
30	177.8	182.3	186.7	161.9	178.2	191.0
35	177.1	181.9	185.9	161.4	177.3	190.0
40	176.3	181.5	185.1	160.9	176.3	189.0
45	175.6	181.0	184.2	160.2	175.4	188.0
50	174.8	180.4	183.2	159.5	174.5	186.9
55	174.0	179.8	182.3	158.8	173.6	185.9
60	173.2	179.1	181.4	158.1	172.8	185.0
65	172.4	178.4	180.4	157.3	171.9	184.0
70	171.5	177.7	179.5	156.6	171.1	183.0
75	170.7	176.9	178.5	155.9	170.3	182.1
80	169.9	176.2	177.7	155.1	169.4	181.1
85	169.1	175.3	176.7	154.4	168.7	180.2
90	168.3	174.6	175.8	153.6	167.9	179.3
95	167.5	173.7	175.0	152.9	167.0	178.3
100	166.7	172.9	174.0	152.2	166.2	177.4
105	165.8	172.0	173.1	151.5	165.5	176.5
110	165.0	171.2	172.2	150.8	164.7	175.6
115	164.1	170.4	171.4	150.1	164.0	174.7
120	163.3	169.5	170.5	149.4	163.3	173.9

MICROWAVE 3

Run A - 55 Seconds

Time (Sec.)	Probe 1 °F	Probe 3 °F	Probe 5 °F	Probe 7 °F	Probe 9 °F	Probe 11 °F
0	183.0	190.9	169.1	173.5	175.1	148.3
5	186.3	192.6	165.8	174.0	175.7	150.1
10	186.5	193.1	163.1	173.1	175.4	150.7
15	185.9	192.1	162.4	171.8	174.7	151.1
20	185.1	191.0	162.0	170.4	173.8	151.2
25	184.2	189.8	161.7	168.9	172.8	152.6
30	183.3	188.6	161.5	167.5	171.8	152.0
35	182.3	187.4	161.2	166.0	170.8	151.8
40	181.3	186.3	161.0	164.6	169.9	151.6
45	180.4	185.2	160.7	163.2	168.9	151.4
50	179.4	184.2	160.4	161.9	168.0	151.3
55	178.5	183.2	160.1	160.6	167.1	151.0
60	177.5	182.2	159.8	159.4	166.2	150.9
65	176.6	181.3	159.5	158.2	165.3	150.6
70	175.7	180.4	159.1	157.1	164.4	150.4
75	174.8	179.5	158.8	156.0	163.6	150.1
80	173.9	178.6	158.5	155.0	162.8	149.9
85	173.0	177.7	158.0	154.0	162.0	149.6
90	172.1	176.9	157.7	153.0	161.2	149.4
95	171.3	176.0	157.3	152.1	160.5	149.0
100	170.5	175.2	156.9	151.2	159.7	148.7
105	169.7	174.4	156.5	150.3	159.0	148.4
110	168.8	173.5	156.0	149.5	158.2	148.1
115	168.0	172.7	155.6	148.6	157.6	147.8
120	167.2	171.9	155.2	147.8	156.8	147.4

Run B - 55 Seconds

Time (Sec.)	Probe 1 °F	Probe 3 °F	Probe 5 °F	Probe 7 °F	Probe 9 °F	Probe 11 °F
0	188.9	142.3	182.6	173.9	173.6	177.2
5	189.7	144.1	183.8	174.9	175.1	177.6
10	188.9	145.0	183.9	174.5	174.9	177.2
15	187.6	145.3	183.4	173.5	174.3	176.4
20	186.1	145.3	182.7	172.2	173.6	175.6
25	184.6	153.5	181.8	170.9	172.9	174.6
30	183.1	152.3	181.0	169.7	172.1	173.7
35	181.7	151.2	180.0	168.3	171.4	172.8
40	180.3	150.3	179.2	167.1	170.6	171.9
45	179.0	149.4	178.3	165.9	169.9	171.0
50	177.8	148.7	177.4	164.7	169.3	170.1
55	176.6	147.9	176.5	163.6	168.5	169.2
60	175.5	147.1	175.6	162.5	167.8	168.4
65	174.4	146.4	174.8	161.4	167.2	167.6
70	173.5	145.7	174.0	160.4	166.5	166.8
75	172.5	145.0	173.2	159.3	165.8	166.0
80	171.5	144.4	172.4	158.4	165.2	165.2
85	170.6	143.7	171.6	157.5	164.5	164.5
90	169.8	143.1	170.7	156.6	163.9	163.6
95	168.9	142.5	170.0	155.7	163.2	162.9
100	168.0	141.9	169.2	154.8	162.6	162.2
105	167.2	141.3	168.5	153.9	162.0	161.4
110	166.3	140.7	167.7	153.1	161.3	160.7
115	165.6	140.1	166.9	152.3	160.6	160.0
120	164.8	139.6	166.2	151.5	160.1	159.2

