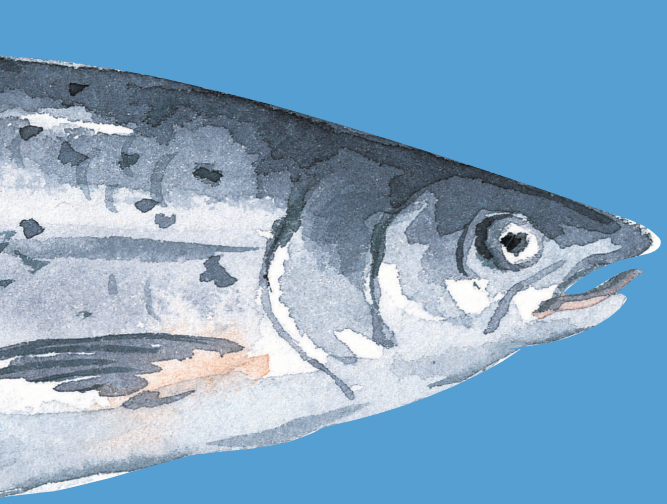
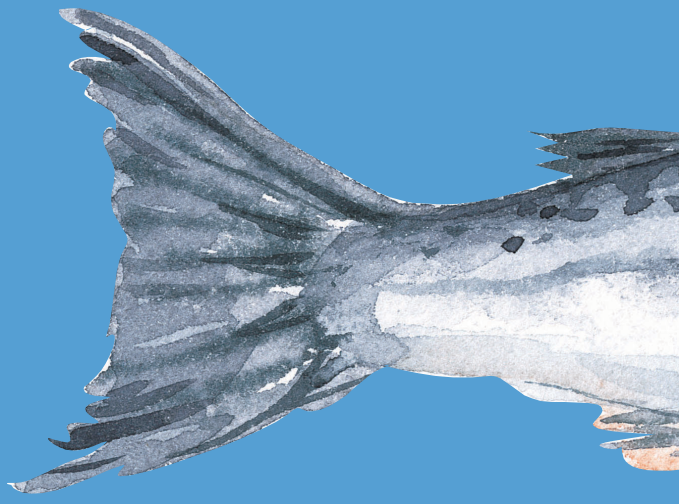
FPA GUIDANCE DOCUMENT:

Establishing or Verifying A Heat Process for Cooked, Ready-to-Eat Seafood Products, and Heat Process Monitoring Considerations Under HACCP

Joe Frazier





Second Edition

FPA
FOOD PRODUCTS ASSOCIATION

FPA Guidance Document: Establishing or Verifying A Heat Process For Cooked, Ready-to-Eat Seafood Products, and Heat Process Monitoring Considerations Under HACCP

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I. Introduction

Many types of seafood products are heat processed by cooking, pasteurizing, smoking, etc., to produce a ready-to-eat (RTE), perishable seafood product that is stored/distributed in either refrigerated or frozen form. Cooked crabmeat, crab sections, lobster, crawfish, shrimp, pasteurized surimi seafoods (*i.e.*, imitation crabmeat), seafood soups and chowders, and hot-smoked fish are a few examples. Since these RTE products may be consumed "as is" or with little/minimal preparation, pathogens that survive the heat process can pose a serious health risk to the consumer. For this reason, FDA guidance states that, first and foremost, the heat process used in the production of a RTE, perishable seafood product must be adequate to reduce potential pathogens present to a safe level (*1*). Further, FDA guidance makes clear the expectation that processors conduct a "scientific study" to establish and/or verify the adequacy of the heat process, to provide documentation that the heat process delivers the proper degree of destruction to proper target pathogen of concern; and that HACCP critical limits (CLs), controls, and monitoring procedures for the heat process step are defined and implemented appropriately, based on the results of the study.

The purpose of this document is to provide additional guidance and assistance to seafood processors in systematically designing and conducting a "scientific study" to establish and/or verify the adequacy of a heat process used for producing a RTE, perishable seafood product. This document also provides guidance for setting appropriate HACCP CLs based on the study results, and for implementing adequate monitoring procedures for the heat process and other critical factors of the process, consistent with both FDA guidance and recognized scientific principles and practices of thermal processing.

II. Applying Principles of Thermal Processing

Although the history of thermal processing or canning of foods can trace its roots back to 1810, it wasn't until around 1870 that early scientists began to truly understand the science of thermal processing (*2*). It was then that Louis Pasteur demonstrated the role that certain microorganisms (bacteria, yeasts, and molds) played in food spoilage and fermentation. Pasteur showed that the microorganisms responsible for spoiling perishable foods could be destroyed by a mild heat treatment; and if the food were packaged to avoid recontamination, it would remain preserved and unspoiled. The term "pasteurization" was borne out of his work. Not long after, it was shown that certain microorganisms were also capable of causing foodborne disease (the bacterial spore was discovered in 1876). The science of thermal processing advanced rapidly thereafter, and included studies that defined the heat resistance of numerous food spoilage and pathogenic bacteria, and the time-temperature parameters necessary for their destruction. It was also observed that microorganisms exposed to lethal temperatures die at a constant rate (logarithmic), which led to the development of mathematical expressions to predict the time and temperature necessary to destroy microorganisms under a different sets of time-temperature conditions.

The principles of thermal processing first described nearly a century ago still form the basis for establishing thermal processes for food today. Data on the rate of product heating (heat penetration, or HP) is combined with thermal death time data (TDT, or heat resistance data) for a particular target microorganism in the product, to mathematically calculate a "safe" time-temperature heat process. For this reason, when undertaking a study to establish or verify a heat process for a RTE seafood product, some general knowl-

edge and information in the area of thermal processing science is needed. *Appendix 1* contains some of the thermal processing terms and definitions used in this guidance document that processors should be familiar with, as they will be useful when establishing and/or verifying the heat process (*3*).

III. General Considerations for Heat Process Establishment and/or Verification

There are basically four questions that a seafood processor must answer with respect to establishing and/or verifying a heat process for a RTE, perishable seafood product, and for adequately controlling the process:

1. What is the pathogen of concern in the product?
2. What is considered a "safe level of reduction" for the target pathogen(s) of concern?
3. Exactly how to determine whether or not the heat process is actually delivering the right amount of heat to the product, in order to achieve the necessary level of pathogen reduction?
4. What HACCP controls—critical limits, monitoring procedures, etc.—should be in place to ensure that the heat process consistently delivers the proper amount heat to the product?

The answers to questions 1 and 2 can be quickly discerned from existing FDA guidance[1]. Regarding question #1, selecting the target pathogen of concern is a critical decision; and in most cases, will be dictated by the packaging style and the method of storage/distribution of the finished product, as follows:

- *L. monocytogenes* is the target organism of concern for RTE perishable products that are either:
  (a) packaged in *air*, and stored/distributed in either refrigerated *or* frozen form, or
  (b) packaged in reduced oxygen atmosphere packaging and stored/distributed in *frozen* form only.
- Non-proteolytic *C. botulinum* type B is the target pathogen of concern for RTE perishable products that are contained in/packaged in reduced oxygen atmosphere packaging[1] and stored/distributed in *refrigerated* form.

