U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
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Kinetics of Microbial Inactivation for Alternative Food Processing Technologies

Executive Summary

(Table of Contents)

This report evaluates the scientific information available on a variety of alternative food processing technologies. The purpose of the report is to help the Food and Drug Administration evaluate each technology's effectiveness in reducing and inactivating pathogens of public health concern. Where information is too limited for a thorough evaluation and conclusion, research needs are identified.

The report begins with a discussion of overarching principles that apply to all of the technologies, specifically focusing on kinetic parameters and pathogens of public health concern. Kinetic parameters and models are used to compare the rates of microbial inactivation for each technology. Limitations of the parameters are discussed at length. Pathogens of concern for all the technologies are also addressed.

The report then provides a detailed review and analysis of the alternative technologies. For each technology, the FDA asked the panel to define the technologies, identify pathogens of public health concern most resistant to the technology, describe the mechanisms of pathogen inactivation and their kinetics, identify ways to validate the effectiveness of microbial inactivation, identify critical process factors and describe process deviations and ways to handle them. The panel also provides a description of synergistic effects between technologies, where available, and articulates research needs for each technology.

OVERARCHING PRINCIPLES

Kinetics

Kinetic parameters and models are used for the development of food preservation processes to ensure safety. They also permit comparison of different process technologies on reduction of microbial populations. The parameters, with their recognized limitations, are used to analyze and report the reduction of a microbial population as a function of process parameters and include empirical coefficients experimentally determined from microbial reduction kinetics. The models and kinetic parameters are used to present and compare microbial inactivation data from thermal, pressure and electromagnetic

processes. The parameters (D-value and z(T), z(P), z(*E*), E, k, K and V) have been calculated from data previously reported and using the models for thermal, pressure and pulse electric field (PEF) technologies. The thermal parameters apply to microwave energy and electrical resistance (ohmic) processes, as well as any other technology where temperature is the primary factor. The parameters for pressure or PEF treatments should apply to any process where pressure or electricity is the primary critical factor in reducing microbial populations. Given the scarcity of data, these are estimated parameters and there is an imminent need for more research in this area. The quantity of data for several of the other technologies, describing the influence of the treatment on reduction of microbial populations, is insufficient for a comparison.

The basic model assumes a linear first-order relationship between microbial population and time. There are considerable discussions about the appropriateness of using a first-order model to describe the reduction in microbial population for all preservation technologies, but without strong evidence to support alternative needs, first-order kinetics were used.

Kinetic parameters for microbial populations exposed to thermal treatments have been assembled over a significant period of time. Published literature has included kinetic parameters needed to respond to most process, product and microbial situations. Thermal parameters provide a sound basis for development of processes for the microwave energy and electrical resistance (ohmic) technologies.

There are limitations to interpreting these parameters. Care should be taken when the parameters are used to develop processes, to compare the resistance of different microbial populations, or to identify appropriate microorganisms.

Data used to determine the D-value and/or k for pressure treatment of microbial populations appear useful. Identifying the key pathogens of concern and their surrogates continue to be an ongoing challenge. Limitations of these data are primarily associated with temperature control or temperature changes during the pressure treatments. Evidence suggesting a synergistic impact of pressure and temperature on microbial populations is too limited for use. Much of the data were collected at a single pressure. Only 4 studies have used 3 to 5 pressure levels, while controlling all other factors affecting the parameters.

Data available on the influence of PEF on microbial populations have many limitations. The kinetic parameters are based on 2 points on the survivor curve. No single report has measured the inactivation of microbial populations at several levels of electric field strength, leading to the quantification of the PEF coefficient, nor has the synergistic influence of temperature been quantified.

Electrothermal alternative technologies utilize the well-established thermal kinetic parameters for thermal inactivation of vegetative cells of *Salmonella, Escherichia coli, Yersinia enterocolitica, Vibrio* spp*., Aeromonas hydrophila, Campylobacter jejuni, Listeria monocytogenes* and *Staphylococcus aureus.* In general, the thermal resistance

constants z(T) for the vegetative microorganisms fall between 4 and 7.7 °C. The largest D-value (smallest k-value) reported at 110 °C for toxin-producing, spore-forming microorganisms is 12.42 min (0.185/min) for *Clostridium botulinum* proteolytic Type B spores at 110 °C in pureed peas.

