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Ministry of Agriculture, Nature and Food Quality

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Advisory report from the director of the Office for Risk Assessment and Research

Advice on the suitability of alternatives for pasteurisation to safeguard microbial food safety of milk

Background

For more than hundred years a heat treatment known as "pasteurisation" has been utilized to realize the microbiological safety of milk". Recently a number of alternative procedures to achieve the reduction of pathogenic microorganisms has been proposed. A few examples:

- Pascalisation, also known as bridgmanization, high pressure processing (HPP) or high hydrostatic pressure (HHP)
- Pulsed Electric Field Treatment
- Ultrasound
- Ultraviolet light
- Microfiltration

The Ministry of Public Health, Welfare and Sport of The Netherlands asked whether it is safe to utilize pascalisation, one of these alternative procedures, to prepare drinking milk from raw milk. Pascalisation is a procedure that uses high pressure, 100-600 MPa, 1-6 kbar, without additional heating, to reduce the number of bacteria. Pascalisation can be an effective way to reduce the number of microbes in milk, but it does not inactivate the enzyme alkaline phosphatase, the indicator for the effectiveness of pasteurisation prescribed by law. Pascalisation is already applied worldwide, including in the EU, to ensure microbial food safety of other foodstuffs, such as fruit juices.

Terms of reference

The director of the Department of Nutrition, Health Protection and Prevention, of the Ministry of Public Health, Welfare and Sport has asked the Office of Risk Assessment (BuRO) of the Netherlands Food and Consumer Product Safety Authority for an opinion on:

1. The food safety risks of treating milk by pascalisation to prepare milk for the consumer market as an alternative for pasteurisation by heating to more than 70°C.
2. The risks for food safety if alkaline phosphatase activity is still present in drinking milk.
3. The need for new legislation in order to permit application of effective alternatives for pasteurisation.

Methodology

The BuRO has conducted a literature search for legal and scientific information and EFSA opinions related to alternative procedures for pasteurisation, in particular pascalisation. The possible application of these procedures for safeguarding the microbial food safety of foodstuffs other than milk has not been assessed.

Results

According to Regulation EU 1308/2013 milk can only be sold to consumers if it has been heat treated as prescribed in Regulation EC 853/2004, or if it is raw milk. The Member States are free to allow sale of raw milk under conditions, or to forbid it. The sale of milk that has been treated using an alternative procedure that has the same goal as pasteurisation, is not allowed under EU legislation. If alternative procedures with convincingly proven effectiveness to achieve killing of pathogenic microorganisms in milk are to be allowed to guarantee microbial safety of milk, the relevant legislation must be adapted.

The legally prescribed test to verify the effectiveness of the pasteurisation process is the absence of alkaline phosphatase activity in the milk. This naturally in milk occurring enzyme is inactivated at the same combination of time and temperature as required for effective pasteurisation. The enzyme itself does not in any way influence the safety of milk, but is used solely as an indicator for an effective pasteurisation procedure.

According the General Food Law (EC 178/2002) the final responsibility for food safety rests with the food business operator. The procedures by which this food safety must be realized is rarely prescribed. Pasteurization as a step in the preparation of drinking milk is an exception in this respect in the sense that the procedure is prescribed by law. This requirement legally excludes any alternative procedure that achieves the same food safety objective. This exception can be understood in a historical perspective. However, it can be doubted whether there is a compelling need for it under the present circumstances. Should the legislation be adapted to allow alternative procedures to pasteurisation, then the producer still has to establish whether or not milk treated by this procedure is a novel food as defined in Regulation (EU) 2015/2283 and to provide a reasoning for the conclusion.

Of all presently known alternative procedures for pasteurisation, pascalisation is the best documented in the scientific literature. This procedure is proven effective in reducing microorganisms in foodstuffs, primarily in drinks and other liquid foods and is already being used for that purpose. The process parameters, pressure, time and temperature, can differ between products. An informal rule of thumb for pasteurisation is that for vegetative cells a reduction of 10^6 must be achieved. This objective is not part of any legislation. The appropriate level of protection (ALOP) to be achieved for drinking milk has not been formally defined.