Regarding question #2, FDA guidance states that, in most cases, an acceptable, safe heat process is one designed with enough "lethal power" to reduce the target pathogen by a minimum of six orders of magnitude (*i.e.*, 6 logarithms). This is typically referred to as a "6D process" (see D-value definition in *Appendix 1*). Thus, when a heat process is described as being "6D", it means the lethality of the process is sufficient to reduce the target organism in numbers by 99.9999%, or 6 log cycles. Lower degrees of destruction may be acceptable, if supported by a scientific study of the normal population of the target pathogen in the particular product. FDA also recognizes that for certain specific products, there is scientific evidence demonstrating that the target pathogen can be controlled by the use of a milder heat process in combination with other "barriers" present in the product (*e.g.*, water-phase salt level). FDA considers such alternatives "equivalent" to a 6D heat process control strategy. Further discussion of both acceptable 6D process control strategies and alternative, equivalent control strategies for *L. monocytogenes* and non-proteolytic *C. botulinum* type B, will occur later, in the section dealing with analyzing product heat penetration data, and determining process lethality and HACCP control strategies.

Probably the biggest challenge for processors of heat treated, RTE perishable seafoods lies in finding answers to questions 3 and 4 above; and most of the remaining discussion within this document focuses on guiding processors through the practical steps and procedures necessary to answer these two questions.

A scientific study to establish and/or verify the adequacy of a heat process for a RTE, perishable seafood product, must demonstrate that the proper heat process is delivered to each unit of product; and hence, must be designed and conducted appropriately. When done correctly, the study should demonstrate that the slowest heating unit/portion of product under the worst set of heating conditions receives the lethality needed to achieve a minimum

[1] See reference 1. Examples of reduced oxygen atmosphere packaging environments are found in FDA Guidance, Ch. 13, page 168.

6D reduction of the target pathogen. In general, the steps involved with establishing and/or verifying the heat process are:

1. **Designing a study that adequately and accurately considers all of the factors/conditions that affect the rate of product heating.**

    - This requires knowledge and information on (a) the type of heat processing system, (b) the heating medium employed (*e.g.*, hot water, pure steam, etc.), (c) the temperature distribution (TD) within the system, and (d) how the equipment is designed, operated, and maintained, including how product is loaded into heating unit. All of these factors could affect the adequacy of the heat process delivered to the product. Characterizing and verifying the TD uniformity within the heating system is essential to the study design, since the existence of "cold spots" will influence the rate of heat penetration into the product. Since heat process systems can come in a variety of shapes and sizes, and use different heating mediums, study design will be system-specific in most cases; and where substantially different types/styles and/or heating media are employed, more than one heat process system study may be needed.

2. **Conducting the study, by gathering data on the rate of product heating.**

    - Product heat penetration (HP) data is gathered, under a specific set of processing conditions, to ascertain information on the heating characteristics of the system itself, the product, and even the container (if applicable). TD data is also collected, and may be done either prior to or concurrent with collecting product HP data.

3. **Analyzing the data and determining the lethality of the heat process.**

    - The data collected in Step 2 must be analyzed to determine if the proper lethality (6D minimum) has been delivered to all units of product, and to assess what the minimum heating time/temperature requirements for the process will be. For determining the total lethality of the heat process, information is needed on the heat resistance of the target microorganism in the product. This information may be available for a variety of different seafood products from existing scientific literature. Where this information is not available, thermal death time (TDT) studies may be needed to determine the product-specific heat resistance of the target organism.

4. **Establishing HACCP CLs and controls for the heat process.**

    - The results of the lethality calculations are used, together with information on the actual conditions of the product HP test, to establish appropriate HACCP CLs for the heat process that, when adhered to, will ensure delivery of a 6D process to each and every unit of product. This also includes establishing CLs for other critical factors/conditions of processing and/or packaging that have been identified as affecting the adequacy of the heat process. Appropriate monitoring procedures must also be established, and implemented with sufficient frequency to ensure the CLs are met. Of course, establishing appropriate HACCP CLs, monitoring procedures, etc. applies for those specific products where FDA has recognized an alternative control strategy considered equivalent to a 6D process control strategy.

IV. Heat Process Study Design and Execution, and Accounting for Factors That May Affecting the Rate of Product Heating

Temperature Distribution Test Design Considerations:

Generally, before product HP testing is done, the TD uniformity within the heating system needs to be defined and characterized. TD information is collected using temperature-measuring devices called "thermocouples" (TCs) that are positioned in various locations within the heating system. Where continuous heat processing systems are employed, wireless TC devices (*i.e.*, temperature dataloggers) are particularly useful gathering TD data; and even for some product HP testing applications.

Depending upon the type and size of the heat processing system, several test runs should be made to profile its temperature distribution. Generally, TD testing should be done under *full load conditions* for the system, as this typically represents worst case with respect to TD uniformity. The data must then be analyzed to determine if any "cold spots" exist in the heating system, *i.e.*, areas or regions within the unit that show a slower heating trend (lower temperature profile) compared to the other areas tested. If a cold spot is identified, it is important that subsequent product HP testing be done in this area or region of the heating system.

For example, for testing a continuous conveyance, pure steam pasteurization system having a 12-ft. wide stainless mesh belt, several wireless TC devices should be placed directly on the belt, in between packaged product, and spread out along its width. The relative "spread" of the dataloggers among the packages might be as follows: one at/near the middle of the belt, one near the left edge of the belt (within 6–8 inches of the edge, for example) and a 3rd datalogger near the right edge of the belt. After the wireless TCs have been conveyed through the pasteurization unit, the data is downloaded to a computer and analyzed to determine temperature uniformity, and to identify if any cold spots exist. If, for example, the temperature data shows that one side of the conveyor belt in particular is consistently 4–5°F lower in temperature compared to the other areas tested, then subsequent product HP testing would be conducted in that "low temperature area" of the pasteurizer belt.

While TD testing is generally done prior to product HP testing, it can be done concurrently, provided there are enough TCs available to undertake both tests simultaneously. An adequate number of test runs must be conducted to simultaneously determine both the adequacy of the TD within the system and the slowest heating product. Doing concurrent TD and product HP testing may be more efficient and/or cost effective for the processor, depending on the circumstances (*e.g.*, resource and/or product availability, length of a particular seasonal fishery, etc.).

The processor should bear in mind that major changes to the heat process system (*e.g.*, changing the size of the unit, modifying the hole sizing and/or spacing on a steam spreader/distributor system, etc.) may negatively impact the adequacy of the TD within the system. This, in turn, may negatively impact (*i.e.*, slow down) the rate of product heating, which could ultimately affect achieving the proper process lethality. Changes to *related* production operations may also impact TD, such as product/package size, product loading patterns, changes to custom-built product holding trays/baskets, conveyor belts with substantially different perforation or mesh size, etc. The processor should evaluate any such changes to determine the potential (negative) effect on adequate TD, and on the adequacy of the heat process to deliver the proper lethality to the product.

It is also important to have a prerequisite, preventive maintenance program in place, which includes periodic inspections of the system components involved in the distribution/circulation of the heating medium (*i.e.*, hot water pumps, steam spreaders and perforations, etc.) to ensure adequate TD is being maintained.

Processors unfamiliar with designing and conducting TD tests may wish to consult with a process authority, to ensure their test protocol takes into account the worst case heating conditions of the heating system (*4*).

