

Heat Process Validation

Though consumers may not know the term “heat processed seafood” they know what it means -- cooked, ready to eat right out of the package - and they expect it to be safe. Heat process validation tests the effectiveness of a firm’s heat process to ensure the safety of their seafood products. There are several kinds of heat processes including blanching, cooking, pasteurization, retorting, even hot holding and all of these processes can destroy or control microbial growth. In this video, we’ll focus on the pasteurization, cooking and smoking processes.

Heat process validation is complex, so it may be best to hire a professional who’s familiar with the product and process to be validated. If that’s not an option, there are some basic steps that processors should know and do, and we will discuss these steps in this video.

A successful heat process validation consists of four steps; determining the target pathogen; pathogen reduction; verifying pathogen reduction; and identifying the controls and critical limits to include in the HACCP plan to ensure a consistently safe product. We’ll go through each of these and show how they interrelate to provide an effective heat process validation.

Let’s look at the first step, determining the target pathogen.

A target pathogen in any heat process is the most heat resistant pathogen of public health significance that is reasonably likely to occur in the product. The goal of the heat process is to eliminate the target pathogen or reduce it to a low enough level that it’s unable to cause illness under normal storage and handling. The pathogen may occur naturally in the raw seafood or may be introduced during processing and handling of the product. The most common target pathogens associated with ready to eat seafood are *Clostridium botulinum* and *Listeria monocytogenes*, but these aren’t necessarily the only target pathogens. FDA’s Fish and Fishery Products Hazards and Controls Guidance, or the Hazards Guide, has tables in the appendices for several common target pathogens associated with seafood products.

To identify the target pathogen, you need a complete description of the finished product, including final packaging, storage and distribution. If the process changes the pH, the water activity, the water phase salt or any combination of these in the final product, then these changes may provide additional barriers that will affect the target pathogen chosen. Table A-1 in Appendix 4 of the Hazards Guide lists these possible barriers and we will discuss them more later.

The product’s packaging and distribution also have a significant impact the target pathogen chosen. The 2 basic types of packaging used for ready to eat foods are oxygen permeable packaging and reduced oxygen packaging. Nearly all packaging has some degree of oxygen transmission, but packaging that provides an oxygen transmission rate of 10,000 cubic centimeters per meter squared per 24 hours at 75 degrees Fahrenheit or 24 degrees Celsius can be regarded as oxygen permeable. Any packaging with a transmission rate less than this is considered reduced oxygen packaging.

Reduced oxygen packaging includes vacuum packaging, modified atmosphere packaging, and controlled atmosphere packaging. It’s important to note that a reduced oxygen environment can form within oxygen permeable packaging under certain circumstances, such as within deep containers, in products packaged in oil, or products that are compacted in the container preventing the flow of oxygen throughout the entire container.

Product distribution and storage will usually fall into one of three categories, refrigerated storage, frozen storage or shelf-stable.

As we mentioned previously, the two most common target pathogens for cooked, ready to eat products are *Clostridium botulinum* and *Listeria monocytogenes*.

C. bot. strains fall into two categories – non-proteolytic and proteolytic, both of which form protective spores that allow the pathogen to survive extremes like cooking. *C. bot.* is an anaerobe – meaning it grows best and produces toxin in the absence of oxygen.

Listeria doesn't produce spores, so it's more susceptible to destruction by cooking; however, *Listeria* is a facultative anaerobe – meaning that it's able to grow with or without oxygen.

These pathogens grow under different conditions created by the products' final packaging. That's why without other barriers, the type of packaging helps dictate the pathogen the heat process should target.

Non-proteolytic *C. bot.* is typically the target pathogen for products in reduced oxygen packaging stored under refrigeration because it's the most heat stable pathogen of public health concern likely to be present, grow and produce toxin under refrigerated conditions. In contrast, proteolytic *C. bot.* is unable to grow and produce toxin at most refrigerated temperatures, so the heat process targeting proteolytic *C. bot.* doesn't need to be lethal so long as the product is stored at proper refrigeration temperatures.

