High pressure processing is a newly emerged technology that has already reached the consumer with a variety of fresh-like products. Recently many applications were developed for fruits and vegetables and they are discussed in the current review. In this context it becomes very important to assess how safe is high pressure processing (HPP) and especially high pressure high thermal processing (HPHT). Chemical and microbiological hazards have to be considered and mapping temperature uniformity is necessary to provide accurate food safety information. Safety indicators available to assess the effectiveness of high pressure treatments are introduced. Different aspects related to food safety are underlined in the current work together with the main findings and the gaps. This information will enable stakeholders to identify the key areas where more insight is needed. Moreover, the legislative framework is presented and the need for a new legislative framework is discussed.

**Keywords**: fresh-like foods, high pressure processing, equipment, vegetal origin foods, safety indicators, food safety objective, legislation.

**Introduction**

Consumers increasingly demand high quality and convenient foods with natural flavour and taste, with a fresh appearance, improved nutritional value, but above all, to be safe. These demands have opened the way for alternative technologies to conventional food processing, including high pressure technique.

Over the past two decades, high pressure technology has attracted considerable research attention, mainly related to understanding the impact of high pressure treatment on biomolecules, microorganisms and enzymes.
High pressure processing (HPP) or high hydrostatic treatment of foods involves subjecting food materials to pressures as high as 1.000 MPa. Pressure is defined as the force applied on a surface. Pressure has a uniform impact on the product, independent of its mass and geometry.

With regard to the food safety impact, the HP operation can be divided into two categories: 1) High pressure pasteurization at 300 to 600 MPa, for 1-15 minutes and at the initial product temperature of 5...25°C in order to inactivate vegetative pathogens, and 2) High pressure sterilization, or HPHT (high pressure, high temperature), when the initial product temperature is 70...90°C, the process temperature is 110...120°C and the holding time is 1 to 10 minutes -method that also inactivates bacterial spores (Grauwet et al., 2012).

Lately, many of the microbiological, (bio)chemical, technological, environmental and energetic aspects related to high pressure processing were studied and reviewed by scientists (Oey, et al. 2008; Toepfl, et al. 2006). High pressure processing can also be applied as an additional safety measure to the refrigerated foods with a short shelf-life.

In fact, HPP is the only alternative technology that has reached consumer market with a large variety of products made of vegetables or raw fruit materials, such as juices, jams, jellies, fruit or veggie sauces, avocado pulp, guacamole, etc. (López-Fandiño, 2006).

It is well documented that the highest number of high pressure industrial equipment is in North America. Although the potential of HPP has been described in numerous studies and HP pasteurized foods have been successfully marketed in Asia and the U.S., Europe is lagging behind (Grauwet et al., 2012). Many different reasons, including the high price of the high pressure equipment and the EU legislation that is considered still vague when it comes to the classification of the high pressure foods under the novel foods regulation umbrella, could explain this situation (Cholewinska, 2010).

Despite the fact that high pressure is viewed as a minimal processing technology, it should rather be considered minimal in terms of the effect on the constituents, and not necessary in terms of processing. Nonetheless, taking into consideration the advantages offered by the high pressure technology i.e. the fresh-like taste of foods, it should be discussed how the safety criteria are met in relation with the high pressure pasteurization or sterilization, the uniformity of the process parameters and the effects on its constituents.

The present paper deals with the safety criteria that are applied to HPP, considering the process variables that might affect the process uniformity, but also taking into account the differences in the legislative framework in Europe and in the US.

**High pressure technology**

The isostatic (constant and equal pressure in all directions) principle states that pressure is transmitted quasi-instantaneously and uniformly through the whole sample. Thus, it makes the process independent of volume and geometry of the
product. In order to be able to deliver a high pressure to the food product, the high pressure vessel which is a key component of the high pressure equipment has to withstand the rapid pressurization / depressurization rate, the pressure-temperature operating parameters and, sometimes, successive short cycles of processing that can rapidly increase metal fatigue. Another important component is the high pressure intensifier that is increasing the pressure above 100 MPa using pressurizing medium (mixtures of water and propylene glycol, ethanol solutions, castor oil or even plain water) to transmit the pressure into the vessel.

**High pressure equipment**

The equipment typically consists of a pressure vessel with an external insulation layer, top and bottom end closures, yoke (structure for restraining the end closures), high pressure intensifier, process controller and instrumentation, handling system for loading and removing the product. Processing can be made: a) in batch processing where food is already pre-packed (Figure 1).