Product Heat Penetration Test Design Considerations:

Gathering product HP data is also done using thermocouples, with the TC being positioned in the slowest heating area/portion of product. For conduction heating products such as crab, shrimp, surimi analogs, etc., the slowest heating area/portion of product will generally be the geometric center (center core) of the product at its thickest

point (*e.g.*, in the shoulder section of a crab cluster or at the center core of a vacuum-packaged surimi seafood product). For products that heat by a combination of convection/conduction heating, such as formulated seafood soups or chowders that contain cut/minced seafood particles and perhaps other vegetable pieces (*e.g.*, diced potatoes, carrots, celery, etc.), the slowest heating area/portion of product is generally at geometric center of the largest solid food particle present, located approximately one-fourth of the way up from the bottom of the container. For such products, the tendency for food particles/pieces to clump or mat together should also be considered.

In general, a somewhat conservative approach should be followed in designing the product HP study, in order to show that the *slowest* heating unit/portion of product under the defined set of specific heating conditions receives the appropriate lethality necessary to control the target microorganism.

When conducting the product HP tests, attention must be paid to the specific set of heat system operating conditions, since this information will need to be considered when subsequently establishing HACCP controls for the heat process. However, besides simply product heating time and temperature, the rate of heat penetration into the product may be influenced by a number of other conditions or "critical factors" related to the processing or packaging of the particular product. These other identified critical factors need to be given due consideration in designing and conducting the HP tests, since appropriate HACCP CLs, monitoring procedures, etc. will be required for them as well. Some examples of critical factors that may affect the rate of product HP may include, but are not limited to:

- the TD uniformity within the heating system,
- the initial temperature (IT) of product,
- the size/shape, thickness, density or "mass" of product,
- the product preparation/formulation (particularly as it affects the percent solids)

As with TD testing, processors that are not familiar with designing and conducting product HP tests may wish to consult with a process authority when developing their test protocol (*4*).

Initial Temperature (IT) of Product and Size or Thickness of Product:

The starting temperature of the product—or the "initial temperature" (IT)—will influence the rate of product heating. Other factors affecting product HP being equal, a product with a lower IT (*e.g.*, 35°F) will heat more slowly (and thus, reach the desired 6D reduction end point more slowly) compared to a product that begins with a warmer IT (*e.g.*, 50°F).

Similarly, thicker and/or denser products heat more slowly. For example, a shrimp processor using a continuous conveyance belt cook system needs to consider not only the size of the individual shrimp, but also how deep the pile of shrimp is on the cook belt. A crab processor will need to consider the packing configuration of the individual sections or clusters of product in the cooking baskets or cages. In some cases, even before performing the actual product HP tests to determine process lethality, preliminary testing to determine the true "cold spot" in irregularly shaped products and/or product packing configurations may be necessary.

Product Preparation/Formulation:

For seafood products such as surimi seafood products, soups and chowders, etc., product formulation and/or preparation may affect the rate of product HP. For example, in formulated products that heat by conduction, as a general rule, new product HP data should be generated for new or revised formulation resulting in a 5% increase or more in solids contents (*i.e.*, a drier product) compared to the original formulation. Other examples of product formulation/preparation procedures that may affect the rate of product heating include:

- Soup/sauce viscosity
- Particle size
- Particle tendency to clump or mat together
- Fill weight
- Solids-to-liquid ratio

There may be others depending upon the product.

IN SUMMARY, it is recommended that a *conservative* study be designed to demonstrate the adequacy of the heat process—one that accounts for the worst case conditions that could be encountered in the process, including those factors that commonly influence rate of product heating; and should include:

- the coldest portion/region within the heating system (under full load conditions),
- the lowest heat process temperature,
- the shortest heat process time,
- the coldest (lowest IT) product,
- the thickest (or largest mass) product, and
- product preparation/formulation (if applicable)

In designing the study, it may be possible, or even desirable at times, to set up extremely conservative, artificial test conditions for certain factors that affect the rate of product HP, such that the condition(s) would never exist in the actual processing environment. The reason for designing the study in this manner would be to exclude the factor from being considered a "critical" factor of the heat process; and thus eliminating the need to establish HACCP-based controls for it. For example, if inherent in the process is the fact that the IT of the product never falls below 50°F, then conducting product HP tests using refrigerated product (*e.g.*, 38–40°F) would be justification enough to exclude IT as a critical factor of the heat process, since the artificially created condition would never occur during "real" production.

Similarly, the existence of inherent equipment design, or other self-limiting or self-controlling conditions of the process itself, may preclude an otherwise critical factor from having to be considered. An example of this might be the inherent design of certain makes/models of vacuum packaging equipment using top and bottom roll-stock, poly plastic film, which might be used in the production of a pasteurized, surimi seafood product. For certain models, the thickness of the package is defined by the depth of the filling pocket, which is physically self-limited to the depth of the metal forming heads on the equipment itself; such that a certain maximum package thickness cannot be exceeded and still maintain a proper package seal/seam integrity. Thus, if the thickest packages of product that the metal forming heads are capable of producing were used in the product HP study, this would be justification enough to exclude package thickness as a critical factor of the process, since the equipment itself precludes thicker packages from being made. In this example, a prerequisite program should be in place that ensures the vacuum packaging equipment is set to the appropriate package size/specification.

Finally, when performing TD and product HP tests, proper records are essential. It is important to record all relevant information about the test and potential critical factors discussed above, including those test conditions involving the set-up and operation of the pasteurization process system equipment. While it is not possible to list all possible types of information that may be needed, the processor may wish to consider the following list of test parameters to record:

- Test date and test ID,
- Name(s) of individual(s) conducting the test,
- Description of the heating system and heating medium,
- Product or product style,
- Product preparation/formulation, including viscosity, percent solids, fill procedure & weight, etc., if applicable,
- Product or package size, type, and thickness,
- Test product or package ID and corresponding thermocouple ID,
- Thermocouple position in the product,
- Initial temperature of product,
- Pasteurization system operating parameters or settings,
- For TD tests, a record that "maps" the locations of the various thermocouples in the system.

V. Analyzing the Product Heat Penetration Data and Determining Process Lethality

Calculating the Total Lethality of a Heat Process:

The total lethality, or total "F-value", of a heat process against a particular target pathogen can be calculated using what's known as the General Method (GM) (*5,6*). The GM is the reference method for all other thermal process calculations (*e.g.*, Ball formula method). The GM utilizes time/temperature data obtained directly from product HP testing, coupled with heat resistance information for the target pathogen (*i.e.*, D- and z-values, as determined by thermal death time, or "TDT" studies) to directly calculate the total F-value of the heat process.

The GM takes full advantage of the additive or "cumulative" lethal effect of the heat process, that is, it maximizes the total F-value by taking into account all lethality accumulated under the heat penetration curve, during both the heating and cooling phases. As a result, by using the GM calculation, the heat process time/temperature can usually optimized; in turn, optimizing process throughput, minimizing undesirable quality changes from overcooking, etc., which is to the processor's benefit. The lethality may be calculated for any portion of the heating phase or cooling phase of a process. However, for reasons that will be discussed later, it is generally recommended that lethality accumulated during only the process of *heating* the product be considered when determining whether or not the minimum 6D process lethality has been achieved (*i.e.*, potential lethality contributed from the product cooling step of the process should *not* be considered in the total F-value calculation).