Run C - 60 Seconds

Time (Sec.)	Probe 1 °F	Probe 3 °F	Probe 5 °F	Probe 7 °F	Probe 9 °F	Probe 11 °F
0	192.9	186.1	191.5	182.9	164.6	179.7
5	193.3	185.4	191.6	181.8	167.8	179.8
10	193.8	184.1	191.0	180.3	168.1	178.9
15	192.6	182.5	190.1	178.8	167.7	177.7
20	191.4	180.9	189.1	177.3	167.1	176.4
25	190.2	179.4	188.0	175.8	166.4	175.0
30	189.0	177.9	187.0	174.4	165.7	173.6
35	187.8	176.5	186.0	173.1	165.0	172.3
40	186.7	175.1	184.9	171.9	164.3	171.0
45	185.6	173.8	183.9	170.7	163.6	169.8
50	184.5	172.5	182.9	169.5	163.0	168.6
55	183.5	171.3	181.9	168.4	162.4	167.4
60	182.5	170.1	180.9	167.3	161.8	166.2
65	181.4	169.0	179.9	166.3	161.2	165.1
70	180.4	168.0	179.0	165.3	160.6	164.0
75	179.5	166.9	178.0	164.2	160.1	163.0
80	178.6	166.0	177.1	163.3	159.5	162.0
85	177.6	165.0	176.1	162.4	159.0	161.0
90	176.7	164.0	175.2	161.5	158.4	160.1
95	175.8	163.1	174.3	160.6	157.9	159.2
100	174.9	162.3	173.4	159.7	157.4	158.2
105	174.0	161.4	172.5	158.9	156.8	157.4
110	173.2	160.6	171.6	158.1	156.3	156.5
115	172.3	159.7	170.7	157.3	155.8	155.7
120	171.5	159.0	169.9	156.6	155.2	154.8

Cumulative Lethality Evaluation

		Microwave 3 Run A Probe 11			**Microwave 3 Run B Probe 3**	
Time (Minutes)	**Temperature °F**	**Lethality Equivalent [a]** (Sec. at 160 °F)	**Cumulative Lethality Equivalent [a]** (Sec. at 160 °F)	**Temperature °F**	**Lethality Equivalent [a]** (Sec. at 160°F)	**Cumulative Lethality Equivalent [a]** (Sec. at 160 °F)
0	148.3		0	142.3		0
0.083333	150.1	1.018591388	1.018591388	144.1	0.258642566	0.258642566
0.166667	150.7	1.183859054	2.202450442	145.0	0.315210009	0.573852575
0.25	151.1	1.274089686	3.476540128	145.3	0.33954708	0.913399655
0.333333	151.2	1.313711495	4.790251623	145.3	0.342294562	1.255694218
0.416667	152.6	1.810923064	6.601174687	153.5	2.235115653	3.49080987
0.5	152.0	1.598453475	8.199628162	152.3	1.690051738	5.180861609
0.583333	151.8	1.496924857	9.696553019	151.2	1.320687295	6.501548904
0.666667	151.6	1.448771854	11.14532487	150.3	1.073000687	7.574549591
0.75	151.4	1.390272716	12.53559759	149.4	0.879224943	8.453774533
0.833333	151.3	1.345550494	13.88114808	148.7	0.733162089	9.186936622
0.916667	151.0	1.270281578	15.15142966	147.9	0.612209409	9.799146031
1	150.9	1.219270314	16.37069997	147.1	0.514162028	10.31330806
1.083333	150.6	1.160379373	17.53107935	146.4	0.439136969	10.75244503
1.166667	150.4	1.093956366	18.62503571	145.7	0.37290654	11.12535157
1.25	150.1	1.032761406	19.65779712	145.0	0.319153786	11.44450535
1.333333	149.9	0.974989638	20.63278676	144.4	0.273086355	11.71759171
1.416667	149.6	0.912851219	21.54563798	143.7	0.235559162	11.95315087
1.5	149.4	0.861787122	22.4074251	143.1	0.204833035	12.15798391
1.583333	149.0	0.800202677	23.20762778	142.5	0.176603782	12.33458769
1.666667	148.7	0.743019138	23.95064691	141.9	0.153214546	12.48780223
1.75	148.4	0.695664754	24.64631167	141.3	0.134183773	12.62198601
1.833333	148.1	0.644614396	25.29092606	140.7	0.117814841	12.73980085
1.916667	147.8	0.598963006	25.88988907	140.1	0.103133558	12.84293441
2	147.4	0.546134988	26.43602406	139.6	0.091706475	12.93464088