Not all pressure, time and temperature combinations of pascalisation achieve the same risk reduction as pasteurisation for all relevant bacteria. Nevertheless, the procedure of pascalisation can under optimized conditions be as effective as or more effective than pasteurisation in reducing the microbial load in milk. A point of attention is Shiga-toxin producing *Escherichia coli* (STEC). Some reports indicate that certain strains of pathogenic *E. coli* are more resistant to pascalisation than most microbes. Hence this procedure might be less effective than pasteurisation in reducing these pathogens. This can be addressed by adjusting the process parameters, increasing time and pressure. Insufficient reduction of STEC's can cause a risk for the food safety of the final product.

Conclusions

From the standpoint of food safety there is no reason to prohibit the use of alternative procedures to pasteurisation for preparing safe drinking milk. Pascalisation is one of the procedures that can possibly replace pasteurisation in adequately reducing the number of pathogenic microbes in milk. The effective reduction of STEC is a point of attention. The presence of alkaline phosphatase activity in drinking milk is not a food safety risk.

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Answer to the terms of reference

1. Drinking milk that has been pascalized can be as safe as pasteurised milk, provided processing conditions such as, time, temperature and pressure, have been shown to achieve adequate reduction of pathogens, including STEC. Other alternative procedures may, provided proper processing conditions apply, guarantee safety of milk as well.
2. Inactivation of alkaline phosphatase is not required from a food safety perspective, as phosphatase activity does not pose any health risk in itself.
3. The present EU regulation concerning preparation of drinking milk prohibits application of alternative procedures to pasteurisation for guaranteeing microbial food safety. To enable sale of drinking milk prepared by alternative procedures a change of the relevant EU legislation is required and a performance objective for alternative procedures must be defined.

Advice

To the director of the Department of Nutrition, Health Protection and Prevention, of the Ministry of Public Health, Welfare and Sport

- Consult with the EU Commission on the possibilities to make legal the sale of milk produced with alternative procedures for pasteurisation, provided they achieve an appropriate level of protection for regular consumers of drinking milk.
- Propose that as part of this consultation procedure the Commission will ask EFSA to formulate an opinion on the demands that procedures other than pasteurisation to guarantee microbial food safety of milk should meet.

Yours sincerely,

Prof. Antoon Opperhuizen, PhD
Director of the Office for Risk Assessment and Research

SUBSTANTIATION

Milk is a fluid rich in nutrients and therefore forms an almost ideal growth medium for many microbial species. Contamination with bacteria during the production process is unavoidable. When the pathogenic species are not killed before the milk reaches the consumer, these can cause gastro-enteritis or other illness. The number of vegetative cells of pathogens in milk can be adequately reduced by a process named "pasteurisation" which consists of a heat-treatment of minimally 72^{o}C for at least 15 seconds or at least 63^{o}C during minimally 30 minutes. Sterilization is possible as well and kills both vegetative cells and spores of all bacteria. Before the general introduction of pasteurisation and sterilization, milk was an important source of foodborne disease (BuRO, 2017) and today raw milk is still a food safety risk (EFSA, 2015). To reduce this risk, sale of milk that has not undergone a heat treatment at least equivalent to pasteurisation can be prohibited by EU Member States (MS's) at the national level. Individual MS's, however, have the possibility to allow sales of raw milk under specific conditions (EC 853/2004). After the general introduction of pasteurisation or sterilization, the proportion of foodborne disease cases that were linked to milk or dairy products was reduced considerably (Claeys *et al.*, 2013). In the Netherlands pasteurised milk has not been linked to foodborne outbreaks in recent years (Friesema *et al.*, 2016).

Pasteurisation and sterilization

Pasteurisation is a heat treatment procedure that aims to reduce vegetative cells of all pathogenic microorganisms to acceptable levels, including the most heat resistant pathogen found in milk, *Coxiella burnetii* (Claeys *et al.*, 2013). As a rule-of-thumb a minimal reduction of 10^6 for vegetative cells of *Coxiella burnetii* is adhered to, but neither the indicator organism nor the factor of 10^6 is incorporated in the legislation. The elimination of vegetative pathogenic bacterial cells is achieved by the regular pasteurisation process and hence in correctly pasteurised milk, non-spore forming pathogens are unlikely to cause disease (Claeys *et al.*, 2013). However, it turns out that under experimental conditions some heat-resistant variants of pathogens can survive pasteurisation. For example, the reduction of heat resistant *Staphylococcus aureus* (Pearce *et al.*, 2012) and STEC O157 (Kim & Kang, 2015) added to milk was less than the factor 10^6 reduction aimed for. As not all vegetative bacteria and also not the spores of pathogenic spore formers are killed, pasteurised milk must be kept at a temperature of 7^{o}C or lower, to prevent bacterial growth and even then storage time is limited. Even though pasteurisation does not kill all bacteria, the safety of the product for the consumer seems to be guaranteed, because an extensive literature search did not yield reports of outbreaks or illness that could be attributed to properly handled pasteurised drinking milk. The rare outbreaks were almost always caused by improper handling or processing (Oliver *et al.*, 2005). Apparently milk spoils before pathogens reach dangerous densities.