Since the area under the HP curve cannot be easily integrated directly over time, the GM uses a summation technique to approximate the solution, *i.e.*, the total (cumulative) F-value. This involves breaking down the area under the heat penetration curve into smaller "time segments of heating", and calculating the lethality for each segment or section using the following formula:

$$\text{Lethality (F-value)} = (\text{Lethal Rate}) \times (\text{time})$$

$$\text{where: Lethal Rate} = \log^{-1}[(T - Tr)/z] = 10^{[(T - T_r)/z]}$$

T = Product Temp (in °F)

T_r = Reference Temp (in °F)

z = z-value (in °F)

Although there are a couple of variations of GM mechanics, the "trapezoidal" GM calculation described by Patashnick (*6*) is preferred. This method is relatively simple and easy to use for HP data that has been collected at *even time intervals*, and optimizes the lethality accumulated under the heating curve (although there is a small amount of lethality unaccounted for). The lethal rate is determined for each time interval; either calculated using the above equation or its value looked up in reference table. The lethality for the time intervals, and the total F-value of the process, is calculated using the following formula:

$$F = t \left\{ \frac{(L_0 + L_1)}{2} + \frac{(L_1 + L_2)}{2} + \ldots + \frac{(L_n + L_{n+1})}{2} \right\}$$

where: t = time interval (in minutes)

L_0 = lethal rate calculated at "time/temp. 0" (the IT of the product immediately prior to entering the heating system/unit. The lethal rate is usually zero at time/temp. 0)

L_1 = lethal rate at heating time/temp. 1,
L_2 = lethal rate at heating time/temp. 2, etc.

L_n = lethal rate at last heating time/temp.

L_{n+1} = lethal rate for 1st cooling time/temp.

Using the above formulas, the total cumulative F-value of a heat process can be calculated fairly easily, using a number of readily available computation or "spreadsheet" PC programs (Excel, Lotus, etc.). *Table 1* provides an example of a total (cumulative) F-value calculation, for the heating phase only, for a refrigerated, vacuum packaged pasteurized imitation crabmeat product, where non-proteolytic *C. botulinum* type B is the target organism of concern. It should be noted that the example in *Table 1* uses 2 different z-values when calculating the lethal rate for any given time interval[2],

[2] See reference (7). For lethal rate calculations for target organism n-p *C. botulinum* type B: z = 12.6°F when product temperature (T) is less than reference temperature (T_r) = 194°F ; and z = 18.0°F when T is greater than T_r.

however, in most cases, calculations involve using a single z-value, particularly if the target organism involved is *L. monocytogenes*.

The results of the lethality calculations, together with information regarding the actual test conditions and other critical factors identified as affecting the rate of product heating, must be considered when establishing HACCP CLs for the heat process, since adhering to such conditions is paramount to ensuring delivery of a 6D process lethality to each and every unit of product. Processors must keep in mind that the GM total F-value calculation is dependent upon the *specific set of conditions* used to generate the product HP data. This is why, as mentioned earlier, it is advisable to design and conduct the product HP tests under conservative test conditions, since HACCP CLs, monitoring procedures, etc. may need to be established for some or all of these conditions.

Section VI includes a more detailed discussion of setting appropriate HACCP CLs, monitoring procedures, etc. based on the product HP data and total F-value calculations.

Heat Process Lethality and Target Organism Control Strategies:

As mentioned earlier, determining the total F-value of a heat process requires information on the heat resistance of the target microorganism in the product (*i.e.*, D- and z-value); so it can, in turn, be determined whether or not a 6D process lethality is achieved. Where product-specific heat resistance data is not available for the target organism from previous TDT studies, FDA has provided a wide range of recommended process times/temperatures adequate to achieve a 6D process for *L. monocytogenes* and non-proteolytic *C. botulinum* type B. These recommendations can be found in *Tables #A-3* and *#A-4*, *Appendix 4*, of the FDA *Fish & Fishery Products Hazards* and *Controls Guidance*, respectively (*7*). The processes listed in both tables are correctly based on conservative heat resistance data for these two target pathogens, in order to account for their possible heat resistance variation in different seafood products. Both tables are best described as "equivalent F-value" or "equivalent lethality" process tables, since the process time/temperature recommendations contained therein represent the equivalent number of minutes, at a given reference temperature and z-value, to provide for a 6D process. For example, from the time/temperature processes listed in *Table #A-4*, for control of non-proteolytic *C. botulinum* type B, it can be seen that a heat process with a total $F_{185°F}$ ($F_{85°C}$) = 51.8 minutes is *equivalent* to a process with a total $F_{194°F}$ ($F_{90°C}$) = 10 minutes.

For the pathogen *L. monocytogenes*, product-specific D- and z-value data exists for many different seafood products, and is summarized in the scientific review paper by Doyle, *et al.* (*8*). Therefore, when appropriate, the product-specific heat resistance data described in this scientific paper may be used to calculate the total F-value of the heat process, and for determining the appropriate time/temperature necessary to achieve a 6D process for control of *L. monocytogenes*, in lieu of using one of the more conservative time/temperature processes recommended by FDA in *Table #A-3*. By using product-specific D- and z-value data and the equations found in *Appendix 1*, a processor could develop its own "equivalent F-value" table for that particular product, for a wide range of process times/temperatures adequate to achieve a 6D process for control of *L. monocytogenes* (similar in appearance to FDA guidance *Table #A-3*).

Conversely, there is little information in scientific literature on the product-specific heat resistance for non-proteolytic *C. botulinum* type B for different seafoods, with the exception of codfish and dungeness crabmeat. FPA is currently conducting TDT studies that will describe the heat resistance of non-proteolytic *C. botulinum* type B in surimi seafood product (*i.e.*, imitation crabmeat). However, until this and other product-specific TDT studies are completed, processors that need to employ a 6D process control strategy to control non-proteolytic *C. botulinum* type B in the product must use the time/temperature processes recommended by FDA guidance and FDA *Table #A-4* (*1,7*), as follows:

- **Heating product to achieve a minimum, total (cumulative) lethality, $F_{194°F}$ ($F_{90°C}$) = 10 minutes, or equivalent.**

This control strategy can be applied to most "generic" heat-processed, refrigerated RTE seafood products contained in a reduced oxygen atmosphere package, with the exception of dungeness crabmeat.

For pasteurized, refrigerated dungeness crabmeat product, adequate 6D time/temperature processes should be developed using the product-specific heat resistance data (D- and z-values) for non-proteolytic *C. botulinum* type B deter-

mined by Peterson *et al.* (*9*), in lieu of the processes listed in FDA in Table #A-3, as follows:

- **For dungeness crabmeat, the product should be pasteurized to achieve a minimum, total cumulative lethality, $F_{194°F}$ ($F_{90°C}$) = 57 minutes (z = 15.48°F), or equivalent.**

As previously mentioned, FDA also recognizes that non-proteolytic *C. botulinum* type B can be adequately controlled *in certain specific products* by *other* alternative process control strategies, considered to be "equivalent" to the 6D control strategy mentioned above (*1*). FDA recognizes three such alternative control strategies; two of which are accomplished by the use of a milder heat process in combination with other barriers present in the product. These alternative control strategies can be summarized as follows (for refrigerated product contained in a reduced oxygen atmosphere package):

