

Best Practices

Pathogen Control During Tenderizing/Enhancing of Whole Muscle Cuts

Supported by:

National Cattlemen's Beef Association
American Meat Institute
National Meat Association
Southwest Meat Association

March 2005

The American Meat Institute, National Cattlemen's Beef Association, National Meat Association, and Southwest Meat Association are pleased to have developed these industry Best Practices for Pathogen Control for Tenderizing Operations of Whole Muscle Cuts. In September 2003 leading manufacturers of non-intact meat products collaborated under the guidance of the American Meat Institute, National Meat Association, Southwest Meat Association, National Cattlemen's Beef Association, and industry members developed the Best Practices for review by the Beef Industry Food Safety Council (BIFSCo). Additionally, the Best Practices for Beef Slaughter and Best Practices for Handling Vacuum Packed Sub-Primal Beef Cuts were used as resources.

The operating practices at every company may vary slightly from these Best Practices, depending on differing operating situations. Producers of non-intact whole-muscle cuts are urged to consider these Best Practices as guidelines for their own internal practices and documentation. These practices are the best conditions known as of the date of publication.

The following individuals and companies are due thanks for their contribution to the development of these Best Practices:

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INDUSTRY BEST PRACTICES FOR PATHOGEN CONTROL DURING TENDERIZING/ENHANCING OF WHOLE MUSCLE CUTS

Purpose

This document is designed to discuss Best Practices that can be implemented throughout the tenderizing or enhancing operation, as well as during cleaning and sanitizing operations, to reduce the likelihood that contamination with potential pathogens (specifically *E. coli* O157:H7) will occur. There are multiple ways to reach the optimal end-result, and each operator must be able to apply the practices and procedures that best fit their individual operation. This document is not designed to force the use of any specific system or technology, but to stress the importance of validating that the tenderizing or enhancing system is optimized to reduce the risk of contamination.

Introduction

FSIS defines non-intact beef products as ground beef; beef injected with solution, beef that has been mechanically tenderized by needling, cubing, Frenching, or pounding devices, and beef that has been reconstructed into formed entrees. Whole muscle cuts (e.g., chucks, ribs, tenderloins, strip loins, top sirloin butts, rounds) may be treated to increase tenderness or to add ingredients for quality purposes, often before subsequent fabrication at the same or external location. Treatments may include solid-needle tenderizing or hollow-needle tenderizing where a solution is pumped into the whole muscle. In the latter case, the solution typically is recirculated, refrigerated and treated to ensure the quality of the pumping solution. It is important that the management of these operations be such that the equipment, refrigeration, solutions and product are optimized for quality and safety.

Producers of raw non-intact beef products recognize that these products may pose a risk if potential pathogens are moved to the interior portions of the meat products (Krizner, 1999; Phebus *et al.*, 2000; Lambert *et al.*, 2001; Hajmeer *et al.*, 2002), and the product is not cooked adequately to destroy the pathogens inside the meat product. As is discussed below, the likelihood of potential pathogens being transferred to the inside from the outside of the product is very, very low because of a very low prevalence of pathogens on meat portions being tenderized or enhanced (Ransom *et al.*, 2002; Warren *et al.*, 2003). If equipment used in the operation is contaminated somehow, and not cleaned and sanitized, the tenderizing or enhancing equipment, and perhaps the solution to be injected, may become the vehicle of the contamination. To reduce the risk, it is extremely important that processors implement Best Practices by focusing on cleaning and sanitation practices associated with the tenderizing and enhancing operations.

One of the primary considerations in assessing the likelihood of contamination of products that are tenderized or enhanced is whether or not contamination (*E. coli* O157:H7) is a hazard reasonably likely to occur on the surface of intact meat portions before the tenderizing or enhancing operation. Several studies indicated that *E. coli* O157:H7 is not a hazard reasonably likely to occur on the surface of intact meat portions. A study was conducted by Warren *et al.*

(2003) where sponge samples were taken of 1,014 subprimal cuts from six beef processing plants over a five-week period. Only two samples (0.2%) tested positive for *E. coli* O157:H7; enumeration indicated that each sample had <3.0 CFU per 200 cm² sampled.

Two later studies were conducted by ABC Research Corporation (Gainesville, FL) throughout 2004 to determine the prevalence of *E. coli* O157:H7 and indicator organisms on the surface of beef sub-primals that would be used as raw materials for tenderizing or enhancing operations. These studies used cuts of meat specifically used for tenderizing or enhancing operations, namely, briskets, round chuck and middles. One study (I) focused on raw materials produced during the winter months (January and February); the second study (II) collected data during the late summer and fall (August into November).

