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Campden BRI
food and drink innovation

The application of validation principles to continuous thermal and non-thermal processing

The beauty of continuous thermal processing is that it allows a large quantity of product to be processed in a short time. It is also possible to minimise unwanted chemical changes if the product is processed at the highest possible temperature for the shortest time needed to achieve the required lethality. As a result, a profitable, high quality product can be produced from continuous thermal processing. Continuous non-thermal processing offers alternative mechanisms to inactivate the microorganisms. This can potentially reduce/avoid any adverse effects resulting from high temperature exposure, thus enabling high quality product to be produced.

In an attempt to drive quicker and larger production throughput, the risk of producing undercooked products can arise. Therefore, it is of paramount importance for food manufacturers to be able to confidently prove that their large and rapid food production is safe. A validation study helps to provide scientifically robust evidence to support such claims. The validation study should be considered as an intrinsic part of a HACCP system covering the safe production of food products.

This white paper describes how validation principles are applied in continuous thermal processing (such as heat exchangers, hot filling and pasteurisation tunnels) and in continuous non-thermal processing (such as high pressure processing, pulsed electric fields and ultraviolet light). For a more in-depth analysis on any specific process please contact us. We can provide technical support, advice and training.

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Issued: February 2018

The principle of thermal process validation

From a product safety point of view, the thermal validation principle ensures that, in the worst case scenario, the slowest heating point in the food attains a specified thermal process (time and temperature) that has proven to be sufficient to reduce a given target microorganism to an acceptable level, should it be present.

Continuous flow heat exchangers

In a continuous heat exchanger system, the slowest heating point in the food is often difficult to identify and measure. This is one of the reasons that lethality contribution in the come-up and cooling phases are not considered in the overall declaration of lethality. The delivered lethality is only considered in the holding (tube) section of the heat exchanger. This requirement is consistent in Campden BRI[1], DOH[2], European[3,4] and FDA[5] guideline documents. The holding section extends from the final product heater outflow coupling, to the point where the temperature of the product is measured before it flows into the product cooler. From a validation point of view, it is within this section that the scheduled thermal process is achieved.

The holding tube should be designed so that no portion of the tube between the product inlet and the product outlet can be heated[5], and the simultaneous temperature difference between the hottest and coldest product, in any cross section of flow, at any time during the holding period, is not greater than 0.5°C[6]. This assumes that there is no significant cold point in the holding section. The temperature that should be used for validation is the set temperature of the divert valve, as the system should reject any products below this temperature. In other words, this is the lowest product temperature possible in the holding section.

The next important parameter is the retention time. Retention time can be calculated from the flow rate and the volume of the flow. However, the reading from the flow rate meter is only an indication of the average flow rate. It is the fastest moving part of the product (i.e., the food that receives the least heat treatment) that is of interest for validation purposes. Correction of the flow meter reading is therefore required to reflect the difference between the average flow rate and the worst case flow rate. This correction depends on the flow regime, either laminar or turbulent: different correction factors may be applied. Reynolds number (Re) is the parameter that helps to predict the flow regime. Generally, Re<2,000 is laminar, and Re>10,000 is turbulent[1] (note that the US FDA uses 4000 as Reynolds number for the onset of turbulent flow). If the flow regime falls between 2,000 and 10,000 (the so called transitional flow regime), a laminar flow correction factor should be applied as a worst case approach.

It becomes much more complicated if the product contains particulates, although the same validation principles can be applied. The heat has to be conducted through the liquid to the centre of the particulate, and the slowest heating point of the product will be somewhere within the particulate, depending on its geometry and dimensions. The lowest temperature within the particulate in the holding tube is required, as well as the retention time of the fastest moving particulate.

Validation of the thermal process in heat exchangers can be done by either theoretical calculation or a practical approach. By obtaining the lowest product temperature and the shortest product retention time in the holding tube, the minimum delivered lethality (P value) can be calculated. If the product contains particulates, prediction of the centre temperature of the particulate is possible for regular

shapes such as spheres, cylinders and bricks[7, 8]. Assuming that the fastest moving particulate is located at the same place as the fastest moving part of the flow, the minimum P value can then be calculated. A practical validation approach involves introducing enzyme or microorganism surrogate carriers into the heat exchanger system. A known population of heat sensitive enzyme or microorganism surrogates is made to have similar thermal death kinetics as the target microorganism. These are then encapsulated into a carrier that is allowed to travel through the entire holding tube section, and retrieved for final analysis. By comparing the population (i.e. log reduction) before and after heat treatment, the P value can be calculated.

For product flows that contain particulates, the density of the carrier bead can be manipulated to ensure that it moves in a similar manner to the product particulates. The thermal diffusivity, geometry and dimension of the enzyme carrier can also be manipulated to ensure that the enzyme carrier is heated in a similar manner to the product particulates.

Hot filling

The purpose of hot filling is to make use of the residual product heat to decontaminate the entire food contacting pack surface and closures, so that any microbial hazards present on the pack can be reduced. However, it is often the case that the food product temperature drops dramatically as it comes into contact with the food pack and, consequently, provides a limited degree of thermal decontamination to the inside pack surface[9]. It is the food manufacturer's responsibility to provide evidence that the level of thermal process delivered to the food package is sufficient to reduce the microbial hazards.

