Food Safety
AUTHORITY OF IRELAND

Report of the Scientific Committee
of the Food Safety Authority of Ireland

2020

Appraisal of new and emerging food processing technologies and their potential risks to food safety

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Published by:

Food Safety Authority of Ireland
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Dublin 1, D01 P2V6

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ISBN: 978-1-910348-38-3

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Glossary

DC	direct current
EFSA	European Food Safety Authority
EU	European Union
FBO	food business operator
FCM	food contact materials
FDA	U.S. Food and Drug Administration
FSAI	Food Safety Authority of Ireland
FSMS	food safety management system
GHP	good hygiene practices
GMP	good manufacturing practices
HACCP	hazard analysis and critical control point
HPP	high-pressure processing
IFT	Institute of Food Technologists
LED	light-emitting diodes
PEF	pulsed electric fields
RTE	ready to eat
spp.	species
UK	United Kingdom
UV	ultraviolet

Units of measurement

cps	centipoise
D	decimal reduction time
Hz	hertz
J/cm^3	joule/cubic centimetre
kV/cm	kilovolt/centimetre
L/h	litre/hour
log$_{10}$	logarithm base 10
mEq/kg	Milliequivalents/kilogram
mJ/cm^2	millijoule/square centimetre
MPa	megapascals
mS/cm	millisiemens/centimetre
mW/cm^2	milliwatt/square centimetre
nm	nanometre
NTU	nephelometric turbidity units
ppb	parts per billion
V	voltage
mg	microgram
ms	microsecond

1. Background

The most common or traditional food processing techniques used by the food industry remain those which apply or remove heat or water:

- Input of thermal energy to increase food temperature, e.g. pasteurisation, sterilisation, etc.
- Removal of thermal energy to decrease food temperature, e.g. cooling, freezing, etc.
- Removal of water from the food, e.g. drying, osmotic dehydration, freeze-drying, etc.

Historically, the main purpose of these technologies has been food safety and preservation through the destruction of pathogenic and/or spoilage microorganisms and enzymes. However, in order to provide a variety of food choices and on-the-go convenience for today's consumers, food scientists, processors and equipment manufacturers continually develop new food processing and packaging technologies to ensure food safety, stability and quality. In addition to food safety and preservation, these technologies can address concerns associated with environmental protection, energy reduction and optimisation of water resources. New and emerging food processing technologies (including thermal and non-thermal technologies) are being developed in order to safely meet the growing demand of consumers for greater choice, while maintaining the sensory and nutritional quality of food. Some of these new and emerging food processing technologies include:

- High-pressure processing (HPP)
- High-voltage pulsed electric fields (PEF)
- Ultraviolet (UV) light
- High-intensity pulsed light
- Blue light
- Radio frequency heating
- Moderate electric fields
- Cold (atmospheric) plasma
- Oscillating magnetic fields
- High-intensity ultrasound
- Electron beam processing
- Hydrodynamic shock waves
- Ozone treatment.

Many of these new and emerging technologies are at the research or pilot phase of development and are limited in the potential number and type of commercial applications. Others such as UV light, PEF and, particularly, HPP are in more widespread commercial use by the food industry for

the preservation (microbial and enzyme inactivation), extension of shelf life and quality improvement/maintenance of processed foods. Several scientific books and peer-reviewed publications reveal the extensive research on these innovative technologies while also providing case studies and real-life experiences demonstrating the successful use of some novel processes for food preservation.

While most regulators across the European Union (EU) have considerable experience in assessing the safety of foods produced using traditional thermal processes like pasteurisation, similar experience with new and emerging technologies is less common. Therefore, the knowledge and experience of traditional processing technologies may not be of significant assistance in identifying any food safety issues resulting from the use of new and emerging technologies.

Much of the current food safety legislation and best practice guidance relates to the use of more traditional thermal processes by the food industry, rather than some of the new and emerging technologies.

In accordance with Article 4 of the European Union Novel Food Regulation (EU) 2015/2283, a formal system is in place to determine the novel food status of foods or food ingredients, including those produced using a new process. The safety of a food deemed to be novel due to a new production method will be assessed by the European Food Safety Authority (EFSA) as part of an EU-wide authorisation process.

The Food Safety Authority of Ireland (FSAI) asked its Scientific Committee to appraise new and emerging food processing technologies and their potential risks to food safety. In the context of this request, three key questions were put to the Scientific Committee:

a) What science should be considered in order to allow the continued development and implementation of new technologies in food production?
b) What are the risks regarding the use of these new technologies (e.g. microbiological, toxicological, product - packaging interactions, process capability and product stability and chemistry)?
c) What information would be required to establish equivalence to traditional food processing technologies to ensure food safety, particularly if new food processing technologies are to be used as a replacement for thermal pasteurisation?

2. Objective

The objective of this report is to address the questions that the FSAI asked its Scientific Committee. It also provides a template for the proportionate and consistent appraisal of new and emerging processing technologies that will both protect public health and support technological innovation by the food industry in Ireland. Two examples are provided to illustrate the appraisal process envisaged.

3. Scope

The scope of this report is confined to the appraisal of new and emerging processing technologies for food preservation, including any associated changes in nutritional value and/or safety when compared to traditional processes. It is without prejudice to the novel food authorisation process set out in Regulation (EU) 2015/2283 and associated Commission Implementing Regulations.

While there is increasing interest in the use of new and emerging technologies to provide greater choice and better-quality processed foods for consumers, these attributes are outside the scope of this report.

4. Appraisal procedure

The appraisal procedure for new and emerging technologies has three key steps.

4.1. Overview

Give an overview of the technology and its existing applications, including information regarding current use in a commercial environment.

4.2. Novel food status

Provide information on the novel food status of food products subjected to the new technology. Novel foods are foods or food ingredients that were not used for human consumption in the EU to a significant degree before the novel food regulation came into force (15 May 1997). A food produced by a new production process that gives rise to significant changes in composition or structure of a food affecting its nutritional value, metabolism or level of undesirable substances may be considered a novel food and require pre-market authorisation.

4.3. Food safety assessment of technology

Assess the potential risks to food safety from the technology using the information outlined in Table 1.

Table 1 Food safety assessment of categorised technologies[a]

	Information required	Clarifications
1	Describe the food product(s) that will be processed using the technology	See Note 1
2	Outline the rationale for using the technology	See Note 2
3	Describe the operating principles of the technology, including the mechanism for inactivation of microorganisms	See Note 3
4	Identify the key intrinsic/extrinsic factors which can affect the safety of food produced using the technology	See Note 4
5	Outline any potential hazards identified or associated with the use of the technology	See Note 5
6	Describe the proposed production process into which the technology will be integrated	See Note 6
7	Outline the Food Safety Management System incorporating Good Manufacturing Practices (GMP), Good Hygiene Practices (GHP) and procedures based on hazard analysis and critical control point (HACCP) principles, for the proposed production process using the technology	See Note 7
8	Outline validation studies illustrating food safety control measures and/or equivalence to traditional technologies	See Note 8

[a] Please note that this is a minimum starting point and other supplemental information or data, as appropriate, may be required in order to establish food safety.