In study I, 600 samples comprising six sub-primal cut types (100/type) were collected from five plants from the southern Midwest, Midwest, northern Midwest and the Southeast. Each sample was a sponge sample of the entire surface of a sub-primal. None of the 600 samples had *E. coli* O157:H7. In study II, 599 samples (following the same scheme described above for study I) tested negative for *E. coli* O157:H7. Based on limits of methodologies and the results from studies I and II, the authors concluded that the overall incidence of *E. coli* O157:H7 on beef sub-primals was < 0.083%.

This document provides Best Practices for tenderizing and enhancing operations and can be used by establishments to develop plant specific programs. Although these Best Practices are applicable to both production of raw and fully cooked tenderized and/or enhanced items, this document primarily focuses on the manufacture of raw non-intact products (excluding ground beef). These Best Practices are designed to provide a recommended set of practices and procedures that processors may want to adopt in their entirety or in part to ensure optimal quality and food safety.

It should be noted that the following items are not addressed in this document, but they should be covered by existing Sanitation Standard Operating Procedures (SSOPs) and/or other plant-specific processing programs.

- Personnel — disease control, hygiene, clothing, training, etc.
- Plant and grounds — construction and design, product flow, drainage, etc.
- Sanitary operations — general maintenance, cleaning and sanitizing, pest control, etc.
- Sanitary facilities and controls — water supply, plumbing, sewage disposal, rubbish and offal disposal, etc.
- Freezer and coolers — monitored and maintained to ensure temperature control, recording devices, alarms, etc.
- Equipment maintenance and calibration — adequate frequency for thermometers, recording devices, compressed air equipment, etc.

Further details regarding these items listed above can be found in 21 CFR Part 110 – Current Good Manufacturing Practices in Manufacturing, Packing, or Holding Human Food (Appendix A). This document (21 CFR 110) was developed by the Food and Drug Administration and serves as a good resource for more information on any of the above areas.

INDUSTRY BEST PRACTICES FOR PATHOGEN CONTROL DURING TENDERIZING/ENHANCING OF WHOLE MUSCLE CUTS

Raw Material Control

Best Practices begin with optimizing raw material (whole muscle cuts) quality and safety. Tenderizing and enhancing operations should identify requirements for raw material suppliers and have a system for verification that the requirements are being met and achieving the goals of the quality and safety program.

Criteria to select raw material suppliers should include that suppliers have process interventions in place to reduce or eliminate potential enteric pathogens. Raw material suppliers should have validated process interventions and/or validated critical control points (CCPs) in place to prevent, eliminate or reduce *E. coli* O157:H7 to a non-detectable level. Validation may include scientific literature and/or plant specific validation using indicator organisms, and it should be specific to the process being applied at the establishment. This can be incorporated into the processor's purchase specifications or other plant programs to ensure that all raw materials are produced using validated CCPs or process interventions. This is true for both domestic and imported suppliers of raw materials to be used in production of non-intact product.

Another important criterion for supplier selection is the ability and demonstrated maintenance of cold chain management. This includes rapid chilling of hot carcasses to control microbial growth and proper carcass rotation within the cooler to ensure timely fabrication.

Lastly, it is important for non-intact beef processors to have specific data on *E. coli* O157:H7 incidence to support the position taken during the hazard analysis as "not reasonably likely to occur." These data must relate to the raw materials and/or finished product(s). Routine microbiological testing may include sampling and testing for *E. coli* O157:H7. Other microbiological testing includes analyses for *Salmonella*, Aerobic Plate Count (APC), Total Plate Count (TPC), coliforms, and generic *E. coli*. For all microbiological testing, it is important that there be a written protocol for sample collection, lab analysis and proficiency testing, as well as the procedures for reporting the results. It is important to establish how the results will be used before the data are collected. Most of these microbiological tests are used for tracking supplier trends over time; however, each establishment must clearly define how they are going to use the information and the consequences of failing to meet internal microbiological guidelines.

Supplier Evaluations

Raw material suppliers are critical to both food safety and quality aspects of producing tenderized and enhanced products. In addition to well-defined requirements it is important that there are procedures established to evaluate the raw material supply whether from an internal or external vendor source. The following guidelines developed for the Raw Ground Products Best Practices can be used to help design a system for evaluating supply sources for other non-intact raw materials.

