Campden BRI
Station Road
Chipping Campden
Gloucestershire
GL55 6LD, UK

Tel: +44 (0)1386 842000
Fax: +44 (0)1386 842100
www.campdenbri.co.uk

Thermal process compliance: 7 things you should know.....

Thermal processing is at the very centre of food preservation and is one of the most well-known and practiced areas of food manufacturing. The thermal process has a critical role in ensuring that foods are safe from microbiological contamination and remain high in nutritional and sensory attributes. There is today an extensive and ever-growing range of food products preserved by means of thermal technologies, ranging from full sterilisation (such as canning) to milder pasteurisation heat treatments (such as cook-chill and cook-freeze). There are also rapid advances being made in the equipment and environment used for thermal processing. Examples such as continuous flow heating and cooling systems, hot-fill processes and novel thermal technologies (e.g. microwave, radio-frequency, and ohmic heating) are becoming common in food manufacturing.

Whatever the thermal process, each has a common requirement – the need for food manufacturers to prove the safety of their food product through a structured programme of thermal process validation. This is part of the four pillars of Good Manufacturing Practice (GMP), namely:

- Prevention of pre-processing contamination or spoilage of the food product
- Assurance of package integrity, before, during and after processing
- Development and application of a suitable, scheduled thermal process to the product
- Prevention of post-process contamination to the food product

Validation is a continuous exercise. It is not a one-off trial, nor is it merely an annual check-up. There needs to be a full, demonstrable commitment for validation to be a continuous process of monitoring and surveillance. An ongoing thermal process validation programme needs to assure, and keep on assuring, the safety of thermally processed food.

This white paper summarises some of the key aspects that food processors should have under control for Due Diligence. For a more in-depth analysis of how specific aspects of thermal process validation may apply to your company, there are many opportunities for individual consultancy, advice or tailored training. We are here to help!

Contact Martin George, +44(0)1386 842037 martin.george@campdenbri.co.uk

1. What are the general requirements for thermal food processing?

It is, of course, the responsibility of a Food Processor to assure the safety of their food at all times and under all circumstances. They need to have clearly identified any steps in the activities of their business which are critical for food safety. A systematic approach, based on the principles of Hazard Analysis and Critical Control Point (HACCP), should always be the starting point and this approach should ensure that adequate safety procedures are identified, implemented, maintained and reviewed consistently.

Good practice for accurate, consistent and safe processing of heat preserved foods needs the Food Processor to develop and apply validated and verified heating (and cooling) processes to ensure food safety. However, it is often the case that a Food Processor does not have such specialist expertise or resources within the business to do this. In such circumstances, external consultation from a Thermal Process Authority is advisable.

A Thermal Process Authority can be an individual, or group, expert in the development, implementation and evaluation of food thermal processes. The Institute of Food Thermal Processing Specialists (IFTPS), an International organisation promoting food thermal processing technologies, suggests a number of areas of expertise (Box 1).

Box 1. Suggested areas of competency for a Thermal Food Processor (IFTPS)

- knowledge of microbial risks, product and packaging characteristics, critical factors, commercial equipment, and manufacturing procedures, and their effects on the delivery of a thermal process and maintenance of product sterility;
- knowledge of the applicable regulations and codes of practice;
- knowledge of the underlying principles, process calculations, analysis tools, and evaluation techniques related to thermal processing;
- knowledge and understanding of the appropriate design and methods of conducting studies relating to thermal processing of food, such as: heat penetration, temperature and heat transfer distribution studies, thermal-death-time experiments, process validation and verification studies, and applying other scientific methods related to aseptic and/or thermal processing;
- ability to analyze data generated by scientific studies, and evaluate the effectiveness of a thermal processing and packaging system to ensure safe and commercially sterile products;
- experience and ability to identify and evaluate process deviations and spoilage incidents;
- ability to document process establishment methods and results, and communicate thermal process requirements and recommendations.

Setting up and implementing a safe thermal process begins at the product development stage. This involves the initial product concept, development of product specification, production of samples and commercial scale production. Standardised procedures to allow the consistent and safe development of foods should include:

- Clearly defining the product specification. At a minimum, this should include a product description, an ingredient listing and the required processing, packaging, storage and distribution characteristics. It may also include any legislative, microbiological, chemical, nutritional, allergen and packaging requirements.