- **For blue crabmeat, pasteurizing the product to achieve a minimum, total cumulative lethality, $F_{185°F\ (F85°C)}$ = 31 minutes (z = 16°F), or equivalent.**
- **For a surimi-based seafood product that contains a minimum 2.4% water-phase salt (WPS)[3], pasteurizing the product to a minimum internal temperature of 185°F and holding it at or above this temperature for at least 15 minutes.**
- **For a hot-smoked fish product that contains a minimum 3.5% WPS (in the loin muscle), hot smoking the product to a minimum internal temperature of 145°F and holding it at or above this temperature for at least 30 minutes.**

Note that for the last two product-specific alternative control strategies, calculating the total F-value is not even necessary. Instead, the time/temperature data obtained directly from product HP test(s) must simply be analyzed to determine the number of minutes that the product is at or above the minimum required temperature. Processors should keep in mind that even when employing one of these alternative, equivalent control strategies, the basic concepts previously discussed for establishing and/or verifying the process need to be followed (*i.e.*, properly designed/conducted TD and product HP studies, to account for slowest heating product under the worse case heating conditions, including identifying other critical factors/conditions that affect the adequacy of process). It should also be recognized and understood that when employing either of these last two alternative control strategies, it is also necessary gather and conduct data analysis on the %WPS content in the product, and to identifying appropriate critical factor(s) and corresponding HACCP controls needed to achieve and maintain the minimum %WPS content (*i.e.*, 2.4% for surimi analog and 3.5% for hot smoked fish, respectively).

Similarly, total F-value calculations may not be necessary when *L. monocytogenes* is the target organism of concern, but this ultimately depends upon the processor's choice of HACCP CLs established for the process, and how conservative the CLs are with respect to achieving the minimum 6D process lethality. An example of this will be discussed later in *Section VI*.

Potential Lethality Attributed by the Cooling Phase:

When calculating the total F-value of the process, it is generally not recommended to include any potential lethality contributed by the "cooling" phase of the process, *i.e.*, lethality that may still accumulate after exiting the heat process due to a significant amount of heat still present in the product. There are several reasons for this. First, it is important to cool the product as rapidly as possible, to minimize the potential for heat tolerant microorganisms that may survive the heat process from growing (*e.g.*, injured cells of thermo-tolerant yeasts and molds, heat-resistant spores of *Bacillus* spp. or proteolytic *Clostridium* spp., etc.), and potentially causing a food safety hazard or a reduction in product shelf life. Therefore, the focus should be on attaining the necessary total lethality for the product from the heating phase only. Secondly, by excluding any potential lethality contributed by the cooling phase, the advantage to the processor is two-fold:

1. there is a inherent "safety factor" built in to the process, that provides not only additional assurance of process

[3] It should be noted that the current FDA *Fish and Fishery Products Hazards and Control Guide, 3rd Ed.*, lists "2.5% salt", but should state "2.4% water-phase salt" in surimi-based products using this alternative control strategy. It is FPA's understanding that this will be corrected in the next edition of the FDA guide.

adequacy, but which may also be an important consideration if heat time/temperature deviations were to occur; and

2. only the heating phase of the process will require subsequent HACCP control/monitoring, to assure that the minimum 6D process lethality is achieved.

There may be certain situations, however, where the processor deems it necessary, or even desirable, to include some or all of the lethality contributed by the cooling process in the total F-value calculation, for achieving the minimum 6D process. In some seafood operations, the product "cooling process" is often accomplished in two phases, actually: first, a brief period of "ambient air" or room temperature cooling (perhaps several minutes), which is followed by a longer but more rapid cooling step where ice and/or mechanically chilled media is used (*e.g.*, chilled water bath, refrigerated air blast, etc.). Remembering that the goal is to cool the product as rapidly as possible, when the processor must rely on using some of the lethality contributed by the cooling process, only the lethality contributed by the *ambient air/room temperature cooling phase* should be considered in the calculation, as this will be the most significant contributor to the total F-value. Little, if any, "lethal" heat remains in the product once it has come into contact with ice or some type of mechanically chilled cooling medium.

If it is absolutely necessary to include any/all potential lethality contributed by mechanical chilling phase in meeting a 6D process lethality, then a study to establish and/or verify the adequacy of the cooling process is also necessary (*i.e.*, conducting TD and product HP tests), to ensure the total F-value calculation accounts for the worst case, fastest cooling scenario possible. Doing so will greatly complicate the overall HACCP plan for the facility, since in addition to a CCP at heat process step, the subsequent cooling step is a CCP as well; and HACCP CLs, monitoring procedures, etc. will also be required for the mechanical chilling phase of the cooling process.

VI. Establishing HACCP Controls for the Heat Process Step

To ensure the continued and consistent delivery of the proper lethality to the product, a HACCP plan for the heat process step must be developed. When establishing appropriate HACCP CLs for the heat process, including limits for other critical factors identified as affecting the rate of product heating, the processor must consider both the results of the lethality calculations and all relevant information regarding the actual conditions of the TD and product HP tests conducted. Appropriate monitoring procedures must also be established, with sufficient frequency to ensure the CLs are met. The following is a discussion of HACCP CLs and monitoring considerations for the heat process step.

HACCP Control/Monitoring Options When L. monocytogenes *is the Target Organism:*

For products where *L. monocytogenes* is the target organism of concern, there are basically two HACCP control options available for controlling and monitoring the heat process:

Option (A)—a HACCP plan based on establishing CLs for the minimum product dwell time and the minimum process temperature CLs for the process, or

Option (B)—a HACCP plan based on achieving a minimum "End-Point Internal Product Temperature" or "EPIPT", for product as it exits the heat process.

For Option (A) above, FDA guidance describes well how the processor should establish CLs and appropriate monitoring procedures for the heat process, which can be summarized as follows:

1. Establishing minimum time/temperature CLs for the heat process, and limits for other critical factors identified as affecting the rate of product heating, that assure a 6D process is achieved.

2. For batch systems: Monitor the heat process time and temperature with a continuous temperature-recording device (*e.g.*, a circular or strip chart recorder) or a dig-

ital time/temperature data logger. In heat processes where cooking is performed at the boiling point, visually observing the number of minutes at a boil is an acceptable alternative to continuous temperature recording. For dwell time, the start and end of each batch heating cycle is monitored.

3. For continuous systems: Monitor the heating time and temperature with a continuous temperature-recording device (*e.g.*, a circular or strip chart recorder) or a digital time/temperature data logger. For dwell time, acceptable monitoring methods include: measuring the speed or RPM of the conveyance system with a stopwatch or instrument (*e.g.*, tachometer); or measuring the time necessary for a test unit or belt marking to pass through the heat process equipment (using a stopwatch or other accurate, calibrated timing device).

However, Option (B)—HACCP control of the heat process based on achieving a minimum EPIPT—is not addressed in existing FDA guidance[4], but can be summarized as follows:

1. Establishing a minimum EPIPT CL is for the heat process, and limits for other critical factors identified as affecting the rate of product heating, that assures a 6D process lethality is achieved.

2. For either "batch" and/or "continuous" heat process systems: Monitoring consists of measuring the EPIPT for an appropriate number of product units representing the slowest heating portion/unit of product, that are located in the "cold spot" of the heat process system (as identified by the TD and product HP study), at some designated frequency that ensures the EPIPT CL is consistently met. Some of the factors to consider with respect to frequency of monitoring are discussed later in this section.