![Batch high pressure processing equipment](image)

**Figure 1.** Batch high pressure processing equipment: 1 – product in, 2 – product out.

Several pressure vessels could be operated to minimize the lag time associated with pressurization and depressurization of the vessel; b) in semi-continuous processing mode with multiple pressure vessels that can provide a continuous flow by having in the same time compression in one vessel and decompression in another vessel; c) in continuous high pressure systems with long stainless-steel coil pipes (Hjelmqvist, 2005).

A hydraulic pump introduces the liquid and then the pressure is applied. The outlet valve gradually releases the pressurized product in a continuous way. This type of equipment is not readily commercially available (Gupta and Balasubramaniam, 2012). Most of the high-pressure applications in foods are not only pressure but also temperature dependant.

Food compression is about 15% for 600 MPa treatment, reflecting mostly the compression of its moisture content, but will be larger if the food contains empty
spaces as in the case of fruits and vegetables that have between 9% to 30% of their volume filled with air, or in high fat content products, as fat has a higher compressibility than water (Mújica-Paz et al., 2011).

**Steps of HPHT treatment**

The main steps for a combined HPHT treatment are presented in Figure 2. A preheating phase to bring packed food products from the initial temperature to the target temperature ($T_t$) is required for reducing the temperature difference between the pressurizing fluid and the food product. This will also reduce the equilibration time for the sample ($t_e$, $t_c$). After equilibration, during the come up time ($t_e$, $t_{p2}$), the pressure also increases from $P_1$ to $P_2$ which will generate adiabatic effect and, as a consequence, the temperature of the food product will increase from $T_e$ to $T_{p2}$.

The come-up time is the time required for the pressure of the treated sample to increase from the atmospheric pressure $P_1$ (0.1MPa) to the processing pressure $P_2$. Most of the high pressure equipments use one to three minutes’ pressure-come-up time to reach the process pressure.

![Figure 2](image)

**Figure 2.** Graphical representation of the main steps for a combined high pressure-high temperature treatment (Gupta and Balasubramaniam, 2012)

Pressurization is usually accompanied by a uniform temperature increase called adiabatic heating. The adiabatic heating of foods refers to the temperature increase during compression due to inner friction of the food particles. The heat of compression of food materials depends on the final pressure, the initial
temperature, the come-up time and the food composition. Food materials have specific values for heat of compression; during compression, the water temperature increases by about 3°C/100 MPa at room temperature, and the fats and oils temperature increases by about 8...9°C/100 MPa.

The magnitude of the temperature change depends on the compressibility rate of the food, its thermal properties, rate of the pressure increase, the initial and the target pressure. To achieve the desired thermal effect (high pressure pasteurization or high pressure sterilization) all the food particles should reach the temperature \( T_{p2} \) and pressure \( P_{2} \) during the holding time. A temperature drop in the food product is registered from \( T_{p2} \) to \( T_{p3} \) due to heat loss through the vessels’ walls. The heat loss occurs via thermal gradients due to the difference between the lack of compression heating at the steel walls of the vessels and the presence of adiabatic heating of the fluid and of the food matrix. Decompression phase suddenly decreases the product temperature below the equilibration temperature. Finally, the food product is slowly cooled down to temperature \( T_{c} \).

Thus, even if according to Pascal’s law the pressure is uniformly and instantaneously transmitted, the thermal gradients generate an inhomogeneous temperature distribution during the treatment. Temperature non-uniformity has been reported to originate from differences in compression-heating between pressurized products, vessel walls and carriers (Grauwet, et al., 2012).

Water and high moisture-content foods have the lowest compression value (approx. 3°C/100MPa) at initial temperature of 25°C, while fats and oils have the highest compression values, of 6...9°C/100 MPa (Patazca et al., 2007).

**Value of pH shift under pressure**

Another important change produced by the high pressure treatment is the pH shift, typically to more acidic (Mathys et al., 2008). The acid-base equilibria responsible for the pH of a solution are affected by both temperature and pressure. For example, a pressure increase of 100 MPa at 25°C results in a water pH decrease between 0.39 to 0.73 units (Van der Plancken et al., 2008a). The pH plays an important role in gelation, protein denaturation and microorganisms’ recovery ability from sub-lethal injury.

**Fresh-like products on the market**

Many successful applications of HPP are coming from fruits and vegetables sector, where the advantage of HPP is the fresh-like taste of the end-products while maintaining nutritional properties, inactivating microorganisms and enzymes, triggering the extension of shelf-life.