- Demonstrating a good general understanding of the principles of thermal processing, including the factors affecting heat resistance of pathogens and the factors affecting the operation of heating and chilling processes. This may be through appropriate qualifications, experience or training.

- Using recognised, standardised procedures where appropriate, e.g. ISO, BSI.

There are several intrinsic properties of the food product that dictate the extent of the thermal process needed. This may be expressed as the time and temperature treatment required by the food product, or more defined measurements such as process lethality (e.g. F_0 or P-values). Product properties such as pH, salt content and water activity will dictate what degree of thermal processing is needed. This is particularly relevant where pasteurisation heat treatments are considered and further details are contained in Campden BRI Guideline 51.

2. What does the term 'thermal process' mean?

A thermal process is designed to eliminate or reduce to safe levels, pathogen(s) identified through risk assessment as the most heat resistant, the most likely to outgrow during chilling, or presenting the greatest risk as regards food safety.

Heating (and cooling) processes should ensure the uniform and complete heating (and cooling) of every food unit in every product batch processed. Processes should be designed to inactivate a pathogen or group of pathogens, e.g. vegetative pathogens and/or spore-formers. Based on the specification for a product and the desired shelf-life, the target pathogen for the heat process should be identified which will ensure the safety of the product for its entire marked shelf-life. At a minimum, heat processing should eliminate all vegetative pathogens, e.g. *Listeria monocytogenes*, *Salmonella* spp., *Staphylococcus aureus*, *Campylobacter jejuni*, and *Escherichia coli* O157:H7 in foods. For longer shelf life products, targets move towards the more heat resistant strains of *Clostridium botulinum* and for these pathogens, a higher thermal process is required (Department of Health, 2003).

Following heat processing, cooling should also be considered and, as a minimum, should prevent or reduce the opportunity for any surviving spores of *Clostridium perfringens, Cl. botulinum* and *Bacillus cereus* to germinate and grow in the food after the heat treatment.

Having established the process targets, a heat treatment should then be developed to raise every part of the product to a given temperature for a given period of time and to prevent the product from becoming contaminated during the process.

3. What instrumentation and probes are needed for validation?

With our process targets (e.g. time-temperature) in place, the task of measuring our thermal treatment emerges. Instrumentation for this purpose should have sufficient accuracy and precision. Temperature is our key indicator and it is recommended that the accuracy of daily or working temperature monitoring instrumentation should be a minimum of ± 1.0^{o}C (preferably ± 0.5^{o}C).

All instrumentation should be initially calibrated prior to use. All daily or working and reference temperature instrumentation should be calibrated against measurement standards traceable to the International Temperature Scale ITS90. The calibration frequency for daily or working thermometers should be at least annual or at shorter intervals determined by risk assessment by the Food Processor

For reference thermometers, which may themselves be used to calibrate working thermometers, the calibration frequency should be as specified by the thermometer manufacturer. It may also be determined through a risk assessment by the Food Processor. As a minimum it is recommended that reference temperature probes used to calibrate working probes in the factory should be calibrated at least every three years (more often if there are any signs of deterioration in the device performance). Valid and up to date certificates of calibration should be kept on file for all instrumentation used in the validation and verification of thermal processes. Also, uncertainty of measurement in relation to the calibration of temperature measuring instrumentation should be used by Food Processor when setting the minimum targets for processing.

4. What is needed to set up the thermal process?

When setting a thermal process, it is necessary that Food Processors plan and test for all expected batch sizes, operating conditions and product types under 'worst case scenarios'. These 'worst cases' are a way of challenging the process – examples would be using the largest (slowest heating) product, starting from the lowest initial temperature, placed in the coldest location in the cooker and processed for the shortest cycle time used. Setting the process for this worst case helps to ensure that, under normal process conditions, the product would routinely achieve the target thermal process.

A Food Processor should validate the thermal process and then establish monitoring and verification procedures to ensure this validation data remains accurate. Setting up the thermal process for a food product involves two main stages:

- Temperature mapping of the heating environment (a temperature distribution test)
- Heat penetration tests within the food product.

It should be noted that this 'setting' of the process is valid for a specific product/package in a specific process environment. If there are any changes to a food product or thermal process system (e.g. product type, size, loading conditions, cooker/retort temperature) the validation must be repeated to ensure that each product unit receives the same specified time/temperature combination required to deliver a microbiologically safe product.

For this reason, processing of different batch sizes, e.g. half or quarter batch capacity, is not recommended. Only validated batch size loadings should be processed. No deviation from this should be allowed in production as this is critical to the safety and quality of the heat treatment delivered to the food product.

Temperature distribution (TD) tests are conducted to locate both points of slowest heating (cold-spots) and quickest heating (hot-spots) in the heating medium. The cold spot will be the point that must be monitored for food safety purposes. TD is required to develop, implement and validate heating and chilling processes in preparation for heat penetration studies.

TD tests should be repeated at least every three years or more frequently if new equipment is installed, or equipment is repaired or serviced. It should also be repeated if the loading in the heating chamber changes (e.g. new loading/stacking patterns) or there are any suspicions of equipment deteriorating with time. As this is such an important element in process validation, many Food Processors conduct full TD tests in their equipment each year – an annual calibration of their processing system.

A typical procedure is to load the heating equipment with the configuration of product to be validated. Temperature measurement probes are then located throughout the processing chamber, the position of these probes being dependent on the system:

- In horizontal stacking heating chambers, the product is usually placed in the chamber in racks. Probes should be positioned in the centre of each rack at the top, centre and bottom.
- In vertical stacking, probes should be positioned in the centre of each crate or basket on the top, centre and bottom shelves of the equipment.

- The arrangement of probes should ensure that data collected are representative of the heating capacity of the equipment. However, a minimum of 7 to 15 probes/m^3 should be used with at least one probe placed in close proximity to the equipment master temperature probe (FSAI, 2006).

The system is then allowed to complete a normal process cycle and temperature readings are taken. The distribution or spread of temperatures throughout the processing environment can then be determined. Ideally, to set up a 'worst case' thermal process, the cold point in the chamber is used for subsequent heat penetration tests in the food product.

TD measurements require some knowledge of the operation of the thermal process equipment. For specialist heating equipment which uses water or steam showering techniques, temperature measurement probes should not be in direct contact with the water. In steam heating equipment, the tips of probes should be pointing upwards to prevent droplet formation from condensing steam and the arrangement of probes within the heating chamber should ensure that they are not in contact with any internal surfaces of the equipment. Where possible, probes should be positioned in void spaces between product packages. It is advisable that duplicate TD tests are conducted to confirm repeatability and consistency of results

The second stage of **Heat Penetration (HP)** testing focuses on taking temperature measurements within the food product. This is usually done at the cold point in the product, which will depend on the product characteristics and the package geometry. In addition, HP tests are often conducted with the product placed at the coldest location within the process environment (identified in the TD tests). From the data gathered in both TD and HP tests, the Food Processor can then validate a time/temperature combination to process the food to meet safety requirements. HP tests should be repeated at least every three years or more if product, package or process conditions change. It is important to note that many factors can change the thermal process delivered to a food product. Examples are changing product formulation (e.g. reduced salt or sugar, alternative starches or gums) or changing package materials, size or shape. Any product or package changes need the HP test to be re-visited and a re-test conducted if appropriate.

Best practice in performing heat penetration tests is described below:

Temperature probes should be positioned at the points of slowest heating (the 'cold point') in the product. These points will vary depending on the nature of the product and the equipment used. In relation to the product, the location of the cold spot will depend on the dominant method of heat transfer:

- In conduction heating products surrounded by heating media, heat will transfer from the outer surfaces of the product to the colder interior and the slowest heating point will often be the geometric centre of the product.
- In products which are heated by convection, the cold point will be somewhere between 1/3 and 1/5 of the height of the package from the base.

- If the product rotates or agitates during processing the product with the slowest heating point will be typically found at the geometric centre.
- In some products, a change of heating mode occurs during processing. This can be from convection to conduction (broken heating) or from conduction to convection (mixed heating).
- If the product has particulates or solids the cold-spot is often when the largest particle is placed at the product cold point.

The temperature probes should record the product temperature at appropriate time intervals throughout the process (e.g. every minute) until the required time/temperature combination is achieved. The frequency of temperature measurements should be sufficient to describe and verify the process. Tests should be repeated in duplicate to ensure repeatability and consistency of results.

