"High pressure law"

The legislation on high pressure processing and other factors that may have an impact on HPP application in the EU food industry

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Summary

Many different high-pressured food products have been launched to the market since 1990. Initially, the high-pressured foods have been introduced in Asia (Japan) and later on in Europe (France) and North America (the USA).

Currently, the highest number of high pressure installations is used in North America. Two times less HP installations are in Europe than in North America, but at the same time in Europe there are much more scientific publications relating to high pressure processing (HPP).

Many factors have an impact on the application of HPP in Europe. They include the characteristics of the food sector in the EU, the innovativeness of companies, the high investment costs, the profitability of the novel foods, consumer attitudes towards HPP and EU legislation on HPP which is perceived as a "grey area".

In Europe, HPP was classified as a novel technology since it was not used to a significant degree in the European food industry before 15 May 1997. High pressured foods may be recognised as the novel foods and consequently may fall under the Novel Foods Regulation, when a significant change occurs in these food products. In 2000, high-pressured fruit based preparations were approved under the NFR by the European Commission. Currently, many different high-pressured food products are available on the EU market although they have not been approved under the NFR.

The competent authorities of the member states agreed in July 2001 that the national authorities should decide on the legal status of high-pressured food products. The European Commission has concluded that HPP was no longer considered to be a novel process. However, some member states were concerned that the HP foods should still be assessed for their safety and argued that data required for an assessment should be determined on a case-by-case basis.
The approach concerning HP foods in the European Union may differ significantly between the member states and it may have an impact on the HPP application.

There may be room for different interpretations of the NFR since the definitions from the regulation – "significant degree" and "significant change" seem to be vague and unclear.
In 2008, the European Commission published a Proposal for a New Novel Foods Regulation. However, according to the majority of experts the Proposal will not change the situation of HPP application in the EU.

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List of Abbreviations

ACMSF	-	Advisory Committee on the Microbial Safety of Food (UK)
ACNFP	-	Advisory Committee for Novel Foods and Processes (UK)
AESA	-	Agencia Española de Seguridad Alimentaria (Spain)
AFSSA	-	Agence Française de Sécurité Sanitaire des Aliments (France)
ALARA	-	As Low As Reasonably Achievable
ATP	-	Adenosine-5'-triphosphate
BSE	-	Bovine Spongiform Encephalopathy
CJD	-	Creutzfeldt–Jakob Disease
DNA	-	Deoxyribonucleic acid
EFSA	-	European Food Safety Authority
EU	-	European Union
FSA	-	Food Standards Agency (UK)
GFL	-	General Food Law
GM	-	Genetically Modified
HACCP	-	Hazard Analysis and Critical Control Point
HHP	-	High Hydrostatic Pressure
HPLT	-	High Pressure with Low Temperatures
HPP	-	High Pressure Processing
MRLs	-	Maximal Residue Levels
MSEs	-	Medium and Small Enterprises
NF	-	Novel Foods
NFR	-	Novel Foods Regulation
NNFR	-	New Novel Foods Regulation
OMF	-	Oscillating Magnetic Fields
PED	-	the Pressure Equipment Directive
PEF	-	Pulse Electric Field
PME	-	pectinmethylesterase (enzyme)
PPO	-	polyphenol oxidase (enzyme)
RNA	-	Ribonucleic acid
SMF	-	Static Magnetic Fields
UHP	-	Ultra High Pressure
US	-	the United States

Introduction

1. Research background and problem statement

Betz [2003] has explained that a technological innovation is "(…) *both the invention of a new technology and its introduction into the market place as a new high-tech product, process, or service.*" This definition emphasised not only the technical side of the innovation, but also the side connected with marketing. The technical feasibility of the novel technology does not often go with the issues like the price of products and customer attitudes towards the novel technology.[1]

Novel non-thermal methods include high pressure processing, high electric field pulses, ohmic heating, light pulses, oscillating magnetic field or ultrasound. Some of these technologies have already been used in the food industry, while others are still being researched.[2]

Currently, there is a great potential for novel technologies in the food industry since these technologies are able to maintain high quality of food products as well as guarantee food safety.
Food quality is mainly important from the consumer perspective whereas food safety is the basic requirement of food law in the European Union. According to EU law, food products must not be injurious to health or unfit for human consumption.[3]
An important piece of legislation concerning indirectly the novel technologies is Regulation (EC) No 258/97 relating to novel foods (the Novel Foods Regulation (NFR)). This regulation requires the safety assessment for novel foods produced by the novel processes.[4]

High pressure processing (HPP) is a novel process that has been commercialised worldwide. Currently, more than hundred high pressure installations are used. The highest number of the installations is applied in North America. In Europe, there are two times fewer installations than in North America but at the same time, as mentioned by an expert, there is the highest number of scientific research concerning an application of HPP in food industry.[5&6] Therefore, it seems that scientific knowledge may not be applied in Europe as efficiently as in North America. Many factors may have an impact on this situation including food law in the European Union.

Except Regulation No 258/97 (the Novel Foods Regulation), scientific literatures as well as experts have mentioned the following pieces of legislation: Regulation No 178/2002 (the General Food Law), rules on microbiological food safety (Regulation (EC) No 2073/2005) and the legislation on the high pressure equipment (the Pressure Equipment Directive (97/23/EC)) as relevant for the high-pressured foods.[7]

[1] Betz, 2003: 22
[2] Butz & Tauscher, 2002: 279
[3] Regulation (EC) No 178/2002, Article 14
[4] Regulation (EC) No 258/97
[5] NC Hyperbaric, 2010
[6] Information provided by an expert during phone interview
[7] Hugas et al., 2002: 367; Garriga et al., 2004: 452; Norton & Sun, 2008: 28; Heinz & Buckow, 2009: 7

Only one food product – *HP pasteurised fruit-based preparations* has been authorised under the NFR. However, there are many other high-pressured food products on the EU market.[8] The situation concerning the NFR has been perceived by the experts as vague. The uncertainties relating to this legislation may increase the risk of a marketing failure when a new product is planned to be launched or a novel technology is concerned to be applied in the food industry.[9]

2. Research objectives

The aim of this thesis research is to identify the relevant EU legislation on HPP and its impact on HPP application in the food industry. Additionally, other factors that are not related to the EU legislation but which may have an impact on HPP application in the EU food industry will be identified and studied in this paper.

3. Research questions

The thesis research will provide answers for the following research questions:

I. Which **EU legislation** should be considered in the case of HPP?

II. What is **the impact of this EU legislation** on the application of HPP in the food industry?

III. What are **other factors** that may have an impact on the application of HPP in the EU food industry?

4. Methodology

The methodology used in this thesis is the exploratory research, proposed by Churchill [1999]. It has been adapted from the marketing studies.[10] The aim of this methodology is to obtain information on the EU legislation on HPP from different sources and perspectives.
This research consists of a literature research and an experience survey. The experience survey includes informal phone interviews with experts and business stakeholders, as well as a questionnaire concerning HPP and European food law.

5. Thesis Outline

This thesis report consists of 12 chapters. The first four chapters introduce information on the novel technologies, particularly on high pressure processing (HPP) to acquaint readers with the thesis subject. The author is of the opinion that to understand the EU legislation on HPP, basic scientific knowledge is necessary. Therefore, chapter 1 describes the development of the research on novel technologies, as well as provides basic information on some novel technologies which are applied or may be applied in the near future in the food industry and thus may follow the same legislation as HPP.
The next chapter provides details on HPP and its impact on the food quality. Chapter 3 presents the safety aspects of HPP and chapter 4 explains consumers' attitudes towards HPP

[8] Commission Decision (2001/424/EC)
[9] Brookes, 2007: 28-29
[10] Churchill, 1999: 101-106

in the EU as well as commercialisation of HPP. Chapter 5 provides some basic information on HP food which is available on the market, and introduces the so-called "Danone case".
The EU legislation on HPP is described in chapters 6, 7 and 8. Chapter 6 provides an overview of EU legislation relating to HP foods, which was identified as important during desk research and interviews with the experts. Chapters 7 and 8 describe the Novel Foods Regulation and the Proposal for a New Novel Foods Regulation.
The detailed information on HPP as well as European food law is presented in this thesis report in order to emphasize the complexity and different dimensions of HPP situation in the EU food industry.
Chapter 9 provides information on a methodology applied in this study – the so-called *exploratory research* which consists of literature research and experience survey, namely informal phone interviews and questionnaires with experts and business stakeholders. The data obtained in empirical research are described and analysed in chapter 10. The discussion part is presented in chapter 11. The final chapter 12 presents the conclusions and recommendations proposed by the author.

1. Novel Food Technologies

This chapter explains stages of the research on novel technologies, and provides short descriptions of the novel technologies that may be commercialised in the future. The novel technologies are mentioned since their introduction in the food industry may follow the same "legislation path" as high pressure processing, which is the main interest of this thesis research.

The ideal processing method is described as: *"(…) able to inactivate spoilage and pathogenic microorganisms, not degrading organoleptic and nutritional values of products, not leaving residues, cheap and convenient to apply and acceptable to consumers and regulatory agencies."*[11]
Nowadays, food production is generally speaking consumer driven. This means that food producers with their products try to meet consumers' demands. The most important demands according to consumers are "fresh-like" characteristics, improved nutritional value and food safety.[12]
In order to be up to these demands, increase in technological developments as well as implementation of modern food technologies are taking place. As stated by Butz & Tauscher [2002], these novel technologies *"(…) usually focus on preservation while keeping food quality attributes*." It is often seen as *"(…) minimal processing"* but it should be understood *"(…) as little as possible, but as much as necessary*."[12]

After the BSE crisis and other food scares in the EU, it became evident that there were some defects in European food law as it stood at that time. The shift in European food law orientation took place from a market focus to a safety and market focus.[13]
Not only were the EU authorities more interested in the food safety but also other organisations, like the Safe Consortium, which is the international association of scientific institutes and universities working together in the area of food safety and related sciences. This organisation works on all spectrums of issues connected with food safety, including the novel food preservation technologies. These technologies were discussed during a Seminar in 2004.[14] Three major trends in research relating to novel technologies were identified.

The first trend focuses on the effect of the new technologies on microorganisms. Crucial aspects of this issue include the mechanism of inactivation, the amount of inactivation, sublethal inactivation, stress response but also differentiation between strains and subpopulations.[14]
The second trend is associated with applying a combination of technologies, for instance a combination of novel technology with another novel technology or with already existing technologies.[14]

[11] Wilson et al., 2008: 289
[12] Butz & Tauscher, 2002: 279
[13] van der Meulen & van der Velde, 2008: 229
[14] The Safe Consortium, 2004: 9

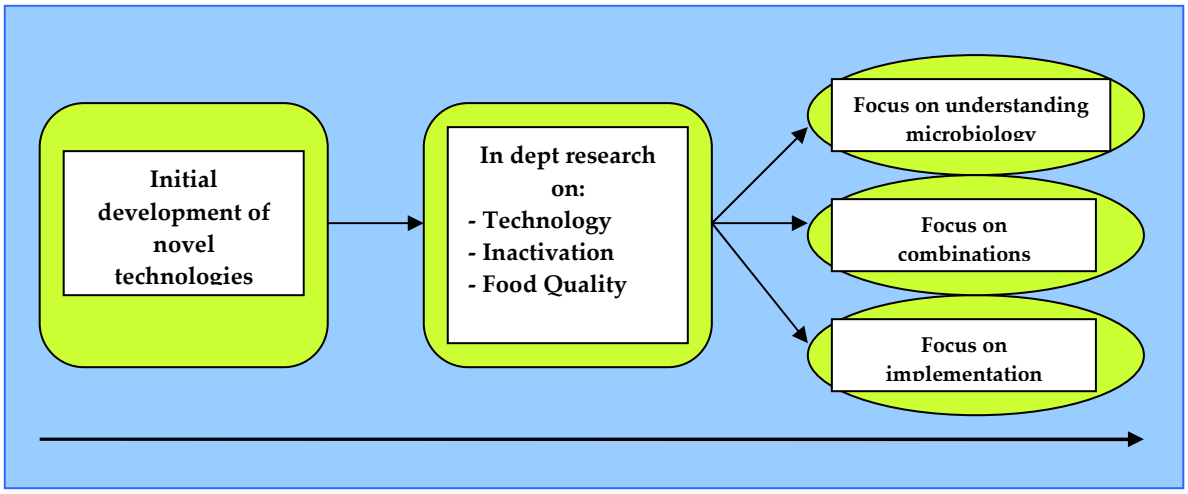

Figure 1. Development of the research on novel technologies. **Source:** The Safe Consortium, 2004

The third trend describes the importance of implementation of these technologies. Hence, besides food safety aspects, like microbiology and toxicology, other issues, for instance the processing conditions of novel technology and hygienic aspects are also significant [Figure 1].[14]

In summary, if a novel technology is developed, it is crucial to ensure that the process performs properly and that the goals of the process are achieved. Therefore, a whole set of factors has to be taken into consideration by the food producers as well as by the equipment producers and the authorities.[14]

In the "Review of Novel Processing Techniques" prepared by the Advisory Committee for Novel Foods and Processes (ACNFP), which is a non-statutory, independent body of scientific experts that advises the Food Standards Agency in the UK on any matters relating to novel foods and novel processes, "possible" novel processes were mentioned. These processes include high pressure processing (HPP), ohmic heating, high electric field pulses, light pulse, oscillating magnetic fields (OMF) and ultrasound. The review stated that "*Foods and food ingredients that have been subjected to novel processes fall within the scope of the novel foods regulation (EC No 258/97) if the process was not used before May 1997 and it results in significant changes (compared with similar products from existing processes).*"[15]

It is important to mention that some of these processes are still not applied on an industrial scale but are in a stage of research. Ohmic heating, high electric field pulses, light pulse, oscillating magnetic fields and ultrasound are briefly described below, while high pressure processing is characterized in the next chapters.

1.1. Ohmic Heating

Ohmic heating is a thermal method that characterizes with minimized thermal damages to food. This method utilises the conductive electric resistance heating. It means that an electric current is passing through food which is a conductive medium and as a result the food

[15] ACNFP, 2006: 1-2

warms up because of the movement of ions. In processing plant, the food product is continuously pumped through special equipment - a column with several electrodes.[16]
Microbial inactivation is mainly possible because of thermal effects.[17]

The strong point of ohmic heating is that the heating is performed rapidly and uniformly. However, a weak point of the technology is a limitation in its applicability only to foods which possess the appropriate conductivity. The ohmic technology is used in pasteurisation and sterilisation of ready-to-serve meals, fruits, vegetables, meat, poultry or fish.[18]

1.2. High Electric Field Pulses

High electric field pulses or pulsed electric field (PEF) was first seen as possible method for food (milk) preservation at the end of 1920s in the US. Many studies have been done to apply PEF on a broader scale in the food industry until now.[18]

The technology utilises short pulses of high voltage (usually in a range of 20-80 kV/cm) to a food placed between two electrodes. The duration of the pulses is less than 1s (2-20μs), and during these pulses only a minimal heat is generated. For this reason the process is regarded as non-thermal. Furthermore, the sufficient interval between pulses minimizes the increase of temperature.
A few forms of PEF can be distinguished: bipolar, square wave, exponentially decaying or oscillatory pulses. The process can be applied at ambient, sub-ambient or a little above the ambient temperature.[18&19]

The factors that influence microbial inactivation in the case of PEF include the pulse duration, shape and number of pulses, an increase of PEF strength, temperature and ionic strength of the medium, as well as type, maturity and concentration of the bacteria. Increasing the pulse duration can be associated with the elevated temperature of the treatment system. Therefore, the increase in the temperature should not exceed the acceptable range.[20&21]

Many theories try to explain the inactivation of microorganisms in liquid media by PEF. The most studied scenarios are electrical breakdown and electroporation.[22] Due to high-voltage electric pulses, a trans-membrane potential is generated across the cell membrane for instance of bacterium, which overlays the natural membrane potential. When a difference between the potential of outer and inner membrane exceeds a critical value of about 1V, the polarisation and then breakdown of the membrane are triggered. As stated by Butz & Tauscher [2002]: *"At sufficient high field-strength (above 10 kV/cm) and duration of the pulses (usually between nano- and microseconds) vegetative micro-organisms in liquid media are inactivated due to irreversible membrane destruction."*[21]

[16] Butz & Tauscher, 2002: 279
[17] Cho et al., 1996: 334-340
[18] Butz & Tauscher, 2002: 281
[19] Barbosa-Cánovas et al., 1998: 73-74, 84
[20] Qin et al., 1996: 603-627
[21] Butz & Tauscher, 2002: 281
[22] Barbosa-Cánovas et al., 1998: 133

The spores of bacteria are not sensitive to PEF treatment. However, they lose their resistance after germination induced by other methods. Therefore, the combination of PEF with other methods can results in inactivation of spores.[23&24]

The application of PEF is limited to foods without bubbles and with low electrical conductivity. The additional restriction is the size of particles in liquid food. High electric field pulses can be used in the pasteurisation process of liquid foods, for instance juices, milk or liquid whole eggs.[21]
Butz & Tauscher [2002] noticed that: "*Conclusive data on the absence of potential health risks or on the impact of the process on food components are hardly available yet.*" Therefore, there is a need of further research on PEF application in the food industry.[21]

1.3. Light Pulses

Pulsed light is a non-thermal method of food preservation that involves the use of intense and short-duration pulses of broad-spectrum "white light" (ultraviolet to the near infrared region).[24]

High intensity, short duration light in a range of 1 to 20 pulses are usually applied to food surfaces and packaging material. Such factors as the number of lamps, flashing configuration, and pulse rate, depend on the type of the product and degree of treatment required.[25]

This technology is applicable mainly in sterilizing or reducing the microbial population on the surfaces of packaging materials, on packaging, processing equipment and foods. Light Pulses can reduce the microorganisms and extend the shelf-life of such foods, like cakes, bread, sea food, meat, vegetables or fruits.[26]

Furthermore, there is a need of more research concerning the inactivation kinetics in a wider spectrum of food matrixes and surfaces, as well as the impact of light pulses on the food properties.[26]

1.4. Oscillating Magnetic Fields

Oscillating magnetic fields (OMF) or strong static magnetic fields (SMF) in a range of 5-50 Tesla is seen as non-thermal method that can have the potential to inactivate microorganisms. The impulse duration is between 10 μs and several milliseconds, and the frequencies are maximally 500 MHz.[27] The magnetic field is the region in which magnetic body is capable to magnetize the particles around. OMF is applicable to the food products with high electrical resistivity (greater than 10 to 25 ohms-cm).[22]
Generally, the preservation of foods with OMF *"(…) involves sealing the food in plastic bag, subjecting it to 1 to 100 pulses with a frequency between 5 and 500 kHz at a temperature of 0° to*

[23] Knorr et al., 1994: 71-75
[24] Grahl & Maerkl, 1996: 148-157
[25] Barbosa-Cánovas et al., 1998: 139
[26] Barbosa-Cánovas et al., 1998: 148-159
[27] Butz & Tauscher, 2002: 281 -282

50°C for a total exposure time ranging from 25 μs to 10 ms. Frequencies above 500 kHz are less effective for microbial inactivation and tend to heat the food material."[28]

The identified advantages of OMF are a minimal thermal denaturation, reduced energy requirements for adequate processing, and the possibility to treat foods in packaging what prevents the cross-contamination after the process.[28]

Further research concerning OMF is needed to elaborate such issues, like the effects of OMF on the food quality, the mechanism of microbial inactivation, as well as the efficacy of the method.[28]

1.5. Ultrasound

Ultrasound is a method that applies sound waves with frequencies above that of human hearing (above 16 kHz). The waves can be propagated in a liquid media as alternating compression. When ultrasound possesses sufficient energy, a phenomenon known as cavitation takes place. Cavitation involves the formation, growth, and rapid collapse of microscopic bubbles that results in production of extremely high temperatures and pressures.[29]

The mechanism of microbial inactivation is associated with *"(…) intracellular cavitation, that is, micro-mechanical shocks that disrupt cellular structural and functional components up to the cell lysis."* However, the separate use of ultrasound technology does not guarantee the satisfactory level of microorganism reduction. The cause of the low reduction rate might be seen in a complex and protective character of food matrix. Therefore, most applications combine ultrasound with other preservation methods, like high pressure treatment.[30]

Still more studies are needed to obtain more information on microbial inactivation by ultrasound and to elaborate the effect of the combination of ultrasound with other methods.[30]

[28] Barbosa-Cánovas et al., 1998: 135-136
[29] Raso & Barbosa-Cánovas, 2003: 274
[30] Butz & Tauscher, 2002: 282

2. High Pressure Processing

2.1. Introduction

The technology of high pressure processing (HPP), also known as ultra high pressure (UHP) or high hydrostatic pressure (HHP), is defined as a process that applies pressure between 100 and 800 MPa[31] to solid or liquid foods, with or without packaging. The time of exposure may be in a range from a few seconds to over 20 minutes and the temperatures during processing may range from below 0°C to above 100°C.[32]

The application of HPP in food industry has been known since the end of nineteen century. However, for nearly a hundred years this method was not utilised, mostly because of engineering problems. At the beginning of 1990s, a dynamic development of HPP was possible due to technical and scientific progress.[33]

The first country that commercialized high-pressured foods was Japan. Around 1990, acid foods such as jams and fruit drinks were introduced to the market.[34]
In Europe, the first high-pressured food was an orange juice, which was produced in France by UltiFruit® in 1996. Later on, in 1999 a Spanish meat producer (Espuña SA Company) installed high pressure equipment to process cooked ham.[34]
In North America, the food company Avomex Inc. applied the first high pressure installation in 1996. It was applied to avocado products and turned out to be very successful. This was because of the fact that the avocado pulp is heat sensitive so the application of thermal treatment is limited. Additionally, the avocado enzyme polyphenol oxidase (PPO) which is responsible for undesirable food browning can be easily inactivated by HPP as it has rather low pressure stability. Furthermore, the HPP treated guacamole reveals superior characteristics similar to the fresh product.[34]

Nowadays, it is estimated that there are more than 130 high pressure installations worldwide. The volumes of these installations vary between 55 and 420 litres, and the annual production volumes of high-pressured food are about 200,000 tons.[35]

2.2. Description of high pressure processing

High pressure processing can be performed as batch or semi-continuous production.[32]

Two ways of generating pressure can be distinguished:

1. **Direct compression** utilises the small-diameter end of a piston to pressurize a medium while the large-diameter end of the piston is driven by a low pressure pump. This system is used in laboratory systems or pilot plant systems [Figure 2(a)].

[31] Factors to convert units of pressure see Table 1 in Annex I
[32] Butz & Tauscher, 2002: 282
[33] Ledward, 1995: 1
[34] Rovere, 2001: 251-253
[35] Heinz & Buckow, 2009: 2

2. **Indirect compression** to reach the desired pressure uses a pressure intensifier to pump a pressure medium from a reservoir into high pressure vessel. This system is mainly applied in the food industry [Figure 2(b)].[36]

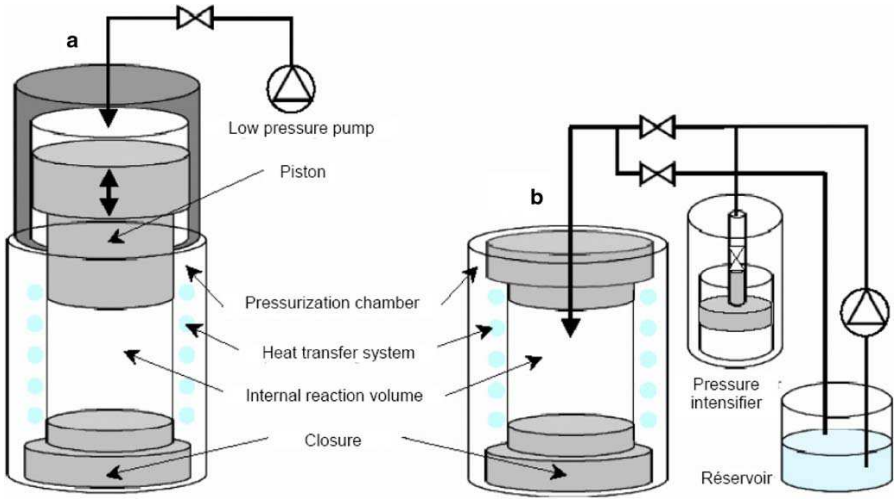

Figure 2. Examples of a direct system **(a)** and **(**an indirect systems **b)** [Urrutia-Benet 2005]. **Source:** Norton & Sun, 2008

The process in the indirect system starts with filling the flexible containers with food products. Then, the containers with food products are loaded into a HP chamber [Figure 3(1)]. Next, the vessel is sealed and the pressure is applied by pumping the medium, usually water mixed with oil for lubrication and anticorrosion purposes [Figure 3(2)]. Increasing the free energy by mechanical volume reduction generates the high pressure. This process lasts till a certain pressure is achieved inside the vessel [Figure 3(3)]. The pressure is held for a certain time and then is released.[37]

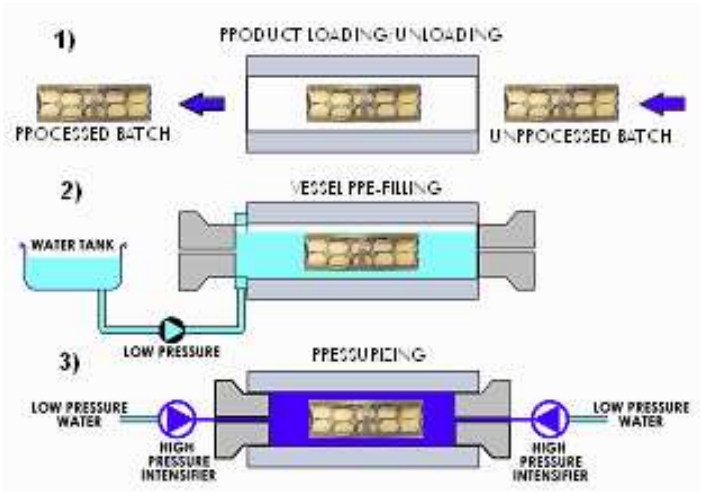

Figure 3. The steps of high pressure food processing. **Source:** NC Hyperbaric, 2006

The basic rules of high pressure processing are *the principle of Le Chatelier* and *the isostatic rule*. The first principle describes the fact that if a disruption takes place in a system at

[36] Deplace & Mertens, 1992: 469
[37] Barbosa-Cánovas et al., 1998: 20-22

equilibrium, then the system reacts in such a way to minimise the effect of this disturbance. In the case of HPP, some phenomena, like change in molecular configuration or chemical reaction are stimulated. Furthermore, these phenomena are accompanied by a decrease in volume, and reactions that involve an increase in volume are opposed.[38] For instance HP influences breakage of ions since this causes a volume decrease due to the electrostriction of water. Moreover, it stabilises hydrogen bonds since their formation is also responsible for a volume decrease. However, it does not influence the covalent bonds. In consequence, the large molecules, like enzymes, proteins, lipids or cell membranes are disrupted during HPP and some small molecules, like vitamins and flavour components remain untouched.[39]
The isostatic rule states that HP is transmitted uniformly and instantaneously throughout a food no matter if the food is hermetically packed or not. Furthermore, high pressure is independent of size, shape and food composition.[40]

Due to compression, the temperature of the food in the HP vessel can be increased of about 3°C per 100 MPa. This phenomenon is known as adiabatic heating. Additionally, pH of the food may be shifted.[40]

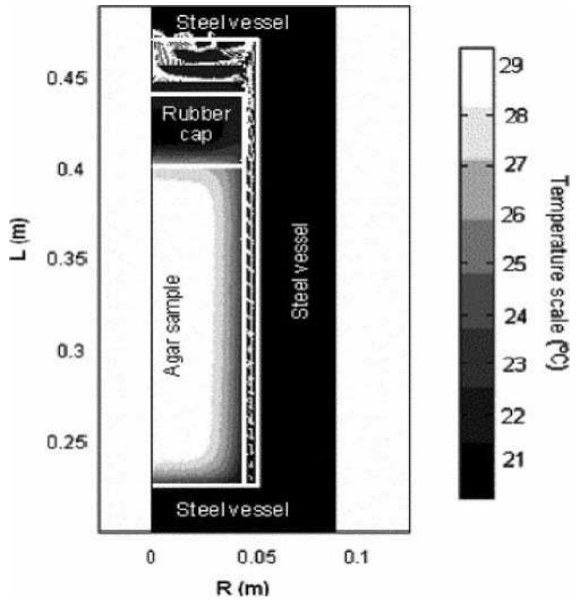

Figure 4. Temperature distribution in an HP chamber. **Source:** Otero et al. 2006 in Norton & Sun, 2008

It is essential to mention that the temperature is not uniformly distributed inside the HP vessel as well as in food product [Figure 4]. And therefore, it can affect the number of the surviving microorganisms.[41]

Apart from HPP performed at moderate temperature, some HP processes are combined with low temperature (high pressure with low temperatures) and elevated temperature (high pressure sterilisation).