Listeria is usually the target pathogen chosen for refrigerated products in oxygen permeable packaging. While *Listeria* can grow in reduced oxygen packaging, it's only chosen as a target pathogen here when other barriers are present that prevent growth and toxin production by *C. bot.*, like salt or low pH. Otherwise, any heat process that targets *C. bot.* is also sufficient to control *Listeria*.

Let's apply this general information to some specific examples to illustrate how you would select the target pathogen.

Our first example is refrigerated, pasteurized crabmeat, which is cooked, picked, packaged then pasteurized. For seafood, pasteurization is a heat process applied to the product after it's in the final container. For example, the crabmeat is packaged in hermetically sealed containers closed under vacuum, creating a reduced oxygen environment, then pasteurized and stored at refrigeration temperatures. Both *C. bot.* and *Listeria* can be present and grow in crabmeat, so the product itself will determine the appropriate target pathogen for pasteurization. Since we haven't processed the crabmeat in any manner that would lower the pH, reduce the water activity, or alter the water phase salt, there are no alternate barriers to prevent the growth of *C. bot.*. As we pointed out earlier, *C. bot.* is inactivated at higher temperatures than *Listeria*, so our pasteurization process to control *C. bot.* will also control *Listeria*, but not vice-versa. We identify *C. bot.* as our target pathogen, but there are different forms of *C. bot.*. Both proteolytic and non-proteolytic types are likely to be present in the crabmeat. Because temperatures below 50 degrees Fahrenheit will control the growth of proteolytic types, the heat process does not target them here. Non-proteolytic types, though, are not controlled through refrigeration and must be subjected to a heat process. That means the target pathogen in the heat processing of pasteurized crabmeat is non-proteolytic *Clostridium botulinum*.

Our next example is whole, cooked Dungeness crabs that are boiled and then placed on ice. Cooking is a heat treatment, usually performed before placing the product in the finished product container, and is applied to fishery products that are distributed either refrigerated or frozen.

Like the pasteurized crabmeat scenario, both *C. bot.* and *Listeria* are likely to be present in the raw crabmeat, but here the packaging is oxygen permeable so we target *Listeria* rather than *C. bot.*. It's important to note that strict sanitation measures are needed to prevent *Listeria* from recontaminating the product after the cook.

Our final example is refrigerated, hot smoked salmon that's vacuum packaged. Hot smoking is a process that uses a combination of smoke and heat for drying along with the addition of salt and sometimes nitrites to control pathogen growth. The vacuum package creates a reduced oxygen environment where *C. bot.* and *Listeria*, which are both likely to be present, are able to grow. The finished product is stored under refrigeration, which controls proteolytic types of *C. bot.*. That leaves us with non-proteolytic types of *C. bot.* and *Listeria* as potential target pathogens.

Unlike our prior examples, how the hot smoked salmon is prepared dictates the target pathogen. For this example, we use a salt brine soak prior to the actual smoking process. A combination of salt, smoke, and drying brings the salmon's water phase salt to 3.5% or greater, as recommended in the Hazards Guide. These barriers along with the heat applied during smoking will control the non-proteolytic types of *C. bot.* and will eliminate the *Listeria*. Again, strict sanitation measures are needed to prevent *Listeria* from recontaminating the product after the cook.

The second step in developing a successful heat process is determining the process time and temperature to achieve pathogen reduction.

The heat process should typically be designed to achieve a reduction of six orders of magnitude – called a 6D reduction. The D-value is the time needed to kill 90% of the target organism at a specific temperature. A 90% reduction means reducing 1 million organisms to one-hundred thousand, which is a 1- log reduction in numbers. A 6D reduction, which is 6 times the D value, is suitable in most cases, and means that you're achieving a six logarithmic reduction in the target pathogen. A 6-log reduction would provide a 99.9999 percent reduction in the number of the target pathogen in the product.

Tables A-3 and A-4 in Appendix 4 of the Hazards Guide provide 6D process time and temperature combinations for *Listeria* and non-proteolytic *C. bot.* that have been determined to be effective in most cases. However, processors are still responsible to verify their effectiveness. An alternative cook can be used if a heat resistance study is conducted to determine the D value needed for the specific product or if the scientific literature supports using a different D value. We'll discuss this further a little later.