Note 1 – Describe the food product(s) that will be processed using the technology

Provide a detailed description (e.g. specification) of the food product to be commercially produced using the technology. The specification should include:

- Ingredient list and specifications for each ingredient (Note: If the food is produced from a source that in itself is not normally consumed as part of the diet, details should be provided as a novel food authorisation may be required)
- Information regarding whether the food consists of or contains engineered nanomaterials as referred to in parts (a)(viii) and (ix) of Article 3(2) of Regulation (EU) 2015/2283 (novel food authorisation may be required)
- Good manufacturing and hygiene practices
- Quality control parameters and measures
- Labelling considerations (e.g. shelf life declaration, food allergens)
- Storage, distribution and retail display conditions
- Intended use(s)
- Instructions for use of the product as applicable
- Any other relevant legislative requirements or considerations.

Note 2 – Outline the rationale for using the technology

Outline the reasons for using the technology during the manufacture of the selected food product(s).

- Indicate if the technology will be used for food preservation purposes and if it is designed to deliver a targeted process lethality, i.e. kill step. If the technology is to be used for lethality as an alternative to more traditional technologies such as thermal pasteurisation, then its equivalence to that technology must be documented by the applicant through a validation study, with verification of the technology. Include reference to published scientific peer-reviewed papers, opinions (e.g. EFSA opinions), reports, etc. that outline equivalence in similar processes and products.
- Indicate if the technology will be used as a hurdle for food preservation purposes in combination with other hurdles and document the reason(s) for its use.
- Indicate if the technology will be used for quality (e.g. prevent discolouration), functional (e.g. oyster shucking) and/or nutritional purposes (e.g. increase in vitamin levels) in addition to food preservation.
- Indicate the type of equipment used – if it is industrial scale commercial equipment indicate the model and manufacturer, if it is a lab scale or prototype include a detailed description.

Note 3 – Describe the operating principles of the technology, including the mechanism for inactivation of microorganisms

Irrespective of the technology used to inactivate or destroy microorganisms, the effectiveness of that technology is mainly associated with three key factors: the process, the product, and the target microorganism(s).

Provide details of how the technology works, including key process control parameters, advantages and disadvantages, limitations of use, etc.

Include reference to scientific published peer-reviewed papers, opinions (e.g. EFSA opinions), reports, etc. Advice on possible sources of relevant scientific information should be sought from the equipment supplier and/or in consultation with the relevant competent authority.

Note 4 – Identify the key intrinsic/extrinsic factors that can affect the safety of food produced using the technology

All foods can have their compositional/physico-chemical characteristics broadly divided into intrinsic and extrinsic characteristics, and details of these should be established. Intrinsic characteristics are those inherent to the composition of the food, such as its pH, water activity, salt content, etc. Extrinsic characteristics are those that relate to the external environment and which impact on the food such as temperature, nature of processing, type of packaging, etc.

Microorganisms have specific requirements for survival and growth in food that depend on the intrinsic and extrinsic characteristics of the food and which are inherently variable. Furthermore, while each intrinsic and extrinsic characteristic may affect microbial growth and survival, it is the interaction between these properties that determines whether a microorganism will grow or survive in a food. In addition, microorganisms can adapt and increase their resistance to a wide variety of environmental stresses (e.g. cold shock, heat shock, etc.).

As appropriate, consider and document the individual effect and the interaction of intrinsic and extrinsic characteristics on the effectiveness of the technology for food preservation, including the shelf life, quality characteristics and nutritional properties of the food.

Include reference to published scientific peer-reviewed papers, opinions (e.g. EFSA opinions), reports, etc.

Note 5 – Outline any potential hazards identified or associated with the use of the technology

Provide details of any identified food safety issues related to the use of the technology and strategies to manage them. These can include issues associated with microbiological, chemical, physical or allergenic hazards. Where significant changes are identified due to the use of the technology, an Article 4 request regarding novel food status under the novel food Regulation (EU) 2015/2283 should be considered.

Provide details of any identified pathogens of concern related to the food produced using the technology. The type of pathogens of concern will depend on the characteristics of the food, the mode of action and effectiveness of the technology for inactivating microorganisms, and the environment in which the technology is embedded. Microbial tolerance or sensitivity to any particular technology may not equate to tolerance or sensitivity to traditional (e.g. thermal) processing.

Changes in the food's structure that are of functional benefit, and those that might represent a safety concern, should be considered. Changes due to the technology that could affect food safety (e.g. formation of nanoparticles), composition, nutritional value, metabolism or level of undesirable substances, should be considered and details provided. Where significant changes are identified, an Article 4 request regarding the novel food status under the novel food Regulation (EU) 2015/2283 should be considered.

Details of any product recalls, outbreaks of foodborne illness, or regulatory actions taken against manufacturers using the technology should be provided.

Details of any quality issues with the food including chemical changes or storage stability should also be considered. Where significant impacts are associated with the use of the technology, an Article 4 request regarding novel food status under the novel food Regulation (EU) 2015/2283 should be considered.

Details of the suitability of any food contact materials (e.g. in packaging) used during processing of the food with the new/emerging technology should be provided. Information should be provided regarding the effect of the technology on the integrity and safety of the food contact materials; such information could include migration studies, declaration of compliance from suppliers, etc.

Note 6 – Describe the proposed production process into which the technology will be integrated

Provide details of the complete process flow (including manufacturing parameters) for the production of the food product(s) to be processed using the technology. The process flow must sequentially include all steps related to production, including any off-site processing, distribution and storage. If the technology is combined with other technologies, this should be included in the process flow.

Note 7 – Outline the GMP, GHP and HACCP plan for the proposed production process using the new technology

Provide details of a Food Safety Management System incorporating GMP, GHP and procedures based on HACCP principles for the proposed production process. All food businesses, with the exception of primary producers, are legally obliged to put in place, implement and maintain permanent procedures based on HACCP principles. These procedures provide a structured, systematic approach to food safety that involves the identification of potential hazards (microbiological, chemical, physical or allergenic) and plans for their monitoring and control.

During hazard analysis, the extrinsic and intrinsic factors of the food may be identified as critical control points in the HACCP-based procedures. In such cases, critical limits need to be established, assigned and monitored. In this way, consistently and systematically applied procedures based on HACCP principles should reduce the level of risk posed by various hazards.

Note 8 – Outline validation studies illustrating food safety control measures and/or equivalence to traditional technologies

Process verification and validation are essential components in the appraisal of a new technology's capacity to produce safe foods. Provide documented details of validation studies illustrating the capacity of the technology to produce safe food. The validation studies should be representative of the chosen technology and food product to be commercially produced.