An independent additional inactivation mechanism due to the electric current during ohmic heating may occur, but at this time evidence is not sufficient to consider the use of alternate kinetic parameters for development of ohmic heating processes. The non-thermal effects of microwave processes on microbial inactivation have not been confirmed and appear insufficient in magnitude to be considered during development of processes. For processes involving the use of pressure for reduction of microbial populations, the F-value is the time the product needs to be exposed to the specified pressure and other conditions (that is, temperature) to accomplish the recommended amount of inactivation.

The combined influence of pressure and temperature on inactivation kinetics has been investigated on only a limited basis. Pressure appears to significantly inactivate *S. aureus*. However, in comparable experiments, inactivation rates of selected strains of various *Listeria* spp. with, for example, D-values ranging from 1.48 min (k = 1.556/min) at 350 MPa to 15 min (k = 0.154/min) at 400 MPa were lower than the ones for *S. aureus*. These data were measured at ambient temperatures (20 to 25 °C).

Comprehensive data on inactivation rates of *Clostridium sporogenes* spores show the influence of pressure on inactivation rate, z(P), to be 725 MPa at 93 °C, 962 MPa at 100 °C and 752 MPa at 108 °C. Data for *C. botulinum* Type E Alaska and Type E Beluga indicate that their D-values were in the same range as *C. sporogenes.* The D-values for *C. botulinum* Type A 62-A are generally higher than the values for *C. sporogenes,* even when considering the influence of temperature and pressure. In another study, high-pressure resistance was reported for *L. monocytogenes* and *S. aureus.* The most pressure-resistant pathogenic vegetative cell populations appear to be those of *E. coli* O157:H7 with a D-value of 6 min (k= 0.384/min) at 600 MPa, and *S. aureus* with a D-value of 7.14 min (k = 0.323/min) at 600 MPa. The most resistant pressure spores appear to be *C. sporogenes* with a D-value of 16.772 min (k = 0.138/min) at 600Mpa (T = 90 °C) and *C. botulinum* Type A 62-A with a D-value of 6.7 min (k = 0.344/min) at 827 MPa (T = 75 °C). The pressure coefficient z(P) of 1524 MPa for *C. botulinum* Type A 62-A constitutes an additional indication of the pressure resistance of the spore populations. A recent report shows little if any inactivation after 30 min of *C. botulinum* 17B and Cap 9B exposure to 827 MPa at 75 °C.

Adequate inactivation data for estimating the kinetic parameters for microbial populations exposed to PEF are scarce but in a form that fits the basic model. Even with major limitations, the models could be used to establish process time (F) in the short term, but a great effort would be needed to evaluate the outcome.

Parameters based on 2-point curves allowed direct comparisons of the effectiveness of PEF in reducing different microbial populations and the influence of the media on

microbial inactivation. The D-values for *Bacillus cereus* spores are higher than for other microbial populations at the same field strength and temperature. The survivor data for PEF are too limited for definite conclusions. For instance, data based on the same field strength and temperature are lacking. In addition, only a few of the published reports provide information on the threshold field strengths needed to initiate inactivation.

For pasteurization purposes, one is mostly concerned with the inactivation of vegetative cells of disease-producing microorganisms. However, to have a commercially sterile product, the process must control or inactivate any microbial life (usually targeting spores of *Clostridium botulinum*) capable of germinating and growing in the food under normal storage conditions.

Efficacy of any preservation technology is influenced by a number of microorganism-related factors that are generally independent of the technology itself. These include the type and form of target microorganism; the genus, species and strain of microorganism; growth stage; environmental stress selection mechanisms; and sub-lethal injury. Each influences the resistance independently of the apparent inactivation capacity of that particular process.

Extreme environments may select for forms resistant to severe conditions leading to a microbial population of greater resistance. An example of this is the higher heat resistance of acid- or salt-adapted, heat-shocked or starved *E. coli* O157:H7 cells. The questions relative to process design and verification are: (1) Are the microorganisms and food environments likely to result in stress induction? (2) Would stress induced resistance possibly occur? and (3) If it did, would it significantly impact the inactivation?