[38] Pauling, 1960 in Norton & Sun, 2008: 4
[39] Linton & Patterson, 2000 in Norton & Sun, 2008: 4-5
[40] Butz & Tauscher, 2002: 282
[41] Norton & Sun, 2008:9

2.3. High-pressure low-temperature

High pressure with low temperatures (HPLT) is an application of high pressure processing in new fields. HPLT processes include three categories: pressure-supported freezing, pressure-supported thawing and subzero storage. The basis for these processes is the fact that the freezing temperature of water decreases together with increasing pressure.[42]
HPLT are considered as processes that may have a positive effect on quality attributes of some foodstuffs.[43] Much was done to develop and optimised HPLT processes, but still there is a need of further studies.[44]

2.4. High pressure sterilisation

Nowadays, high-pressured foods are usually high-acid products since low pH guarantees the microbial safety. Food products, like vegetable products, cheese, red meat or poultry, are low-acid foods so in these cases pH does not pose a barrier for microbial growth. Therefore, to inactivate pathogens including proteolytic *Clostridium botulinum*, the additional inactivating processes (usually heating) must be introduced next to HPP.[45]
High pressure sterilisation, which is a synergistic process of temperature and pressure, results in inactivation of microorganisms, spores and enzymes. In this process, high pressure is applied at elevated temperature (60-90°C) and the adiabatic compression is used to heat product rapidly to higher temperature. The most important factors of high pressure sterilisation are: pressure, the initial temperature of product, vessel as well as pressure liquid, temperature during process, time of the process and number of cycles.[46] High pressure sterilisation results in a shelf stable product usually with superior quality compared to the product produced by a conventional method.[47]

Adiabatic heating, which results in the uniform temperature elevation, is an important advantage of HP sterilisation. The rate of increase in temperature for most foodstuffs due to pressure treatment is unknown. However, for water, some oils and alcohols it has been already established.[48]
HP sterilisation of canned products in contrast to traditional sterilisation characterises with:

1) application of lower temperature,
2) shorter processing time,
3) quicker heating and cooling,
4) more uniform temperature distribution.[49]

The weak point of the process is the fact that the wall of steel vessel does not have the same rate of temperature increase as foodstuffs [Figure 4]. Consequently, during the retention time cooling of foods occurs near the vessel wall. The temperature differences may impact

[42] Norton & Sun, 2008: 22-23
[43] Fuchigami et al., 1998 in Norton & Sun, 2008: 23
[44] Norton & Sun, 2008: 3, 24
[45] Wilson et al., 2008: 290-291
[46] Matser et al., 2004: 80
[47] Hoogland et al., 2001 in Matser et al., 2004: 79
[48] Ting et al., 2002 in Matser et al., 2004: 80
[49] Matser et al., 2004: 81

significantly the process of microorganisms' or spores' inactivation. Thus, there is a need for careful monitoring of the process and the temperature distribution in the vessel.[50]
High pressure sterilisation and its effect on vegetative microorganisms and spores have been described by a number of scientists.[51] Meyer et al. [2000] explained the sterilisation process as two pulse process in which pulse length was 1 minute and the interval time 30 seconds. The food products in this study were inoculated with 10^6 spores of *Bacillus subtilis*, *Bacillus cereus*, *Bacillus stearothermophilus*, and *Clostridium sporogenes* per gram.[52]

The pressure and initial temperature parameters were: 1700 MPa and 60°C for eggs and milk, 1172 MPa and 70°C for all vegetables, all potato products and seafood, 828 MPa and 80°C for most vegetables and whole potatoes, and 690 MPa and 90°C for main meal entrees, meats, pasta dishes, sauces and most vegetables. The study revealed that if the pressure was increased, the temperature could be lowered.[53]
However, the differences in response to pressure among species and strains of bacteria should be taken into account.[53]

In case of HP sterilisation, the food quality depends on a food matrix.[54] For instance, Krebbers et al. [2002] showed that HP sterilisation resulted in the best retention of the essential oils in fresh basil when it was compared with other methods, such as freezing, traditional heat sterilisation, and drying. However, colour and texture of HP sterilised basil was similar to heat sterilised basil.[55]
For most vegetables and fruits treated with HP, a good retention of texture was observed. However, some foods like apples or strawberries soften if they are HP sterilised.[56]
In general, HP sterilisation is believed to characterise with a good retention of foods colour. Nevertheless, as each food product has a unique and complex matrix, each food quality should be evaluated separately.[56]
This process uses lower temperature and shorter time than traditional sterilisation method, thus it can remain heat labile components of foods, for instance vitamins. However, in case of vitamin C, the effect of pressure and temperature was concluded to depend on food matrix.[56]

2.5. The effect of HPP on some food components

The application of the pressure higher than 400 MPa in the biological systems can cause reversible and irreversible cleavage of intermolecular and intramolecular bonds, including hydrogen bonds or hydrophobic interaction.[57]
The covalent bonds which share pairs of electrons between atoms, characterize with very low compressibility at pressure below 2,000 MPa. Therefore, low molecular weight compounds possessing these bonds are rarely influenced by HPP.[58]

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[50] De Heij et al., 2002 in Matser et al., 2004: 80
[51] Reddy et al., 1999; Rovere et al., 1999; Meyer et al., 2000; Okazaki et al., 2000 and Wilson et al., 2008 in Matser et al. 2004: 80
[52] Meyer et al., 2000 in Matser et al., 2004: 80
[53] Wilson et al., 2008: 291
[54] Matser et al., 2004: 82
[55] Krebbers et al., 2002 in Matser et al., 2004: 83
[56] Matser et al., 2004: 83
[57] Hugas et al., 2002: 369; Knorr et al., 2006 in Heinz and Buckow, 2009: 3

The effects of HPP on some food components, namely starch, proteins and enzymes are described below.

2.5.1. The effect of HPP on starch

Starch is a polysaccharide carbohydrate which consists of two polysaccharides: amylose (mainly linear structure) and amylopectin (highly branched structure). The ratio of amylose and amylopectin depends on the plant source. Starch is present in such foods as wheat, maize, rice or potatoes.[59]

The structure of these macromolecules can be altered by HPP. For instance, a weak gel can appear from the solution of starch granules as a result of pressure induced swelling of the granules.[60] The conditions for gelatinization are impact by the origin of the starch[61] Starches that characterise with high amylase/amylopectin ratios are very resistant to high pressure.[62]

High pressure can induce in starches a whole range of physicochemical changes, including crystallinity, loss of anisotropic order, hydration, and increase of viscosity. Those changes are simultaneously similar to changes caused by heat treatment. However, the main difference is that during pressure treatment there is lack of amylase leaching in cereal starches. This explains the great difference in rheological properties (physico-mechanical properties). Furthermore, high pressure increases swelling of granules, which causes high rigidity of the starch gel in case of potato starch.[63]

2.5.2. The effect of HPP on proteins

Proteins are linear polymers consisting of amino acids. Three or four levels of structural organisation within the protein molecule can be distinguished. The structure of proteins is stabilized by non-covalent bonds (ionic, hydrogen, hydrophobic) as well as by covalent bonds (disulphide).[64]

When intra- and interprotein interactions are affected by factors, such as temperature, pH and high pressure, the changes of conformation occur. These changes lead to protein denaturation, aggregation or gelation. Significant difference between heat-induced and pressure-induced protein denaturation as well as aggregation was noticed among different food proteins.[65] It was also reported that pressure and/or temperature influence the degree of protein denaturisation. Furthermore, gels formed during high pressure treatment were seen as less elastic, weaker, and more exudative than heat-induced gels.[66]

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[58] Gross & Jaenicke, 1994; van den Broeck et al., 1998; Oey et al., 2006 ; Cheftel & Culioli, 1997 in Heinz & Buckow, 2009: 6

[59] Hendrickx et al., 2002: 191

[60] Stolt et al., 2000 in Heinz & Buckow, 2009: 6

[61] Autio & Stolt, 1998 in Hendrickx et al., 2002: 191-192

[62] Hendrickx et al., 2002: 192

[63] Hendrickx et al., 2002: 195

[64] Hendrickx et al., 2002: 116

[65] Funtenberger et al., 1995; Heremans, 1997; Heremans et al., 1997, 1999 in Hendrickx et al., 2002: 198

[66] Cheftel & Dumay, 1996 in Hendrickx et al., 2002: 199

2.5.3. The effect of HPP on enzymes

Enzymes belong to the special group of protein. Their role is to catalyse reactions in which the molecules (substrates) are being converted by the enzyme into different molecules (products). Enzymes characterise with huge catalytic power and their specificity to the type of reaction catalyzed and to the substrate.[67]

Processes, which take place in a biological cell, need enzymes to occur at significant rates. As enzymes are selective for their substrates and speed up only a few reactions from among many possible, the set of enzymes made in a cell determines which metabolic pathways will take place.[57]
However, the activity of the enzymes can be affected by the changes of temperature, pressure or micro-environmental conditions. Enzymes are usually inactivated by the temperature in the range of 40°C and 80°C, and by pressure exceeding 200 to 300 MPa.[68]

Enzymes important for food quality were ranked by Seyderhelm et al. [1996] from the least to the most pressure stable: lipoxygenase, lactoperoxidase, pectinmethylesterase, lipase, phosphatase, catalase polyphenoloxidase, and peroxidase.[69]
Polyphenoloxidase (PPO) is a cause of undesirable changes (enzymatic browning) in fruits and vegetables during postharvest handling, storage and processing. It is also one of the most pressure resistant enzymes. However, it was noticed that the effect of high pressure at ambient temperature on PPO inactivation depends greatly on its origin and the pH of the medium. For instance, the inactivation of PPO derived from apple in phosphate buffer (pH 7, 0.5 M) was possible at a pressure of 100 MPa while the inactivation of PPO derived from avocado in phosphate buffer (pH 7, 0.1 M) took place at 800 MPa.[70]
Another enzyme - pectinmethylesterase (PME), which is responsible for such food changes as induction of cloud destabilisation in orange juices, gelation of concentrates and loss of consistency in tomato products, was inactivated in the range of the pressure between 150 and 1200 MPa, depending on the enzyme origin and the medium.[70]

2.6. Food quality and HPP

The food quality prosperities include colour, flavour, texture, and nutritive value. These properties influence consumers' attitude towards food products.[71] However, often these quality properties are negatively affected by food processing and storage. Therefore, an important issue in the food industry is to deliver safe foods with a superior quality.[71] One of the potential solutions in this situation is application of novel technologies, such as HPP.

2.6.1. The effect of HPP on the colour of food product

HPP was reported to preserve the fresh colour in many vegetables and fruits.[72] In the case of fruit jams, as well as tomato juice, the colour of the pressurised product was superior to conventionally treated product.[73] Furthermore, an increased stability of chlorophyll (green

[67] Tucker, 1995: 1-5
[68] Hendrickx et al., 2002: 117
[69] Seyderhelm et al., 1996 in Hendrickx et al., 2002: 121
[70] Hendrickx et al., 2002: 121
[71] Hendrickx et al., 2002: 167
[72] Donsi et al., 1996 in Hendrickx et al., 2002: 168
[73] Poretta et al., 1995; Matser & Bartels, 1999 in Hendrickx et al., 2002: 168-169

pigment) in green vegetables was noticed when the pressure treatment at low temperature (below 50°C) was applied. This phenomenon has been reported for other pigments, such as annatto, carotene, anthocyanins, and hibiscus extract as well.[74]
However, high pressure treatment can also affect the colour of foods. For example, the colour of mushrooms and onions may be negatively changed if pressure applied to these foods is not sufficient to inactivate the pressure resistant enzymes, for instance PPO which is also responsible for food browning.[75]

Only minor changes of colour were reported in milk after pressure treatment sufficient to ensure the reduction of microorganisms to an acceptable level.[76]

However, HP causes drastic changes of the colour in case of the red meat. Some scientists have noticed that an increased pressure causes an increase of lightness and reduction of redness in meat.[77] Therefore, high pressure treatment could be recommended for products from red meat which are cooked before sale or consumption (ready-to-eat meals). The colour problem does not exist in case of cured or white meats.[78]

2.6.2. The effect of HPP on the flavour of food product

The application of HPP in the processing of fruit juices results in the maintenance of the fresh flavour, which is seen as a major advantage of cold high pressure treatment. Bignon [1996] stated that the flavour profile of HP orange juice is similar to that of freshly squeezed juice and remains so for more than 30 days.[79] Flavour of high-pressured fruit jams was assessed as better than flavour of thermal treated products.[80]

The negative effect of HPP on flavour was noticed in the case of tomato juice and onions. High-pressured onions smell like cooked or fried onions, while high-pressured tomato juice demonstrates inedible and strong rancid taste.[81]

In the case of meat, HPP changes the content of taste-related amino acids and peptides comparable to meat conditioning, which can be explained briefly as the process that "(…) *starts at the moment of animal death and ends with the exhaustion of degradable energy-rich compounds such as ATP, creatine and glycogen.*"[82]

[74] Kimura et al., 1994; Donsi et al., 1996; Salanski et al., 1997 in Hendrickx et al., 2002: 169
[75] Butz et al., 1994 in Hendrickx et al., 2002: 171
[76] Mussa & Ramaswamy, 1997 in Hendrickx et al., 2002: 171
[77] Shigehisa et al., 1991; Nose et al., 1994; Carlez et al., 1995; Cheftel & Culioli, 1997; Colmenero et al., 1997 in Hendrickx et al., 2002: 173
[78] Hendrickx et al., 2002: 173
[79] Bignon, 1996 in Hendrickx et al., 2002: 174
[80] Watanabe et al., 1991; Kimura et al., 1994 in Hendrickx et al., 2002: 174
[81] Butz et al., 1994, Poretta et al., 1995 in Hendrickx et al., 2002: 174
[82] Fadda et al., 2008; Cheftel & Culioli, 1997 in Hendrickx et al., 2002: 176

2.6.3. The effect of HPP on the texture of food product

Fruits and vegetables treated with high pressure often demonstrate increased softness and pliability. However, any major effect on texture in the plant system was not noticed up to 350 MPa.[83]

A study of Basak & Ramaswamy (1998) revealed that the changes in firmness of treated product depend on the applied pressure and treatment time. Furthermore, it was noticed from the softening curves for different plant derived products that pressure-induced changes in the product texture occurred in two phases:
"(1) a sudden loss as a result of the pulse action of pressure, followed by
(2) further loss or gradual recovery during pressure-holding phase."[84]

Many plant derived food products recover most of the loss in texture after a holding time of 30 to 60 minutes at 100 to 200 MPa, some are even more firm than non-treated products. However, in the case of some vegetables and fruits (for instance carrots or green pepper) further texture loss was observed.[85]
High pressure was reported to affect the viscosity of tomato juice, and to cause protein-tissue coagulation as well as compacting which resulted in the formation of jelly-like structure.[86]

Milk viscosity was seen as only slightly affected by the high pressure.[87] However, the texture of pressure-treated milk cheeses was assessed as worse (pasty and weak texture) than in the case of raw or pasteurized milk cheeses.[88]
For pre-rigor meat, high pressure in a range of 100 to 200 MPa was reported as effective in meat tenderization.[89] In post-rigor meat, the application of pressure of 150 MPa together with elevated temperature (55°C to 60°C) counteracts toughening induced by cold-shortening.[90] Meat tenderization can also take place when only higher pressure up to 500 MPa is used. However, as it was mentioned hereinabove high pressure can affect colour and appearance of the meat product. Hence, this method is especially recommended for cured meat, white meat and ready-to-eat meals.[91]

2.6.4. The effect of HPP on nutritive value and health components of food product

In general, the content of vitamins in fruits and vegetables is not significantly affected by high pressure treatment. Vitamins C, A, B1, B2, E, as well as folic acid, were not degraded by pressure treatment.[92] Donsi et al. [1996] reported that vitamins (vitamin C, B6, B2, B1, and niacin), sugars (sucrose, fructose, and glucose), as well as organic acids (malic acid, citric acid, and isocitric acid) in orange juices were not substantially modified by the pressure in

[83] Knorr, 1995 in Hendrickx et al., 2002: 177
[84] Basak & Ramaswamy, 1998 in Hendrickx et al., 2002: 177
[85] Hendrickx et al., 2002: 177
[86] Poretta et al., 1995 in Hendrickx et al., 2002: 177
[87] Mussa & Ramaswamy, 1997 in Hendrickx et al., 2002: 178
[88] Drake et al., 1997 in Hendrickx et al., 2002: 179
[89] Elgasim & Kennick, 1980; Ohmori et al., 1991 in Hendrickx et al., 2002: 179
[90] Bouton et al., 1977; Ohmori et al., 1991 in Hendrickx et al., 2002: 180
[91] Suzuki et al., 1990 in Hendrickx et al., 2002: 180
[92] Bignon, 1996 in Hendrickx et al., 2002: 180

the range of 200 to 500 MPa.[93] Ascorbic acid was seen as unstable only when combination of very high pressure with elevated temperature was used.[94]

Currently, one of the most problematic diseases worldwide is cancer. Therefore, the antimutagenic activity of vegetables and fruits seems to be especially interesting issue. Traditional food processes, such as heat treatment can noticeably reduce this potential in vegetables and fruits.
The effect of HPP on antimutagenic activity of vegetables and fruits was studied by Butz et al. [1997]. It appears that strong antimutagenic activity of carrots, cauliflower, kohlrabi, leeks and spinach was not affected by high pressure in contrast to heat treatment. In the case of strawberry and grapefruit, which demonstrates only a moderate antimutagenic activity, this potential was affected neither by heat treatment nor by pressure treatment. In the case of beets and tomatoes, the antimutagenic potential was only affected, when extreme conditions of the treatment were applied, for example 600 MPa at 50°C or 800 MPa at 35°C.[95]

It is important to mention that high pressure can be used to eliminate some undesirable compounds from foods. For instance, milk products contain β-lactoglobulin, which is an allergenic compound.[96]
The elimination of β-lactoglobulin from milk products including modified milk for infants is possible due to hydrolysis with enzyme-thermolysin at elevated pressure. High pressure accelerates the reaction and makes it more complete in comparison to the reaction at atmospheric pressure.[96]

[93] Donsi et al., 1996 in Hendrickx et al., 2002: 180
[94] van den Broeck et al., 1998 in Hendrickx et al., 2002: 180
[95] Butz et al., 1997a in Hendrickx et al., 2002: 181
[96] Hayashi et al., 1987 in Hendrickx et al., 2002: 182

3. Food safety aspects of HPP

3.1. Introduction

Food safety is defined by Codex Alimentarius as *"(…) assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use."*[97]

European law does not provide a definition of food safety, but it explains what unsafe food means. As stated in Article 14(2) of the General Food Law (GFL) (Regulation (EC) No 178/2002):

"Food shall be deemed to be unsafe if it is considered to be:

a) injurious to health;

b) unfit for human consumption."[98]

In other words, a safe food is not injurious to health and unfit for human consumption.

Moreover, Article 14(4) of GFL refers to the term "*injurious to health"*:

"In determining whether any food is injurious to health, regard shall be had:

(a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;

(b) to the probable cumulative toxic effects;

(c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers."[98]

And Article 14(5) of GFL refers to term "*unfit for human consumption"*:

"In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay."[99]

The agents that can affect the safety of food are called hazards. They are defined in the GFL as *"(…) a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect."*[99] It is especially important to be aware of the potential hazards during the food production chain.

3.2. Microbiological aspects

The inactivation of pathogens and/or extension of food shelf-life are the main objective of high pressure processing in the food industry.[100]

3.2.1. Vegetative bacteria

Bacteria are microscopic, single-celled and relatively simple organisms, which are ubiquitous in nature. They can cause food spoilage or foodborne illnesses. The main foodborne bacteria

[97] Codex Alimentarius, 2003: 5

[98] OJ L 31, 1.2.2002, pp. 1-24

[99] Article 3(14) of Regulation 178/2002

[100] Heinz and Buckow, 2009: 4

include *Campylobacter* spp., *Salmonella* spp., *Listeria monocytogenes*, *Staphylococcus aureus*, *E. coli* and *Vibrio* spp.[101]

Microbial inactivation by high pressure was concluded to be caused by a combination of different factors.[102] One of the main targets of high pressure is the cell membrane. Changes, like modification in permeability and ion exchange, may cause loss of resistance to selective chemical inhibitors. Consequently, the inhibitors can not be excluded from the cell since the cell membrane becomes damaged.[103] Another important factor in bacteria inactivation is disruption of the enzymatic systems, which control the metabolic actions.[104]

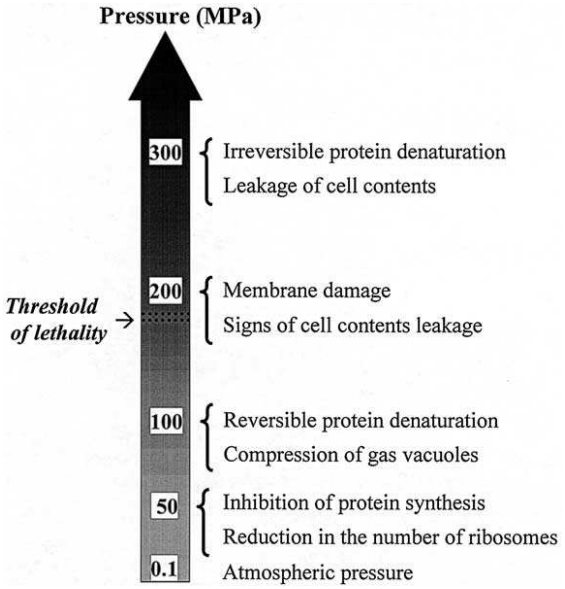

Figure 5. The changes in microorganisms induced by different pressures. **Source:** Lado & Yousef, 2002

Figure 5 shows changes in microorganisms induced by different pressures. Pressures in the range of 20-180 MPa are responsible for retardation of microbial growth and inhibition of protein synthesis. At approximately 180 MPa, loss of cell viability begins. The rate of inactivation increases exponentially with increase of the pressure. Pressures above 300 MPa cause the irreversible denaturation of proteins.[105]

In the case of bacterial spores, treatment at 50-300 MPa triggers the formation of pores in spore coats what may indicate inducing spore germination by HPP. However, no signs of germination were observed at higher pressures. Probably, higher pressure was lethal to germinating spores.[105]
Additionally, Norton & Sun [2008] stated that cellular inactivation may depend on morphological changes that take place in individual microbial cells during high pressure processing, and possibly on the geometry of bacteria.[106]

[101] Norton & Sun, 2008: 20
[102] Manas & Pagan, 2005 in Norton & Sun, 2008: 20
[103] McClements et al., 2001 in Norton & Sun, 2008: 20
[104] Knorr & Heinz, 2001 in Heinz & Buckow, 2009: 4
[105] Lado & Yousef, 2002: 435
[106] Norton & Sun, 2008: 6

Pressure resistance can be associated with the stage of microbial growth. Generally, cells in stationary stage seem to be more resistant compared to cells in the exponential phase.[107] Furthermore, Gram-positive[108] bacteria are identified as more resistant to high pressures than Gram-negative[108] bacteria. This may be connected with differences in the cell wall composition. The peptidoglycan layer of cell wall of Gram-positive bacteria includes teichoic acids, which increase the rigidity of the wall.[109]

Kinetics of bacterial inactivation was elaborated only for a few spoilage and pathogenic bacteria. Figure 6 shows pressure-temperature combinations that result in 5 log reduction (10^5 cfu (colony forming unit)) of bacteria after 5 minutes of high pressure treatment. Pressure combined with high temperature usually act synergistically on the bacterial inactivation.[110]
As presented in Figure 6, maximal pressure stability of bacteria appears usually at the range of 20-40°C.[111] At lower temperature, pressure stability is gradually lost by bacteria since compressibility of water and cell cytoplasm increases with the decrease of temperature. Consequently, the transfer of mechanical energy to the microbial cell is increased. Moreover, if it is assumed that a certain threshold of this energy causes bacterial inactivation, then lower pressure is needed at lower temperature for bacterial inactivation than at higher temperature.[112]

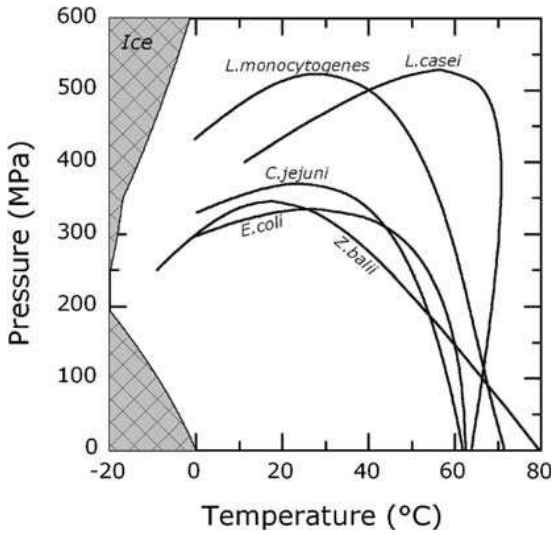

Figure 6. Pressure-temperature isorate diagram for 5 log (10^5 cfu (colony forming unit)) reduction of some pathogenic and spoilage bacteria. **Source:** Heinz & Buckow, 2009

According to Lado & Yousef [2002]: *"Microorganisms are more likely stressed or injured than killed in food processed by alternative preservation technologies. Adaptation of microorganisms to*

[107] McClements et al., 2001 in Norton & Sun, 2008: 6
[108] When bacteria are observed microscopically, **Gram-positive** bacteria are stained dark blue or violet by Gram staining in contrast to **Gram-negative** bacteria which cannot retain the crystal violet stain and instead take up the counterstain and appear as red or pink. This difference is caused by the high amount of peptidoglycan in the cell wall of Gram-positive bacteria.
[109] McClements et al., 2001 in Norton & Sun, 2008: 6
[110] Hayakawa et al., 1994 & Arroyo et al., 1999 in Lado & Yousef, 2002: 437
[111] Heinz & Buckow, 2009: 5
[112] Lori et al, 2007 in Heinz & Buckow, 2009: 5

stress during processing constitutes a potential hazard." The well-known fact is that sub-lethal stress may induce the expression of cell repair systems [Figure 7]. Consequently, the stress-adopted cells may survive the preservation by the so-called hurdle technology, which combines several antimicrobial factors, such as increased temperature and pressure as well as low pH.[113]

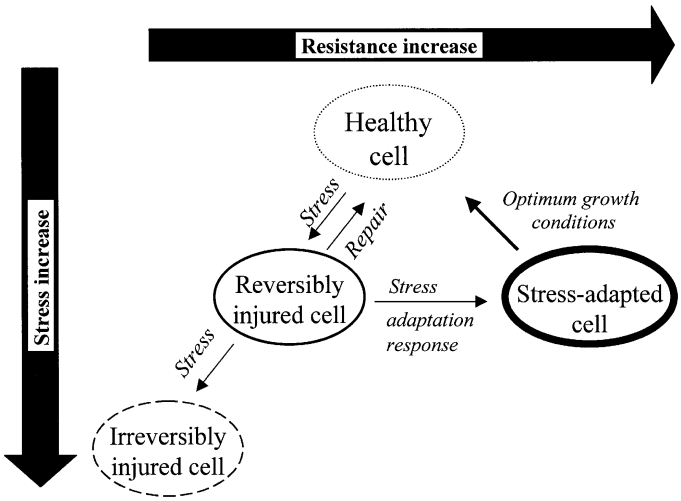

Figure 7. Microbial stress and resistance to processing. **Source:** Lado & Yousef, 2002

Listeria monocytogenes is a Gram-positive rod. It can be present in acidified and moderate heated foods and has ability to grow anaerobically in fridge conditions. Lopez-Pedemonte et al. [2007] observed in their research study on *Listeria monocytogenes* that safety of cheese may be significantly improved by a combination of moderate pressure treatment at mild temperature with appropriate ripening time at refrigerating temperatures.[114]

In other research, Alpas and Bozoglu [2003] have showed that nine different *L. monocytogenes* strains in fruit juice demonstrate decrease between 0.92 and 3.53 log cycle[115] after high pressure treatment (350 MPa at 25°C for 5 min.). However, when the temperature of HP treatment was elevated (350 MPa at 50°C for 5 min.), no survivors were detected for all strains.[116]

Another important pathogenic bacterium is *Staphylococcus aureus.* It is a Gram-positive coccus which is considered to be highly resistant to pressure.[117] However, strains can vary greatly between each other in pressure resistance.[118]

Escherichia coli belongs to the Enterobacteriaceae family, and it is Gram-negative rod. *Escherichia coli* O157:H7 has the status of a foodborne pathogen of emerging importance. According to Upmann et al. [2000], the growth of *E. coli* in high-pressured food is inhibited after storage in fridge conditions for a number of days. The cause of this effect could be

[113] Lado & Yousef, 2002: 438
[114] Lopez-Pedemonte et al., 2007 in Norton & Sun, 2008: 21
[115] ~8 - $3.38 \cdot 10^3$ cfu since 1 log cycle is 10^1 cfu (colony forming unit)
[116] Alpas and Bozoglu, 2003 in Norton & Sun, 2008: 21
[117] Erkmen & Karatas, 1997 in Norton & Sun, 2008: 21
[118] Norton & Sun, 2008: 21

explained by the sensitisation of bacteria to the low temperature and/or reduced oxygen conditions. Additionally, this bacterium is probably more susceptible to subsequent heat treatment.[119]

3.2.2. Bacterial toxins

Enterotoxins of *Bacillus cereus*, *Staphylococcus aureus*, *Vibrio cholera* and pathovars of *Escherichia coli* are well-known causes of a wide range of diseases. Depending on their thermal stability, those proteins are classified as either heat-stable or heat-labile.[120]
The combination of thermal and high pressure treatment may have an effect on the heat-stable toxins. According to Margosch et al. [2005], high pressure may increase toxin inactivation caused by heat treatment.
The additional advantage is that the combination of pressure and temperature treatments may be more effective than single treatment at lower temperature and/or shorter time.[120]

3.2.3. Bacterial spores

Bacterial spores, in comparison with vegetative cells, demonstrated the increased resistance towards environmental stresses including high temperatures and pressures.[121] Heinz & Buckow have described them as *"(…) the most pressure-resistant life forms known."*[122] Spores do not pose a hazard to the food industry themselves but their germination (the process by which a dormant spore changes into a vegetative cell), outgrowth and proliferation of the bacteria do.