As appropriate, provide details of any identified pathogens of concern related to the food produced using the technology, expected pathogen reductions (i.e. logarithmic reductions) using the technology and equivalence to traditional technologies if the new technology is intended to replace them.

5. Conclusions

There are significant challenges associated with the process of ensuring the safety of foods processed using new and emerging technologies and which are captured under four key areas:

- Gaps in scientific knowledge about new and emerging technologies
- Demonstrating the equivalence of new and emerging technologies to existing processes
- Applicability of current legislation to effectively regulate new and emerging technologies
- Ensuring consistency in evaluations of new and emerging technologies.

This report addresses not only the questions the FSAI asked its Scientific Committee, but also the challenges identified above. It provides a template for proportionate and consistent appraisal of new and emerging food processing technologies that should protect public health while supporting technological innovation by the food industry in Ireland.

6. Recommendations

The Scientific Committee of the FSAI makes the following recommendations:

a) Without prejudice to any aspects of the novel food authorisation process as governed by Regulation (EU) 2015/2283 and associated Commission Implementing Regulations, the described template for appraisal of new and emerging food processing technologies should be used by the food business in conjunction with the competent authority to evaluate food safety.
b) Research needs (e.g. the effect of the technology on migration of chemicals from food packaging) or data gaps (e.g. the survival of specific pathogens) related to the technology and identified by the food business should be documented and provided to the competent authority.
c) The structure and content of the described template should be updated as new and reliable information becomes available.

Appendix 1 Worked examples

Example 1

Technology: High-pressure processing (HPP)

Food product: Traditional hummus

1. Overview

High-pressure processing (HPP) – also called high hydrostatic pressure processing, ultra-high-pressure processing, or cold pressing – is a non-thermal technology which applies high pressure to foods in order to ensure food safety and increase shelf life while also retaining product quality.

Traditionally, foods that receive HPP must first be pre-packed in vacuum packs or other flexible packaging such as plastic bottles. HPP of food in non-flexible, harder packaging materials such as ceramics, glass or metal is relatively uncommon as they are likely to shatter or permanently distort due to the pressure applied. Packaging selected for HPP must be able to withstand the high pressures applied without losing seal integrity or barrier properties, i.e. it must be able to withstand volume changes (up to 15%) and be able to return to its original shape without leaching undesirable packaging chemicals into the product. Bulk HPP equipment for high pressure processing of unpackaged beverages (10,000 litres/hour) that could subsequently undergo aseptic packaging was launched in 2018 (Hiperbaric, 2018).

Traditional HPP involves placing the packaged food(s) into a sealed pressure chamber which is filled with potable water and a small amount of oil to lubricate the pump and protect the vessel's inner surface from corrosion. A pump applies pressure to the water, which is then transmitted to the food through the packaging. The pressure involved in HPP can range from 200 to 800 MPa. By comparison, traditional retorting uses approximately 0.2 MPa and high-pressure homogenisation applies pressures of between 150 and 200 MPa.

As the pressure acts instantaneously and is equally distributed (as per Pascal's principle/law), there is no obvious crushing effect on the packaged food. The isobaric or isostatic pressure is applied for a set time period and on completion, the chamber depressurises, and the food product can be removed.

Commercial manufacturers of HPP equipment

Despite cost and other barriers to investment, the use of HPP technology on food products such as premium fruit juices, vegetable products, ready-to-eat (RTE) meats, and seafood is increasing.

This in turn is boosting the development and market demand for specialised HPP equipment. In 2016, the estimated value of the global HPP market was more than (US)$11 billion (Visiongain, 2016).

Manufacturers of HPP equipment have been established in Spain, Germany, China, Japan and the USA.

The high cost of HPP equipment internationally has led to larger food businesses establishing equipment manufacturer cooperation platforms that provide HPP services to smaller food businesses through the use of their excess production capacity. This initiative allows quicker recovery of equipment investment costs, but more importantly, it facilitates access to HPP technology for a greater range of food businesses.

Other initiatives involve stand-alone companies purchasing HPP equipment and providing direct access to the HPP equipment. Tolling services are widespread worldwide and are facilitated by some of the larger equipment manufacturers (Huang *et al.*, 2017). In Ireland, there is currently one provider of this service to the food industry.

Established commercial use of HPP

The first commercial HPP foods were launched in Japan in the early 1990s which served to demonstrate the potential of HPP as an alternative to thermal technologies for pasteurising foods with minimum heat damage (Knorr, 1993; Balasubramaniam *et al.*, 2015; Elamin *et al.*, 2015; Farkas, 2016).

The first commercial HPP food launched in the EU was an orange juice product in France in 1994 (Eisenbrand, 2005). The commercial application of HPP internationally has been increasing rapidly since the 1990s and is evident from the increased number of HPP equipment installations worldwide (Hiperbaric, 2017). In 2014, the worldwide production of HPP food products was estimated at greater than 500 million kg (Flores, 2015).

Many types of food are suitable for HPP, particularly those with high water content such as fishery products, shellfish, meat and dairy products, fruit and vegetable juices, smoothies, dips, jams, and baby food (Wang *et al.*, 2016). Food products containing air bubbles such as breads and mousses are not suitable for HPP as the food structure can be damaged by the high pressures applied. A wide variety of HPP-treated food products have been identified internationally:

- cold-pressed juices
- smoothies
- ground beef patties
- deli meat and cold cuts

- ready-to-eat meals
- refrigerated soups, salads, dips, specialty sides
- liquid cow's milk
- vegan, lactose and gluten free yogurts
- cheese
- baby food
- pasta sauce
- fresh avocado
- hummus
- guacamole
- fish fillets
- shellfish.

In Ireland, HPP food ingredients have been used in manufactured foods since 2014, primarily fruit and vegetable juices and smoothies, but also other food types including:

- noodles
- cooked meat products aimed at children
- wheatgrass and barley grass juice shots
- hummus.

2. Novel food status

In the context of Regulation (EU) 2015/2283 on novel food, a new production process is not novel simply because it is new. Only where the new process has a significant effect on the composition or structure of a food, which in turn affects its nutritional value, metabolism or level of undesirable substances, would that food be considered novel and subject to authorisation under novel food legislation.

HPP is generally considered a physical (pressure) decontamination when it is used to reduce the bacterial load. Despite the fact that "Pasteurised fruit-based preparations produced using high-pressure treatment" were authorised as novel food in 2001, it is acknowledged in the EU that a food subjected to HPP is not considered to be novel unless it can be demonstrated that the process results in significant changes to the composition, metabolism, nutritional value or level of undesirable substances within the food.

