

HIGH PRESSURE PROCESSING

PRODUCT CONSIDERATIONS IN HPP



Department of
Primary Industries
Food Authority

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Introduction

This guidance document has been developed as an introductory guideline for new entrants looking to introduce High Pressure Processing (HPP) into their operations. This document is not exhaustive, only a starting point.

High pressure processing (HPP) is an excellent addition to a food technologist's tool kit. For some foods HPP provides a good technology solution to processing challenges. For other products the use of pressure alone has limitations and processes that combine pressure and temperature might be required to achieve the sought-after product characteristics. The desired outcome and product characteristics must be taken into account during validation studies and when assessing shelf life.

A recent review (Balasubramaniam, Martínez-Monteagudo, & Gupta, 2015) provides detailed information on HPP and combined processing technologies. The review notes that pressure alone at or near ambient temperatures has very limited or no effect on spore destruction. This has clear implications for the HPP treatment of low-acid foods. HPP low-acid foods stored at ambient temperature will be at risk of growth and toxin production by *Clostridium botulinum* and rapid spoilage. Extended refrigerated storage of HPP low-acid foods will be at risk of growth and toxin production by cold-tolerant (psychrotrophic) *Clostridium botulinum*. Over time, spoilage is also likely to be a problem.

These risks are no different to those faced when preparing pasteurised products and foods cooked at conventional temperatures. HPP needs to be used wisely and with an appreciation of the limitations of the technology. A review by Rendueles et al (2011), quoting a number of authors said “broadly speaking, HPP applied at ambient temperatures destroys vegetative cells and inactivates certain enzymes, with a minimal change in organoleptic properties”. They go on to say that large differences in sensitivity to HPP among pathogenic microorganisms (*Listeria monocytogenes*, *Staphylococcus aureus*, *Escherichia coli*, *Salmonella Typhimurium*) have been reported, with reductions in the range 0.5-8.5 log units.

This document aims to assist those new to HPP navigate their way through some basic issues including product design, process validation and estimation of shelf life. Balasubramaniam et al (2015) state that food processors interested in validating pressure-pasteurisation treatment should work with competent pressure-processing experts in designing and conducting validation trials.



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Part 1 – An overview of HPP science and technology

HPP technology (IFT & USFDA, 2014)

HPP subjects liquid or solid foods, with or without packaging to pressures between 100 and 800 MPa (14,500 to 116,000 PSI). Process temperature during pressure treatment can be specified below 0°C to above 100°C. Vessels are uniquely designed to withstand these pressures over many cycles. Commercial exposure times can vary from a millisecond pulse to over 20 minutes. Foods subject to HPP treatment at or near room temperature will not undergo significant chemical transformations due to the pressure treatment itself.

HPP acts instantaneously and uniformly through a mass of food independent of size, shape and food composition. Thus package size, shape and composition are not factors when determining the process. The work of compression will increase the temperature of the foods by approximately 3°C per 100 MPa, depending on the composition of the food. If a food contains a significant amount of fat the temperature rise can be larger. Foods cool down to their original temperature on decompression if no heat is lost or gained from the vessel walls of the chamber during the hold time at pressure. A uniform initial temperature is required to achieve a uniform temperature increase in a homogenous system during compression.

While the temperature of a homogenous food (one with less than 25% fat) will increase uniformly due to compression, the temperature distribution in the mass of food during the holding period at pressure can change due to heat transfer to or from the walls of the pressure vessel. The pressure vessel must be held at a temperature equal to the final food temperature increase from compression for truly isothermal conditions. Temperature distribution must be determined in the food and reproduced each treatment cycle if temperature is an integral part of the HPP microbial inactivation process specification.

Food characteristics affect HPP

pH (IFT & USFDA, 2014)

As pH is lowered most microbes become susceptible to HPP inactivation and sublethally injured cells fail to repair. Experience with acid foods suggests that shelf-stable (commercially sterile) products, having a water activity close to one, and pH values less than 4.0, can be preserved using a pressure of 580 MPa and a process hold time of 3 min. This treatment has been shown to inactivate 10^6 cfu/g of *E. coli* O157:H7, *Listeria* spp., *Salmonella* spp., or *Staphylococcus* spp. in salsa and apple juice.

Acid foods between the pH values of 4.0 and 4.5 can be made commercially sterile using a pressure of 580 MPa and a hold time of 15 min. Products would have an initial temperature in the range of 22 °C.