Heinz & Buckow [2009] identified three strategies to minimise the risk of spore outgrowth.[122] The first strategy is described as *"(…) inactivation in one step by severe temperature conditions or suitable pressure-temperature combinations."* The second strategy is seen as milder than the first one. It postulates to trigger spore germination by temperature and/or pressure. Since vegetative bacteria are less temperature and pressure resistant than spores, subsequent temperature or pressure/temperature treatment can easily inactivate them.[123]
The last proposition of spore inactivation strategy is based on temperature or pressure/temperature treatment. This strategy is perceived as milder than the first one, and its aim is spore injury. Germination or outgrowth is prevented by matrix inherent hurdle.[124]

Amongst spore-forming bacteria, *Clostridium botulinum* and *Bacillus cereus* are considered as the most important since they are the most pressure-resistant (above 1000 MPa at room temperature). Moreover, they are responsible for food spoilage and food poisoning.[125]
Combination of elevated temperature (80-110°C) with pressure of about 600 MPa has been demonstrated to inactivate spores of *B. cereus*.[126] The inactivation of other bacterial spores

[119] Upmann et al. [2000] & Linton et al., 2000 in Norton & Sun, 2008: 21
[120] Margosch et al., 2004: 212
[121] Wilson et al., 2008: 290
[122] Heinz & Buckow, 2009: 5
[123] Norton & Sun, 2008: 22
[124] Heinz & Buckow, 2009: 5
[125] van Opstal et al., 2004 in Norton & Sun, 2008: 22; Margosch et al., 2004, 2006 in Heinz & Buckow, 2009: 5
[126] van Opstal et al., 2004 in Norton & Sun, 2008: 22

takes place at pressures of 600 MPa or greater and at temperature above 60°C.[127] The mode of action of high pressure on bacterial spores is still not entirely known.[128]

3.2.4. Fungi

Fungi consist of two groups: unicellular fungi (yeasts) and fungi producing hyphae (moulds, mushrooms). Generally, fungi are more susceptible to pressure than bacterial spores.[128]

Yeasts are single-celled fungi which reproduce by budding or fission. They are often responsible for food spoilage.[129]
As stated by Chen and Tseng [1997], high pressure below 400 MPa for a few minutes may inactivate yeasts. However, some strains within species seem to be more pressure resistant.[129]
Pressure of about 100 MPa affects the nuclear membrane of yeast while higher pressure (more than 400 to 600 MPa) causes changes in mitochondria and cytoplasm.[130]

Moulds, which are mycelial fungi, are usually inactivated by pressures between 300 and 600 MPa.[130]

3.2.5. Viruses

Viruses are defined as *"(…) extracellular organelles evolved to transfer nucleic acid from one cell to another."* They contain either RNA or DNA enclosed in a protein coat or capsid and additionally they may produce a small number of enzymes that are used during infection of a host cell. Viruses have no cellular structure and they are structurally diverse. Consequently, there is a wide range of pressure resistances.[131]
Amongst human enteric viruses, the most frequent cases are Norwalk-like viruses (SRSVs), hepatitis A, rotavirus and human astrovirus.[131]

Several experiments concerning inactivation of viruses by high pressure treatment were performed. As a result, the following inactivation parameters were obtained: 275 MPa for 5 minutes for suspensions of feline calicivirus (a Norwalk-like virus surrogate), 400 MPa for 15 minutes for adenovirus, and 450 MPa for 5 minutes for adenovirus and hepatitis A.[132]
In the case of poliovirus, several research papers noticed their high pressure resistance.[133]

The mechanism of inactivation of viruses by pressure has not been fully understood. However, viral envelope, if present, was recognized as a target for high pressure treatment.[134] Pressure may also cause the dissociation of virus particles and trigger some minor alteration in viral structures.[135]

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[127] Heinz & Knorr, 2002 in Heinz & Buckow, 2009: 5
[128] Norton & Sun, 2008: 22
[129] Chen and Tseng, 1997 in Norton & Sun, 2008: 22
[130] Smelt, 1998 in Norton & Sun, 2008: 22
[131] Grove et al., 2005 in Norton & Sun, 2008: 21
[132] Wilkinson et al., 2001, Kingsley at al., 2002 in Norton & Sun, 2008: 21
[133] Oliveira et al., 1999, Wilkinson et al., 2001, Kingsley at al., 2002 in Norton & Sun, 2008: 21
[134] Nakagami et al., 1992 in Norton & Sun, 2008: 21
[135] Da Poian et al., 1994, Gaspar et al., 2002 in Norton & Sun, 2008: 21

3.2.6. Prions

Prions were described by Prusiner [1998] as *"(…) transmissible particles that are devoid of nucleic acid and seem to be composed exclusively of a modified protein (PrPSc)."*[136]

The same author explains that: *"Prion diseases may present as genetic, infectious, or sporadic disorders, all of which involve modification of the prion protein (PrP). Bovine spongiform encephalopathy (BSE), scrapie of sheep, and Creutzfeldt–Jakob disease (CJD) of humans are among the most notable prion diseases."*[137]

Prions were also reported to be possibly more difficult to inactivate than bacterial spores as some of them can survive sterilisation at temperature of 134°C. Brown et al. [2003] noticed that use of high pressures (690-1200 MPa) and temperature (121-137°C) reduced the prion infectivity.[138]

3.3. Toxicological aspects

No evidence, which would demonstrate that high-pressured food is more toxic than unprocessed or heat-treated food, has been found so far. It is important to mention that the elimination of toxins present in foods may differ between pressure treatment and heat treatment.[139]

However, if there is any evidence that HPP causes significant changes in the chemical composition and/or structure of food products, toxicological studies are necessary to elaborate the safety of high-pressured food. In this case, the nature of changes induced by HPP and the expected magnitude of consumption should be taken into account.[139]

Another important toxicological aspect is ensuring that the migration of packaging components does not take place, when foods in the packaging are treated by high pressure. The packaging of HP food must meet the relevant migration limits.[140] The usage of ethylene-vinyl alcohol copolymer film (EVOH) or polyvinyl alcohol film (PVOH) as packaging material for high-pressured food is recommended.[141]

3.4. Allergenic aspects

Allergens are proteins that naturally occur in food and may cause abnormal immune responses in susceptible individuals. The main food allergens are present in peanuts, tree nuts, soy, milk, eggs, cereals, seafood, fish and sesame.[142]
During food processing, inactivation of the allergic potential as well as formation of new allergens may take place.[143]

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[136] Prusiner, 1998: 13363
[137] Taylor, 1999 in Norton & Sun, 2008: 22
[138] Brown et al., 2003 in Norton & Sun, 2008: 22
[139] Eisenbrand et al., 2005: 1171
[140] Eisenbrand et al., 2005: 1172
[141] Barbosa- Cánovas et al., 1998: 20-22
[142] Allergen Bureau
[143] Jankiewicz et al., 1997, Besler et al., 2001 in Eisenbrand et al., 2005: 1171-1172

Most technological processes, especially thermal ones, result in a partial inactivation of food allergenicity. There is very little evidence of increasing allergenicity in food after processing even though heat treatment causes drastic structural and chemical changes.[144]

Current knowledge which is based on few studies can not entirely exclude the impact of HPP on an increase of food allergenicity. To assess this impact, HP food should be compared with traditionally processed food, for instance heat-treated food.[145]

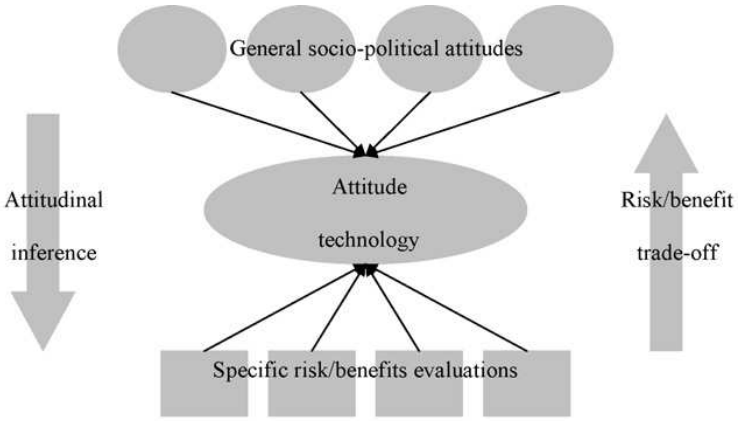
[144] Eisenbrand et al., 2005: 1171
[145] Eisenbrand et al., 2005: 1172

4. Consumers' attitudes and commercialisation of HPP

4.1. Consumers' attitudes towards HPP

Nowadays, a continuous progress in food technology is observed. Nevertheless, consumers still often reveal more conservative approach to the technological innovations and do not perceive their benefits. This situation can be explained by the fact that food technology and production processes are very technical and complex issues, and thus they may be difficult to understand. Therefore, even if a new technology possesses many advantages, there is no guarantee that food produced by the technology will be successful on the market. The best examples of this situation in the EU are food produced by genetic modification or irradiation.[146]

The consumer's perception of benefits gained from a technology seems to be a crucial part in attitude formation, which can be explained by the two theories: top–down approach and bottom–up approach. These theories are not contradictory and they both correspond to two mechanisms of attitude formation. Moreover, they both can influence the process of attitude formation to different degrees in any case [Figure 8].[147]



Source: Søndergaard, Grunert & Scholderer (2005) and Scholderer, Bredahl & Frewer (2000).

Figure 8. Attitude formation based on the top–down and bottom–up approach. **Source:** Scholderer et al., 2000 & Sondergaard et al., 2005 in Boel Nielsen et al., 2009

The top-down approach is based on the general socio-political attitudes and values. In the case of HPP, a general attitude may embrace concerns related to the environment, general attitude towards new technologies or general scepticism towards extensive processing.[148]
The bottom-up approach is based on the consumers' knowledge about the product or process. In the case of HPP, consumers can broaden their knowledge on a new technology by comparing this new technology with the traditional technologies. For instance, the advantages of HPP include improved sensory properties and nutrition value, and a

[146] Boel Nielsen et al., 2009: 115-116
[147] Scholderer & Frewer, 2003 in Boel Nielsen et al., 2009: 116
[148] Boel Nielsen et al., 2009: 116

disadvantage is that high pressured food is more expensive than the traditional one. Consequently, the attitude of consumers is based on a trade-off between identified benefits and risks of the technology.[148]

Two qualitative studies investigating consumer perception of high pressure processing (HPP) and pulsed electric field (PEF) in food production in Europe were performed by Butz et al. [2003] and Boel Nielsen et al. [2009].

The first survey amongst 3000 adults (aged 14 years and over) from France, Germany and the United Kingdom was performed as a part of an EU-founded research project. It showed that the average acceptance value of HPP amongst European was 67%. When individual countries were taken into account, then the individual acceptance values were 74% in Germany, 71% in France and 55% in UK. It is important to mention that the majority of potential buyers consisted of conditional buyers. It means that those consumers take into account the characteristics of HP food [Figure 9].[149]

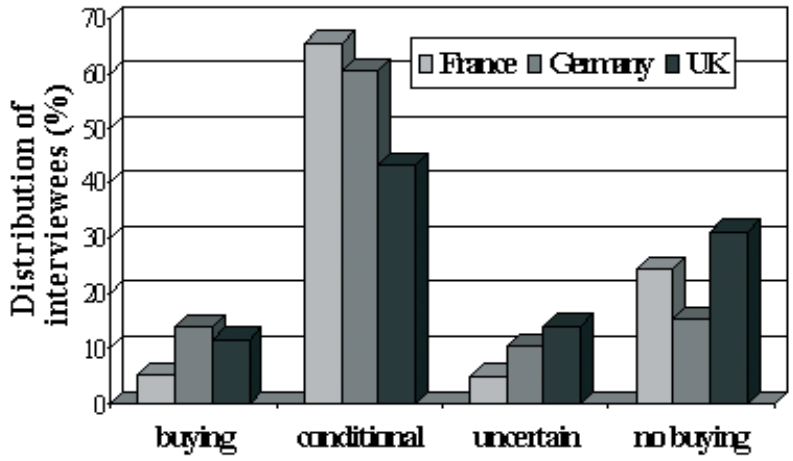


Figure 9. Subdivision of interviewees: buyers including the conditionals and unconditionals, and non-buyers for each country. **Source:** Butz et al., 2003

Consumers from UK and Germany tended to demonstrate similar manners, when the most important characteristics of HP food were evaluated in this survey. For both groups the most important characteristic was the price which should not be higher than for conventional products, as well as health benefits of the food product.[150]
French consumers were willing to pay slightly more for HP products, but the relevant issues for them were quality and shelf-life of food [Figure 10].[150]

The most important conclusion of this survey was that the consumers who *"(…) perceived the greatest personal advantage from the technology were most likely to buy the products. This group tended to include a higher proportion of young educated people."*[151]

[149] Butz et al., 2003: 30
[150] Butz et al., 2003: 31-32
[151] Butz et al., 2003: 33

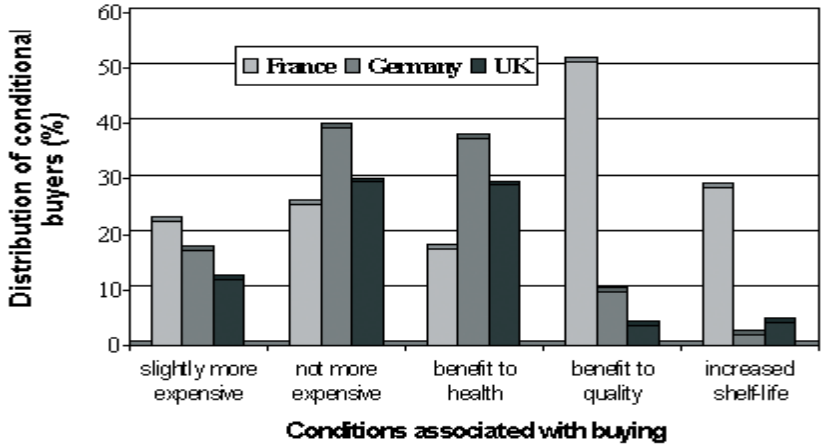


Figure 10. Conditional buyers grouped by condition and country. **Source:** Butz et al., 2003

The second survey carried out by Boel Nielsen et al. [2009] was broader in the view of the number of participating countries as well as the number of investigated issues. It was conducted in Slovenia, Hungary, Serbia, Slovakia, Norway and Denmark, and 97 adults (between 20 and 71 years of age) participated in 12 focus groups using a common guideline. The HPP and PEF technologies were introduced by a moderator and then the effect of these technologies on two specific product categories: juice and baby food was described.[152]

One of the conclusions from this survey was *"(…) that attitudes towards the PEF and HPP processes were formed based on the participants' general sociopolitical attitudes as well as on a risk/benefit trade-off of the product attributes, whereas attitudes towards the PEF and HPP products were formed mainly based on a risk/benefit trade-off of the product attributes."*[153]
Moreover, the results of the survey showed that in the case of HPP or PEF products, consumers were particularly positive about the naturalness, improved taste and high nutritional value (especially vitamin content).[153]

On the other hand, the negative features of these products included higher price, longer shelf-life in contrast to fresh squeezed products, insufficient information about HPP or PEF products, and general sceptical attitude towards these technologies.[153] Referring to prolonged shelf-life, it can be seen *"(...) that what is in the interest of food producers and retailers is not always in the interest of consumers."*[154]

The participants generally had a positive attitude towards HPP and PEF. The processes were perceived as environmentally friendly and their outcome as a "natural product". Additionally, lack of additives in the high-pressured products was seen as a benefit. Some participants who generally had a positive attitude towards innovations considered HPP and PEF as valuable. On the other hand, the participants worried about body and health, and were sceptical towards food producers.[155]

[152] Boel Nielsen et al., 2009: 115
[153] Boel Nielsen et al., 2009: 120
[154] Boel Nielsen et al., 2009: 124
[155] Boel Nielsen et al., 2009: 120

Other findings identified in this survey include the fact that HPP technology was seen as more positive than PEF technology. This situation was associated with the name of PEF and a fear of electricity amongst participants. Additionally, there was belief that PEF can cause allergic reactions. The North European participants were found to be a bit more sceptical towards these two technologies than the East European participants. The East European participants worried more about higher price, whereas the North European participants even in some cases perceived higher price as an advantage. One of the participants stated: *"If I were to choose between different types of baby food, I would choose the more expensive one because I hope it is of a better quality"* (Female, 26 years old, baby food, Denmark).[156]

In the conclusions, Boel Nielsen et al. [2009] suggested that there should be possibility for consumers to *"(…) get product experience and consequently preference for the PEF- and HPP-treated products."* In addition, more information concerning these new technologies should be provided to consumers as the key factor that may attain the consumer acceptance. Furthermore, the food producers and food scientists should be responsible for providing the evidence about safety to convince consumers.[157]

4.2. Commercialization of high pressure processing

Nowadays, food safety and quality are main driving forces behind consumers' choices. And the high pressure processing is believed to *"(…) potentially address many, if not all, of the most recent challenges faced by the food industry*."[158]
However, the main barrier for broader implementation of HPP in the food industry seems to be the initial investment. The high pressure equipment is seen as quite expensive. The price is estimated on the level of $700,000 for the smaller vessels and $3 million for the largest size vessels.[159] According to Balasubramaniam and Farkas [2008], high-pressured products may cost about 6-22 cents per kg more than those that are produced in the traditional way.[160]

A crucial aspect of any production process is profitability of the business. The production costs should be lower than the value added to the product in this process. In the case of high pressure processing, the added value to the product can be improved quality and safety as well as prolonged shelf-life. Aditionally, these features may have beneficial effect on other important issues, such as transportation, storage, insurance, labour costs or consumer convenience. Hence, it is essential to take into account all different aspects of high pressure processing to perform reasonable cost-benefit analysis of the potential rewards in investments.[161]

Different reasons may influence the application of HPP. Sometimes it is combinations of different reasons and another time it is just one key reason. For instance, as stated by Norton & Sun [2008]: *"The value of HP in terms of increasing food safety assurance, in some cases, may alone be sufficient to justify an investment."* Although it is difficult to estimate the value of food safety before the incident, from previous cases concerning the pathogenic contamination, it is

[156] Boel Nielsen et al., 2009: 120-122
[157] Boel Nielsen et al., 2009: 123
[158] Norton & Sun, 2008: 3
[159] Crews, 2007
[160] Balasubramaniam & Farkas, 2008: 414
[161] Ting & Marshall, 2002, Corkindale, 2006 in Norton & Sun, 2008: 29

well known that such incident may cause unrecoverable damage of a producer's reputation or brand name.[162]

The food manufacturer using HPP can encounter different costs. They depend on many factors, for instance operating pressure, cycle time, product geometry, labour skills or energy costs. In the case of equipment, the more frequently it is used the more cost-effective it is. Additionally, in the course of time, the technology maturates and the food manufacturer gains experience. This usually decreases the costs of equipment and process operations.

HPP seems to be especially successful in the ready meals sector as it offers unique opportunities, like the production of fresh-taste and safe food with desirable shelf-life.[163]

[162] Norton & Sun, 2008: 29

[163] Ting & Marshall, 2002 in Norton & Sun, 2008: 29

5. The high-pressured food on the market

5.1. Background

The first research concerning the application of high pressure processing in the food industry was performed at the beginning of the 20th century by Hite. However, at that time it was not commercially feasible to preserve foods by high pressure as it was not possible to generate pressure that would be high enough.[164]

The process was forgotten for nearly a century till the 1990s, when the industrial application of high pressure processing in the food area was used in Japan. The success of HPP in food preservation has stimulated the research in other countries. In order to commercialise the process, a wide range of scientific discipline has been taken into account, including microbiology, chemistry or engineering.[164] Currently, HPP is applied to a wide range of foods.

5.2. High-pressured food

The HP installations are not spread uniformly amongst the regions. In early 90s, Asia dominated in regard to HP applications in the food industry.

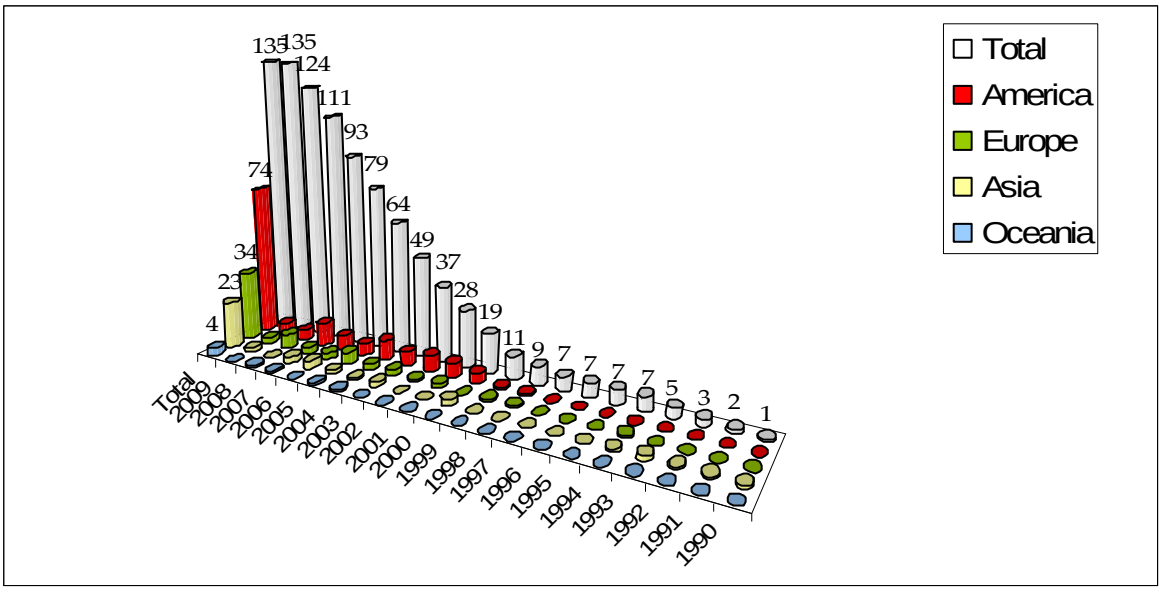


Figure 11. The number of the high pressure equipment installed worldwide versus a year of instalment. **Source:** NC Hyperbaric, 2010

Since 2000, there have been more and more HP installations in North America, which is the current leader in HPP applications (74 HP installations in 2009). At the same time, there were only 34 HP equipments in Europe (nearly two times less than in North America). The smallest number of HP equipment was installed in Asia (23) and Oceania (4) [Figure 11]. The increase of HPP applications in the food industry has been almost exponential since 2000.[165]

[164] Ledward et al., 1995: 1

[165] NC Hyperbaric, 2010 (obtained from Dr Carolle Tonello)

High pressure processing may be applied to a wide range of foods, but in practice HPP is not homogenously used throughout all food industry [Figure 12 & 13].
Vegetable and meat products are the most often subjected to the pressure treatment. HPP was also significantly used in beverages, seafood and fish sectors.[166]

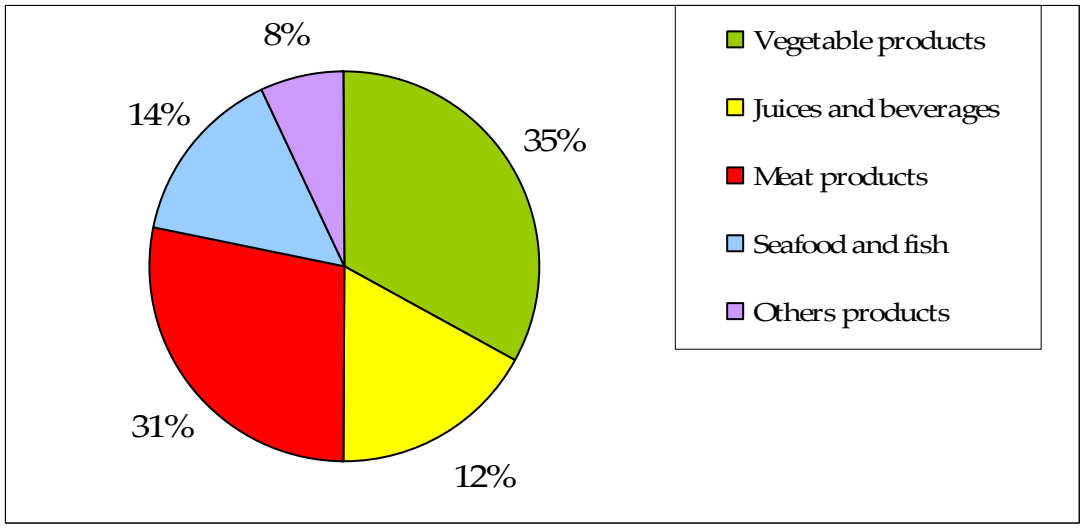


Figure 12. Application of HPP in different segments of food industry. **Source:** NC Hyperbaric, 2010

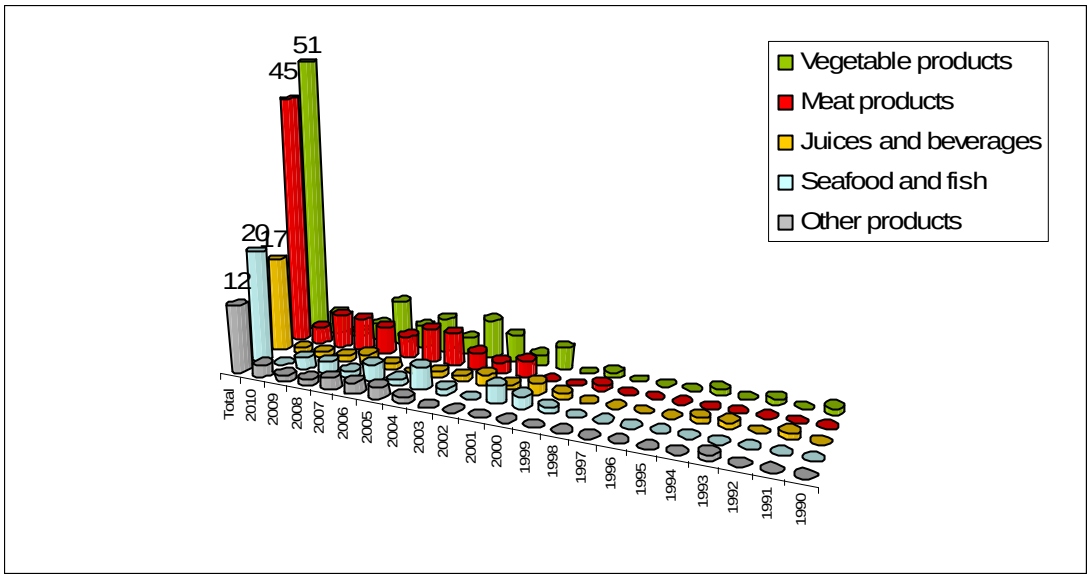


Figure 13. The industrial sector for the instalment of the high pressure equipment. **Source:** NC Hyperbaric, 2010

5.2.1. Vegetable and fruit products

High-pressured vegetable and fruit products are available on the market They includes: jams, coatings, sauces, fruit jellies, fruit desserts, fruit-based purees and sauces, precooked rice and hypoallergenic rice, avocado based products, sliced onions, soya products, tofu and ready-to-eat vegetable dishes.[167]

[166] Norton & Sun, 2008: 3
[167] Annex I Table 1

The main aims of HPP in these food products are:

- sanitization,
- gelification,
- preservation of fruit colour and fresh taste,
- unfolding of allergenic proteins,
- enzymes (PPO) inactivation,
- increase of shelf-life without the help of chemicals.[167]

5.2.2. Juices and beverages

High pressure may be applied to a wide range of juices and beverages: fruit and vegetable juices, smoothies, lemonade and alcoholic beverages.[168]

The pressure treatment aims at:

- yeast inactivation without thermal treatment in the case of sake,
- sanitization,
- keeping sensory qualities of fresh juices,
- keeping anti-cancer properties of fresh juice.[168]

5.2.3. Meat products

The meat products that may be treated by high pressure include sliced ham, turkey or chicken cuts, ready-to-eat products, and whole pieces of cured ham.[169]

The pressure treatment aims at:

- sanitization without colour and taste modifications,
- *Listeria* spp. destruction,
- increase of shelf-life,
- reduction of additives.[169]

5.2.4. Seafood products

The seafood products that can be treated with high pressure include shellfish, crustaceans, shrimps, prawns and ready-to-eat fish products.[170]

The most important advantages of HPP in the case of seafood are:

- opening of the shells,
- destruction of *Vibrio vulnificus*[171],
- sanitization of sliced fish without colour and taste modifications,
- increase of shelf-life,
- reduction of additives.[170]

[168] Annex I Table 2

[169] Annex I Table 3

[170] Annex I Table 4

[171] *Vibrio vulnificus is a pathogenic bacterium that occurs in* shellfish and can cause serious illness or even human death.

The primary aims of HPP application in seafood were food safety issues, like controlling the microorganisms, but also extension of product shelf-life. Currently, the commercialization of high-pressured seafood is often connected with economic benefits.[172]

In the cases of the lobster and crab industries, HPP makes it possible to place on the market fresh and shucked meat which does not have to be treated with heat [Figure 14]. Another strong point of HPP is that meat recovery is increased by even 50% comparing to traditional cooking methods. Additionally, product weight is increased by as much as 10% from the natural hydration of proteins, and improves product quality (improved texture).[172]

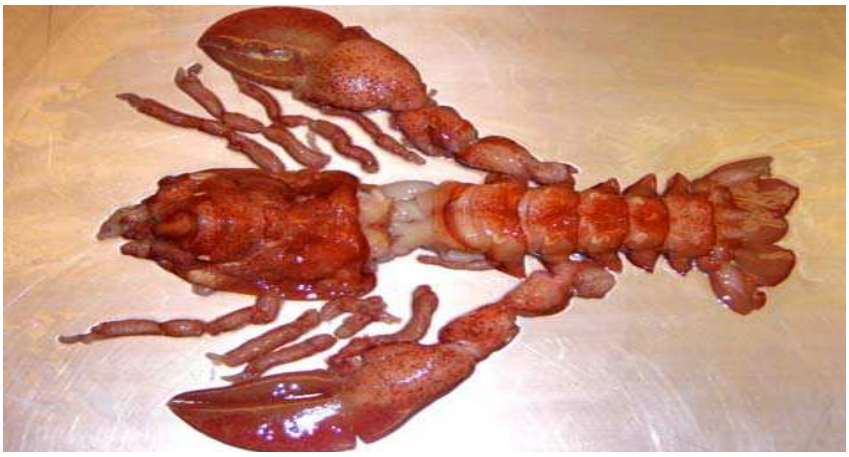


Figure 14. Complete removal of meat from Maine lobster using high pressure (HPP) technology **Source:** Raghubeer, 2007

Furthermore, physical damage of meat from shucking knives are reduced, and there is a possibility to find a new market for raw lobster and crab meat, for instance in the sushi industry.[172]

In the case of shellfish, pressure treatment is used to open and release the meat from the shells [Figure 15]. This can greatly impact the costs of labour, even by more than 50%. The parameters of HPP that are usually applied for shucking are pressures between 250 and 400 MPa and time between 1 and 3 minutes.[172]

Figure 15. Shellfish shucked by hand (left side of the picture) and by HPP (right side of the picture) **Source:** NC Hyperbaric, 2006

[172] Raghubeer, 2007: 1-5 (obtained from Avure Technologies)

Seafood, such as oysters, is consumed raw, hence HPP may improve protection of public health.[172]

5.2.5. Dairy products

Even though milk was the first product treated with high pressure, currently there are no high-pressured dairy products available on the market. The reasons of this situation are the complex changes induced in milk products by high pressure.[173]

5.3. History of high pressure food processing in the EU

Nowadays, there are more than thirty HP installations in Europe [Figure 13] which seems to be a relatively small number if the size of whole food industry in Europe is considered. HP installations in food industry are mainly applied to meat products, as well as vegetable and fruit products. Examples of high-pressured foods available on the EU market are presented in Table 5 (Annex II).