[a] z value = 12.98 °F

Example 4

VALIDATION OF MICROWAVE COOKING INSTRUCTIONS:

FOR A PATTY PRODUCT

NRTE Validation
for a Patty Product

Package has separate cooking instructions per microwave class. Medium and high wattage microwave cooking instructions are validated using five replicates each in four microwave ovens. Although no observation is less than 160 degrees, the low wattage class cooking instruction validation does not pass. Sample size, average and standard deviation lead us to predict 8.4% of the population of all low wattage microwave oven trials will have a cold spot less than 160 degrees.

Temperature Data Validation Test of Cooking Instructions:
Students t-distribution is appropriate for evaluating small samples

	Wattage Group	N	Avg	Stdev	Predicted %<160	Minimum Observed	
Cook Time 2:15	Low 700W	20	179.9	13.9	8.4%	160	
Cook Time 1:45	Medium	20	193.5	6.9	0.0%	180	Pass
Cook Time 1:30	High	20	190.4	9.3	0.2%	176	Pass

Validation Example: New Product XXX
Low Wattage Class 700-800
Cooking Instruction= 2 min 15 sec on High

Oven	Cold Spot
LW 1, 700	182
LW 1, 700	183
LW 1, 700	171
LW 1, 700	169
LW 1, 700	205
LW 2, 700	178
LW 2, 700	160
LW 2, 700	165
LW 2, 700	170
LW 2, 700	172
LW 3, 700	168
LW 3, 700	165
LW 3, 700	172
LW 3, 700	182
LW 3, 700	180
LW 4, 700	204
LW 4, 700	202
LW 4, 700	190
LW 4, 700	179
LW 4, 700	201
Count	20
Average	179.90
Standard Deviation	13.90
Minimum Observed	160

Validation Example: New Product XXX
Medium Wattage Class >800-1100
Cooking Instruction= 1 min 45 sec on High

Oven	Cold Spot
MW 1, 1000	188
MW 1, 1000	180
MW 1, 1000	195
MW 1, 1000	197
MW 1, 1000	196
MW 2, 1000	182
MW 2, 1000	199
MW 2, 1000	198
MW 2, 1000	199
MW 2, 1000	181
MW 3, 1100	186
MW 3, 1100	190
MW 3, 1100	195
MW 3, 1100	193
MW 3, 1100	197
MW 4, 1100	195
MW 4, 1100	192
MW 4, 1100	202
MW 4, 1100	202
MW 4, 1100	202
Count	20
Average	193.45
Standard Deviation	6.91
Minimum Observed	180

Validation Example: New Product XXX
High Wattage Class >1100
Cooking Instruction= 1 min 30 sec on High

Oven	Cold Spot
HW 1, 1150	178
HW 1, 1150	177
HW 1, 1150	194
HW 1, 1150	176
HW 1, 1150	186
HW 2, 1200	176
HW 2, 1200	186
HW 2, 1200	192
HW 2, 1200	193
HW 2, 1200	182
HW 3, 1300	192
HW 3, 1300	188
HW 3, 1300	185
HW 3, 1300	195
HW 3, 1300	202
HW 4, 1350	199
HW 4, 1350	199
HW 4, 1350	204
HW 4, 1350	201
HW 4, 1350	202
Count	20
Average	190.35
Standard Deviation	9.33
Minimum Observed	176