Pathogens of Public Health Concern

The following bacteria are known to be responsible for causing foodborne disease: *A. hydrophila*, *B. cereus*, *C. jejuni, C. botulinum, Clostridium perfringens*, pathogenic *E. coli*, *L. monocytogenes, Salmonella* serovars, *Shigella* spp, *S. aureus*, *Vibrio* spp. and *Y. enterocolitica.* The primary virus of concern that is carried by foods is Hepatitis A. *Cryptosporidium* and *Cyclospora* are protozoa of concern mainly because they produce resistant cysts. When exploring the new preservation technologies, their preservation level should be compared to that of classical pasteurization or commercial sterilization technologies.

Establishment of traditional thermal processes for foods has been based on 2 main factors: 1) knowledge of the thermal inactivation kinetics of the most heat-resistant pathogen of concern for each specific food product, and 2) determination of the nature of heat transfer properties of the food system. Validity of the established process is often confirmed using an inoculated test pack study tested under actual plant conditions using surrogate microorganisms as biological indicators that can mimic the pathogen. Thus, the 2 factors described above, which are well established for thermal processes, should be used for establishing and validating scheduled electrothermal processes.

For other preservation processes not based on heat inactivation, key pathogens of concern and nonpathogenic surrogates need to be identified and their significance evaluated. Surrogates are selected from the population of well-known organisms that have well-defined characteristics and a long history of being nonpathogenic. Surrogates need to be nonpathogenic organisms and not susceptible to injury, with non-reversible thermal or other inactivation characteristics that can be used to predict those of the target organism. The durability to food and processing parameters should be similar to the target organism. Population of surrogates should be constant and have stable thermal and growth characteristics from batch to batch. Enumeration of surrogates should be rapid and with inexpensive detection systems that easily differentiate them from natural flora. Genetic stability of surrogates is desirable to obtain reproducible results. It is recommended also that surrogates do not establish themselves as "spoilage" organisms on equipment or in the production area. The validation process should be designed so that the surrogate exhibits a predictable time-temperature process character profile that correlates to that of the target pathogen. Introduction of system modifications or variables, leading to inaccurate results (e.g. thermocouple probes changing heating rates, nutrients added to the product for surrogate growth altering viscosity, etc.) should be avoided.

MICROWAVE AND RADIO FREQUENCY PROCESSING

Microwave and radio frequency heating refers to the use of electromagnetic waves of certain frequencies to generate heat in a material through 2 mechanisms-- dielectric and ionic. Microwave and radio frequency heating for pasteurization and sterilization are preferred to conventional heating because they require less time to come up to the desired process temperature, particularly for solid and semi-solid foods. Industrial microwave pasteurization and sterilization systems have been reported on and off for over 30 y, but commercial radio frequency heating systems for the purpose of food pasteurization or sterilization are not known to be in use.

For a microwave sterilization process, unlike conventional heating, the design of the equipment can dramatically influence the critical process parameter--the location and temperature of the coldest point. This uncertainty makes it more difficult to make general conclusions about processes, process deviations and how to handle deviations.

Many techniques have been tried to improve the uniformity of heating. The critical process factor when combining conventional heating and microwave or any other novel processes would most likely remain the temperature of the food at the cold point, primarily due to the complexity of the energy absorption and heat transfer processes.

Since the thermal effect is presumably the sole lethal mechanism, time-temperature history at the coldest location will determine the safety of the process and is a function of the composition, shape and size of the food, the microwave frequency and the applicator (oven) design. Time is also a factor in the sense that, as the food heats up, its microwave absorption properties can change significantly and the location of cold points can shift.

OHMIC AND INDUCTIVE HEATING

Ohmic heating (sometimes also referred to as Joule heating, electrical resistance heating, direct electrical resistance heating, electroheating and electroconductive heating) is defined as the process of passing electric currents through foods or other materials to heat them. Ohmic heating is distinguished from other electrical heating methods either by the presence of electrodes contacting the food, frequency and waveform.

Inductive heating is a process wherein electric currents are induced within the food due to oscillating electromagnetic fields generated by electric coils. No data about microbial death kinetics under inductive heating have been published.

A large number of potential future applications exist for ohmic heating, including its use in blanching, evaporation, dehydration, fermentation and extraction. The principal advantage claimed for ohmic heating is its ability to heat materials rapidly and uniformly, including products containing particulates. The principal mechanisms of microbial inactivation in ohmic heating are thermal. While some evidence exists for non-thermal effects of ohmic heating, for most ohmic processes, which rely on heat, it may be unnecessary for processors to claim this effect in their process filings.