The first high-pressured product that was brought to the market was orange juice. It was in 1994 and the juice was produced by UltiFruit® in France.[174]

Then, three years later, Regulation (EC) No 258/97 of the European Parliament and the Council concerning novel foods and novel food ingredients (NFR) came into force on 15 May 1997. This piece of legislation stated that food products that have been produced by novel processes fall within its scope if two conditions are met: process was not used before 15 May 1997 and it causes significant changes in food product compared to its traditional counterpart.[175]

In December 1998, the Groupe Danone put the request to the competent authority of France (Agence française de sécurité sanitaire des aliments (AFSSA)) for placing on the market high-pressured fruit preparations in accordance with the NFR. In May 2001, the European Commission took the positive decision concerning placing this products on the EU market.[176]

Later on, in July 2001 the competent authorities of the member states agreed *"(…) that in future* ***the national authorities*** *should decide on the legal status of high pressure treated foodstuffs on the basis of appropriate data provided by the manufacturer. If the competent authority arrives at the decision, that the product does not fall within the scope of Regulation (EC) No 258/97 and thus can be marketed without approval, the Commission and the other Member States should be informed accordingly."*[174]

The same year, the UK Advisory Committee on Novel Foods and Processes (ACNFP) received two separate requests for an opinion in accordance with the NFR. The first application was received from ATA SpA Foods of Italy and concerned fruit based products: salads, purees, smoothies and juices that were treated with high pressure. The second application was received from Orchard House Foods and involved fruit based products:

[173] Huppertz et al., 2006 in Norton & Sun, 2008: 19
[174] Eisenbrand et al., 2005: 3
[175] ACNFP, 2006: 1
[176] Commission Decision (2001/424/EC)

lemonades, fruit crushes, and smoothies treated with high pressure. After providing relevant information concerning food safety, both companies were offered a positive Scientific Opinion.[177]

In the letter to Orchard House Foods, ACNFP states: *"The ACNFP is of the opinion that as a successful application under the (EC) 258/97 for HPP Fruit Based Products was made by Danone in 2000,* ***High Pressure Processing per se is no longer considered a novel process****. However any future use of HPP that used different operating conditions, or treated substantially different foodstuffs from those described in the Danone application must be able to* ***demonstrate adequate kill of pathogenic bacteria****, and have measures in place that prevent the germination of Clostridium botulinum spores."*[178]

In 2001, the competent authority of Spain (Agencia Española de Seguridad Alimentaria (AESA)) notified that high pressure pasteurised cooked ham was not considered novel food and may be brought to the EU market without approval. Then, in 2002 the British Food Standards Agency (FSA) informed that high-pressured oysters were not novel foods as well.[174]
The Minutes from the 51st meeting of the UK Advisory Committee on Novel Foods and Processes (ACNFP) held on 13 September 2001 provides the following information on high pressure processing:
"(…) the Commission had concluded that ***High Pressure Processing was no longer considered to be a novel process****. Nevertheless* ***some Member States were concerned that the foods treated in this way should still be assessed for their safety****. A copy of the letter sent to the Commission asking that guidance be provided on the use of High Pressure Processing technology was tabled for Members' information.*
Members emphasised that the data required for a safety assessment would be determined on ***a case by case basis****, but that in all cases* ***microbiological data*** *on products should be provided. They also noted that* ***allergenicity and nutrition issues*** *would need to be addressed."*[179]

The aim of second Open Meeting of ACNFP, which was held in Cambridge on 13 November 2002, was to give the general public the opportunity to discuss some of the issues that fall within the remit of the ACNFP. During this meeting, Mr. Nigel Rogers from Flow UK asked whether it is possible to get technology out of the novel category once and for all.
The ACNFP explained their view *"*(…) *that* ***HPP was an alternative to existing processes such as pasteurisation*** *and said that there was no evidence to suggest that processed foods were less safe than unprocessed foods."*[180]

Furthermore, on the website of ACNFP, the following note was made public: *"*(…) *although not mentioned at the meeting, the European Commission has discussed the status of HPP with representatives from the EU member states. As a result, it has been accepted that* ***the process does not produce any material change in the composition of the food and as a result does not***

[177] ACNFP/MIN/49, 2001
[178] ACNFP, 2001
[179] ACNFP/MIN/51, 2001
[180] ACNFP Open Meeting minutes, 2002

***require further assessment under the novel foods procedures**. The Food Standards Agency has informed the company of this."*[180]

5.4. "Danone Case"

As mentioned in previous section, till now one food manufacturer - Groupe Danone in the EU has asked for product approval under Regulation (EC) No 258/97.

On 3 December 1998, a French company – Groupe Danone put the request to the competent authority of France (AFSSA) for placing on the market *"pasteurized fruit-based preparations produced by high-pressure pasteurization."* Groupe Danone in the application proposed process parameters of 8 kbar (800 MPa) for 6 minutes at 20°C.[181]
The application was supported by scientific studies, which included: detailed physico-chemical characterization, cytotoxicity, mutagenicity, impact of high pressure treatment on allergenic risk, microbial challenge tests, contact material migration tests and HACCP plan. The main objective that Groupe Danone took into consideration was that HP product would be: *"at least as safe as conventionally processed products*."[181]
The results presented by Groupe Danone revealed that this HP product was neither cytotoxic nor mutagenic. Moreover, the stability of vitamins C, B_2 and B_6 was equivalent or improved in comparison to the traditionally produced products. The inactivation of vegetative bacteria was equivalent to heat treatment. However, the bacterial spores were shown as resistant to the employed pressure. Therefore, the applied risk management was based on prevention of spores germination and growth. Groupe Danone defined also the agronomic and manufacturing conditions.[182]

The application was accepted by AFSSA and the initial assessment report was forwarded to the Commission on 8 February 2000. Later on, on 16 May 2000 the report was forwarded to all member states by the Commission.[182]

During the time to review the application by the member states (60 days), reasoned objections were raised. Consequently, the decision was taken in accordance with the procedure laid down in Article 13 of the NFR.[183]

*"At a meeting on 9 October 2000 experts of Groupe Danone were called upon to provide the necessary information in response to the comments and objections raised by Member States. In particular, a technical explanation was given **that the high-pressure treatment provides the same level of safety as the generally used heat pasteurisation process with respect to the bacteriological risks and the allergenic potential**."*[184]

The initial assessment report and the summary of the application were also sent to the competent authority of United Kingdom on 23 June 2000. The Advisory Committee on Novel Foods and Processes (ACNFP) was asked to comment on the received documents and to consider whether they agreed with the proposed approval. ACNFP met on 6 July 2000 and

[181] O'Brien, 2003 (Presentation)
[182] ACNFP/46/4, 2000
[183] Recital 2 of Decision 2001/424/EC
[184] Recital 3 of Decision 2001/424/EC

reviewed the summary application and initial assessment report of the French competent authority.[185]

ACNFP required clarification of a number of points regarding the specifications of the food preparation, quality assurance testing and the process controls. Furthermore, ACNFP stated that so as to protect against botulism, the authorization for the use of high-pressured fruit preparations should be applicable only to final products. These products should comply with the recommendations included in the Report on Vacuum Packaging and Associated Processes published by the UK Advisory Committee on the Microbial Safety of Food (ACMSF).[186]

Generally, ACNFP *"(…) agreed with the opinion of the French Competent Authority and was content for clearance to be given for the fruits listed when processed in the manner described in the application dossier only."*[186]

ACNFP replied to the European Commission in the letter expressing its views on 17 July 2000 (Annex III).[186&186]
The letter specifies the conditions that are relevant for ensuring the safety of high-pressured fruit preparations. It states: *"In particular, in addition to chill temperatures, which should be maintained throughout the chill chain, the following controlling factors should be used singularly or in combination* ***to prevent growth and toxin production by psychrotrophic Clostridium botulinum in prepared chilled foods*** *with an assigned shelf-life of more than 10 days;*

- *A heat treatment of 90°C for 10 minutes or equivalent lethality,*
- *a pH of 5 or less throughout the food and throughout all components of complex foods,*
- *a minimum salt level of 3.5% in the aqueous phase throughout the food and throughout all components of complex foods,*
- *an a_w of 0.97 or less throughout the food and throughout all components of complex foods."*[187]

"Where chilled storage is the sole controlling factor, chilled foods stored between 5°C and 10°C should have an assigned shelf-life of 5 days or less. If a shelf-life of up to 10 days is required, the chilled storage temperature should be 5°C or below."[187]

In April 2001, the Standing Committee on Foodstuffs delivered by qualified majority a favourable opinion on a Draft Commission decision on authorising pasteurised fruit-based preparations.[187]

Additionally, during the meeting of the Standing Committee on Foodstuffs, it *"(…) was clarified that the mention "pasteurised by high-pressure treatment" in the labelling of the product should refer to the fruit preparations as ingredient, but not necessarily to the whole product."*[188]
Moreover, Germany proposed to carry out a follow-up research on *"(…) the allergenic potential of allergens that are inactivated by heat treatment under the conditions of high-pressure treatment."* Sweden who were opposed to the Draft Decision, stated: *"(…)that the specification*

[185] ACNFP/MIN/46, 2000
[186] ACNFP, 2000: 7, 63-64
[187] www.reading.ac.uk/foodlaw/news/eu-01-67.htm

for pH, storage temperature etc. should be applied to the whole foodstuffs and not only to the fruit-preparations."[188]

On **23 May 2001**, the Commission took the positive decision authorising placing on the market of pasteurised fruit-based preparations using high-pressure pasteurisation under the NFR (**Commission Decision 2001/424/EC**) on the basis of initial assessment report prepared by the French competent authority. It was concluded that *"(…) high pressure treatment (8 kbar for 6 minutes at 20°C) may be* ***safely used instead of the specified generally used heat pasteurisation process*** *(85°C for 10 minutes)."*[188]

Annex of Commission Decision specified the HP fruit preparations. It includes the following information about fruit preparations treated by HP: types of fruits, conditions of fruit storage before high-pressure treatment, the percentage of added fruits to other ingredients, pH, the dissolved sugar-to-water mass ratio of preparations (°Brix), water activity (a_w), and conditions of final storage (Annex IV).[189]

Although the approval was granted, the high pressured fruit-based preparations were never brought by Danone Groupe to the EU market.[190]

[188] Recital 1 of Decision 2001/424/EC

[189] Decision 2001/424/EC

[190] Information obtained during the phone interview

6. European Legislation and High Pressure Processing

This chapter provides brief information on history of European food law, and describes the important pieces of EU legislation on HPP which relate mainly to process and product.

The author is of the opinion that the knowledge on history of European food law, especially on the food law transformations, may improve reader's understanding of the HPP status within the EU. History also shows that food law is a dynamic system that evolves over time due to changes in the food industry but also due to the occurrence of practical problems, such as food safety incidents/crisis.

6.1. History of European Food Law

European food law has been formed within few phases along during the creation of the European Union. A first phase of this process lasted from the beginning of the European Community in 1958 till 1979. The most important issue was to create an internal market for food products in the EU, and the main instruments to achieve that goal were vertical directives.[191]

A second phase of changes began just after the so-called case of "Cassis de Dijon". This case turned out to be a turning point and played a tremendous role in establishing the principle of mutual recognition. In simple words, this principle means that products which *"(…) have been lawfully produced and marketed in one of the member states, may not be kept out of other member states on the grounds that they do not comply with national rules."* At this phase, the main focus was still the creation of internal market, but the main instruments from now on were horizontal directives.[193]

The third phase has started just after the BSE crisis and other food scares that took place in the EU in mid-1990s.. The food safety crises revealed the imperfection of European food law regarding food safety in the EU and subsequently induced changes in the legal system European food law began to focus on food safety. In 2000, a *"White Paper on Food Safety"* was published by the Commission. The document was a plan for future European food law which described changes in focus from orientation on internal market to orientation on both food safety and internal market. Regulations have become the most important instruments from now on.

Since the appearance of a *"White Paper on Food Safety"*, a number of important legislations have entered into force, and there are still many proposals under consideration.[193]

6.2. Introduction to European Legislation

Current food law in the EU has envolved since 1950s. European food law consists of many different pieces of legislation and thus, it is often perceived as a complex system which requires specific knowledge in order to follow relevant provisions. Being aware of the challenge to describe all important pieces of legislation on HPP in straight forward way, the

[191] van der Meulen & van der Velde, 2008: 229-230, 234

author decided to adopt the frame proposed by van der Meulen and van der Velde [2008] [Figure 16].[192]

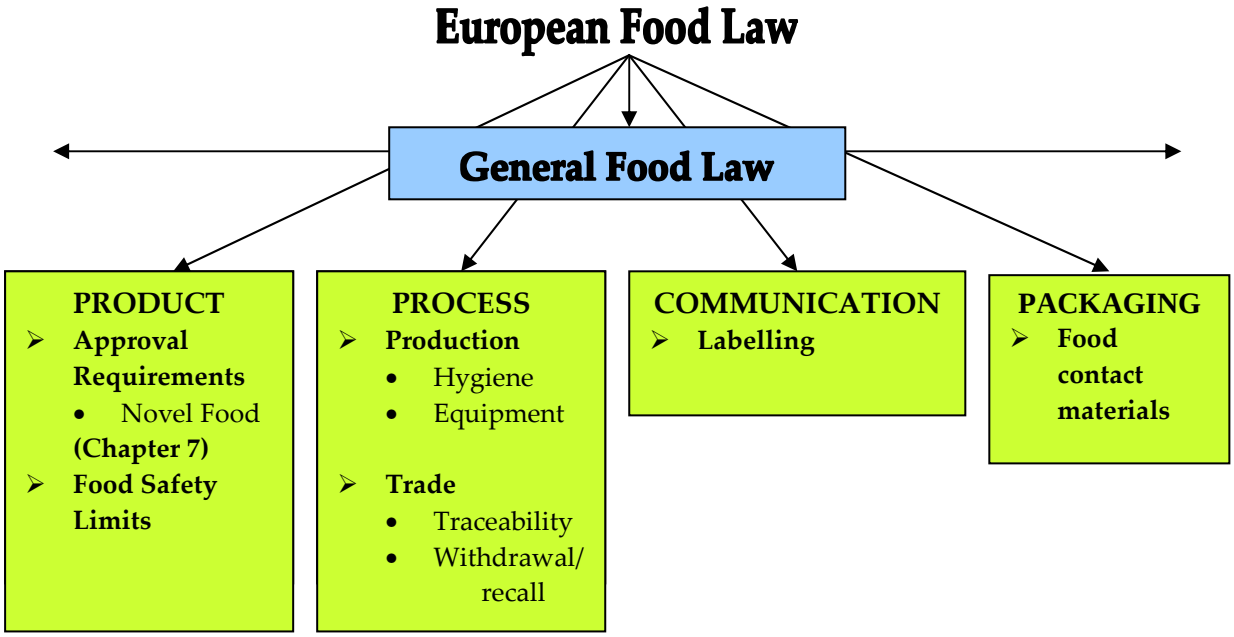


Figure 16. The elements of European food law. **Source:** van der Meulen & van der Velde, 2008

European food law may be divided into several elements. In the case of high pressure processing, the most important rules seem to be those which apply to *product*, *process*, *communication* and *packaging* [see Figure 16].[193] Therefore, the pieces of legislation in this chapter will be grouped and discussed under the following main headings: general food law, rules applying to product, rules applying to process, rules applying to communication and rules applying to packaging. The only exception is legislation concerning approval requirements for novel foods which will be described in more details in separate chapters - chapter 7 (Novel Foods Regulation) and chapter 8 (Proposal for a New Novel Foods Regulation).

6.3. General Food Law

The first piece of legislation that will be discussed here is Regulation (EC) No 178/2002, also known as General Food Law (GFL)[193] The GFL is a basis of a general part of food law. Hence, it is relevant for all food brought to the EU market, including high-pressured foods.
Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety was also the first step in reforming the legal system.[194]

The general objectives of the GFL are the protection of human life and health as well as consumers' interests, but also assurance of free movement of food and feed in the EU

[192] van der Meulen & van der Velde, 2008: 251
[193] van der Meulen & van der Velde, 2008: 253
[194] OJ L 31, 1.2.2002, pp. 1-24

market.[195] To meet those objectives, food law is based on risk analysis, which takes into account scientific evidence.[196]

Additionally, the GFL introduces the general principles which are valid in the EU. One of these principles is **the precautionary principle** which states that when *"(…) the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures (…) may be adopted, pending further scientific information (…)"* However, those measures must be proportionate, no more restrictive to trade than required, with regard to technical and economic feasibility and other legitimate factors. Moreover, they shall be reviewed by the competent authorities within a reasonable period of time.[197]
This principle is applicable to novel foods, including those produced by novel processes. Hugas et al. [2002] stated that the Novel Foods Regulation *"(…) establishes an evaluation and a license system compulsory (…)"* for a novel food.[198]

The main requirement of the GFL is that **unsafe food** shall not be placed on the EU market. Food is considered to be unsafe in the two cases if it is injurious to health, for instance the product is contaminated with pathogenic bacteria, and/or unfit for human consumption, for instance the product is spoiled.[199]
Another important requirement of the GFL is that food law shall protect the consumers' interests and provide consumers with the possibility to make informed choices relating to the food they consume.[201] The GFL also provides a wide range of useful definitions to clarify the provisions of legislation.

It is important to note that the food business operator is obligated by the GFL to follow the requirements of food law, and also to verify if those requirements are met at all stages *"from farm to fork"*.[200]

6.4. Rules concerning product

The rules of European food law can be classified into four legislative approaches: "*free*", "*conditional*", "*restricted*" and "*banned*". [201] The so-called **"*free*" approach** is applicable to the conventional ingredients with a history of safe use. The so-called **"*conditional*" approach** requires pre-market approval of foods. It is applicable to additives, sweeteners, supplements, genetically modified foods and novel foods. Another approach is the **"*restricted*" approach** and it allows only limited amount of certain substances in foods, for instance residues of pesticides or veterinary drugs. The last but not least is the **"*banned*" approach**, which forbids some materials (for instance BSE risk material) to be used in foods.[203]

This section describes a group of rules that apply to the high-pressured foods; hence it focuses on the ***"conditional"* approach** (Paragraph 6.4.1., chapters 7 and 8) and on the ***"restricted"* approach** (Paragraph 6.4.2.).

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[195] Article 5(1/2) of Regulation 178/2002
[196] Article 6 of Regulation 178/2002
[197] Article 7 of Regulation 178/2002
[198] Hugas et al. [2002]: 367
[199] Article 8 and 14(1) & (2) of Regulation 178/2002
[200] Article 17(1) of Regulation 178/2002
[201] van der Meulen & van der Velde, 2008: 283-284

6.4.1. Approval requirements

Only one piece of legislation from the *"conditional"* approach - a pre-market approval for novel foods produced by the novel processes (NFR) seems to be significant for high-pressured foods. Chapter 7 provides broad information on the NFR and chapter 8 describes provisions of the Proposal of the Novel Foods Regulation.

It is essential for food producers in the EU to be aware that in some cases approval under other legislation than the NFR may be required for the high-pressured foods as well.

6.4.2. Food safety limits

Hazard is defined in the GFL as: *"(…) a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect."*[202] Most of the hazards are regulated by rules based on the *"restricted"* approach.
However, when the risk, which is defined as *"(…) a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard"*[203] is perceived as unacceptable, the *"banned"* approach should be applied.
As it is not always possible to eliminate or avoid hazards in food products, the legislation restricts their presence and sets up the safety limits in order to guarantee the protection of consumer's health. This limit is called a food safety criterion and is described as: *"(…) a criterion defining the acceptability of a product or a batch of foodstuff applicable to products placed on the market."*[204]

The relevant pieces of legislation concerning safety criteria as well as high-pressured foods are described briefly below.

Regulation (EEC) No 315/93 lays down Community procedures for contaminants in food. This legislation provides the basic principles on contaminants in foods, and introduces the definition of contaminant which includes both chemical and biological hazards. This regulation is only relevant for those contaminants that are not regulated by other more specific pieces of legislation.[205]
The most relevant provisions of this legislation are included in Article 2, which states that: "*Food containing a contaminant in an amount which is unacceptable from the public health viewpoint and in particular at a toxicological level shall not be placed on the market."*[206]
An important requirement of this legislation is to keep contaminants as low as can reasonably be achieved by applying good practices at all steps of food chain.[208]
Regulation (EEC) No 315/93 also describes a need of establishing the maximum tolerances. *"These tolerances shall be adopted in the form of a non-exhaustive Community list and may include:*
— limits for the same contaminant in different foods;
— analytical detection limits;
— a reference to the sampling and analysis methods to be used."[209]

[202] Article 3(14) of Regulation 178/2002
[203] Article 3(9) of Regulation 178/2002
[204] Article 2(c) of Regulation 2073/2005
[205] OJ L 37, 13.2.1993, pp. 1-3
[206] Article 2 of Regulation 315/93

Foods containing microbiological hazards are perceived as a major source of food-borne diseases in humans.[207] As high pressure processing is used as an attractive alternative for thermal preservation technique, the main aim of this technology is to inactivate microorganisms and extend the shelf-life of food products. Therefore, it is crucial that HPP decreases microbial contamination below the microbiological criteria.[208]

The microbiological criteria are set up in **Regulation (EC) No 2073/2005** on microbiological criteria for foodstuffs.[209] The regulation explains the term ***"microbiological criterion"*** as *"(…) a criterion defining the acceptability of a product, a batch of foodstuffs or a process, based on the absence, presence or number of micro-organisms, and/or on the quantity of their toxins/metabolites, per unit(s) of mass, volume, area or batch;"*[210] and also provides the definition of ***microorganisms*** which includes *"(…) bacteria, viruses, yeasts, moulds, algae, parasitic protozoa, microscopic parasitic helminths, and their toxins and metabolites;"*[211]
The regulation lays down food safety criteria for such microbiological hazards as: *Listeria monocytogenes*, *Salmonella*, *Staphylococcal* enterotoxin, *Enterobacter sakazakii* (now *Cronobacter* spp.), *Escherichia coli* and histamine.[212]

It is important to note that microbiological criteria allow assessing the acceptability of food products as well as enable to check safety of production, handling and distribution processes.[213] To ensure food safety, the preventive measures, such as good hygiene practice or procedures based on hazard analysis and critical control point (HACCP) should be applied.[214] HACCP procedures and other hygiene control measures can be validated and verified by using microbiological criteria.[215] Therefore, it is essential for food manufacturers to combine microbiological criteria with HACCP-based procedures and other hygiene control measures in an integral form.[216]

Regulation (EC) No 852/2004 on the hygiene of foodstuffs, which is described in more details in next section, puts an obligation on food business operators to comply with microbiological criteria.[217] This includes "(…) *testing against the values set for the criteria through the taking of samples, the conduct of analyses and the implementation of corrective actions, in accordance with food law and the instructions given by the competent authority."*[218]

Additionally, Regulation (EC) No 2073/2005 provides process hygiene criteria[219] as well as rules for sampling and preparation of test samples.[220] However, there is also some discretion

[207] Recital 1 of Regulation 2073/2005
[208] Norton & Sun, 2008: 3
[209] OJ L 338, 22.12.2005, pp. 1-26
[210] Article 2(b) of Regulation 2073/2005
[211] Article 2(a) of Regulation 2073/2005
[212] Chapter 1 of Annex I of Regulation 2073/2005
[213] Recital 4 of Regulation 2073/2005
[214] Recital 5 of Regulation 2073/2005
[215] Recital 5 of Regulation 2073/2005
[216] Recital 4 of Regulation 2073/2005
[217] Article 4 of Regulation 852/2004
[218] Recital 6 of Regulation 2073/2005
[219] Chapter 2 of Annex I of Regulation 2073/2005
[220] Chapter 3 of Annex I of Regulation 2073/2005

since "*Food business operators should decide themselves the necessary sampling and testing frequencies as part of their procedures based on HACCP principles and other hygiene control procedures.*"[221]

Another important piece of legislation - **Regulation (EC) No 1881/2006** sets maximum levels for certain contaminants in foods.[222] This regulation was established to keep contaminants at levels which are toxicologically acceptable. Recital 4 of this regulation marks out that: "*Maximum levels should be set at a strict level which is reasonably achievable by following good agricultural, fishery and manufacturing practices and taking into account the risk related to the consumption of the food."* Furthermore, it adds that: "*In case of contaminants which are considered to be genotoxic carcinogens or in cases where current exposure of the population or of vulnerable groups in the population is close to or exceeds the tolerable intake, maximum levels should be set at a level which is as low as reasonably achievable (ALARA)."* The reasoning behind this rule is to prevent and reduce contamination as far as possible.[223]

Food products exceeding the maximum levels of contaminants are not allowed to be placed on the EU market either as such, after mixture with other food products or used as an ingredient in other foods.[224]
This piece of legislation regulates limits for: nitrites, mycotoxins including aflatoxins, achratoxin A, patulin, deoxynivalenol, zearalenone, fumonisins, T-2 and HT-2 toxin, heavy metals including: lead, cadmium, mercury and tin, 3-monochloropropane-1,2-diol (3-MCPD), dioxins, PCBs and PAH.[225]

Other important pieces of legislation concerning food safety limits include **Regulation (EC) No 396/2005** on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC[226], and **Regulation 470/2009**[227] and **Regulation 37/2010**[228] concerning veterinary drugs.

6.5. Rules concerning process

This section describes the most relevant rules on process since safety of high-pressured food also depends on each stage of production.
The GFL provides the definition of the term "*stages of production, processing and distribution"* which "*(…) means any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed;"*[229]

[221] Recital 23 of Regulation 2073/2005
[222] OJ L 364, 20.12.2006, pp. 5-24
[223] Recital 4 of Regulation 1881/2006
[224] Recital 6, Article 1 & Annex of Regulation 1881/2006
[225] OJ L 70, 16.3.2005, pp. 1-16
[226] Regulation (EC) No 396/2005 is applicable from 1 September 2008; OJ L 70, 16.3.2005, pp. 1-16
[227] replaces Regulation 2377/90 on 6 July 2009; OJ L 152, 16.6.2009, pp. 11-22
[228] replaces Regulation 2377/90 on 9 February 2010; OJ L 15, 20.1.2010, pp. 1-72
[229] Article 3(16) of Regulation 178/2002

6.5.1. Production and hygiene rules

Food safety is one of the most important issues for novel processes, such as HPP. It must be guaranteed by the food business operators during all stages of production, processing and distribution.

It is important to note that: "*Food safety is a result of several factors: legislation should lay down minimum hygiene requirements; official controls should be in place to check food business operators' compliance and food business operators should establish and operate food safety programmes and procedures based on the HACCP principles.*"[230]

Consequently, food safety in the EU is supported by the set of regulations, known also as "*hygiene package*":

- **Regulation (EC) 852/2004** on the hygiene of foodstuffs,[231]
- **Regulation (EC) 853/2004** laying down specific hygiene rules for food of animal origin,[232]
- **Regulation (EC) 854/2004** laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.[233]

The "*hygiene package*" was adopted in April 2004 by the European Parliament and the Council, and it became applicable on 1 January 2006. These rules are also supported by Directive 2004/41/EC[234] and Regulation (EC) No 882/2004[235] on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Additionally, those regulations are accompanied by guidance documents which provide the explanations of the regulations. They can be helpful for food business operators to understand the provisions of the regulations, and consequently to comply with them.[236]

Food hygiene or ***hygiene*** is defined in Regulation (EC) 852/2004 as *"(…) the measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use."*[237]

To ensure food safety, hygiene should be present at all stages, beginning with primary production and ending with placing food on the market.

Moreover, an integrated approach was found as essential to ensure that food safety would not be compromised by any food business operator along the food chain.[238] Hence, every food business operator in the EU is obligated to notify the appropriate authority and to apply for registration of each establishment under her/his control that carries out any of the stages of food production, processing or distribution. Additionally, the competent authority should always have up-to-date information on establishments.[239]

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[230] Recital 12 of Regulation 852/2004:

[231] OJ L 226, 25.6.2004, pp.1-54

[232] OJ L 139, 30.4.2004, pp. 55-205

[233] OJ L 226, 25.6.2004, pp. 83-127

[234] It repeals certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption; OJ L 195, 2.6.2004, pp. 12-15

[235] OJ L 191, 28.5.2004, pp. 1-59

[236] van der Meulen & van der Velde, 2008: 331-337

[237] Article 2(a) of Regulation 852/2004

[238] Recital 8 of Regulation 852/2004

[239] Article 6(2) of Regulation 852/2004

In the case of establishments that produce or handle food products of animal origin, the food business operator has to obtain the approval from the competent authority of the member state in the EU.[240]

Regulation 854/2004 lays down the provisions concerning approval and approval number[241], while Regulation 882/2004 obligates the member state to make procedures that have to be followed by the food business operators to gain the approval.[242]

The core of the hygiene legislation is **Regulation (EC) 852/2004**, which lays down general rules for food business operators on the hygiene of foods. As mentioned in Article 1(1)*: "This Regulation shall apply to all stages of production, processing and distribution of food and to exports, and without prejudice to more specific requirements relating to food hygiene.*"

The most essential principles described in Regulation (EC) 852/2004 are that:

- "*primary responsibility for food safety rests with the food business operator;*
- *it is necessary to ensure food safety throughout the food chain, starting with primary production;*
- *it is important, for food that cannot be stored safely at ambient temperatures, particularly frozen food, to maintain the cold chain;*
- *general implementation of procedures based on the HACCP principles, together with the application of good hygiene practice, should reinforce food business operators' responsibility;*
- *guides to good practice are a valuable instrument to aid food business operators at all levels of the food chain with compliance with food hygiene rules and with the application of the HACCP principles;*
- *it is necessary to establish microbiological criteria and temperature control requirements based on a scientific risk assessment;*
- *it is necessary to ensure that imported foods are of at least the same hygiene standard as food produced in the Community, or are of an equivalent standard."*[243]

Regulation (EC) 852/2004 introduces three different instruments to ensure safety of food products: ***prescriptive rules***, ***procedures based on the Hazard Analysis and Critical Control Point (HACCP) principles***, and ***guides to good hygiene practice***.[244]

The first type of instruments - ***prescriptive rules*** is present in many articles of Regulation 852/2004 and Regulation 853/2004, but also in two Annexes of the first regulation.
According to Article 4 of Regulation 852/2004, the food business operator from primary production should follow the provisions from Annex IA of this regulation and any specific requirements of Regulation 853/2004, while other food business operators, including the producers of HP food, are obligated to follow Annex II of Regulation 852/2004 and any specific requirements of Regulation 853/2004.
The rules from Annex II are the so-called "*prerequisites*" which have to be fulfilled by the food producers before HACCP is applied.