The characteristics of pasteurised milk differ from those of raw milk. Drinking milk is standardised as to fat content, homogenised and most bacteria are killed by the heat treatment. These processes also affect the taste of the milk. In the past years the potential health benefits of raw milk over pasteurised milk have been investigated, but as to date there is no scientific evidence for these (FAVV, 2011). Still, there are claims that proteins that are denatured during the heat treatment have health benefits in their native configuration (van Neerven *et al.*, 2012, Brick *et al.*, 2017). The health risk of raw milk, specifically the chance of infection with microorganisms, is considerable (EFSA, 2015, Costard *et al.*, 2017). Other procedures to guarantee the microbial safety of milk are being developed that preserve the taste of raw milk, but control these risks. Of these various procedures pascalisation has been best investigated.

Legal requirements

In the EU, drinking milk is considered to be delivered or sold to the final consumer only when it is either raw or heat-treated (Reg. EU 1308/2013). Regulation EC 853/2004 stipulates that raw milk is milk that has not been heated to more than 40°C and has not received another treatment that has the same effect as such heat treatment. Therefore milk that has undergone an alternative treatment to pasteurisation or sterilization, such as pascalisation, that has the same purpose, may not be sold in the EU (Reg. EU 1308/2013). In addition there are general (EC 852/2004) and specific (EC 853/2004) regulations on the demands that heat treatment of milk must fulfil. Reg. EC 853/2004 stipulates that milk may be pasteurised by heat-treatment of at least 72°C for 15 seconds or at least 63°C for 30 minutes, or any other combination of time-temperature conditions that obtains an equivalent effect. Immediately after treatment no activity of alkaline phosphatase may be present anymore. The alkaline phosphatase activity is an indicator for the correct execution of the pasteurisation process, because this enzyme that is naturally present in milk is inactivated by the same temperature time combinations as needed for pasteurisation. In addition, the regulation prescribes the criteria for sterilization by ultra-high temperature (UHT). This treatment kills all vegetative cells and spores, but the consumer appreciates the taste of this milk less (Griffiths & Wakling-Ribeiro, 2012).

Alternative procedures for pasteurisation used under for milk optimal conditions as a rule do not inactivate alkaline phosphatase. The phosphatase activity in itself is not a health risk in any way, but is solely used as an indicator for effective pasteurisation. Milk that has been treated with an alternative procedure with an equivalent effect to pasteurisation, such as pascalisation, can be positive for phosphatase activity and pose no health risk.

The producer of milk treated with an alternative procedure instead of pasteurisation will, when such alternatives are legally allowed, have additional obligations in the framework of the novel food regulation (EU) 2015/2283. The food business operator needs to ascertain whether to this milk that he intends to place on the market is considered a novel food under the definitions of the regulation and to provide a rational supporting the conclusion. If it is considered a novel food it can be included on the list of authorized novel foods only if it fulfils the demands of article 7 regarding safety, nutritional value and information for the consumer.

Milk is not only sold directly to the consumer, but also used for the production of cheese, porridge and a large variety of other products (NVWA, 2017). The relevant legislation does not explicitly prohibit the use of pascalized milk or milk treated with another alternative method for the production of other foodstuffs, but it is clear that this has not been considered. There are for instance no microbiological criteria for cheese or other dairy products produced from pascalized milk. It is not clear whether this omission is intended and thus should be considered an implicit prohibition of the use of pascalized milk for the production of foodstuffs, or that this is an unintended oversight.