A Hazard Analysis and Critical Control Point (HACCP) plan is essential to ensure that ingredients entering the process have low counts of pathogens and spoilage microbes. Shorter hold times are possible if the product is to be refrigerated. Actual hold-time values must be determined from challenge packs and storage studies perhaps twice the length of the intended shelf-life of the product.

Water activity (a_w)

Reducing water activity appears to protect microbes against inactivation by HPP; however, it is expected that microbes may be sublethally injured by pressure and recovery of sublethally injured cells can be inhibited by low water activity. Consequently the net effect of water activity may be difficult to predict (IFT & USFDA, 2014).

A highly technical paper (Georget et al., 2015) also concludes that HPP inactivation of microorganisms at low or variable a_w is reduced but the impact appears in part to be related to a_w and in part to the impact of the solute.



Temperature

An increase in food temperature above room temperature and to a lesser extent a decrease below room temperature increases the inactivation rate of microorganisms during HPP treatment. Temperatures in the range of 45 to 50 °C appear to increase the rate of inactivation of food pathogens and spoilage microbes and thus warrant the development of processes which incorporate a uniform initial food temperature in this range. Process temperatures in the range of 90-110 °C in conjunction with pressures of 500-700 MPa have been used to inactivate spore forming bacteria such as *Clostridium botulinum*. The use of elevated temperatures as part of a specified HPP process will require monitoring the food temperature during the process to ensure every element of the food is at or above the specified value (IFT & USFDA, 2014).

Rendueles et al (2011) explore some reasons why temperatures might affect inactivation. They report the decrease in resistance to pressure at low temperatures may be due to changes in membrane structure and fluidity through weakening of hydrophobic interactions and crystallisation of phospholipids. Moderate heating (40–60 °C) can also enhance microbial inactivation by pressure, which in some cases makes application of lower pressure an option.

Fat or oil content of the food

During pressure treatment, the temperature of different food materials increases quickly due to physical compression and returns back to its initial value upon decompression. The heat of compression of most of the high-moisture food materials is very similar to that of water, 3°C per 100 MPa at 25°C. However, fatty foods have higher compression heating due to their higher compressibility with long-chain unsaturated fatty acids and lower specific heat. Although the heat of compression of water and high moisture–content foods generally increases with increasing initial product temperature, the heat of compression value of fatty materials does not vary as a function of initial temperature (Balasubramaniam et al., 2015).

Heat of compression values of selected food

Substance at 25°C	Temperature change per 100 MPa
Water, juice, tomato salsa, 2% milk, and other water-like substances	3.0
Mashed potato	3.0
Salmon	3.2
Chicken fat	4.5
Beef fat	6.3
Olive oil	8.7 to 6.3a
Soy oil	9.1 to 6.2a

a - Substances exhibited decreased temperature rise as pressure increased.(Balasubramaniam et al., 2015)



Composition of food

The microbial susceptibility to HPP inactivation is clearly influenced by the conditions of the environment where microorganisms are present. Therefore, the results obtained in model systems using artificial substrates cannot be directly compared to “real” foods, and should be validated. The chemical composition of the food is important, since the presence of fats, proteins, minerals and sugars serves as a protector and increases microbial resistance to pressure. Nutrient-rich foods, such as milk or poultry meat, can protect microorganisms (Rendueles et al., 2011).

Microbiological food safety and HPP (Rendueles et al (2011))

HPP does not attack just one point of cellular structure or function. Cell death is due to a multiplicity of damage accumulated in different parts of the cell. When the accumulated damage exceeds the cell’s ability to repair, cell death occurs. In some cases the cell is damaged but repair can occur if post-treatment conditions are appropriate. The cell membrane is the main target of HPP resulting mainly in permeability changes and functionality disruption.

Higher rates of inactivation by HPP are usually reported in more complex organisms. Organisms with simpler structures, such as bacteria, are usually more resistant to HPP inactivation. HPP is effective in eliminating foodborne parasites, such as *Toxoplasma gondii*, *Cryptosporidium parvum*, *Anisakis simplex*, *Trichinella spiralis* and *Ascaris*, in low pressure ranges. Moulds and yeast have intermediate resistance with mould mycelia being particularly susceptible but mould spores that are quite resistant to HPP have been reported. Yeasts including *Saccharomyces cerevisiae* and *Zygosaccharomyces bailii* have high susceptibility but environmental factors can have an impact.