[240] Article 4 of Regulation 853/2004
[241] Article 3 of Regulation 854/2004
[242] Article 31 of Regulation 882/2004
[243] Article 1(1) of Regulation 852/2004
[244] van der Meulen & van der Velde, 2008: 339

The Annex consists of the following parts:

(I) General requirements for food premises,
(II) Specific requirements in rooms where foodstuffs are prepared, treated or processed,
(III) Requirements for movable and/or temporary premises,
(IV) Transport,
(V) Equipment requirements,
(VI) Food waste,
(VII) Water supply,
(VIII) Personal hygiene,
(IX) Provisions applicable to foodstuffs,
(X) Provisions applicable to the wrapping and packaging of foodstuffs,
(XI) Heat treatment,
(XII) Training.

Other specific hygiene measures include microbiological criteria for foodstuffs, temperature control requirements for foodstuffs, maintenance of the cold chain, sampling and analysis[245]. To implement successfully all hygiene measures, the food business operator may use the guides to good hygiene practice.[246]

The HACCP system is another important instrument which helps food business operators to attain food safety and control over the production process.[247] According to Regulation 852/2004, *"Food business operator shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles."*[248]

The HACCP principles are:

"(a) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;
(b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;
(c) establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;
(d) establishing and implementing effective monitoring procedures at critical control points;
(e) establishing corrective actions when monitoring indicates that a critical control point is not under control;
(f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively;
(g) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f)."[249]

Guides to good hygiene practice are the last instrument and they are developed by food industry itself. The national guides should be approved by the member states and registered

[245] Article 4(3) of Regulation 852/2004
[246] Article 4(6) of Regulation 852/2004
[247] Recital 13 of Regulation 852/2004; van der Meulen & van der Velde, 2008: 351
[248] Article 5(1) of Regulation 852/2004
[249] Article 5(2) of Regulation 852/2004

by the Commission. The acceptation of guides to good hygiene practice by the food business operators is voluntarily.[250]

The last two categories of instruments provide food business operators with a certain degree of autonomy since these instruments ought to be used according to their experience and knowledge.[251]

6.5.2. Legislation concerning equipment

The hygienic requirements concerning equipment are regulated by *"hygiene package"* (Paragraph 6.5.1.).

Another legislation which particularly concerns the high pressure equipment is **Directive 97/23/EC** on the approximation of the laws of the Member States concerning pressure equipment.[252] This Directive is also known as the Pressure Equipment Directive (PED). PED was adopted in May 1997 and came into force on 29 November 1999. However, until 28 May 2002, the producers of HP equipment had a choice between applying the directive and continuing with the application of existing national legislation. This directive is obligatory within the Community from 29 May 2002.

Directive 97/23/EC aims at harmonising law concerning the design, manufacture, testing and conformity assessment of pressure equipment and assemblies of pressure equipment within the Community. Consequently, it is mainly relevant for the producers of HP equipment. Nevertheless, the food business operator, who applies HPP in the EU, may use only HP equipment complying with this legislation.[253]

According to this directive, pressure equipment above specified pressure and/or volume thresholds must:

- *"be safe;*
- *meet essential safety requirements covering design, manufacture and testing;*
- *satisfy appropriate conformity assessment procedures; and*
- *carry the CE marking and other information."*[256]

"Pressure equipment and assemblies below the specified pressure/volume thresholds must:

- *be safe;*
- *be designed and manufactured according to sound engineering practice; and*
- *bear specified markings (but not the CE marking)."*[256]

6.5.3. Issues concerning trade

In the case of food safety problems, the GFL provides two instruments that may help to cope with food safety incidents or food safety crises – *traceability* and *withdrawal/recall*. Those instruments are relevant for all foods including high-pressured foods.

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[250] Article 4(6) of Regulation 852/2004; van der Meulen & van der Velde, 2008: 340

[251] van der Meulen & van der Velde, 2008: 347

[252] OJ L 181, 09.7.1997, pp. 1 – 55

[253] ec.europa.eu/enterprise/sectors/pressure-and-gas/documents/ped/

The principle of **traceability** puts requirements on the food business operators at all stages of food chain to have in place systems which allow identifying the suppliers and the purchasers (one step up as well as one step down) in order to identify quickly unsafe products in the food chain.[254] This principle has a vital role when withdrawal/recall of the unsafe food from the market is necessary.

The food business operator should **withdraw** any food from the market that is considered or believed not to be in compliance with the food safety requirements. If "*(…) the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection."*[255]
Moreover, the competent authorities should be informed about the withdrawal/recall, and the cooperation should be established.

6.6. Legislation concerning communication

The GFL provides the basic principles on labelling in Article 8 and 16. According to Article 8, "*Food law shall aim at the protection of the interests of consumers and shall provide a basis for consumers to make informed choices in relation to the foods they consume. It shall aim at the prevention of:*

(a) fraudulent or deceptive practices;
(b) the adulteration of food; and
(c) any other practices which may mislead the consumer."

Labelling is defined as "*(…) any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a foodstuff and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such foodstuff."*[256]
The labelling of HP food must be in compliance with the provisions of **Directive 2000/13/EC** on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs.[257] This directive is well known in the EU as the Labelling Directive. The Labelling Directive lays down the rules on the labelling of all foods as well as certain aspects relating to the presentation and advertising.[258]

The particulars that are required by the Labelling Directive for all food products are:
"*(1) the name under which the product is sold;*
(2) the list of ingredients;
(3) the quantity of certain ingredients or categories of ingredients (…);
(4) in the case of prepackaged foodstuffs, the net quantity;
(5) the date of minimum durability or, in the case of foodstuffs which, from the microbiological point of view, are highly perishable, the 'use by' date;
(6) any special storage conditions or conditions of use;
(7) the name or business name and address of the manufacturer or packager, or of a seller established within the Community.

[254] Article 18 of Regulation 178/2002
[255] Article 19(1) of Regulation 178/2002
[256] Article 1(3)(a) of Directive 2000/13/EC
[257] OJ L 109, 6.5.2000, pp. 29-42
[258] Article 1(1) of Directive 2000/13/EC

(8) particulars of the place of origin or provenance where failure to give such particulars might mislead the consumer to a material degree as to the true origin or provenance of the foodstuff;
(9) instructions for use when it would be impossible to make appropriate use of the foodstuff in the absence of such instructions;
(10) with respect to beverages containing more than 1,2 % by volume of alcohol, the actual alcoholic strength by volume."[259]

The date of minimum durability of foods specifies the boundary between safe and unsafe foods and it is defined as: "*(…) the date until which the foodstuff retains its specific properties when properly stored."*[260]
This date "*(…) shall be preceded by the words:*
— 'Best before …' when the date includes an indication of the day,
— 'Best before end …' in other cases."[261]
The *'use by date'* instead of the date of minimum durability should be applied if foods placed on the market are highly perishable.[262]

One of the provisions of the Labelling Directive states: "*The name under which the product is sold shall include or be accompanied by particulars as to the physical condition of the foodstuff or the specific treatment which it has undergone (e.g. powdered, freeze-dried, deep-frozen, concentrated, smoked) in all cases where omission of such information could create confusion in the mind of the purchaser."*[263]
Additionally, any food products treated with ionising radiation are required to bear indications in the language of the one of member states: *'irradiated'* or *'treated with ionising radiation'*. In contrary to irradiation, HPP does not have to be mentioned on the label.

6.7. Legislation concerning packaging

Another important legislation, which does not relate directly to food as such, but to the material of packaging, is **Regulation (EC) No 1935/2004** on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.[264]

"*The principle underlying this Regulation is that any material or article intended to come into contact directly or indirectly with food must be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties."*[265] This provision is important for high-pressured foods since food in the packaging may be treated by high pressure.

[259] Article 3(1) of Directive 2000/13/EC
[260] Article 9 of Directive 2000/13/EC
[261] Article 9(2) of Directive 2000/13/EC
[262] Article 10 of Directive 2000/13/EC
[263] Article 5(3) of Directive 2000/13/EC
[264] OJ L338, 13.11.2004, pp. 4-17
[265] Recital 3 of Regulation 1935/2004

The purpose of this legislation, similarly to the GFL, is to ensure a high level of protection of consumers' health and the interests as well as the effective functioning of the Community market.[266]

The subjects of this regulation will be materials and articles, including active and intelligent food contact materials and articles,[267] if:

- these materials and articles "*(…) are intended to be brought into contact with food;"*
- these materials and articles "*(…) are already in contact with food and were intended for that purpose;"*
- these materials and articles "*(…) can reasonably be expected to be brought into contact with food or to transfer their constituent.*"[268]

According to this regulation, materials should be produced in compliance with good manufacturing practice. Additionally, "*(…) under normal or foreseeable conditions of use, they* [those materials] *do not transfer their constituents to food in quantities which could:*

(a) endanger human health;
or (b) bring about an unacceptable change in the composition of the food;
or (c) bring about a deterioration in the organoleptic characteristics thereof."[269]

The legislation states also that the substances, which are used in the production of materials and articles intended to come into contact with food, should undergo a safety assessment.[270] "*The safety assessment of substances should be followed by a risk management decision as to whether those substances should be entered on a Community list of authorized substances.*"[271]

[266] Article 1(1) of Regulation 1935/2004
[267] Article 1(2) of Regulation 1935/2004
[268] Article 1(2) of Regulation 1935/2004
[269] Article 3 of Regulation 1935/2004
[270] Recital 12 of Regulation 1935/2004
[271] Recital 14 of Regulation 1935/2004

7. Novel Foods Regulation

This chapter is a continuation of chapter 6 and provides detail information on the authorisation requirement concerning novel foods (NF) including those produced by novel processes.

Novel foods are forbidden to be placed on the EU market unless the permission is granted by the competent authority. This rule applies to novel foods and food ingredients that have not been used for human consumption to a significant degree within the Community before 15 May 1997. In order to obtain permission (authorisation) the food business operator has to prove that the food product is safe.[272]

High pressure processing is a novel technology and high-pressured food may fall under the scope of Regulation (EC) No 258/97 as it happened on 23 May 2001, when the European Commission took decision to grant authorisation to place high pressured fruit-based preparations on the EU market.[273]

7.1. Introduction

Regulation (EC) No 258/97 concerning novel foods and novel food ingredients[274] was enacted on 27 January 1997 and came into force on 15 May 1997. This regulation is known as the **Novel Foods Regulation (NFR),** and its main objective is to protect proper functioning of the internal market within the Community as well as consumers' health.[275]

7.2. Determination of novelty of food product

The crucial aspect that should be taken into account when one determines the novelty of food product is the question if this food product has been consumed to significant degree in the EU before 15 May 1997. Food products commercialised in, at least, one Member State before that date, may be placed on the EU market under the "*principle of mutual recognition*"[276] However, van der Meulen & van der Velde [2008] described this criterion as rather vague.

An opinion on this criterion was also provided by the Advocate-General. The Advocate-General stated: "*Foods, within the meaning of Article 1(2) of Regulation No 258/97, are not used to a significant degree within the Community, if upon the entry into force of that regulation they were not on the market in one or more Member States. The reference date for determining the degree of significance of human consumption of the food in question is 15 May 1997.*"[277]

This opinion was not taken into consideration by the Court during the clarification of the concept. The Court did not explain the meaning of term but replaced the term "*significant degree*" with the term *"significant quantity*", which actually seems to be vague as well.[278]

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[272] van der Meulen & van der Velde, 2008: 283-834
[273] Commission Decision (2001/424/EC)
[274] OJ L 43, 14.2.1997, pp. 1-6
[275] Recital 1 & 2 of Regulation 258/97
[276] http://ec.europa.eu/food/food/biotechnology/novelfood/index_en.htm
[277] Opinion of A.G. Geelhoed of 3.2. 2005 in Case 211/03, at paragraph 97
[278] van der Meulen & van der Velde, 2008: 295

In a discussion paper concerning implementation of the NFR from 2002, the term "*human consumption to a significant degree within the Community*" has been explained as food that demonstrates to be **generally available within the Community**. For instance, if a food was sold only in pharmacies in the EU, it would not prove that a food was consumed to significant degree. However, if it was sold in general food stores, this would constitute evidence that a food was consumed to a significant degree.[279]

F**our categories of novel foods** that fall under the scope of the NFR are distinguished in Article 1(2). [280]
"*This Regulation shall apply to the placing on the market within the Community of foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the Community and which fall under the following categories:*
(c) foods and food ingredients with a new or intentionally modified primary molecular structure;
(d) foods and food ingredients consisting of or isolated from microorganisms, fungi or algae;
(e) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use;
(f) foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances."

The regulation covers a broad spectrum of novel foods. But, which paragraphs are relevant for HPP, then? In general, foods that are produced by novel processes are covered in paragraphs: (c) and (f). However, the latter is more relevant for HPP.[281]

One can ask how the procedure of determining the novelty of food looks in practice. The procedure starts with a decision of the potential applicant. Firstly, the applicant has to consider if her/his food product is novel and collect the evidence supporting the case. If the applicant is not sure whether the product is novel, she/he may consult the Commission or authorities in the member states.
In general, if the application is accepted by a member state, the food is considered to be novel. In situations, when it is not clear for a member state whether a food falls under the NFR, they may consult the Novel Foods Working Group. This body is a platform, where the matters concerning novel food are considered. It consists of experts from the member states and a chairman who is an officer of the Commission. If the Novel Foods Working Group is not able to form an opinion concerning the novelty of food, the arbitration procedure from the NFR (Article 13) should be followed.[282]

The basic requirements for novel foods to be placed on the EU market are regulated by Article 3(1) of the NFR. They state that the food products **must not**:

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[279] DG SANCO, 2002: 2

[280] It is important to notice that until 18 April 2004, the NFR covered also genetically modified (GM) foods (used to be mentioned as point (a) and (b)). However, currently GM food is regulated by separate legislation – **Regulation (EC) 1829/2003** on genetically modified food and feed (OJ L 268, 18.10.2003, pp. 1-23).

[281] van der Meulen & van der Velde, 2008: 293

[282] DG SANCO, 2002: 3-4

*"— **present a danger** for the consumer,*
*— **mislead** the consumer,*
*— **differ** from foods or food ingredients which they are **intended to replace** to such an extent that their **normal consumption** would be **nutritionally disadvantageous** for the consumer."*

7.3. Novel food procedures

Recital 2 states: *"(…) in order to protect public health, it is necessary to ensure that novel foods and novel food ingredients are subject to a single safety assessment through a Community procedure before they are placed on the market within the Community; whereas in the case of novel foods and novel food ingredients which are substantially equivalent to existing foods or food ingredients a simplified procedure should be provided for;"*
It provides two kinds of procedures: notification and a single safety assessment through a Community procedure. Notification procedure is a simplified procedure and is applicable when novel foods are substantially equivalent to existing foods.

7.3.1. Notification

Notification procedure is applicable for novel foods from **Article 1(2)(d) & (e)** (novel foods consisting of or isolated from **microorganisms**, **fungi** or **algae** as well as novel foods consisting of or isolated from **plants** and isolated from **animals**) that are generally recognized as substantial equivalent to existing counterparts on the basis of the scientific evidence or are classified as substantial equivalent on the basis of an opinion of the competent bodies. In order to establish substantial equivalence, the composition, nutritional value, metabolism, intended use as well as the level of undesirable substances should be taken into consideration by the applicant.[283]

In this procedure, the applicant has to notify the Commission that she/he wants to place the novel food on the market. The applicant shall also deliver all relevant details which are mentioned in Article 3(4). The copy of notification shall be forwarded by the Commission to member states within 60 days. However, member states may also request a copy of relevant details. The notifications shall be published by the Commission in the 'C' series of the *Official Journal of the European Communities*.[284]

7.3.2. Authorisation

Novel foods from **Article 1(2)(c) & (f)** - novel foods with a **new or intentionally modified primary molecular structure** and novel foods produced by **novel processes** have to be authorized through a Community procedure since these foods is not recognized as substantial equivalent and have to pass the safety assessment.
When is this procedure relevant for HP foods? There is one criterion, namely occurance of a significant change. So every time, when HP food is significantly changed by HPP, it should follow the Community procedure.

How does the procedure look in practice? First, the applicant, who is responsible for placing NF on the market, must submit a request to the member state where the product is to be placed on the market for the first time. Furthermore, she/he must send the copy of this

[283] Article 3(4) of Regulation 258/97
[284] Article 5 of Regulation 258/97

request to the Commission.[285] The details regarding the application are broadly discussed in section 7.4. of this chapter.
When such a request is received, the member state is obligated to ensure that an initial assessment of novel food is carried out. Furthermore, the member state must provide the name of the competent food assessment body responsible for preparing the initial assessment report to the Commission. If there is a problem with arranging the competent food assessment body, the member state may ask the Commission to arrange it from other member state in order to prepare the report.[286]

The Commission is responsible for forwarding a copy of the applicant's summary as well as the name of the competent body carrying out the initial assessment to all other member states.[287]

The competent body shall draw up the initial assessment report according to requirements of Commission Recommendation 97/618/EC within a period of three months (90 days). Moreover, it shall decide if additional assessment is needed.[288] The prepared initial assessment report shall be forwarded by the member state to the Commission. Next, the Commission shall forward it to the other member states.
Within 60 days from the date of circulation of the report, member states and the Commission may make comments or present a reasoned objection relating to NF and its presentation or labelling. It is important to notice that objection differs from comment since the first one activates a Community decision in respect of authorization while the second does not.[288&289]

If member states have comments or objections, they shall be forwarded to the Commission. Then, these comments or objections shall be circulated to the other member states within the period of 60 days. Furthermore, a member state may require additionally a copy of any relevant information.[292]

If there is neither the requirement of additional assessment nor objection, the member state shall inform the applicant that she/he may place food product on the market without delay.[290]
If the additional assessment is needed or an objection is raised, the **"*Comitolog*" procedure** will be adopted.[291] The Commission in this procedure is assisted by the Standing Committee for Foodstuffs.[292]
The applicant shall be informed by the member state about the requirement of authorization decision.[293] This decision as stated in Article 7(2): "*(…) shall define the scope of the authorization and shall establish, where appropriate:*
— the conditions of use of the food or food ingredient,
— the designation of the food or food ingredient, and its specification,

[285] Article 4(1) of Regulation 258/97
[286] Article 6(2) of Regulation 258/97
[287] Article 6(3) of Regulation 258/97
[288] DG SANCO, 2002: 6
[289] Article 6(4) of Regulation 258/97
[290] Article 4(2) of Regulation 258/97
[291] Article 7(1) of Regulation 258/97
[292] Article 13 of Regulation 258/97

— specific labelling requirements (…)"

Furthermore, the applicant shall be informed about the decision without delay and the decision shall be published in the *Official Journal of the European Communities*.[293]

7.4. Application

Article 4(4) of the NFR puts a requirement on the Commission to publish recommendations that concerns the scientific information necessary to support an application as well as requirements concerning the safety assessment reports.

When the food business operator wants to launch a novel food into the EU market, she/he should submit the request to the member state accompanied by all necessary information, including a proposal for the presentation and labelling. Additionally, she/he should include a summary of the dossier.[294]

All relevant requirements for constructing the application are described in **Commission Recommendation 97/618/EC** of 29 July 1997. It includes the scientific aspects of information necessary to support applications for placing NF on the market and its presentation, but also requirements for preparing the initial assessment reports under the NFR.[295]

It is noticed in this document that the assessment of NF may be a difficult task, since food is a complex mixture. Moreover, there are a number of scientific challenges, like problems with applying conventional toxicological evaluation methods or traditional metabolic and pharmacokinetic studies.[296]

The Commission Recommendation mentions the concept of "**substantial equivalence**" as one of the key issues for the assessment of NF. It is an approach that allows comparing NF with its already existing counterpart in terms of safety. This concept may be useful in evaluating foods from novel sources and processes.[297]

In order to establish substantial equivalent but also a prerequisite for nutritional and toxicological studies, the **compositional analysis** is required.
Furthermore, the importance of the **consumption pattern** has been emphasized, since the introduction of novel foods to the diet may affect the nutritional status of consumers. If it is difficult to predict these effects, a surveillance programme should be combined with marketing.[298]

The assessment of novel food also requires the **toxicological data**. However, they shall be considered on a case-by-case basis.
Three different scenarios may be taken into account:

[293] Article 7(3) of Regulation 258/97
[294] Article 6(1) of Regulation 258/97
[295] OJ L 253, 16.9.1997, pp. 1-36
[296] Commission Recommendation 97/618/EC, p. 5-8
[297] p. 5-6
[298] p. 6

- substantial equivalence may be established to an accepted traditional food, and there is no need of further tests;
- substantial equivalence may be established, but not for all traits of the novel food, therefore further safety assessment concerns specifically these traits;
- substantial equivalence can not be established; in this case the wholesomeness of whole novel food must be assessed.[299]

One of the serious obstacles is that the adverse effects of NF in animal studies may be caused by toxic effects and/or nutrition imbalance of animal diet, therefore circumspection is required.[300]

An important issue that should be taken into account during assessment is also **allergenic potential** of NF.[301]

A food business operator, who applies a novel process including HPP, should follow Recommendation 97/618/EC in term of the essential information for assessment.[302]

The information that should be considered includes: specification of the novel food, effect of the production process, history of the organism used as the source of the novel food, potential intake of the novel food, information about previous human exposure, as well as nutritional, microbiological and toxicological information. Other information may also be required as the recommendation provides only some guidance for the applicant.[305]
This information submitted by the applicant should be presented under the following headings:

- **administrative data,** including name and address of the applicant, the manufacturer and person responsible of dossier;
- **general description**, including the allocation of the food to one of the types of novel food together with scientific justification;
- **essential information** concerning safety and nutritional evaluation of the novel food;
- **consultation of structured schemes** from Part I of the Recommendation;
- **evaluation and conclusion** by the applicant;
- **summary**.[303]

7.5. The initial assessment report

As stated in the NFR, the competent authority of the member state is responsible for preparing the initial report.[304]
The construction of this report consists of:

1. checking of the application;
2. reviewing the interpretations and evaluations by the applicant of the submitted data;
3. assessment of data, summary conclusions and recommendations.[305]

[299] p. 7
[300] p. 6-7
[301] p. 8
[302] p. 17-18
[303] Commission Recommendation 97/618/EC, p. 32-33
[304] Article 6(3) of Regulation 258/97
[305] Commission Recommendation 97/618/EC, p. 34-36

7.6. Labelling

The NFR provides, where it is appropriate, additional labelling requirements for NF.
The labelling should "(...) *ensure that the final consumer is informed of:*
(a) any characteristic or food property such as:

— *composition,*
— *nutritional value or nutritional effects,*
— *intended use of the food,*

which renders a novel food or food ingredient no longer equivalent to an existing food or food ingredient.

(b) the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which may have implications for the health of certain sections of the population;
(c) the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which gives rise to ethical concerns."[306]

7.7. Protection of information

Article 10 of the NFR lays down the requirement for the Commission to establish the rules to protect information provided by the applicant. On 10 October 2001, **Regulation (EC) No 1852/2001** laying down rules for making certain information available to the public and for the protection of information submitted under the Novel Food Regulation came into force.[307]

The information submitted under the NFR relating to the manufacturing process should be kept confidential when its disclosure might harm a competitive position of the applicant.[308] And this information may be divulged by the Commission, member states and competent food assessment bodies only if making it public will protect human health.[309]

Certain information concerning the application and the initial assessment report shall be publicly available since it may improve transparency in the operation of the procedures.[310&311]

[306] Article 8(1) of Regulation 258/97
[307] OJ L 253, 21.9.2001, pp. 17-18
[308] Article 1(2) of Regulation 1852/2001
[309] Article 1(1) of Regulation 1852/2001
[310] Recital 3 of Regulation 1852/2001
[311] Article 2 of Regulation 1852/2001

8. Proposal for a New Novel Foods Regulation

This chapter provides some basic information about a proposal for a New Novel Foods Regulation (NNFR) since it will replace the NFR in the future.

8.1. Background

The Commission submitted the "White Paper on Food Safety" in 2000. One of the intentions of this document was to examine the application of the Novel Foods Regulation and to make the necessary changes to the existing legislation based on the conclusions of the report on the implementation of the NFR.[312]

The first step of the NFR alteration was adoption of Regulation (EC) 1829/2003 concerning genetically modified food and feed in 2003.[315]

The Revision of the Novel Foods Regulation was seen as necessary *"(…) in order to clarify the legislation after removal of GM food from the scope of the Regulation, to create a more favourable environment for innovation for the food industry and to facilitate internal and external trade."*[315]

A number of consultations took place with different stakeholders including food industry, consumers, third countries, national and EU authorities as well as international organisations. During the discussions, the decision was taken to develop and update the Novel Foods Regulation.[315]

A proposal for a Regulation on novel foods and amending Regulation (EC) No 1331/2008 [*establishing a common authorisation procedure for food additives, food enzymes and food flavourings*] was published by the Commission on 14 January 2008.[313] The revision of the NFR presents the Commission intention to combine NNFR with the common horizontal legislation.[314]
Regulation (EC) No 1331/2008[315] is the first building block of a horizontal legislation and it harmonises the authorisation procedures for all the approvals in the food area.

The Explanatory Memorandum states that NNFR *"(…) is in line with the Commission's Better Regulation Policy, the Lisbon Strategy and the EU's Sustainable Development strategy. The emphasis is on simplifying the regulatory process, thus reducing the administrative burden and improving the competitiveness of the European food industry, while ensuring the safety of food, maintaining high level of public health protection and taking global aspects into consideration."*[316]

The Proposal for NNFR provides the basis for a centralised authorisation procedure and it introduces "one door – one key" principle to approve novel foods. It means that the application for authorisation will be sent to the Commission and then the scientific assessment of novel food will be carried out by the European Food Safety Authority (EFSA).

[312] Explanatory Memorandum to Proposal COM(2007) 872, 2008: 2
[313] Proposal COM (2007) 872
[314] Explanatory document, 2006: 5
[315] OJ L 354, 31.12.2008, pp. 1-6
[316] Explanatory Memorandum to Proposal COM (2007) 872, 2008: 3

Furthermore, the Proposal for NNFR introduces data protection rules and a notification procedure for traditional food from a third country.[317]
In general, the Proposal for NNFR is more open toward exotic foods, but it does not really change the situation of high-pressured foods and other novel foods produced by novel processes.

8.2. The aims of the Proposal

The main aims of the Proposal are:

- ensuring a high level of human health and consumers' protection;
- ensuring the effective functioning of the internal market.[318]

In order to achieve these goals, the Proposal intends to:

- streamline the authorisation procedure;
- develop a more adjusted safety assessment system for traditional food from third countries;
- clarify the definition of novel food and the scope of the NFR;
- improve the efficiency, transparency and application of the authorisation system, which also contributes to better implementation of the Regulation;
- empower consumers by informing them about food.[319]

8.3. Determination of novelty

The Proposal provides a definition of novel food, which "*(…) means:*

(i) food that has not been used for human consumption to a significant degree within the Community before 15 May 1997;

The use of a food exclusively as or in a food supplement shall not be sufficient to show whether it has been used for human consumption to a significant degree within the Community before 15 May 1997. However, if a food has been used exclusively as or in a food supplement prior that date, it can be placed on the Community market after that date for the same use without being considered as novel food. Further criteria for assessing if a food has been used for human consumption to a significant degree within the Community before 15 May 1997, which are designed to amend non essential elements of this Regulation, inter alia by supplementing it, may be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).