Alternatives for pasteurisation

There are several procedures that could be used as alternatives for pasteurisation. For example:

- Pascalisation, also called "High Pressure Processing (HPP)", "bridgmanization", high hydrostatic pressure (HHP) or "Ultra High Pressure Processing (UHP)" (Gervilla *et al.*, 2000, Chen, 2007, Baptista *et al.*, 2016), uses very high pressure to kill bacteria
- Pulsed Electric Field Treatment inactivates microbes using short, milli- or microsecond, pulses of 10 to 80 kilovolt (Bermudez-Aguirre *et al.*, 2011, Lee *et al.*, 2015)

- Ultrasound, high frequency sound waves, can break membranes and other structures in microorganisms, thereby killing them (Cameron *et al.*, 2008)
- Ultraviolet light treatment damages DNA, killing the bacteria in the process (Donaghy *et al.*, 2009)
- microfiltration uses very fine filters to remove bacteria from the milk, but lets other components of the milk pass (Walkling-Ribeiro *et al.*, 2011).

Most research has focussed on pascalisation, but for each of these procedures at least some documentation is available in the scientific literature suggesting that this procedure might be a suitable alternative to pasteurisation. Even for pascalisation, it is not yet proven in a convincing manner. In addition, the exact settings and conditions under which the procedure is used are of great importance for the effectivity. Hence, before a procedure can be accepted as an alternative for pasteurisation, it must be tested thoroughly and a file must be compiled proving the safety and effectiveness of the procedure. It might be useful to ask EFSA for an opinion on the proof of safety and effectiveness to be demanded and the requirements for the documentation to be provided by requestors.

Pascalisation

Before an alternative to pasteurisation can be allowed, it must be proven to achieve the same level of public health protection. Most research on alternatives for heat treatment to guarantee the safety of milk has concentrated on pascalisation and hence this opinion focusses primarily on that procedure. This procedure is already being used in the EU on other foodstuffs than milk, in particular fruit juices and outside of the EU on milk as well (http://www.foodauthority.nsw.gov.au/news/newsandmedia/departmental/2016-06-03-HPP-milk). Without additional heating, the foodstuff is put under a pressure of 100-600 MPa, which equals 1000-6000 Bar. This procedure kills microorganisms, but small molecules, such as nutrients, vitamins and most enzymes remain unchanged. This also applies to alkaline phosphatase which is not inactivated by pascalisation (Kouassi *et al.*, 2007).

Physical and chemical risks

To judge whether pascalized milk is as safe as pasteurised milk, the chemical properties must be judged as well. There is little scientific information on negative chemical consequences of pascalisation, but the little that is known suggests that the effects are very limited and that the physical and chemical risks of pasteurised and pascalized milk are identical (Trujillo, 2002, Augustin & Udabage, 2007). The body of evidence, however, is not sufficient to conclude this with confidence.

Microbiological risks

The use of techniques other than heat treatment to reduce the number of pathogenic bacteria is likely to result in another microbial profile of the treated milk in comparison to pasteurised milk. For individual pathogenic bacterial species, both greater and lesser reduction is possible. To set a standard for the appropriate level of protection (ALOP) for microbial risks in milk, a comparison can be made with the ALOP for drinking water. The current ALOP for drinking water accepts that 1 person out of 10,000 inhabitants of an area served by a water supplier gets ill with a mild and self-limiting disease caused by drinking tap water every year (Macler & Regli, 1993). For milk that would mean that per year 1 in 10,000 regular consumers of milk who each drink on average 200 litre of milk per year, gets ill because of a disease transmitted by milk. According to this line of reasoning, a single case of mild disease resulting from the consumption of 2 million litre of milk would be acceptable. This ALOP can be translated into a performance objective (PO). Given the proven effectiveness of pasteurisation to safeguard the food safety of milk, the reduction realized by the present procedures can function as PO. The rule of thumb to judge the effectiveness of pasteurisation procedures is that for the vegetative cells of all pathogens a reduction of 10^6 must be achieved. In principle this applies also to the most heat

resistant variants. In reality the variation in heat resistance even between closely related strains is so large that that this factor of 10^6 is not always achieved. Below the application of the PO of 10^6 reduction to alternative methods for pasteurisation is discussed for a number of pathogens.

The most important microbiological hazards in raw milk are *Campylobacter* spp., *Salmonella* spp., Shigatoxin-producing *E. coli* (STEC), *Brucella melitensis, Mycobacterium bovis* and tick-borne encephalitis virus (BuRO, 2017; EFSA, 2015). In Europe, drinking raw milk correlates with foodborne illness associated with these hazards. In the case of milk used for preparing other food products, such as cheese, hazards such as *Staphylococcus aureus* and *Listeria monocytogenes* must be taken into account as well (EFSA, 2015). In milk that is used for the production of foodstuffs that also contain starch, *Bacillus cereus* can become a biological hazard (BuRO, 2017). Any potential residual risks in milk treated with an alternative method for pasteurisation, must be judged form the perspective of the ALOP of 1 case of disease per 10,000 consumers per year. This standard may not be acceptable in the case of STEC, because the severity of individual cases invalidates the ALOP that was defined for mild and self-limiting illness and a more strict limit must be set.

The conditions during pascalisation and the settings in time, pressure and temperature of the equipment determine the effectivity in killing microorganisms. Reports in the scientific literature suggest that a number of microbial species is killed more effectively by pascalisation than by sterilization, while in other cases the reverse holds (FDA, 2000). Since the actual killing effectivity depends on the conditions applied, such as the time, pressure and temperature combination as well as the type of food or liquid, the file supporting a request to market pascalized milk will have to demonstrate convincingly that all relevant pathogens are killed effectively under the conditions applied. One possible criterion for this is that in all cases a 10^6 reduction is realized.

The sensitivity for pascalisation has been investigated for a large number of microorganisms (FDA, 2000). A general rule seems to emerge that parasites are most sensitive, followed by fungi and yeasts, gram-negative bacteria, gram positive bacteria and viruses, in order of descending sensitivity. The variation within groups and even between strains of the same species is very large, so the applicability of general principles is very limited (Trujillo, 2002, Chen, 2007). For individual pathogenic species of interest in milk there are data available for *Campylobacter* spp (Lori *et al.*, 2007), *L. monocytogenes* (Dogan & Erkmen, 2004), *S. aureus* (Baptista *et al.*, 2016), *Salmonella* spp (Patterson *et al.*, 1995, Patterson & Kilpatrick, 1998) and *E. coli* variants such as STEC (Trujillo, 2002, Yoo *et al.*, 2015). The reported effectivity varies considerably depending on the actual settings and conditions. Therefore applications for utilization of alternative procedures will have to very precisely describe the actual conditions in experiments provided as evidence for effectivity.

Pathogenic *E. coli*, such as the many STEC variants, requires extra attention, because it can cause severe disease and some strains have a low infectious dose (Buvens *et al.*, 2011). Approximately 400 *E. coli* strains are classified as STEC. Out of the 373 strains known to be associated with cattle, 123 are pathogenic for humans (EFSA, 2013). The degree of virulence varies greatly between strains. Genetically closely related strains can be particularly virulent or completely harmless. In exceptional cases the minimal infectious dose of EHEC/ STEC can be as low as 1 cfu, compared to 500 for *Campylobacter* (Buvens *et al.*, 2011) and a varying number for *Salmonella* that can also be very low, but almost always higher than the most infectious EHEC (Hara-Kudo & Takatori, 2011, Vigre *et al.*, 2016). Milk cows have STEC in the intestines and on the skin, rarely as pathogen in udder infections. Milk can be contaminated with STEC if the udders are not

cleaned well before milking and some faecal material remains or due to lack of hygiene in general allowing contamination of milk from the environment. This could lead to a worst-case scenario in which a highly virulent STEC ends up in milk. When the milk is consumed untreated, this creates a health risk (EFSA, 2015). This risk must be reduced to an absolute minimum, given the severe consequences for each individual illness.

Some strains of the STEC O157 serotype are much less sensitive to pascalisation than related strains and STEC's in general are more pressure resistant than most microbial species (Patterson *et al.*, 1995, Huang *et al.*, 2014). Because of the pressure resistance, the sometimes low infectious dose and the severity of the disease, the reduction of STEC by pascalisation requires specific attention. One test using a single selection of settings suggested that pascalisation is 20 times less effective on STEC than pasteurisation, but the effect of pascalisation strongly depends on the settings applied. Higher pressure is likely to eliminate STEC's more effectively, but this must be verified experimentally. The combination of high pressure and temperature treatment increases the effectiveness (Patterson & Kilpatrick, 1998).