A. New Supplier Approval:

- Each new supplier should provide written acknowledgement of the processor's purchase specifications and the supplier's willingness to comply.
- Each supplier should meet the guidelines outlined in the purchase specifications for microbial testing and profiling. A processing operation may want to establish an intensified sampling program to determine if the new supplier can consistently meet the specifications.
- Each supplier should have a plant audit conducted on a specified frequency to ensure compliance with the purchase specifications and other programs. The audits may be conducted by the processor or by a third-party auditor. The audit requirements should be provided to the new supplier as part of the purchase specifications.
- Processors should conduct quality inspections of incoming materials to ensure that they are acceptable.

B. Ongoing Suppliers:

- Processing operations should periodically provide an update of the purchase specifications to each supplier and request on updated acknowledgement of receipt of the specifications and the supplier's willingness to comply.
- Data should be collected and tracked to identify supplier trends and help make purchasing decisions, e.g.,:
 - Microbial profile data (e.g., *E. coli* O157:H7, *Salmonella*, generic *E. coli*, TPC, APC, coliforms)
 - Foreign object contamination
 - Defects (e.g., unacceptable indigenous inclusions)
 - Plant audit results
 - Age of product at receipt
 - Temperature of product at receipt
 - On-time delivery

Temperature Control

Cold chain management is a continuum from the time a carcass leaves the slaughter process and enters the chilling process through processing, packaging, storage and distribution. The goal is to achieve and maintain the temperature that will inhibit the growth of foodborne pathogens and slow the growth of spoilage microflora. The minimum growth temperatures for the pathogens of most concern are 44.6°F (7°C) for salmonellae and 44.6-46.4°F (7-8°C) for pathogenic *E. coli* (ICMSF, 1996). If cold chain control is violated at any point in the chain, product safety and quality may be compromised.

Cold chain management is especially important at the tenderizing or enhancing operation. Specific points where temperature should be controlled, other control points related to temperature control, and examples of operating limits in tenderizing or enhancing operations include:

- Receiving and storage of raw materials at 45°F or lower (40°F optimal)
- Processing raw materials using a "First In First Out" (FIFO) rotation

- Monitoring raw materials and finished products using a cooler control program
- Verifying the potability of process water
- Maintaining process water at 45°F or lower (40°F optimal)
- Maintaining finished product temperatures at 45°F or lower (40°F optimal) throughout their shelf life
- Controlling brine solutions to 45°F or lower (40°F optimal)
- Pre-chilling shipping containers to 45°F or lower (40°F optimal) before loading
- Maintaining temperatures at 45°F or lower (40°F optimal) throughout transport

While temperatures are specified at 45°F or lower in the above list based on the growth limitations for pathogenic *Salmonella* and *E. coli* O157:H7, it is generally recognized that the colder the temperature the better.

Process Controls

There are three general types of processing that are recognized within tenderizing and enhancing operations. These include: Needle Tenderizing, Brine-Injecting (Enhancing), and Suspension Injecting. Specific Best Practices will be presented for each of these categories due to unique differences between the processes.

Needle Tenderized Products

- Documented GMPs (including needle integrity checks) exist for tenderizing operations
- Established protocol exists for managing rework, including traceability and a time frame for incorporation into manufacturing
- Traceability program is in place for all finished products
- Biosecurity program exists to prevent tampering with operational equipment, and raw materials

Enhanced/Brine-Injected Products

- Letters of guarantee and certificates of analysis exist for ingredients used in pumping solution (brine or pickle solution)
- Documented GMPs (including needle integrity checks) exist for injecting operations
- Chilled water feeding system is preferable to complete chilling of brine following mixing
- Maximum age is established for reuse brine (pickle) solutions (e.g., 24 hours), with a mandatory break in the use cycle (e.g., every 24 hours)
- Use of an antimicrobial intervention (e.g., filtration, UV) for re-circulating pickle solution is implemented if needed as determined by the hazard analysis
- Established protocol exists for managing rework, including traceability and a time frame for incorporation into manufacturing
- Traceability program is in place for all finished products
- Biosecurity program exists to prevent tampering with operational equipment, raw materials and pickle solutions