Additionally, many different HPP food products can be found on the EU market even though they have not been approved as novel foods. A 2013 report by the Max Rubner Institute commissioned

by the German Federal Ministry of Food, Agriculture and Consumer Protection concluded that HPP-treated meat products are substantially equivalent to meat products produced using conventional technology.

3. Food safety assessment

(1) Describe the food product(s) that will be processed using HPP technology

The food to be treated by HPP is traditional hummus. The specifications for this food include:

- Ingredient list: cooked chickpeas, water, olive oil, sesame paste, lemon juice, garlic, salt, pepper, dried cumin
- The food does not contain or consist of engineered nanomaterials
- GMP and GHP
- Quality control parameters and measures
- Ready-to-eat (RTE) food
- Labelling considerations: Allergens (sesame seeds)
- Storage: refrigerated storage ≤5 °C; not suitable for freezing
- Product shelf life: use-by date of 21 days at ≤5 °C from day of manufacture; after opening, shelf life of 3 days at ≤5 °C.

(2) Outline the rationale for using HPP

HPP has primarily been used to improve the microbiological safety and shelf life of ready-to-eat products as a novel pre- or post-packaging non-thermal decontamination technology (Rubio *et al*., 2018). However, HPP can be used for a wide variety of both food safety and food quality applications as outlined below:

- Pathogen control (instead of or in addition to thermal processing) by elimination or reduction to safe levels of vegetative (non-spore-forming) pathogens
- Spoilage control by reducing the microbial load
- Shelf life extension
- Acceleration of proteolysis during cheese ripening
- Modification of food quality attributes such as texture, taste (lipolysis and proteolysis), colour and structure
- Product yield improvement, such as shucking shellfish and extracting crustacean meat

- Physical form improvement of food products, such as reformed/restructured meats facilitating better binding or cohesion
- Reformulation of foods, e.g. salt reduction
- Reduction of additive use (clean labelling)
- Reduction of food waste, e.g. shelf life extension.

HPP will be used for food safety purposes to produce a traditional, chilled hummus product with an extended shelf life of 21 days. HPP will be a lethality step (i.e. kill step) used as an alternative to more traditional technologies such as thermal pasteurisation for food safety reasons. The product will be HPP-treated post-packaging in order to reduce the risk of post-process contamination and extend product shelf life.

(3) Describe the operating principles of HPP, including the mechanism for inactivation of microorganisms

How microorganisms are inactivated by HPP has not been fully elucidated. However, extensive published scientific literature suggests that a number of cellular targets are negatively affected by HPP (Knorr *et al.*, 2011; Rendueles *et al.*, 2011; Kingsley, 2013; Balasubramaniam *et al.*, 2015; Georget *et al.*, 2015; Van Impe *et al.*, 2018).

Empirical evidence shows that HPP applied within specific temperature, pressure and time combinations can destroy vegetative cells and inactivate certain enzymes, with only minor changes to the sensory properties of the food (Simpson and Gilmour, 1997; IFT, 2000). The destruction of vegetative cells is due to accumulated cell damage, predominantly affecting cell membrane permeability, changes in intracellular pH and protein denaturation (Van Impe *et al.*, 2018). The destruction of vegetative cells by HPP has been shown to extend a product's shelf life and improve food safety (Considine *et al.*, 2008).

In most HPP operations, pressures of 400–800 MPa are applied to food for 2 minutes or more at temperatures below the threshold for microbial inactivation. This can reduce the numbers of most vegetative bacterial cells by 4 $\log_{10}$ units or more. However, the stage of growth can affect the resistance of microorganisms to HPP, with microorganisms typically being more resistant to HPP when they are in the stationary phase of growth compared to the exponential phase (Arroyo *et al.*, 2011; Huang *et al.*, 2014b; Van Impe *et al.*, 2018).

Because of their structure and physiological state, the spores of bacteria (particularly the genera of *Bacillus* and *Clostridium*) and moulds are largely resistant to inactivation by HPP, representing a significant challenge for HPP as a sterilisation technology (Balasubramaniam *et al.*, 2015). The endospores of *Bacillus* and *Clostridium* can tolerate pressures greater than 1000 MPa at 25 °C

(San Martín *et al.*, 2002; Black *et al.*, 2007). Nonetheless, it has been reported that moderate HPP (i.e. <300 MPa) can initiate germination of bacterial spores, and along with high temperatures combined with reciprocal rapid decompression can cause disruption and injury to germinated spores (Wimalaratne and Farid, 2008; Van Impe *et al.*, 2018).

The level of resistance shown by viruses to pressure is wide-ranging and dependant on their structural diversity (Kingsley, 2013). Studies on the effectiveness of HPP in eliminating foodborne parasites show the sensitivity of protozoa and parasites to relatively low pressures of between 100 MPa and 400 MPa (Rendueles *et al.*, 2011).

(4) Identify the key intrinsic/extrinsic factors which can affect the safety of food produced using HPP

Key intrinsic characteristics of the hummus treated by HPP:

- pH: 4.1–4.3
- Water activity: 0.975–0.985
- Salt content: 1.4–1.6%
- Composition: fat 13–17%, protein 33–37%
- Type of microorganisms present and load.

Note: It is very important to understand how the intrinsic characteristics of the final product compare to those of the individual ingredients.

Key extrinsic characteristics of the hummus treated by HPP:

- Product temperature: the product's initial temperature, the product's temperature during HPP (the temperature of the food will increase due to the physical compression and return to its initial value upon decompression; water, carbohydrate, fat and protein content will influence the temperature rise of the food under HPP), and the product's final temperature
- Pressurisation fluid's initial temperature (the temperature of the fluid will increase due to the physical compression and return to its initial value upon decompression)
- HPP conditions: come-up time, target pressure, holding time and decompression time
- Storage atmosphere
- Packaging material.

(5) Outline any potential hazards identified or associated with the use of HPP

The main safety issues to consider when using HPP to preserve traditional hummus include:

- Microbiological hazards associated with the food product itself. It is well known that microbial resistance to HPP depends on different intrinsic and extrinsic factors, including: (i) the product's intrinsic characteristics, (ii) the processing conditions, (iii) the conditions previous to and following the HPP treatment, and (iv) the microorganisms' characteristics, such as species, strain and growth phase. Through hazard analysis, both *Listeria monocytogenes* and *Salmonella* spp. have been identified as significant food safety hazards associated with the hummus product.
- Food contact materials (FCM): any material intended to come into contact with food, that is already in contact with food, or that can reasonably be expected to come into contact with food, is considered to be a FCM. All FCMs can potentially contaminate food by transferring substances to it and so must be made and used in a way to minimise that risk. In the EU, all FCM must comply with Regulation (EC) 1935/2004 and Regulation (EC) 2023/2006. Food businesses using HPP should request documented clarification from their FCM supplier(s) that any packaging or equipment used during HPP is suitable for such use.
- Allergenic hazards: There is no evidence to suggest that HPP can create allergenic proteins through reactivity of food components during processing operations. Some research has shown that the extraction of allergenic proteins by dissociation of the plant cell structure or through enhanced enzymatic hydrolysis may reduce allergenicity or allergenic potential (Johnson *et al.*, 2010; Peñas *et al.*, 2011; Shriver and Yang 2011; Li *et al.*, 2012; Huang *et al.*, 2014a; Huang *et al.*, 2014c; Verhoeckx *et al.*, 2015).