For example, based on the D- and z-values for *L. monocytogenes* published by Harrison and Huang (*10*), if crab sections were heated *instantaneously* to an internal core temperature of 160°F and held there for 45 seconds, a 6D process for *L. monocytogenes* control would be achieved. However, conservative HP studies conducted by FPA for crab sections and whole crab[5], and corresponding total lethality calculations, demonstrate that by the time the slowest heating portion of product simply *reaches* an internal core temperature of 160°F, a 10D process is achieved; which is "4D" more lethality than necessary. On this basis, FPA has recommended to its members that implementing a HACCP plan based on achieving a minimum EPIPT CL of 165°F is a conservative and acceptable alternative to a HACCP plan based on minimum time/temperature CLs and continuous time/temperature monitoring, since the total (cumulative) F-value at this EPIPT greatly exceeds a 6D process needed for control of *L. monocytogenes* in this product and in similar products.

Depending upon how high an EPIPT CL is selected, total F-value calculations for the heat process may not even be necessary. Using the above example for crab sections, if a very high minimum EPIPT CL = 183°F is established, a 6D process would be achieved in *1 second* at the CL; and practically speaking, this is less than the time it would take for a person to physically measure the EPIPT. This illustrates one manner in which a HACCP plan based on EPIPT can be designed to be extremely conservative, since in this example, lethality that actually accumulates as the product heats is not accounted for. Since some commercial seafood cooking processes do consistently achieve EPIPTs of this high magnitude (*e.g.*, most crab cooks, some surimi analog pasteurizing processes); processors opting to take an extremely conservative approach by setting a very high EPIPT CL could potentially alleviate to the need to perform complicated total F-value calculations for the heat process.

Some considerations that may affect a processor's decision regarding whether to implement a HACCP plan based on EPIPT or one that is based on continuous time/temperature monitoring and control may include: (a) the physical characteristics of the heat process system; (b) the control/monitoring methods and devices that are available, and feasibly applied to the particular system; and (c) other product quality/characteristics and production throughput considerations. There may be other considerations, depending upon the unique characteristics of the product and/or the production environment. The physical limitations of older heat process systems may preclude effectively retrofitting the

[4] Early last year, the FDA Office of Seafood began to recognize EPIPT as a viable HACCP control/monitoring option, in lieu of continuous time/temperature monitoring, when the processor had conducted a scientific study to verify/assure a 6D process is achieved, consistent with the protocol/principles found in the February 2004 version of this FPA guidance document.

[5] HP studies for king, snow, and dungeness crab sections and whole dungeness crab were done in a water heating medium at temperatures of 205–209°F, to simulate typical commercial crab cook operations.

unit with a continuous time-temperature monitoring device, or such devices may not be suitable for uniquely difficult processing environments. For example, for a cook system located aboard an at-sea crab processing facility, the accuracy of continuous recorder devices/charts is generally uncertain because of the constant, unpredictable pitch and roll movement of the vessel.

Such considerations will also influence how the prudent processor establishes appropriate HACCP CLs, monitoring procedures, the frequency of monitoring, etc. for the heat process step, and for any other critical factors identified as affecting the adequacy of the heat process. FDA guidance directs the processor to (a) describe monitoring procedures that will ensure that the critical limits are met, and (b) to monitor often enough so that normal variability in the values being measured (*e.g.*, EPIPT) will be detected; this being especially true if the measured values are typically close to the critical limit. Another consideration that FDA correctly points out is that the greater the time period between CL measurements the greater the quantity of product that is put "at risk" should a measurement show that a CL has not been met. In a batch heating system, it is important that the EPIPT be measured for each batch cook, to assure conformance to the CL (*e.g.*, 165°F for cooked crab sections); and other critical factors identified as affecting the adequacy of the heat process should be monitored/measured for each batch as well. For a continuous heat process system, the frequency of EPIPT monitoring will be influenced by the factors previously mentioned; particularly if the inherent, functional (operating) process results in an EPIPT considerably higher than 165°F, making the margin of safety for *L. monocytogenes* is even more pronounced. For example, other factors affecting product HP being equal, if a minimum EPIPT CL = 165°F is established, the frequency of monitoring needed to ensure the CL is consistently met will likely be greater in instances where the actual operating EPIPT is close to the 165°F CL; whereas a process that consistently reaches actual EPIPTs that are much higher than the CL value (*e.g.*, 180–190°F) may require less frequent monitoring. As mentioned earlier, some commercial cooking and pasteurizing operations (*e.g.*, crab, shrimp, other crustaceans, and some surimi-based products) consistently achieve EPIPTs in the range of 180–190°F. Many processors employ a product coding system that identifies the year, day, month, and time period the product was produced, to help readily identify "lots" of product during sale or distribution. Processors using such a coding system and employing continuous heat processes, should consider taking the EPIPT CL measurement at least once for any given time period of production (as defined by the product coding scheme), as well as for other critical factors identified as affecting the adequacy of the heat process.

Regardless of whether the heat process system is batch or continuous, when using EPIPT it is important to ensure that: (a) the EPIPT measurement is taken for an appropriate number of product units, representing the slowest heating product located in the "cold spot" of the heat process system (if applicable); and (b) the monitoring of other critical factors identified as affecting the adequacy of the heat process be done with sufficient frequency to achieve and assure control. Of course, this latter point applies also to processors choosing to employ a HACCP plan for the heat process where CLs for both minimum product dwell time and process temperature have been established

In addition, since a HACCP plan based on EPIPT monitoring precludes the use of a time and/or temperature recording device, it is important for the processor to address in their hazard analysis how plant personnel responsible for monitoring the heat process are alerted to an event that would cause a sudden loss of heat in the system (*e.g.*, a boiler failure alarm, etc.), since such an event would most likely affect achieving the minimum EPIPT CL (and achieving the minimum 6D process lethality).

We also recommend that processors document the logic and reasoning used in determining the frequency of monitoring, the number of product units measured, etc. to better substantiate how/why the selected monitoring frequency is sufficient to achieve and assure control of the process. This can be useful in responding to questions from auditors, inspectors, etc. in this regard. For example, besides the various heating process considerations previously mentioned, it would be advisable for the processor to document any statistical analysis or other mathematical probability methods used to help determine and/or justify their selected frequency of monitoring, number of product units, etc.

IN SUMMARY, for a heat process that targets the control of *L. monocytogenes*, a HACCP plan based on a minimum EPIPT CL and monitoring can be as effective as on establishing minimum time/temperature CLs and associated continuous time/temperature monitoring. It must be stressed that a HACCP plan based EPIPT may be implemented *only when* L. monocytogenes *is the target pathogen of concern*;

and that regardless of the HACCP control method selected, the basic principles/protocols described in Section III for establishing and/or verifying the heat process still apply:

- Properly designing and conducting a TD and product HP study that accounts for slowest heating product under the worse case heating conditions, including identifying other critical factors/conditions of processing and/or packaging that affect the rate of product heating,
- Analyzing the study data to determine the lethality of the heat process, and
- Establishing appropriate HACCP CLs and monitoring procedures for the heat process and other identified critical factors that, when adhered to, will ensure delivery of a 6D process lethality to each and every unit of product.