Studies with foodborne vegetative pathogens show large variations in sensitivity when low pressures (300 MPa) are combined with intermediate temperatures. Differences are seen between species of pathogenic microorganisms and differences have also been reported between strains belonging to the same genus or species. Gram positive bacteria are generally more resistant than gram negative bacteria. Bacteria are more sensitive during logarithmic growth compared to the stationary phase. In general the presence of proteins that protect against adverse conditions increase resistance to HPP.

Spores show great resistance to inactivation by high pressure. This is especially relevant for the spore forming foodborne pathogens *Clostridium botulinum*, *Clostridium perfringens* and *Bacillus cereus*. The production of shelf stable, low acid foods requires inactivation of spores by combining HPP with other processes, usually elevated temperature.

Viruses vary in pressure resistance depending on their structural complexity. Enveloped viruses are usually more sensitive than naked viruses.

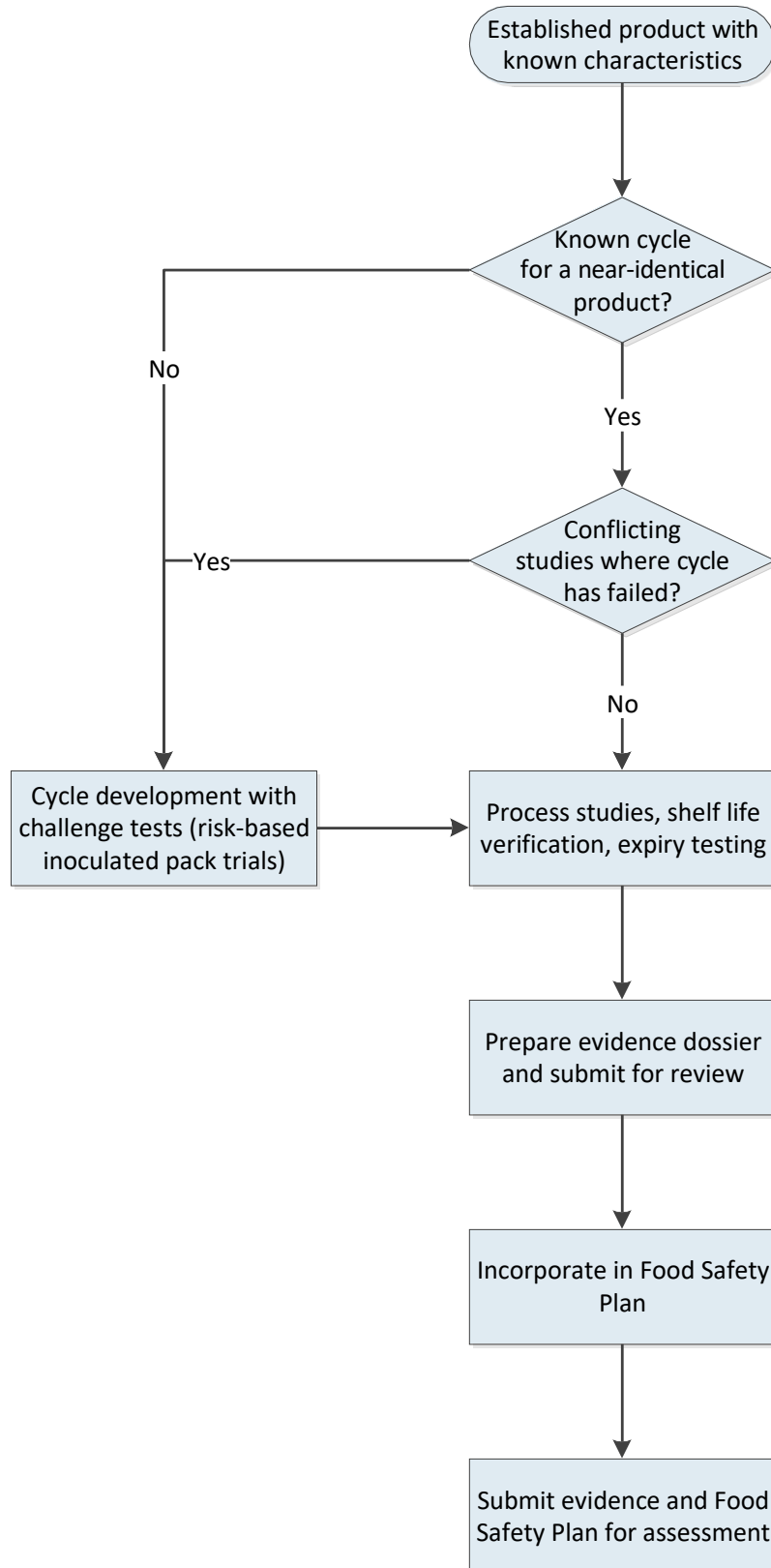
Part 2 – Considerations for manufacturers

Cycle development and validation

When product development is well advanced¹ and a HPP packaging system has been identified, processing cycle issues must be resolved. Small manufacturers that contract a HPP processor will generally look for a published cycle for a food that closely matches their product. The cycle should originate from a scientific journal, an expert research organisation or the equipment manufacturer. The graphic below describes an approach.

¹ For further discussion of product development and shelf life refer to http://www.foodauthority.nsw.gov.au/Documents/scienceandtechnical/shelf_life_testing.pdf

Figure 1: HPP cycle development or verification



Where a cycle has to be developed from scratch a manufacturer would usually require the services of a HPP expert and a microbiological laboratory with experience in the conduct of challenge trials. The types of risk to be considered when designing the challenge trial vary depending on the characteristics of the product.

Table 1 provides guidance on food safety risks that might be considered for products produced using Good Manufacturing Practices (GMP). The manufacturer should still complete an assessment of risk for their product.

Table 1: Food safety risks associated with food types

Product	Shelf life	Risks	Equivalence target
Chilled acid food with pH below 4.2	Long	Survival of vegetative cells of pathogenic bacteria	Pasteurisation ²
Chilled acid food with pH from 4.2 to <4.6	Long	Above risk plus potential growth of vegetative cells of some pathogenic bacteria	Pasteurisation
Low acid chilled foods	0 to 5 days	Above risks	Cook time as recommended for the type of food ³
Low acid chilled foods	5 to 10 days	Above risks plus <i>Listeria monocytogenes</i>	Recommended <i>Listeria</i> -safe cooking process ⁴
Low acid chilled food	10+ days	Above risks plus cold tolerant <i>Clostridium botulinum</i>	Recommended psychrotrophic <i>Clostridium botulinum</i> cooking process ⁴
Low acid shelf stable foods	Long	Above risks plus conventional <i>Clostridium botulinum</i>	Suitable retorting process

Shared responsibility for subcontract⁵ HPP processing

Contract manufacture must be correctly defined, agreed and controlled in order to avoid misunderstandings which could result in a product or work of unsatisfactory quality. There must be a written agreement between the manufacturer and the processor which clearly establishes the duties of each party.

The manufacturer is responsible for assessing the competence of the processor to carry out successfully the work required. The manufacturer should ensure that the processor is fully aware of any problems associated with the product which might pose a food safety hazard. The manufacturer should ensure that all processed products delivered to the processor have been released by an authorised person. A manufacturing record should log transport to the processor, storage at the processor, processing times and cycle numbers and the return transport.

² For juice see <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=120.24>

³ For example <http://www.foodauthority.nsw.gov.au/consumers/keeping-food-safe/cooking-correctly>

⁴ For example http://www.foodauthority.nsw.gov.au/_Documents/industry/guidelines_vulnerable_persons.pdf Appendix 3

⁵ Concepts derived from PIC/S Guide to GMP <http://www.tga.gov.au/publication/manufacturing-principles-medicinal-products#part1>



The processor must have:

- adequate premises and equipment
- knowledge and experience; and,
- competent personnel to satisfactorily carry out the work ordered by the manufacturer.

Records of the relevant cycles should:

- be available to the manufacturer
- have a clear link between the manufacturers batch number and the processors cycle number(s); and
- ensure that any records relevant to assessing the quality of a product in the event of complaints or a suspected defect are accessible and specified in the complaints handling or recall procedures of the manufacturer.

Technical aspects of the agreement should be drawn up by competent persons suitably knowledgeable in food manufacturing and GMP (Good Manufacturing Practice). All cycle parameters for processing must be included. The agreement should specify the way in which the authorised person releasing the batch for sale ensures that each batch has been processed and checked for compliance with the requirements for food safety.

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