Use of high pressure-treated milk to make cheese and other dairy products
High pressure (HP) treatment of milk causes some modifications on renneting properties and native milk enzymes, while leaving small molecules, such as flavours and many nutrients intact. These characteristics may allow the production of cheeses resembling those produced using raw milk. Studies carried out using pasteurized (72°C, 15 s) and HP-treated (500 MPa, 15 min, 20°C) milk have shown some changes in milk composition resulting from the technological processes applied. A decrease in the amount of non-casein nitrogen fraction soluble at pH 4.6 and non-casein nitrogen fraction obtained by ultracentrifugation is observed in HP-treated milk relative to pasteurized milk. Pressure treatment causes loss of whey protein solubility and therefore a decrease in the amount of proteins remaining in solution. Free fatty acids are higher in HP-treated milk in comparison to pasteurized milk. This suggests that lipoprotein lipase is still partially active after HP treatment whereas in pasteurized goat milk it is completely denatured. Therefore, a higher lipolysis can be expected in HP-treated-milk cheeses (Trujillo *et al.*, 2000).

HP-treatment induces significant changes in milk components particularly in proteins (whey proteins and caseins), as well as on their applicability in innovative dairy productions. HPP influences technological properties of various milk products such as firmness, water-holding capacity of the gel and network structure, cheese yield, rennet coagulation time and ripening (Ozcan *et al.*, 2017). The possibility of treating milk with high-pressure prior to cheese manufacture helps to eliminate a number of microbiological risks, yet results in cheese with similar characteristics as cheese made from untreated raw milk. This could help to develop new innovative cheese that does not entail the risks associated with raw milk (Voigt *et al.*, 2012).

Safety of pascalized milk
A number of pathogenic microbes is killed more effectively by pascalisation than pasteurisation. The most important among these are *Salmonella* spp and *S. aureus*. Possibly this will yield some public health gains, because even though *Salmonella* outbreaks have rarely been reported in connection to milk, cheese made from pasteurised milk has been a source (De Buyser *et al.*, 2001). Specific attention must be focussed on STEC, as this highly virulent pathogen shows more pressure resistance than other pathogens. Hence, the principal additional risk of pascalized milk in comparison to pasteurised milk seems to be the minute chance of a highly virulent STEC in the milk. This problem can be addressed by adjusting the settings of the pascalisation process so that all STEC's are adequately

reduced. Considering all relevant available information, it seems that for milk pascalisation can be turned into a realistic alternative for pasteurisation. The exact conditions to be applied need to be determined in a HACCP approach and the appropriate documentation assembled into a complete application file so that the equivalence can be judged objectively and based on all relevant information.

Performance objective
The effectivity of alternative procedures to pasteurisation and specifically of pascalisation depends on the settings of the procedure. To enable an objective judgement of this effectivity a performance objective must be formulated. An example of such performance objective could be: "reduction of the most resistant vegetative cells by a factor of at least 10^6". This performance objective should be derived from a still to be defined appropriate level of protection.

Indicator for effectivity
Absence of alkaline phosphatase is an indicator for an effective pasteurisation process. This indicator cannot be used for the pascalisation process, because the activity of this enzyme is not affected. In the absence of a proper indicator, a HACCP approach must be applied. Hence, the controls must be aimed at the correct application of the procedure, as is the case for the production process of many foodstuffs.

In conclusion
A number of procedures may qualify as alternatives for pasteurisation in reducing the microbial load of drinking milk. The present methodology of pasteurisation guarantees the safety of milk very well and any alternative will have to realize at least the same level of protection. Pascalisation is the best documented of these alternative procedures and this process is already used to prepare drinks other than milk, such as fruit juices. Current legislation at the EU level prevents marketing of milk that has been prepared using microbe reducing methods other than pasteurisation or sterilization. From the point of view of food safety there is no reason for this prohibition. Therefore it may be appropriate to examine how the relevant legislation can be adapted so as not to exclude alternative procedures to pasteurisation beforehand. As for all other foodstuffs, it may be possible to prescribe safety targets of the process instead of the actual technique and procedure. Any changes of the legislation will have to be made at the EU-level and hence it may be advisable to ask EFSA for an opinion on this matter and in particular on the demands that an alternative for pasteurisation must fulfil. These demands can be formulated as performance objectives derived from an appropriate level of protection to be established as part of the same process.

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