(6) Describe the proposed production process into which HPP will be integrated

An example process flow for HPP-treated traditional hummus is shown in Figure 1.

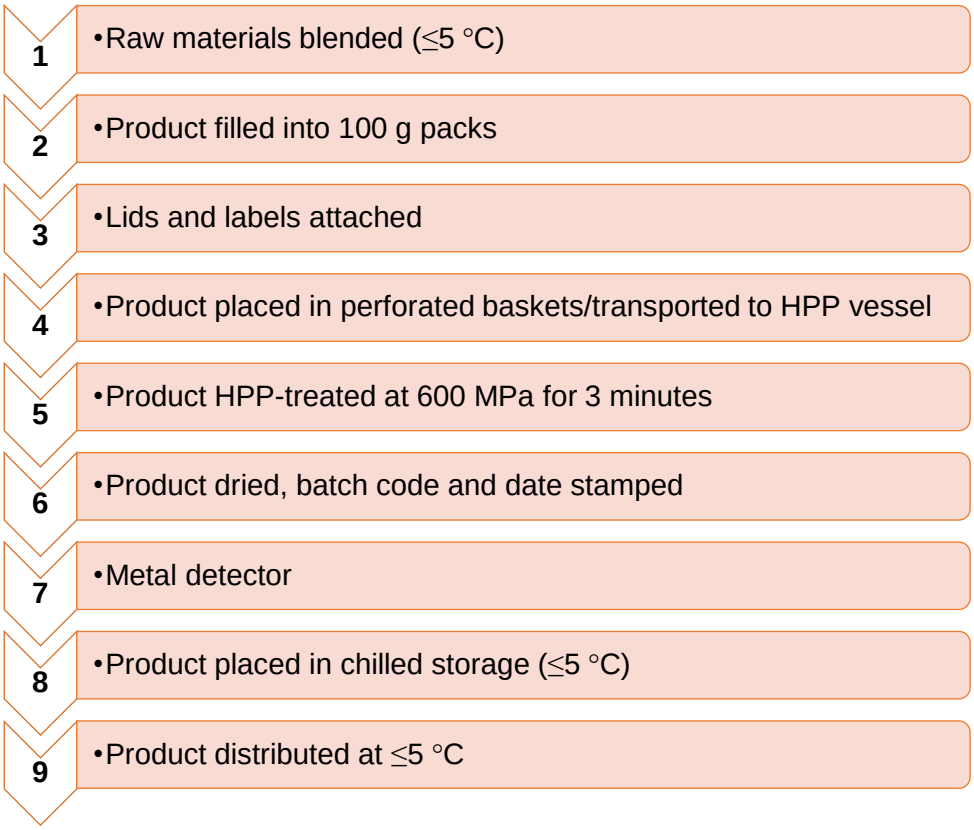

Figure 1 Process flow for HPP-treated traditional hummus

(7) Outline the Food Safety Management System incorporating GMP, GHP and procedures based on hazard analysis and critical control point (HACCP) principles, for the proposed production process using HPP

In the absence of regulatory requirements, the frequency of verification checks should be established by the food business in consultation with the relevant competent authority. Checks of the validated process can include:

- Review of HACCP plan
- Review of records
- Targeted end-product sampling and microbiological testing
- Targeted environmental sampling and microbiological testing
- Calibration of monitoring devices
- Internal audits, inspections and complaints

- Regulatory audits and inspections.

Guidelines for the development of a HACCP plan can be found on the FSAI website.

(8) Outline validation studies illustrating food safety control measures and/or equivalence of HPP to traditional technologies

Where HPP is used for food preservation, the following five steps can be used as a guide for conducting a validation study:

1. Document a detailed specification for the product, including:
   - Ingredient list, specifications for each ingredient and supplier details
   - Processing parameters
   - Good manufacturing practices and good hygiene practices
   - Product-specific procedures based on HACCP principles
   - Quality control parameters and measures
   - Packaging details and specifications for all packaging
   - Labelling considerations including shelf life declaration and list of allergens
   - Storage, distribution and retail display conditions
   - Instructions for use of the product, as applicable
   - Details of microbiological and compositional specifications, including limits
   - Legislative requirements.

   If the food business has completed the development of its HPP food, the product specification can be amended and finalised for normal production.

2. Document detailed procedures based on HACCP principles. If the food business is using an off-site co-packer and/or HPP service provider, the off-site company must have HACCP-based procedures in place that take account of the food business's specific product and comply with all legislative requirements.

3. When developing and implementing a new technology, the process should be designed to inactivate an identified (target) pathogen commonly associated with a particular food.

   Food businesses should understand that all pathogens have specific requirements for their survival and growth in food that depend on the intrinsic and extrinsic characteristics of the food, which in turn are inherently variable. While each intrinsic and extrinsic characteristic may affect pathogenic growth and survival, it is the interaction between these properties that determines whether a pathogen will grow or survive in a food. In addition, pathogens can adapt and increase their resistance to a wide variety of environmental stresses (e.g. cold shock, heat shock, etc.).

4. Establish the validation and acceptance criteria for the process and the product under worst-case scenarios. Define under what conditions (a range for each parameter related to HPP) the success criteria should be validated in order to ensure food safety. If available, predictive modelling and/or published scientific literature can be used by food businesses to establish their validation and acceptance criteria for the process and the food.

   Microbial tolerance or sensitivity to HPP may not equate to tolerance or sensitivity to traditional processes. A suitable $\log_{10}$ reduction of an identified or target pathogen in the food should be established by the food business in order to ensure food safety and/or equivalence when using HPP.

   The FSAI currently recommends a minimum target for thermal processing of food as a 6 $\log_{10}$ reduction (6-*D*) in the number of vegetative cells of the pathogen *L. monocytogenes*. This is because *L. monocytogenes* is currently regarded as the most heat-resistant foodborne pathogen that does not form spores. In other thermally processed foods where risk assessments indicate that the growth and toxin production of *Clostridium botulinum* or other spore-forming bacteria is a particular risk, the FSAI recommends treatment at 90 °C for 10 minutes to achieve a 6-*D* reduction in the number of psychrotrophic (non-proteolytic) *C. botulinum* Type B. However, as indicated above, the pathogen of concern must be identified for each preservation process, because a high tolerance to heat may not equate to a high tolerance to other preservation strategies. Knowledge of the mode of action of the technology, the food formulation and the history of the food (e.g. association with outbreaks or cases of illness) is paramount for determining the pathogens that will define the process.