HIGH PRESSURE PROCESSING

High pressure processing (HPP), also described as high hydrostatic pressure (HHP) or ultra high pressure (UHP) processing, subjects liquid and solid foods, with or without packaging, to pressures between 100 and 800 MPa. Process temperature during pressure treatment can be specified from below 0 °C to above 100 °C. Commercial exposure times can range from a millisecond pulse to over 20 min. Chemical changes in the food generally will be a function of the process temperature and treatment time.

HPP acts instantaneously and uniformly throughout a mass of food independent of size, shape and food composition. Compression will uniformly increase the temperature of foods approximately 3 °C per 100 MPa. The temperature of a homogenous food will increase uniformly due to compression. Compression of foods may shift the pH of the food as a function of imposed pressure and must be determined for each food treatment process. Water activity and pH are critical process factors in the inactivation of microbes by HPP. An increase in food temperature above room temperature and to a lesser extent a decrease below room temperature increases the inactivation rate of microorganisms during HPP treatment. Temperatures in the range of 45 to 50 °C appear to increase the rate of inactivation of food pathogens and spoilage microbes. Temperatures ranging from 90-110 °C in conjunction with pressures of 500-700 MPa have been used to inactivate sporeforming bacteria such as *Clostridium botulinum*. Current pressure processes include batch and semi-continuous systems, but no commercial continuous HPP systems are operating.

The critical process factors in HPP include pressure, time at pressure, time to achieve treatment pressure, decompression time, treatment temperature (including adiabatic

heating), product initial temperature, vessel temperature distribution at pressure, product pH, product composition, product water activity, packaging material integrity and concurrent processing aids. Other processing factors present in the process line before or after the pressure treatment were not included.

Because some types of spores of *C. botulinum* are capable of surviving even the most extreme pressures and temperatures of HPP, there is no absolute microbial indicator for sterility by HPP. For vegetative bacteria, nonpathogenic *L. innocua* is a useful surrogate for the foodborne pathogen, *L. monocytogenes*. A nonpathogenic strain of *Bacillus* may be useful as a surrogate for HPP-resistant *E. coli* O157:H7 isolates.

PULSED ELECTRIC FIELDS

High intensity pulsed electric field (PEF) processing involves the application of pulses of high voltage (typically 20-80 kV/cm) to foods placed between 2 electrodes. PEF may be applied in the form of exponentially decaying, square wave, bipolar, or oscillatory pulses and at ambient, sub-ambient, or slightly above ambient temperature for less than 1 s. Energy loss due to heating of foods is minimized, reducing the detrimental changes of the sensory and physical properties of foods.

Some important aspects in pulsed electric field technology are the generation of high electric field intensities, the design of chambers that impart uniform treatment to foods with minimum increase in temperature and the design of electrodes that minimize the effect of electrolysis.

Although different laboratory- and pilot-scale treatment chambers have been designed and used for PEF treatment of foods, only 2 industrial-scale PEF systems are available. The systems (including treatment chambers and power supply equipments) need to be scaled up to commercial systems.

To date, PEF has been applied mainly to improve the quality of foods. Application of PEF is restricted to food products that can withstand high electric fields have low electrical conductivity, and do not contain or form bubbles. The particle size of the liquid food in both static and flow treatment modes is a limitation.

Several theories have been proposed to explain microbial inactivation by PEF. The most studied are electrical breakdown and electroporation.

Factors that affect the microbial inactivation with PEF are process factors (electric field intensity, pulse width, treatment time and temperature and pulse waveshapes), microbial entity factors (type, concentration and growth stage of microorganism) and media factors (pH, antimicrobials and ionic compounds, conductivity and medium ionic strength.

Although PEF has potential as a technology for food preservation, existing PEF systems and experimental conditions are diverse, and conclusions about the effects of critical

process factors on pathogens of concern and kinetics of inactivation need to be further studied.

HIGH VOLTAGE ARC DISCHARGE

Arc discharge is an early application of electricity to pasteurize fluids by applying rapid discharge voltages through an electrode gap below the surface of aqueous suspensions of microorganisms. A multitude of physical effects (intense wave) and chemical compounds (electrolysis) are generated, inactivating the microorganisms. The use of arc discharge for liquid foods may be unsuitable largely because electrolysis and the formation of highly reactive chemicals occur during the discharge. More recent designs may show some promise for use in food preservation, although the reported results should be confirmed by independent researchers.