Time-temperature data from these tests are used to calculate the process lethality. The General Method is most widely used,a mathematical conversion of time and temperature to process effectiveness. Box 2 shows the equation used:

Box 2: The General Method for process lethality calculation

$$P = \int_0^t 10^{\frac{T(t)-Tref}{z}} \cdot dt$$

Where:

For the process P -

T (°C) is the product temperature and each time interval t (minutes)

T_{ref} (°C)is the reference temperature used for the process calculation

z is the z value (°C) of the microorganism for which the process is set

For pasteurisation heat treatments, processes are compared to industry accepted targets (e.g. 70°C for 2 minutes; 90°C for 10 minutes; see Campden BRI Guideline 51). For sterilisation processes, reference temperatures of 121.1°C and F_0 values (equivalent minutes at 121.1°C) are used as the basis for acceptance.

Campden BRI provides training in each of these areas: Canning, Thermal Process Validation, Pasteurisation, Cooking Process Validation.

5. What monitoring and verification is needed?

On-going product temperature monitoring is required for all food thermal processes to verify that the specific requirements of product safety such as minimum time and temperature combinations in heating (and chilling) are consistently being achieved. When a Food Processor uses a validated and verified thermal process for production, a programme of on-going process validation and verification should be undertaken.

Monitoring and verification requires rigorous record keeping. Of particular note should be:

- Process schedules. Details of the scheduled process, outlining all the key factors that make up the product and the process limitations, should be documented. This should also contain specific requirements, such as pH and Aw conditions for the product.

- Thermal process requirements for the product. The target process should be clearly documented and clear to all operators of the process equipment.

- The process validation records. These should include results from the temperature distribution on the process, the cold point determination in the package and the replicate heat penetration testing. For auditing purposes, it is also useful to have a record that the process equipment has been reviewed on an ongoing basis (an equipment audit or survey) and also calibration records from key instrumentation.

Production records are also important and can be a good indication that the process is well controlled. Example information that might be captured would be: line hygiene records (including filler), alarm checks, seal integrity and dud detection records, incubation records, temperature checks (product and process), belt speed checks, process timings, and cooling water quality checks. Note that this list is by no means exhaustive.

6. Is it acceptable to change process conditions?

The scheduled thermal process should be adhered to at all times. Changes to product, package or process conditions can have a dramatic effect on the safety (and quality) of the thermally processed food product.

Food Processors should ensure that:

- Processing of mixed batches of product is not allowed, unless the Food Processor can provide evidence to validate and verify the thermal process delivered to this mixed product load.

- Processing of different batch sizes, e.g. half or quarter batch maximum capacity, is not allowed, unless the Food Processor has validated and verified the process for that specific batch size.

- The effect of any changes to product, package or process is validated before it is used in production. Typically, changes in processing such as product stacking, racking and orientation of product in the heating chamber, type of racks used to stack product during processing, design and use of separator or divider sheets between layers of product units and/or location of point of slowest heating in the heating chamber, e.g. stacking arrangement of product during heating, can affect the safety of the product.

A particular case of a process change may be a process deviation, when the actual process is less than the scheduled process or when any critical factor does not comply with that specified in the scheduled process. Examples of deviations that can occur are power or boiler failures during the process, excessive delays in processing, use of the wrong cooker program, or an instrument failure. In such cases, process calculations can be used to assess the impact of the deviation on the product safety. Process modeling is a rapid and cost-effective method of conducting calculations rapidly. Campden BRI has a numerical modelling software (CTemp) available for such applications; details can be provided on request.

7. What information and guidance is available?

Gaze, J.E. **(2006).** Pasteurisation: a food industry practical guide (second edition). Guideline No.51. Campden BRI (www.campdenbri.co.uk)

Department of Health **(2003).** Guidelines for the safe production of heat preserved foods. TSO (copies available from Campden BRI).

Food Safety Authority of Ireland **(2006)** Guidance Note No. 20. Industrial processing of heat-chill foods

Institute for Thermal Processing Specialists **(2004)** Protocol for carrying out heat penetration studies. http://www.iftps.org/

Contact:

Martin George +44(0)1386 842037 martin.george@campdenbri.co.uk

Issued Nov 2013