5. A significant amount of scientific literature relating to the validation of HPP for foods has been published. However, in the absence of relevant published research, food businesses may need to carry out a challenge study to demonstrate the efficacy of the new technology in producing safe food. The FSAI recommends that food businesses should consult with the relevant competent authority before beginning or contracting a challenge study.

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Example 2

Technology: Pulsed electric fields (PEF)

Food product: Orange juice

1. Overview

Pulsed electric fields (PEF) is a non-thermal food processing technology that applies short pulses (e.g. 1–50 µs) of very high DC voltages (≤100,000 V) at frequencies up to 1000 Hz to a food. The food is placed between two electrodes and subjected to PEF for a short period of time, often less than one second. The application of these high-intensity electric pulses causes the electro-permeabilisation or electroporation (transient or permanent) of the membranes of microbial, plant and animal cells.

The capacity of PEF to inactivate microorganisms at temperatures that do not negatively impact on the flavour, colour or nutritional value of foods is sometimes used to promote PEF as an alternative to thermal processing. In addition, PEF can be exploited for accelerating and enhancing mass and heat transfer phenomena such as for the extraction of valuable cell components, curing and drying.

Commercial manufacturers of PEF equipment

Globally, there are a number of suppliers of industrial-scale PEF processing systems that can process fluids and solid foods (Golberg *et al.*, 2016; Blahovec *et al.*, 2017). These devices have also been used in laboratories for testing the electroporation effects of PEF on cell membranes.

Established commercial use of PEF

Applications of PEF to food generally involves the ‘cold’ pasteurisation of liquids such as juices and smoothies.

In 1996, the U.S. Food and Drug Administration issued a ‘letter of no objection’ for the use of a PEF processing systems in the treatment of liquids and pumpable foods such as milk, liquid eggs, fruit juices and emulsions (Dunn, 1996; Barbosa-Cánovas *et al.*, 2007; Blahovec *et al.*, 2017).

In 2006, the FDA approved the first commercial PEF installation for fruit juice preservation (Clark, 2006). The first commercial PEF operation in Europe involved the installation of a 1,500 L/h orange juice preservation line in 2009. PEF treatment was performed at an initial temperature of 40 °C, with a field strength of 20 kV/cm and an energy input of approximately 120 kJ/kg. This resulted in a final temperature of less than 60 °C (using intermediate cooling) and a 5 $\log_{10}$ reduction of the total bacteria count in the orange juice (Toepfl, 2011).

Apart from the cold pasteurisation of liquid foods, PEF can also accelerate heat transfer and assist processes such as softening, drying, osmotic dehydration, freeze-drying, freezing and thawing. PEF can also be used to enhance the mass transfer efficiency of water, solutes, juices or high-value compounds from matrices of biological origin, such as plant tissues, microbial and algal cells, food waste, and by-products generated during food processing (Raso *et al.*, 2016).

There are numerous examples of the industrial use of PEF in the production of potato-based foods (McHugh and Toepfl, 2016). For example, during the production of French fries, PEF can replace thermal blanching (usually done in water tanks at 60 °C for 30 min) with a very short (<1 s) treatment (e.g. 40 pulses of 1.8 kV/cm). This can reduce potato starch loss by avoiding immersion-softening, reduce oil uptake upon frying, reduce structural damage to the fries and result in a crispier end product. In terms of production efficiency, it can free up limited floor space and extend the lifetime of cutting blades.

2. Novel food status

The novel food status of food subjected to PEF has not been addressed at EU level so far.

3. Food safety assessment

(1) Describe the food product(s) that will be processed using PEF technology

The food to be treated by PEF is orange juice. The specifications for this food include:

- Ingredient list: freshly squeezed orange juice (100%)
- The food does not contain or consist of engineered nanomaterials as referred to in points (a)(viii) and (ix) of Article 3(2) of Regulation (EU) 2015/2283.
- GMP and GHP
- Quality control parameters and measures
- Labelling considerations: no specific labelling considerations for compliance with Regulation (EU) No 1169/2011. Shelf life declaration is included on the bottle neck (best-before date). None of the 14 EU-regulated food allergens present.
- Intended use: Fruit drink
- Storage, distribution and retail display conditions: the juice should always be kept chilled between 0 °C and 5 °C.

- Instructions for use: the instructions should read: Keep this juice chilled between 0–5 °C before and after opening. Shake well before opening and pouring. Once opened, drink within 4 days. For best before date see the bottle neck.
- Relevant legislative requirements or considerations: the PEF-treated product may fall under the scope of Regulation (EU) 2015/2283 on novel food.

(2) Outline the rationale for using PEF

The main reasons for PEF to be used for cold pasteurisation and shelf life extension of the orange juice are:

- Retention of fresh taste and colour due to the low-temperature nature of the process
- Enhanced extraction of vitamins, colour and antioxidants from the fruit due to the plant cell electroporation
- Increased yield of juice due to the plant cell electroporation
- Increased shelf life due to microbial inactivation, which allows for an extended market reach.

In this case, PEF is to be used as an alternative to traditional thermal pasteurisation. A number of comparative studies have been published that show the relative equivalence of fruit juices resulting from PEF and conventional thermal pasteurisation (Cserhalmi *et al.*, 2006; Schilling *et al.*, 2008; Timmermans *et al.*, 2011; Vervoort *et al.*, 2011).

(3) Describe the operating principles of PEF, including the mechanism for inactivation of microorganisms

The PEF process involves high-voltage, short duration (microseconds-milliseconds) pulses to generate an electric field between two electrodes in the PEF chamber where the food product is located (in either a static or continuous design). The external electric field is directly proportional to the voltage applied across the electrodes and inversely proportional to the distance or gap between them.

The electric field is responsible for cell membrane electroporation, leading to an increased permeability of the membrane to ions and small molecules. Plant, animal and microbial cells are susceptible to electroporation as long as the electric field applied surpasses a threshold value, called the transmembrane potential, which is characteristic to each cell type.

Depending on the processing parameters applied and the cell characteristics, the membrane can either become transiently or permanently permeable, making electroporation either reversible or

irreversible. In reversible electroporation, the pores created can reseal after the PEF treatment is completed, while in irreversible electroporation, the pores remain permanently and can eventually lead to cell death. The key parameters in PEF processing of liquid products for cold pasteurisation and shelf life extension (e.g. orange juice) in a continuous flow are as follows:

- Electric field strength: voltage and distance (gap) between electrodes
- Treatment time: number of pulses and pulse width (or duration)
- Pulse characteristics: amplitude (voltage and current), number, width, polarity, shape and repetition rate (or frequency)
- Specific energy input per pulse
- Inlet and outlet temperature
- Flow rate
- Residence time
- Food product characteristics: composition, electrical conductivity, pH, particle size (chunks, pulp), microbial load and types of microorganisms
- PEF equipment design: treatment chamber design (configuration, flow dynamics, electrode dimensions, shape, gap, material) and number of chambers.