HACCP Control/Monitoring Options When Non-Proteolytic C. botulinum *type B is the Target Organism:*

As previously mentioned, **when the objective is control of non-proteolytic *C. botulinum* type B spores, EPIPT monitoring is NOT an appropriate or feasible option.** Therefore, for controlling non-proteolytic *C. botulinum* type B, processors are left with implementing HACCP control "Option (A)" discussed at the beginning of this section, *i.e.*, a HACCP plan based on establishing minimum CLs for heat process time and temperature, to assure a 6D process is achieved. For cooked, RTE products packed in reduced oxygen atmosphere packaging and stored/distributed in refrigerated form, the heat process step is being appropriately implemented as the *second safety barrier* for control of *C. botulinum* (*i.e.*, heat to control non-proteolytic *C. botulinum* species and refrigeration to control the proteolytic *C. botulinum* species). This is frequently the case for in-package, pasteurized seafood products such as imitation crabmeat, or cooked, hot-filled soups, chowders, or sauces that are filled directly from the cook kettle using sanitary, automated filling systems designed to minimize risk of recontamination[6]. Spores of non-proteolytic *C. botulinum* type B are far more heat resistant than vegetative cells of *L. monocytogenes*; and it would take an EPIPT of approximately 232°F to achieve a 6D process for controlling them. Of course, temperatures of this magnitude cannot be achieved in the type of heat process systems under discussion here, *i.e.*, those that are maintained at "atmospheric" pressure, where process temperatures are no greater than 212°F.

Note that even when employing one of the FDA alternative process control strategies, considered to be "equivalent" to the 6D (see Section V discussion), HACCP control of the heat process necessarily involves continuous time/temperature monitoring: either continuous monitoring of the time/temperature of the heat process itself to assure a certain lethality is achieved, or continuous monitoring of the internal product core temperature during the heat process to assure the product is held at/above some minimum temperature for the appropriate minimum time (*e.g.*, for hot smoked fish, placing TCs in three portions of product that represent the slowest heating, and being located in the cold spot of the smokehouse, as determined by study).

As expected, not only will minimum CLs for the heat process time and temperature be necessary, appropriate CLs must be established for any other critical factors/conditions identified as affecting the adequacy of the heat process (based on study design); and monitoring procedures developed and implemented with sufficient frequency to achieve/assure their control. Considerations that processors should take into account when establishing the frequency of monitoring of CLs set for other critical factors of the process were discussion earlier, and are also applicable to HACCP plans concerned with controlling non-proteolytic *C. botulinum* type B.

[6] See reference 1 (FDA Guide, Ch 13). Some cooked, RTE refrigerated products in reduced oxygen atmosphere packaging are significant handled between cooking and packaging; and the process may not employ a final in-package heat process step. In such instances, a second safety barrier such as water activity, pH, water-phase salt, the use of time-temperature integrators on the retail packages, etc. would be needed. This may be the case for some operations producing cooked, crabmeat, lobster meat, or crayfish meat products, canned or vacuum packaged and refrigerated.

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APPENDIX 1:

Terms and Definitions Used in Thermal Processing and Some Examples

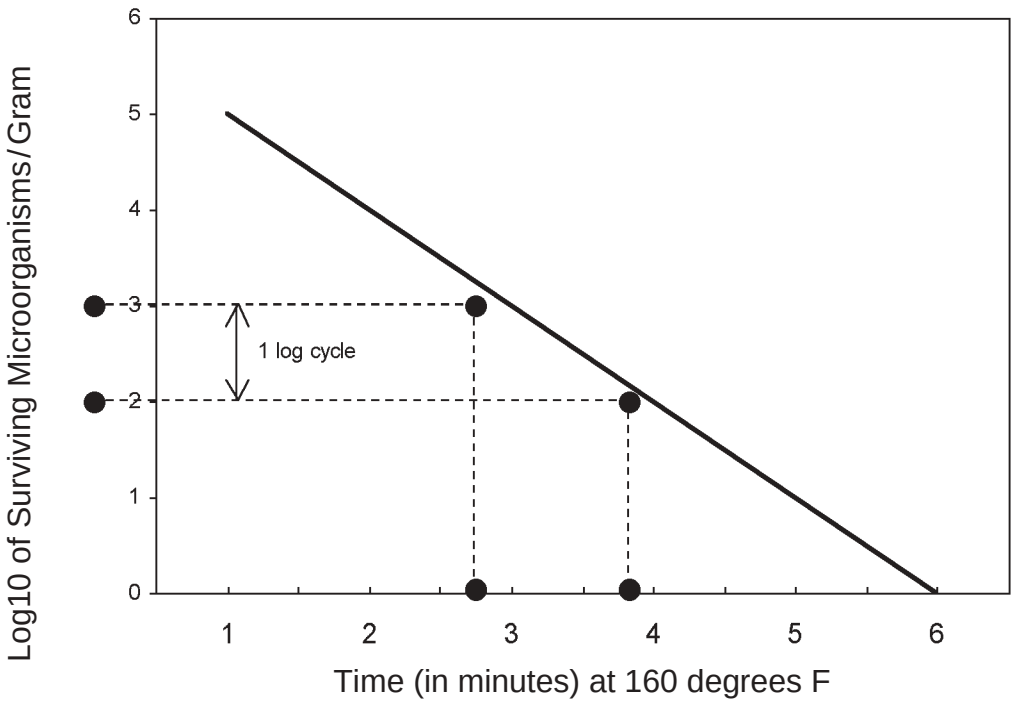
D-value:

The D-value is known as the "decimal reduction time", and is defined as the time (usually in minutes), required to kill 90% of the spores or vegetative cells of a given microorganism at a specific temperature in a specific medium. A 90% reduction in bacteria is equivalent to a reduction from 10,000 bacteria/g to 1,000 bacteria/g or 1 log cycle. D-values can be determined from survivor curves when the log of population is plotted against time (see *Figure 1*), or by the formula:

$$D_T = \frac{t}{(\log A - \log B)}$$

Where: t = time of heating,
A = the initial no. of microbial cells, and
B = the final no. of surviving microbial cells after heating time

Figure 1: Decimal Reduction Time Graph (hypothetical data). Graph Illustrates a Decimal Reduction Value at 160°F of 1 minute (D_{160} = 1.0 min.)



z-value:

The z-value is the number of degrees (°F or °C) that results in a 10-fold change (1 log cycle) in an organism's heat resistance, *i.e.*, an organism's D-value will be 1 log higher or lower when it is heated by "z degrees F " higher or lower, respectively. The z-value, therefore, gives an indication of the relative impact of different temperatures on a microorganism, with smaller z-values indicating greater sensitivity to increasing heat.