PULSED LIGHT TECHNOLOGY

Pulsed light is a method of food preservation that involves the use of intense and short-duration pulses of broad spectrum "white light" (ultraviolet to the near infrared region). For most applications, a few flashes applied in a fraction of a second provide a high level of microbial inactivation.

This technology is applicable mainly in sterilizing or reducing the microbial population on packaging or food surfaces. Extensive independent research on the inactivation kinetics under a full spectrum of representative variables of food systems and surfaces is needed.

OSCILLATING MAGNETIC FIELDS

Static (SMF) and oscillating (OMF) magnetic fields have been explored for their potential to inactivate microorganisms. For static magnetic fields, the magnetic field intensity is constant with time, while an oscillating magnetic field is applied in the form of constant amplitude or decaying amplitude sinusoidal waves. OMF applied in the form of pulses reverses the charge for each pulse. The intensity of each pulse decreases with time to about 10% of the initial intensity. Preservation of foods with OMF involves sealing food in a plastic bag and subjecting it to 1 to100 pulses in an OMF with a frequency between 5 to 500 kHz at temperature of 0 to 50^{o}C for a total exposure time ranging from 25 ms to 100 ms.

The effects of magnetic fields on microbial populations have produced controversial results. Consistent results concerning the efficacy of this method are needed before considering this technology for food preservation purposes.

ULTRAVIOLET LIGHT

There is a particular interest in using ultraviolet (UV) light to treat fruit juices, specially apple juice and cider. Other applications include disinfection of water supplies and food

contact surfaces. Ultraviolet processing involves the use of radiation from the ultraviolet region of the electromagnetic spectrum. The germicidal properties of UV irradiation (UVC 200-280 nm) are due to DNA mutations induced by DNA absorption of the UV light. This mechanism of inactivation results in a sigmoidal curve of microbial population reduction.

To achieve microbial inactivation, the UV radiant exposure must be at least 400 J/m^2 in all parts of the product. Critical factors include the transmissivity of the product, the geometric configuration of the reactor, the power, wavelength and physical arrangement of the UV source(s), the product flow profile and the radiation path length. UV may be used in combination with other alternative process technologies, including various powerful oxidizing agents such as ozone and hydrogen peroxide, among others.

ULTRASOUND

Ultrasound is energy generated by sound waves of 20,000 or more vibrations per second. Although ultrasound technology has a wide range of current and future applications in the food industry, including inactivation of microorganisms and enzymes, presently, most developments for food applications are nonmicrobial.

Data on inactivation of food microorganisms by ultrasound in the food industry are scarce, and most applications use combinations with other preservation methods. The bactericidal effect of ultrasound is attributed to intracellular cavitation, that is, micro-mechanical shocks that disrupt cellular structural and functional components up to the point of cell lysis. The heterogeneous and protective nature of food with the inclusion of particulates and other interfering substances severely curtails the singular use of ultrasound as a preservation method. Although these limitations make the current probability of commercial development low, combination of ultrasound with other preservation processes (e.g. heat and mild pressure) appears to have the greatest potential for industrial applications.

Critical processing factors are assumed to be the amplitude of the ultrasonic waves, the exposure/contact time with the microorganisms, the type of microorganism, the volume of food to be processed, the composition of the food and the temperature of treatment.

PULSED X-RAYS

A number of studies have compared the effects of electron beam, gamma rays and X-rays, but comparison between these technologies is inconclusive due to differences in the doses applied. Electrons have a limited penetration depth of about 5 cm in food, while X-rays have significantly higher penetration depths (60 □ 400 cm) depending upon the energy used.

Pulsed X-ray is a new alternative technology that utilizes a solid state-opening switch to generate electron beam X-ray pulses of high intensity (opening times from 30 ns down to

a few nanoseconds; repetition rates up to 1000 pulses/s in burst mode operation). The specific effect of pulsed in contrast to non-pulsed X-rays has yet to be investigated.

The practical application of food irradiation by X-rays in conjunction with existing food processing equipment is further facilitated by: (1) the possibility of controlling the direction of the electrically produced radiation; (2) the possibility of shaping the geometry of the radiation field to accommodate different package sizes; and (3) its high reproducibility and versatility.

Potentially, the negative effects of irradiation on the food quality can be reduced.

RESEARCH NEEDS

This is a summary of research needs applicable to all or most of the technologies. See the chapters on each technology for additional research needs, as well as the complete list of research needs at the end of the full report.