For example, in Japan, HPP has been used for almost 22 years. Acidic foods such as jams and fruit drinks pressure processed were introduced to the market at the beginning of 1990s by Meiji-ya Store. In addition, strawberry, apple and kiwi have been packed in plastic cups and pressure processed at 400 MPa for 20 minutes. It was demonstrated that for fruit juices such as grapefruit, lemon, orange, apple and tangerine the benefit of high pressure processing instead of traditional thermal
processing is preserving the natural colour of the end product and also the natural fresh-like taste and flavour (Rastogi et al., 2007).

In Europe the first high-pressured food was an orange juice which was produced by a French company, UltiFruit, which began the production of pressure-pasteurized orange and grapefruit juices for the local market in 1994. The citrus juices were marketed as “freshly squeezed”, packed in polyethylene bottles and processed at 400 MPa.

Current HPP fruit and vegetable products on the European market include fruit juices like orange juice (Italy), apple juice (Portugal), apple juice with lemon (Closed Loop Foods, UK), Bravo fruit juice with no sugar and no preservatives produced in Portugal for the Nordic market by a Swedish company (Skånemejerier), mixed vegetables (Spain), etc.

Thus, it should be noted that from all food products obtained with high pressure technology, the highest share is brought by vegetables and fruits, representing 35% (Cholewinska, 2010) of the total foods processed with high pressure technology.

Given the interest in high pressure products of vegetal origin, much development has been directed towards the understanding of the complex transformations that are taking place during the high pressure pasteurization or sterilization.

<table>
<thead>
<tr>
<th>Table 1.</th>
<th>Researches on high pressure processing of the vegetal origin food</th>
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<tbody>
<tr>
<td>Product</td>
<td>General conditions and parameters</td>
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<tr>
<td>Orange juice</td>
<td><strong>HP-P</strong> 350 MPa, 1 min, 30°C</td>
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<tr>
<td>Orange juice</td>
<td><strong>HP-P</strong> 350 MPa, 5 min, 40°C</td>
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<td>Orange juice</td>
<td>400–600 MPa, 15 min</td>
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<td>Orange juice</td>
<td>500 MPa, 5 min, 35°C</td>
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<tr>
<td>Orange juice</td>
<td><strong>HP-P</strong> 600 MPa, 1 min, 20°C</td>
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<tr>
<td>Orange juice</td>
<td><strong>HP-P</strong> 600 MPa, 4 min, 40°C</td>
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<tr>
<td>Orange juice</td>
<td><strong>HP-S</strong> 600 MPa, 5 min, 80°C</td>
</tr>
<tr>
<td>Lemon juice</td>
<td><strong>HP-P</strong> 450 MPa, 10 min, room temperature</td>
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<tr>
<td>Apple juice</td>
<td>400 MPa, 25 min</td>
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<td>Product</td>
<td>Pressure/Frequency</td>
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<tr>
<td>Strawberry juice &amp; puree</td>
<td>HP-P</td>
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<tr>
<td>Blackberry puree</td>
<td>HP-P, HP-S</td>
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<td>Raspberry puree</td>
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<tr>
<td>Mango &amp; mango puree</td>
<td>HP-P</td>
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<td>Pineapple</td>
<td>HP-P</td>
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<td>Tomatoes</td>
<td>HP-P</td>
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- Guerrero-Beltran et al., 2006
- Bazrul et al., 2008
- Kingsly et al., 2009
- Qiu et al., 2006
- Tangwongchaisuk et al. 2000
300–500 MPa, 25°C, 10 min | Microbial inactivation and physico-chemical properties | Hsu et al., 2008

400 MPa, 25°C, 15 min | Evaluation of colour and texture changes | Sánchez-Moreno et al., 2006

HP-P and HP-S | PG inactivation | Fachin et al., 2002, 2004

300–600 MPa, 5 min, 65°C or 95°C | Tomato lipoxygenase (LOX) and hydroperoxide lyase (HPL) inactivation in tomato juice | Rodrigo et al., 2006

100–650 MPa, 25...90°C | Less texture loss | Sila et al., 2004, Smout et al. 2005

Carrots | Significant loss of hardness | Araya et al., 2007

HP-P | Better quality and carotene content | De Roeck et al., 2008

HP-S | Chlorophylls a and b exhibit extreme pressure stability at room temperature but a PATP with temperature higher than 50°C significantly reduces chlorophyll content | Van Loey et al., 1998

Broccoli | Evaluation of the high pressure and heat on myrosinase activity, glucosoinolates and isothiocyanates | Van Eylen et al., 2006, 2009

HP-P | 5 log microbial inactivation | 200–800 MPa, 30...50°C

Safety issues related to HPP processed fruits and vegetables

When developing a new process, the first concern is consumer safety. Thus, evaluation of the microbiological, chemical and physical hazards of the product is mandatory. These aspects should be closely analyzed based on the HACCP principles to identify ways to minimize, control or eliminate them.