(ii) food of plant or animal origin when to the plant and animal is applied a non-traditional breeding technique not used before 15 May 1997; and

(iii) food to which is applied ***a new production process****,* ***not used before 15 May 1997****, where that production process gives rise to* ***significant changes*** *in the composition or structure of the food which affect its nutritional value, metabolism or level of undesirable substances."*[320]

[317] ec.europa.eu/food/food/biotechnology/novelfood/initiatives_en.htm
[318] Article 1 of the Proposal
[319] Explanatory Memorandum to Proposal COM (2007) 872, 2008: 2-6
[320] Article 3(2) of the Proposal

The last category covers foods treated by new production processes, such as nanotechnology and nanoscience, which may have an impact on food safety.[321]

The Proposal also states that in order to establish the novelty of food, the Commission can collect information concerning the use of a food for human consumption within the EU before 15 May 1997 from the member states and/or from food business operators.[322]

8.4. Community list

As stated in Recital 15 of Regulation (EC) No 1331/2008: *"In order to ensure that both business operators in the sectors concerned and the public are kept informed of the authorisations in force, the authorised substances should be included on a Community list created, maintained and published by the Commission."*

The Proposal for NNFR introduces the Community list of novel foods. NF may be placed on the EU market only if it is included on this list.[323] In order to update the Community list, the common procedure included in the Regulation (EC) No 1331/2008 should be followed.[324] The Commission is responsible for updating the Community list.[325]

In this context, "updating" means:

> "*(a) adding a substance to the Community list;*
> *(b) removing a substance from the Community list;*
> *(c) adding, removing or changing conditions, specifications or restrictions associated with the presence of a substance on the Community list."*[326]

Furthermore, NF that are introduced to the Community list, should be accompanied by the information: the date of entry of the novel food in the Community list, the statement that the entry is based on newly developed scientific evidence and/or proprietary data, the name and address of the applicant, a specification of the food, and where necessary, the conditions of use, additional specific labelling requirements and a post-market monitoring requirement.[327]

The novel foods may be included in the Community list if the following conditions are met:

"*(a) it **does not**, on the basis of the scientific evidence available, **pose a safety** concern to the health of the consumer under normal consumption conditions;*
*(b) it **does not mislead** the consumer, by the way it is presented or by its intended use;*
*(c) in the case where it is intended to replace another food, it **does not differ** from that food **to such an extent** that its **normal consumption** would be **nutritionally disadvantageous** for the consumer."*[328]

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[321] Recital 6 of the Proposal
[322] Article 4
[323] Article 5
[324] Article 7(1)
[325] Article 2 of Regulation 1331/2008
[326] Article 2(2) of Regulation 1331/2008
[327] Article 7(2)&(3)
[328] Article 6

8.5. The common procedure

The Proposal for NNFR provides a harmonised **centralised procedure for safety assessment and authorisation** which should be efficient, time-limited and transparent. To achieve the harmonisation of different authorisation procedures, the approval of NF should be carried out in accordance with the procedure laid down in Regulation (EC) No 1331/2008.[329]
Regulation (EC) No 1331/2008 of 16 December 2008 establishes a common authorisation procedure for food additives, food enzymes and food flavourings.[330]
The essence of this legislation is stated in the words: "*This Regulation will thus complete the regulatory framework concerning the authorisation of the substances by laying down the various stages of the procedure, the deadlines for those stages, the role of the parties involved and the principles that apply. Nevertheless, for some aspects of the procedure, it is necessary to take the specific characteristics of each sectoral food law into consideration.*"[331]

The common procedure starts with the initiative of the Commission or the application made by the member states or by an interested party who may also represent several interested parties. In the last two situations, the application should be delivered to the Commission.[332]

After the Commission receives the application in order to update the Community list, it:
"*(a) shall acknowledge receipt of the application in writing to the applicant within 14 working days of receiving it;*
(b) where applicable, shall as soon as possible notify the Authority [the European Food Safety Authority (EFSA)] *of the application and request its opinion (…).*
The application shall be made available to the Member States by the Commission."[333]

In case when the Commission initiates the procedure, it should notify the member states and, if necessary, request the opinion of EFSA.[334]

EFSA is a body which is responsible for providing a scientific opinion within nine months of receipt of a valid application. This period of time may also be extended. The opinion should be forwarded to the Commission, member states and, where appropriate, to the applicant.[335]

Additionally, Regulation (EC) No 1331/2008 states: "*The deadlines laid down in the procedure take into account the time needed to consider the different criteria set in each sectoral food law, as well as allowing adequate time for consultation when preparing the draft measures. In particular, the nine-months deadline for the Commission to present a draft regulation updating the Community list should not preclude the possibility of this being done within a shorter period.*"[336]

[329] Recital 15
[330] Recital 7 of Regulation (EC) No 1331/2008
[331] Recital 9 of Regulation (EC) No 1331/2008
[332] Article 3(1)
[333] Article 4(1)
[334] Article 4 (2)
[335] Article 3(2) & 5
[336] Recital 10

The Commission may request additional information from applicants on matters concerning risk management. In this situation, a period within which that information can be provided should be determined by both the Commission and the applicant.[337]

During the period when EFSA is giving its opinion, the Commission should submit a draft regulation updating the Community list to the Standing Committee on the Food Chain and Animal Health. If the draft regulation is not in accordance with the opinion of EFSA, the Commission shall explain the reasons for its decision.[338]

The final stage of the procedure is the Regulation updating the Community list. It should take into consideration, where appropriate, the opinion of EFSA as well as the views of the member states, relevant Community law and other relevant factors.[339]

The Commission may *"(…) decide not to proceed with a planned update, at any stage of the procedure, if it judges that such an update is not justified."* However, it should notify directly the applicant and the member states about reasons of such decision.[344]

8.6. Opinion of EFSA

EFSA is an authority that performs the safety assessment of NF. Thus, as stated in the Proposal, **EFSA shall**:

"(a) compare, where appropriate, if the food is as safe as food from a comparable food category already existing on the market in the Community or as the food that the novel food is intended to replace;
(b) take into account for traditional food from a third country, the history of safe food use."[340]

8.7. Technical guidance

The Proposal requires cooperation between the Commission and EFSA to set up **technical guidance and tools** to assist food business operators. The guidance and tools are especially aimed for **small and medium-sized enterprises**.[341]

8.8. Obligations of the food business operators

In case when novel foods are placed on the EU market, the Commission may require post-market monitoring of the food business operators.[342] It is necessary if the Commission follows the opinion of EFSA or because of the safety reasons.[353]

Moreover, the food business operators should inform the Commission of:
"(a) any new scientific or technical information which might influence the evaluation of the safety in use of the novel food;
(b) any prohibition or restriction imposed by the competent authority of any third country in which the novel food is placed on the market."[353]

[337] Article 8
[338] Article 7(3)
[339] Article 3(4)
[340] Article 10
[341] Article 9
[342] Article 11

8.9. Data protection

The Proposal establishes the protection of the data concerning the inclusion of NF in the Community list during a period of five years. It means that those data can not be used for the benefit of another application.[343]

In order to protect the data, the food business operator shall put a request and support the application dossier with appropriate information.[354]

[343] Article 12

9. Methodology

The first eight chapters of this report present the results of literature research on HPP and the EU legislation on HPP, which together with experience survey are parts of the exploratory research – the methodology applied to this thesis research.
This chapter provides details on the methodology as well as on the data collection and the data analysis. The results of experience survey are presented in chapter 10.

9.1. Background

The methodology used in this thesis project is **exploratory research** since as stated by Churchill [1999]: *"In general, this method is appropriate to any problem about which little is known."* It is adopted from marketing studies.[344]

The purposes for using exploratory research are:

- *"formulating a problem for more precise investigation or for developing hypotheses;*
- *establishing priorities for further research;*
- *gathering information about the practical problems of carrying out research on particular conjectural statements;*
- *increasing the analyst's familiarity with the problem;*
- *clarifying concepts."*[355]

Because of the fact that knowledge is lacking at the beginning of the study, exploratory research characterizes with flexibility relating to the methods used for achieving deeper insight and developing hypotheses. Churchill [1999] described it in words: *"Investigators follow where their noses lead them in an exploratory study."*[355]

9.2. Scheme of the research

Two types of research: literature research and experience survey were used in this exploratory research.[355]

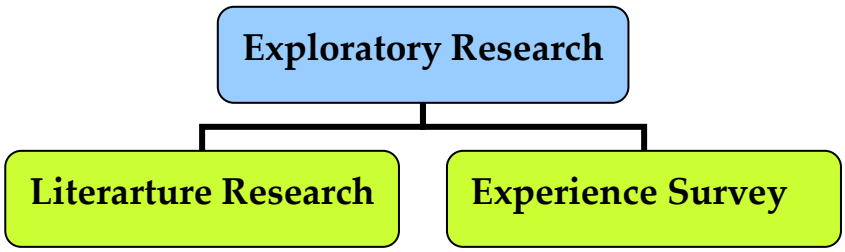

Figure 17. The scheme of exploratory research applied in the thesis project. **Source:** Churchill, 1999

The first stage of this study included gathering and analyzing relevant literature[345] concerning HPP and relevant pieces of European food law. This literature included: scientific journals, books, and websites of the competent authorities, institutes and industry.

[344] Churchill, 1999: 101-103
[345] Churchill, 1999: 104-105

The next stage was experience survey, also called the key informant survey, which was performed amongst the experts and business stakeholders familiar with HPP and EU food law.[346]

The core of this survey was informal phone interviews with experts and business stakeholders. The interviews were recorded with the help of a digital voice recorder. The reports were prepared on the basis of those interviews, and were then revised by the interviewees.

Finally, a questionnaire concerning the particular problems on HPP and the EU food legislation was prepared and sent to interviewees in order to compare their opinions. The questionnaire consists of twenty statements which were based on the interviews (Annex V). Likert summated rating form was chosen as the scale to express the intensity of feelings. The interviewees were asked to indicate their degree of agreement or disagreement with the statements.[347]

9.3. The research area and data collection

High-pressured food and high pressure processing similarly like other food and traditional processes are regulated by the general rules of EU food law. HPP can be considered as a novel process by some stakeholders. This technology was described as possibly not novel in certain applications in *A Review of New Food Processing Techniques and an Assessment of their Food Safety Implications* prepared by ADAS Management Consultancy in 2004.[348]
Consequently, the questions that may arise are: *When is the high-pressured food product regarded as novel? What legislation is applicable?*
Additionally, Heinz & Buckow [2009] noticed: *"With regard to the manufacturing process the question may arise whether a technology that can be considered as ''novel'', is necessarily producing ''novel food'' within the meaning of the law."*[349]
The fact that only one authorization was granted to HP foods under the NFR in the EU, while more high-pressured food products are available on the market, may additionally influence the vagueness of HPP situation.

To gain inside in the situation relating to the legal status of HPP and high-pressured foods, the interviews with the experts from the EU were performed. It was of great importance to establish contacts with experts who have had different experiences relating to HPP and food law. However, it is also essential to point out that the number of the experts working in the area of HPP and the EU legislation on HPP is limited.

The contact details were obtained from one of the experts as well as from websites and scientific papers. The identified experts were from the competent authorities of member states, the EU authorities, the food industry, the HPP equipment industry and science. Although many experts were contacted via the internet, the response rate was quite low. Finally, seven phone interviews were performed.

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[346] Churchill, 1999: 105-106
[347] Churchill, 1999: 392-395
[348] ACNFP, 2006
[349] Heinz & Buckow, 2009: 7

First, a general question was asked: *"What kind of legal issues do you encounter in the case of the high pressure food?"*, as the experts have had different experiences, background and views relating to HPP and the EU legislation on HPP
Then, depending on the answers, other questions were asked in order to obtain as much information concerning the main topic as possible. The time of collecting the data was between October 2009 and February 2010. After the phone interviews, the experts were asked to fill the questionnaires, which were sent by email (see Annex V).

9.4. Analysis and validation of the data

The obtained data from the interviews and questionnaires were analysed, and the main motifs were identified during the reports' preparation. First, information from all reports was combined under the common headings and subsequently, the data from the questionnaires were incorporated.

10. Empirical Data

This chapter merges and analyses information gathered during the phone interviews and obtained from the questionnaires in order to answer the research questions.

Seven experts with different backgrounds and experiences relating to high pressure processing (HPP) took part in the research. Amongst the experts some work in the competent authorities in the UK and the Dutch assessment body, others work as scientists on HPP, and some others work in the food industry, in a company producing HP equipment and in an independent research organisation.

The first stage of the research was an interview with experts and the second stage included a questionnaire containing twenty statements on HPP and the EU legislation.

10.1. The EU legislation on high pressure processing

The aim of this section is to find out which EU legislation is considered by the experts as relevant for a food producer who wants to introduce high pressure processing to her/his company.
In general, both technology and food product should be in compliance with appropriate European food law but also with the national legislation of the individual member states.

During the interviews with experts, the following question was asked: *"What kind of legal issues do you encounter in the case of the high-pressured food?"*

The expert from the competent authority in the UK (the Food Standard Agency) stated that: *"There are novel food aspects of high pressure processing, and other issues regarding safety of the technology which are really covered by general food safety legislation and are not specific to the use of this technology.*"
Dr Clemens M.A. van Rossum who is an assessor in Novel Foods Unit in the Medicines Evaluation Board (MEB) in the Netherlands, also referred to the Novel Foods Regulation (NFR) and regulations concerning the microbial safety, including the so-called *"hygiene package"* as well as the General Food Law (Regulation (EC) No 178/2002).

The results obtained from the questionnaires have shown that half of the experts *"agree"* or *"strongly agree"* with statement: *"The most important regulatory issue facing HPP is the Novel Foods Regulation (Regulation (EC) No 258/97)."*
However, the expert from the competent authority in UK, who did not take part in the questionnaire research but instead offered some comments and observation relating to the questionnaire, explained: *"It is important that any foods sold in the EU comply with all relevant aspects of food law, and I am not convinced that any single framework is more or less 'important.'"*
Mr. Michael Cockerill who works in a British food company and Dr van Rossum disagreed with the statement from the questionnaire. Ms Ariette Matser who is a scientist working on HPP at Wageningen University and Research Centre, neither agreed nor disagreed. All these experts have a great practical experience concerning both HPP and the EU legislation. The experts from the UK competent authority, from the Dutch assessment body as well as from

the British food company seem to have similar opinion on the EU legislation on HPP to the opinion of the European Commission. This opinion is presented in the note on the website of ACNFP. It states: "***the process* [HPP] *does not produce any material change in the composition of the food and as a result does not require further assessment under the novel foods procedures***" (See Chapter 5 Section 5.3.).

Dr Carole Tonello who is an Applications and Process Development Manager in NC Hyperbaric (a producer of high pressure equipment) informed about the special requirements concerning high pressure equipment.
The expert stated: "If *producers* [of the HP equipment] *want to put their HP equipment on the EU market, they have to comply with the Pressure Equipment Directive (97/23/EC))."* Dr Tonello continued that "*(…) the compliance with this directive is checked by the inspection of the competent authority. The inspection is to validate the machine performance; it includes the test with fixed parameters (pressure and time), and the inspection of the safety of separate parts of machine, like the material (steel) or the electric installation."*

Besides the expert, also literature mentions the Directive (97/23/EC) as the relevant European legislation on HPP.
"All new pressure vessels to be used in the EU have to comply with the "pressure equipment directive" (PED) which came into force in 2002. This directive is an extension of the 'CE' safety standard already employed in the EU and now recognised worldwide where CE indicates conformity with mandatory European safety requirements. As pressure vessels of all types utilize potentially hazardous energy, the PED regulation seeks to identify good design, good manufacturing practices and detailed safety assessment for safe operation and maintenance of the vessels and auxiliary parts."[350]

Dr Tonello added that other requirements concerning HP equipment can be demanded in the EU member states, for instance the submission of calculations connected with the machine design is necessary in Germany.
Moreover, the HP equipment has to be inspected in processing plant by the competent authority. However, this inspection is not perceived as any obstacle for the food manufacturer.

10.1.1. The Novel Foods Regulation

During interviews, all experts mentioned the Novel Foods Regulation as possibly relevant in the case of high pressure processing. In addition, a number of publications[351] describe the NFR as an important piece of legislation on HPP. For instance, Hugas et al. [2002] argued that high-pressured foods fall within a scope of the NFR and may be considered as novel foods *"(…) since they fulfil two conditions: their history of human consumption has so far been negligible and secondly they have been produced by a new manufacturing process."*[352]
Dr Tonello explained that the food producer is obligated to check if high-pressured food falls within the scope of the NFR. In order to verify this, Article 1(f) of the NFR should be taken into consideration. Dr van Rossum also agreed on the importance of Article 1(f), he stated: *"I*

[350] Norton & Sun, [2008]: 28
[351] Hugas et al., 2002: 367; Norton & Sun, 2008: 28; Heinz & Buckow, 2009: 7-8
[352] Hugas et al., 2002: 367

think that the provisions given in this Article form a good base to see if a product from HPP would fall under the scope of NFR."

The expert from the UK competent authority was of the opinion that from the way the NFR was drafted, it was clear that technologies such as HPP were potentially subject to this regulation. The NFR requires an evaluation of food so then the initial assessment is carried out. However, the result of the assessment may be that there is no significant change in the final product. Furthermore, the expert admitted that this may be confusing for stakeholders.
However, he also said: *"I think that the legislation makes it quite clear if the technology has not been used before 15 May 1997, it fulfils the criteria of being a novel process. The difficulty than, is concerning whether it will actually be under the scope of the legislation. Because the regulation requires that there are* [significant] *changes in the final products."*

A number of different high-pressured food products are available on the EU market. However, only fruit based preparations by Danone Groupe were authorised according to under the NFR. Dr van Rossum explained that two reasons maybe responsible for that situation. *"One is (…) the legal side. So, they* [HP food] *would fall under the NFR only if there are certain changes in the final product."* The second reason is that *"(…) it is impossible for us* [the competent authority] *to see, if food companies just did not consider the fact that the NFR may have been applicable."*
Moreover, a lack of clarity in relation to the EU legislation on HPP seems to be present. The expert, who works in an independent research organisation, stated that some experts perceive the legislation on high pressure processing as vague and *"grey area"*. The same respondents also said that she was of the opinion that HPP falls under the scope of the NFR as high pressured fruit preparations (Danone Groupe) were authorized under NFR.

The results obtained from the questionnaire have revealed that about 67% of experts (four out of six) agreed or strongly agreed with the statement: *"The EU legislation on high pressure processing is perceived by many stakeholders as "grey area"",* while 33% of experts neither agreed nor disagreed.

10.1.2. Proposal for a NNFR

The Proposal for a New Novel Foods Regulation was published on 14 January 2008 after years of consultations, as mentioned before in chapter 8.
The centralised procedure and changes concerning exotic food are considered as the most important modifications of the Proposal. Dr van Rossum declared: *"I think that there are two main issues (…). One is the fact that the central procedure is foreseen now, so the applicant has to go to EFSA to start the assessment process. EFSA will arrange the assessment procedure in a consistent way for all applications, which would be a major improvement in the design of the procedure. The second issue is the fact that a separate assessment procedure will be in place for traditional foods, which have a history of safe consumption outside the EU."*

The expert from the independent research organisation also agreed that the Proposal *"(…) would change some things but not everything."* The expert stated that it seemed that the process of authorization would still be quite slow.
Furthermore, some definitions and conditions important in case when food products may be considered as novel foods seem to be unclear. A new regulation was expected to improve

this situation but according to the expert there would be still room for interpretation and discussion.

Referring to novel processes, particularly to high pressure processing, the expert from the UK competent authority stated: *"The proposal of NFR will not change the situation regarding HPP, because the novel production processes are embodied in the same sort of warding."*

10.1.3. Interpretation of term "significant changes"

Article 1(f) of the NFR states: *"foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in* ***the composition or structure*** *of the foods or food ingredients which* ***affect their nutritional value, metabolism or level of undesirable substances****."*

Referring to the term *"significant changes"*, Ms. Matser said that the NFR is a general regulation, and that it is difficult to specify in this regulation, what a *"significant change"* is and what is not. Therefore, there may be a room for interpretation of this term.
The expert from the independent research organisation stated that term *"significant changes"* is not clearly defined in the NFR, and that the decisions whether changes are significant or not should be taken on a case-by-case basis.

Additionally, the results obtained from the questionnaire stated that about 83% of the respondents (five out of six) agreed with the statement: *The term "significant change" is NOT clearly defined in the Novel Foods Regulation, so there can be room for interpretation.* Only Ms. Matser neither agreed nor disagreed.
It seems from the time perspective that there was no *"significant change"* in high-pressured fruit preparations [Groupe Danone]. The expert from the UK competent authority stated: *"It depends how you define significant change. So you can argue that the significant change can be a reduction of a desirable substance. Your thought is whether it will make* [food product] *better or worse."*
Dr van Rossum added: *"This is up to the applicant, the whole interpretation of the Article, which defines whether or not the product is a novel food. There is no institution in the EU, which determines if this is the case or not. So the legislator has just drawn this definition, and it is up to any company working in this field to determine for themselves whether or not the Novel Foods Regulation is applicable to their product."*

About 83% of the experts agreed with the following statement from the questionnaire: *"It is the responsibility of the applicant to interpret Article 1(f) of the Novel Foods Regulation and the term "significant change.""*
Mr. Cockerill from Orchard House Foods was the only expert who disagreed. The expert from the UK competent authority also disagreed with the statement in his comment and declared that it is a responsibility of the competent authorities of the member states.

When the experts were asked about the opinion on the statement: *"There are differences in interpretation of the term "significant change" in case of HPP among the EU Member States"*, about 67% of the experts (four out of six) neither agreed nor disagreed with the statement, while about 33% of experts - Dr Houska and Dr Tonello agreed with the statement.

In conclusion, it seems that the food producer is primarily responsible for establishing whether or not a significant change is present in high pressured food. However, the competent authorities are responsible for answering the producers' inquiries relating to HP food. Dr van Rossum stated: *"(…) that is true not only for this kind of processes, but for any kind of new products that company would develop. They* [the food producers] *have to ask themselves the question whether or not their product would be a novel food. And if they have doubts about that, they should contact us or our colleagues from other member states and discuss the details on the product they have, and their interpretation of the legal text for novel foods."*

10.1.4. The case-by-case approach

It was mentioned by one of the respondents that the occurrence of a *"significant change"* in HP food should be considered on a case-by-case basis.

The need of involving the "case-by-case approach" has been noticed in the Opinion of the Senate Commission on Food Safety (SKLM) of the German Research Foundation (DFG). This opinion on safety assessment of high-pressured foods stated:
"Hitherto, investigations on high pressure treated foodstuffs have not revealed any evidence of any microbial, toxicological or allergenic risks as a consequence of high pressure treatment. However, these findings do not suffice for a general evaluation, because they derive from only a few already marketed products. At present it is necessary, when a new product category is involved, always to carry out an individual case-by-case examination of high pressure treated foodstuffs."[353]

On the other hand, the expert from the UK competent authority noticed that there was a low probability of significant changes in HP food. He stated: *"Probably it would not be a significant change but there would be a scenario where there would be a problem, and we want to review it. But there has not been any since. Technology is studied and it is used for relatively wide range of products and there was no requirement for an assessment."*

Regarding the statement: *"High pressure technology is well studied and it is used for relatively wide range of products, and there is a marginal chance that requirement for an assessment under the Novel Foods Regulation will occur"*, the respondents were equally divided between three categories: "Disagree", "Neither agree nor disagree" and "Agree". Mr. Cockerill and Dr Houska disagreed with the statement, Dr van Rossum and the expert from independent research organisation neither agreed nor disagreed, while Ms. Matser and Dr Tonello agreed with the statement.
Furthermore, about 67% of the experts agreed or strongly agreed with the following statement: *"It is necessary to use case-by-case approach for high-pressured food."* The rest of experts, namely Ms. Matser and Dr Tonello disagreed with this statement.
It is noticeable that both experts were of the same opinion in the case of these two statements from the questionnaire.

Additionally, Ms. Matser during interview noticed that there are many HP (pasteurized) products on the market, so then HP pasteurization can be considered as not novel anymore, consequently the approval under the NFR would not be necessary. But the food producer still has to prove that her/his product is safe.

[353] Eisenbrand, 2005: 1173

In reference to statement: *"It is clear how to prove that high-pressured food does not pose a risk for consumers"*, about 67% of the respondents (four out from six) agreed with the statement. The experts from the independent research organisation neither agreed nor disagreed, and Dr Tonello strongly disagreed with the statement.

10.1.5. HP pasteurisation and HP sterilization

According to Ms. Matser, it is important to distinguish the HP pasteurisation and HP sterilization.

It has been found that there are some high-pressured food products without the approval under the NFR on the EU market. Those products have been considered as not novel anymore.
On the other hand, there are no food products produced by HP sterilization. It is because of the fact that the appropriate equipment for HP sterilization is not available, and food manufacturers can perceive the approval of foods under the NFR as a hurdle in developing new technology.

The results of questionnaire demonstrated that half of the experts (three out of six) strongly disagreed or disagreed with the statement: *"There is no need to assess the safety of HP treated products as the condition for market access."* On the other hand, two experts – Dr Houska and Ms. Matser strongly agreed or agreed with the statement, and Dr Tonello neither agreed nor disagreed.

In the case of HP sterilization, there is still debate in scientific literature relating to the safety of this technology. Two strategies can be distinguished when a new process, such as HP sterilization is introduced. A first strategy is to classify HP sterilized product as NF and to ask for the approval under the NFR, while a second strategy is to consider HP sterilized food as equivalent to heat sterilized food, and thus follow the standard safety rules.
If the second scenario is considered, the food manufacturer may state that HP sterilization is also a heat process and that the mechanism of inactivation is the same as in traditional heat process. In result, the NFR may be concluded to be not applicable.

Ms. Matser expressed the opinion that in both strategies the result would be the same - the food manufacturer has to prove that the product is safe and that the spores are inactivated.

10.1.6. "Danone case" and a current situation concerning HP food

Danone Groupe applied for the authorisation concerning placing fruit-based preparations treated with high pressure on the EU market in December 1998. The positive decision in this case was taken by the Commission on 23 May 2001.

The questionnaire used in this thesis research included three statements relating to the "Danone case". The results obtained from the questionnaire revealed that about 67% of experts (4 out of 6) agreed with the statement: "*It was necessary to submit the application to place high-pressured foodstuffs on the EU market by Danone under the Novel Foods Regulation."* One expert disagreed and one neither agreed nor disagreed.

The experts were of the same opinions on the following statement: "*It was necessary to grant the authorisation of placing high-pressured foodstuffs on the EU market (Danone) by the European Commission."*

Ms. Matser noticed that Danone Groupe had two options. High-pressured fruit-based preparations could have been considered NF or not NF as there was no "significant change" in the fruit preparations.
She stated: "*With the application of Danone, it was clear that they* [Danone Groupe] *considered HP food as a novel food. But Danone could also apply a different strategy. They could start the production and say that HP food is a substantial equivalence to existing products. And then, the NFR would not be applicable."*
On the other hand, the expert from the UK competent authority stated: "*(…) when that application was submitted, it was just the beginning of the legislation framework; back in 1998 and 1999. We did not have the same amounts of experience and expertise in dealing with the legislation. But that the technology is a novel process, it was quite clear. This technology was not used significantly.*"

The first high-pressured food product, which was brought to the EU market, was orange juice by UltiFruit® in 1994. However, it was argued by France that the HP juice was produced in a relatively small amount and that it was not consumed to a significant degree.
The expert from the UK competent authority said: "*To be outside the scope of the NFR, technology or product has to be used or consumed to a significant degree before 15 May 1997. HPP was not. In France the orange juice was produced before 15 May 1997, but France said that it was a small amount. So this technology needs to be coped by the NFR."*
He continued: "*The question was rather whether or not the final product is significantly changed."*
To answer this question, Danone Groupe gathered all important data and carried out research to prove that product is safe. Later on, on the basis of scientific results, it was found that HPP did not affect negatively the properties of fruit products.
The expert from the UK competent authority added: "*The producer can say that it does not look like there is a significant change but at the beginning of the process you do not know that. What happened, after the submission the original dossier, was the discussion whether or not* [there was a significant change]."

As it was mentioned before, HPP is currently applied to a wide range of food products, whereas the initial risk assessment was carried out only for the fruit-based preparations. The expert from the UK competent authority explained: *"Theoretically, when you look at any other foodstuffs, the legislation will still apply. So there was a feeling that we need to look at the technology and to see whether the technology would be generally coped by the legislation in the future. Member states agreed that technology would fall outside the scope because there was no effect (significant change) in the final product. This is really what our position is.*"
However, if HPP caused a significant change in food, this food would still fall within the scope of the NFR. The expert explained further: *"There could be some scenario when there would be requirement for assessment. (…) the regulation may apply because the product may significantly change."* He also stated: *"I do not know what it would be but it could be in theory. So, (…) we want to have a look at the technology again. But in vast majority of cases, we would review it as outside the scope* [of the NFR]*."*

The expert summarised: *"Broadly speaking nobody thinks that the Novel Foods Regulation applies to high pressure processing anymore. It is generally accepted now. Coming back to 2001-2002, when the discussion was being held, there was a view that the technology would be stopped by the legislation all the time. This was the situation at that time."*

Dr van Rossum from the Dutch assessment body noticed that HPP is not currently perceived as novel process anymore. He stated: *"What I recall from the discussion within the Novel Food European Working Group is that from that point, people just accepted the fact that HPP as such would not be regarded as a novel process. So, only products would be novel foods if they were indeed significantly changed according to the legal text* [the NFR]*."*
Additionally, it was stated by the competent authority in the UK that *"(…) high pressure processing is a non-thermal technology, and as an alternative pasteurization would not require a pre-market safety evaluation according to the NFR."*

In contrary, the results of the questionnaire revealed that about 67% of the experts (four of six) strongly disagreed or disagreed with the statement: *"After the approval granted to Danone, HPP is no longer novel."* One of the experts agreed with the statement and another one neither agreed nor disagreed.

10.1.7. The Commission and the authorities' opinions on HPP

The reasons for using the approval procedure for HPP were explained by Dr van Rossum: *"(…) the legislators determined that for some types of introduced products, there had to be a safety assessment before the product was marketed. So, it is clearly reasoning from* ***a safety perspective****, and with the knowledge that all kind of new products will be developed."*

Dr van Rossum also referred to the NFR and genetically modified organisms as they were a source of concerns.
He stated: *"At the time when the original NFR was defined, for instance also genetic modification was a major issue. These products were included in the NFR first, although later on, a separate legislation was introduced."*

The NFR was set up in 1997 to cope with NF, mainly with genetically modified food. At that time, GM foods were perceived as something that triggers reluctance in consumers in Europe and should be controlled. Therefore, the rules in the NFR are perceived as quite strict.
Currently, there is separate legislation concerning GM food in the EU. However, the rules that were created for NF including GM food have not changed yet.

The high-pressured fruit-based preparations are the only examples of NF produced by a novel process.
Dr van Rossum also added: *"Nowadays, from the EU list of NF applications, you can see what types of products have been submitted for the authorisation procedure."* They are mainly *"(…) exotic foods, bioactive substances, and carbohydrates with altered structures."*

However, if food treated with high pressure or other novel technology was considered as possibly novel, the NFR would be followed. Dr van Rossum explained: *"It all has to do with the interpretation of Article 1(f), if there are significant changes in the final product, as they are*

mentioned in the legal text, this could make the final product a novel food, but not just the fact that HPP is used."

The expert from the UK competent authority explained further: *"When you look at the legislation, it is not all about killing bacteria and safety in that respect. There are* ***nutritional value aspects*** *as well. The regulation does not deal with HP but it may. It deals with novel processes per se. There are other aspects, like level of undesirable substances. In case of microbial kill, we are also taking into account the nutritional value. There could be a scenario when yeast can have an effect on the nutritional value of the product and in this case there may be a need of assessment. It is not always very obvious."*

The results from the questionnaire revealed that about 67% of the experts (four out of six) agreed with the following statement: *"The safety assessment of HPP under the Novel Foods Regulation includes the question if sufficient reduction of pathogens is achieved."* One expert neither agreed nor disagreed, and other disagreed.

During the literature research, there was found only one statement referring to the opinion of the Commission on HPP. The short note on the website of ACNFP, which was mentioned before, stated: *"although not mentioned at the meeting, the European Commission has discussed the status of HPP with representatives from the EU member states. As a result,* ***it has been accepted that the process does not produce any material change in the composition of the food*** *and as a result does not require further assessment under the novel foods procedures. The Food Standards Agency has informed the company of this."*[354]
Since this opinion is not available on the official website of the Commission, it may not be clear for stakeholders in the EU what the Commission's position on HPP and the NFR is. The expert from the UK competent authority stated that there was no need for the Commission or for the member states to make the position that the legislation [the NFR] was not applicable. Since the technology was not used significantly before 15 May 1997, so it was still a novel technology.
He also added: "*It is not for the Commission to make that clear. The member states may judge whether or not the technology is covered by the novel food regulation. So, it is up to the member states to do that. But you do it either the way we* [the UK competent authority] *have done it or you do it just case-by-case assessment of the technology or the product*."

As mentioned before, there is some vagueness in respect to the legislation on HPP. The expert from the UK competent authority admitted: "*It is something* [lack of clarity of the message relating to the legislation on HPP] *that I heard from industry as well. But is there something more, we could do to make it quite clear what our position relating to HPP in the UK is. We have had it since 2002. So it is not a new position."*

One of the statements in the questionnaire was: "*It is clear and well known by all stakeholders that it has been accepted by the European Commission and representatives of the EU Member States that the high pressure processing does NOT produce any material change in the composition of the food and as a result does NOT require assessment under the novel foods procedures."* Five experts expressed their opinion in this case. 60% of the experts agreed with the statement. The expert

[354] ACNFP, 2002

from the food industry disagreed with the statement and the expert from the Dutch competent authority neither agreed nor disagreed. Although the sample size in the research is small and thus not representative, the results may suggest that there are different levels of knowledge on legislation and HPP between the stakeholders.