Several techniques can be used to quantify the level of heat delivered to the pack surface, such as flexible temperature sensors, time and temperature integrators (TTIs) and infra-red imaging. Each technique has its pros and cons, depending on the accessibility of the process and the type of package concerned. For example, in the case of typical 'form-fill-seal' processing, where conventional temperature sensors are difficult to be applied on the pack surface, TTIs may be the best option. The 'worst case' principle is still applicable in hot filling validation. The lowest possible hot filling temperature should be used (usually the critical control point (CCP) temperature), and the slowest heating points on the inside surface of the package and closure need to be identified, in order to obtain the least delivered lethality (P value) on the pack. As many factors[9] in practice can have significant impacts on the final P value obtained, hot filling is only recommended to be validated via a practical approach.

If there is additional thermal process given to the pack before or after hot filling (e.g. pre-heated packages, steam capping or pasteurisation tunnels), the validation study should also quantify such contributions (as the worst case scenario) on the final lethality on the pack.

Pasteurisation tunnel

The pasteurisation tunnel is one of the most common post filling options for additional pasteurisation on pack surfaces after hot filling. For cold filled products, the pasteurisation tunnel can also be used as an in-pack pasteuriser to deliver the necessary heat treatment to the final packed product.

The filled product packs are loaded at one end of the pasteurisation tunnel and pass under sprays of heated water as they move along the conveyor belt. The tunnel is usually divided into different zones (e.g. heating, holding, and cooling). In each zone, the spray bars are positioned above the belt and heated or cooled water is sprayed downward onto the product. When the containers pass through the tunnel, they are gradually heated up to the desired pasteurisation temperature and then cooled down towards to the exit of the tunnel.

The used water from each zone is usually collected in individual tanks and re-circulated in the same zone; where necessary, steam may be used to re-heat the water within individual tanks to maintain the desired water temperature.

The length of the process depends on the product and the packaging.

Validation of a pasteurisation tunnel comprises two tests:

(1) Temperature distribution tests to determine the slowest heating locations within the tunnel, (i.e. the points that are slowest to reach the scheduled processing temperature) and also to confirm that the range of temperatures experienced throughout pasteurisation is within prescribed limits.

(2) Heat penetration test on the packaging surface to determine the slowest heating location on the internal surface of the product packaging, i.e. that point on the pack that receives the lowest overall heat treatment (lowest P value).

Non thermal technologies

There are several non thermal technologies that are commercially available for food preservation. Examples include high pressure processing (HPP), pulsed electric fields (PEF) and ultraviolet light (UV-C). Although these example technologies have different lethal factors responsible for microbial inactivation, the basic principles of process validation would still need to be followed. The process and product parameters which impact on lethality need to be understood in order to establish worst case conditions for the validation study.

The first important parameter to consider is the targeted microorganism, including its microbial loading and its selective resistance to the lethal factor of the technology. For some processes the relationship between the lethal factor and microbial inactivation is not well known compared with thermal processing. It is therefore essential to perform challenge tests with the actual target organism to ensure that the process works. For a worst case challenge of the processing technology the strain which has the greatest resistance to the lethal factor should be selected. There are a number of factors which can impact on this resistance/survival to the process, such as the growth state of the organism, the inoculation method and the food product inoculated.[10]

The second parameter to understand is the worst case test conditions of the product. The characteristics of the product can influence the lethality of the process and the targeted microorganisms' resistance. For instance, HPP involves the application of pressure which is accepted to be uniformly applied throughout the vessel and products. An example process could be 600MPa for 1 minute. Product factors that may influence microbial resistance/sensitivity and inactivation by HPP

may include the distribution of lipids in the product, the differences in water activity (aw), salt concentrations and the pH of the product.[10] With technologies such as PEF, the electrical conductivity of the food product can influence the resistance of the treatment chamber and the resultant effect on microbial inactivation. Higher conductivities can reduce the resistance and require higher energy to achieve the same electric field.[11] Understanding of the variability of key product characteristics during processing can be used to establish the worst case conditions for the validation study.

The third parameter is the technology process itself. The process needs to be characterised to understand how reproducible it is, how uniform the lethal factor delivered is, and the point where the least lethality is achieved. UV-C is an example where the light distribution in the treatment chamber would need to be known to identify areas that may result in shadowing and receive the lowest treatment. Factors such as different product sizes, volume of the product throughput and the belt/support structures of the treatment may reduce the amount of light delivered to the surface of the product. Once these factors are known, the process can be set up to ensure that these areas at least achieve the threshold required for the lethal factor. For HPP, although the pressure is applied uniformly throughout the vessel, the pressurization rate may influence the microbial inactivation.[10] One factor that could influence this is the amount of air in the product load being pressure treated. If the product is under-filled and excess air exists in the head space, this could influence the pressurization rate of the process.

Another factor to consider when validating these technologies is the effect the lethal factor may have on any chemical changes in the product being treated. It is important to understand whether anything in the product can interact with the lethal factor and result in chemical changes which present harm to the consumer. For example, can the product interact with the PEF electrodes or does the UV-C catalyse any other reactions in the product?

To learn more about validation studies and associated procedures, please contact us.

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