Chemical hazards

The chemical hazards were not taken into account by some researches up till now, but certain topics like acrylamide formation and the evaluation of allergens from plants should be considered. Acrylamide in foods is formed as a result of a reaction between amino acids, namely asparagines and reducing sugars, particularly glucose and fructose as part of the Maillard reaction. Carbohydrate-rich foods such as potato and cereal products could potentially lead to acrylamide formation via Maillard reaction during thermal treatment. Dietary acrylamide intake may increase the risks of kidney and breast cancer. Animal studies have shown that acrylamide
has genotoxic and neurotoxic effects, causing gene mutation and DNA damage, and it may represent a health hazard for humans (Mojiska et al., 2010). The impact of HPHT of 400-700 MPa, 100-115°C, from 0-60 min was studied in a model system. It has been demonstrated that pressure is delaying the acrylamide formation, although the buffer system also contributed to the reduction of acrylamide formation. Researchers have found that the maximum concentration of acrylamide is considerably lower than the one formed during a conventional thermal treatment and they concluded that acrylamide is not a hazard in HPP (Claeys et al., 2005).

Allergens represent another important chemical hazard that should be evaluated in food processing. It is known that the secondary and tertiary structure of these proteins is important for the allergenic potential and high pressure impacts on the tertiary and quaternary structure of proteins (Rivalain et al., 2010). The idea of reducing the allergenicity of proteins via high pressure treatments was studied for rice (Kato et al., 2000), apple (Meyer-Pittroff et al., 2007), soybean (Peñas et al., 2006) and pollen (Setinova et al., 2009), but only at ambient temperature. Husband et al. (2011) have studied the allergenicity of two main allergens from apple and demonstrated that only a strong treatment at 115°C, 700 MPa for 10 minutes disrupted the proteins’ structures. The explanation for this behaviour could be found in the protective effect offered by pectin.

With regards to other important chemical contaminations, more research is needed to evaluate the potential of mycotoxins reduction by high pressure.

**Microbiological hazards**

High pressure pasteurization treatments inactivate pathogenic and spoilage bacteria, yeasts, moulds and viruses. However, the treatment has a limited effect on spores and on ascospores of some fungi. Fungi such as *Byssoclamys fulva*, *Byssoclamys nivea*, *Neosartorya fischeri* and *Talaromyces macrosporus*, which produce resistant structures known as ascospores, frequently cause spoilage of heat-processed fruit products. They can withstand pressures of 300-800 MPa. Although the fungal inactivation mechanism is not completely understood, it is known that the vegetative cells (conidia) of heat-resistant moulds are not resistant to pressure (Voldřich et al., 2004). On the contrary, high pressure can induce the germination of some dormant fungal spores, i.e. *Talaromyces macrosporus* (Van der Plancken et al., 2008b). Therefore, if pressure cycles are applied for inactivation, the survival rate can significantly decrease.

The target organisms of high pressure treatments are vegetative microorganisms, whose inactivation results in a pasteurized food product. Pressure sensitivity can differ widely even within strains from one species and is not necessarily similar to their temperature sensitivity. Gram-positive bacteria are more resistant than Gram-negative bacteria, and cells in exponential growth are displaying higher sensitivity compared to the ones in stationary phase. The inactivation depends on the type of microorganism, food matrix, water activity and pH. *Staphylococcus aureus* and *E. coli* O 157:H7 appear to be the most pressure resistant pathogenic vegetative cells
with a D-value at 600 MPa and 50°C of 7.14 min for \textit{S. aureus} and 6 min for \textit{E. coli} O 157:H7 (Van der Plancken et al., 2008a).

The most resistant microorganisms to pressure are bacterial spores, for which the pressure levels of even up 400-800 MPa do not guarantee inactivation. Thus, refrigeration, reduced water activity or acidic protection (low pH) should be used in food matrices for preventing the growth of spores. Another approach is to combine pressure and temperature to obtain a synergistic effect. For the heat sterilization, the “12 D” reduction criteria for \textit{Clostridium botulinum} is used as target for process design, where at 121.5°C, the D-value is 21 minutes. \textit{Clostridium sporogenes}, which is considered a non-toxigenic surrogate of \textit{C. botulinum} and an important spoilage bacteria, at 60°C and 400 MPa after 30 minutes of treatment exhibits only one decimal reduction (Mújica-Paz et al., 2011). \textit{C. sporogenes} at 90°C and 600 MPa has a decimal reduction time of 16.8 min and 0.7 min at 800 MPa and 108°C.

**Indicators for safety assessment**

The concept of Food Safety Objective (FSO) has been introduced by the Codex Committee on Food Hygiene (2004) as the “maximum frequency or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP)” (NACMFS, 2005). This concept is a regulatory parameter for evaluating the efficacy of novel technologies to inactivate target pathogenic microorganisms (Barbosa-Cánovas et al., 2008).

An inactivation performance criterion can be expressed by the equation:

\[ H_0 - \sum R + \sum I \leq FSO(\text{or PO}) \]  

(Eq. 1)

where FSO is the food safety objective, PO is the Performance Objective, \( H_0 \) is the initial level of the hazard, \( \sum R \) is the total reduction of hazard on a decimal logarithmic scale, and \( \sum I \) is the total increase of hazard on a decimal logarithmic scale.

Alternatively, the Performance Objective (PO), or the maximum frequency or concentration of a hazard in a food prior to consumption that provides or contribute to an FSO or ALOP as applicable (Codex, 2004), can be used to establish process performance.

For example in HPHT, the \textit{Clostridium sporogenes} surrogate for FSO would be less than 100 CFU/g in a food product at the point of consumption (Barbosa-Cánovas et al., 2008).

A HPHT process may be validated by applying concepts as the decimal reduction time (\( D_t, D_p \)), the temperature sensitivity (\( z_t, z_p \)) used for the thermal processing of low acid foods. It is also possible to evaluate the effectiveness of the HPHT process by a food target attribute using the \( F^2_{Tref} \) criterion.

\[ F^2_{Tref} = \frac{2.303}{k_{ref}} \left( \log \frac{X_0}{X} \right) \]  

(Eq. 2)
The processing value $F_{T_{\text{ref}}}^2$ represents the equivalent time at the chosen reference temperature, $T_{\text{ref}}$, causing the same reduction in the specific target attribute as the time-temperature history to which the food was subjected. This \textit{in situ} method has the advantage of directly evaluating a known component. The disadvantages are related to the evaluation of the microbial reduction beyond the detection limit of currently available analytical methods (Van der Plancken et al., 2008b). The distribution of pressure-temperature-time profiles in a food product can result in inhomogeneous inactivation of enzymes and or microorganisms. However, it is important to note that the thermal related process non-uniformity has a major impact on HP sterilization. There are two methods currently used for temperature uniformity mapping: computational thermal fluid dynamics (CTFD) and pressure-temperature-time indicators (pTTIs).

\textbf{Legislative framework in EU and the US}

In the US, the Food Drug and Cosmetic Act states that all food products should be processed, packed and held under sanitary conditions. HPP products are required to be processed under GMP conditions, and commodity specific regulations are applied for juice (HACCP juice) seafood (Sea Food HACCP) and milk (Pasteurized Milk Ordinance) (Barbosa-Cánovas and Juliano, 2008).

In Europe the legislation framework and the history of high pressure products create a more intricate environment. In 1997, the Regulation (EC) No 258/97 of the European Parliament enforced the novel food ingredients (NFR) legislation. Under this regulation novel foods are considered \textit{“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.”}

One year later, the Danone Group requested to the competent authority in France an approval for a high pressure fruit product. In May 2001, the European Commission decided to approve placing this product on the EU market. This is the only high pressure product approved on the list of Novel food regulation since 2001 until now.

During the first evaluation of a high pressure treated fruit product, Danone was requested to demonstrate the safety of high-pressured fruit preparations. Refrigeration conditions, pH and water activity were discussed as measures to prevent the growth of \textit{C. botulinum} in the products. However, Danone never marketed the product they had approval for, but that approval protects similar products marketed in Europe. EU practices could still consider for approval under NFR a product obtained through high pressure processing technology, if the product is significantly different from that already approved.
Conclusions
The HPP has potential to develop new products with added value but in the same time there is a strong need for evaluating its impact on food safety and quality. The HPP and HP/HT treatments open new areas of applications. New indicators for the temperature uniformity during high pressure treatment can enable better characterization of the transformations that take place in the food products. These new indicators required to map the temperature uniformity during high pressure thermal processing should be further investigated and made available for an adequate validation of the treatment effectiveness. In the near future of the EU, legislations concerning high pressure food product should be revised for encouraging the presence on the market of new high pressure treated food products.

Acknowledgments
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Abbreviations
CTFD – computational thermal fluid dynamics
GMP – good manufacturing practice
HP – high pressure
HPHT – high pressure high thermal processing
HPP – high pressure processing
NFR – Novel Food Regulation
pTTIs – pressure-temperature-time indicators

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