During the interview the expert from the independent research organisation stated that when a new product is introduced to the market, the producer should find out which legislation is applicable. According to the expert, the NFR is a well known regulation within the EU. However, in practice some food producers, especially those smaller, do not know the relevant legislation as they are not the regulatory experts. Furthermore, it is sometimes difficult to decide whether something is novel, and thus falls under the scope of the NFR.
The expert emphasized that the reason of the potential problems relating to the EU legislation could be that some food producers, especially Small and Medium Sized Enterprises (also known as SMEs), do not possess enough knowledge about the regulatory issues. "*It is rather an expert area and not everybody knows how to interpret correctly the legislation.*"

Dr Milan Houska, who is a scientist from the Food Research Institute Prague, noticed that there are not many big international companies applying HPP, there are rather SMEs interested in the novel technologies. "*Smaller companies are more flexible and often respond to the changes on the market quicker. The Novel Foods Regulation can be a barrier for these companies since they do not usually possess the great financial resources to make research needed to analyse the risk connected with novel food.*"

In regard to the food manufacturers in the EU, the expert from the UK competent authority said: "*Industry should know the situation regarding HP. And when they feel that there is a scenario when the technology may have an effect on the final product, they should come and speak to member states and have a discussion about it.*"
He also explained: "*The industry that deals with the high pressure processing is not a large industry. There are not hundreds of companies that produce by using the technology. They* [companies] *should know exactly to which member states speak to.*" The expert advised food industry: *"There are three or four member states that have got an experience in HPP, so then speak with them (for instance UK, France) to get correct answers. It is not required to go to all member states. You can go to one or two member states and get the correct answer,r you need. If we say that a product is not a novel food, it applies across the EU and not just in the UK (…). If the member states view the food product, which is produced as the result of the new technology, to fall outside the scope of the regulation, that will apply across the EU.*"
He also added that a good advice for industry would be: "*What, the company could do, is to approach a member state if they want the piece of paper that tells them whether or not the food is outside the scope of legislation. In order to say that it falls outside the scope of legislation, it would have to be on the market before 15 May 1997. I know there was some use before 1997, but more the discussion is case-by-case, now. I suspect the technology would be used for most applications that would be outside the scope of regulation. But, when the companies may want to get the clarification from the member state, it is not a difficult thing to do.*"

The expert form the UK competent authority also stated: "*It is up to the companies to ensure that they comply with all relevant aspects of food law. All (…)* [the companies] *have to do in a very many cases with high pressure is just contact the competent authority (…).*
The lack of clarity is maybe there, but it is up to the company to deal with that and move forward. I think we are in the UK quite clear. We have very rarely any discussion about HPP anymore. The discussion about HPP (whether it is within the scope of the legislation or not), we had way back in 2001, 2002 and 2003. Now, we hear very few enquiries about technology. So maybe, there is clarity about the situation now."

10.1.8. The EU member states

A large number of countries joined the European Union at the beginning of XXI century, first on 1 May 2004 a big group of ten countries from the central and eastern Europe: Czech Republic, Cyprus, Estonia, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia, and then on 1 January 2007 further two countries - Bulgaria and Romania.[355] Nowadays, the European Union consists of 27 member states.[356]

The European Union is an organisation that consists of the individual countries, and therefore it is not uniform. The differences between the EU member states may have an impact on many issues, for instance the perception of new technologies.
As described in chapter 4, there are different attitudes towards novel technologies as well as prices of food within the Community. The aspect of price will probably strongly depend on the economic situation of the member states.

The gross domestic product (GDP) is a basic measure of a country's overall economic output and is also often positively correlated with the standard of living in the country. For instance, GDP per capita in Purchasing Power Standards (PPS) in 2008 for Bulgaria was 41.3, while for Luxembourg it was 276.4. The average of GDP per capita in PPS for all 27 the EU member states was 100. These differences may indicate that the consumers in some EU member states would be willing to pay more for foods than the consumers in other member states.[357&358]

Furthermore, as mentioned, twelve countries joined the EU in 2004 and 2007. The time to gain experience as a member state of the European Union has been relatively short in those cases. This situation may also explain that the "new" EU members are not as experienced in dealing with certain issues, for instance European food law as the "old" members.

It is also important to mention that some members, for instance the UK had legislation on novel food in place before 1997, so this could also explained why some countries are more experienced in respect of NF.[359]

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[355] http://europa.eu/abc/history/2000_today/index_en.htm

[356] Germany, France, Italy, the Netherlands, Belgium, Luxembourg, Denmark, Ireland, United Kingdom, Greece, Spain, Portugal, Austria, Finland, Sweden, Czech Republic, Cyprus, Estonia, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia, Slovakia, Bulgaria and Romania

[357] Eurostat, 2009: 24

[358] Eurostat website

[359] EUFIC

Ms. Matser admitted that the competent authorities of the member states in the EU are not equally experienced with regard to HPP or the NFR. However, the expert added that in such situation, the companies may seek for an advice in other member states which are more experienced in that matter.
The expert from the UK competent authority mentioned countries, which are experienced in the NFR. *"I think it is not only the UK but five or six other member states that are particularly active in the novel food area. These countries are France, Belgium, the Netherlands, Finland and Germany."* He also referred to less experienced member states: *"(…) the other member states tend to be less active in terms of submission of dossiers. That means they do not receive and review dossiers as much as other member states. But still there are discussions relating to novel foods and novel technologies that involve all twenty seven member states. There is a mechanism: if a member state is unclear about food or technology, this member state can always approach all the other member states by e-mail or by speaking on the workshop meeting."*

The results of the questionnaire revealed that all experts strongly agreed or agreed with the statement: *"The levels of experience relating to novel foods and the Novel Foods Regulation differ among the EU Member States."*

Dr Tonello stated that the interpretation of novelty of HP food may differ between the member states. There are opinions in the Mediterranean countries, such as Spain, Italy, Greece that HPP at cool or ambient temperature (HP pasteurisation) is not a novel process. However, HPP at higher temperature (HP sterilization) may cause significant changes in the product. As a result, this product may fall within the scope of the NFR.
However, HP sterilization is not used in practice, since there are still technical problems with the equipment.
The questionnaire revealed that half of the experts (three out of six) neither agreed nor disagreed with the statement: *"The interpretation of the novelty of high-pressured foodstuffs depends on the temperature applied during the process as at higher temperature significant changes can occur in high pressured foodstuffs."* Two experts agreed with statement, while one disagreed with the statement.

Ms. Matser noticed that some experts are of the opinion that HP pasteurized foods, such as meat products require approval under the NFR, since only fruit-based preparations have been authorised (Decision 2001/424/EC). On the other hand, some other experts do not consider HP pasteurized foods as novel anymore.

10.1.9. The NFR as a barrier

According to Ms. Matser, the food industry find the NFR not very transparent, as it is difficult to predict how long the process of approval could take and what questions should be answered by the food manufacturer.
Additionally, the expert from the independent research organisation noticed that the NFR is seen as the factor inhibiting the innovations. The expert also agreed that the authorisation procedure under the NFR is long and quite complex process.

The questionnaire revealed that about 67% of the experts (four out of six) agreed or strongly agreed with the following statement: *"The Novel Foods Regulation is a regulatory barrier in the*

European Union, especially for small and medium enterprises", whereas two experts neither agreed nor disagreed with this statement.

In reference to HPP, the expert from the UK competent authority stated: *"To be honest, I think for the use of technology, there is no real barrier for the vast majority of products. You have just this idea that there could be occasional product when the legislation could apply."*

On the other hand, the same expert suggested that the NFR may be perceived as legislation which promotes the new technology through the regulatory framework since it provides reassurance that the safety of new technologies has been established by the wide assessment process. He stated: *"In the discussion about regulatory barriers, you can also argue that the way the new technology is reviewed, it gives a positive outcome as a result of pre-market safety evaluation."*

However, about 83% of the experts (five out of six) strongly disagreed or disagreed with the statement: *"The Novel Foods Regulation promotes new technology through the regulatory framework in the European Union."* Only one expert neither agreed nor disagreed with the statement.

Furthermore, the expert from the UK competent authority noticed that the data provided to prove the safety of food and technology are the same as for a conventional food.
"They are not different from the data you would have to provide anyway. The analysis should be made to ensure there is no microbial risk for consumers. This you would do as a part of your due diligence."
The respondent from the UK competent authority also added: *"I appreciate that there is a delay if it goes through the regulatory framework."*
There are other aspects of the technology that seem to affect the use of the technology as well. Therefore, according to the competent authority in the UK, *"(…) it is unfair to say that it is only because of regulation."*

Dr van Rossum stated: *"In fact, the safety assessment within the framework of the NFR has the possibility to be used in a proportionate way. If a company wants to produce a new food by using a new technology, I personally think that it is important to check the safety of using this technique. And the way, it is formulated now in the NFR makes it already clear that a pre-market safety assessment, according to the NFR, would not be needed if there are no significant changes."* The expert also added: *"A recast of the NFR is currently being discussed, where using nanotechnology or cloned animals for food are considered as important issues related to production techniques (...)."*

10.1.10. Strategies concerning HPP in the food industry

Three strategies may be applied to HPP by a food manufacturer in the EU. A first strategy recognises HP food as not novel since no significant changes occur. Consequently, a high-pressured food could be brought to the market without safety approval. A second strategy is to seek advice from the competent authority when the food manufacturer is not sure whether the HP product falls within a scope of the NFR or not. If the authority states that the product is not novel, the manufacturer may place product on the EU market. Otherwise the approval is required. A third strategy is to apply for an authorisation of the competent authority as the probability that product falls within the scope of the NFR is high.

As mentioned before, only one authorization for HP food - pasteurised fruit-based preparations (Danone Group) was granted and it concerns.

Nowadays, many other high-pressured food products are available on the EU market. For instance, HPP is applied to fruits or fruit juices in the Netherlands and Czech Republic. In the United Kingdom, the files for fruits and vegetables products as well as for oysters were reviewed. Those foods are not perceived as novel.

On the other hand, Dr Tonello informed that the files for meat products treated by HPP had not been accepted. On 25 May 2007, the French competent authority was asked to give an opinion relating to the authorisation of duck magrets dried, or dried and cured, stabilized by HPP under the NFR. The producer concluded in the file that the cured duck ham treated by HPP is substantially equivalent to traditionally produced cured duck ham (not novel food). The competent authority in France criticized the file since there was an opinion that the file was incomplete:*"(…) the dossier does not provide sufficient evidence in literature and empirical studies. Some data are missing. Moreover, the claim that the shelf-life is prolonged twice is not correctly proven."* At the end, no final decision was taken by the authority in this case.

In Spain, four companies – Campofrio, Espuña, Martiko and MRM - produce meat products using HPP. In 2002, Campofrío and Espuña presented separately NF files to the authority in Spain. However, there was no official response. Probably, the reason of this situation was that at that time there was no competent authority to deal with the files in Spain. Later on, when the competent authority was established, a knowledgeable team of scientists to conduct the analysis of files was still missing. Both companies decided to put the products on the market. Dr Tonello stated that it seemed that in Spain high-pressured food was not perceived as novel or the regulation was ignored.

One of the Spanish meat producers, who submitted the file to the Spanish authorities, was not willing to present the opinion on the NFR. They stated: *"(…) until we receive official notification in this regard, we prefer not to comment in reference to EU legislation concerning high pressure food processing."*[360]

In Belgium and Germany, food manufacturers export the high-pressured foods outside the EU, hence they do not have to comply with the NFR.[361]
Abraham Schinken GmbH & Co. KG from Germany exports raw ham and other meat products to the USA. The company introduced high pressure processing as a way to ensure safe *Listeria*-free products as the rule "zero tolerance" for *Listeria monocytogenes* in 25 g of ready-to-eat products is in force in the USA. The relevant parameters of the process were designed in close cooperation between producer, university, different institutions responsible for food safety and hygiene in Germany as well as equipment producer.[362]

The questionnaire included the statement: "*Food producers from the EU may export the foodstuffs produced by the pressure treatment to avoid dealing with the Novel Foods Regulation."* Half of the

[360] information received via e-mail

[361] Article 12 of the GFL provides rules on food and feed exported from the Community. In general, food shall comply with relevant provisions of food law unless the authority of importing country decided otherwise or the provisions of the laws, regulations, standards, codes of practice and other legal and administrative procedures that are in force in the importing country requested otherwise.

[362] Harms, 2006: 40-41

experts (three out of six) neither agreed nor disagreed with statement. Two experts agreed and one disagreed with the statement.

10.2. High pressure processing

This section provides information on high pressure processing and experiences related to HPP gained by the food industry in the European Union. The aim of this section is to broaden knowledge on HPP through the experiences of food industry.

10.2.1. High pressure processing in Europe and North America

Currently, Europe has two times less high pressure installations than North America (chapter 5, section 5.2.). Dr Houska stated: *"There was some research done displaying the number of HPP installation and the number of scientific publications in different world regions. And, from this information, it could be seen that there are much more publications in Europe compared to the US and Canada, but at the same time there are less HPP applications. So, this could be an effect of legislation in Europe since the scientists in Europe were asked by the companies to evaluate the effects and safety of HPP."*

Dr Tonello stated that all food manufacturers make their own analysis to ensure food safety before putting the products on the market. The problem relating to HPP is that it is not clear how to prove that food does not bring a risk to consumers. Additionally, the food manufacturers want to be sure that they will reach safety goals with HPP, since the costs of investments in this technology are rather high. Therefore, many organisations, like universities, scientific institutes or research centres are involved in the study on the application of HPP to food industry.

Only traditional health regulations are applicable in the US as there are no specific regulations on HPP. According to Dr Houska, it is just *"(…) enough to comply with GMP, GHP, HACCP to ensure food safety. And in Europe, we added another barrier, which is behind and above the general rules. This is the Novel Foods Regulation, which main aim was to regulate GMOin Europe. But this regulation has also been used in the case of novel food, including application of novel technology as the so-called "precautionary principle"."*

On the other hand, Ms. Matser explained that many other factors influence the situation of HP pasteurised products in the EU, for example investment costs (equipment), culture of the companies (innovative attitude of companies), differences between consumer attitudes towards novel technologies and prices of food between the member states. Therefore, it is important for the food companies which want to introduce HPP, to produce high-added value products, since only then it is cost-effective.
Nowadays, more and more HP equipments are installed in the EU.

One of the statements in the questionnaire is: *"The main problems relating to high pressure processing are costs and operational issues, and NOT the Novel Foods Regulation."* The expert from the food industry strongly agreed with the statement, while the experts who are scientists strongly disagreed or disagreed with statement. Two experts neither agreed nor disagreed.

HP sterilization is still not commercialised. There are a number of weak points of HP sterilization. The most important are that: the equipment is not available, the costs are high and technology does not possess all scientific data to approve its safety.

Dr Tonello also added that if in the US the food producer wants to apply the HP sterilization, it is necessary to have authorisation for equipment and product, otherwise it is not allowed to apply this process. Furthermore, *Clostridum botulinum* must be shown to be eliminated by the HP sterilization from the food product. So far only one machine and one product (mash potatoes) have been authorised.

10.2.2. Strong and weak points of HPP from the food industry perspective

Nowadays, the most important features of food product from consumers' perspective are safety, as well as nutritional and sensory quality. HPP is a process that maintains all these properties of foods and at the same time ensure safety.[363] As mentioned before in chapters 2 and 3, foods treated with high pressure are shown to keep the original freshness, colour, flavour, taste and nutritional value.[364] Additionally, this process inactivates pathogenic and spoilage microorganisms.[365]
And as high pressure can be subjected to already packed foods, the post-pasteurisation contamination is avoided.[366]

Besides many advantages, there are also some disadvantages of HPP. The initial capital investments for HPP are rather high. In consequence, the application of HPP is limited only to **high-value products** as the commercial feasibility of technology depends on the business profitability.[367]

Michael Cockerill explained the issues relating to HPP from the food manufacturer perspective. The expert is a Technical Director in Orchard House Foods Ltd. This food manufacturer produces ready-to-eat fresh fruit products, fresh fruit patisserie and drinks in the UK.

The expert noticed that the operational efficiency of key unit processes, such as HPP, should be 90% or better. For some HP equipment, which was used particularly in the early years, the operational efficiency was often well below desirable level. Thus, Orchard House Foods always struggled to really make a good commercial return on the equipment.
The expert noticed that currently, the company does not use HPP since it is an expensive way of doing things. When the manufacturer takes into account all processing costs including capital costs, running costs, labour costs and other, she/he will get £0.30 (about €0.33) per litre. Mr. Cockerill stated: *"And when the company is in a competitive market place, even in case of high quality products, there is a limit to the amount of premium that consumer is prepared to pay for an HHP product."* He added: *"(…) when you add everything together, it does not make quite sense. So in this case it can be said that the main minus of the HPP are costs and not the regulatory issues."*

[363] Corkindale, 2006 in Norton & Sun, 2008: 28
[364] Butz & Tauscher, 2002: 282
[365] Norton & Sun, 2008: 20-22
[366] Harms, 2006: 40
[367] Corkindale, 2006 in Norton & Sun, 2008: 29

There is also an issue with the process as HP equipment (which is intrinsically a batch process) does not fit comfortably with normal filling line which is a continuous process. Mr. Cockerill explained: *"There needs to be an intermediate buffer somewhere in the middle."*

However, there are cases that HPP works well. *"One of the examples is Avomex in the US. There are some phytosanitary reasons that you can not take the avocados to the US before some former treatment, so HPP can be applied there. Furthermore, the HPP can be applied nicely to the process of avocado guacamole. As a result, a cheap raw material source is transformed into an expensive and high-value product. There is a similar unique situation with oysters where HPP opens up the adductor muscle."*
Another example of HPP application is production of ham. HPP is a technology that ensures that meat product complies with the requirement - "zero tolerance" of *Listeria monocytogenes* in the US.

10.2.3. Experiences relating to HPP

10.2.3.1. Orchard House Foods and HPP

Orchard House Foods has been the first producer of freshly squeezed and unpasteurised juices in UK. Consequently, there was a very clear understanding of the differences in flavour profile between fresh and pasteurised products within the company.

Mr. Cockerill emphasised that the fresh flavour of the product is the unique feature and HPP was seen as a technology that delivers products with longer shelf-life (the inactivation of spoilage microorganisms particularly yeasts) while maintaining the excellent fresh flavour profile. Therefore, the company noticed the potential of high pressure processing to produce safe products with superior quality.
During the period between 1997 and 2008, Orchard House Foods used five different HP machines and gained a lot of experience.

Mr. Cockerill described the beginning of high pressure processing in his company. First, around 1997 and 1998, HPP was used on trial basis to test the market. The company wanted to produce an orange juice, and fortunately this product had already been produced and marketed in France before the Novel Foods Regulation entered into force in 1997. At that time, there was a market test that lasted 2-3 months and was performed in two stores in London.
The Food Standards Agency (FSA) in UK was content with the French experiences relating to the orange juice. The orange juice treated by HP was not regarded as a novel food anymore and HPP was not regarded as a novel process in this case. Orchard House Foods launched the product after the market test, and then the company decided to launch other fruit variations. However, to make that possible the company had to prepare the documents to support the case on the basis of substantial equivalence. Formally, it took about nine months to gather sufficient information requested by the FSA. The documents contained confirmation of food safety and food standards. The prepared information was not particularly massive but some expertise was needed in terms of toxicity and other issues. It took a bit of time but it was not a big issue.

At the end of this process, there was a formal communication from the FSA that Orchard House Foods could use this technology for processing a range of fruit juices with a pH below 4.2.
In 2008, the company had a very short life product (6 days in chilled conditions) which was a fresh fruit smoothie with the fresh fruits. HPP was decided to be used to extend the shelf-life to 14 days in order to penetrate a wider market.

Costs connected with the scientific data

Mr. Cockerill stated that the expenses on the research were not very high. Opinions of six experts were obtained. In the case of toxicity, the scientific literature search was made by a university professor, and then a simple document was prepared. All issues were included so it was satisfactory for the FSA; furthermore the request to extend approval for a range of different fruit juices was just variation on the original orange juice theme. Summarizing everything up, the total cost of gathering data was around £10,000 (about €11,042).

Cooperation with the competent authority

Mr. Cockerill stated that the cooperation with the FSA was good. There were a couple of meetings face to face with contact person from the FSA.

Legislative issues

The legislative issue that is taken into account in the case of HPP is the Novel Foods Regulation.

The key aspect was that the company was producing short life, unpasteurized, fruit juices. Orchard House Foods has been always very conscious to keep the pH acidic because of the safety reasons. There was an internal standard for pH to be below 4.2 (regarded as important parameter to prevent germination of *Clostridium botulinum* spores). This was a relevant matter for the FSA as well. The authority was aware of the characteristics of the company's products (short life and high acid) and of the fact that Orchard House Foods did not want to use HPP to do something extraordinary. The only reason of applying this technology was to prolong the shelf-life of the product (maximally 21 days in chilled conditions, pH 4.2).
During the consultation between the company and the FSA, the authority was mainly interested in the pathogens, pathogenic growth and food safety. The spoilage problem was rather perceived as the company's issue.

Consumer attitude towards HPP

The market trial lasted 8–12 weeks and was performed in a couple of stores in London. The short life unpasteurised product was replaced by the HP product, but HPP was not mentioned on the label. The changes in complaints and sales level were screened, and the trial did not indicate any differences. Later on, this trial was used as a part of evidence when the substantial equivalence was taken into account. Subsequently, Orchard House Foods had a lot of HP products on the market in the early part of 2000 and again in 2004.
The company had also some HP products on the market for a short period of time in 2008. No negative reactions were noticed amongst the consumers.

Orchard House Foods did not choose to promote that the products were high pressure treated. The company did not believe that an HPP tag was relevant. Furthermore, it was not obligatory to put on the label that the product is high pressure treated. Mr. Cockerill stated: "*We were selling orange juice, not technology. Did the consumers find that the product met their expectations? – The answer was clearly – yes.*"
The company has never provided consumers with wider knowledge about HPP, since this technology was used to extend the shelf-life.
However, Mr. Cockerill admitted that HPP may be a hard message to put across the consumers.

10.2.3.2. Introducing HP foods on the market in the Czech Republic

Dr Milan Houska provided some detailed information on HP food in Czech Republic.
He explained that the development of HP food product in Czech Republic started in 1998 in the Food Research Institute Prague. At first, there was just an idea, and later on the cooperation with the Ministry of Agriculture started a three-year project concerning building an HP experimental unit (chamber of 2 litres).
Later on, the equipment company (ZDAS j.st.co.) proposed a project of building a prototype of HPP equipment to the Ministry of Trade and Industry. The cooperation with a food producer - Beskyd Frycovice was also established since the company was interested in applying HPP. When the project ended, Beskyd Frycovice took over the equipment and performed some trials. However, some technical problems relating to the equipment occurred. Then, new equipment was bought from the Spanish producer of HP equipment and the first HP products were launched.

Meantime, there was a new project from the Ministry of Agriculture to develop a HP treated functional food, which would have some beneficial effect on human health. The overall time needed to transform the idea to a final food product was about 7 years.
A high-pressured mixture of broccoli and fruit juices was brought to the market in the Czech Republic. This product was a result of collaboration between Beskyd Frycovice - a food producer in the Czech Republic, and scientists from the Food Research Institute Prague.[368]

The juice is a mixture of broccoli juices with fruit juices: apple, orange and key lime. Addition of fruit juices help to decrease the pH and also positively influence consumer's acceptance of the product. Broccoli is used as a rich source of compounds that have been shown to possess antigenotoxic properties. Consequently, they may help prevent cancer. High pressure processing was recognized as technology which did not affect the antimutagenic effect of broccoli.[379]

This product characterises with shelf-life of 10 days stored at temperature below or equal 5°C. HPP combined with pH, shelf-life, storage temperature as well as HACCP system ensures the safety of the product.

In order to identify the legal status of HP broccoli juice, the producer and scientists from the Food Research Institute Prague collaborated with the Ministry of Agriculture in the Czech Republic, and contacted the European Commission.

[368] Anonym, 2007: 36

The European Commission took into account the opinions of ACNFP and informed about the conditions that must be met by HP products to be considered as not novel products. As a result, it was decided that the juice was not a novel food.

Dr Houska noticed that the product was not a commercial success since the price of the product (bottle of 0.3 litres) was quite high (about 50 Kč what is about 1.94 Euro), and the selling rate was rather low.
Additionally,, the manufacturer of HP broccoli juice was charge with extra costs, such as fee for introducing the juce into the retailer's distribution chain.

11. Discussion

Nowadays, a number of HP foods are available on the EU market. However, the application of HPP in the EU food industry (about 25% of total number installed HP equipments) is not as intense as in North America (about 55% of total number installed HP equipments).[369] At the same time, as one of the experts noticed, there are much more scientific publications on HPP in Europe than in other parts of the world.
This chapter will discuss the factors, including EU legislation (especially the NFR), which may have an impact on the situation relating to HPP application in the EU food industry.

11.1. The EU legislation on HPP and its impact on the food industry

As soon as a food producer wants to launch a new food product to the market, she/he has to take into account all relevant legislation concerning product as well as applied process. The EU legislation on HPP does not differ considerably from the legislation concerning the traditionally processed food. Similarly like in the case of traditionally processed food, the producer should consider the rules applying to product, process, communication and packaging.[370]

The only difference is two additional rules applying to HPP. A first rule is the so-called **Pressure Equipment Directive** (**Directive 97/23/EC** on the approximation of the laws of the Member States concerning pressure equipment) which concerns the high pressure equipment. This piece of legislation is primary relevant for the equipment producer.

A second rule that was seen by the experts as potentially important from the food producer perspective is **the Novel Foods Regulation**.[381]
It is essential to add that the EU legislation on HPP was perceived by many experts as **vague** and **"grey" area**. The probable reason of the legislation's vagueness is that it is not clear if/when the NFR is applicable to the high-pressured food. The lack of clarity may be **an obstacle for food industry**, especially for Small and Medium Enterprises (SMEs) since they may not have scientific and financial resources to establish if the NFR is applicable or to support the application. It is important to notice that SMEs accounted for over 99% of the total number of companies in the EU food sector.[371] Therefore, the NFR may be perceived as **a regulatory barrier** for the food businesses in the European Union.

The NFR requires novel food, which is produced by a novel process, to be authorised. An important issue to emphasize is that it is the **food product** which is approved under the NFR and **not the technology**.
As a result, the vertical approach is used. It means that each single food produced by the novel process should be approved under the NFR if it meets **two conditions**.
A first condition states that the process is regarded as novel when it was **not used before 15 May 1997 to significant degree**. A second condition requires **occurrence of significant**

[369] see Figure 14 in chapter 5
[370] see chapter 5 and 6
[371] Brookes, 2007: 13

changes in the food composition or structure, and these changes would affect nutritional value of food, metabolism or level of undesirable substances.[372]

When the first condition is considered, it must be noticed that one HP food product (high-pressured orange juice) was available on the French market before 15 May 1997. Thus, it has not been perceived as a novel food by some experts. On the other hand, some other experts claim that **the quantity of juice was too small** to consider it as consumed to **a significant degree**, so in this case it should be classified as a novel food if the second condition occurs. These contradictory opinions on an orange juice may be confusing for the stakeholders and have influence on the vagueness connected with the status of HP food.

In the case of second condition, the definition of **significant change** in the NFR seems to be rather general and imprecise; therefore there may be a room for interpretation. Two main questions that may rise are: *What is a significant change? And who is responsible for interpretation?*

To answer the first question, one should consider the **characteristics** of processed food and especially its **safety**. The author suspects that the change, which is produced by the novel process in the food product, is classified as significant if it may **affect** negatively **food safety or nutritional value**. This way of thinking seems to be logic since both elements - food safety as well as nutritional value may have an **impact on human health**. And the protection of human health is nowadays the main aim of food law in the European Union.

Another interesting aspect is the application of the NFR to HP food in practice. A role of the regulation is to harmonise food law in the EU, it means that if a food would be classified as a novel food and would fall within the scope of the NFR, it should be regulated by the same mechanisms across the EU. However, the decision on the legal status of HP food is taken individually by every member states. So, although all aspects relating to NF are considered on the EU level, some aspects of HPP are judged on the level of member states.
So, if it happens that the opinions of the member states on the HP food are contradictory, this situation may be confusing for the food producers, especially for SMEs. Furthermore, some member states may have more stringent policies relating to novel food (high-pressured food) than is required.

The results of the questionnaire revealed differences in the expert's opinions concerning the responsibility for the interpretation of the definition. The majority of experts agreed with the statement that **the food producer** is responsible for interpretation of the definition concerning novel food and the term "significant change". At the same time, **two experts from the UK** were of the opinion that **the competent authorities** are responsible for interpretation of those definitions. This difference between the opinions may mean that the approaches of the member states vary across the Community or that it is more matter of sequencing. It means that the first who should take a position on HP food is the food producer. When she/he has done so, subsequently the authority is obliged to agree or to disagree with producer's position.

[372] Article 1(2)(f) of the NFR

Additionally, it is important to notice that the competent authorities of the individual EU member states differ in **a level of experience** relating to NF and the NFR as well as in **a level of cooperation** with the food industry. For instance, the competent authorities in the UK, France, the Netherlands, Germany or Finland are more experienced in NF than other EU member states. Moreover, as found out during the interviews, the competent authority in the UK cooperates closely with the food industry and formulates clear messages concerning NF and HPP on their website. The openness and transparency may support the confidence of the food producers and thus shorten the time of bureaucratic procedures.

All mentioned factors are strongly connected with each other and they all may impact the approaches of the member states. Consequently, all these factors affect the HPP situation in the EU.

11.1.1. "Danone case" and determination of novelty

As mentioned in chapter 5, Groupe Danone was the first and at the same times the only company that has been granted authorisation for a HP food product under the NFR until now. The authorisation for placing high pressure treated fruit-based preparations was granted by the Commission in May 2001. During the assessment, it was realized that HP pasteurisation like traditional heat pasteurisation causes changes in the structure or composition of food. The Commission Decision (2001/424/EC) concerning Danone Groupe stated that *"(…) the high-pressure treatment provides the same level of safety as generally used heat pasteurisation process with respect to the bacteriological risks and the allergenic potential."*
This decision of the European Commission may have affected the situation relating to the status of HP food in the EU.