- Evaluate the adequacy of the linear first-order survivor curve model. Although there is evidence of various types of deviations from this historical model, a universally accepted alternative has not evolved. Future research on an appropriate model(s) would be beneficial to all preservation technologies.
- Establish experimental protocol for obtaining statistically reliable kinetic parameters to describe survivor curves for microbial populations exposed to various alternative technologies, especially pulsed electric fields, pulsed light, oscillating magnetic fields and X-rays. For example, PEF studies should incorporate multiple levels of electric field intensity, as well as test the potential for synergy with temperature.
- Identify differences of inactivation action/mechanism(s) among alternative technologies. For example, pulsed light and ultraviolet light, ohmic and microwave, PEF and thermal, etc.
- Determine the synergism or antagonism of one alternative process used with another and their combined effect on microbial inactivation efficiency.
- Determine potential formation of unpalatable and toxic by-products due to processing.
- Develop methods for measuring and monitoring temperatures or other treatment actions within individual, large, solid particulates.
- Identify new or changing critical process factors and their effect on microbial inactivation.
- Investigate 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 z(P) and/or activation volumes (V) are quantified. Synergistic effects among pressure, temperature and other variables also should be evaluated.

Status of the Report on Technologies[1,2,3]

FDA QUESTIONS	ALTERNATIVE	PROCESSING TECHNOLOGIES
	OHMIC HEATING	**MICROWAVE AND RADIO FREQUENCY**
PROCESS DESCRIPTION	Well described	Well described
MECHANISM OF INACTIVATION	Well described	Well described
CRITICAL PROCESS FACTORS AND QUANTIFICATION	Well described Hard to predict cold zones	Well described Hard to predict cold zones
PROCESS DEVIATIONS	As in conventional thermal processing	As in conventional thermal processing
ORGANISMS OF CONCERN	As in conventional thermal processing	As in conventional thermal processing
INDICATOR ORGANISMS	As in conventional thermal processing	As in conventional thermal processing
MAIN RESEARCH NEED	Prediction of cold zones	Prediction of cold zones and uniformity of heating

[1] Not enough information was available on pulsed X-rays processing to be presented in this table.

[2] UV not presented in this table because only recent studies were discussed, not a comprehensive review.

[3] Not enough information was available on inductive heating processing to be presented in this table.

Status of the Report on Technologies

FDA QUESTIONS	ALTERNATIVE	PROCESSING	TECHNOLOGIES	
	HIGH VOLTAGE ARC DISCHARGE	**PEF**	**PULSED LIGHT**	**OMF**
PROCESS DESCRIPTION	Well described	Well described	Well described	Well described

MECHANISM OF INACTIVATION	Well described	Well described	Described	Not identified
CRITICAL PROCESS FACTORS AND QUANTIFICATION	Not identified	Described Kinetic models proposed, need validation	Not well defined	Not well defined
PROCESS DEVIATIONS	Not identified[1]	Identified	Not identified[1]	Not identified[1]
PATHOGENS OF CONCERN	Not identified	Not identified	Not identified	Not identified
INDICATORS[2]	Not identified	Not identified	Not identified	Not identified
MAIN RESEARCH NEED	Independently conducted research	Treatment measurement and kinetic models validation	Independently conducted research	Consistent microbial effects

[1] Lack of critical process factors quantification does not permit suggested responses to process deviations.

[2] Must identify pathogens of concern before indicators are finalized.

Status of the Report on Technologies

FDA QUESTIONS	**ALTERNATIVE**	**PROCESSING TECHNOLOGIES**
	ULTRASOUND	**HIGH PRESSURE**
PROCESS DESCRIPTION	Well described	Well described
MECHANISM OF INACTIVATION	Described	Well described
CRITICAL PROCESS FACTORS AND QUANTIFICATION	Suggested	Well described Proposed models

PROCESS DEVIATIONS	Not identified[1]	Well described
PATHOGENS OF CONCERN	Not identified	Identified
INDICATORS	Not identified[2]	Suggested
MAIN RESEARCH NEED	Multiple in combination with other technologies	Validation of kinetic models Influence of synergistic processing conditions

[1] Lack of critical process factors quantification does not permit suggested responses to process deviations.

[2] Must identify pathogens of concern before indicators are finalized.

Table of Contents

Home | HACCP

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