The normal, active growing state for microorganisms is the vegetative state. Under stressful conditions, some microorganisms form spores. A spore is a thick-walled dormant cell that's highly resistant to extreme conditions. Generally, spores are more heat tolerant than vegetative cells, and several different pathogens are able to form spores to protect them until suitable growing conditions return. The pathogenic bacteria capable of forming spores, like *C. bot.*, are the greatest concern because the spores may be capable of surviving processes such as pasteurization and cooking. In addition, different spores have different levels of heat resistance, so some pathogen spores are more difficult to kill than others.

There's a vast difference in the heat tolerance of vegetative cells, too. For example, *Listeria* and *Vibrio vulnificus* are both vegetative cells, but *Listeria* is quite heat tolerant and more difficult to kill compared to *Vibrio*. Neither of these compare to the heat tolerance of proteolytic *C. bot.* or *Bacillus cereus* in their spore form, whose spores will survive most heat processes other than retorting.

Some of a food's characteristics make it easier or harder to destroy the pathogens in it. Sugars and oils in food tend to shield pathogens from the effects of heat, while pathogens are killed more easily in foods with an acidic pH or with high moisture contents.

While there's scientific data available for many pathogens, when developing new or unusual products, processors need to collect their own data to establish a heat process for the target pathogen in their particular product. Product-specific heat resistance data that's developed may be used to determine the appropriate time and temperature necessary to achieve a 6D process for control of *Listeria* or *C. bot.* in the product, in lieu of using one of the more conservative time-temperature processes recommended in the Hazards Guide.

Just because a processor has successfully used a process for years without any associated consumer illness doesn't mean that the process is safe. Processors are responsible for validating that their heat process consistently renders a safe product for consumers.

This leads us to the third step -- verifying that the process delivers enough heat to reach an acceptable level of pathogen reduction.

The effectiveness of the heat process is dependent on 3 factors -- first, how heat is distributed to the product within the heating vessel; second, the rate that heat penetrates into the product; and finally, how the target pathogen responds to the heat. These three factors are interdependent when it comes to achieving an acceptable level of pathogen reduction. Earlier in this video, we talked about the interaction between the target pathogen and the food, so now we'll look at the role of heat in the process.

Let's begin with the first factor -- how heat is distributed to the product within the heating vessel. This is accomplished through a temperature distribution study. This study evaluates how evenly heat is distributed throughout the heating equipment.

Temperature distribution is influenced by the type of heat processing system, the heating medium such as hot water or steam, the design of the equipment, the amount and distribution of the product to be heated, and the position of the product containers within the heating equipment. For example, is there a cold spot in a certain location?. A temperature distribution study will help ensure that every unit of product in the heating equipment is exposed to the heating media at the desired temperature. Temperature measuring devices placed throughout the heating equipment will identify any inconsistencies in the temperature distribution within the heating equipment.

The second factor -- verifying an acceptable level of pathogen reduction, is the rate that heat penetrates into the product.

After establishing the time and temperature combination needed to achieve a 6D reduction, the next step is to determine how long it takes the coldest point in the food to reach the target temperature. This is determined by performing a heat penetration study.

Many factors affect heat penetration, including the size and initial temperature of the raw food, the type of heating medium, and the proportion of liquid to solid. The 6D time and temperature combination is applied to the food's cold spot under the worst possible conditions that could occur during regular processing.

Heat penetration into the food can be measured using thermocouples or other measuring devices placed within the product prior to starting the heat process. These devices measure how long it takes for product in the cold spot of the heating vessel to reach the appropriate temperature.

Let's review some of the basics of "heating". There are two principal ways that heat is transferred within a container of food. The first is conduction, where the heat transfer is slow, moving from one particle of food to the next. This is how heat transfers when crabmeat is pasteurized in a can or a surimi analog is pasteurized in a reduced oxygen package. With conduction, the slowest part of the food to heat is typically the center because it's the furthest away from the heat source. Place the thermocouple here for the heat penetration study.