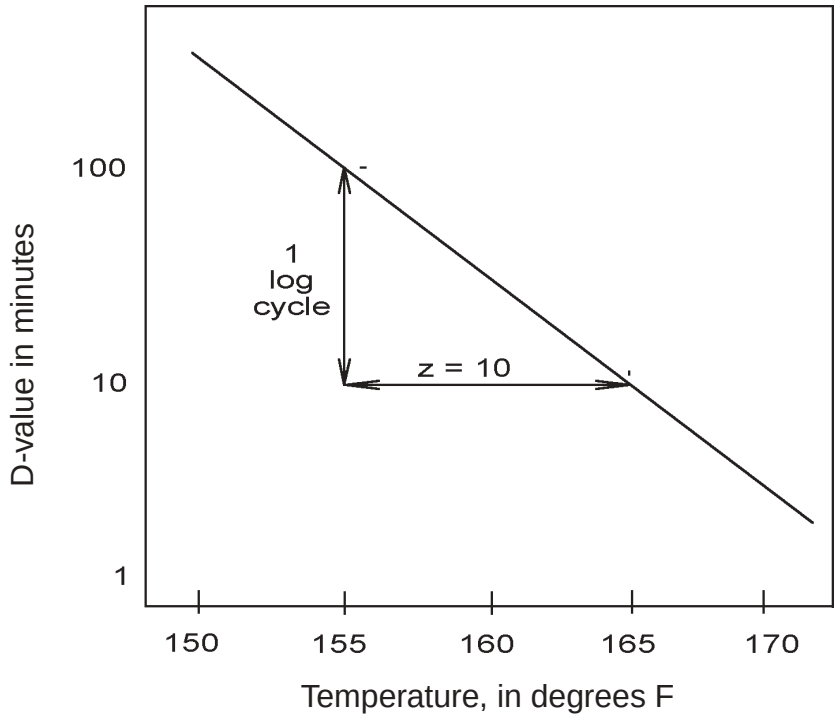
On a thermal death time curve, where the logarithms of at least 2 D-values are plotted against temperature, the z-value is number of degrees required for to traverse 1 log cycle (see *Figure 2*).

The z-value can also be calculated by the formula:

$$z = \frac{(T_1 - T_2)}{(\log D_2 - \log D_1)}$$

Where: T_1 and T_2 are temperatures, and D_1 and D_2 are D-values at temperatures T_1 and T_2

Figure 2: Example of a thermal death time curve, depicting an organism with a z = 10°F.



Equivalent D-value:

Using the z-value of a particular organism, and by expressing the above equation in a different way, a D-value for a different temperature can also be determined, as follows:

$$\log D_2 - \log D_1 = \frac{(T_1 - T_2)}{z}$$

Where: D_1 = Known D-value at temperature T_1
D_2 = Unknown D-value at temperature T_2

For example, suppose D_{151} = 0.40 minutes and z = 10.26°F for the target pathogen *L. monocytogenes*. Then a different D-value at 140°F can be calculated as follows:

$$\log D_{140} - \log D_{151} = [(151 - 140)/10.26]$$
$$\log D_{140} - \log(0.4) = 1.072$$
$$\log D_{140} = 1.072 + \log(0.4) = 1.072 + (-.398) = 0.674$$

By raising both sides of the equation by "power 10" to eliminate the log expression, the result of the equation becomes:

$$D_{140} = 10^{(0.674)} = 4.72 \text{ minutes}$$

Thus, the *equivalent* D-value at 140°F is 4.72 minutes.

F-value (Lethality Value):

The F-value, or lethality value, is defined as the time necessary to destroy a given number of microorganisms at a specific, constant temperature; or the number of equivalent minutes spent at a given reference temperature and z-value.

F-values and D-values are related, in that the F-value of a heat process generally represents multiple D-values; as described by the formula:

$$F_T = D_T \times \log(A)$$

Where: A = target number of microorganism to destroy.

Using the same example values from above, if the D_{151} = 0.40 minutes for *L. monocytogenes*, then a heat process with an F-value = 2.4 minutes (F_{151} = 2.4) would achieve 6-log reduction for the target microorganism (A = *1,000,000* in the above equation), and would be described as being a "6D" process.

Equivalent F-values:

F-values allow the direct comparison of two or more heat processes (having the same z-value). The equivalent lethality of processes at different temperatures can be calculated in a similar manner to equivalent D-values for different temperatures:

$$\log F_2 - \log F_1 = \frac{(T_1 - T_2)}{z}$$

Where: F_1 = Known F-value at temperature T_1
F_2 = Unknown F-value at temperature T_2

Using the above example, where a "6D" process for *L. monocytogenes* a lethality value, F_{151} = 2.4 minutes (z = 10.26°F), a heat process that delivers the same equivalent lethality be achieved at a temperature of 170°F in 0.033 minutes, *i.e.*, F_{170} = 0.033 minutes (about 2 seconds). (Note: T_2 = 170°F in the equation above).

Table 1: Example Lethality Calculation, F_{194}, for a Pasteurized Surimi Seafood Product (Heating Phase Only), for Target Organism Non-Proteolytic *C. botulinum*

HP TEST INFORMATION:

Product ID : Imitation Crab Flakes, Formula 001	**Net Wt :** 2.5 Lb vac pack	**Test Date/Time**: 12/5/03, 9:45AM
Pastrzr. ID/ Heat Medium: #1/ Continuous/ Steam	**Pkg ID/TC Loc.:** #1, TC at GC	**Pkg Thickness:** 1.5 inches
Pkg Loc. On Past. Belt : Middle	**Belt Speed Set Point (ft/min)**: 2.00	**Belt Speed, Measured (ft/min)**: 1.99
Pasteurizer Temp-Controller Set Points: #1 Front: 210°F #2 Mid: 210°F #3 Back: 208°F	**Pasteurizer Temp, Actual:** 210.5°F	**Pastrzr. Dwell Time, Actual:** 33 minutes

	Ref Temp, °F (T_{ref})	z-value, °F (when $T < T_{ref}$)	z-value, °F (when $T > T_{ref}$)	Time Interval (min.)
Target Organism Data for: Non-proteolytic *C. bot.*	**194.0**	**12.6**	**18.0**	**1.0**

	Elapsed Time (Minutes)	Internal Product Temp. (T_p)	Lethal Rate (L): $\log^{-1}[(T - T_{ref})/z]$	Lethality at this time: $\{(L_{prev.} + L_{curr.})/2\} \times$ time	Total Cumulative Lethality, F @ 194°F
Enter Pasteurizer	**0**	73.07	0.000		
	1	87.1	0.000	0.000	0.000
	2	98.19	0.000	0.000	0.000
	3	108.19	0.000	0.000	0.000
	4	116.83	0.000	0.000	0.000
	5	124.32	0.000	0.000	0.000
	6	130.99	0.000	0.000	0.000
	7	136.97	0.000	0.000	0.000
	8	142.37	0.000	0.000	0.000
	9	147.38	0.000	0.000	0.000
	10	152.08	0.000	0.000	0.001
	11	156.5	0.001	0.001	0.001
	12	160.6	0.002	0.002	0.003
	13	164.39	0.004	0.003	0.006
	14	167.92	0.009	0.006	0.013
	15	171.15	0.015	0.012	0.025
	16	174.15	0.027	0.021	0.046
	17	176.89	0.044	0.035	0.081
	18	179.45	0.070	0.057	0.138
	19	181.8	0.108	0.089	0.227
	20	183.99	0.161	0.134	0.361
	21	186	0.232	0.196	0.557
	22	187.9	0.328	0.280	0.837
	23	189.65	0.452	0.390	1.227
	24	191.29	0.609	0.531	1.757
	25	192.84	0.809	0.709	2.466
	26	194.22	1.029	0.919	3.385
	27	195.54	1.218	1.123	4.508
	28	196.74	1.420	1.319	5.827
	29	197.63	1.591	1.505	7.332
	30	198	1.668	1.630	8.962
	31	197.83	1.632	1.650	10.612
Exit Pasteurizer	**32**	195.23	1.170	1.401	12.013
	33	---	0.000	0.585	**12.60**

NOTES: