# NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL CRITERIA FOR FOODS

# REQUISITE SCIENTIFIC PARAMETERS FOR ESTABLISHING THE EQUIVALENCE OF ALTERNATIVE METHODS OF PASTEURIZATION

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# EXECUTIVE SUMMARY

In response to the Farm Security and Rural Investment Act of 2002 which calls for a broadening of the definition of pasteurization, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) was charged with determining requisite scientific parameters for establishing the equivalence of alternative methods of pasteurization.

NACMCF agreed to the following definition of 'pasteurization' to guide its work.

> Any process, treatment, or combination thereof, that is applied to food to reduce the most resistant microorganism(s) of public health significance to a level that is not likely to present a public health risk under normal conditions of distribution and storage.

NACMCF recognizes that pasteurization does not necessarily achieve commercial sterility and many pasteurized foods must be frozen or refrigerated to preserve product quality. While some pasteurization processes are based on traditional thermal pasteurization, alternative non-thermal processes and combinations of processes and treatments for pathogen reduction can be equally effective.

NACMCF recommends that regulatory agencies establish a Food Safety Objective (FSO) and/or a performance standard for food/pathogen combinations that can be used as the basis for judging equivalency when a proposed process is evaluated as an alternative to traditional pasteurization.

One must consider numerous factors when establishing the efficacy and equivalency of different pasteurization processes, including identification of the most resistant pathogen(s) of concern in the food, the efficacy of the specific technology to reduce the pathogen(s) of concern, the food matrix characteristics, normal conditions of distribution and storage, and the intended use of the food. NACMCF recommends the following guidelines as essential to developing a proposed pasteurization process:

- Conduct a hazard analysis to identify the microorganism(s) of public health concern for the food.
- Determine the most resistant pathogen of public health concern that is likely to survive the process.
- Assess the level of inactivation needed. Ideally, this would involve determining the initial cell numbers and normal variation in concentration that occurs before pasteurization.
- Consider the impact of the food matrix on pathogen survival.
- Validate the efficacy of the pasteurization process.
- Define the critical limits that need to be met during processing so that the food will meet the performance standard.

- Define the specific equipment and operating parameters for the proposed pasteurization process. This may include developing specific Good Manufacturing Practices (GMPs) in addition to the Hazard Analysis Critical Control Point (HACCP) system.

Research needed to determine the equivalency of new pasteurization processes is technology dependent. All pasteurization processes need to be validated through the use of process authorities, challenge studies, predictive modeling, and/or safe harbors. All pasteurization processes must be verified to ensure critical processing limits are achieved.

In addition to traditional thermal pasteurization, other technologies can satisfy the definition of pasteurization for certain foods: ohmic heating, microwave heating, steam and hot water treatments, high pressure processing (HPP), UV radiation, irradiation, pulsed electric field, and chemical treatments. Other technologies, such as filtration, infrared, and high voltage arc discharge, may also have the potential to be used alone or in combination with other treatments.

As new technologies are applied commercially, consumer research is needed to develop label statements about pasteurization that are understood by consumers.

## I. Charge and Statement of Problem

The Farm Security and Rural Investment Act of 2002 (FSRIA) was signed into law on May 13, 2002 as Public Law 107-171. This law was passed to provide for the continuation of agricultural programs through 2007. FSRIA addresses commodity programs, conservation, trade, credit, rural development, research and related matters, forestry, energy, and miscellaneous items. Title X, Subtitle I, Section 10808(b) of FSRIA broadens the definition of pasteurization by mandating that Section 403 (h) (Misbranded Food) of the Federal Food, Drug, and Cosmetic Act be amended to include a definition for pasteurization. Section 403(h) reads as follows with the FSRIA amendment:

**SEC. 403 [343]** A food shall be deemed to be misbranded - …

(h) If it purports to be or is represented as –

(1) a food for which a standard of quality has been prescribed by regulations as provided by section 401, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such a standard;

(2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 401, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

(3) a food that is pasteurized unless –

(A) such food has been subjected to a safe process or treatment that is prescribed as pasteurization for such food in a regulation promulgated under this Act; or

(B) (i) such food has been subjected to a safe process or treatment that –

(I) is reasonably certain to achieve destruction or elimination in the food of the most resistant microorganism of public health significance that are likely to occur in the food.

(II) is at least as protective of the public health as a process or treatment described in subparagraph (A);

(III) is effective for a period that is at least as long as the shelf-life of the food when stored under normal and moderate abuse conditions; and

(IV) is the subject of a notification to the Secretary, including effectiveness data regarding the process or treatment; and

(ii) at least 120 days have passed after the date of receipt of such notification by the Secretary without the Secretary making a determination that the process or treatment involved has not been shown to meet the requirements of subclauses (I) through (III) of clause (i).

The Food and Drug Administration (FDA) and the U.S. Department of Agriculture/ Food Safety and Inspection Service (FSIS) are seeking the advice of the NACMCF to determine appropriate requisite scientific parameters for establishing the equivalence of alternative methods of pasteurization. In order to do so, FDA and FSIS have determined that the following questions deserve consideration.

1. What are the scientific criteria that should be used to determine if a process is equivalent to pasteurization?

2. What, if any, further research is needed to determine criteria?

3. What is the most resistant microorganism of public health significance for each process?

4. What data need to be acquired to scientifically validate and verify the adequacy of a proposed technology? How much data would be considered adequate? To what degree can models and published literature be relied upon as contributing to validation?

5. What biological hazards might be created as a consequence of the pasteurization treatment?

## II. NACMCF Definition of Pasteurization

Traditional time-temperature pasteurization is well understood by regulators, industry, and consumers. Information on the history of pasteurization of milk, crabmeat, egg products, and juice is presented in Appendices A – D. An examination of the development of these pasteurization processes can assist in evaluating the equivalence of alternative processes and underscores the need for periodic reevaluation of such standards to protect public health.

Based on NACMCF's evaluation of traditional pasteurization processes, it was evident that the term pasteurization has no universally recognized definition that applies to all foods. Therefore, the NACMCF agreed to the following definition to guide its work.

> Any process, treatment, or combination thereof, that is applied to food to reduce the most resistant microorganism(s) of public health significance to a level that is not likely to present a public health risk under normal conditions of distribution and storage.

The Committee recognizes that while an effective pasteurization process will deliver a safe product, public health protection cannot be assured without steps to minimize the potential for re-contamination.

The following discussion further clarifies important phrases in the above concepts.

**“Any process, treatment or combination thereof…”**

- Historically, pasteurization has had two roles, one being public health protection and the other being shelf life extension. This document focuses on public health protection.
- Pasteurization can be achieved using multiple treatments that in combination achieve the intended effect but individually do not.
- Pasteurization should not be equated with commercial sterility. Pasteurized products usually require refrigeration whereas commercially sterile products are shelf stable. However, pasteurization in combination with other factors, such as pH, can provide a shelf stable product.
- Traditional pasteurization processes are based on thermal inactivation as practiced for milk and liquid eggs.
- The same principles of microbial inactivation apply to other technologies based on thermal inactivation, such as microwave processing, ohmic heating, and surface pasteurization with steam.
- The mechanisms of microbial inactivation may differ for technologies not based on thermal inactivation, such as high pressure, UV radiation , and irradiation.

**“…that is applied to food to reduce…”**

- This phrase means “reasonably certain to achieve destruction or elimination in the food” as provided in Sec. 403[343].
- Elimination can refer to the removal of undesirable microorganisms and their products, such as through filtration.
- In principle, total destruction or elimination cannot be achieved because there is a statistical probability that an organism will survive in a fraction of products (e.g., 1 in 1,000,000 packages). However, the level of pathogen reduction is such that the product does not present a reasonable certainty of harm to the consumer.
- Pasteurization was first developed for raw liquid products, but it is now applied to solid foods as well.
- For most products, pasteurization assures that every particle of the food is treated, e.g., milk and liquid eggs.
- In some instances, pasteurization can be applied to food surfaces when internal contamination is not likely, such as when the product was previously cooked, e.g., hot dogs.

**"…most resistant microorganism(s) of public health significance…"**

- Epidemiological data of relevance to the targeted food should be considered in selecting the organisms of concern.
- Organisms of concern may include infectious and toxigenic bacteria, viruses, and parasites. The Committee did not address fungal toxins and prions in the scope of the document because other mitigations are necessary.
- The identification of the organism(s) of concern is a function of intrinsic resistance, initial populations, and the influence of the food on growth and survival.
- Typically pasteurization is designed to inactivate the vegetative cells of pathogens, including vegetative cells of sporeformers.
- In limited instances, pasteurization is also designed to inactivate spores; e.g., non-proteolytic (psychrotrophic) *Clostridium botulinum* in pasteurized crabmeat.

**"…level that is not likely to present a public health risk. "**

- Public health risk is a function of the specific pathogen(s), initial populations and types, the ability of the food to support pathogen growth/survival, and the susceptibility of the host.
- Presence of a pathogen does not necessarily mean that a public health risk exists; e.g., pathogenic sporeformers in products that do not support growth.
- If the food product supports the growth of the pathogen, the length of the shelf life can influence the potential public health risk. For example, certain sporeformers may not be inactivated by the pasteurization process but their population may be controlled throughout shelf life through time and temperature or other means.
- Pasteurization does not protect public health when product is subsequently recontaminated during manufacture or after the container is opened.
- The concept of public health risk is intended to address whether the product bears or contains numbers of organisms of concern or levels of their toxins that may render it injurious to health. In addition, this concept of risk is intended to address the issue of reasonable certainty of no harm.

**"…under normal conditions of distribution and storage."**

- Pasteurization is not intended to prevent growth of microorganisms under all time and temperature conditions. The manufacturer should specify how the product should be safely handled and stored. Adequate or proper refrigeration temperatures vary depending on the qualities of the food product.
- Normal conditions of distribution and storage include a range of temperature conditions. In many instances, this will include conditions of moderate abuse with respect to the product.
- Based on the Audits International study (*11*), a significant number (90%) of consumers' refrigerators are below 45°F. However, optimum refrigerated storage is $\leq$41°F. Temperatures above 50°F for the shelf life of the product would be

considered gross abuse for most refrigerated foods. Storage time must also be considered when determining if a situation constitutes abuse.
- Pasteurization should not be expected to provide protection under gross time/temperature abuse conditions.

## III. Response to Questions in the Charge

The five questions posed to the Committee are answered broadly below. Additional consideration specific to a given technology is addressed in Section V.

### 1. What are the scientific criteria that should be used to determine if a process is equivalent to pasteurization?

The term pasteurization has been used to describe a process or a combination of processes that has been broadly applied to different food-pathogen combinations. As examples, milk pasteurization is based on inactivation of at least 100,000 guinea pig infectious doses of *Coxiella burnetii* (*51*; see Appendix A); the process for pasteurized crabmeat is based on shelf life extension and significantly exceeds a 12-$\log_{10}$ reduction of type E non-proteolytic *C. botulinum* (*132*; see Appendix B); the reduction of *Salmonella* in liquid eggs was originally based on an 8.75-$\log_{10}$ reduction, whereas in-shell egg pasteurization targets a 5-log reduction (see Appendix C); and juice pasteurization is based on a 5-$\log_{10}$ reduction of the most resistant microorganism of public health significance (*34*; see Appendix D). As these examples illustrate, currently recognized processes are not "equivalent" in reduction values but all afford an appropriate level of public health protection.

An FSO and or a performance standard to achieve an appropriate level of public health protection for food/pathogen combinations could serve as the basis for judging equivalency when a proposed process is evaluated as an alternative to traditional pasteurization (Appendix E).

One must consider numerous factors when establishing the efficacy and equivalency of different pasteurization processes, including identification of the most resistant pathogen(s) of concern in the food, the efficacy of the specific technology to reduce the pathogen(s) of concern, the food matrix characteristics, and the intended use of the food. NACMCF recommends the following guidelines as essential to developing a proposed pasteurization process:

- Conduct a hazard analysis to identify the microorganism(s) of public health concern for the food.
- Determine the most resistant pathogen of public health concern that is likely to survive the process.
- Consider the level of inactivation needed. Ideally, this would involve determining the initial cell numbers and normal variation in concentration that occurs before pasteurization.

- Assess the impact of the food matrix on pathogen survival.
- Validate the efficacy of the pasteurization process.
- Define the critical limits needed during processing to meet the performance standard.
- Define the specific equipment and operating parameters for the proposed pasteurization process. This may include developing specific GMPs in addition to the HACCP system.

Like traditional pasteurization, alternative technologies for pasteurization greatly reduce the numbers of pathogenic and non-pathogenic microorganisms, but do not destroy or eliminate all microorganisms. Thus, to prevent spoilage throughout the shelf life of the product, traditional preservation techniques, such as freezing, refrigeration, low pH, low water activity, high salt, or modified atmosphere packaging, could be used in addition to pasteurization to preserve the product. These parameters need to be assessed to determine critical factors for the specific food when defining the proposed process.

**2. What, if any, further research is needed to determine criteria?**

Criteria to determine the adequacy of thermal processes are well established. As illustrated in the examples for traditional thermal processes, it is difficult to assess equivalence of different pasteurization processes for different commodities (Appendices A-D). Research needed to determine the adequacy of alternative technologies can be found in Section V. The following research needs apply to all pasteurization processes.

- Identify surrogate organisms for in-plant validation of processes.
- Determine initial populations of pathogens in products to be pasteurized.
- Identify appropriate indicators of microbial safety or quality if relevant for the product/process combination.
- Develop, optimize, and validate recovery and enumeration methods for process validation purposes.
- Identify factors that influence reproducibility of resistance characteristics for test strains.
- Develop predictive models for pathogens subjected to processes used alone or in combination.

**3. What is the most resistant microorganism of public health significance for each process?**

The microorganism of public health significance for a specific process depends on its resistance, the process, the initial numbers present, and its ability to grow in the food. As with thermal processing, the most resistant microorganism of public health significance depends on the food product, its intended use, and the technology used to process the food. The pathogen with the greatest resistance to one treatment, e.g., heat, may not be the most resistant to another type of treatment, e.g., irradiation. The most resistant microorganisms for specific technologies are discussed in Section V. When determining

the target microorganism, it is necessary to consider all pathogens that have an epidemiologically relevant association with a product, as the most resistant pathogen may not be present in the highest numbers. Conversely, pathogens controlled by other means may not be of public health significance in a product when growth is required for illness (e.g., *C. botulinum* type A control by refrigeration in pasteurized crabmeat). The term 'pasteurization' implies destruction, elimination, or control of all microorganisms likely to pose a public health risk in the specific product.

**4. What data need to be acquired to scientifically validate and verify the adequacy of a proposed technology? How much data would be considered adequate? To what degree can models and published literature be relied upon as contributing to validation?**

Validation is the collection and evaluation of scientific and technical information to determine if the treatment, when properly applied, will effectively control the hazard(s). For validation, an expert in the technology area needs to determine the critical factors for each proposed use. Product and process variability, batch-to-batch variation, influence of product characteristics, size of product pieces, etc., need to be considered. Guidelines for challenge tests and inoculated pack studies have been published (*70*). Important considerations include:

- Statistical power in experimental design such as conducting multiple trials.
- The specificity and sensitivity of the validated method used to recover the target pathogen.
- The use of multiple microbial strains including clinical, environmental and product isolates for the food being studied. Use strains with high but not abnormal resistance.
- Varying the critical factors to determine the margin of safety achieved by the process. This may be useful in evaluating process deviations and assuring uniformity of treatment.
- The use of appropriate experimental and data analysis procedures to confirm that the least lethal treatment is included in measurements.
- Predicting the degree of inactivation that is achieved may be difficult if delivery of the process is non-uniform, e.g., non-uniform heating by microwaves or in particulate foods.
- The use of previously validated approaches or safe harbors.

It is important to note that validation studies are not always necessary when the safe harbor approach is used. A safe harbor, for the purpose of this document, is defined as a recognized procedure that can be employed without further validation studies.

There are sources of variability and uncertainty involved in the design of a pasteurization process that need to be considered in the validation studies. The sources for variability include the choice of the isolates used for the validation study [e.g., to determine the D-value (decimal reduction time, or the time required to destroy 90% of the organisms, or time at a given pressure to effect a one $\log_{10}$ reduction of a target organism)], the phase of

growth in which the organisms are harvested (e.g., for *Listeria monocytogenes* in refrigerated foods, a growth phase culture may be appropriate), the substrate upon which the culture is grown and the associated environmental conditions (e.g., pH, temperature, atmospheric conditions), the suspending medium, the sample size and packaging conditions, the method (including media and counting method) by which the cells are enumerated following the process, and the selection of appropriate measurement systems.

Predictive models and published literature can be used as tools in validation of pasteurization; however, there are limitations. Models may not include all the influences on microbial growth and survival for the particular food to be treated or all the critical parameters for the specific processing technology. However, models that represent a conservative estimate of the potential for growth or survival may be used (*96*). Laboratory studies may not reflect actual processing conditions. Scale-up of laboratory-based studies in a pilot plant may be necessary to confirm that the processing parameters and conditions are consistent with the laboratory studies. In-plant validation is rarely done with pathogens; non-pathogenic surrogates are used for such studies (*116*). When surrogates are not available it may not be possible to obtain data on the pathogens of concern under actual production conditions. Despite these limitations, laboratory studies have been used successfully to validate traditional pasteurization processes and should be useful in the future.

The hazard analysis may change as research provides new data or epidemiological data on pathogens and/or efficacy of technologies. Models are particularly useful in evaluating the effects of formulation changes on efficacy of treatments. It is important that published literature and models used are appropriate for the food being studied. If there are significant differences between the intrinsic properties of the food of concern and the properties used in the model or the literature study, then the model or study may not be applicable to the product. However, if the validation study is conducted using parameters that are more conservative (i.e., the actual process would provide a safer product than the parameters tested), then additional validation studies need not be conducted. For example, if a pasteurization process is more effective at lower pH, then validation studies conducted at pH 6.0 could apply to product with pH 5.0 if all other critical factors are the same.

The need to revalidate should be assessed when new hazards are identified or changes are made to the process or product. For example, milk pasteurization was reassessed when the hazard of *L. monocytogenes* was identified (Appendix A). The need for additional validation studies should also be determined when there are unexplained process failures.

Verification includes those activities that demonstrate the system is operating as designed.

Once the critical factors have been identified for a process, they are monitored and documented during process delivery by a manufacturer. This information can also be independently verified by observations of monitoring and record review.

Effective pasteurization should deliver lethality such that testing finished product for pathogens is impractical and has no statistical reliability due to sampling probabilities.

**5. What biological hazards might be created as a consequence of the pasteurization treatment?**

The Committee limited its response to this question to changes in microbial ecology and new microbial hazards that might occur due to pasteurization treatments based on guidance from the NACMCF Chair.

Eliminating competition. Pasteurization will inactivate many nonpathogenic organisms that may grow faster than pathogens and therefore limit pathogen growth. Therefore, once products are pasteurized they need to be protected against recontamination. For example, *Staphylococcus aureus* is noted for its inability to compete with other microorganisms in food. Once competition is removed it can grow to high numbers and, if conditions are satisfactory, potentially produce toxin. The elimination of spoilage organisms can also extend shelf life to a point where toxigenesis precedes spoilage, e.g., non-proteolytic *C. botulinum* outgrowth in a refrigerated product.

Selecting for more resistant organisms. Microorganisms with resistance greater than the target microorganism can survive the pasteurization process. For example, pathogenic sporeformers may germinate and grow unless proper controls, such as refrigeration or formulation, are applied.

Sublethal injury. If organisms are injured rather than inactivated during processing, assurance must be provided that they do not repair and grow during the product shelf life. Although research has shown that sublethal injury can result in increased resistance, at least one study has demonstrated this may not be significant with respect to some heat processes (*99*). There should be an awareness that application of one mechanism of processing may result in concomitant selection for resistance to other mechanisms (*79, 85)*. Although it has been proposed that cross-adaptation could have a significant impact on food processing (e.g., if acidification of food products is combined with a pressure treatment) (*133*), this has not been shown to be a problem to-date in commercial processing.

## IV. Conclusions

In response to the FSRIA of 2002, which asks for a broadening of the definition of pasteurization, NACMCF was charged with determining requisite scientific parameters for establishing the equivalence of alternative methods of pasteurization. NACMCF recommends the following guidelines as essential to developing a proposed pasteurization process:

- Conduct a hazard analysis to identify the microorganism(s) of public health concern for the food.

- Determine the most resistant pathogen of public health concern that is likely to survive the process.
- Assess the level of inactivation needed. Ideally, this would involve determining the initial cell numbers and normal variation in concentration that occurs before pasteurization.
- Consider the impact of the food matrix on pathogen survival.
- Validate the efficacy of the pasteurization process.
- Define the critical limits that need to be met during processing that will meet the performance standard.
- Define the specific equipment and operating parameters for the proposed pasteurization process. This may include developing specific GMPs in addition to the HACCP system.

Research is needed to determine the adequacy of pasteurization for alternative processes and is technology dependent. All pasteurization processes need to be validated through the combined use of process authorities, challenge studies, predictive modeling, and/or safe harbors. All pasteurization processes must be verified to ensure critical processing limits are achieved.

In addition to traditional thermal pasteurization, other technologies can satisfy the definition of pasteurization for certain foods. These include treatments such as ohmic heating, microwave heating, steam and hot water treatments, HPP, UV radiation, irradiation, pulsed electric field, and chemical treatments. Other technologies, such as filtration, infrared processing, and high voltage arc discharge, may also have the potential to be used alone or in combination with other treatments.

The Committee recognizes that while an effective pasteurization process will deliver a safe product, public health protection cannot be assured without steps to minimize the potential for recontamination.

Finally, NACMCF concludes that consumer research is needed to understand how consumers interpret and respond to labeling statements about pasteurization and related terms. More research is needed to develop label statements that are understood by consumers.

## V. Processes and Technologies

This section describes considerations that are specific to each technology. Traditional thermal processes, non-traditional thermal processes, and alternative non-thermal technologies, are addressed, in that order. Where possible, all questions posed to the Committee are addressed for a technology. However, for some technologies, research is insufficient to address the questions, and they are only briefly described.

## A. Cooking

Although cooking has not traditionally been referred to as pasteurization, it is clearly capable of achieving that effect. FSIS has developed lethality performance standards for the production of certain meat and poultry products (e.g., cooked beef, roast beef, cooked corn beef, and cooked poultry products) that require a 6.5-$\log_{10}$ reduction of *Salmonella* (or alternative equivalent lethality) for certain beef products (*27*) and a 7-$\log_{10}$ reduction of *Salmonella* (or alternative equivalent lethality) for poultry products (*29*). Time and temperature parameters to comply with the performance standards ("safe harbors") have been published by FSIS (*61, 62)*. FSIS is proposing similar lethality performance standards for other ready-to-eat (RTE) meat and poultry products. FSIS has determined that products meeting the lethality performance standards, when properly cooled and handled, would contain no viable pathogenic microorganisms of concern.

FDA, in its Fish and Fisheries Products Hazards and Controls Guidance (*58*), indicates that cooking processes are generally designed to eliminate vegetative cells but not spores of pathogens. FDA considers *L. monocytogenes* to be the target pathogen, and a 6-D process to be suitable. FDA notes that cooking is usually performed before the product is placed in the finished container, whereas pasteurization of these types of fishery products is performed on products in hermetically sealed containers (see Appendix B).

### 1. What are the scientific criteria that should be used to determine if cooking is equivalent to pasteurization?

As with any heat treatment, time/temperature parameters are critical. In general, these depend on two main factors: (i) knowledge of the thermal inactivation kinetics of the most heat-resistant pathogen of concern in a specific food product; and (ii) heat transfer properties of the food system. The pathogen of concern will be product-specific. The cooking process should be designed to deliver the required heat treatment to the slowest heating point in the product. Heat transfer is influenced by many factors, including type of food and its characteristics, e.g., shape, size, composition (moisture, salt, etc.), whether or not the product contains multiple components (such as stews), state of the product (liquid vs. solid), consistency or viscosity, etc. Some cooking processes are applied to products prior to packaging, whereas others, such as cook-in-bag or sous vide processes, are applied to packaged product. When product is cooked inside the package, the type of packaging material and shape of the package may influence heat transfer. When the cooking process is applied prior to packaging, prevention of recontamination with pathogens is essential for the cooking process to be considered equivalent to pasteurization.

**2. What, if any, further research is needed to determine criteria?**

The Committee believes that the criteria listed in Section III above are adequate to determine if cooking is equivalent to pasteurization. Research will be needed to develop data on these criteria as they apply to specific products.

**3. What is the most resistant microorganism of public health significance for cooking?**

The pathogen of concern will depend on the product. Bacterial spores are more resistant than vegetative bacteria, viruses, and parasites. Cooking processes are not designed to inactivate spores.

**4. What data need to be acquired to scientifically validate and verify the adequacy of cooking? How much data would be considered adequate? To what degree can models and published literature be relied upon as contributing to validation?**

The critical process parameters in cooking are the time and temperature at the coldest point in the product. This is influenced by a variety of factors, most notably product formulation and equipment design. There are many models for inactivation of pathogens by heat. In most cases, process validation would be to determine the coldest spot in the product and develop data to demonstrate that the required time/temperature parameters are met at this point. In some instances it may also be necessary to determine the heat resistance of the pathogen of concern in the food.

**5. What biological hazards might be created as a consequence of cooking?**

Cooking does not create unique microbiological hazards other than those previously discussed in Section III.

**B. Microwave Processing**

Microwave processing is defined as the use of electromagnetic waves of certain frequencies to generate heat in a material. Since it is an electro-thermal process, microbial destruction by microwave occurs through heat. Industrial microwave pasteurization and sterilization systems have been around for over 30 years. The most promising relevant applications include the following: (i) continuous pasteurization processing of milk, (ii) pasteurization of juices (apple and orange), and (iii) pasteurization of intact shell eggs. Bacterial pathogens whose inactivation has been demonstrated using microwave technology include the following: *Bacillus cereus*, *Campylobacter jejuni*, *Clostridium perfringens*, pathogenic *Escherichia coli*, *Enterococcus* spp., *L. monocytogenes*, *S. aureus*, and *Salmonella* spp. Parasitic pathogens (*Trichinella spiralis*,

*Toxoplasma gondii*, and *Anisakis simplex*) have all been found to survive various microwave treatments, but this is probably due to unevenness of temperature distribution during the process (*46, 68)*. At the time of document preparation, there was no literature available on enteric virus inactivation specifically using microwave heating.

**1. What are the scientific criteria that should be used to determine if microwave processing is equivalent to pasteurization?**

Microwave technology is capable of achieving an effect equivalent to thermal pasteurization. In studies where microwave heating is compared directly to conventional heating, microwave heating is frequently found to be less effective due to non-uniform heating effects, the unpredictability of cold spots (areas of less heat penetration leading to lower internal temperature and less destruction of target organisms), and changing product parameters (such as specific heat). Since traditional thermal destruction parameters form the basis for microwave inactivation, time/temperature parameters are critical. In general, these depend on two main factors: (i) knowledge of the thermal inactivation kinetics of the most heat-resistant pathogen of concern in a specific food product, and (ii) heat transfer properties of the food system. Accordingly, the scientific criteria that should be used to determine if microwave heating is equivalent to traditional thermal pasteurization include:

- Type of food and its characteristics, e.g., shape, size, volume, composition (moisture, salt, etc.), whether or not the product contains multiple components (such as frozen dinners), state (liquid vs. solid, including the presence of ice).
- Properties associated with the process, such as power level, cycling, equilibration time, and the presence/absence of hot water or air surrounding the food.
- Properties associated with the equipment, including dimensions, shape, and electromagnetic characteristics of the oven, agitation, presence of stirrers and turntables, frequency (2450 and 915 MHz), and age of the magnetron.
- The effect of packaging material on process delivery.
- Demonstration that lethal temperature is achieved in all parts of the product.
- Reliable means by which to monitor temperature during the process to prevent significant process deviations.

Time-temperature history at the coldest location in the product will determine the safety of the process. Both the magnitude of the time-temperature history and the location of cold spots in the product are functions of the critical process factors listed above. Time is a factor in that as the food heats up, its microwave absorption properties can change and the location of cold spots can shift.

**2. What, if any, further research is needed to determine criteria?**

The Committee believes that the criteria listed above are adequate to determine if microwave processing is equivalent to pasteurization. Research will be needed to develop data on these as they apply to specific products.

**3. What is the most resistant microorganism of public health significance for microwave heating?**

The kinetics of microwave inactivation of organisms should be the same (except for cold spot issues) as for conventional thermal inactivation. There are no notable microwave-resistant foodborne pathogens. As with heat, bacteria are more resistant to microwave heating than are yeasts and molds; spores are more resistant than vegetative cells. A recurring conclusion is that if non-uniform heating occurs then there could be survival, and this must be addressed by equipment and process design.

**4. What data need to be acquired to scientifically validate and verify the adequacy of microwave heating? How much data would be considered adequate? To what degree can models and published literature be relied upon as contributing to validation?**

The critical process parameter in microwave processing is the location of and temperature at the coldest point in the product. This is influenced by a variety of factors, most notably product formulation and equipment design. For validation and verification purposes, determining the effects of small deviations in food formulation on heating patterns would be advisable. Microwave systems are not standardized making comparison between makes and models difficult. The design of equipment to assure uniformity of heating is critical. Finally, establishment of reliable monitoring methods and the means to detect process deviations would also be necessary to validate the process.

Although literature abounds regarding the efficacy of microwave heating for cooking and even for achieving commercial sterility, there is very little information in the published literature about microwave pasteurization (Table A). In many instances, the literature reports inactivation of total aerobic bacteria, coliforms, or other normal spoilage microflora, rather than evaluating the behavior of a target pathogen. Predicting the degree of inactivation that might be achieved by microwave technology may be difficult if non-uniform heating occurs.

**5. What biological hazards might be created as a consequence of microwave heating?**

Microwave heating does not create unique microbiological hazards other than those previously discussed in Section III.

**Table A. Summary Table of Microwave (MW) Applications to Pasteurization**

| Microorganism | Food | Comments | Reference(s) |
|---|---|---|---|
| aerobes, coliforms, psychrotrophs | Milk | Compared low temperature long time (LTLT) batch process (65°C [149°F], 30 min) using MW vs. conventional heat; both achieved 6-$\log_{10}$ reduction in 3 groups of microorganisms and negative phosphatase test. | *89* |
| aerobes, coliforms | Milk | Compared continuous MW heat at 72°C (161.6°F) for 15 s to conventional high temperature short time (HTST) process; methods gave comparable inactivation and negative phosphatase test. | *72* |
| *Salmonella* Typhimurium, *E. coli*, *Pseudomonas fluorescens*, *Streptococcus faecalis* | Milk | Examined MW as means to deliver LTLT and HTST processes; LTLT treatment reduced *S. faecalis* by 3-4 $\log_{10}$; MW treatment at 78.6°C (173.5°F) for 65 s did not completely inactivate organisms. Suggest survival due to non-uniform heating. | *76* |
| *Yersinia enterocolitica, C. jejuni, L. monocytogenes* | Milk | Batch process at 71.1°C (160°F) for various times. Complete inactivation (8-9 $\log_{10}$) of *Y. enterocolitica* after 8 min, of *C. jejuni* after 3 min, and of *L. monocytogenes* after 10 min. | *23, 24* |
| *Salmonella* Enteritidis | In-shell eggs | Hot water, hot air, and MW compared; combination of rapid MW-heating step to 55°C (131°F) followed by holding at 55°C (131°F) in hot air or hot water resulted in 7-$\log_{10}$ reduction. | *123* |
| *Lactococcus plantarum* | Orange juice | Continuous-flow MW process at 70°C (158°F) for 15 s produced 6-$\log_{10}$ reduction; 80°C (176°F) for 15 s eliminated the organism. | *98* |
| *Saccharomyces cerevisiae, L. plantarum* | Apple juice | Compared batch heat treatment with continuous-flow MW; faster microbial destruction rate with MW. | *124* |

## C. Ohmic Heating

Ohmic heating uses electrical resistance to heat products. Currents (usually alternating current [AC]) are passed through the food or other material using electrodes in direct contact with the food. In ohmic heating, heat energy occurs from within foods as opposed to microwave or inductive heating. In inductive heating, electric coils placed near the food generate electromagnetic fields that send electric current through the food, thus heating it. There are no known current commercial applications for inductive heating, and it will not be discussed further.

Ohmic heating behavior is different from conventional heating. With conventional heating methods, liquids heat faster than solids. With ohmic heating, solids can heat faster than liquids because the heating rate is a function of particle shape and particle orientation to the applied electric field. Therefore, process parameters for ohmic heating depend on food characteristics.

Time as a function of particle concentration and volumetric flow rate has been studied. Mean passage time decreases with increase in flow rate; however, mean required passage time remained constant with an increase in solid/particulate concentration. A wide range of temperatures in the heating section was observed. Large standard deviations in required passage times during heating were observed, which could cause problems of overcooking some particles to ensure commercial sterility (*50*).

Commercial and pilot scale ohmic heaters heated a homogeneous liquid uniformly except in certain sections of the heating column where lumen size changed. Heating of a fluid containing suspended solids was a function of particle location and concentration when electrical conductivity differed between liquid and particulate phases. Heating of potato chunks in a sodium sulfate solution showed marked non-uniform heating within particles. Solids heated faster than liquid (*22*).

Ohmic heating is used in the following fruit and juice applications:

Pasteurized whole fruits (Japan and United Kingdom)
Pasteurized sliced peaches and pears (Italy, Greece, Spain, France, and Mexico)
Pasteurized orange juice (Mexico)

Applications of ohmic heating include cauliflower (*49*), fluid containing apple particles (*131*), apple slices (*16*), and prepared meals (*141*). Agriculture and Agri-Food Canada's Food Research and Development Centre have studied the use of ohmic heating in meat product cooking. Experimental trials have not only yielded excellent results in energy savings, they have also produced brine-cured meat products that are of excellent visual quality, closely similar to products made by conventional cooking (*81*).

**1. What are the scientific criteria that should be used to determine if ohmic heating is equivalent to pasteurization?**

Ohmic heating is a thermal process. As a result, the same traditional time/temperature relationships for pasteurization can be achieved. Critical factors that must be known or monitored:

- Time and temperature.
- Physical properties and composition of the food product (e.g., pH, water activity, fat content).
- Heating characteristics of food components of the product.

**2. What, if any, further research is needed to determine criteria?**

The following research needs were recommended in the Institute of Food Technologists report (*69*) and endorsed by NACMCF:

- Develop a more complete body of knowledge to assess the impact of deviations for specific designs of ohmic heaters. This would include improved models for ohmic processing.
- Develop methods for monitoring temperatures within individual solids.

**3. What is the most resistant microorganism of public health significance for the use of ohmic heating?**

Ohmic heating is a thermal process that is rapid, volumetric, uniform, and the most resistant pathogen is likely to be the same as that for other thermal processes. No organisms with unusual resistance to ohmic heating have been identified.

**4. What data need to be acquired to scientifically validate and verify the adequacy of the use of ohmic heating to achieve pasteurization? How much data would be considered adequate? To what degree can models and published literature be relied upon as contributing to validation?**

Since the main critical process factor is the thermal history and location of the cold spot in the product, the effects on microbial inactivation are the same as for thermal processes (*113*).

**5. What biological hazards might be created as a consequence of the use of ohmic heating to achieve pasteurization?**

The biological hazards discussed in Section III should be considered. In addition, slow cooking can also present a hazard as prodigious multiplication of vegetative bacterial pathogens can occur during the "come-up period" of the cooking cycle. Such multiplication should be minimized in order to ensure the process is adequate.

## D. Steam and Hot Water

The most likely application of steam or hot water to achieve 'pasteurization' would be for precooked, prepackaged meat and poultry products that have been exposed to the processing environment between cooking and packaging, particularly where the product surfaces exposed to the environment remain as surfaces readily heated in the packaged state (i.e., whole muscle as compared to sliced and shingled products where interior surfaces exposed to a conveyor belt may be "buried" within the shingle pack after packaging, and thus, are not readily heated).

There may be other examples, e.g., seafood products, where steam or hot water treatments may lead to 'pasteurized' products (see Section V. A. Cooking). In some instances, regardless of the food type, a raw product may be packaged, and then heat-treated with steam or hot water to become 'pasteurized' by definition. In these instances, the raw food product will be cooked in the package to destroy all potential hazards.

One possible barrier to the use of steam and hot water is that the product characteristics may be sufficiently changed to result in the product no longer being considered "fresh."

**1. What are the scientific criteria that should be used to determine if the use of steam and hot water are equivalent to pasteurization?**

In traditional thermal pasteurization, steam and hot water are often used in an indirect manner (i.e., without direct food contact through a heat exchanger) to produce the heat for thermal pasteurization. An alternative to this traditional thermal pasteurization is the use of steam or hot water for foods that are pre-packaged in films to avoid additional water gain and prevent negative organoleptic changes. As for traditional thermal pasteurization, this application of steam or hot water has the potential to reduce the populations of pathogenic and non-pathogenic bacteria, but does not eliminate all bacteria.

Additionally, the application of steam or hot water for pathogen reduction for packaged food products will be most often used for reducing or eliminating the potential for pathogens on the surface of the product since treatment times typically are limited. Thus, the heat transfer will be limited to surfaces of the product, and will not penetrate to interior surfaces of the food product. To prevent spoilage throughout the shelf life of the product, traditional preservation techniques such as freezing, refrigeration, low pH or low water activity, high salt, or modified atmosphere packaging, must be used subsequent to hot water or steam to preserve the product. Clearly, the scientific criteria for establishing if hot water or steam treatments are equivalent to pasteurization are linked to the specific food type.

The criteria used to measure the efficacy of traditional thermal pasteurization in creating safe food is appropriate for treatment with steam or hot water as well. The criteria used to assess a specific steam or hot water process would include the following:

- Temperature of steam or hot water.
- The resulting temperature profile on the surface layer of the food product.
- Type of food processed and its characteristics, e.g., density, physical dimensions.
- Specific information on how the food was handled before, during and after treatment with steam or hot water, e.g., prior heat lethality steps, packaging conditions.
- Target organism to assess the efficacy of the steam or hot water process.

**2. What, if any further research is needed to determine criteria?**

The defining criteria for 'pasteurization' by steam or hot water treatment do not require further development. However, the specific criteria associated with various food products treated with steam or hot water will need to be developed for each product category (e.g., precooked, prepackaged whole-muscle products; precooked, prepackaged, stacked sliced products; precooked, prepackaged, shingled products).

**3. What is the most resistant microorganism of public health significance for the use of steam and hot water to achieve pasteurization?**

The organism used to assess the efficacy of steam or hot water as a pasteurization technology will be linked to the specific food product, its history, and its intended use. For a selected food product, there may be multiple organisms that could be considered as potential hazards. The organism of concern would be that one most likely to be present at the time of steam or hot water treatment with the greatest resistance to the steam or hot water process being used.

For example, in the case of processing precooked, prepackaged deli meats, the organisms of concern identified in a HACCP plan might include *E. coli* O157:H7, *L. monocytogenes*, and *Salmonella*. However, after a validated cooking process, these pathogens would be killed; subsequent handling, slicing, and packaging may re-introduce *L. monocytogenes* as a hazard. In this instance, the steam or hot water treatment would be developed based on a validated thermal destruction of *L. monocytogenes* that may be on the surface of the sliced product.

Bacterial spores are more resistant to steam and hot water than are vegetative cells; thus, if bacterial spores are considered to be the microbial hazards likely to occur and present a problem (i.e., through growth) during subsequent storage and distribution, steam and hot water treatment likely would not be a technological solution to "pasteurize" the food product containing these hazards.

**4. What data need to be acquired to scientifically validate and verify the adequacy of the use of steam and hot water to achieve pasteurization? How much data would be considered adequate? To what degree can models and published literature be relied upon as contributing to validation?**

In general, to validate that a steam or hot water process is adequate to pasteurize a food product, one must have knowledge on the inactivation kinetics of the most heat resistant microorganism of concern for each specific food product, and determine the heat transfer characteristics associated with the treatment of each specific food. For food products, there are physical and chemical characteristics that determine the effect of heat on pathogenic microorganisms, e.g., product thickness and density.

The thermal treatment that is provided to a food product by a steam or hot water process will be determined by regulatory requirements or scientific considerations. The optimal approach is to have knowledge on the range of potential contamination levels by the hazard of concern (e.g., based on actual enumeration results from positive food product samples), and then base the validation (i.e., lethality) requirements on these results.

Models have been created to demonstrate the effect of food type and characteristics on the efficacy of thermal processing using steam or hot water to process prepackaged foods (*92, 93, 94*). As for any model, the assumptions and uncertainties must be clearly stated. The value of the model will be more useful if the product used to create the model, and the conditions surrounding the steam or hot water process used for development of the model, are similar to those for which the model is being applied.

**5. What biological hazards might be created as a consequence of the use of steam and hot water to achieve pasteurization?**

There is no evidence that biological hazards might be created as a consequence of steam or hot water treatments.

**E. High Pressure Processing**

HPP is the application of hydrostatic compression in the range of 100-1000 megapascal (MPa) that is capable of inactivating microorganisms. In the early 1990s, Japan and other nations introduced the use of HPP of food to inactivate barosensitive microorganisms. An advantage of HPP is the minimal effect it has on covalent bonds; thus, minimal damage occurs to flavors, aromas, provitamins, and vitamins. A brief review of high-pressure biotechnology in medicine and pharmaceutical sciences discusses some effects of HPP action on biological substances (*87*). HPP has been successfully applied to RTE meats, seafood, marinated raw meats, and some processed fruit and vegetable products. However, HPP caused product damage to watermelon, raw apple slices, and bread.

HPP is used in commercial operations to specifically reduce *Vibrio parahaemolyticus* and *Vibrio vulnificus* to non-detectable levels in raw molluscan shellfish. Insufficient data are available to determine if other more resistant bacteria are destroyed by this process. HPP has current commercial utility as a *L. monocytogenes* post-lethality treatment for packaged RTE meat and poultry products (Table B).

A recent review by Koopmans and Duizer (*77*) lists many processes that successfully inactivate foodborne viral agents, however; only one example of HHP was cited. Wilkenson et al. (*134*) indicated less than a 1-log reduction in poliovirus (a highly resistant virus) following HHP treatment at 600 MPa for 1 h. Kingsley et al. (*75*) demonstrated a 7-$\log_{10}$ reduction in hepatitis A virus (HAV) after 450 MPa treatment for 5 min. Complete inactivation of a 7-$\log_{10}$ $ID_{50}$ for feline calicivirus (a norovirus surrogate) was accomplished by a 5-min treatment at 275 MPa, suggesting the value of HPP as a treatment for contaminated shellfish.

Although well suited to the destruction of vegetative cells, HPP has limited efficacy against sporeformers unless combined with other treatments, such as heat and pH.

**1. What are the scientific criteria that should be used to determine if HPP is equivalent to pasteurization?**

Due to the wide variety and combinations of HPP parameters, it is currently necessary to define a process for every type of food treated. Defining a process requires careful monitoring of food composition, including pH and water activity. Critical parameters for the process include initial temperature, process pressure, process hold time at pressure, time to achieve pressure, decompression time, treatment temperature, and the absence or presence of added $CO_2$.

Factors such as pH, water activity, composition, and preservatives, need to be evaluated to determine if normal variation makes these critical factors for a specific food. There is a minimum critical pressure below which microbial inactivation by pressure will not take place regardless of process time (~300 MPa). Important items of information not to be overlooked in HPP are the come-up times (period necessary to reach treatment pressure), pressure-release times, and changes in temperature due to compression. Obviously, long come-up times will add appreciably to the total process time and affect the product throughout, but these periods will also affect inactivation kinetics of microorganisms; therefore, consistency and awareness of these times are important in the development of HPP conditions.

**2. What, if any, further research is needed to determine criteria?**

HPP is very difficult to evaluate because of the multiple combinations of pressure with temperature, number of passes, pH, time, isotonic strength, and content of organic compounds. Some of these relationships are not linear, and while some mathematical projections have been developed, the combined effects listed above may need to be experimentally determined. There is a wide variety of conditions discussed in the reviews

listed in the following table, but one of the biggest obstacles is understanding the various mechanisms of resistance to HPP. Specific structural mechanisms, such as porins (proteins that form transmembrane channels for entry of molecules into the cell) and broad-acting stress resistance proteins, affect the ability of organisms to survive.

There is a need for the development of models to predict survival and calculate processes for HPP. Modeling research, using data generated by multiple-cell pressure units that allow for similar come-up times should be conducted. Although HPP-derived semi-logarithmic survival curves appear nonlinear (for example, sigmoidal or biphasic), in HPP predictive microbiology, a logarithmic order of reduction is normally assumed. This assumption carries the danger of underestimating the subpopulation of pressure-resistant organisms. Synergistic effects among pressure, temperature, $CO_2$, and other variables on microbial survival exist.

There is also a need for research on the mechanism(s) of resistance to HPP. Investigation of the influence of pressure on reduction of microbial populations using the proper experimental design (statistically valid, collection of data at different pressures and control of temperature and product), so that kinetic parameters are quantified is also needed. In this way, critical process factors can be evaluated for survival of pathogens or surrogates in a statistical manner. Accurate predictions could be used to develop HACCP plans.

More research will be needed to establish an equivalent to the traditional temperature-related D-value. Since the ease or difficulty of irreversible protein denaturation is a function of protein structure, a wide range of pressure resistances must be expected among microbes.

### 3. What are the most resistant microorganisms of public health significance for HPP?

In general, Gram-positive bacteria are more pressure resistant than Gram-negative bacteria, and spores are more resistant than vegetative cells. There appears to be a wide range of pressure sensitivity among the pathogenic Gram-negative bacteria. Some strains of *Salmonella* and *E. coli* O157:H7 have demonstrated relatively high levels of pressure resistance (*17, 54, 101, 102, 118*).

Published data are supplied in Table B for salmonellae, *Listeria* and *Clostridium* spp. in meats, milk, and sausage. Extensive work has also been done to examine the reduction of S. *aureus* and *L. monocytogenes* in milk. There has been a great deal of information collected on HPP reduction of *E. coli* O157:H7 in fruit juices.

**Table B. Selected Examples of High Pressure Processing**

| Microorganism type | Food | Comments | Reference(s) |
|---|---|---|---|
| *Enterobacteriaceae* and *Listeria* | Sausages | 500 MPa for 5 min = 80°C (176 °F) 40 min. | *139* |
| *L. monocytogenes*, *Salmonella*, and *E. coli* O157:H7 | Milk | Required multiple passes for pressures <300 MPa. 46-60°C (114.8-140°F) prior to Dynamic High Pressure (DHP) enhanced killing.<br>DHP less effective than HPP.<br>Best if total bacterial load $<10^5$ | *130* |
| *E. coli* O157:H7 (NCTC12079) | Milk | 400 MPa/ 50°C/15 min treatment for 5 $\log_{10}$ reduction. | *101, 102* |
| *L. monocytogenes* | Milk | Growth at 43°C (109.4°F) increases resistance to HPP. | *19* |
| *S. aureus, Bacillus spp.*, *L. moncytogenes*, *E. coli* O157:H7, *Salmonella* Enteritidis, *S.* Typhimurium, yeast | Juices and organic acid liquids | 8-$\log_{10}$ reduction at 345 MPa at 50°C (122°F) 5 min except for *S. aureus*. Most vegetative cells are sensitive to 700 MPa, but not spores.<br>8-$\log_{10}$ reduction in yeast at 304 MPa at 25°C (77°F) pH 4.0 for 10 min.<br>Generally, Gram-negative bacteria are more sensitive to HPP. | *3* |
| Multiple pathogens – | Yogurt, jams, jellies, juices, tomato sauces, and other acidic products, guacamole, dairy products, fish, sliced meats | Use where spores are not an issue as they cannot grow out at low pH. Variable pressure sensitivities with various commodities. Exponential phase is more sensitive than stationary phase. Strain to strain variability is greater for HPP than other processes.<br>Net volume decrease, proteins may denature, gelation may occur, lipid phase changes may occur, increased ionization of dissociation. | *66* |
| *E. coli* | Eggs | Accumulation of injured cells at pressures less than 400 MPa. Biphasic inactivation of *E. coli* | *83* |

| Microorganism type | Food | Comments | Reference(s) |
|---|---|---|---|
| | | at 5°C vs. linear exponential at 25°C. | |
| Small size and cocci | Vegetables and general | Mechanisms of pressure resistance. Small size and cocci shape are generally more resistant to HPP. Specific porins increase resistance. | *10* |
| *L. monocytogenes* | In general | Heat shock proteins provide cross protective resistance to stresses. | *79, 85* |

**4. What data need to be acquired to scientifically validate and verify the adequacy of HPP? How much data would be considered adequate? To what degree can models and published literature be relied upon as contributing to validation?**

There is a vast amount of data in the literature; however, it is all unique in terms of the pressures and other contributing conditions used for each commodity. A detailed literature search could likely lead to enough data to establish some criteria for HHP; however, much of the data may not be comparable and D-values may need to be generated and not extrapolated. Mathematical models that deal with multiple variables are difficult, but can be applied if substantial numbers of data points are available to plot.

The critical process factors in HPP include pressure, time at pressure, time to achieve treatment pressure, decompression time, treatment temperature (including adiabatic heating), initial product temperature, and vessel temperature distribution at pressure. Product variables, such as pH, composition, water activity, and packaging material integrity must also be considered. Pressure pulsing would require additional monitoring of pulse shape frequency, and high and low pressure values of the pulse.

An increase in food temperature above room temperature increases the inactivation rate of microorganisms during HPP treatment (*3*). Temperatures in the range of 45 to 50°C (113 to 122°F) appear to increase the rate of inactivation of food pathogens and spoilage microbes and thus merit the development of processes that incorporate a uniform initial food temperature in this range.

**5. What biological hazards might be created as a consequence of HPP?**

Resistance to HPP does not create unique microbiological hazards other than those previously discussed in Section III.

## F. UV Radiation

UV processing involves the treatment of foods with radiation from the UV region of the electromagnetic spectrum to inactivate microorganisms. UV has wavelengths in the region of 100 - 400 nm. Wavelengths of 200 - 280 nm inactivate bacteria and viruses. Sastry et al. (*114*) reviewed critical factors relevant to UV treatment of food products (excluding pulsed UV). The effectiveness of the treatment depends on the specific product characteristics. The technology can be used as an alternative to chlorine for disinfection of water and wastewater (*21,122).* For microbial inactivation in water, 400 $J/m^2$ must be achieved in all parts of the fluid (*122*).

UV treatments have been applied effectively to water supplies and food contact surfaces (*114*), and to apple juice (*67, 104, 137*). Pulsed UV has a higher penetration depth and may be more effective than continuous UV light (*78*). Pulsed UV has been shown to inactivate 4-$\log_{10}$ CFU/g *E. coli* O157:H7 on alfalfa seeds (*117*). Monochromatic pulsed UV has been shown to inactivate bacteria in milk (*121*); however, its effectiveness against the target organism for traditional milk pasteurization, *C. burnetii*, has not been evaluated, so equivalence to thermal pasteurization is unknown.

FDA has given premarket approval to use UV radiation for the treatment of water and food (including juices) under specific conditions of use (*40*). The technology is capable of delivering a process that achieves an effect equivalent to thermal pasteurization in some foods (e.g., fruit juices).

### 1. What are the scientific criteria that should be used to determine if a UV process is equivalent to pasteurization?

General considerations described previously in Section III apply to UV technology. Specific critical parameters that must be considered in monitoring, verifying, and validating the effectiveness of UV treatments include light (radiation) and product characteristics. UV wavelength, intensity, duration, and number of pulses (if pulsed) impact the effectiveness of the treatment. System configuration is critical, as this will define the thickness of the radiation path through the food. Shielding of organisms will reduce the effectiveness of the process and must be considered. Product characteristics that influence shielding include surface geometry (solid product); transparency and depth of fluid column (liquid product); product color, solids content, and overall chemistry; homogeneity of product flow pattern; and packaging transparency and color.

In determining the effectiveness of UV treatments, the potential for repair of the organisms under normal handling conditions should be considered. The mechanism of inactivation of microorganisms by UV involves damage to nucleic acids, and some strains have enzymes that can repair UV damage through photoreactivation or dark repair. The report by Sommer et al. (*122*) is an example of how inactivation and repair

are both considered in demonstrating the effectiveness of UV to achieve a 6-$\log_{10}$ reduction of pathogenic strains of *E. coli* in water.

**2. What, if any, further research is needed to determine criteria?**

In addition to general research considerations that apply to all technologies (see Section III), the following needs are relevant to UV radiation:

- Establishment of parameters such as suspended and dissolved solids concentration.
- Identification of pathogens most resistant to UV.
- Optimization of critical processing factors and development of protocols to monitor critical factors.
- Identification of differences between pulsed light technology and UV (254 nm) treatment, especially with respect to mechanism of inactivation. It has been reported that pulsed UV light is more effective than continuous UV light for inactivation of microbes due to higher penetration depth and greater dissipation power (*78*).

**3. What is the most resistant microorganism of public health significance for UV?**

Although there have been numerous studies published on inactivation of microorganisms by UV light, the most resistant microorganisms of public health significance have not been fully determined. Bacterial spores appear to be the most resistant forms, however, they may not be of concern when water or fruit juice are the products undergoing treatment. Chang et al. (*21*) described UV inactivation of *E. coli, Salmonella typhi, Shigella sonnei, S. faecalis, S. aureus, Bacillus subtilis* spores, poliovirus, rotavirus, and amoebic cysts. The doses of UV light for 99.9% inactivation of the vegetative bacteria were comparable; however the viruses, spores and amoebic cysts required 3-4 times, 9 times and 15 times, respectively, the dose required for *E. coli*. A 4-$\log_{10}$ reduction for a variety of bacteria has been achieved in water at exposures ranging from 50 to 200 J/$m^2$ (180-330 J/$m^2$ when considering photoreactivation); while poliovirus, rotavirus, and *S. aureus* phage A994 required 290 to 380 J/$m^2$ for the same lethality (*114*). Hanes et al. (*67*) demonstrated the effectiveness of UV for inactivating *Cryptosporidium parvum* in apple cider. A 3.8-$\log_{10}$ reduction could be achieved for *E. coli* O157:H7 in apple cider, with turbidity of the cider impacting effectiveness of the treatment (*137*). A 5-$\log_{10}$ reduction was achieved in cider containing low initial levels of yeast and mold with high UV doses and a slow flow rate. However, Duffy et al. (*47*) and Quintero-Ramos et al. (*104*) have demonstrated at least a 5-$\log_{10}$ reduction of an *E. coli* surrogate for O157:H7 in multiple trials using the CiderSure UV pasteurizer. Data on UV effectiveness against *L. monocytotgenes* are not available, and data on *Salmonella* are limited. Sommer et al. (*122*) showed that UV inactivation of eight strains of *E. coli* differed considerably, with a 6-$\log_{10}$ reduction of the most sensitive strain being achieved with a fluence of 12 J/$m^2$ and the most resistant strain requiring 125 J/$m^2$.

**4. What data need to be acquired to scientifically validate and verify the adequacy of a proposed technology? How much data would be considered adequate? To what degree can models and published literature be relied upon as contributing to validation?**

General principles described previously for validation and verification apply to UV (see Section III). The effectiveness of UV treatment for water has been demonstrated (*122*). Sastry et al. (*114*) described considerations for fruit juices.

UV treatment does not demonstrate linear inactivation kinetics. Initial treatment damages or injures cells, which is demonstrated by a shoulder in the inactivation curve. Rapid inactivation is often followed by a tailing of survival. Some of the tailing effect can be explained by shielding effects of the microbes in the food matrix. Models would need to account for the non-linearity of the inactivation curve. Sommer et al. (*122*) stressed that the microbiocidal effective UV dose cannot be calculated or predicted by mathematical modeling but must be proven by standardized biodosimetric full-scale testing.

Because variations in the manufacture of the quartz tubes for the CiderSure UV pasteurizer can alter the fluid dynamics and bacterial efficacy of the UV process, the individual tubes were validated to deliver a 5-$\log_{10}$ reduction (*47*). The investigators modeled the variability associated with UV inactivation of *E. coli* in apple cider and suggested that consistency of the $\log_{10}$ reduction could be improved by more stringent criteria for a tube to pass. Quintero-Ramos et al. (*104*) have developed a predictive model to relate the $\log_{10}$ reduction factor to the UV dose. They determined that doses of 6,500 $\mu J/cm^2$ or more were sufficient to achieve a greater than 5-$\log_{10}$ reduction of *E. coli* in apple cider; pH ranging from 2.99-4.41 had significant impact at higher UV doses. However, the authors note that the predictive model should be combined with knowledge of other factors, such as physical and chemical properties of the cider and other microbial physiology concepts that were not considered in the development of the model. Thus, it would appear that models, where they exist, can serve as a guide but additional data will be needed to validate UV processes.

**5. What biological hazards might be created as a consequence of the pasteurization treatment?**

Depending on commodity, surviving pathogenic sporeformers may require additional controls. Recovery of injured microorganisms may occur in UV treated products. Because of this, the potential for repair, either through photoreactivation or dark repair, needs to be considered in relation to the distribution and handling of the product in question.

## G. Irradiation

In the U.S., governmental agencies have approved irradiation (gamma energy, high-energy electrons, X-rays) for various food items. The U.S. regulations pertaining to the

irradiation of foods are contained in the *Code of Federal Regulations* (Appendix F). Worldwide, over 50 countries permit the use of irradiation on over 50 different foods and classes of food. One can refer to the joint Food and Agriculture Organization/International Atomic Energy Agency (FAO/IAEA) food clearances database to determine the specific food approvals in specific countries (*56*).

When food irradiation is approved, the upper treatment level (referred to as "dose") generally is limited to 10 kGy, with the exception of spice treatment in the U.S. and some countries where higher doses are approved. The effect of the irradiation process on food safety needs to be equivalent to that of thermal pasteurization, and result in no changes in the food that present a public health risk. The U.S. FDA has approved the use of irradiation for several foods, as well as some packaging materials. The Joint Expert Committee on Food Irradiation representing the FAO, IAEA and the World Health Organization (WHO) concluded that irradiation of any food up to 10 kGy caused no toxicological hazards and introduced no nutritional or microbiological problems (*135*). An expert committee gathered under the auspices of the WHO recently reconfirmed the safety of doses above 10 kGy (*136*). The Codex Alimentarius Commission adopted a standard in 2003 for irradiated foods that accepts the use of doses higher than 10 kGy for food products to achieve specific technical purposes (*44*). As with all processes, the minimum dose required to achieve the intended effect will have to be established for each specific product.

Irradiation can achieve an effect equivalent to thermal pasteurization. While irradiation is useful for a wide variety of foods, its use is limited for some products, e.g., some dairy products, because of negative organoleptic changes that occur following treatment. Irradiation at doses higher than required for control of sprouting or disinfestation can damage or soften some produce items. The end result depends on the type of produce, variety, harvest practices, and other treatment issues and cannot be generalized.

**1. What are the scientific criteria that should be used to determine if irradiation is equivalent to pasteurization?**

The scientific criteria that should be used to determine if irradiation is equivalent to pasteurization are linked to the specific food type and include:

- Use of approved source of ionizing radiation, and selection of an appropriate source and technology to achieve the stated purpose,
- Selection of appropriate absorbed dose that is within regulatory limits [note: dose of 1 Gray (Gy), involves the absorption of 1 Joule of energy by each kg of matter through which the energy passes; 1 Gy=100 rad),
- Type of food irradiated and its characteristics, e.g., composition, temperature, density, packaging,
- Specific information on how the food was handled before, during and after irradiation, e.g., time and temperature profile, history and types of processing steps, packaging conditions,

- Target organism and efficacy of the irradiation process in controlling the target organism,
- Selection and use of appropriate dosimetry system for the product and its processing requirements (dosimetry in food irradiation facilities should be conducted according to American Society for Testing Materials [ASTM] standards or equilvalent); and
- Selection and use of approved and appropriate packaging materials; packaging material suppliers can obtain proprietary approval; [an additional list of approved packaging materials is also published (*42*)].

**2. What, if any further research is needed to determine criteria?**

The Committee believes that the criteria listed above are adequate to determine if irradiation is equivalent to pasteurization.

**3. What is the most resistant microorganism of public health significance for irradiation?**

Viruses, bacterial spores, and some mold and yeasts are more resistant to irradiation, e.g., whereas doses between 1.5 and 4.5 kGy typically kill vegetative cells of bacterial pathogens, higher doses will be required to inactivate bacterial spores and some viruses. Thus, if these more resistant microorganisms (or the outgrowth from spores) were considered to be microbial hazards likely to present a public health risk under the proposed storage conditions for the food, irradiation may not be a technological solution to pasteurize the food product containing these hazards, depending upon the maximum allowable dose and organoleptic changes.

**4. What data need to be acquired to scientifically validate and verify the adequacy of irradiation? How much data would be considered adequate? To what degree can models and published literature be relied upon as contributing to validation?**

There are many sources of variability and uncertainty involved in the design of an irradiation process. These need to be considered in the validation of an irradiation process (*127*). To validate that an irradiation process is adequate to pasteurize a food product, one must have knowledge of the irradiation dose required. The dose of irradiation that is to be provided to a food product will be determined by regulatory and scientific limitations. The maximum permitted radiation dose for meat (4.5 – 7.0 kGy) and poultry (3.0 kGy) is sufficient to reduce common foodborne pathogens, e.g., *Salmonella* and *E. coli* O157:H7, at least 1000-fold (*64*).

Thayer (*127*) pointed out that the absorption of radiation by food depends upon its bulk density and the energy and type of incident radiation. It is important that the magnitude, location, and reproducibility of the maximum and minimum absorbed dose for a given set of experimental parameters be determined. The dosimeter must be appropriate for both the dose range and temperatures of the process, with reference to the national standards

(7). The variability of the absorbed dose needs to be reported as part of all validation research. The radiation processing industry in the U.S. follows and recommends that food irradiation be conducted according to ASTM Standards. There are approved ASTM Standards for gamma and electron beam facility operation; irradiation of food and packaging materials; and selection of appropriate dosimetry systems, products and practices (*8*).

**5. What biological hazards might be created as a consequence of irradiation?**

Irradiation does not create unique microbiological hazards other than those previously discussed under general considerations (see Section III).

## H. Pulsed Electric Fields

Pulsed electric field (PEF) treatment involves the application of high voltage (typically 20-80 kV/cm) to foods placed between two electrodes (*12*). Energy loss due to heating foods is minimized, reducing detrimental changes of the sensory and physical properties of foods. Destruction of microbial cells is the result of electroporation of cell membranes. The process can be static or continuous. Due to design limitations of current treatment chambers (gap between the electrodes is in the range of 3 mm), the process is currently limited to fluids. However, one investigation used a static processing chamber into which an inoculated molten medium was flowed and allowed to gel before applying PEF treatment; the results indicate that inactivation of microorganisms within the homogeneous semi-solid was more effective than in a fluid menstrum (*140*). One research note reportedly tested the effects of PEF on beef burgers, however, no details of how they did this, or of the process conditions, were provided (*18*). The researchers concluded that with their system, the process was ineffective for inactivating *E. coli* O157:H7 on beef.

Considerable data have been published that support the adequacy of PEF technology as a feasible pasteurization treatment for fluids. Data substantiate the mechanism of inactivation as electromechanical instability in the cell membrane at a critical electric field strength, with increasing field strength correlated with increased leakage of UV-absorbing cellular material and the loss of ability to maintain pH homeostasis (*111*). There was no correlation with inhibition of membrane H+-ATPase (as is for high pressure treatments), indicating this is not a site of bacterial inactivation (*119*). Teissié et al. (*126*) however, indicate that it is not only the membrane that is altered but also changes occur in the cell wall indicating hydromechanical and electrical stress. Nevertheless, the ‘fatal event’ is undoubtedly the membrane damage. Further research is required to understand the specific alteration in the lipid bilayer (especially with regard to composition of the lipids when cells are grown at low versus high temperatures) and effects on altering resistance.

**1. What are the scientific criteria that should be used to determine if PEF treatment is equivalent to pasteurization?**

General considerations discussed previously apply to this technology. In addition, scientific criteria that should be used to determine if pulsed electric field treatment is equivalent to pasteurization will include an understanding of the effect of the type of food to be processed and its characteristics (including electrical conductivity, ionic strength, pH, water activity, particulate size and content, viscosity) on delivery of the process. Additional hurdles, e.g., organic acids, can enhance process efficacy; the presence of such hurdles may be critical to achieving equivalence with thermal pasteurization. Specific equipment and operating parameters based on equipment design, including static versus continuous processing, flow rate (if applicable), pulse width, pulse frequency and duration, and electrical field strength are critical to deliver required inactivation.

**2. What, if any further research is needed to determine criteria?**

Survival curves extrapolated from few experimental values cannot correctly calculate the inactivation kinetics to obtain reliable kinetic parameters, hence multiple experimental data points need to be calculated for target organism(s) and specific process parameters (*4*). Currently, comparison of PEF inactivation reported in the literature is difficult because of the different experimental conditions employed and lack of kinetic parameters. Research is needed in areas of effects of combining one or more hurdles with the PEF treatment.

**3. What is the most resistant microorganism of public health significance for PEF treatment?**

Rotovirus is completely resistant to PEF processing, as it does not have a lipid membrane (*74*). Yeast cells are more susceptible to PEF treatment than bacterial cells [one investigation had an exception (*73*)]. It is not unequivocal that Gram-postive bacteria are more resistant than Gram-negative bacteria; however, *L. moncytogenes* (NCTC 11994) is more resistant than *S.* Typhimurium (strain CRA 1005) in distilled water (at 10, 15 and 20 kV/cm), Tris-maleate buffer and a model beef broth at 15 kV/cm (*112*).

Of note is the work done by Lado and Yousef (*80*) comparing the sensitivities of nine different strains of *L. monocytogenes* to PEF treatment in 0.1% NaCl and 25kV/cm. Two regimens were used: 23°C (73.4°F) for a treatment time of 144 μs and 37°C (98.6°F) for 72 μs. Under the first set of conditions, inactivation ranged 0.7 to 3.7 $\log_{10}$; at the higher temperature and shorter time, inactivation ranged from 0.3 to 2.5 $\log_{10}$. Strain OSY-8578 was significantly more resistant than other strains; Scott A (often the *L. monocytogenes* strain of choice for PEF investigations) was one of the most sensitive strains. This was confirmed by plotting survivor curves for PEF in diluted acid whey at pH 4.2. Clearly, the most resistant strains of a pathogenic species must be identified for PEF process optimization and validation. This study also noted that (a) resistance is not genotype-linked; and (b) the resistant strain OSY-8578 was dramatically less sensitive to phase of growth than the Scott A strain. The latter observation differs from the general thinking

(based on laboratory data) that bacterial cells are more sensitive to PEF during exponential growth vs. lag or stationary phases. Scott A, however, was more sensitive during early stationary phase, but acquired some resistance in late stationary phase. This phenomenon has not been noted for other microorganisms; however, studies of this nature are limited. Resistance variation among three stationary-phase serovars of *Salmonella enterica* has also been described (*4*).

With consideration for establishing processing criteria for any one commodity, the potential presence of stressed cells before PEF treatment may be of concern. Evrendilek and Zhang (*53*) investigated the sensitivity of *E. coli* O157:H7 in M9 medium to PEF at three field strengths (20, 25, and 30kV/cm) after exposure to different stresses. Incubation at pH 3.6 for 0 – 6 h at room temperature, or at pH 7.0 for 0 – 6 h at 4°C (39.2°F) and 40°C (104°F) resulted in significant decreases in sensitivity (similar results were noted for inactivation by heat at 60°C (140°F) for 3 min). Pre-treatment with PEF at doses of 10, 15, and 20 kV/cm were reported not to have any effect on resistance to the treatment field levels. However, the authors did not comment on the fact that their data also showed that at all levels of PEF pre-treatment and all levels of subsequent treatment at 20, 25 and 30 kV/cm, the levels of inactivation were considerably lower than for non-stressed cells (pH 7.0 at room temperature for 0 - 6 h).

**4. What data need to be acquired to scientifically validate and verify the adequacy of PEF treatment? How much data would be considered adequate? To what degree can models and published literature be relied upon as contributing to validation?**

Processing criteria must be established based on the characteristics of the commodity (e.g. electrical conductivity, ionic strength, pH) and further research is needed for fluids containing particles/viscous fluids. Liang et al. (*84*) noted significant differences in *S.* Typhimurium inactivation by PEF treatment of inoculated orange juice when the juice was pasteurized (greater inactivation) versus unpasteurized; containing pulp (less inactivation) versus without pulp. Ionic strength, conductivity and pH also influence the effectiveness of the process. There is evidence of additive/synergistic effects with the addition of organic acids, antimicrobials such as nisin, and high pressure $CO_2$ treatment, either prior to, during or following PEF treatment (*109*). Further research is needed to understand the mechanisms of such additional hurdles in potentiating the effectiveness of PEF.

Modeling PEF inactivation is complicated by the large number of different parameters that are involved. The individual effects of each parameter are not easily separated (*5, 6, 120*). Various models have been proposed to describe the kinetics of microbial inactivation by PEF using Weibull distribution functions that attempt to account for all relevant parameters affecting the inactivation kinetics [electric field strength, pulse wave strength, pulse wave shape, pulse length, number of pulses and temperature (*1, 106, 107*)]. Although the process is considered non-thermal, the electrical charge does generate small temperature increases, which affects fluidity of lipids. Variation in cell sizes, and hence stage of growth (cells in exponential vs. stationary phase), is suggested

by Lebovka and Vorobiev (*82*) to cause the deviation from first-order kinetics of inactivation by PEF.

Work by Lado and Yousef (*80*) and others indicating that significant differences in resistance to PEF may exist among different strains of a pathogenic species suggests that developmental investigations using a single strain should be interpreted cautiously. Some anomalies have been reported by researchers using exponential wave pulses, e.g., the pulse is followed by a short "spike" which increases the inactivation rate; however the authors of such reports do not offer an explanation of how and why spikes occur.

## 5. What biological hazards might be created as a consequence of PEF treatment?

A potential consequence of PEF processing, as with other processes, is sub-lethal rather than lethal injury of cells that may later repair and multiply under storage conditions. Total plate count studies of PEF-treated liquid whole egg have shown a sudden microbial growth during long-term shelf life studies, from undetectable levels post-treatment, suggesting the presence of injured cells that could repair during refrigerated storage of the product (*65*). However, the majority of studies with pathogens indicate that once a critical electric field is applied, cells are essentially completely inactivated. At less than the critical level, damage is reversible (*128*). A thorough investigation of this phenomenon by Wuytack et al. (*138*) compared *Salmonella* survivor counts on non-selective and three selective media. No difference in counts was noted between the non-selective media and certain selective media. Inactivation was linear between 15 and 30 kV/cm. Counts were slightly less on tryptic soy agar adjusted to pH 5.5. The authors propose a mechanistic model to explain differences in induction of sub-lethal injury by different non-thermal treatments, with a "single-target, single-copy" mechanism for damage incurred by PEF, consistent with the "all or nothing" observations made by most researchers for a variety of microorganisms (*Salmonella, Lactobacillus, Micrococcus luteus, L. monocytogenes,* and *E. coli* O157:H7 in apple cider). This is due to the physical/structural damage caused by PEF rather than physiological or metabolic alteration. It is noted, however, there is one study (*84*) that does report conflicting results for *Salmonella* in orange juice with greater degrees of sub-lethal injury.

A recent study by Reyns et al. (*105*) describes secondary inactivation of PEF survivors (*E. coli*, *S.* Typhimurium, and *L. monocytogenes*) when treated then stored in certain buffers and water containing 10% NaCl. Populations of non-exposed cells decreased when inoculated into PEF-treated solutions, indicating bactericidal agents generated during PEF. The Ames mutagenicity test showed a mutagenic effect in PEF-treated TRIS buffers and treated grape juice. The authors suggest it is the formation of chlorine and hypochlorite as a result of electrochemical reactions that produces these effects, which should be considered in the specification of treatment conditions.

## I. Chemical Treatments

Chemical treatments are not typically considered pasteurization treatments. Nonetheless, chemical treatments have a long history of effectiveness in controlling and inactivating microbial pathogens. Chemical treatment technologies can cover a wide range of applications, including fumigation (e.g., spice treatment), liquid treatment (e.g., ozonation of water and juice), topical treatments (e.g., application of bactericidal sauces or marinades), and formulation (e.g., mayonnaise and salad dressings). Chemicals can also be used in combination with other treatments to enhance the effectiveness of the lethality treatment (e.g., nitrites in heat-treated cured meat products and acidification of low acid foods).

A discussion of the broad spectrum of chemical treatments available is beyond the scope of this document. A list of chemicals that have potential food application include: ozone, peroxyacids, chlorine dioxide, ethylene oxide, acidified sodium chlorite, hypochlorites, and organic acids. Organic load can have a marked influence on the effectiveness of certain chemicals (e.g., hypochlorites), and this must be considered in the evaluation of food applications.

One example of chemical pasteurization is the use of ethylene oxide in spice reconditioning. Dimethyl dicarbonate has been approved for use as a microbial control agent in beverages such as tea and carbonated dilute beverages containing juice (*38*). The compound has been shown to be more effective than either sodium bisulfite or sodium benzoate against *E. coli* O157:H7 in apple cider at 4°C (*55*). Anhydrous ammonia has been used to achieve lethality of pathogens of concern in raw beef (*97*). The process involves injection of ammonia gas, which combines with the free moisture in the product to form ammonium hydroxide. This causes a dramatic pH change from approximately 6 to 9, which results in cell injury, especially to Gram-negative organisms. Chilling the meat to approximately 28°F causes the formation of ice crystals that are believed to further cause cell disruption and death of injured organisms. Use of chemicals to reduce pathogen levels on fresh and fresh-cut produce has been reviewed (*100*).

### 1. What are the scientific criteria that should be used to determine if the use of chemicals is equivalent to pasteurization?

As for traditional thermal pasteurization, the application of chemicals to a food product during processing and before packaging has the potential to reduce the populations of pathogenic and non-pathogenic bacteria, but most likely will not eliminate all bacteria. Frequently, chemicals are used in combination with other treatments, such as heat, HPP, freezing, refrigeration, low pH, low water activity, or modified atmosphere packaging, to improve effectiveness in controlling pathogenic bacteria. The effectiveness of many chemicals is influenced by the presence of organic compounds and other food constituents; therefore, the scientific criteria used to establish if chemical treatments are

equivalent to pasteurization are linked to the specific food type, how it has been processed and packaged, and its intended use.

In addition to the general criteria described in Section III, the criteria used to assess a specific chemical treatment would include the following:

- Concentration of the chemical(s).
- The immediate and persistent antimicrobial efficacy of the chemical(s).
- The antimicrobial spectrum of the chemical(s).
- Type of food processed and its characteristics, e.g., pH, water activity.
- The impact of organic load, pH, and other intrinsic properties on the effectiveness of the chemical.
- Specific information on how the food was handled before, during, and after the chemical treatment, e.g., additional lethality steps, packaging conditions.

**2. What, if any, further research is needed to determine criteria?**

The specific criteria associated with various food products treated with chemicals need to be developed for each product. Furthermore, research on the potential impact on human health is needed to ensure the use of the chemical is safe.

**3. What is the most resistant microorganism of public health significance for the use of chemicals to achieve pasteurization?**

In general, microbial resistance to chemicals from most to least resistant is as follows: bacterial spores > fungal spores > non-enveloped viruses > fungi > vegetative bacteria > enveloped viruses. There are, however, notable exceptions.

The organism used to assess the effectiveness of chemicals as a pasteurization technology must be linked to the specific food product, its history, and its intended use. For a selected food product, there may be multiple organisms that could be considered as potential hazards. The organism of concern would be that one most likely to be present at the time of chemical treatment with the greatest resistance to the chemical treatment being used.

For example, in the case of processing precooked, prepackaged deli meats, the organisms of concern might include *E. coli* O157:H7, *L. monocytogenes*, and, *Salmonella*. However, after a validated cooking process, these pathogens would be killed; subsequent handling, slicing, and packaging may re-introduce *L. monocytogenes* as a hazard. In this instance, the chemical pasteurization treatment would be developed based on a validated destruction of *L. monocytogenes*.

**4. What data need to be acquired to scientifically validate and verify the adequacy of the use of chemicals to achieve pasteurization? How much data would be considered adequate? To what degree can models and published literature be relied upon as contributing to validation?**

There are sources of variability and uncertainty involved in the design of a chemical pasteurization process. General considerations for verification and validation apply to potential chemical methods of pasteurization. It is especially important to consider the effect of variations in organic load, temperature, and pH for certain treatments. It is beyond the scope of this document to address all relevant factors in detail, as these will depend on the specific chemical and food under study. Published literature may provide information on some chemicals, however, it is important to avoid extrapolation of information generated in water, for example, to food systems, which may have a decided influence on the effectiveness of certain chemical treatments, such as chlorine.

Models have been created to demonstrate the effect of food type and characteristics on the efficacy of chemicals in killing or inhibiting the growth of pathogens. As for any model, the assumptions and uncertainties must be clearly stated. The value of the model will be enhanced if the product used to create the model, and the conditions surrounding the chemical treatment process used for development of the model, are similar to those for which the model is being applied.

**5. What biological hazards might be created as a consequence of the use of chemicals to achieve pasteurization?**

There is no evidence that biological hazards might be created as a consequence of chemical treatments. As mentioned under research needs, potential human health factors from exposure to the chemicals or their byproducts must be considered.

## J. Pulsed Light

Pulsed light technology involves treatment of food or package material surfaces with intense, short duration (< 1 up to 2 millisecond) pulses of broad-spectrum "white light" that includes wavelengths in the UV to near-infrared region (200-1000 nm); other systems use pulsed UV light (247-248 nm; see discussion on UV). Barbosa-Canovas et al. (*14*) reviewed the use of pulsed light for inactivating microorganisms. Pulsed light technology is generally restricted to surface treatment of foods and packaging materials because of the lack of penetrating power of UV radiation. The technology has been approved by FDA for control of microorganisms on food surfaces (*41*). Most applications target spoilage organisms for shelf life extension rather than pathogens. A commercial application for treating grapes in Chile has been reported (*14*), however the reported wavelength (247 nm) is in the UV range. Pulsed light containing higher levels of UV light has been demonstrated to be significantly more effective than that with low levels of UV (*110*). Significant gaps in information related to the effectiveness of this technology against a broad spectrum of pathogens and in specific food products make the potential application as a process equivalent to pasteurization unlikely at this time.

**1. What are the scientific criteria that should be used to determine if a pulsed light process is equivalent to pasteurization?**

General considerations discussed previously in Section III apply to this technology. Both product and light characteristics are important considerations in monitoring, validating, and verifying the effectiveness of pulsed light processes. Critical characteristics of the light include wavelength, intensity, duration, and number of pulses applied. Product surface properties that may provide shielding of microbes, the transparency of the food, the depth of required penetration, and light absorbing properties of packaging materials (e.g., transparency and color) are also important.

**2. What, if any, further research is needed to determine criteria?**

Extensive research on the effectiveness of pulsed light on pathogens is needed before this technology can be demonstrated to be equivalent to pasteurization. As previously mentioned, most research has focused on spoilage organisms, rather than on pathogens. The effectiveness of pulsed light treatments is, at least in part, related to the intensity of UV light in the pulses (*110*). The discussion on UV light is therefore relevant to pulsed light.

In addition to general research considerations that apply to all technologies, the following are relevant to pulsed light:

- Data on pulsed light effectiveness for specific commodities
- Comparison of resistance of specific pathogens, including bacteria, viruses, and parasites, exposed to pulsed light
- Identification of critical process factors and their effect on microbial inactivation
- Optimization of critical processing factors and development of protocols to monitor critical factors
- Suitability of the technology for solid foods and non-clear liquids
- Differences between pulsed light technology and UV (254 nm) light treatment, especially with respect to mechanism of inactivation

**3. What is the most resistant microorganism of public health significance for pulsed light processes?**

The most resistant microorganisms of public health significance have not been determined for pulsed light. Patent application data demonstrate significant reductions of vegetative bacterial pathogens and spores, with spores being more resistant than vegetative cells. Rowan et al. (*110*) demonstrated the relative resistances of single strains of organisms on agar plates from most to least resistant is as follows: *L. monocytogenes* >*S. aureus* = *S.* Enteritidis > *E. coli* O157:H7 > *B. cereus* vegetative cells = *S. cerevisiae* > *P. aeruginosa*. No data are readily available on the effectiveness of pulsed light on inactivation of viruses or parasites. Data on inactivation of spores of pathogenic sporeformers are also lacking.

**4. What data need to be acquired to scientifically validate and verify the adequacy of pulsed light processing? How much data would be considered adequate? To what degree can models and published literature be relied upon as contributing to validation?**

Since the targeted application of this technology is reduction of spoilage microflora, particularly molds, rather than the reduction of pathogens, there are no models and published literature is insufficient to validate effectiveness for a process equivalent to pasteurization. Most of the data on pulsed light are limited to those provided with the patent application for the technology; therefore peer reviewed literature for validation purposes would be needed.

**5. What biological hazards might be created as a consequence of the pasteurization treatment?**

There are no known biological hazards that might be associated with pulsed light applications other than those noted in Section III.

## K. Other Technologies

Other technologies may also have the potential to be used alone or in combination to achieve pasteurization. Some of these technologies are briefly discussed here, but the Committee felt that there was not sufficient information in the published literature for a detailed discussion. There was insufficient detail to determine equivalence with traditional pasteurization. These technologies are briefly described.

### Infrared Processing

Infrared processing is a non-traditional thermal heat process that is used commercially to 'pasteurize' the surface of meat products that may have been recontaminated with *L. monocytogenes* after cooking. Little information is available in the published literature regarding its application to reduction of microbial pathogens, however, it has shown some use as a means of post-lethality pasteurization process, e.g., infrared tunnels to inactivate *L. monocytogenes* on the surface of cooked hot dogs (*63, 91).*

### Non-Thermal Plasma (e.g., High Voltage Arc Discharge)

Arc discharge uses electricity to pasteurize fluids by applying rapid discharge voltages through an electrode gap below the surface of aqueous suspensions of microorganisms. This technology was reviewed by Barbosa-Canovas et al. (*13*). A multitude of physical effects (intense wave, hydraulic shock) and chemical effects (electrolysis) are generated, inactivating microorganisms by damaging cell membranes. The potential for the formation of highly reactive chemicals that occurs during the discharge requires consideration. This technology was first used in the 1920's in combination with heating to 70$^{o}$C (158°F) to inactivate *Mycobacterium tuberculosis* and *E. coli*. This was one of

the first electronic techniques used by the food industry to pasteurize milk. A 5-7 $\log_{10}$ microbial and endotoxin reduction in citrus juices and a 6-7 $\log_{10}$ reduction of pathogenic bacteria in milk have been reported. These results should be independently validated and there are insufficient data in the literature to determine critical process factors.

Barbosa-Canovas et al. (*13*) identified the following research needs:

- Understanding how delivery of highly reactive ozone and UV irradiation by electric arc discharge inactivates microorganisms.
- Quantifying the inactivation kinetics and mechanisms.
- Identifying reaction process products generated during the submerged arc discharge process due to the highly reactive nature of ozone and UV irradiation.
- Defining maximum allowable dose, in a manner similar to food irradiation.

While this technology shows some potential, chemical reaction products need to be identified and results validated in order to determine if this process meets the current definition of pasteurization. Based on this information, the Committee concluded that due to a lack of data on the efficacy of this technology, it cannot be applied as a process equivalent to pasteurization at this time.

**Oscillating Magnetic Fields**

Preservation of foods with oscillating magnetic fields (OMF) involves sealing food in a plastic bag and subjecting it to 1 to 100 pulses in an OMF with a frequency between 5 and 500 kHz at temperatures of 0 - 50°C (32 to 122°F) for a total exposure time ranging from 25 to 100 ms. The factors determining the effects of OMF on microorganisms are not well understood but may include: magnetic field intensity, number of pulses and frequency; and properties of the foodstuff (e.g., resistivity, electrical conductivity, and thickness of the foodstuff). Experiments have been conducted with milk, yogurt, orange juice, and bread roll dough.

Barbosa-Canovas et al. (*15*) reviewed research on OMF and concluded that reproducible microbial inactivation results are needed before considering this technology for food preservation purposes. Based on this information, the Committee concludes that due to a lack of data on the efficacy of this technology, it cannot be applied as a process equivalent to pasteurization at this time.

**Ultrasound**

By definition, ultrasound is the use of energy generated by sound waves. High-power ultrasound is of current interest to some in the food industry. The bactericidal effect of ultrasound has been attributed to intracellular cavitation resulting in cell lysis (*115*). Application of ultrasound with sodium hypochlorite and copper ions has been successfully used to reduce microbial pathogens in apple cider (*108*). Observations do indicate, however, that the potential of ultrasound as a sole treatment to pasteurize foods is minimal. Combinations of ultrasound and other preservation technologies, may have

potential for commercial application. A more comprehensive review of ultrasound food safety treatments has been prepared by Piyasena et al. (*103*).

Thermosonic (heat plus sonication), manosonic (pressure plus sonication), and manothermosonic (heat and pressure plus sonication) treatments are more energy-efficient and effective in killing microorganisms. Ultrasonic processing is still in its infancy and requires a great deal of future research in order to develop the technology on an industrial scale, and to more fully elucidate the effect of ultrasound on the properties of foods (*103*).

**Filtration**

Filtration involves the removal of microorganisms from fluids. Recent research evaluated the effect of temperature (7, 25, and 50°C [44.6, 77, 122°F]) and pore size (0.1, 0.8, and 1.4 µm) on the separation of proteins and lipids (neutral lipids and phospholipids) during microfiltration of fresh or reconstituted buttermilk, but did not address its use relative to microbial reduction (*90*). Filtration of other liquids, such as clear juices, beer, and wine utilize "cold pasteurization," a microfiltration process to eliminate fermentation organisms. Again, there are few references to its use for food safety.

**Appendix A. Milk Pasteurization**

Milk pasteurization is based on two fundamental principles: 1) every particle must be heated to a specified minimum temperature for a specified time and 2) equipment is properly designed and operated. The evolution of U.S. milk pasteurization requirements demonstrates the need to make adjustments to standards based on new information as scientific knowledge expands (Table 1). The first federal standard for milk pasteurization, 61.7°C (143°F) for 30 min, was established in 1924 based on destruction of *Mycobacterium tuberculosis* (88). In 1956, *C. burnetii* was recognized as the most resistant organism of concern, leading to an increase in the minimum batch pasteurization temperature to 63°C (145°F) for 30 min and establishment of "HTST" pasteurization of 72°C (161°F) for 15 s (*51*). These conditions eliminated 100,000 infectious guinea pig doses or more. Enright (*52*) demonstrated the need for more rigorous pasteurization treatments for cream, chocolate milk, and ice cream mixes (Table 1). This work was also based on destruction of 100,000 infectious guinea pig doses. The effectiveness of milk pasteurization was reexamined in the 1980s after several milk-associated *L. monocytogenes* outbreaks (*20*). FDA concluded that existing requirements were sufficient to control *L. monocytogenes*.

**Table 1. Evolution of Milk Pasteurization Standards in the United States.**

| Product | Batch | HTST | Target | Reference |
|---|---|---|---|---|
| Milk - 1924 | 61.7°C (142°F) for 30 min | None | *M. tuberculosis* | *88* |
| Milk | 63°C (145°F) for 30 min | 72°C (161°F) for 15 s | *C. burnetii* | *51* |
| Cream | 66°C (150°F) for 30 min | 75°C (166°F) for 15 s | *C. burnetii* | *52* |
| Chocolate milk | 66°C (150°F) for 30 min | 75°C (166°F) for 15 s | *C. burnetii* | *52* |
| Ice cream mix | 69°C (155°F) for 30 min | 80°C (175°F) for 25 s | *C. burnetii* | *52* |

Thermal Pasteurization as recommended by FDA in the current edition of the Pasteurized Milk Ordinance (PMO) (*59*) is conceptually founded in four generic premises:

- The human pathogen that is most resistant must be identified. In the case of thermal pasteurization of milk and milk products, the most resistant known organism is *C. burnetii*.

- The thermal process must be applied at levels of intensity that will inactivate the most resistant pathogen and assure the safety of the pasteurized milk or milk product. In this case, the times and temperatures that are specified in the PMO and in 21 CFR 1240.61 (*43*) are appropriate.

- The thermal process must be applied in properly designed and operated equipment, and is dependent on raw material quality. In the case of Grade A pasteurized milk and milk products, the PMO provides detailed specifications for state regulatory agencies and the dairy industry in regard to fail-safe systems that must be used to deliver the pasteurization process, as well as initial quality (Grade A standards for raw milk).

- There must be some means for regulators in those jurisdictions that are receiving the pasteurized milk and milk products to independently verify that the thermal process has been adequately applied. In the case of milk and milk products, the phosphatase test is commonly used for this purpose.

Processes other than thermal pasteurization, which are proposed to be applied to milk and milk products, must be recognized by FDA as equally efficient in the destruction of microbial organisms of public health significance. It is reasonable that the same generic premises as addressed above, modified based on the alternative technology involved, would apply.

## Appendix B. Crabmeat Pasteurization

In the U.S., crabmeat is sold in three forms: fresh, pasteurized, and shelf stable. Traditionally, live crabs are cooked, and then the meat is hand picked and packed in containers for market under refrigeration and sold as fresh crabmeat, or the crabmeat undergoes further heat treatment and is sold as a pasteurized product with an extended shelf life (6-18 months). Canned, commercially sterile product is also available.

Early in the development of crabmeat pasteurization, the emphasis was on extending the shelf-life of this perishable product and no target spoilage organisms or pathogens were identified. Later, because of the documented presence of type E *C. botulinum*, a psychrotrophic pathogen commonly found in the aquatic environment, there was concern about the safety of pasteurized crabmeat. Subsequent studies to determine the thermal death time (TDT) of *C. botulinum* type E in blue crabmeat found that an $F_{185}^{16}$ of 4.2 min resulted in a 12-$\log_{10}$ reduction of *C. botulinum* type E (*25, 86)*. Currently, the National Blue Crab Industry Pasteurization and Alternative Thermal Processing Standards define pasteurization as "a thermal process short of commercial sterilization whereby blue crabmeat products are packed in hermetic containers, heated to achieve a specific standard ($F_{185}^{16} \geq 31$ min) and stored/distributed at refrigerated temperatures." When *L. monocytogenes* was recognized as an organism of concern in refrigerated RTE products, the thermal resistance of the organism was evaluated and determined not to be an issue in pasteurized crabmeat (*25, 86*).

With respect to fishery products in general, the 2001 FDA Fish and Fisheries Products Hazards and Controls Guide (*58*) defines pasteurization for seafood as "a mild or moderate heat treatment, usually performed on fishery products after the product is placed in the finished product hermetically sealed container". It indicates that the purpose of pasteurization is either to make the product safe for an extended refrigerated shelf life or to eliminate or reduce the numbers of other target pathogens (e.g., *L. monocytogenes*, *V. vulnificus*). FDA considers a 6-$\log_{10}$ process for non-proteolytic *C. botulinum* to be adequate for pasteurization of seafood. If a target pathogen other than *C. botulinum* type E is selected, the potential for *C. botulinum* type E or other relatively heat tolerant pathogens to survive the pasteurization process and grow under normal storage or moderate abuse conditions must be considered.

**Table 2. Evolution of Blue Crab Pasteurization Standards in the United States.**

| Batch | Container | Target | Reference(s) |
|---|---|---|---|
| 171.1°C (160°F) for 10 min<br>76.7°C (170°F) for 1 min | Not specified | Shelf life extension | *9* |
| 85°C (185°F) for 1 min | 401x301 can | Shelf life extension | *125* |
| 85°C (185°F) for 4.2 min | 401x301 can | *C. botulinum* type E<br>12-$\log_{10}$ kill | *25, 86* |
| 85°C (185°F) for 31 min | Any container | *C. botulinum* type E<br>>12-$\log_{10}$ kill | *132* |

## Appendix C. Egg Product Pasteurization

### Traditional Egg Processing

Under the Egg Products Inspection Act (*48*), egg products are, with few exceptions, pasteurized before they leave the official plant. The term "egg product" means any dried, frozen, or liquid eggs, with or without added ingredients. The term "pasteurize" means the subjecting of each particle of egg products to heat or other treatments to destroy harmful viable microorganisms by specific processes prescribed by regulations. Egg products must be free of viable *Salmonella* microorganisms (*37*).

The current FSIS regulations governing the processing of egg products require the use of a combination of times and temperatures for pasteurization in order to inactivate *Salmonella* in liquid eggs (*30*). The pasteurization requirement for liquid whole eggs (60°C [140°F] for 3.5 min) is expected to achieve a relative 8.75-$\log_{10}$ reduction of *Salmonella* (*129*). Currently, FSIS regulations provide pasteurization times and temperatures for liquid whole eggs, albumen, and yolks, with or without added salt, sugar or other ingredients. Pasteurization parameters for dried egg whites are also provided (Table 3) (*33*).

**Table 3. FSIS Pasteurization Requirements (*30, 33*)**

| Products | Minimum temperature °C (°F) | Minimum holding time |
|---|---|---|
| Albumen (without use of chemicals) | 56.7 (134)<br>55.6 (132) | 3.5 min<br>6.2 min |
| Whole egg | 60 (140) | 3.5 min |
| Whole egg blends (<2% added non-egg ingredients)<br>Sugar whole egg (2-12% sugar added)<br>Plain yolk | 61.1 (142)<br>60 (140) | 3.5 min<br>6.2 min |
| Fortified whole egg and blends (24-38% egg solids, 2-12% added non-egg ingredients) | 62.2 (144)<br>61.1 (142) | 3.5 min<br>6.2 min |
| Salt whole egg (≥2% salt added)<br>Sugar yolk (≥2% sugar added)<br>Salt yolk (2-12% salt added) | 63.3 (146)<br>62.2 (144) | 3.5 min<br>6.2 min |
| Spray-dried albumen | 54.4 (130) | 7 days |
| Pan-dried albumen | 51.7 (125) | 5 days |

Pasteurization procedures must assure complete pasteurization of the product, and holding, packaging, facilities, and operations shall be such as to prevent contamination of the product. The FSIS Administrator may approve other methods of pasteurization when such treatments give equivalent effects to those specified in Table I of 9 CFR 590.570(b) (*31*) for those products or other products. Nonetheless, these other methods of pasteurization must result in *Salmonella*-negative product (*32, 33*).

**In-Shell Processing**

Technologies are being developed for in-shell pasteurization of eggs. As one example, eggs pass through a series of clean warm water baths that provide enough heat to kill salmonellae without cooking the eggs. The FDA criterion for pasteurization is a 5-$\log_{10}$ reduction in *Salmonella* count after introducing a mixture of salmonellae containing *S.* Enteritidis into the intact egg. An evaluation of the pasteurization process includes a review of the time/temperature data necessary to achieve a 5-$\log_{10}$ reduction of salmonellae, and an evaluation of survival and growth of bacteria from eggs held for 30 days at 5°C (41°F) after pasteurization. Additionally, processors are also required to demonstrate that product integrity can be ensured after pasteurization. This is done by the marking and/or packaging of the pasteurized eggs to ensure that the unpasteurized eggs are not substituted in the containers after processing (*2*).

## Appendix D. Juice Pasteurization

FDA has for many years had a regulation on pasteurized orange juice (*36*); however, this regulation is a standard of identity, and the pasteurization process is for quality (to reduce substantially the enzymatic activity and the number of viable microorganisms). As a result of several outbreaks of foodborne illness from juices, the NACMCF was asked to address the issue of fresh juice safety. In April 1997, the NACMCF made recommendations for control of pathogens in fresh juices (*95*) that were subsequently accepted by FDA and incorporated into regulations (*34*). In these regulations FDA requires that juice (defined as the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of edible portions of one or more fruits or vegetables, or concentrates of such liquids or purees) to be used in a beverage be processed under HACCP. HACCP plans must include control measures that will consistently produce, at a minimum, a 5-$\log_{10}$ reduction of the most resistant microorganism of public health significance in the product (*35*). This performance standard, which was recommended by NACMCF, defines the term pasteurization with respect to juices. Any beverage containing juice where neither the juice nor the beverage has received this 5-$\log_{10}$ reduction treatment must bear a statement that says, "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems."

A detailed discussion of the pathogens of concern in juice can be found in the preamble to the rule, published in the *Federal Register* (*57*). These are dependent on the juice product and process, but include *E. coli* O157:H7, *Salmonella*, and *Cryptosporidium parvum*. For low-acid juices such as carrot juice, *C. botulinum* may be a target organism. Guidance on validated pasteurization treatments for juices can be found in FDA's Juice HACCP Hazards and Controls Guidance (*60*). Although treatments such as high pressure and UV can be used to deliver the 5-$\log_{10}$ reduction, at this time, juice produced by such means cannot be labeled as pasteurized.

## Appendix E. The Application of FSOs and Related Concepts to the Pasteurization Process

The concept of FSOs is emerging (*71*). The following terms, as defined by the Codex Committee on Food Hygiene, apply:

- **Food Safety Objective (FSO):** The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP) (*45*).

- **Performance Objective (PO):** The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to an FSO or ALOP, as applicable (*45*).

- **Performance Criterion (PC):** The effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a PO or an FSO (*45*).

- **Microbiological Criterion (MC):** Defines the acceptability of a product or a food lot, based on the absence or presence, or number of microorganisms including parasites, and/or quantity of their toxins/metabolites, per unit(s) of mass, volume, area or lot (*45*).

In the context of a risk analysis framework, an FSO would be based on a public health goal that provides an ALOP. (A general ALOP for food in the U.S. can be expressed as "reasonable certainty of no harm.") The primary purpose of an FSO is to translate a public health goal, or ALOP, into a parameter that can be understood by those who have to deliver and verify control measures. Since an FSO applies at consumption, if the hazard can increase in the food it may be necessary to establish performance objectives that are essentially FSOs at points in the food chain prior to consumption. Performance criteria reflect the outcome of control measures that are applied to meet a PO or FSO. A performance criterion is met by implementing process criteria (the critical factors of a process, such as time and temperature of a thermal treatment) or product criteria (such as pH, $a_w$) that control the hazard.

We have defined pasteurization as:

> Any process, treatment, or combination thereof, that is applied to food to reduce the most resistant microorganism(s) of public health significance to a level that is not likely to present a public health risk under normal conditions of distribution and storage.

The most resistant microorganism of public health significance may be different for different food products, and different pasteurization process technologies. Since the level of contamination that would lead to a public health hazard may be different for each organism of concern, the FSO needed will be different per organism. Therefore, it is difficult to establish a specific FSO or other criteria that can be used to define pasteurization in general.

Application of these concepts to pasteurized milk:

> FSO: low probability that a serving of milk contains a viable vegetative pathogen (e.g., <1 cell per 1,000 servings)
> PO: generally the same
> PC: treatment sufficient to reduce the levels of *C. burnetii* by greater than 6-$\log_{10}$ cycles (inactivation of greater than 100,000 guinea pig infectious doses, assuming that each guinea pig infectious dose contains at least one, and more likely more than one, viable rickettsia)

Process Criteria: 62.8°C (145°F) for 30 min; 161°F for 15 s (minimum time to destroy 100,000 guinea pig infectious doses plus 2 σ)
MC: not practical

Application of these concepts to pasteurized juice:

FSO: the level of enteric pathogens is <1 CFU per 10 L
PO: the same
PC: treatment sufficient to reduce the levels of the most resistant pathogen of concern by 5-$\log_{10}$ cycles
Process Criteria: Depends on the juice and the treatment used
MC: not practical for juices treated after expression from the raw fruit or vegetable. For juices where the surface of the fruit is treated prior to expression of juice:
Two 10 ml samples tested for generic *E. coli* every 1,000 gal with a 7-sample moving window, c=2

A performance criterion is expressed by the equation:

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

FSO = food safety objective
PO = performance objective
$H_0$ = initial level of the hazard
$\sum R$ = Total (cumulative) reduction of the hazard on a $\log_{10}$ scale
$\sum I$ = Total (cumulative) increase of the hazard on a $\log_{10}$ scale

## Appendix F. Regulations Pertaining to Irradiation of Foods Contained in the *Code of Federal Regulations*

### Irradiation in the Production, Processing and Handling of Food; Subpart B: Radiation and Radiation Sources; Ionizing radiation for the treatment of food (*39*)

Ionizing radiation for treatment of foods may be safely used under the following conditions:

(a) Energy sources. Ionizing radiation is limited to:

(1) Gamma rays from sealed units of the radionuclides cobalt-60 or cesium-137.

(2) Electrons generated from machine sources at energies $\leq$ 10 million electron volts.

(3) X-rays generated from machine sources at energies $\leq$ 5 million electron volts.

(b) Limitations

| Table 4. 21 CFR 179 - Allowable Irradiation Doses for Food (*39*) | | |
|---|---|---|
| **Food** | **Minimum Dose** | **Maximum Dose** |
| For control of *Trichinella spiralis* in pork carcasses or fresh, non-heat- processed cuts of pork carcasses. | 0.3 kGy or 30 krad | ≤ 1 kGy |
| For growth and maturation inhibition of fresh foods | | ≤ 1 kGy |
| For microbial disinfection of dry or dehydrated enzyme preparations (including immobilized enzymes). | | ≤ 10 kGy |
| For microbial disinfection of the following dry or dehydrated aromatic vegetable substances when used as ingredients in small amounts solely for flavoring or aroma: culinary herbs, seeds, spices, vegetable seasonings that are used to impart flavor but that are not either represented as, or appear to be, a vegetable that is eaten for its own sake, and blends of these aromatic vegetable substances. Turmeric and paprika may also be irradiated when they are to be used as color additives. The blends may contain sodium chloride and minor amounts of dry food ingredients ordinarily used in such blends. | | ≤ 30 kGy |
| For control of food-borne pathogens in fresh or frozen, uncooked poultry any packaging used products that are: (1) Whole carcasses or disjointed portions of such carcasses that are “ready-to-cook poultry" within the meaning of 9 CFR 381.1(b)(44), or (2) mechanically separated poultry product (a finely comminuted ingredient produced by the mechanical deboning of poultry carcasses or parts of carcasses) (*28*). | | ≤ 3 kGy |
| For the sterilization of frozen, packaged meats used solely in the NASA space flight programs. | 44 kGy | |
| For control of foodborne pathogens in, and extension of shelf life of, refrigerated or frozen, uncooked products that are within the meaning of 9 CFR 301.2 (rr), meat byproducts within the meaning of 9 CFR 301.2 (tt), or meat food products within the meaning of 9 CFR 301.2 (uu), with or without nonfluid seasoning, that are otherwise composed solely of intact or ground meat, meat byproducts, or both meat and meat byproducts (*26*). | | ≤ 4.5 kGy for refrigerated products; ≤ 7.0 kGy for frozen products |
| For control of *Salmonella* in fresh shell eggs. | | ≤ 3.0 kGy |
| For control of microbial pathogens on seeds for sprouting. | | ≤ 8.0 kGy |

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