Meat Protein Suspension Injection Products¹

- Letters of guarantee and certificates of analysis exist for ingredients used in the processing of the suspension solution (to include all meat and non-meat ingredients in the brine or pickle solution, as well as documentation on “supplier evaluation” on the sources the trim raw material used)
- Documented GMPs (including needle integrity checks) exist for injecting operations
- Chilled water feeding system is preferable to complete chilling of brine following mixing and as the suspension is generated from it
- Maximum age is established for reuse brine (pickle) solutions (e.g., 24 hours), with a mandatory break in the use cycle (e.g., every 24 hours)
- Maximum age is established for reuse suspension solutions (e.g., 8 hours), with a mandatory break in the use cycle (e.g., every 16-20 hours)
- Use of an antimicrobial intervention (e.g., UV) for re-circulating pickle solution is implemented if needed as determined by the hazard analysis
- Established protocol exists for managing rework, including traceability and a time frame for incorporation into manufacturing
- Traceability program is in place for all finished products
- Biosecurity program exists to prevent tampering with operational equipment, raw materials and pickle solutions

Interventions/Inhibitors

New antimicrobial intervention and inhibitors that may be applicable in tenderizing or enhancing operations continue to be developed. Current applied technologies include the application of antimicrobial solutions to the raw materials before processing, treatment of the brine with an inhibitory process (e.g., UV filtration), and the use of an intervention or inhibitor applied to the finished product or packaging materials. A list of potential interventions at the time this document was written is included in Appendix B.

Lotting

All non-intact processors should have a lotting mechanism for coding and recording all products to allow trace back and trace forward of products throughout the manufacturing and distribution system. FSIS recognizes that the establishment will define a lot and expects scientific or other supportive basis for defining the lot. Lotting systems can range from very simplistic, e.g., handwritten numbering, to very elaborate, e.g., computerized, automated bar coding. Lotting is often based on some unit of time (e.g., hour, shift, day); however lotting can be driven by other factors including raw material source, production line or processing room.

¹ Cozzini’s SUSPEN^{TEC}™ system is a patented method of reducing meat, poultry or fish trimmings to micron size and incorporating them into traditional brines to create a suspension; the suspensions can then be injected into whole-muscle products. The use of this equipment is governed by FSIS Policy Memo PM041B. At the time this document was put together, Cozzini’s SUSPEN^{TEC}™ system was the only such technology available for Beef, Pork and Poultry. These practices may or may not be applicable to other suspension technologies when they become available.

Some processors may choose to further divide lots of product into sub-lots. By creating smaller lot units, process control can be demonstrated and documented more frequently; and there is a potential to minimize the volume of product implicated in the event a recall is ever required. Additionally, establishments should maintain records associated with all production lots. Information to be recorded is dependent on the individual system; however the following data typically are recorded:

- Raw material vendor, vendor lot
- Process date, time of production
- Raw material, brine, room and product temperature
- Microbiological data
- Equipment evaluations

A more detailed discussion of lotting can be found in the Best Practices for Raw Ground Products document (www.bifsc.org/BestPractices.htm).

Finished Product Microbiological Testing

Finished product microbiological testing is a means to verify process control and evaluate that the Best Practices discussed throughout this document are being used effectively to reduce the likelihood of contamination by potential pathogens and the overall microbial load on the finished product. However, finished product sampling cannot be used to ascertain the safety of the product unless enough samples are taken to develop a statistically based rationale for acceptance (e.g., 95% confidence that the probability of contamination is no greater than 5%). Generally, the economics of testing finished products and the high numbers of samples required to have a relatively high degree of confidence that a low level of contamination will be detected, make finished product testing impractical. There may be instances where finished product testing has some value, e.g., for periodic verification using indicator organisms, or when a process is out-of-control and an assignable cause is being sought. Final product testing for pathogenic *E. coli* O157:H7 also may be helpful to minimize the volume of product implicated in a recall situation.

Packaging

Packaging of non-intact beef cuts must occur in a manner to minimize the likelihood of contamination from packaging equipment, the environment, or food contact surfaces. Routine microbiological audit sampling and testing may be used to verify the efficacy of cleaning and sanitation, both on a routine basis and following equipment maintenance or relocation (AMI et al., 2003).

Sanitation and Facilities

Production of tenderized and enhanced products must occur in facilities that meet all Federal regulations (9 CFR 307, 310, 313, 314, 317, 318, 320, and 416) and the equipment used must meet sanitary operating guidelines. Establishments should meet all regulatory requirements

of the Sanitation Standard Operating Procedures and should consider the guidelines presented in the Sanitation Performance Standards.

