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## International Regulations & Validations for High Pressure Thermal Processing

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High-pressure thermal processing (HPTP) refers to the application of both high pressure (400-600 MPa) and temperature (40-130°C). This approach aims to reduce the temperature and/or the duration for which the product is processed. However, the widespread adoption and industrial implementation of HPTP face several limitations, including regulatory and validation challenges.

On the regulatory side, it is required to take into consideration regulations in force for regular pasteurization or sterilization processes. Moreover, some countries have dedicated regulations for high pressure processing and also for novel foods (food submitted to novel processes) in general.

Validation challenges in HPTP include various aspects, such as engineering, biological factors, and chemical considerations. For the validation of HPTP techniques applied to sterile low-acid foods (pH  $\geq$  4.6), certain key challenges must be addressed. These challenges include obtaining access to HPTP systems housed within Biosafety Level 3 laboratories and identifying suitable surrogates for *Clostridium botulinum* spores.

Additionally, it is crucial to evaluate the potential formation of undesired compounds under pressure induced by temperature, which can come from the food matrix or from the packaging material. Packaging validations for commercial HPTP applications have to be performed to verify mechanical properties and compliance with chemical migration standards.

The number of approved commercial applications of HPTP remains limited in the United States, Europe, and Australia. The U.S. Food and Drug Administration (FDA) has granted authorization for the utilization of HPTP techniques for the sterilization of mashed potatoes (2009) and multi-component dishes (2015). Similarly, French authorities validated in 2016 a process of high pressure assisted pasteurization of fat duck liver (foie gras) with conditions of 600 MPa, 10 minutes, and 60°C which effectively eliminates pathogenic microorganisms. In 2022, Australian state of Queensland authorized an industrial HPHT process for milk pasteurization.