Some of the key advantages of PEF processing are that it is a non-thermal treatment that does not seem to affect product quality and provides the possibility of a continuous flow at both pilot and industrial scales. Even though an electric current travels across part of the product with a subsequent increase in its temperature, the thermal effects of PEF are considered negligible. Some technical limitations of the PEF technology have been noted:

- The presence of bubbles may lead to non-uniform treatment as well as operational problems including electrical issues (sparks, electrical arcs or flashovers).
- Electrode fouling can occur with a distortion of the local electric field, process flow and increased probability of electrical breakdown.
- Inactivation of microbial spores is not achieved.
- For applications requiring high electric field strengths, electrode corrosion (short electrode lifespan) can occur, with the consequent release of metallic ions (e.g. iron, chromium, nickel and manganese) into the food leading to a distortion of the local electric field. This can result in a significant deterioration in flavour, a metallic mouth perception from the product and possible noncompliance with regulatory limits for metals. Other undesirable electrochemical reactions at the electrode-liquid food interface of the PEF chamber can result in the production of gas (hydrogen and oxygen), toxic chemicals (e.g. hydrogen peroxide, hydrogen chloride), electrolysis of water and changes to the chemical properties (pH, electrical conductivity) of the processed fluid.

- Non-uniform distribution of the electric field can occur in particular treatment chamber configurations, or due to electrode fouling or corrosion.

(4) Identify the key intrinsic/extrinsic factors which can affect the safety of food produced using PEF

For PEF-treated orange juice, key intrinsic characteristics are:

- pH: 3.5–3.7
- Water activity: 0.99
- Conductivity: 3.7–3.9 mS/cm
- Turbidity: 4500–4600 NTU
- Particle size: up to 1 mm in diameter (the juice was strained through a 1 mm mesh)
- Viscosity: 5.0–5.5 cps
- °Brix: 11.5-12.5
- Composition (per 100 mL): fat (0 g), carbohydrates (8 g), protein (0.7 g), salt (0 g), vitamin C (22 mg)
- Type of microorganisms present and load.

The extrinsic characteristics are:

- Temperature: inlet and outlet temperature of the PEF treatment and during storage
- PEF processing conditions: Primarily, the total specific energy input (J/mL). Other factors include electric field strength, pulse polarity, pulse duration, number of pulses, pulse shape, pulse repetition frequency, product flow characteristics and residence time.
- Storage atmosphere
- Packaging material.

(5) Outline any potential hazards identified or associated with the use of PEF

The main safety issues to consider if PEF is used for cold pasteurisation and shelf life extension of liquid products (e.g. orange juice) include:

- Microbiological hazards: Microbial resistance to PEF depends on different intrinsic and extrinsic factors, including: (i) the product's characteristics, (ii) the processing conditions, (iii) the conditions prior to and following the PEF treatment, and (iv) the microorganisms' characteristics, such as species, strain and growth phase. For fruit juices, *Escherichia coli* and *Salmonella* spp. have been identified as pathogens of concern.

- Chemical hazards: Undesirable electrochemical reactions at the electrode-liquid food interface of the PEF chamber can occur. Applications requiring high PEF treatment intensities can lead to electrode corrosion by oxidation of the electrode metal, which could trigger the release of metallic ions (e.g. iron, chromium, nickel and manganese) into the food. Electrochemical reactions are unavoidable but can be managed using electrode materials (e.g. titanium, platinised titanium or conductive polymers) with a higher resistance to electrochemical reactions, modifications in the pulse polarity (use of bipolar pulses) and pulse repetition rate (frequency), and limitations in the physico-chemical properties of the food to be treated.
- Allergenic hazards: A limited number of studies have investigated possible structural changes in selected food allergens associated with PEF processing. PEF was not found to induce significant changes in the structure of peanut allergens Ara h 2 and Ara h 6, as well as apple proteins Mal d 3 and Mal d 1b (Johnson *et al.*, 2010). However, PEF processing has been shown to have the potential to decrease the allergenicity of egg ovalbumin (Yang *et al.*, 2017) by altering its conformation, which decreases its immunogenic properties (as estimated by the IgG and IgE binding abilities).

(6) Describe the proposed production process into which PEF will be integrated

An example process flow for PEF-treated orange juice is shown in Figure 2:

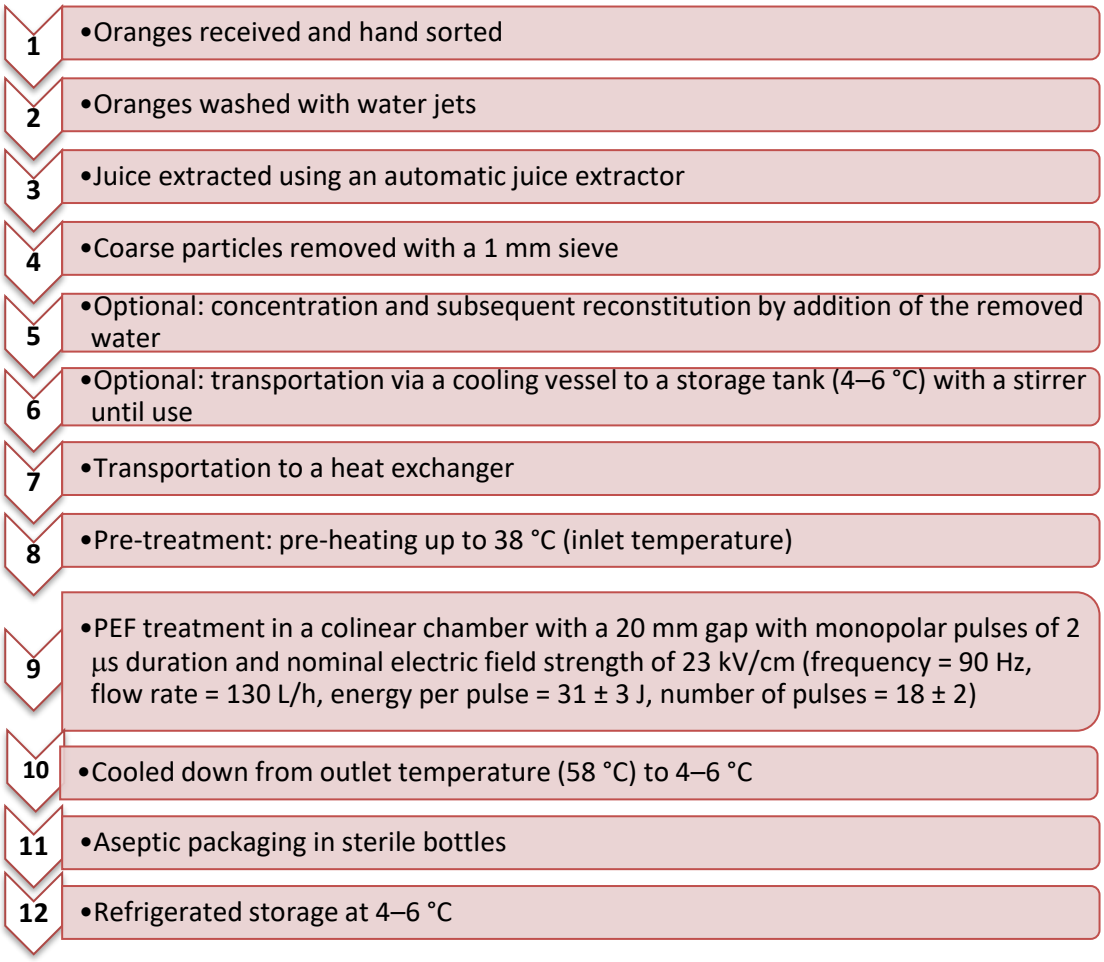

Figure 2 Process flow for PEF-treated orange juice

(7) Outline the Food Safety Management System incorporating GMP, GHP and procedures based on hazard analysis and critical control point (HACCP) principles, for the proposed production process using PEF

In the absence of regulatory requirements, verification checks and their frequency should be established by the food business in consultation with the relevant competent authority. Verification checks of the validated process can include:

- Review of HACCP principles
- Review of records
- Targeted end-product sampling and microbiological testing

- Targeted environmental sampling and microbiological testing
- Calibration of monitoring devices
- Internal audits and inspections and review of complaints
- Regulatory audits and inspections.

Guidelines for the development of a HACCP Plan can be found on the FSAI website.

(8) Outline validation studies illustrating food safety control measures and/or equivalence of PEF to traditional technologies

Where PEF is used for food preservation, the following five steps can be used as a guide for a validation study:

1. Document a detailed specification for the product to include:
   - Ingredient list, specifications for each ingredient and supplier details
   - Processing parameters
   - Good manufacturing practices and good hygiene practices
   - Product-specific procedures based on HACCP principles
   - Quality control parameters and measures
   - Packaging details and specifications for all packaging
   - Labelling considerations such as shelf life declaration and allergens
   - Storage, distribution and retail display conditions
   - Instructions for use of the product, as applicable
   - Details of microbiological and compositional specifications, including limits
   - Legislative requirements.

   If the food business has completed the development of its PEF-treated food, the product specification can be amended and finalised for normal production.
2. Document a detailed HACCP plan. If the food business is using an off-site co-packer and/or PEF service provider, the off-site company must have a working HACCP plan in place that takes account of the specific product and complies with all legislative requirements.
3. When developing and implementing the use of a new technology, the process should be designed to inactivate an identified pathogen commonly associated with a particular food. Food businesses should understand that all pathogens have specific requirements for survival and growth in food. The survival and growth of pathogens will depend on the intrinsic and extrinsic characteristics of the food. It is important to note that the intrinsic and extrinsic characteristics of foods are inherently variable. Furthermore, while each intrinsic and extrinsic

characteristic may affect pathogenic growth and survival, it is their interaction which determines whether a pathogen will grow or survive in a food. In addition, pathogens can adapt and increase their resistance to a wide variety of environmental stresses (e.g. cold shock, heat shock, etc.)

4. Establish the validation and acceptance criteria for the process and the product under worst-case scenarios. If available, predictive modelling and/or published scientific literature can be used by food businesses to establish their validation and acceptance criteria for the process and the food.

   Microbial tolerance or sensitivity to PEF may not equate to tolerance or sensitivity to traditional processes such as thermal processing. A suitable $\log_{10}$ reduction of an identified target pathogen in the food should be established by the food business in order to ensure food safety and/or equivalence when using PEF.

   The FSAI currently recommends a minimum target for thermal processing of food as a 6 $\log_{10}$ reduction (6-*D*) in the number of vegetative cells of the pathogen *Listeria monocytogenes*, which is regarded as the most heat-resistant foodborne pathogen that does not form spores. In other thermally processed foods where risk assessment indicates that the growth and toxin production of *Clostridium botulinum* or other spore-forming bacteria is a particular risk, the FSAI has recommended treatment at 90 °C for 10 minutes to achieve a 6-*D* reduction in the number of psychrotrophic (non-proteolytic) *C. botulinum* Type B. However, as indicated above, the pathogen of concern must be identified for each preservation process, as a high tolerance to heat may not equate to a high tolerance to other preservation strategies. Knowledge of the mode of action of the technology, the food formulation and the history of the food (e.g. association with outbreaks or cases of illness) is important for determining the pathogens that can be used to define the process.

5. In the absence of documented relevant scientific research, the food business may need to carry out a challenge study to demonstrate the efficacy of the process and safety of the food following processing using the new technology. The FSAI recommends that the food business should consult with the relevant competent authority before beginning a challenge study.

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Appendix 2 Request for advice from the Scientific Committee

Topic Title: Appraisal of new technologies for food preservation and their potential risks to food safety

Date Requested: 30 September 2016

Date Accepted: 8 March 2017

Target Deadline for Advice: 12 months from date of acceptance

Form of Advice Required: Written advice

Background/Context

Historically food processing has used four basic concepts for food preservation:

- Input thermal energy to increase food temperature e.g. pasteurisation, sterilisation, etc
- Remove thermal energy to decrease food temperature e.g. cooling, freezing, etc.
- Remove water from the food e.g. drying, osmotic dehydration, freeze drying, etc.
- Packaging to maintain anti-spoilage food properties achieved during production or processing.

In the last number of years many novel food processing technologies such as high-pressure processing, pulsed electric field, radio frequency heating, ohmic heating, high intensity pulsed light and cold plasma have emerged. Many of these technologies are still at the research phase and so not in commercial use. However, others particularly high-pressure processing, are in commercial use by the food industry for the preservation or extension of shelf life of food and drink products. However, little is known about potential unintended effects on food or packaging quality or safety, efficacy in terms of preservation, determining equivalence to traditional food processing technologies or the regulatory status of these technologies. A 2015 fact finding mission to Ireland on high-pressure processing by the European Commission's DG Health and Food Safety highlighted some of these issues.

Questions for the Scientific Committee

1. What science should be considered to allow the continued development and implementation of new technologies in food production?
2. What are the risks regarding the use of these new technologies? (e.g. microbiological, toxicological, product and packaging interactions, process capability and product stability and chemistry)

3. What information would be required to establish equivalence to traditional food processing technologies to ensure food safety, particularly if new food processing technologies are to be used as a replacement for thermal pasteurisation?

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