Each plant should develop and implement an effective sanitation program that will ensure sanitary conditions for both pre-operational and operational activities. The program should focus on specific areas such as complete equipment breakdown, and zone cleaning. The plant should set a target level (microbiological limit) to demonstrate sanitary conditions and develop a system for monitoring and documenting that the target level is being met routinely (AMI et al., 2003).

Best Practices for tenderizing or enhancing operations include effective cleaning and sanitation of the equipment and production environments. Specific examples of these Best Practices include the following:

- Verified and documented cleaning and sanitation protocols are in place for all equipment, reservoirs and piping associated with the tenderizing or enhancing operation
- Appropriate and effective “Clean in Place” (CIP) and “Clean out of Place” (COP) systems are used
- Established cleaning and sanitizing protocols exist for needles, including frequency, methods, chemicals and verification
- Fully dismantle needle assembly for a deep thorough cleaning on a regular basis
- Ideally, have at least two sets of injector needles to allow for dismantling and soaking in a sanitizing solution for extended periods
- Effective preoperative and operative sanitation programs are implemented and measured
- Recognize that differences exist in general microbial load of equipment following the processing of bone-in and boneless systems
- Effective employee GMPs are implemented
- Actionable environmental microbiological (e.g., aerobic plate count, bioluminescence) monitoring program is implemented

HACCP System

Non-intact products will be produced under FSIS or state inspection, thereby meeting all Federal or state (equal to) requirements pertaining to HACCP systems (9 CFR 417), Sanitation SOPs (9 CFR 416) and pre-requisite programs. All processors should be able to support the decisions that are made in the HACCP program and to use the documentation generated from the program to demonstrate product safety.

HACCP is a proactive, systematic approach to food safety designed to prevent, eliminate or reduce food safety hazards to an acceptable level. Processing establishments must consider biological, physical, and chemical food safety hazards. As far as the authors know, there are no data to suggest that through a hazard analysis, *E. coli* O157:H7 should be considered a hazard reasonably likely to occur in tenderizing or enhancing operations. In fact, as mentioned earlier, data (nearly 1200 data points collected in the winter, fall and summer of 2004) have established that *E. coli* O157:H7 is not a hazard reasonably likely to occur on whole muscle cuts destined for tenderizing or enhancing operations.

However, because this is a raw meat processing operation, consideration should be given to *E. coli* O157:H7 as a potential, sporadic contaminate that could find its way into the processing environment and specific tenderizing or enhancing processing system. Thus, processors must focus on what practical strategies can be applied during the tenderizing or enhancing process to minimize the potential for growth of *E. coli* O157:H7, if present as an environmental contaminant or as a highly unlikely contaminant of sub-primals. These strategies typically involve prevention of harborages and niches through cleaning and sanitation of equipment, maintaining cold temperatures and using antimicrobial interventions during recirculation of enhancement solutions.

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Appendices

Appendix A – Current Good Manufacturing Practices in Manufacturing, Packing, or Holding Human Food

**FOOD AND DRUG
ADMINISTRATION,
DEPARTMENT OF
HEALTH AND HUMAN
SERVICES**

**21 CFR PART 110 -
CURRENT GOOD
MANUFACTURING
PRACTICE IN
MANUFACTURING,
PACKING, OR HOLDING
HUMAN FOOD**

**Subpart A - General
Provisions**

Sec. 110.3 Definitions.
Sec. 110.5 Current good
manufacturing practice.
Sec. 110.10 Personnel.
Sec. 110.19 Exclusions.

**Subpart B - Buildings and
Facilities**

Sec. 110.20 Plant and grounds.
Sec. 110.35 Sanitary operations.
Sec. 110.37 Sanitary facilities
and controls.

Subpart C - Equipment

Sec. 110.40 Equipment and
utensils.

Subpart D - [Reserved]

**Subpart E - Production and
Process Controls**

Sec. 110.80 Processes and
controls.
Sec. 110.93 Warehousing and
distribution.

Subpart F - [Reserved]

**Subpart G - Defect Action
Levels**

Sec. 110.110 Natural or
unavoidable defects in food
for human use that present no
health hazard.

**SUBPART A - GENERAL
PROVISIONS**

110.3 Definitions.

The definitions and
interpretations of terms in
section 201 of the Federal
Food, Drug, and Cosmetic
Act (the act) are applicable to
such terms when used in this
part. The following
definitions shall also apply:

(a) “Acid foods or acidified
foods” means foods that have
an equilibrium pH of 4.6 or
below.

(b) “Adequate” means that
which is needed to
accomplish the intended
purpose in keeping with good
public health practice.

(c) “Batter” means a
semifluid substance, usually
composed of flour and other
ingredients, into which
principal components of food
are dipped or with which they
are coated, or which may be
used directly to form bakery
foods.

(d) “Blanching,” except for
tree nuts and peanuts, means
a prepackaging heat
treatment of foodstuffs for a
sufficient time and at a
sufficient temperature to
partially or completely
inactivate the naturally
occurring enzymes and to
effect other physical or
biochemical changes in the
food.

(e) “Critical control point”
means a point in a food
process where there is a high
probability that improper

control may cause, allow, or
contribute to a hazard or to
filth in the final food or
decomposition of the final
food.

(f) “Food” means food as
defined in section 201(f) of
the act and includes raw
materials and ingredients.

(g) “Food-contact surfaces”
are those surfaces that contact
human food and those
surfaces from which drainage
onto the food or onto surfaces
that contact the food
ordinarily occurs during the
normal course of operations.
'Food-contact surfaces'
includes utensils and food-
contact surfaces of
equipment.

(h) “Lot” means the food
produced during a period of
time indicated by a specific
code.

(i) “Microorganisms”
means yeasts, molds,
bacteria, and viruses and
includes, but is not limited to,
species having public health
significance. The term
'undesirable microorganisms'
includes those
microorganisms that are of
public health significance,
that subject food to
decomposition, that indicate
that food is contaminated
with filth, or that otherwise
may cause food to be
adulterated within the
meaning of the act.

Occasionally in these
regulations, FDA used the
adjective 'microbial' instead
of using an adjectival phrase

containing the word microorganism.

(j) "Pest" refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.

(k) "Plant" means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.

(l) "Quality control operation" means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act.

(m) "Rework" means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

(n) "Safe-moisture level" is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity (a (INFERIOR w)). An a (INFERIOR w) will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a (INFERIOR w) will not support the growth of undesirable microorganisms.

(o) "Sanitize" means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

(p) "Shall" is used to state mandatory requirements.

(q) "Should" is used to state recommended or advisory procedures or identify recommended equipment.

(r) "Water activity" (a (INFERIOR w)) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

110.5 Current good manufacturing practice.

(a) The criteria and definitions in this part shall apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in

determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

110.10 Personnel.

The plant management shall take all reasonable measures and precautions to ensure the following:

(a) *Disease control.* Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be

excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.

(b) *Cleanliness.* All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining

cleanliness include, but are not limited to:

(1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.

(2) Maintaining adequate personal cleanliness.

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.

(6) Wearing, where appropriate, in an effective manner, hair nets, headbands,

caps, beard covers, or other effective hair restraints.

(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

(9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

(c) *Education and training.* Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

(d) *Supervision.* Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned

to competent supervisory personnel.

110.19 Exclusions.

(a) The following operations are not subject to this part: Establishments engaged solely in the harvesting, storage, or distribution of one or more 'raw agricultural commodities,' as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.

(b) FDA, however, will issue special regulations if it is necessary to cover these excluded operations.

SUBPART B - BUILDING AND FACILITIES

110.20 Plant and grounds.

(a) *Grounds.* The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.

(2) Maintaining roads, yards, and parking lots so that

they do not constitute a source of contamination in areas where food is exposed.

(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a) (1) through (3) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(b) *Plant construction and design.* Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:

(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.

(2) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous

material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.

(3) Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:

(i) Using protective coverings.

(ii) Controlling areas over and around the vessels to eliminate harborage for pests.

(iii) Checking on a regular basis for pests and pest infestation.

(iv) Skimming the fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.

(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.

(7) Provide, where necessary, adequate screening or other protection against pests.

110.35 Sanitary operations.

(a) *General maintenance.* Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

(b) *Substances used in cleaning and sanitizing; storage of toxic materials.* (1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

- (i) Those required to maintain clean and sanitary conditions;
- (ii) Those necessary for use in laboratory testing procedures;
- (iii) Those necessary for plant and equipment maintenance and operation; and
- (iv) Those necessary for use in the plant's operations.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products should be followed.

(c) *Pest control.* No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(d) *Sanitation of food-contact surfaces.* All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.

(1) Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have

become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.

(3) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.

(4) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.

(5) Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.

(e) *Storage and handling of cleaned portable equipment and utensils.* Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.

110.37 Sanitary facilities and controls.

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

(a) *Water supply.* The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(b) *Plumbing.* Plumbing shall be of adequate size and design and adequately installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(5) Provide that there is not backflow from, or cross-

connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

(c) *Sewage disposal.* Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.

(d) *Toilet facilities.* Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:

(1) Maintaining the facilities in a sanitary condition.

(2) Keeping the facilities in good repair at all times.

(3) Providing self-closing doors.

(4) Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive air-flow systems).

(e) *Hand-washing facilities.* Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:

(1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.

(2) Effective hand-cleaning and sanitizing preparations.

(3) Sanitary towel service or suitable drying devices.

(4) Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.

(5) Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, of food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.

(6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

(f) *Rubbish and offal disposal.* Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

SUBPART C - EQUIPMENT

110.40 Equipment and utensils.

(a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.

(b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.

(c) Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.

(d) Holding, conveying, and manufacturing systems,

including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

SUBPART D - [RESERVED]

SUBPART E - PRODUCTION AND PROCESS CONTROLS

110.80 Processes and controls.

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the act shall be rejected, or if permissible, treated or processed to eliminate the contamination.

(a) *Raw materials and other ingredients.* (1) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to

ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

(2) Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration

regulations, guidelines, and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.

(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable Food and Drug Administration regulations, guidelines, and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination.

(5) Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the act. Material scheduled for

rework shall be identified as such.

(6) Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of the act.

(7) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.

(b) *Manufacturing operations.* (1) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(2) All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, a (INFERIOR w), pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors

do not contribute to the decomposition or contamination of food.

(3) Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act.

Compliance with this requirement may be accomplished by any effective means, including:

(i) Maintaining refrigerated foods at 45 (degree)F (7.2 (degree)C) or below as appropriate for the particular food involved.

(ii) Maintaining frozen foods in a frozen state.

(iii) Maintaining hot foods at 140 (degree)F (60 (degree)C) or above.

(iv) Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

(4) Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling a (INFERIOR w) that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act.

(5) Work-in-process shall be handled in a manner that

protects against contamination.

(6) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary.

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food shall be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination.

(8) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.

(9) Food, raw materials, and other ingredients that are adulterated within the meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be

effective or it shall be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food.

(10) Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.

(11) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.

(12) Batters, breadings, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:

(i) Using ingredients free of contamination.

(ii) Employing adequate heat processes where applicable.

(iii) Using adequate time and temperature controls.

(iv) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.

(v) Cooling to an adequate temperature during manufacturing.

(vi) Disposing of batters at appropriate intervals to protect against the growth of microorganisms.

(13) Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including:

(i) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.

(ii) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.

(iii) Using materials for food containers and food-packaging materials that are safe and suitable, as defined

in Sec. 130.3(d) of this chapter.

(iv) Providing physical protection from contamination, particularly airborne contamination.

(v) Using sanitary handling procedures.

(14) Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a (INFERIOR w) for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the a (INFERIOR w) of food.

(ii) Controlling the soluble solids-water ratio in finished food.

(iii) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the a (INFERIOR w) of the food does not increase to an unsafe level.

(15) Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the pH of raw materials, food in process, and finished food.

(ii) Controlling the amount of acid or acidified food added to low-acid food.

(16) When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

(17) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

110.93 Warehousing and distribution.

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

SUBPART F - [RESERVED]

SUBPART G - DEFECT ACTION LEVELS

110.110 Natural or unavoidable defects in food for human use that present no health hazard.

(a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug Administration establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.

(b) Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.

(c) Compliance with defect action levels does not excuse

violation of the requirement in section 402(a)(4) of the act that food not be prepared, packed, or held under unsanitary conditions or the requirements in this part that food manufacturers, distributors, and holders shall observe current good manufacturing practice.

Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of the act, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated within the meaning of the act, regardless of the defect level of the final food.

(e) A compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from the Industry Programs Branch (HFF-326), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 202