A faster method of heat transfer is convection. Here, as the food heats, it rises, usually along the sides of the container. At the same time, the cooler food at the center falls, creating a current that moves heat throughout the cooking vessel. Convection only occurs if the food can move within the cooking vessel. Examples include liquids like soup, or mixtures of solids and liquids like boiling crabs. In this case, the slowest heating point is usually along the container's vertical centerline where the currents diverge, about a third of the way up from the bottom. This is where the thermocouple is placed in the heat penetration study.

For products that heat by a combination of convection/conduction, such as formulated soups or chowders with cut seafood and vegetables the slowest heating area is the geometric center of the largest food particle, located about a quarter of the way up the bottom of the container.

Pathogens in the food's cold spot will be inactivated more slowly than those at the surface because the heat takes longer to reach them, so cumulatively they are subjected to less total heat. This is why, as we have already pointed out, the final cooking time should be long enough to inactivate or destroy any pathogens in the food's cold spot.

Pasteurization, cooking, and smoking are achieved with specific types of processing equipment. While there are standard temperatures that must be reached during processing, each individual piece of equipment will have its own rate of heating as well as possible temperature variations within the heating unit. These variations in processing equipment also lead to cold spots. If you find cold spots during the temperature distribution study, the equipment should be redesigned to achieve uniform temperature distribution, or, if that can't be achieved, operated in a manner that compensates for the lowest temperature in those cold spots. The processing equipment should be designed so that every unit of the product is subjected to the minimum time and temperature to eliminate the target pathogen.

The third factor in verifying an acceptable level of pathogen reduction evaluates how the target pathogen responds to heat. The combination of heat penetration and temperature distribution should allow your heat process to achieve the 6D reduction.

In order to verify that an acceptable level of pathogen reduction has been reached, use the parameters established during the heat resistance, heat penetration and temperature distribution studies in actual trial runs. Using the cold spot, measure the temperature in the product continuously as its processed – verifying that the desired time and temperature for pathogen reduction has been reached. In short, a successful process will apply the correct amount of heat, use the appropriate heating method, and result in a 6D reduction of the target pathogen in the particular product. A heat process should be tailored for each individual product taking all the characteristics of the food, the packaging, the processing equipment, and the pathogen into consideration.

Let's go back to our examples and pull all this information together.

We'll begin with refrigerated pasteurized crabmeat. In the first step, we established that non-proteolytic *C. bot.* is the appropriate target pathogen for the heat step. In our second step we said that pathogen inactivation is called a 6D process, which means that the process should provide a 6 log reduction of the pathogen load in the product. Processors can either have a study conducted for them or use the time and temperature combinations listed in Appendix 4 in the Hazards Guide, which may be adequate for most seafood products. For our examples, we use Table A-4 of the Hazards Guide for non-proteolytic *Clostridium botulinum* type B to determine the starting time and temperature combination needed to achieve a 6D process. It's important to remember that the table rates are based on the cold spot in the product reaching the stated temperature and remaining at that temperature for the designated period of time.

The heat penetration and temperature distribution studies can be conducted simultaneously. In order to do this, we use thermocouples placed throughout the product within multiple cans of crabmeat. We then place these cans in various locations throughout the pasteurizer. We also place additional thermocouples throughout the pasteurizer itself, but not inside the cans of product. Then, we run a pasteurization cycle at the time and temperature we established to reach a 6D process. We repeat this process multiple times and record all the data collected and evaluate it for consistency. The information we gain from these experiments includes how heat is distributed throughout the pasteurizer, how the heat penetrates into the canned product, where the cold spot in the canned product is, and whether the time and temperature combination we established is actually applied to that cold spot. Now remember, it's imperative that all the crabmeat within the can receives enough heat for enough time to destroy the pathogens.

For our boiled crabs and other cooked products, the heat validation process is similar. There will be variations based on the actual process used, but the general questions to answer are largely the same.

Now, let's validate the heat process for refrigerated, reduced oxygen packaged, hot smoked salmon. We've already established that our target pathogen is non-proteolytic *C. bot.*. Evaluating the effectiveness of our heat process is somewhat more involved than in the first two examples for pasteurized and cooked crab. Here, we must validate the effectiveness of the barriers to control *C. bot.* such as measuring the water phase salt level in the product to confirm that the brine step is effective.

The heat treatment for properly salted, hot smoked salmon is an internal temperature of 145 degrees Fahrenheit for 30 minutes. The brine concentration must be high enough so that the salmon reaches a water activity of 0.97 or below by the end of the hot smoking and drying process. We conduct our heat penetration and temperature distribution studies simultaneously as we did for our pasteurized canned crabmeat example, though we also have the option of conducting them separately.

When conducting the heat penetration and temperature distribution studies, we must consider the thickness of the raw salmon, accounting for the thickest possible fish we may process. Again, we use thermocouples placed in the thickest pieces of salmon and place these pieces throughout the smoker. We also place thermocouples throughout the smoker itself to measure how evenly the temperature is distributed in the smoker. We complete multiple smoking cycles in this manner, collect and record the data obtained, and evaluate the data for consistency. Finally, we test the product to determine the water phase salt level and or water activity.

Now we come to the fourth step in validating the heat process - making sure that the appropriate controls are in place for the target pathogen and the critical limits necessary to ensure a consistently safe product are incorporated into the HACCP plan. The data collected during the heat penetration and temperature distribution studies along with the heat resistance of the target pathogen will provide the basis for the time and temperature critical limits.

It's best to set the critical limits using the worst possible conditions that may occur during processing.

Using these worst case scenarios will better ensure that the critical limits reflect not only the minimum times and temperatures necessary to heat the product adequately under normal conditions, but also under conditions that are not ideal. One way to do this is to base the critical limit determination on starting temperatures for raw materials that are cooler than the norm. For example, whole cooked crabs might start out at a temperature of 50 degrees Fahrenheit before cooking. So, the studies for the thermal process could use raw crabs that are at 35 degrees instead of 50 degrees. Product that begins at a colder temperature will take longer to heat. Basing critical limits on this worst case scenario builds in additional cook time and provides further assurance that the product is heated long enough to control pathogen growth, even when the initial product temperatures are lower than would normally be expected.

Another worst-case scenario is the use of raw product that is larger than what you would normally expect to process. For example, let's look again at hot smoked salmon. A smoked salmon processor could determine its critical limits by smoking thicker pieces than are processed under normal conditions. Thicker pieces require more time to reach the necessary internal temperature, which will build in extra cooking time to account for variation in product thickness during the normal course of processing.

Time and temperature may not be the only critical-limits. For example, with hot smoked salmon, the time and temperature during the smoke step is combined with the brine strength and brine time in order to achieve the required 3.5% water phase salt that controls the non-proteolytic *C. bot.*. So, in this example, brine critical limits must be set to work in combination with the time and temperature critical limits established for the heat process.

Remember that the critical limits are based on the factors defined during the heat distribution study and vary based on the processing equipment. For example, if the product is processed in a continuous cooker, then belt speed would be a critical limit.

Once the critical limits are established, then a monitoring system that assures the critical limits are met should be established.

A heat process with time and temperature critical limits may require continuous monitoring to ensure that the time and temperatures critical limits are always met. And, with monitoring comes record keeping. Records permanently document that the critical limits were met for each batch or lot, providing valuable information about the product safety.

The Seafood HACCP regulation requires processors to provide monitoring records to FDA during their inspections. They're one of the tools that FDA uses to ensure that processors are implementing the HACCP plan.

The Hazards Guide can be used as a resource to help validate a heat process. It can provide answers to questions regarding target pathogens and guidance that would likely help create a HACCP plan acceptable to FDA.

We can't stress enough the importance of maintaining records of any validation procedures and studies conducted. These records and resulting data should include the methods used to establish the D value – if different than those in the Hazards Guide's, the data from the heat resistance, heat penetration and temperature distribution studies, as well as verification that the final process actually provides the right amount of heat to each piece of seafood in the cooking vessel.

Consumers depend on processors to provide them with safe fish and fishery products, so you must have thorough and effective heat processing procedures in place addressing all the issues we've discussed. As we stated in the beginning of this video, because of the difficulty involved in heat process validation, FDA recommends that processors consider seeking professional assistance to perform this important task. While the initial costs may seem high, knowing that the product has been processed properly and is safe for the consumer will be worth the cost by providing peace of mind and minimizing foodborne illness associated with these products.