It is important to realize that the application was submitted by Groupe Danone in December 1998, so a relatively short time after the NFR came into force on 15 May 1997. At that time, the member states were not much experienced in dealing with the NFR. Probably, it was difficult to establish whether the changes caused by HPP in the food product were significant or not.
HPP, as mentioned before in chapter 2 and 3, similarly like heat treatment causes chemical and physical changes in the food products. The approval of HP food from Groupe Danone may indicate that fruit-based preparations treated by high pressure were seen as significantly changed at that time.
Moreover, the majority of experts who took part in this thesis research were of the opinion that both submitting the application by Groupe Danone as well as granting the approval by the Commission was necessary.

Although the authorisation was granted exclusively to high pressure pasteurised fruit-based preparations, later on other HP foods appear to be placed on the market without the approval under the NFR. So, one can ask: *Why was other HP food not assessed for authorisation?*
In the author's interpretation, the "Danone case" allowed to take a closer look at HPP and assess its safety. Although some changes in the food occurred, they did not affect the safety of the food. On this basis, the authorisation was granted. Later on, the changes in the food product caused by HP pasteurisation were recognised as not significant.

The food producers are obligated to ensure that any foods including those treated by HPP are safe for consumers. However, if a food producer is not sure whether the product falls within the scope of the NFR or not, she/he may make an enquiry to the competent authority. In this case, the member state may require the data concerning microbiological, toxicological and allergenic aspects of a new HP food product.

The European Commission with representatives from the EU member states have accepted that HPP does not produce any material change in the composition of the food and as a result does not require further assessment under the NFR.[373] However, this information was only found officially on the UK competent authority website and not on the Commission website.
Although the Commission's opinion concerning HPP was not made public, most of the experts who took part in the research were aware of this statement. On the other hand, the representative of the food industry disagreed that this statement is clear and well-known. This finding may indicate that there are different levels of familiarity with HPP and legislation between the stakeholders in the European Union.

Furthermore, the status of HPP is not clear, since the competent authorities of the EU member states decided in July 2001 that the national authorities should decide on the legal status of high-pressured food.[374] Some member states are not clear about the legal status of the HP food products, for instance the competent authorities of Spain did not react when the food companies had submitted all relevant documentation relating to HP food.
Another finding of the research revealed that some experts agreed that the interpretation of the novelty of high-pressured food depends on the temperature applied during the process. Thus, two high pressure processes should be distinguished: **HP pasteurisation** and **HP sterilisation**.

HP pasteurisation which is currently applied to many food products is **not perceived** by many experts **as novel process** anymore. These experts support **the horizontal approach** which means that HP pasteurised food is not considered as falling within the scope of the NFR. However, another group of the experts is of the opinion that HP products should be **assessed on a case-by-case basis**.

Additionally, this research showed that **the competent authorities** in the member states have two different approaches concerning HPP as well. Some member states in the EU accepted that the probability of HP pasteurisation to cause a significant change is rather low and thus **HP food is generally considered as not a novel food**. On the other hand, other member states seem to be of the opinion that it is more appropriate to consider HP pasteurised food on **case-by-case basis**, although this technology is used widely in many countries outside the EU, for instance the US or Japan without any requirement of approval.

Taking into consideration all scientific data, especially those relating to the safety, the author is of the opinion that **the horizontal approach** stating that HP pasteurised food is not a novel food, should be applied. Author's suspicion is that different opinions and approaches

[373] ACNFP, 2002
[374] Eisenbrand, 2005: 1169

relating to HP pasteurised food in the EU may be a result of the BSE crisis and other food scares that took place in Europe in 1990s.
Currently, the main focus of the EU authorities is the food safety and consumer health. In addition, some member states have rather careful approach towards novel foods. It seems that the "precautionary principle" may be applied quite often, although the risk relating to the occurrence of health problems caused by this food is rather low.

High pressure sterilisation combines high pressure with elevated temperature. This process is not used at an industrial scale, since the appropriate equipment is still not available. The main aim of the sterilisation is to inactivate bacterial spores, so HP sterilisation similarly like heat sterilisation must guarantee the safety of the food products. This process is still studied, thus it is possible that it causes significant changes in the food products. Consequently, the authorisation under the NFR may be required. However, one should take into account that HP sterilisation may cause changes similar to traditional heat sterilisation. In this case, HP sterilisation should not be considered as novel process, and the horizontal approach should be applied. However, likewise in the case of HP pasteurisation, the food producer will have to deliver scientific data on the inactivation of spores.

All mentioned issues relating to the legislation on HPP trigger **uncertainty**. According to Brookes [2007], uncertainty may have an impact on the attractiveness of a market. The uncertainty of the legal status of a HP food product may have an impact on an additional cost burden and loss of sales in the member states. The uncertainty connected with the authorisation process may add extra risk and thus, also result in additional costs.[375]

It seems that the Proposal for a new NFR, which was published by the Commission in 2008, will not change the situation relating to the HP products and will not reduce the uncertainty. The Proposal provides a similar definition of novel foods produced by novel processes to the one from the current NFR, which is perceived as general and rather vague.

In conclusion, it seems that the EU legislation on HPP and more precisely the NFR may have a negative impact on HPP application in the EU food industry.

11.2. Other factors that may have an impact on the application of HPP in the EU

Legislation is not the only factor that may affect the application of HPP in the EU. There are also other issues that may be relevant, for instance consumer attitudes to novel products, the profitability of products or the innovativeness of the companies.

11.2.1. The EU food market

The European Union beside the US and Japan, is an attractive market for introducing novel foods since it characterizes with the large consumer populations with reasonable levels of disposable income. Currently, the EU population accounts for about 500 million people.
The food sector in the EU is the first production sector, when the size is being considered.[376] The food products turnover was €836 billion (13.6%) in 2005 and it demonstrated the trend of

[375] p. 5-6
[376] van der Meulen & van der Velde, 2008: 41

growth. These data may indicate that the EU market possess a large potential for introducing new products.

11.2.2. Prices and expenditure

The average expenditure of EU household on food and drink (non alcoholic beverages) accounted for 12.4% of the total household expenditure in 2005.[388]
It should be noticed that the proportion of expenditure spent on food and drink may vary between the member states. For instance this number accounted over 20% in Latvia and Lithuania and below 10% in the UK and Ireland. The majority of the new member states that joined the EU in 2004, showed average household expenditure levels on food and drink of over 15% in 2005.[388]

The differences in household expenditure on food and drink between the EU member states may indicate different level of income and also willingness to pay more for food products. In the member states, where the income is higher, the consumers may be willing to pay more for a new food product with additional benefits.

11.2.3. Number, type and culture of companies in the sector

The predominant type of companies in the EU food sector is Small and Medium Sized Enterprises. According to Brookes [2007], SMEs accounted for over 99% (282,600) of the total number of companies. Moreover, they generate 47.8 % of food and drink turnover and employ 61.3% of the sector workforce.[377]

The author suggests that policy makers in the EU should consider the fact, when a new legislation is proposed, that SMEs have usually limited financial resources and often lack the expert knowledge on legislation. Therefore, food law should be clear and understandable for all stakeholders and may be primary for SMEs.

Brookes [2007] reported that large companies were 0.9% of the number of companies in the EU and generated 52.2% of the total sector turnover and employed 38.7% of the workforce.[377]
Those companies usually invest a lot in research and development (R&D) as it plays an important role in a company's innovation.
The average intensity of R&D in the EU, which is expressed as a % of industry output in the EU food and drink industry, was 0.24% in 2004.
The intensity of R&D varied between 0.6% and 7.1%, when the group of 20 leading companies was considered.[377]
In comparison, the average level of R&D intensity in the US, Australia and Japan was 0.35%, 0.4% and 1.21% respectively. So, the intensity of R&D in the EU (0.24%) was below comparable levels of R&D expenditure in competitor countries.
The intensity of R&D in the leading non EU food companies was comparable with the rates amongst the leading EU food companies since it varied between 1.3% and 4.6% for the six leading companies.[377] So, the leading companies in the EU seem to be as innovative as in other countries, but SMEs in the EU seem to invest less in R&D.

[377] Brookes, 2007: 13

Summing up, Brookes [2007] noticed that *"(…) the EU tends not to be the highest priority target market for new (novel) food product development. As a result, EU consumers are losing out from decreased choice and "non availability" of improved products, as well as levels of income and employment generation in the EU are probably lower than they might otherwise have been if the regulatory environment had been more innovation-friendly."*[378]

11.2.4. The profitability of the product

Many elements including financial aspects compose successful food products. Brookes [2007] explained the aspects that a food producer has to take into consideration before a product will be brought forward for development and then for approval for use in the EU.[379]

Before a novel product is launched, the food producer should be certain that it will earn a reasonable rate of return relative to the cost of investment. In general, food companies are looking for internal rates of return on their investment within a range of 20% to 25%.[379]

The important data for the food producer are obtained during the research which should provide the following information:

- the extent to which consumers may be interested in buying a novel product,
- the probability of consumers using a novel product, when its improvement and price are taken into consideration,
- the expected sale and profitability of a new product,
- the expected competitors on the market,
- the probability of approval being granted and connected with it costs,
- the costs of launching and marketing of a novel food.[379]

Both the scientific literature and the experts are of the opinion that the initial costs in the case of HPP are high. According to Balasubramaniam & Farkas [2008] commercial scale high-pressure equipment costs between $ 500,000 and $ 2.5 million dollars, depending on the capacity and extent of automation.[380]
The high initial costs and also other costs cause that high-pressured food products are more expensive than traditionally processed food. The higher price of HP food seems to be an important issue, especially on the competitive market.

High pressure processing is primary recommended to high value food products that make financial sense.
It seems to be of a great importance to provide consumers with clear information about the benefits connected with HP food and thus impact the consumer's attitude towards HPP. However, some food producers do not want to put on the label that the food product has been produced with use of HPP as they regard HPP as a "hard massage" for consumers. Like in case of genetic modification or irradiation, there is a risk that HPP would not be successful on the market although the technology posses many advantages. It is true that it is sometimes difficult to predict consumers' attitude since attitude may depend on many

[378] Brookes, 2007: 6
[379] Brookes, 2007: 15
[380] p. 414

factors like the consumer's age, level of education, place of living (big city, town, village), material status, etc.

Additionally, EU member states differ sometimes considerably between each other in many areas. Therefore, the number of HPP applications in the food industry and the market for HP food may differ noticeably between the individual EU member states.

In conclusion, it seems that other factors beside legislation may also have an impact on HPP application in the EU food industry.

12. Conclusions and Recommendations

The main aim of this research was to elaborate the impact of the EU legislation on the application of high pressure processing in the food industry. Additionally, some other factors which may also affect HPP application in the EU were identified and discussed briefly.

12.1. Conclusions

High pressure processing has a great potential in the food industry and has become especially popular since 1990. This technology similarly to heat treatment assures food safety and extends the shelf-life of food products but unlike heat treatment it maintains the quality of fresh foods. However, as one of the experts noticed during the interview, **in Europe** there is **much more scientific research** on HPP but **less applications** of HPP in the food industry than in North America.

Many different reasons, including the EU legislation on HPP, are responsible for this situation. As one expert mentioned, European food law on HPP is perceived as vague and a **"grey area"**. Additionally, the opinions relating to HPP may sometimes vary considerably within the EU.

The legislation on HP food is basically the same as for a conventional food, except from PED and the NFR. The first one is only relevant for the producers of HP equipment and the second one is applied only when certain conditions are met by HP food. The concern of the food industry, especially SMEs, is to establish whether an HP food falls within the scope of the NFR or not. The conditions may be unclear, since the definitions of terms "consumed to significant degree" as well as "significant changes" from the NFR are rather general and imprecise, consequently they may be interpreted differently by the stakeholders.

Additionally, it was resolved that the decision on the legal status of HP food is taken at member states level. It is relevant to mention that the member states (the competent authorities) may differ significantly in the experience and attitude relating to HPP (some member states have a horizontal approach whereas some other are of the opinion that a case-by-case approach is more suitable) as well as in the level of cooperation with the food industry.

Summing up, the uncertainties connected with the NFR may have a role in affecting HPP application in the food industry, especially in the case of SMEs.

Other factors like the high initial costs or consumers' attitude towards HPP appear to be also relevant for HPP application in the EU food industry.

12.2. Recommendations

For the food industry:

- HPP is recommended to the food industry as innovative technology to preserve and to extend the shelf-life of the food products.
- The author proposes that the food producer applying HPP should ensure that HP pasteurisation is as efficient as heat pasteurisation, since it is the major concern from the food safety point of view in the case of HP foods.
- The author advises that if the food producer is not sure whether or not the product falls within the scope of the NFR, she/he should seek the opinion of the competent authorities that have an experience in HPP applications and cooperate closely with the food industry, for instance the UK competent authority.

For the competent authorities:

- In order to support the development and innovativeness of food industry in the EU, especially SMEs, the competent authorities should **cooperate** closely with the food producers and establish **the communication channels**.
- The author is of the opinion that in the case of HP pasteurisation **the horizontal approach** is more appropriate than the case-by-case approach.

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Annex I

Table 1. Factors to convert units of pressure. **Source:** FAO, 2001

Unit	atmosphere standard	MPa	bar	kg/cm²	psi
atmosphere standard	1	0.101325	1.01325	1.0332	14.69594
MPa	9.8692	1	10	10.197	145.0377
bar	0.98692	0.1	1	1.0197	14.50377
kg/cm²	0.9679	0.0981	0.9807	1	14.2236
psi	0.068046	0.006894	0.068947	0.0703	1

M = 10^6, k = kilo, Pa = Pascal, psi = pounds per square inch

Annex II

Table 1. HP vegetables and fruits. **Source:** NC Hyperbaric, 2006

Country (year)	Product	Process	Shelf-life	Interests of high pressure and comments
Japan (1990)	**Jams** Apple, strawberry, blueberry **Coatings** Apple, strawberry, blueberry **Sauces** Apple-onion, orange, grapefruit **Fruit jellies** Orange , pineapple, grapefruit, mandarin	Indirect 400 MPa 10-30 min without temperature regulation	2 to 3 months at 4°C	Sanitization, induction of gelification of the fruit-sugar-pectin mix, and sugar intake in fruits pieces. Preservation of fruit color and fresh taste. Vitamin C content is unmodified.
Japan (2000)	**Precooked rice Hypoallergenic rice**	400 MPa	Stored at room temp.	Increase of water content due to HPP process facilitates cooking process. Unfolding of allergenic proteins by high pressure followed by a salt extraction of these proteins and a heat sterilization. Product for hospitals.
Italy (2001)	**Fruit desserts : Apple, pear and strawberry**	Indirect 3 to 5 min at 600 MPa and 17ºC	1 to 2 months	Enzymes (PPO) inactivation, sanitization, keeping sensorial properties of fresh fruit purees. Shelf-life increase without the help of chemicals.
USA (2002)	**Avocado based products**	Indirect		Enzymes (PPO) inactivation, sanitization, keeping sensorial properties of fresh avocado. Shelf-life increase without help of chemicals.
Mexico (2002)	**Avocado based products**	Indirect		Enzymes (PPO) inactivation, sanitization, keeping sensorial properties of fresh avocado. Shelf-life increase without help of chemicals.
USA (2003)	**Sliced onions**	Indirect	45 days	No bitterness, fresher and crunchier. Sanitization and increase of shelf-life.
Canada (2003)	**Apple-based purees and sauces**			Sanitization, preservation of sensorial properties of fresh apple. Increase of shelf-life.
USA (2004)	**Soya products, tofu**			Sanitization, increase of shelf-life.
Spain (2005)	**Ready-to-eat vegetable dishes**	500 MPa	1 month	Sanitization, increase of shelf-life.

Table 2. HP juices and beverages. **Source:** NC Hyperbaric, 2006

Country (year)	Product	Process	Shelf-life	Interests of high pressure and comments
Japan (1993)	**Sake (Rice wine)**	Indirect (PE pouches) 400 MPa 30 min 15°C	6 to 12 months at 4°C	Yeast inactivation without thermal treatment. Keeping of the raw sake specific taste
France (1994)	**Citrus juices Orange, lemon and grapefruit**	Indirect 400 MPa 1 min at room temp.	18 days at +4°C	Sanitization keeping sensory qualities of fresh juices.
Mexico (2000)	**Citrus juices Smoothies**	Indirect 500 MPa and direct	?	Sanitization keeping sensory qualities of fresh juices.
Lebanon (2001)	**Fruit juices (54 different varieties or blends)**	Indirect 500 MPa	1 month	Sanitization keeping sensory qualities of fresh juices.
USA (2001)	**Organic apple juice**	Direct semicontinuous	2 or 3 time more longer than untreated	Sanitization keeping sensory qualities of fresh juices.
Portugal (2001)	**Apple juice, Citrus-apple juices**	Indirect 450 MPa 20 s to 90s +12ºC	28 days	Sanitization keeping sensory qualities of fresh juices.
Italy (2001)	**Fruit juices : apple, pear, strawberry, carrot.**	Indirect 3 to 5 min at 600MPa and + 17ºC	1 to 2 months	Sanitization keeping sensory qualities of fresh juices.
USA (2002)	**Orange juice, lemonade**	Direct 2 min ?	21 day	Sanitization keeping of sensory qualities of fresh fruit products.
Czech Republic (2004)	**Broccoli-apple juice**	Indirect	21 day	Sanitization keeping sensory qualities and anti-cancer properties of fresh juice. First HPP functional food.

Table 3. HP meat products. **Source:** NC Hyperbaric, 2006

Country (year)	Product	Process	Shelf-life	Interests of high pressure and comments
Spain (1998)	**Delicatessen : Cooked sliced ham and "tapas" (pork and poultry cuts)**	400 MPa 10 min at 8°C	2 months	Sanitization without colour and taste modifications.
USA (2001)	**Cooked sliced ham, pork meat products and Parma ham**			Sanitization without colour and taste modifications. *Listeria* destruction.
USA (2001)	**Poultry ready-to-eat products**			Sanitization without colour and taste modifications. *Listeria* destruction.
USA (2002)	**Spicy sliced precooked chicken and beef for fajitas**		21 days	Sanitization without colour and taste modifications. *Listeria* destruction. The Fajitas kit is made of HPP meat but also HPP onions, peppers and guacamole.
Spain (2002)	**Thick sliced ham, chicken and turkey products. Cooked and Serrano ham, Chorizo**	500 MPa 4 to 10 min at + 8ºC	2 months for cooked products	Sanitization without colour and taste modifications. *Listeria* destruction. Increase of shelf-life and additives reduction.
Italy (2003)	**Parma ham (Prosciutto), salami, mortadela**	600 MPa 10 min at +7ºC		Sanitization without colour and taste modifications. *Listeria* destruction. Increase of shelf-life. Products for USA and Japan exports.
Japan (2005)	**Cooked pork meat products nitrites-free : ham, sausages and bacon**	600 MPa 5 min at + 5ºC	4 weeks	Sanitization. Increase of shelf-life.
Germany (2005)	**Smoked German ham: whole, sliced and diced products**	600 MPa 2 min at + 5ºC		Sanitization. *Listeria* destruction. Products for USA export.

Table 4. HP seafood products. **Source:** NC Hyperbaric, 2006

Country (year)	Product	Process	Shelf-life	Interests of high pressure and comments
USA (1999)	**Oysters Sauce for oyster dish**	200 to 350 MPa 1 to 2min	10 to 15 day (fresh oysters)	Opening of the shells (kept closed by a plastic band). Destruction of *Vibrio vulnificus.* Marketing of fresh and frozen opened oysters.
USA (2001)	**Oysters**	240 MPa 90 s		Opening of the shells (kept closed by an elastic band).Destruction of *Vibrio.*
USA (2001)	**Oysters**			Opening of the shells (kept closed by an elastic band). Destruction of *Vibrio.*
USA (2001)	**Oysters**			Opening of the shells. Destruction of *Vibrio.*
Canada (2004)	**Seafood**			Opening of the shells.
Spain (2004)	**Ready-to-eat Fishes salmon, hake**	500 MPa	2 months	Reconstituted sanitased sliced fish without colour and taste modifications. *Listeria* destruction. Increase of shelf-life and additives reduction. Ready to eat after 1.5 min in a microwaves.
Italy (2004)	**Desalted cod**	600 MPa		Shelf-life increase, sanitization.
S. Korea (2006)	**Oysters**	Indirect		Opening of shells, destruction of Vibrio

Table 5. Certain cases of HP products in Europe (till May 2005). **Source**: NC Hyperbaric

Authorisation	Company and Year	Products	Comments
France	**ULTI** (F) 1994	Orange Juice	Commercialisation before the entry into force of the NFR
Based on the NFR; obtained in 2000	**DANONE** (F) 1996	Fruit-based preparations	Not commercialised due to process, equipment and market problems
Regarded as not a Novel Food; obtained in 2001 and 2002 from FSA	**ORCHARD** (UK) 2001 **ATA** (I) 2002	Fruit juices, purees and smoothies	Referred to the Danone case to obtain authorisation from the FSA
No, but the dossier has been studied by the Spanish Food Safety Agency since 2002	**ESPUÑA** (E) 1998 **CAMPOFRÍO** (E) 2002	Meat products	Awaiting authorisation under the NFR
None	**FERRARINI** (I) 2003 **ABRAHAM** (D) 2005	Meat products	No authorisation requested as the products are exported to the US and Japan
None	**FRUBAÇA** (P) 2001	Fruit juices, purees and smoothies	Not fall under the scope of the NFR
None	**GHEZZI** (I) 2004 **Confidencial** (E) 2005	Desalted cod Vegetable products	Not fall under the scope of the NFR

Conclusion: 2/3 companies sell HPP products without authorisation in Europe

Annex III

Patrick Deboyser
European Commission DG Sanco
Rue de la Loi 200
B-1049 Brussels
Belgium

Reference: NFU 19

17 July 2000

Dear Mr Deboyser

Application for Authorisation to Market Fruit Preparations Pasteurised Using a High Pressure Treatment Process

At its forty sixth meeting on 6 July, the Advisory Committee on Novel Foods and Processes (ACNFP), the UK Competent Assessment Body, considered the French Competent Authority's Initial Opinion on the above application from Danone.

The ACNFP generally agreed with the opinion of the French Competent Authority and accordingly the UK Competent Authority is content for clearance to be given **for the fruits listed when processed in the manner described in the application dossier only**, subject to the following conditions:

Significant changes to the operating conditions or to the types of foods to be processed would require a further application for approval.

The ACNFP was concerned that, as high pressure processing does not inactivate bacterial spores, products processed in this way could represent a risk to consumers of botulism poisoning. The ACNFP agreed that approval for the use of the high pressure treated fruit preparations should be limited only to final products whose characteristics conformed with the criteria recommended in the enclosed report published by the UK Advisory Committee on the Microbial Safety of Food (ACMSF) in 1992, and amended in 1995.

In particular, in addition to chill temperatures, which should be maintained throughout the chill chain, the following controlling factors should be used singularly or in combination to prevent growth and toxin production by psychrotrophic *Clostridium botulinum* in prepared chilled foods with an assigned shelf-life of more than 10 days:

• a heat treatment of 90°C for 10 minutes or equivalent lethality,

• a pH of 5 or less throughout the food and throughout all components of complex foods,

• a minimum salt level of 3.5% in the aqueous phase throughout the food and throughout all components of complex foods,

• an aw of 0.97 or less throughout the food and throughout all components of complex foods.

Where chilled storage is the sole controlling factor, chilled foods stored between 5°C and 10°C should have an assigned shelf-life of 5 days or less. If a shelf life of up to 10 days is required, the chilled storage temperature should be 5°C or below.

The ACNFP agreed with the French CA Initial Opinion that high-pressure processing would not introduce into fruit products further allergens that were not already present in unprocessed fruit. However, the ACNFP noted that, as high pressure processing is a mild treatment that may not denature potential allergens, this could have implications for susceptible individuals who are allergic to unprocessed fruit, but not thermally processed fruit.

Yours sincerely

Sue Hattersley
ACNFP Secretariat

Cc: Competent Authorities, Ms A. Davi (Groupe Danone)

Source: ACNFP, 2000

Annex IV

L 151/42 EN Official Journal of the European Communities 7.6.2001

COMMISSION DECISION
of 23 May 2001
authorising the placing on the market of pasteurised fruit-based preparations produced using high-pressure pasteurisation under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document number C(2001) 1462)

(Only the French text is authentic)

(2001/424/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC)No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (1), and in particular Article 7 thereof,

Having regard to the request by Groupe Danone to the competent authorities of France of 3 December 1998 for placing pasteurised fruit-based preparations produced by highpressure pasteurisation on the market as a novel food ingredient,

Having regard to the initial assessment report drawn up by the competent authorities of France, which the Commission forwarded to all Member State on 16 May 2000.

Whereas:

(1) In their initial assessment report the French competent food assessment body came to the conclusion that highpressure treatment (8 kbar for 6 minutes at 20°C)may be safely used instead of the specified generally used heat pasteurisation process (85°C for 10 minutes).

(2) Within the 60 days' period laid down in Article 6(4)of the Regulation, reasoned objections to the marketing of the product were nevertheless raised in accordance with that provision. In accordance with Article 7 of the Regulation, a Decision is therefore to be taken in accordance with the procedure laid down in Article 13 of the Regulation.

(3) At a meeting on 9 October 2000 experts of Groupe Danone were called upon to provide the necessary information in response to the comments and objections raised by Member States. In particular, a technical explanation was given that the high-pressure treatment provides the same level of safety as the generally used heat pasteurisation process with respect to the bacteriological risks and the allergenic potential.
(4) It is therefore considered that the use of high-pressure pasteurisation in the production of fruit preparations is not likely to have an effect on public health so that a decision can be taken without consultation of the Scientific Committee for Food.

(5) On this basis, it is established that the products comply with the criteria laid down in Article 3(1)of the Regulation.

(6) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee for Foodstuffs,

HAS ADOPTED THIS DECISION:

Article 1

The fruit preparations pasteurised by high-pressure treatment, as specified in the Annex, may be placed on the market in the Community as a novel food ingredient.

Article 2

Without prejudice to the other requirements of Community law concerning the labelling of foodstuffs, the wording 'pasteurised by high-pressure treatment' is displayed next to the fruit preparations in question as such and in any product in which it is used.

Article 3

This Decision is addressed to Groupe Danone, 7 rue de Téhéran, F-75391 Paris CEDEX 08.

Done at Brussels, 23 May 2001.

For the Commission

David BYRNE

Member of the Commission

(1)OJ L 43, 14.2.1997, p. 1.

ANNEX

Specifications for fruit preparations pasteurised by high-pressure treatment

Parameter	Target	Comments
Types of Fruit	apple, apricot, banana, blackberry, blueberry, cherry, coconut, fig, grape, grapefruit, mandarine, mango, melon, peach, pear, pineaple, prune, raspberry, rhubarb, strawberry	Fruit used in conventional process
Fruit storage before high-pressure treatment	Minimum 15 days at – 20 °C	Fruit harvested and stored in conjunction with good/hygienic agricultural and manufacturing practices
Fruit added	40 % to 60 % of thawed fruit	Fruit homogenised and added to other ingredients
pH	3,2 to 4,2	
° Brix	7 to 42	Assured by added sugars
a_w	< 0,95	Assured by added sugars
Final storage	60 days maximum at + 5 °C maximum	Equivalent to storage regimen for conventionally processed product.

Annex V

QUESTIONNAIRE

This questionnaire aims at systematizing information that was obtained during first round of conversations with experts. The questionnaire gathers some issues relating to high pressure processing (HPP) that were mentioned by experts.

Please, mark only one answer that you perceive as the most suitable.

Statements:

1. The most important regulatory issue facing HPP is the Novel Foods Regulation (Regulation (EC) No 258/97).

Strongly Disagree	**Disagree**	**Neither Agree Nor Disagree**	**Agree**	**Strongly Agree**

2. The EU legislation on high pressure processing is perceived by many stakeholders as 'grey area'.

Strongly Disagree	**Disagree**	**Neither Agree Nor Disagree**	**Agree**	**Strongly Agree**

3. It was necessary to submit the application to place high-pressured foodstuffs on the EU market by Danone under the Novel Food Regulation (Regulation (EC) No 258/97).

Strongly Disagree	**Disagree**	**Neither Agree Nor Disagree**	**Agree**	**Strongly Agree**

4. It was necessary to grant the authorisation of placing high-pressured foodstuffs on the EU market (Danone) by the European Commission.

Strongly Disagree	**Disagree**	**Neither Agree Nor Disagree**	**Agree**	**Strongly Agree**

5. After the approval granted to Danone, HPP is no longer novel.

Strongly Disagree	**Disagree**	**Neither Agree Nor Disagree**	**Agree**	**Strongly Agree**

6. It is clear and well known by all stakeholders that it has been accepted by the European Commission and representatives of the EU Member States that the high pressure processing does NOT produce any material change in the composition of the food and as a result does NOT require assessment under the novel foods procedures.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

7. High pressure technology is well studied and it is used for relatively wide range of products, and there is marginal chance that requirement for an assessment under the Novel Food Regulation will occur.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

8. It is necessary to use case-by-case approach for high-pressured food.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

9. It is clear how to prove that high-pressured food does not pose a risk for consumers.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

10. The safety assessment of HPP under the Novel Foods Regulation includes the question if sufficient reduction of pathogens is achieved.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

11. There is no need to assess the safety of HP treated products as the condition for market access.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

12. The term 'significant changes' is NOT clearly defined in the Novel Food Regulation, so there can be room for interpretation.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

13. It is the responsibility of the applicant to interpret the Article 1(f) of the Novel Food Regulation and the term 'significant change'.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

14. The interpretation of the novelty of high-pressured foodstuffs depends on the temperature applied during the process as at higher temperature significant changes can occur in high-pressured foodstuffs.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

15. There are differences in interpretation of the term 'significant changes' in case of HPP among the EU Member States.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

16. The levels of experience relating novel foods and the Novel Food Regulation differ among the EU Member States.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

17. The Novel Food Regulation is a regulatory barrier in the European Union, especially for small and medium enterprises.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

18. The Novel Food Regulation promotes new technology through the regulatory framework in the European Union.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

19. The main problems relating high pressure processing are costs and operational issues, and NOT the Novel Food Regulation.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

20. Food producers from the EU may export the foodstuffs produced by the pressure treatment to avoid dealing with the Novel Food Regulation.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

Thank You!