

**Industrial Processing  
of Heat-Chill Foods**



# **Guidance Note No. 20**

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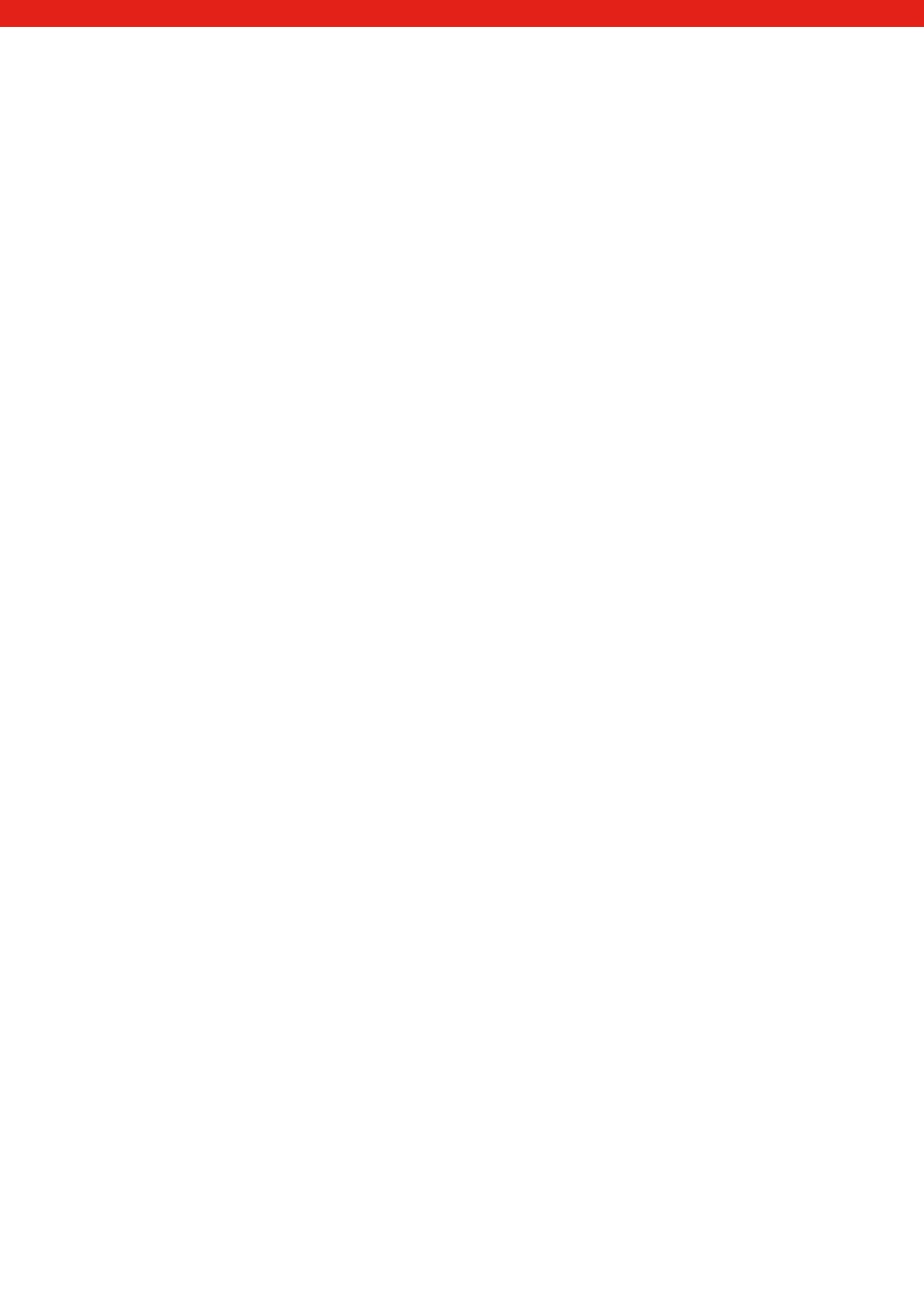


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## ABBREVIATIONS

<b>BS</b>	British Standard
<b>BPF</b>	Base Product Fill
<b>EC</b>	European Commission
<b>EU</b>	European Union
<b>FBO(s)</b>	Food Business Operator(s)
<b>FSAI</b>	Food Safety Authority of Ireland
<b>GHP</b>	Good Hygiene Practices
<b>GMP</b>	Good Manufacturing Practices
<b>HACCP</b>	Hazard Analysis Critical Control Point
<b>ISO</b>	International Standards Organisation
<b>INAB</b>	Irish National Accreditation Board
<b>MAP</b>	Modified Atmosphere Packed/Packaged
<b>Min</b>	Minutes
<b>NSAI</b>	National Standards Authority of Ireland
<b>s</b>	Seconds
<b>S.I.</b>	Statutory Instrument
<b>SOP(s)</b>	Standard Operating Procedure(s)
<b>RTE</b>	Ready-to-eat
<b>VP</b>	Vacuum Packed/Packaged
<b>VTEC</b>	Verotoxigenic <i>Escherichia coli</i>



## BACKGROUND AND PURPOSE

This Guidance Note has been prepared by the Food Safety Authority of Ireland (FSAI) in consultation with an industry working group.

The FSAI believes that Guidance Notes have a major role to play in assisting food business operator(s) (FBOs) and regulators in Ireland to achieve compliance with legislation and with good practice.

A Guidance Note is not a substitute for legislation. However, the FSAI believes a Guidance Note provides a more detailed elaboration of requirements. Adherence to the guide should make compliance easier and provide the basis for a high degree of consistency in the application of legislation.

## SCOPE

The document is applicable to FBOs processing batches of heat-chill pre-packaged foods under static heating conditions which are distributed to retail\* food businesses. These foods will require chilled storage at 5°C (recommended  $\leq 3^{\circ}\text{C}$ ) to maintain shelf-life during distribution, display and sale.

The document is not applicable to:

- i. Food business operators involved in the preparation and direct sale or supply of products directly to consumers, e.g. food service operations such as restaurants, hospitals etc.
- ii. Cook-chill food produced under FSAI Guidance Note No. 15<sup>(1)</sup>
- iii. Liquid and liquid containing particulate foods which are heat processed by pumping through a direct or indirect heat exchanger, e.g. steam injection, steam infusion, plate, tubular or scraped surface before passing through a holding tube
- iv. Heat processed ambient stable foods
- v. Heat processed milk and milk products<sup>(2)</sup>
- vi. Dried, fermented, cold or hot smoked meat, poultrymeat and fish which is heat and/or chill processed
- vii. Live bivalve molluscs (i.e. bivalve molluscs are filter-feeding lamellibranch molluscs)<sup>(2)</sup>

\* Retail means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets<sup>(5)</sup>.

## DISCLAIMER

1. All FBOs must comply with the legislative requirements of all current legislation<sup>(2-7)</sup>.
2. This document is intended to act as a guideline to current legislation which requires FBOs to ensure the safety of their foods<sup>(2-7)</sup>.
3. Responsibility for food safety rests with the FBO<sup>(5)</sup>.
4. It must be noted that legislation is continually being updated and/or amended. Up-to-date information on food legislation is available from the FSAI website: [www.fsai.ie](http://www.fsai.ie).
5. This document is advisory in nature and outlines agreed best practice to be used by FBOs processing heat-chill foods.
6. This document does not purport to be comprehensive or to be a legal interpretation or to constitute legal or other professional advice.
7. The document should be read in conjunction with current food safety and hygiene legislation<sup>(2-7)</sup>, relevant Irish standards<sup>(8-12)</sup>, Irish guidelines<sup>(1, 13-21)</sup>, European guidelines<sup>(22-26)</sup>, international guidelines<sup>(27-30)</sup>, scientific opinions<sup>(31-33)</sup> and industry best practice documents<sup>(34-40)</sup>.
8. Where a FBO has existing procedure(s) not outlined in this document, it is strongly recommended that the FBO take account of the information contained in this Guidance Note and/or seek advice from a competent body.
9. Where a FBO has alternative procedure(s) not outlined in this document, it is strongly recommended that advice from a competent body is sought prior to commencement of production.
10. Reference to any commercial products, process, service, manufacturer, or company does not constitute its endorsement or recommendation by the FSAI.
11. The FSAI is not responsible for the contents of any website referenced in this document.
12. All examples used in this document are for illustration purposes only and are not intended to be exhaustive.
13. All websites referenced in the bibliography were last accessed in June 2006. All legislation referenced in the bibliography will indicate the relevant European legislation, followed by the equivalent Irish Statutory Instrument where available.

## MAIN RECOMMENDATIONS

### General

1. It is the responsibility of a FBO to ensure that the safety of food produced is assured at all times and under all circumstances.
2. Food business operators should clearly identify any step in the activities of their business which is critical in ensuring food safety. A systematic approach, based on the principles of Hazard Analysis Critical Control Point (HACCP), should always be followed to ensure adequate safety procedures are identified, implemented, maintained and reviewed consistently.
3. Best practice for accurate, consistent and safe processing of heat-chill foods requires the development and implementation of validated and verified heating and chilling processes to ensure food safety.
4. If a FBO does not have sufficient expertise or resources within the business to develop and implement a validated and verified heat-chill process, external consultation is strongly recommended.
5. In the event that a non-conforming product is identified due to a failure in the heating or chilling processes (or otherwise), the product batch should be clearly identified and segregated to ensure that it is not inadvertently used or dispatched by the FBO. The FBO should then carry out a risk assessment on the segregated product to assess its safety.

### Food Business Operators

6. Food business operators should determine the properties of the foods they produce which are likely to have an impact on food safety under all reasonably foreseeable conditions of processing, storage and use.
7. Food business operators should have a general understanding of the mathematics behind heat processing.
8. Food business operators should have a general understanding of the factors affecting the growth and survival of pathogens and the factors affecting heating and chilling processes.

### Heating and Chilling

9. When developing and implementing a heat-chill process, it should be 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.

10. The heating and chilling processes should ensure the uniform and complete heating and chilling of every food unit in every product batch processed.
11. At a minimum, heat processing should achieve a six decimal reduction in numbers of the vegetative cells of the target pathogen, *Listeria monocytogenes*, in food.
12. At a minimum, chilling 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 following heat processing. As such, chilling should decrease the temperature of a heat processed food as described in Section 3.10 of this document.

### **Calibration**

13. All instrumentation should be initially calibrated prior to use.
14. All daily or working and reference temperature instrumentation should be calibrated against measurement standards traceable to the International Temperature Scale ITS90.
15. The calibration frequency for daily or working thermometers should be at least annual or at shorter intervals determined by risk assessment by the FBO.
16. The calibration frequency for reference thermometers should be as specified by the manufacturer, or by risk assessment by the FBO but at minimum, should be at least every three years.
17. Valid certificates of calibration should be kept on file for all instrumentation used in the validation and verification of heat-chill processes.
18. Uncertainty of measurement in relation to the calibration of temperature measuring instrumentation should be used by FBO when setting the minimum targets for heat-chill processes.

### **Instrumentation**

19. Instrumentation should have sufficient accuracy and precision. It is recommended that the accuracy of daily or working temperature monitoring instrumentation should be a minimum of  $\pm 1.0^{\circ}\text{C}$  (preferably  $\pm 0.5^{\circ}\text{C}$ ).
20. Reference thermometers used to calibrate daily working thermometers should have a minimum test uncertainty ratio of 4:1.

## **Setting the Process**

21. When setting a process, it is prudent that the FBOs plan and test for all expected batch sizes, operating conditions and product types under worst case scenarios.
22. During temperature mapping, the arrangement of probes within the processing chamber should ensure that data collected are representative of the heating/chilling capacity of the equipment at specific positions/zones within the chamber. A minimum of 7 to 15 probes per/m<sup>3</sup> should be used with at least one probe placed in close proximity to the equipment's own internal temperature controlling probe (i.e. master probe).
23. Heat penetration tests should continue until the required time/temperature combination is achieved in product cold-spots and/or products positioned at the slowest heating point(s) of the processing chamber. Tests should further extend for a short period after the required time/temperature combination is achieved so that a definite temperature profile can be established for all thermocouples used.

## **Monitoring and Verification**

24. On-going product temperature monitoring is required for all heat-chill processes for verification that the specific requirements of product safety (i.e. minimum time/temperature combination in heating and chilling) have been achieved.
25. When a FBO uses a validated and verified heat-chill process, on-going process validation and verification, e.g. temperature checks, should be undertaken on a scheduled, routine basis based on risk assessment. The temperature and time combination should be monitored at the centre of the largest product unit placed at the identified slowest heating point in the heating chamber.

## **Processing and Equipment**

26. Processing of mixed batches of product is not recommended unless the FBO can validate and verify the process.
27. Processing of batch sizes, e.g. half or quarter batch maximum capacity not typically processed by the FBO, is not recommended unless the FBO has validated and verified the process for that specific batch size.
28. Any change 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 effect the safety of the product.

29. The requirements and selection of processing equipment should be based on the specific requirements of the FBO.
30. All equipment should be fit for purpose, capable of the required accuracy and repeatability and lend itself to validation and ongoing monitoring.



## I. LEGISLATION

The intent of this document is to provide guidance to FBOs on compliance with:

1. Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety<sup>(5)</sup>
2. Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs<sup>(3)</sup>
3. Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin<sup>(2)</sup>
4. Regulation (EC) No 2073/2005 of the European Parliament and of the Council on the microbiological criteria for foodstuffs<sup>(6)</sup>.

Legislation specific to heating and chilling of foods exists, but is largely unstandardised throughout the European Union (EU)<sup>(2)</sup>. Foods typically receive heating and chilling based on agreed best practice, national standards or guidelines.

Specific requirements for temperature control are specified in EU legislation for the preparation, handling and storage of raw meats, fish, poultry, shellfish, milk and egg products. However, specific requirements for the chilling of foods following heat processing is not specified except in cases where it is stated that rapid cooling must follow heat processing, e.g. processed fishery products<sup>(2)</sup>.

Under Regulation No 852/2004 (Annex II; CHAPTER XI; Heat Treatment) the following requirements apply to food placed on the market in hermetically sealed containers<sup>(3)</sup>:

1. Any heat treatment process used to process an unprocessed product or to process further a processed product, is:
  - i. To raise every part of the product treated to a given temperature for a given period of time
  - ii. To prevent the product from becoming contaminated during the process.
2. To ensure that the process employed achieves the desired objectives, FBOs are to check regularly, the main relevant parameters (particularly temperature, pressure, sealing and microbiology), including the use of automatic devices.
3. The process used should conform to an internationally recognised standard, e.g. pasteurisation, ultra high temperature or sterilisation.
4. Where foodstuffs are to be held or served at chilled temperatures, they are to be cooled as quickly as possible following the heat-processing stage, or final preparation stage if no heat process is applied, to a temperature which does not result in a risk to health.

## 2. APPLICATION OF HACCP PRINCIPLES

Hazard Analysis Critical Control Point (HACCP) is a logical science based system designed to assure the safety of food. In the context of this document, all aspects of heating and chilling processes should be included as integral parts of a FBO's HACCP plan.

All FBOs, except primary producers, e.g. farms, are legally required to establish and operate procedures based on the principles of HACCP <sup>(2-3)</sup>. The application of HACCP will require FBOs to train staff.

Food business operators should ensure that any step in the activities of the business which is critical to ensuring food safety is identified, e.g. heating and chilling, and that adequate safety procedures are identified, implemented, maintained and reviewed on the basis of the principles used to develop the system of HACCP.

A solid foundation of control, based on a robust prerequisite programme, is required prior to the development and implementation of HACCP. The programme should include the following:

1. Good Management Practices
2. Good Manufacturing Practices (GMP)
3. Good Hygiene Practices (GHP)
4. Standard Operating Procedures (SOP).

The prerequisites should provide the basic environmental and operational conditions necessary to produce safe food.

Six sector specific national guides to good practice for hygiene and the application of HACCP, have been published under the aegis of the National Standards Authority of Ireland (NSAI) <sup>(8-12)</sup>.

The European Commission (EC) has also recently produced a guidance document on the implementation of procedures based on the HACCP principles <sup>(23)</sup>.

FBOs may use these guides on a voluntary basis to implement prerequisites and as an aid to compliance with food hygiene requirements.

Good Management Practices, GMP, GHP and SOPs are also very important. However, only a scientifically based system such as HACCP can be accurately measured and validated to allow for the detection and correction of deviations from critical limits. Adherence to critical limits has been scientifically shown to assure the production of safe food <sup>(19)</sup>.

### **3. OPTIMISING THE PROCESS (Process Selection)**

A heating process should eliminate or reduce to safe levels, pathogens that could endanger public health, maintain product shelf-life and retain the organoleptic attributes of the product.

A chilling process should prevent the outgrowth of spore forming pathogens by rapidly reducing the temperature of the food to a low storage temperature to preserve product safety and shelf-life.

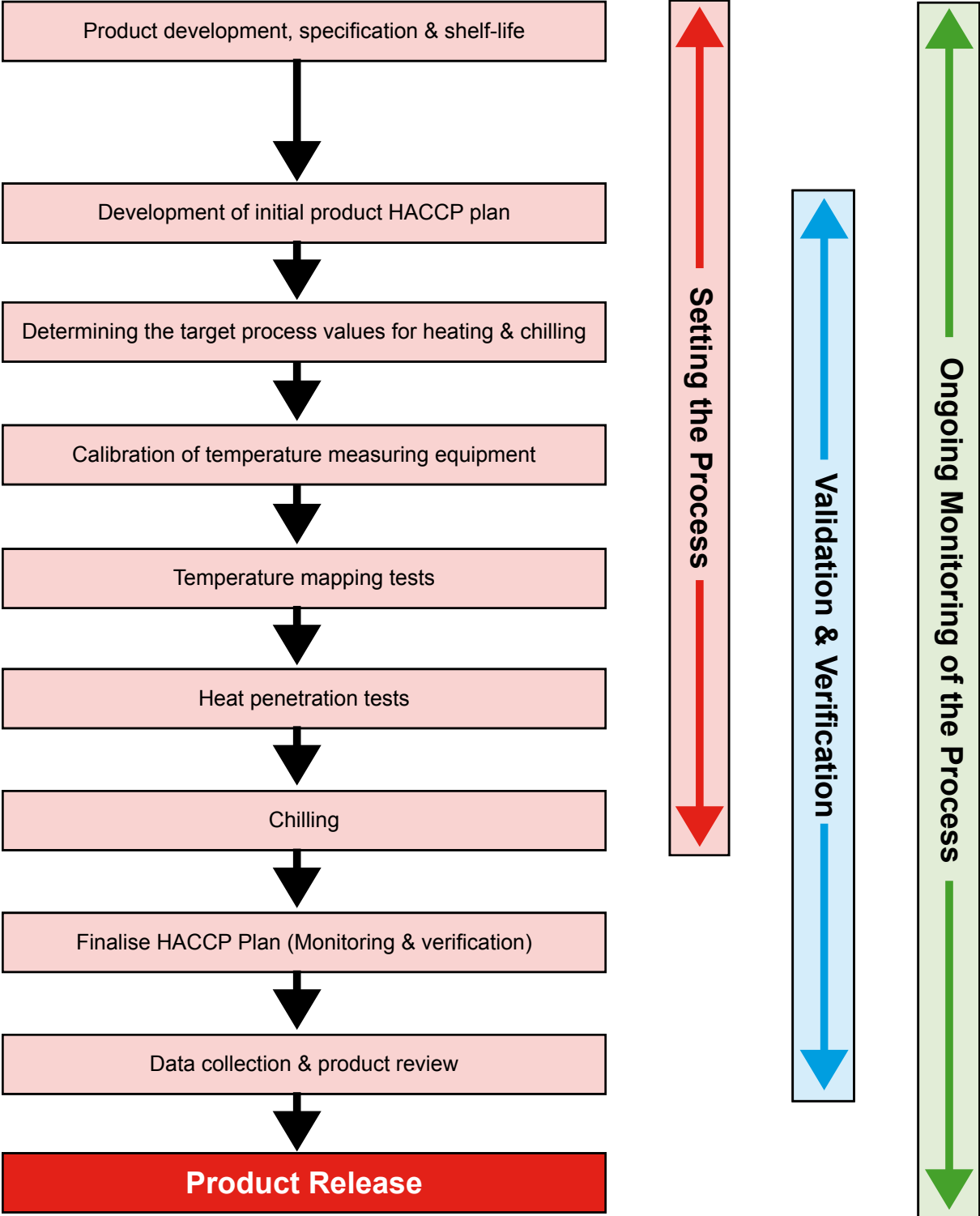
Foods typically receive a heat process that heats the food to a suitable temperature and holds the food at or above that temperature for an appropriate period of time.

The heat process should ensure that the food, if consumed within its shelf-life and not exposed to contamination or temperature abuse during storage, will not endanger the health of the consumer due to pathogenic survival and growth. As such, some heat-chill products are referred to as ready-to-eat (RTE).

With heat-chill processes, it is also important to ensure that levels of spoilage microorganisms are reduced so that bio-deterioration of the product will not occur within the designated shelf-life of the food.

Figure 1 outlines the general stages in the development and implementation of a heat-chill process designed to produce a safe product.

**Figure 1. Stages in the Development, Approval and Implementation of a Heat-Chill Process**



### 3.1 Product Development and Specification

The development and implementation of a safe heat-chill process for food begins at the product development level.

Food product development involves the initial product conception, development of product specification, production of samples and finally, commercial scale production.

Food business operators should develop SOPs to allow the consistent and safe development of foods. To ensure consistent, safe and controlled production of heat-chill processed foods, it is best practice to implement a validated safe process and to verify performance during each production run. This will require FBOs to:

1. Clearly define the product and its characteristics in a specification. At a minimum, the specification should include:
  - i. A product description
  - ii. Ingredient listing
  - iii. Shelf-life required to meet safety, quality and marketing requirements
  - iv. Required processing, packaging, storage and distribution characteristics
  - v. Proposed HACCP plan and any available risk assessment data
  - vi. Legislative requirements, e.g. microbiological, chemical, nutritional, allergens, packaging, labelling etc, and/or customer requirements
  - vii. Nutritional characteristics (i.e. as applicable)
  - viii. Quality characteristics (i.e. as applicable).
2. Use personnel suitably trained commensurate with their duties and responsibilities. If this is not possible, the FBO should employ a suitably competent organisation or person, e.g. consultant, to assist
3. Have a good general understanding of the mathematics behind heat processing, the factors affecting heat resistance of pathogens, the factors affecting heating and chilling processes and the factors which may adversely affect safe processing
4. Use suitable equipment, instrumentation and facilities
5. Use recognised, standardised procedures where appropriate, e.g. ISO, BS etc.
6. Calibrate equipment and instrumentation to an accuracy required for effective validation and verification
7. Develop and implement temperature mapping tests of heating and chilling processes
8. Develop and implement heat penetration tests of heating and chilling processes
9. Collect and review data
10. Verify adequacy of heating and chilling processes
11. Implement on-going monitoring and SOPs for heating and chilling processes.

## 3.2 Product Shelf-life

The required shelf-life for a food is a key factor in developing and implementing a safe heat-chill process. The desired shelf-life of a product in conjunction with product characteristics (including processing and packaging), determines the target pathogen (Section 3.8) for destruction during heat processing.

A validated product shelf-life is critical to the control for specific pathogens, particularly if the food has an extended shelf-life and can support the growth of pathogens. It is important to determine if a pathogen will grow to unacceptable/potentially hazardous levels during the shelf-life. For a food to be microbiologically safe and commercially viable, a FBO must produce a product which has a consistently reproducible and acceptable microbiological safety.

Food business operators are responsible for determining the characteristics of the foods they produce or pack and the subsequent shelf-life<sup>(20)</sup>. Therefore, shelf-life of food is an integral part of food safety. An incorrect shelf-life has the potential to endanger consumer health.

Foods that are highly perishable from a microbiological perspective may constitute a danger to public health after a short period of time and as such, must have the appropriate shelf-life clearly indicated by means of a 'use-by' date<sup>(7)</sup>.

The 'use-by' date will indicate the date up until which the food can be safely consumed, provided it has been stored correctly, e.g. packaging, storage temperature<sup>(20)</sup>. Further details on specific issues related to product shelf-life including labelling are given in FSAI Guidance Note No. 18<sup>(21)</sup>.

## 3.3 Mathematical Principles of Heat Processing

To design and implement a safe heat process requires FBOs to have a good general understanding of the mathematics behind heat processing, associated with the effect of heat processing on pathogens (i.e. thermal destruction). In addition, the FBO should have a general understanding of the factors affecting heat resistance of pathogens and the factors affecting heating and chilling processes.

### 3.3.1 Decimal Reduction Time (D-value)

For every target pathogen or spoilage microorganism under specific conditions of substrate, e.g. food, and temperature, there is a specific time required at a particular temperature to ensure destruction of 90% of all viable (i.e. vegetative) cells and/or spores present. This time (i.e. in minutes or seconds) is referred to as the decimal reduction time or D-value<sup>(41-42)</sup>. A 90% reduction is also referred to as a 1 Log<sub>10</sub> cycle reduction or a ten-fold reduction.

D-values are temperature specific with the temperature at which the D-value is measured, generally given as a subscript to the D-value, e.g. D-value at 75°C is expressed as  $D_{75}$ . D-values are also specific to a particular microorganism. They can also be affected by the composition of the food (i.e. substrate) in which the microorganism is found. The severity of a heat process can be described in terms of D-values, e.g. a 6D process is a heat process which reduces a particular microorganism type by 6  $\text{Log}_{10}$  cycles.

### 3.3.2 z-value

As previously stated, the D-value is temperature specific. If the  $\text{Log}_{10}$  of a series of D-values for a target pathogen or spoilage microorganism is plotted against temperature (°C), a straight line relationship is generally found. The reciprocal of the slope of this graph can be described by the number of degrees Celsius which results in a 1  $\text{log}_{10}$  (i.e. ten-fold or 90%) decrease or increase in the D-value. This temperature change is called the z-value (C deg).

## 3.4 Intrinsic and Extrinsic Properties of Food

It's important to understand the factors which may affect the ability of a FBO to achieve a target heat-chill process. The intrinsic (i.e. water activity, pH, food composition etc.) and extrinsic properties (i.e. storage temperature, gas atmosphere, relative humidity etc.) of a food will affect the heat resistance of pathogens and the ability of a FBO to achieve a target heating process<sup>(43)</sup>. As such, FBOs should determine the properties of the foods they produce, under all reasonably foreseeable conditions of processing, storage and use.

Some of the more important intrinsic and extrinsic properties of food are outlined in Appendix I. Greater detail on intrinsic and extrinsic properties of foods can also be found in FSAI Guidance Note No. 18<sup>(21)</sup>.

## 3.5 Requirements for Pathogenic Survival and Growth

All pathogens have specific requirements for survival and growth in food. The survival and growth of pathogens will depend on the intrinsic and extrinsic properties of the food (Section 3.4).

It is important to note that the intrinsic and extrinsic properties of foods are inherently variable. Further, while each intrinsic and extrinsic property may affect pathogenic growth and survival, it is the interaction between these properties which determines whether a pathogen will grow or survive in a food.

It is important that a FBO understands the ability of pathogens to evolve in response to environmental stresses, e.g. cold-shock, heat-shock, low water activity ( $a_w$ ), low pH etc. Therefore, the efficiencies of processing, e.g. heating and chilling, should be assessed, especially with regard to the potential of pathogens to adapt and increase their resistance to a wide variety of environmental stresses.

Specific pathogens are often associated with specific foods. Some common associations are given in Table I.

**Table I. Common Associations between Pathogens and Foods**

<b>Pathogen</b>	<b>Commonly Associated Food Products</b>
<i>Salmonella</i> species	Eggs, poultry, meats & dairy products
<i>Clostridium botulinum</i> Mesophilic/Proteolytic: Types A, B & F	Canned foods, vacuum packed (VP) & modified atmosphere packed (MAP) foods
<i>Clostridium botulinum</i> Psychrotrophic/Non-Proteolytic: Types B, E & F	Canned foods, VP/MAP foods & jarred foods
<i>Staphylococcus aureus</i>	Eggs, poultry, meats, dairy products & confectionary
<i>Campylobacter jejuni</i>	Poultry, meats & milk products
<i>Yersinia enterocolitica</i>	Fresh meats & milk
<i>Listeria monocytogenes</i>	Ready-to-eat foods
<i>Clostridium perfringens</i>	Cooked meat & poultry products
<i>Escherichia coli</i> O157 & other Verotoxigenic <i>E. coli</i> (VTEC)	Meat, poultry, milk & vegetable products
<i>Bacillus cereus</i>	Cooked rice & pasta, spices, meats, milk, vegetables, fish, sauces, puddings, soups, casseroles, pastries, & salads
<i>Vibrio parahaemolyticus</i>	Fish & seafood products

### 3.6 Product, Process, Equipment and Packaging Properties

It is important to note that any change in the product, process, equipment or packaging may have an impact on whether an existing heat process is valid. A FBO should be aware of the following issues which may affect heating and chilling in achieving target requirements.



### 3.6.1 Product

1. Product nature, formulation and composition, e.g. high levels of starch based ingredients, can increase product viscosity and reduce  $a_w$ . Product nature, formulation and composition will influence the mode, e.g. convection, conduction, and speed of heat transfer during processing, e.g. convection is faster than conduction.
2. Examples of how product formulation and composition affect mode and speed of heat transfer are given below:
  - i. Fast convection heating, e.g. milk, juices, broths, thin soups etc.
  - ii. Slow convection heating, e.g. vegetable soups, fruit syrups, some thin purees – sauces, usually low starch, etc.
  - iii. Convection and conductive heating, e.g. some thick soups or gravies which contain starch, may change their heating behaviour due to starch gelatinisation at a particular temperature. Small variations in product formulation or ingredients may cause the transition from convection to conduction heating to occur at a different temperature and related time. Special care should be taken to identify and control specific product and process variables related to the heating rates of these products
  - iv. Conductive heating, e.g. pasta, rice, thick purees - usually high starch content, meat and fish products, confectionary, dairy products, usually high fat content.
3. Consistency and viscosity of product, particularly in semi-liquid or liquid components and non-homogenous products.
4. Solids to liquids ratio in product.
5. Size, shape and weight of solid components.
6. Initial product temperature.
7. Initial microbial load of product.
8. Thermal properties of the product (i.e. thermal conductivity, thermal diffusivity, specific heat capacity).
9. Hot or cold filling of product.
10. Behaviour of product components during heat processing, e.g. in some products clumping may occur. This is particularly important with sliced products, e.g. meats which can stick or clump together during heat processing. Products which are prone to clumping may affect temperature sensor placement in the product and the cold spot location.

### **3.6.2 Process**

1. Raw material preparation techniques prior to heat processing:
  - i. Mixing/agitation techniques, e.g. incorporation of air, emulsification etc.
  - ii. Mixing/agitation, e.g. rotating, stationary etc., of the product during processing
  - iii. Initial product temperature prior to heat processing
  - iv. Blanching of fruit/vegetables which can cause swelling or shrinkage which can effect heat processing efficiency
  - v. Rehydration of dried components may affect the process with respect to inactivation of microbial spores as they may be less resistant to heat in this rehydrated form.
  
2. Nature of heat transfer in equipment:
  - i. Conduction
  - ii. Convection
  - iii. Radiation.
  
3. Type of cooking equipment:
  - i. Immersion, e.g. water, oil
  - ii. Saturated steam
  - iii. Water and steam/air mixture (i.e. rate of heat transfer here is dependent on heating medium velocity)
  - iv. Water showering.
  
4. Equipment operation:
  - i. Process temperature and time
  - ii. Time taken for heating chamber to achieve the operational temperature (i.e. temperature come-up time)
  - iii. Venting procedure if steam used
  - iv. Excess/over pressure if using steam/air or water
  - v. Product stacking, racking and orientation of product in the heating chamber
  - vi. Type of racks and/or baskets used to stack product during processing
  - vii. Design and use of separator or divider sheets between layers of product units
  - viii. Location of points of slowest heating in the heating chamber.

### **3.6.3 Equipment**

The requirements and selection of equipment, e.g. ovens, should be based on the specific requirements of the FBO. Equipment manufacturers and suppliers are best positioned to give advice to a FBO on the choice of equipment for specific foods, particularly in relation to capacity and design issues. However, it is recommended that wherever possible, FBOs obtain objective information in relation to equipment. The following should be considered by FBOs in selecting and using equipment:

1. Obtain objective information in relation to the performance and practicalities of use, in relation to equipment
2. Selected equipment should have a sufficient performance capability for the required process
3. Selected equipment should use the appropriate mode of heat transfer based on the physical and thermal properties of the food. Some equipment will use saturated steam for the heat transfer medium while others will use water and steam mixtures
4. Selected equipment should have sufficient capacity to allow for projected future production levels
5. Selected equipment should allow for the required pack orientation in the heating chamber (i.e. stacking/racking orientation of individual food units in the chamber)
6. Selected equipment should have good design to allow for effective cleaning and disinfection and minimisation of the risks of cross contamination, e.g. movement of raw product to cooked product
7. Selected equipment should allow for calibration of all monitoring probes, both internal and external, e.g. temperature, pressure probes etc.
8. Selected equipment should allow for validation and verification of the process
9. Selected equipment should be included in planned preventative maintenance programs at each processing site. Planned maintenance should include air velocity checks, checks on flaps, pistons, motors, belts, steam pressure, etc. For conveyor cookers, conveyor speed and loading should also be included.

#### **3.6.4 Packaging**

1. Change of packaging.
2. Type of packaging material used, e.g. plastics, laminates, glass, metals etc.
3. Thermal properties of the packaging materials.
4. Type of containers, e.g. pouches, jars, cans etc.
5. Unit pack size, shape, thickness and other dimensions, e.g. the thickness of packaging has a direct effect on the ability of heat to penetrate into a food.
6. Packaging atmosphere which could affect the heat process required, e.g. vacuum. packaged, modified atmosphere packaged.
7. Sealing characteristics of packaging, e.g. can seals fail during processing?
8. Products fill characteristics, e.g. fill temperature, fill weight, and headspace in packages.
9. Presence of entrapped gases in the headspace of packages, e.g. this can have an insulating effect resulting in decreased heat penetration.
10. Product fill weight measured before and after processing.
11. The percent overfill of key product components such as the solids content.

Having considered all the factors covered in Sections 3.1 to 3.6, the next step for the FBO is to select the target pathogen and the heat-chill process required to achieve an appropriate, e.g. 6-D, reduction of the target organism while preserving the sensory quality of the food product.

### **3.7 Selection of Target Pathogen**

When developing and implementing a heat process, it should be designed to inactivate a pathogen or group of pathogens, e.g. vegetative pathogens and/or spore-formers. This is typically described as the target pathogen(s) for the heat process <sup>(44)</sup>. 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.

Inactivation of pathogens is influenced by the characteristics of the pathogen, the required product shelf-life (Section 3.2) and the intrinsic and extrinsic characteristics of the product (Sections 3.4 – 3.7). Table 2 summarises some of the characteristics of pathogens which can influence their thermal inactivation.

**Table 2. Characteristics of Target Pathogens**

Characteristics	Effect
<b>Genus, Species and Strain of Target Pathogen</b>	Different pathogens will have different levels of heat resistance based on genus, species and strain, e.g. <i>L. monocytogenes</i> serovar 4b.
<b>Type and Form of Target Pathogen</b>	Some pathogens are inherently more heat resistant than others, depending on their type and form. Gram positive bacteria are typically more heat resistant than Gram negative bacteria, while bacterial spores are more heat resistant than the vegetative cells of either Gram positive or negative bacteria.
<b>Stage of Growth of the Target Pathogen</b>	Bacteria have four phases of growth during their life-cycle: the lag, log, stationary and death phases. Microbial cells tend to be more heat resistant as they grow older particularly during the stationary phase and less resistant during the log phase of growth. Heat resistance has also been reported to be high at the beginning of the lag phase and decreases as the cell enters the log phase. Old bacterial spores also tend to be more heat resistant than younger bacterial spores <sup>(43)</sup> .
<b>The History of the Target Pathogen</b>	The previous conditions to which pathogens have been subjected can affect their response to heat treatment. For example, under prolonged exposure to adverse environmental conditions such as sub-lethal temperature or acidic conditions, <i>L. monocytogenes</i> can develop a stress response which can make it more resistant to heat processing.
<b>The Number of Microorganisms Present in the Food</b>	Typically, the larger the numbers of microorganisms present in a food product, the greater the degree of heat resistance <sup>(43)</sup> .

Determining the degree of elimination of the target pathogen is very critical. A basic understanding of mathematical principles of heat processing is required to design and implement a safe heat process.

### 3.8 Minimum Target for Heat Processing

Unless a legal specification for a heat process exists, the FSAI currently recommends a minimum target for heat processing of a 6-D reduction in numbers of the vegetative cells of the target pathogen, *L. monocytogenes* <sup>(1)</sup>.

*Listeria monocytogenes* is regarded as the most heat resistant, foodborne pathogen that does not form spores. Therefore, other non-spore forming vegetative pathogens such as *Salmonella* spp., *S. aureus*, *Y. enterocolitica*, *V. parahaemolyticus* and *E. coli* O157:H7 that may be present in the food, should also be destroyed by a 6-D heat process <sup>(1, 45)</sup>. The Stumbo equation can be used to calculate a 6-D reduction (Equation 1) <sup>(42)</sup>:

Equation 1

$$F = D_r \log_{10} n$$

Where:

- F = Required process lethality
- $D_r$  = D-value at the reference temperature
- n = Required decimal reduction

The FSAI recommends a reference time and temperature combination of 70°C for 2 minutes, with a z-value of 7.5 Centigrade degrees (C deg) to achieve a 6-D reduction in numbers of *L. monocytogenes* <sup>(1, 45)</sup>. Equivalent time temperature combinations to this reference temperature (Equation 1) can then be calculated using the lethal rates equation (Equation 2) from Stumbo <sup>(42)</sup>:

Equation 2

$$10^{\left(\frac{T-T_x}{z}\right)}$$

Where:

- L = Lethal rate
- T = Target temperature (°C)
- $T_x$  = Reference temperature (°C)
- z = z-value (C deg)

Equivalent time and temperature combinations (using Equation 2) are given in Table 3 as an example of the necessary process to achieve a 6-D reduction in numbers of *L. monocytogenes* in foods <sup>(18)</sup>.

**Table 3. Example of Equivalent Time/Temperature Combinations to Achieve a 6-D Reduction in *L. monocytogenes* <sup>A</sup>**

Temperature (°C)	Time	Temperature (°C)	Time
64	12min 37s	70 <sup>B</sup>	2min
65	9min 17s	71	1min 28s
66	6min 50s	72	1min 5s
67	5min	73	48s
68	3min 42s	74	35s
69	2min 43s	75	26s <sup>C</sup>

<sup>A</sup> Assuming a linear z-value = 7.5°C with a reference temperature of 70°C. The interaction between foods intrinsic and extrinsic properties may alter these equivalent lethal rates and as such values must only be used as an indication of the lethal effect of the heat process on *L. monocytogenes* <sup>(18)</sup>.

<sup>B</sup> Recommended by the FSAI as the reference temperature and time required for a 6-D reduction in numbers of *L. monocytogenes*.

<sup>C</sup> With such short times above the reference temperature of 70°C, it is assumed that when 75°C is reached, the equivalent process to 70°C for 2 minutes has been achieved<sup>(18)</sup>.

Some products may change their mode of heat transfer due to a physical change in the product during heat processing, e.g. if a product gels or solidifies during heating. For example, dry pouched rice and pasta products during cooking may have a changing D-value (i.e. as the dry product cooks the D-value changes). Therefore, with these products, e.g. dry rice/pasta etc. a more severe heat treatment may be required to achieve the appropriate, e.g. 6-D reduction of the target organism while preserving the sensory quality of the food product.

### 3.8.1 Test Uncertainty Ratio

When setting the minimum temperature target for heat processing, the test uncertainty ratio should be included. To apply the test uncertainty ratio you must know the target temperature for the product, e.g. after cooking 72°C and the tolerance, e.g. ± 2°C for the process. From this example the true temperature of the product must lie between 70°C and 74°C.

Typically, the instrumentation used to measure the temperature have a tolerance which is four times better (i.e. test uncertainty ratio of 4:1) than the tolerance of the process (i.e. in the example used ± 0.50 °C) (See Section 5.1). Therefore, the total uncertainty of measurement of the

process must be  $\pm 0.50$  °C which takes into account the instrumentation and the medium used to measure the temperature. Applying the test uncertainty ratio to instrumentation used to measure temperature will help ensure products achieve the minimum temperature target for a 6-D process.

### 3.9 Other Targets for Heat Processing

Further controls may be necessary where risk assessment indicates that the growth and toxin production of *Clostridium botulinum* or other spore-forming bacteria is a particular risk. The actual risk will depend on the likely occurrence of *Cl. botulinum* spores in the ingredients <sup>(38)</sup>, the absence of intrinsic controlling factors and an anaerobic environment which would allow outgrowth of spores. Products which may provide such conditions may include; sous vide products <sup>(43)</sup> and other products which may present anaerobic conditions, e.g. reformed meat products, MAP or VP products.

However, the risk that a hazard will occur should be evaluated in each case, and control measures identified should be applied where this evaluation indicates that a risk occurs, e.g. for ingredients known to be positive for psychrotropic *Cl. botulinum* spores from time to time <sup>(38)</sup>. Intrinsic controlling factors which prevent the outgrowth of spores and toxin production by non-proteolytic strains of *Cl. botulinum* are <sup>(31, 38)</sup>:

1. pH of less than 4.5 throughout the food
2. Salt level of 3.5% (aqueous) throughout the food
3. Water activity ( $a_w$ ) of 0.97 or less throughout the food
4. Any combination of heat processing and preservative factors, which has been shown to prevent or eliminate growth and toxin production by *Cl. botulinum*.

Non-proteolytic *Cl. botulinum* Type B is regarded as the most heat resistant form of non-proteolytic *Cl. botulinum*. Therefore, all non-spore forming vegetative pathogens including *L. monocytogenes* that may be present in the food should also be eliminated or reduced to safe levels by this 6-D heating process.

A reference time and temperature combination of 90°C for 10 minutes, with a z-value of 10C° has been suggested to achieve a 6-D reduction in numbers of psychrotrophic (non-proteolytic) *Cl. botulinum* Type B <sup>(34, 38)</sup>.

Equivalent time and temperature combinations (using Equation 2) are given in Table 4 as an example of the necessary process to achieve a 6-D reduction in numbers of psychrotrophic *Cl. botulinum* Type B in foods <sup>(31-32, 38)</sup>.



**Table 4. Example of Equivalent Time/Temperature Combinations to Achieve a 6-D Reduction in Psychrotrophic *Cl. botulinum* Type B<sup>A</sup>**

Temperature (°C)	Time (min)	Temperature (°C)	Time (min)
80	100	92	6.3
82	63	94	4.0
84	40	96	2.5
86	25	98	1.6
88	16	99	1.3
90	10	100	1.0

<sup>A</sup> Assuming a linear z-value = 10C° with a reference temperature of 90°C. The interaction between foods intrinsic and extrinsic properties may alter these equivalent lethal rates and as such, values must only be used as an indication of the lethal effect of the heat process on psychrotrophic *Cl. botulinum* Type B.

### 3.10 Minimum Target for Chilling

Chilling should decrease the temperature of heat processed food as rapidly as possible. The chilling process should ensure the uniform and complete chilling of the food <sup>(2-4)</sup>. In all cases during chilling processes, there must be adequate ventilation to prevent condensation on the surface of products.

The chilling process should achieve a target temperature in a specified time in the food during every chilling treatment. This will ensure that the food, if consumed within its shelf-life, and not exposed to contamination or temperature abuse during storage, will not endanger the health of the consumer.

It is important that FBOs note that most pathogenic and non-pathogenic bacterial spores, including those from mesophilic *Cl. botulinum* and psychrotrophic *Bacillus cereus* and *Clostridium perfringens*, are more heat resistant than psychrotrophic *Cl. botulinum* Type B. As such, these microorganisms will not be eliminated or inactivated by the examples of heat treatment combinations presented in Table 4.

Therefore, when the target heating treatment has been achieved and no post-process contamination of the food has occurred, rapid chilling is used to prevent or reduce the opportunity for surviving spores to germinate and grow in the food.

*Clostridium perfringens* is present in many foods, at low levels. Illness due to *Cl. perfringens* typically occurs after ingestion of large numbers of enterotoxin producing cells present in food. Almost all outbreaks of *Cl. perfringens* illness are the result of inadequate or slow chilling of heat processed product. Slow chilling can allow *Cl. perfringens* spores to germinate and multiply <sup>(32)</sup>.

*Clostridium botulinum* is present less frequently than *Cl. perfringens* in foods. However, like *Cl. perfringens*, spores of some *Cl. botulinum* can survive all but the most severe heat treatments, e.g. sterilisation. Germination of *Cl. botulinum* spores that survive heat processing can be inhibited by rapid chilling after heat processed and refrigerated storage<sup>(32, 47)</sup>.

*Bacillus cereus* like *Cl. perfringens* can be found in low numbers in a wide range of foods. Rapid chilling is necessary to prevent germination and growth of *B. cereus* spores after heat processing<sup>(1, 39)</sup>. Refrigerated storage at < 4°C is necessary to prevent growth of all types of *B. cereus*.

Some foods can contain pathogenic spores of *Cl. perfringens*, *Cl. botulinum* and *B. cereus*. Foods which contain untreated herbs, spices, rice, bean and pulse ingredients may have increased levels of spores. Reformed or restructured meat, poultry and fish products may carry an increased level of microbial contamination than whole muscle products<sup>(39)</sup>.

Based on the above outlined requirements for control of *Cl. perfringens*, *Cl. botulinum* and *B. cereus* in chilling, Table 5 outlines best practice for chilling of heat processed foods.

**Table 5. Suggested Best Practice for Chilling Heat Processed Foods<sup>A</sup>**

Chilling Stage	Requirement	Best Practice
<b>Commencement of Chilling</b>	Begin chilling as quickly as possible after completion of heat processing <sup>(3, 10, 32-33)</sup>	<b>Recommend a period of ≤ 90 minutes after the completion of heat processing<sup>(10)</sup></b>
<b>Initial Chilling Process</b>	Reduce the temperature of the food (at the geometric core/thickest point) from 55°C to ≤ 10°C as quickly as possible <sup>(32-33)</sup>	<b>Recommend a period of not greater than 120 minutes after the beginning of chilling from 55°C to ≤ 10°C<sup>(18, 32-33)</sup></b>
<b>Final Chilling Process</b>	Continue chilling as quickly as possible from 10°C to ≤ 5°C	<b>Recommend a period of not greater than 60 minutes from 10°C to ≤ 3°C<sup>(10)</sup></b>
<b>Final Storage</b>	Following completion of chilling, the food should be immediately placed in controlled refrigerated storage which ensures a final product temperature (at its geometric core/thickest point) of ≤ 5°C throughout the chill chain	<b>Recommended ≤ 3°C throughout the chill chain</b>

<sup>A</sup>All temperatures refer to readings taken at the geometric core/thickest point of the product.

### 3.1.1 Best Practice for Chilling Specific Meat Products

Due to the specific nature and characteristics of heat processed whole/intact meat products, and those made by reforming or restructuring small pieces of meat and other ingredients under good hygienic conditions, into large meat products, other targets for chilling can be recommended<sup>(39)</sup>.

Best practice for chilling of large uncured and cured meat products is outlined in Tables 6 and 7<sup>(39)</sup>. However, the onus is always on the FBO to prove the safety of the process.

**Table 6. Suggested Best Practice for Chilling Large Uncured Meat Products<sup>A, B</sup>**

Temperature Range	Uncured Meats	
	Good Practice	Maximum
	Time (Minutes)	
Final Cooking Temperature to 55°C	60	150
55°C to 12°C	360	360
12°C to 5°C <sup>C</sup>	60	90
<b>Total Cooling Time (Minutes)<sub>D</sub></b>	<b>480</b>	<b>600</b>

<sup>A</sup> All temperatures refer to readings taken at the geometric core/thickest point of the product.  
<sup>B</sup> If high levels of spores are present in the raw meat product before heat processing, a reduction in the chilling time maybe necessary. Products which contain high levels of spores, e.g. > 10<sup>5</sup> *Cl. perfringens*, the chilling time to < 5°C may be ≤ 3 hours. Products chilled in this way should not be portioned until completion of chilling.  
<sup>C</sup> Following chilling, the product should be immediately placed in controlled refrigerated storage which ensures a final product temperature (at its geometric core/thickest point) of ≤ 5°C (recommended ≤ 3°C) throughout the chill chain.  
<sup>D</sup> FBOs who use a secondary heat treatment for products, e.g. roasting after chilling, must calculate the total chilling time for the product by detailing the total time the product remains above 5°C<sup>(39)</sup>.

The presence of salt/nitrite in cured product may allow for longer chilling times. Some indications suggest this can be 25% longer than an equivalent uncured product<sup>(39)</sup>. However, the onus is always on the FBO to prove the safety of the process.

**Table 7. Suggested Best Practice for Chilling Large Cured Meat Products<sup>A</sup>**

Temperature Range	Cured Meats	
	Good Practice	Maximum
	Time (Minutes) <sup>B</sup>	
Final Cook Temperature to 55°C	75	195
55°C to 12°C	450	450
12°C to 5°C <sup>C</sup>	75	105
<b>Total Cooling Time (Minutes)<sup>D</sup></b>	<b>600</b>	<b>750</b>

<sup>A-D</sup> See footnotes for Table 6

### 3.12 Other Chilling Practices

Specifications for chilling outside the recommendations given in Section 3.10 and Section 3.11, may be suitable to ensure product safety. However, appropriate microbiological risk assessment data would be required to ensure the safety of the process. The responsibility for the provision of such risk assessment data lies with the FBO.

## 4. PROCESS VALIDATION

Having selected the appropriate time/temperature parameters (Sections 3.1 to 3.12) delivering a microbiologically safe product, the FBO must now ensure that every product unit achieves this heat process every time.

The large capacity of many commercial cookers can make it difficult to physically temperature probe all individual product units in a batch during cooking. Therefore, the FBO will not know if every product unit has received the appropriate time/temperature parameters during the heating process.

To overcome this issue, the FBO must validate the heating process and then establish monitoring and verification procedures to ensure this validation data remains accurate. The FSAI currently recommends temperature mapping and validation of heating processes for the approval and operation of independent meat production units <sup>(18)</sup>.

The objective of validating the heating process is to confirm that the process, e.g. heating, in every case, effectively reduces or eliminates the target pathogen, e.g. a 6D reduction in *L. monocytogenes*, for which the process was designed (Section 3.8).

It is important that process validation is repeated until consistent results are achieved. This will ensure that the food meets all legislative requirements, e.g. microbiological criteria for food safety and the FBO requirements for shelf-life <sup>(15)</sup>. Validation is recommended when:

1. Existing equipment or process is not already validated
2. After installation of new equipment and/or significant repositioning, modification, repair or servicing of existing equipment
3. After significant modifications are made to equipment water/steam supplies or replacement of parts likely to affect heating capacity, e.g. new heating element, pumps, valves etc
4. After modifications to equipment loading/stacking configuration, patterns etc
5. For processing of new foods, or existing foods with altered composition, packaging, sizes etc.

The significance of all these changes should be assessed by the FBO's HACCP team and the requirement for re-validation risk assessed.

## **4.1 Instrumentation for Temperature Measurement**

Temperature measurement can be achieved using a variety of instrumentation such as bimetal style thermometers, thermistors, thermocouples, infrared thermometers etc. Typically, in the Irish food industry, temperature measurement is achieved using calibrated thermocouples and data loggers.

Due to the variety of available equipment, manufacturers and suppliers are best positioned to give advice to the FBO on the choice of temperature measurement equipment for specific purposes and food products. However, general considerations the FBO should take in relation to instrumentation for temperature measurement, include the following:

1. Glass and mercury thermometers should not be used by the FBO for food temperature measurement
2. Instrumentation should be hygienically designed to allow routine cleaning and sanitising
3. Instrumentation should be sourced from an approved supplier
4. Instrumentation should have sufficient performance in terms of capability to monitor the required process and product temperatures (i.e. operational temperature range) and required accuracy and precision. It is recommended that the accuracy of temperature monitoring instrumentation should be a minimum of  $\pm 1.0^{\circ}\text{C}$  (preferably  $\pm 0.5^{\circ}\text{C}$ )
5. Instrumentation should be able to be calibrated
6. Calibrated reference instrumentation (not used in normal processing) should be available to allow internal calibration of working instrumentation
7. Specific instructions from the manufacturer of the instrument should always be followed.

## **4.2 Thermocouples**

Thermocouples are devices which use the voltage generated by the junction of two dissimilar metals, to measure temperature. The voltage output is proportional to the temperature of the junction. The advantages of using thermocouples are that they have a wide temperature range, practical design, wide application and good performance in the food industry.

It is important that the FBO considers the application of a thermocouple and the factors affecting its performance. This can influence the type of thermocouple chosen. Specific considerations that should be taken in relation to thermocouples, include the following:

1. The required accuracy and precision (i.e. uncertainty of measurement)

2. Environmental conditions the temperature probe and connecting wires will be exposed to and operate in:
  - i. Expected temperature range, e.g. a wide temperature range such as  $-5^{\circ}\text{C}$  to  $+100^{\circ}\text{C}$ , a narrow range such as  $70^{\circ}\text{C}$  to  $75^{\circ}\text{C}$  or at a specific temperature point such as  $70^{\circ}\text{C}$ . These can be expressed in terms of temperature accuracy and precision over a temperature range or at a specific temperature point
  - ii. Expected temperature cycle, e.g. heat-chill environment, freeze-thaw environment etc. The expected temperature cycle will influence the design, e.g. robust design and type of thermocouple and connecting wires required
  - iii. Expected material to be measured, e.g. air/gas, partial or full insertion in solid food, partial or full immersion in liquid, semi-solid foods etc.
  - iv. Mechanical requirements for the thermocouple in terms of shock or vibration performance, electrical requirements in terms of insulation or shielding.
3. Time response required for the thermocouple (i.e. how quickly should the thermocouple be able to respond to a change in temperature?)
4. Thermocouples and connecting wires should be of an appropriate type, e.g. types J, K, T, E, R and S thermocouple probes, manual probes etc., size and length
5. Number of probes required for temperature measurement
6. Electrical interference from plant equipment on long lengths of connecting wires/ thermocouple cable (i.e. long thermocouple cables may require shielding and/or multiple product readings to compensate for resistance. Typically, use 3 or 4 core wires where 1 or 2 strands measure the resistance of the cable and compensate in the calculation of the temperature)
7. Thermocouples should be calibrated before use.

### **4.3 Data Loggers**

Data loggers can be analogue or digital devices which record temperature over time, during heating and chilling processes. The measurements taken are then stored (i.e. on charts, print-outs, electronically or downloaded to a computer) for further analysis or reporting.

It is important that the FBO considers the application of a data logger and the factors affecting its performance. This can influence the type of data logger chosen. Specific considerations that should be taken in relation to data loggers include the following:

1. Manufacturers' instructions for use of the instrument
2. The frequency of recording temperature over time should be adjustable from continuous to defined interval, e.g. every minute depending on the application
3. Data loggers should have a sufficient number of channels to adequately monitor and record temperatures
4. Data loggers should be calibrated before use.

## 5. CALIBRATION

Calibration is a process of adjusting instrumentation and equipment, so that measurements can be correlated to the actual value being measured. Typically, in a heat-chill process, the measurement of temperature will be the most important use of instrumentation.

### 5.1 Calibration of Instrumentation

Food business operators will generally use two types of temperature measurement instrumentation. Daily or working temperature measurement instrumentation is used for routine temperature measurement and monitoring. Reference temperature measurement instrumentation is used to check the accuracy and calibration of working temperature measurement instrumentation. In calibrating all temperature measuring instrumentation, the following should be considered by FBOs:

1. Calibration should follow a written standardised procedure (i.e. SOP) to include:
  - i. The manufacturers' instructions for calibration of each instrument (where applicable/available)
  - ii. The designated personnel and/or external provider authorised to perform calibrations
  - iii. The training requirements for personnel authorised to perform calibrations (where applicable)
  - iv. The recommended calibration interval for each instrument
  - v. The data to be recorded during calibration (including readings taken before and after adjustment, identification of the instrument or instrument component calibrated, date and time of calibration, and the name and signature of the person who performed the calibration). If no adjustments are made, this should also be recorded
  - vi. Where the records of calibration will be stored and the personnel authorised to access them
  - vii. Review procedures and review frequency for calibration records to allow comparisons of performance change over time and to confirm that all calibrations are completed and performed correctly
  - viii. The designated personnel authorised to perform review procedures
  - ix. Procedures to be followed where calibration procedures are changed or updated in the event of equipment modifications or changes.
2. Where an external provider is used for calibration, the FBO should only use an accredited (i.e. accredited to ISO 17025 for a defined scope of activity) provider. The Irish National Accreditation Board (INAB) is the national body with responsibility for accreditation in accordance with the relevant International Organisation for Standardisation ISO 17000 series of standards and guides and the harmonised EN 45000 series of European standards



3. Where an external provider is used for calibration, the FBO should specify the following minimum requirements for traceability in calibration:
  - i. Instrumentation and/or equipment identification, e.g. Manufacturer X Model No. A, Manufacturer Y Model No. B, Manufacturer Z Model No. C, Manufactured Probes etc.
  - ii. Company name, address, contact details and contact name(s) of external provider
  - iii. Range and conditions of calibration, e.g. 24°C to 155°C (at ambient), 20°C to 130°C, at relevant process temperature etc.
  - iv. Method of calibration, e.g. National Metrology Method, SOP against manufacturer X, Y or Z of instrumentation, accuracy check against similar manufacturer's reference instrumentation etc.
  - v. Frequency of calibration, e.g. yearly, prior to use, prior to use then yearly etc
  - vi. Accuracy details. e.g. 0.5°C, 1.0°C, etc.
  - vii. Corrective action(s), e.g. send for repair and recalibrate, discard instrumentation and alter status
  - viii. Documents and records, e.g. National Metrology Report, provider report to client number etc
  - ix. Degree of uncertainty.
4. The factors which can affect temperature monitoring and measurement
5. Temperature measuring instrumentation should be calibrated against measurement standards traceable to the International Temperature Scale of 1990 (ITS-90). The ITS-90 was adopted by the International Committee of Weights and Measures at its meeting in 1989. This scale supersedes the International Practical Temperature Scale of 1968 (amended edition of 1975) and the 1976 Provisional 0.5 K to 30 K Temperature Scale. The ITS-90 defines both International Kelvin Temperatures, symbol  $T_{90}$ , and International Celsius Temperatures, symbol  $t_{90}$
6. Reference instrumentation used for calibration of temperature measurement instrumentation should, at minimum, have an test uncertainty ratio of 4:1 (i.e. be four times more accurate) than the daily or working instrumentation it is calibrating (see section 3.8.1). For example, if the reference thermometer has an uncertainty of  $\pm 0.25$ , the tolerance specified for the working thermometer can only be specified at or above  $\pm 1$  deg C (i.e.  $4 \times 0.25$ )
7. Records of all calibrations should be kept and the date of the next calibration should be indicated on the temperature monitoring equipment itself or its associated documentation
8. All instrumentation should be initially calibrated (prior to use) and re-calibrated at specified calibration intervals

9. Calibration data should be reviewed every six months or more frequently (at a minimum, annually) based on history and risk assessment to identify deviations from defined tolerances, e.g. accuracy
10. When instrumentation is broken or out of calibration it should not be used until repaired or replaced and re-calibrated
11. When internal probes in equipment, e.g. cooker, are broken or out of calibration, the equipment should not be used until the probe(s) are repaired or replaced and re-calibrated.

## **5.2 Calibration Interval for Instrumentation**

Inaccuracies within temperature measuring instrumentation will typically be cumulative. Furthermore, instrumentation susceptibility to aging and contamination (both physical and chemical) means that they can sometimes drift out of calibration quite rapidly.

The calibration frequency for reference thermometers should be as specified by the manufacturer or by risk assessment by the FBO. However, at minimum, it should be at least every three years.

In the absence of manufacturer's instructions for the calibration interval, a FBO should initially calibrate daily working instrumentation prior to use and every six months, or at minimum, at least once per annum thereafter. An annual calibration interval (i.e. in the absence of manufacturer's instructions for the calibration interval frequency) is a good starting point for determining the calibration interval frequency for a specific instrument. However, it should not be used indefinitely. An annual calibration interval is a minimum and it should be formally evaluated and the interval adjusted as required.

If data at the annual calibration interval indicates that the instrument is near or in excess of its acceptable accuracy (i.e. with no other conditions of use suspected of causing the inaccuracy), it should be concluded that the calibration interval frequency is too long. In this case, the calibration interval frequency should be shortened.

The calibration interval should be reduced or increased (as appropriate) until the instrumentation is within its acceptable limit of accuracy at the end of each calibration interval.

More or less frequent calibration intervals may be applied based on site-specific conditions including:

1. Type, age and general conditions of the equipment
2. Calibration history of the instrumentation (where available)
3. Risk assessment, e.g. what is the risk if the instrument is out of calibration? If a probe is used for release of cooked product and found to be out of calibration after six months? Has the FBO been undercooking the product for the last six months and if so is a recall required? Such critical probes should be subject to calibration checks in a similar fashion to other critical control points such as metal detection, e.g. start and finish of shifts
4. Conditions of use of the instrumentation, e.g. the instrumentation is dropped on the ground, instrumentation is frequently used at the upper/lower range of its temperature capability or above/below its recommended maximum temperature capability for prolonged periods it should be recalibrated
5. The operational environment of the instrumentation, e.g. wet, cold, hot, dry etc. conditions
6. The temperature tolerance (including the uncertainty budget which should be based on the temperature instrumentation, the stability of the medium, immersion (if any) and repeatability of measurements), which is deemed tolerable for the production, e.g. cooking, process
7. The calibration of all internal equipment probes should be checked against an annually certified standard thermometer traceable to the International Temperature Scale ITS-90.

## 6. SETTING THE PROCESS

Assuming that products are heat processed by a FBO under the same conditions for each product batch, e.g. same product type, batch size, loading etc, how does the FBO know that every product unit receives the same specified time/temperature combination, required to deliver a microbiologically safe product?

As previously outlined (Section 4), a FBO should validate the processes they use, e.g. heating and chilling, and then establish monitoring and verification procedures to ensure this validation data remains accurate. Validation should only be carried out by trained personnel <sup>(18)</sup> and has two main stages:

1. Temperature mapping of the heating medium (i.e. temperature or heat distribution studies/tests)
2. Heat penetration tests of the product.

A trained person should map the temperature distribution in the cooker under maximum and/or intended/defined standard loading conditions, to determine the cold spot(s). The product at the cold spot should be probed (in its geometric centre). If a meat joint, for example, at the cold spot in the cooker is probed and found to achieve the specified time/temperature combination, it can be assumed that all other meat joints in the cooker are also adequately cooked.

If a FBO changes any aspect of a validated heat process, e.g. product type size, loading conditions etc., then that process must be re-evaluated to ensure that each product unit receives the same specified time/temperature combination, required to deliver a microbiologically safe product.

Processing of different batch sizes, e.g. half or quarter batch maximum 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 efficacy of validation of the process. When setting a process, it is prudent that the FBO plan and test for all expected batch sizes, operating conditions and product types under worst case scenarios including:

1. Simulation of under processing of product, e.g. affects of processing on products positioned at cold-spots
2. Simulation of over-processing of product
3. Simulation of equipment breakdown and effect on product, e.g. to identify position(s) and/or products which may have received full processing
4. Risks of post process contamination.

## **6.1 Temperature Mapping**

Temperature mapping is recording temperature readings within the heating chamber using calibrated instrumentation. This will locate point(s) or zones of slowest (i.e. cold-spots) and quickest heating (i.e. hot-spots) in the heating medium, e.g. air, water, steam etc. of the heat process chamber. The slowest heating spot will be the point that must be monitored for food safety purposes.

Temperature mapping is required to develop, implement and validate heating and chilling processes in preparation for heat penetration studies.

### **6.1.1 When is temperature mapping required?**

Temperature mapping should be repeated at least every three years or more frequently if:

1. New equipment is installed
2. Existing equipment is repaired, serviced, repositioned, replaced or modified
3. Equipment experiences a mechanical or other type of failure
4. The original performance data are invalidated
5. The load in the heating chamber changes, e.g. new loading/stacking patterns, configurations, designs or modes of use
6. The products formulation, composition and assembly changes
7. Equipment performance deterioration with time is suspected. The FBO may be able to recognise from equipment instrumentation and process records when a temperature distribution problem arises. Equipment operators should be trained to observe and identify these potential problems
8. Original performance data are invalidated in any other way (i.e. any other changes which may influence the temperature distribution in the product zone).

### **6.1.2 What is required before temperature mapping?**

Before beginning temperature mapping, the following considerations should be taken by the FBO:

1. All instrumentation should be calibrated for use with the selected equipment to be temperature mapped (i.e. same accuracy and operational temperature range etc.)
2. All instrumentation should be calibrated to measurement Standards traceable to the International Temperature Scale ITS-90
3. All connectors, leads, extensions etc., for instrumentation should be assembled as they would be under normal processing conditions
4. Minimisation of error due to variables inherent in any component of the temperature measuring system, heating equipment or product should be considered
5. For standardisation and consistency of temperature mapping, an SOP for the procedure on specific pieces of equipment should be documented.

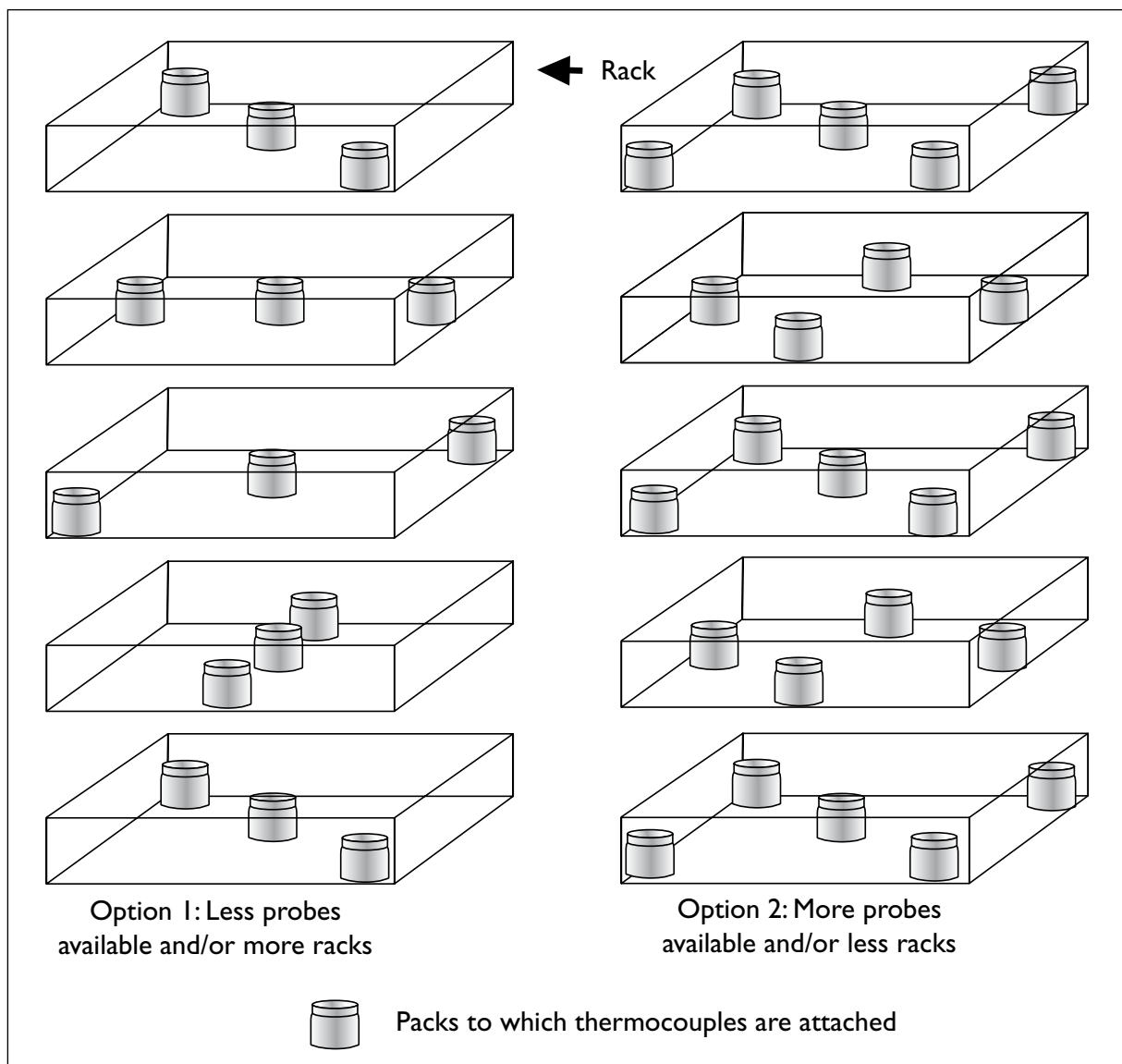
### 6.1.3 Temperature mapping procedure

The location of the zones of slowest heating (i.e. cold spots) do not always follow a logical progression, e.g. zones of slowest heating are located at the greatest distance from the heat source. Therefore, this is an area where the knowledge and experience of competent personnel specialising in temperature mapping can be very important. Best practice in temperature mapping a heating chamber is as follows <sup>(18, 29, 48)</sup>:

1. The heating equipment should be loaded with product and brought up to the operating temperature to be used during temperature mapping. Temperature readings should be taken during this period
2. The heating equipment should then be allowed to operate for a period of time prior to temperature mapping beginning. Temperature readings should be taken during this period
3. Temperature mapping should proceed by checking the processing equipment at full capacity. Where products are routinely heating below the equipments full capacity, the worst case scenario during normal operation should be applied in temperature mapping. From a pragmatic perspective and to ensure effective process control, it may be prudent to keep batch loading options to a minimum
4. Position of probes within the heating chamber should be determined and defined. Basic guidance on the placement of probes within the chamber can be obtained from the design of the heating equipment, the heat supply system, e.g. steam, water etc. and the loading pattern in the heating chamber. However, as general guidance:
  - i. In horizontal stacking heating chambers, the product is usually placed in the chamber in carriages. Probes should be positioned in the centre of each case/crate/basket at the top, centre and bottom of each carriage. If more probes are available, they should be located at the centre of the outside of the four sides of each carriage
  - ii. In vertical stacking, heating chambers probes should be positioned in the centre of each case/crate/basket on the top, centre and bottom shelves of the heating equipment.
  - iii. If more probes are available, other points along the periphery of each case/crate/basket on the top, centre and bottom shelves of the heating equipment should be measured
  - iv. The initial temperature mapping results should be reviewed in determining all locations within the heating chamber requiring mapping.

5. The arrangement of probes within the heating chamber should ensure that data collected are representative of the heating capacity of the equipment at specific positions/zones within the heating chamber. However, a minimum of 7 to 15 probes per/m<sup>3</sup> should be used with at least one probe placed in close proximity to the equipments own internal temperature controlling probe (i.e. master probe)
6. A schematic drawing of the location and position of all probes used in each temperature mapping should be kept on record. For illustration purposes only, Figure 2 outlines the positions of probes in a simple oven

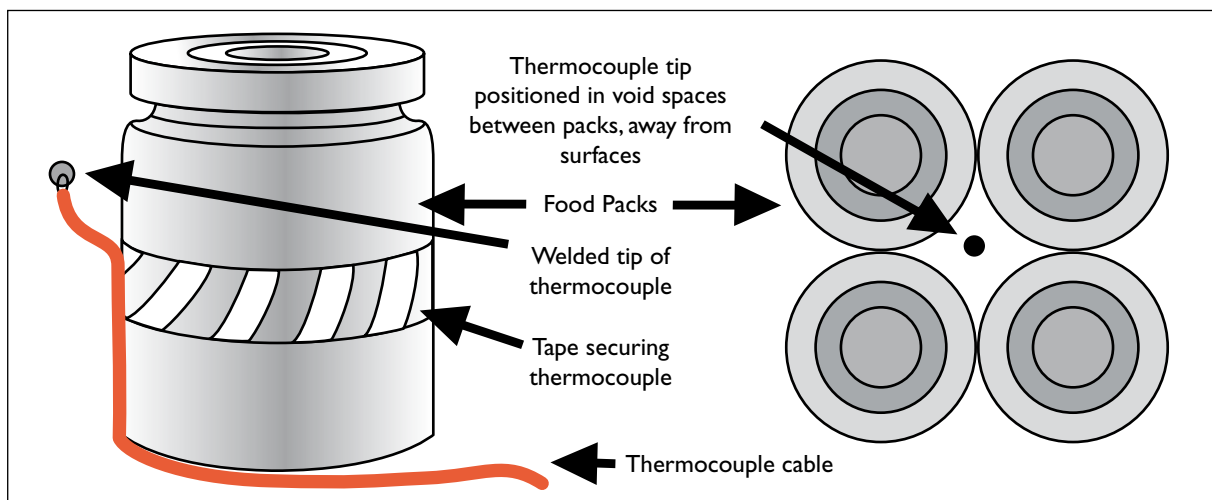
**Figure 2. Exploded Views of Cooker Racks Showing Possible Probe Location Patterns in Temperature Mapping of a Simple Oven \***



\* Only those packs which contain probes are shown. However, for any such testing, full racks of product should be used to emulate worst case production conditions.

7. In heating equipment which uses water or steam showering techniques, 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
8. The arrangement of probes within the heating chamber should ensure that they are not in contact with any internal surfaces within the heating chamber and where possible, positioned in void spaces between product packages (Figure 3). For illustration purposes only, Figure 3 outlines the positions of probes between products in a simple oven
9. Repeat in duplicate, all temperature mapping tests, to ensure repeatability and consistency of results
10. Identify and indicate the location of zones of slowest (i.e. cold spots) and fastest (i.e. hot spots) heating within the heating chamber from the recorded temperature data on a schematic drawing covering all three dimensions (i.e. top, centre and bottom) of the heating chamber.

**Figure 3. Probe Position for Temperature Mapping of a Simple Oven**



## 6.2 Heat Penetration Tests

After completion of temperature mapping and identification of cold spots, the second stage of validation is heat penetration tests. Heat penetration tests focus on taking temperature readings of the products rather than the heating medium, e.g. air, using calibrated instrumentation. Heat penetration tests will confirm the product heating characteristics at product cold spots identified in temperature mapping. Heat penetration tests therefore allow the FBO to determine the behaviour of the product during normal processing at the identified cold spots.

From the data gathered in both temperature mapping and heat penetration tests, the FBO can then validate a time/temperature combination to process the food to meet safety requirements. Therefore, this is an area where the knowledge and experience of competent personnel specialising in heat penetration testing can be very important<sup>(30)</sup>.



### **6.2.1 When is a heat penetration test required?**

Heat penetration tests are required to develop, implement and validate heating and chilling processes after completion of temperature mapping. Heat penetration tests should always be performed after temperature mapping to validate a heating process.

Heat penetration tests should be repeated at least every three years or more frequently as outlined in Section 6.1.1.

### **6.2.2 What is required before heat penetration tests?**

Before beginning heat penetration tests, the following considerations should be taken by the FBO:

1. Review and consider points made under Section 6.1.2
2. Review collected temperature mapping data
3. Ensure:
  - i. Product receives the same processing as in normal processing
  - ii. The product temperature before loading is as low as likely during normal process operation
  - iii. Equipment used is the same as used in normal processing
  - iv. Product formulation, composition and assembly is the same as in normal processing
  - v. Product packaging is the same as used in normal processing conditions
  - vi. The fill weight is not less than the maximum declared under normal processing conditions.

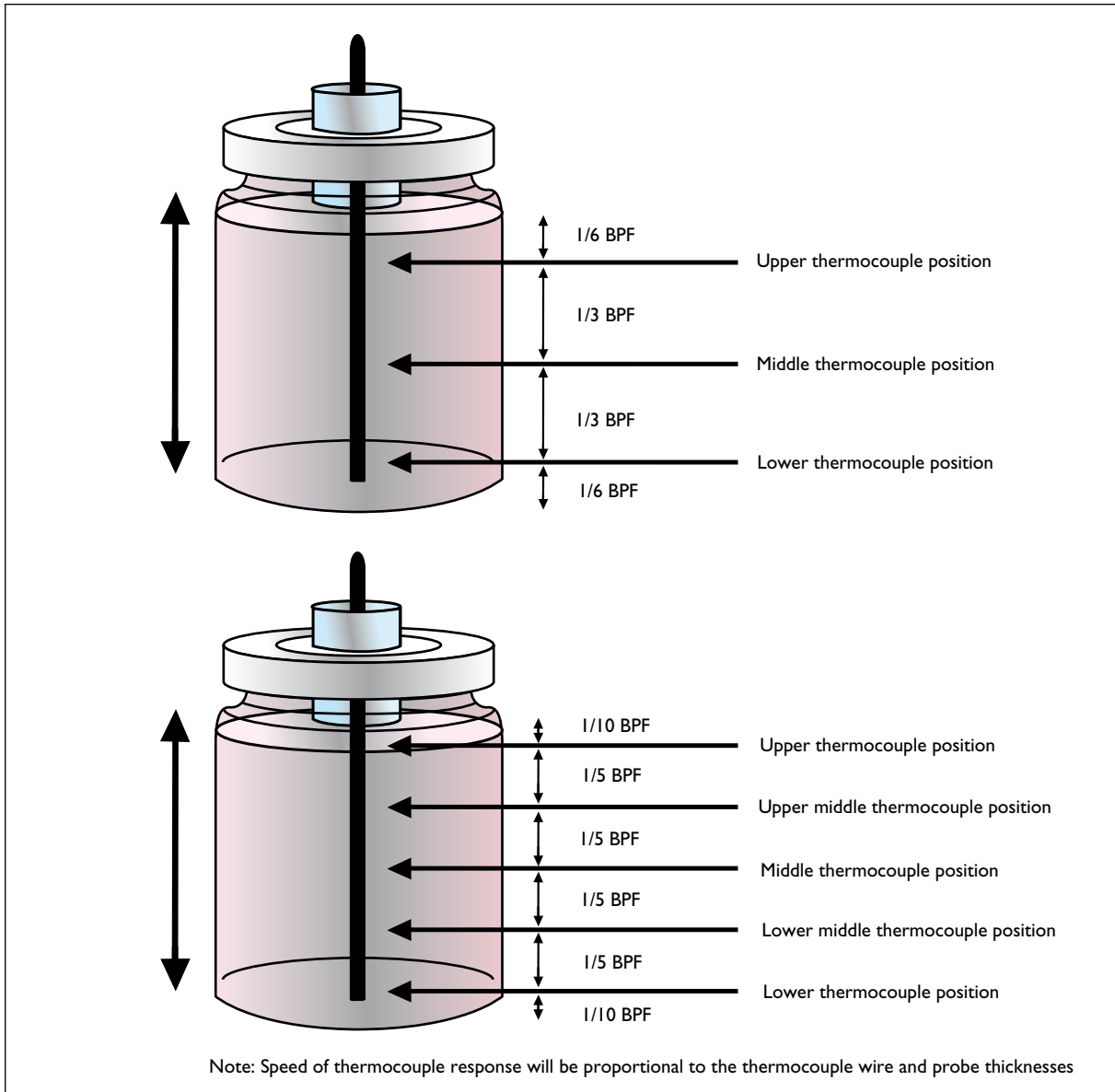
### **6.2.3 Heat penetration test procedure**

Heat penetration tests should be designed to ensure that all factors are considered in delivery of the required heat treatment to products at the identified cold-spots. Therefore, it is important that the FBO understands the product, package and process factors which can affect heat penetration of the product.

Best practice in performing heat penetration tests is as follows <sup>(18,30)</sup>:

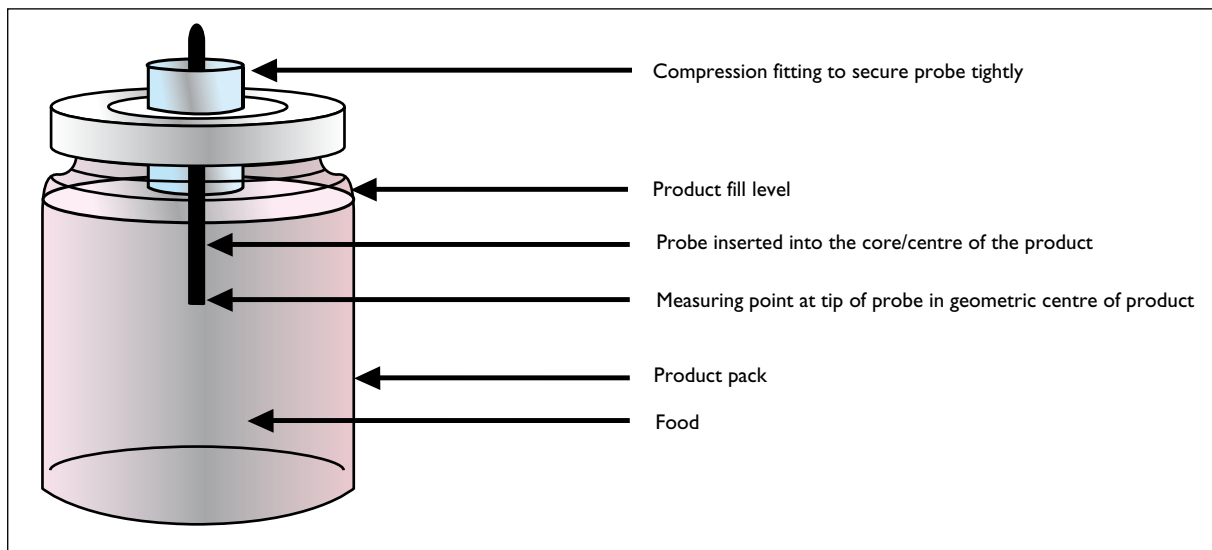
1. The probes should be positioned at the points of slowest heating in the product. These points will vary depending on the nature of the product and the equipment used. In relation to the product, the location of the cold spot will depend on the dominant method of heat transfer (i.e. conduction, convection) within the product. Location of the cold spot can be determined by using a multi thermocouple probe in the product and observing the slowest heating points. For illustration purposes only, Figure 4 shows the ideal locations for thermocouples within multi (3 or 5) thermocouple probes

**Figure 4. Ideal Locations for Thermocouples within Multi (3 or 5) Thermocouple Probes**



2. In conduction products surrounded by heating media, heat will transfer from the outer surfaces of the product to the colder interior. In such products, the slowest heating point will often be the geometric centre or core of the product <sup>(1, 18)</sup> which is typically the thickest point in a product. However, a certain amount of caution is required with irregular shaped products. In such products surrounded on all surfaces by heating media, heat will be approaching the interior from many directions and as a result, the thickest point may not always correspond to the slowest heating point. For illustration purposes only, Figure 5 shows the position of a probe at the slowest heating point (i.e. the geometric centre) of a simple product which heats by conduction

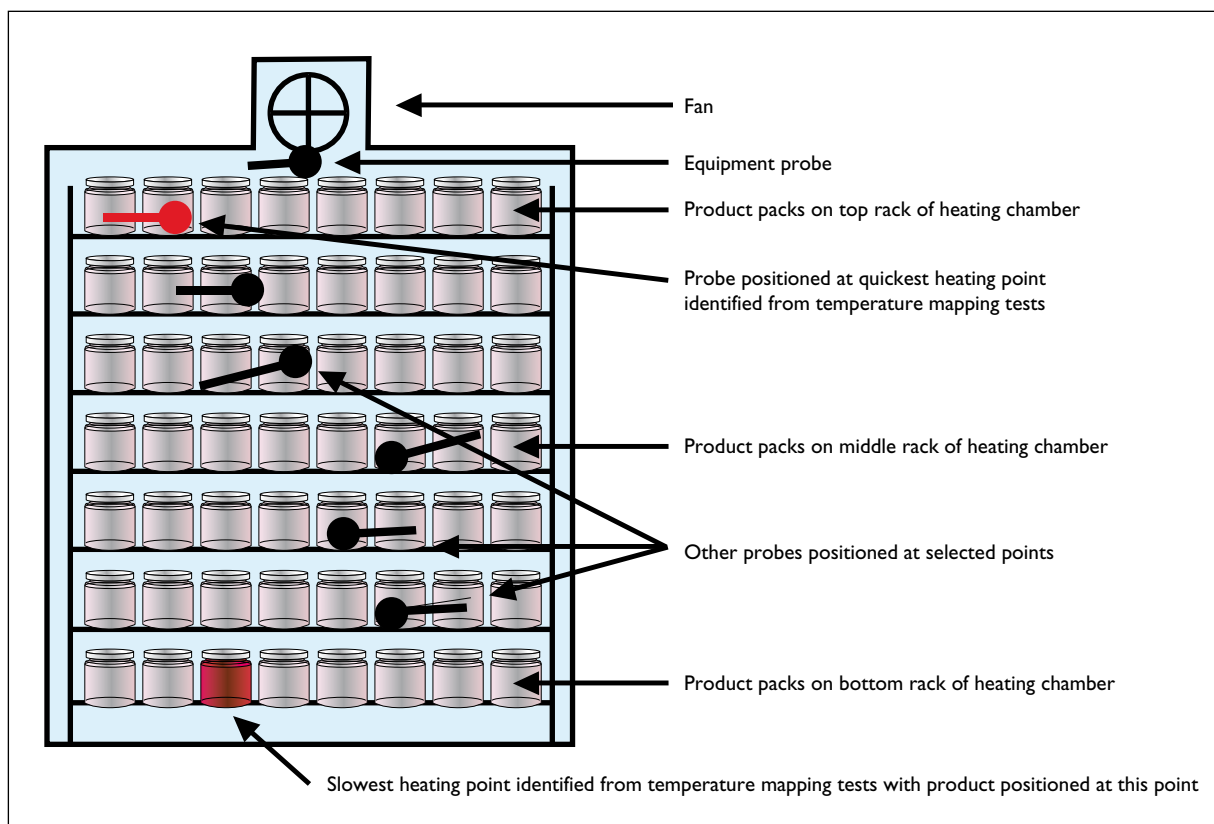
**Figure 5. Probe Positions in a Product which heats by Conduction**



3. In products which are static during heating within which heat is transferred by convection, the thermocouple should be placed at a height from the base of 20% of the total height <sup>(40)</sup>
4. If the FBO rotates or agitates the convection product during heating, the slowest heating point will be typically found at the geometric centre<sup>(40)</sup>. Where appropriate, probes (i.e. thermocouples) can be fitted with a suitable spacer which allows the FBO to accurately position the temperature sensor in the cold spot of the product on a repeated basis. A compression fitting can also be used where appropriate, to securely attach the probe to the package
5. In some products, a change of heating mode occurs during heat processing. This change can be from convection to conduction (which is sometimes called broken heating) or from conduction to convection (which is often referred to as mixed heating). In such products, cold spots can be located using the procedure described for convection heating
6. If the product is of a particulate or solid nature the worst case position for the cold-spot should be used (i.e. worst case scenario in most cases is were the largest available particulate is placed on the temperature measuring part of the probe which is then placed in the product cold spot)
7. Testing should proceed with the heating equipment at full capacity. Where products are routinely heated below the equipments full capacity, the worst case scenario during normal operation should be applied in the heat penetration tests

8. At a minimum, all products positioned at identified cold-spots (i.e. from temperature mapping) should be tested for heat penetration. In addition, the product which is in closest proximity to the equipments own internal temperature controlling probe (i.e. master probe), should also be tested
9. Determine the initial temperature of the product. When determining the initial temperature, the range of initial temperatures to be encountered during normal processing conditions should be taken into account and the coldest (i.e. worst case scenario) initial temperature selected
10. For determining the initial temperature, thermocouples should be placed in a number of product units. Ideally, all product units in the heating chamber should be equilibrated to the same identified initial temperature before beginning testing. For illustration purposes only, Figure 6 shows the position of a selection of probes positioned at various points (including the identified slowest and quickest heating points) in the geometric centre of a product which heats by conduction

**Figure 6. Example of Probe Locations for Heat Penetration Tests in a Simple Oven**



11. The data logger should begin recording the temperature of each thermocouple prior to beginning heat processing, e.g. steam-on in the heating chamber, and thereafter at sufficient intervals, e.g. every minute, throughout the heat process until the required time/temperature combination is achieved
12. The required time interval, e.g. every minute, 2 minutes etc., for recording product temperature during heat penetration tests, should be sufficient to describe and verify the heating chambers operating parameters during testing
13. Heat penetration tests should continue until the required time temperature combination is achieved in product cold spots and/or products positioned at the slowest heating point(s) of the heating chamber. Tests should further extend for a short period after the required time/temperature combination is achieved so that a definite temperature profile can be established for all thermocouples used
14. Repeat in duplicate, all heat penetration tests to ensure repeatability and consistency of results
15. Following heat penetration testing, if a product at the slowest heating point(s) in the heating chamber is probed at the product cold spot(s) and is found to achieve the required time and temperature combination required for food safety, it can be assumed by the FBO that all other products in the chamber are also safely heat processed.

## 7. MONITORING AND VERIFICATION

When a FBO uses a validated heat-chill process, on-going process validation and verification, e.g. temperature checks, should be undertaken on a scheduled, routine basis, based on risk assessment.

### 7.1 Monitoring

On-going product temperature monitoring is required for all heat-chill processes. It is required to verify that specific requirements for product safety (i.e. minimum time/temperature combination necessary in cooking) have been achieved. This will allow the FBO to positively release a batch of product following a heat-chill process.

1. On-going product temperature monitoring should be carried out on a scheduled basis for verification purposes when a FBO operates a validated heating process.
2. Monitoring should be performed on specific products on every batch of every product produced by the FBO.
3. Data, e.g. graphs, showing temperature profile during cooking, output of data logger etc., from all product temperature monitoring, will provide objective evidence that the product has been cooked and chilled on the specified (validated) programmes for that product, necessary to ensure product safety.
4. Data from all product temperature monitoring will help verify that core probes in products have reached the specified core temperature and that the appropriate product stacking arrangement was used for that product to allow adequate the air, steam etc. flow within the heating chamber.
5. On-going product temperature monitoring should provide data from products at identified cold spot(s) and in products on the top, middle and bottom levels of the heating chamber. In addition, the largest products in a batch should always be monitored.
6. Prompt and regular review of all collected data is necessary to verify a process and to quickly identify problems and implement changes to a process or product, if required. Reference should be made to previous verification data to ensure the data gathered are repeatable and accurate. Therefore, monitoring and verification are integral parts of HACCP (Section 2).

### 7.2 Verification

Verification is the confirmation by examination (i.e. temperature monitoring) and provision of objective evidence (i.e. data collection and recording) that specified requirements for the process, e.g. cooking process: required temperature and time combination in every product unit, have been achieved<sup>(4)</sup>.

Verification of a validated process should be an objective assessment of process monitoring data against the data from the validation of the process. This will verify that the specified process has been followed, including:

1. Independent checks by quality assurance staff on product temperatures
2. Stacking arrangements
3. Results of microbiological analysis
4. Results of audits
5. Customer complaints
6. Internal non-conformances
7. Changes in research data available etc.

### **7.3 Data Collection and Record Keeping**

Data should be kept for all validation, monitoring and verification tests (i.e. temperature mapping and heat penetration tests), trials and commercial production runs/batches for audit and inspection purposes.

In addition, data collected on equipment, services and product time and temperatures should be recorded for recall and traceability of product in the event of a food safety incident occurring <sup>(5)</sup>.

Best practice for data collection and record keeping should include the following:

1. Data collected and recorded should be authorised, updated and maintained. The assigned responsible/competent employee should sign off on data recorded before product release
2. All data collected and recorded using computers, should have a back-up copy
3. Data should be collected, collated and recorded for all validation tests, trials and commercial production runs, batches etc. for audit and inspection purposes and should include the following information:
  - i. All dates and times
  - ii. Identification (i.e. if more than one piece of heating equipment available), technical specifications, performance criteria and calibration details for equipment and ancillary equipment
  - iii. Location of temperature probes
  - iv. Calibration details of temperature probes
  - v. Details on personnel operating equipment or carrying out tests
  - vi. Detailed files/printouts of temperature/time profiles for products and equipment
  - vii. Product specification including: name, characteristics, e.g. pack size, number of packs, raw materials used, any available intrinsic/extrinsic data including product prior to heat treatment), formulation, identification code(s), e.g. batch/lot number etc.
4. In relation to the loading and stacking configurations, the exact configuration used must be recorded. The minimum information that should be recorded includes:
  - i. Maximum number of cages/crates/baskets in the heating chamber
  - ii. Container size, loading/racking configuration

- iii. Maximum number of containers per level in heating chamber, e.g. top, middle or bottom shelves, or per cage/crate/basket
  - iv. Aperture size and spacing of the cage/crate or basket base plates
  - v. The open area of the base plate and separator sheets if used in the cages/crates or baskets.
5. Data should be collected, collated and recorded for all equipment and instrumentation including the manufacturer, the model/type, settings and serial numbers, details on dials, fans, motors, boilers, steam pressure monitors, etc. This record should be updated as and when any changes are made
  6. Data should be collected, collated, recorded and documented for all stacking/racking arrangements for all products
  7. If any changes are made to the above parameters, the change must be documented and assessed by the HACCP team and the process re-validated as necessary
  8. Records generated from data loggers and temperature probes, e.g. thermocouples, should indicate the date, time, and source of reading and should be signed by the individual responsible for the device at that time.

From a traceability perspective, the EC recommends that records should be kept by FBOs for five years, starting from date of manufacture of a food product. However, there are some exceptions<sup>(5, 22)</sup>:

- i. If the shelf-life is greater than five years, then records should be kept for the shelf-life plus six months
- ii. In the case of fresh products destined for the consumer, records should be kept up to the use-by date plus six months or six months if no use-by date is required
- iii. In the case of fresh products destined for other food businesses, records should be kept for five years.

#### **7.4 Non-Conforming Product**

Non-conformances in product safety and quality will occur within the quality system of every FBO. In the event that a non-conforming product is identified due to equipment failure, e.g. heating and/or chilling processes, or process deviation, e.g. required temperature in product during heating not obtained, the FBO should have procedures in place to ensure that the product batch is clearly identified, segregated and not in-advertently used or dispatched prior to the safety of the product been established.

The FBO must then carry out a risk assessment on the segregated product to assess the products safety. Based on risk assessment, there are three possible methods of dealing with non conforming product:

1. Accept the non-conforming product following further inspection and testing
2. Rework the non-conforming product to meet specified requirements
3. Dispose of the non conforming product.



## GLOSSARY

For the purposes of this document the following definitions will apply:

**Accuracy** is the closeness of a reading of a measurement device, e.g. temperature, to the actual value of the quantity being measured; usually expressed as  $\pm$  percent of the reading

**Aerobic microorganisms** require oxygen for growth

**Anaerobic microorganisms** do not require oxygen for growth

**Cooking** is preparation of food for human consumption by the application of heat. In the context of this document the application of heat should be sufficient to ensure pasteurisation of the food

**Competent body** means the central authority in Ireland competent to ensure compliance with the requirements of legislation or any other authority to which that central authority has delegated that competence; it shall also include, where appropriate, the corresponding authority of a third country<sup>(3)</sup>

**Commercial Sterilisation (Commercially Sterile)** is a heat treatment designed to render a food free of microorganisms capable of growing in the food at room or ambient temperatures

**Facultative microorganisms** grow with or without oxygen

**Food** (or foodstuff) means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. Food includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment<sup>(5)</sup>

**Food business** means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food<sup>(5)</sup>

**Food business operator** means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control<sup>(5)</sup>

**Food law** means the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level. It covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food producing animals<sup>(5)</sup>

**Microbiological criteria** are tools that can be used in assessing the safety and quality of food products. The use of microbiological criteria should form an integral part of the implementation of HACCP-based procedures and other hygiene control measures<sup>(7)</sup>

**Microaerophilic microorganisms** require a reduced level of oxygen for growth

**Pasteurisation** is a mild heat treatment applied to foods to inactivate heat labile microorganisms such as vegetative bacteria, yeasts and moulds which may cause food spoilage or food poisoning. Therefore, a pasteurised food is unlikely to cause illness if it

is stored correctly and consumed before the end of its shelf-life, typically indicated by a use-by-date<sup>(21)</sup>

**Pathogenic microorganisms** are disease causing microorganisms

**Precision** is the degree of agreement between numbers of independent measurements of the same property, e.g. temperature taken under the same conditions

**Prerequisite(s)** are practices and procedures required prior to and during the implementation and ongoing operation of a HACCP system, e.g. premises, equipment, staff training, pest control, waste management

**Perishable food** is food which is subject to rapid decay, spoilage and/or growth of pathogenic microorganisms with or without production of toxins or metabolites in quantities that may present an unacceptable risk for human health

**Processed products** are food resulting from the processing of unprocessed raw materials/ingredients. These products may contain ingredients that are necessary for their manufacture or to give them specific characteristics <sup>(3)</sup>

**Ready-to-eat** means food intended by the FBO for direct human consumption without the need for further cooking or other processing effective to eliminate or reduce to acceptable level microorganisms of concern <sup>(6)</sup>

**Reformed products** use intact meat/poultry/fish pieces physically or chemically bound together to resemble whole unprocessed products.

**Restructured products** use minced, diced or chopped pieces of meat/poultry/fish physically or chemically bound together into a restructured shape

**Shelf-life** means either the period corresponding to the period preceding the use-by or the minimum durability date as defined respectively in articles 9 and 10 of Directive 2000/13/EC <sup>(6)</sup>

**Sterile product** is a product in which all viable microorganisms are absent

**Uncertainty of measurement** is a quantitative measure of the quality of a measurement result, enabling the measurement results to be compared with other results, references, specifications or standards <sup>(49)</sup>. Typically, uncertainty of measurement is represented by the observed reading on the reference equipment followed by  $\pm$  the uncertainty of measurement, e.g. 30°C  $\pm$  1°C

**Validation** is a procedure for checking if a process satisfies a specific criterion for food safety

**Verification** is the confirmation by examination and provision of objective evidence that specified requirements for a process have been achieved

**Viability (Viable)** is the ability of microorganisms to reproduce when conditions suitable for growth occur

## APPENDIX I. INTRINSIC AND EXTRINSIC PROPERTIES

The intrinsic properties are those properties that are an inherent part of the food such as pH and  $a_w$ . The extrinsic properties are the properties of the environment in which the food is stored such as temperature and packaging atmosphere. Minimum values for pathogenic growth related to singular intrinsic or extrinsic properties are influenced by other intrinsic and extrinsic properties. Pathogenic growth is best when intrinsic and extrinsic properties are optimal.

### Water Activity ( $a_w$ )

Water activity is the availability of water in a food. Water activity will determine the lower limit for pathogenic growth and survival. Water activity ranges in value from 0 to 1.0. Most pathogens grow best at  $a_w$  near 1.0. However, minimal  $a_w$  required for growth can be between 0.88 – 0.91<sup>(50)</sup>.

The heat resistance of some pathogens may increase as  $a_w$  decreases. However, many heat processed foods will have a high  $a_w$  which doesn't significantly affect pathogenic heat resistance in the food. In food processing  $a_w$  can be decreased by the addition of ingredients, e.g. salts, sugars, starches which bind and make water unavailable to pathogens. Evaporation of water from foods during heat processing, e.g. cooking, drying, etc. can also decrease  $a_w$ .

### pH

The pH is a measure of a food's acidity or alkalinity<sup>(43)</sup>. The pH scale ranges from 1 to 14 with the relative extent of acidity and alkalinity defined by their pH value on this scale. Most pathogens grow best at a neutral pH near 7.0. Typically, a pH of 4.0 to 4.5 will inhibit the growth of most foodborne pathogens. However, low-acid foods with a pH of 4.5 typically require heat processing for safety reasons (i.e. growth of *Clostridium botulinum* can occur at or above pH 4.5).

The pH of foods may vary with time due to microbial activity and food composition or formulation. Specific foods such as vegetables and fresh meats may be prone to pH change.

At a processing level a food may have a pH which prevents the growth of pathogens. However, if the pH changes during product shelf-life, conditions may become favourable for pathogens to grow in the product. This can increase the safety risk to the product. Therefore, products of this nature require control of pH and/or heat processing. Organic acids such as ascorbic, sorbic, acetic, lactic, benzoic acid etc. while antimicrobial in nature are extensively used in the food industry to control product pH (i.e. acidity regulators).

### Food Composition

The composition of foods can have an effect on the heat resistance of pathogens. Table 8 outlines the typical effects on heat resistance<sup>(43)</sup>.

**Table 8. Effect of Compositional Characteristics on General Pathogenic Heat Resistance**

Food Compositional Characteristics	Increase Heat Resistance
Increasing Fat <sup>A</sup>	Yes
Increasing Carbohydrate <sup>B</sup>	Yes
Increasing Protein	Yes
Increasing Salt <sup>C</sup>	Variable
Food Structure <sup>D</sup>	Variable

<sup>A</sup> Heat-resistance studies for inactivation of *L. monocytogenes* have shown that heat-resistance increases with increasing fat content

<sup>B</sup> The heat resistance of pathogens will increase in the presence of high concentrations of sugars. This is partially due to a decrease in  $a_w$  associated with high concentrations of sugars. However, the relative affects of different sugars on the heat resistance of pathogens varies widely even if the  $a_w$  remains the same. The heat resistance of pathogens will also increase in the presence of starch(s) in a product

<sup>C</sup> The effect of salt on the heat resistance of pathogens is variable and largely depends on the type of salt and its concentration. Sodium salts, e.g. sodium chloride, will decrease  $a_w$  and therefore may increase heat resistance. Other salts such as calcium and magnesium salts increase  $a_w$  and thereby decrease heat resistance

<sup>D</sup> Many foods will not have a uniform internal structure. As a consequence micro-environments may form within the food. The location of pathogenic cells in the food may also affect their resistance to heat treatment. Micro-environments may have different properties to the food as a whole. This can be problematic if the properties within these micro-environments allow the growth of pathogens if as a whole the product's properties do not allow their survival and growth

The effect of fats, proteins, carbohydrates and high solids contents on the heat resistance of pathogens can be quite significant. Some of these components can increase heat resistance of pathogens by a factor of 2–3<sup>(44)</sup>. The current industry trends to reduce salt, sugars and other additives in foods should be considered by the FBO during product development. Changes in these components may affect the inhibitory properties of a food and therefore, the required heat treatment to maintain food safety.

### Storage Temperature

Pathogens have different temperature requirements for survival and growth in foods. The minimal temperature for pathogenic growth is also influenced by other intrinsic and extrinsic properties. However, it is lowest when these properties are optimal, e.g. pH,  $a_w$  etc. for a specific pathogen. Therefore, when sub-optimal levels for other intrinsic and extrinsic properties are combined with low storage temperature, the safety of heat processed food increases. The effect of storage temperature on the growth and survival of pathogens is very dependent on the relative humidity of the environment and the presence and concentration of gases<sup>(43)</sup>.

### **Gas Atmosphere**

Modified atmosphere packaging (MAP) and vacuum packed (VP) alter the concentration and types of gases found under normal atmospheric conditions. MAP and VP are inhibitory to aerobic pathogens but may permit the survival and growth of facultative, e.g. *L. monocytogenes*, anaerobic, e.g. *Cl. botulinum* and microaerophilic, e.g. *Campylobacter jejuni*, pathogens in foods.

Modified atmosphere packaging and VP also increase product shelf-life and as such, may also increase the risks of anaerobic, facultative or microaerophilic pathogens growing over the extended shelf-life. This can affect the type of heat processing the food requires for microbiological safety <sup>(21)</sup>.

### **Relative Humidity**

The relative humidity of a gaseous mixture at a particular temperature is the ratio of the amount of water vapour in the gaseous mixture to the maximum amount of water vapour which the mixture can hold at that temperature. Relative humidity is usually expressed as a percentage.

When food with low  $a_w$  is placed in high relative humidity environments, the food will absorb moisture until equilibrium with the environment is established. Food with high  $a_w$  placed in low relative humidity environments will lose moisture by desorption until equilibrium with the environment is established. Therefore, the selection and storage of a product at the correct relative humidity is very important in relation to the growth and survival of pathogens.

## APPENDIX 2. OTHER VALIDATION TECHNIQUES

Under specific processing conditions, e.g. heating chamber/vessel with scrapers, or due to the characteristics of specific products it can be difficult to validate the safety of a process based on temperature measurement using temperature probes. In these cases, another means of validation may be employed. Typically, these processes and products will include:

1. Products produced in steam injection, steam infusion, plate, tubular or scraped surface heat exchangers such as milk and milk products, sauces and dressings, some soups, jams and preserves
2. Products produced in deep fat/oil frying units and continuous ovens such as biscuits, breads, processed meats, poultry and fish, particularly breaded products
3. Products produced in agitated steam jacketed vessels such as those containing discrete meat, poultry, fish and vegetable pieces including soups and ready meals.

In these and other cases, alternative methods other than temperature measurement using probes, are required for validation of product safety including:

1. Use of biochemical time-temperature integrators (TTIs). Typically, TTIs use an enzyme that denatures on heating. If the heat reaction kinetics of the enzyme are the same as the microbial death kinetics of the target pathogen, it is possible to use the enzyme as an indication of product safety after heat processing
2. Simulated laboratory trials where the process conditions are replicated and the temperature can be conventionally measured using temperature probes
3. Microbiological methods including challenge tests, inoculation studies, predictive microbiological methods and end-product testing
4. Use of mathematical process models which predict the temperature and time characteristics of products as they pass through a process such as cooking
5. Process safety being inferred from temperature probing of the bulk product and/or the processing environment (where applicable)
6. Over processing of product to ensure that its core or central part(s) receive sufficient processing to ensure product safety, e.g. heating a product at the same temperature but for a longer period of time.

In all cases where alternative methods other than temperature measurement using probes are required for validation of product safety, consultation with an expert is strongly recommended.

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