Appendix B – Decontamination Interventions for Primals, Trim and Ground Meat

Decontamination Interventions

	Intervention	Effectiveness in Lab setting	Effectiveness in Field / Plant	Regulatory Status
MECHANICAL TREATMENT				
	Irradiation	Widely studied. Effective in reducing pathogens at varying levels depending on dose.	Effective, but control of dose is critical to minimize effects on organoleptic factors.	Approved
	Steam	Initial results are limited, but may have an effect	Unknown	Unknown
	Hot water wash	Initial results are limited, but may have an effect	Unknown	Unknown
	High pressure (Flow or Hydrodyne)	Lab batch operations effectively kill bacteria.	Unknown	Unknown, but should not be a limitation
	Ozone	Limited	Not effective to date	Unknown
	UV Light	Limited	Not effective to date	Unknown
	Pulse Light	Limited	Not effective to date	Unknown
	pH Cycling	Unknown	Unknown	Unknown
CHEMICAL TREATMENT				
	Acidified Sodium Chlorite (Sanova)	Company data (unpublished) 2.9 log reduction of E. coli O157. 2.0 log reduction of E. coli (generic). 1.5 log reduction of APC.	Initial trials show approximately a 2 log reduction of APC.	Approved, however weight gain over 0.5% must be labeled.

	Intervention	Effectiveness in Lab setting	Effectiveness in Field / Plant	Regulatory Status
	Lactic Acid (Purac)	Limited evaluation (Kang et al.) showed positive effect, when combined with other treatments	Unknown. 0.4% by weight, of a 2.5% solution was not effective.	Not approved in Beef trim
	Safe2O (KLS) Calcium acidified chlorite (Mionix)	Company trials are encouraging	Unknown	Not approved in Beef trim
	CPC (Safe Foods Inc.)	Company trials show significant log reductions	Unknown	Not approved in Beef trim, residual levels cited as concern.
	Peracetic acid (Inspexx)	Company trials are encouraging	Unknown	Approved
	Citric Acid (Grovac Process)	Trials show promise. Upcoming lab trials.		Approved
	TSP	Possibly effective.	Unknown	Not approved in Beef trim
BIOLOGICAL				
	Nisin	Unknown	Unknown	Not approved
	Pediocin	Unknown	Unknown	Not approved
	Spice extracts	Limited	Not effective	Labeling, Standard of Identity
	Lactate	Unknown	Unknown	Labeling, Standards of Identity
	Diacetate	Unknown	Unknown	Labeling, Standards of Identity

	Intervention	Effectiveness in Lab setting	Effectiveness in Field / Plant	Regulatory Status
	Lactobacillus acidophilus	TTU study demonstrated a 90% reduction in <i>E. coli</i> O157:H7 and a 99.9% reduction in <i>Salmonella</i>	Unknown	Working on petition
	Bacteriophage	Unknown	Unknown	Unknown
OTHER				
	Nanoemulsion	Initial results favorable. Univ. of Michigan owned patent - Nanobio	Unknown	Unknown

Appendix C. Studies on the Antimicrobial Properties of Tenderizing Pickle Solution

PRELIMINARY REPORT

September 10, 2003

Study #1

Objective: To determine antimicrobial properties of a pickle solution used in tenderizing whole muscle cuts

Composition of pickle solution: A typical pickle solution will contain phosphate, salt and flavorings. The solution used in this study contained a proprietary formula based on these components. It is important to note that there are regulatory limits for phosphates in finished products, e.g., 0.5%.

Measurement of the antimicrobial effect: The antimicrobial effect of the pickle solution was measured using a micro-titer assay (i.e., providing minimum inhibitory concentrations) and traditional laboratory plating procedures.

Results: Using micro-titer assays, initial experiments determined that the pickle solution reduced the concentrations of *E. coli* O157:H7 and *Salmonella* by at least 2 logs (100-fold). In follow-up experiments, direct inoculation of pickle solution with a cocktail of 3 *E. coli* O157:H7 strains and 3 *Salmonella* strains at levels near 10⁶ per mL resulted in complete lethality for all pathogens after 30 minutes of exposure (the first measurement time interval after the zero time measurement).

In a laboratory setting using traditional microbiological techniques, the antimicrobial properties of the pickle solution were determined. Pickle solution was inoculated to 1.73 logs per mL with *E. coli* O157:H7 and stored at room temperature (~73°F) or under refrigeration (37°F). No *E. coli* O157:H7 were recovered from the pickle solution after 2 hours at room temperature and after 24 hours under refrigerated conditions.

<i>Time</i>	Storage temp	
	Room	Refrigerator
0 min	Positive	Positive
30 min	Positive	Positive
1 hour	Positive	Positive
2 hour	Negative	Positive
4 hour	Negative	Positive
24 hour	Negative	Negative

These data represent the results of a single study using inoculated organisms, and should not be extrapolated to all situations. The storage temperature and times, while different for room temperature versus refrigerated, simply indicate that the brine solution may exhibit inhibitory

properties against *E. coli* O157:H7. However, further research would be needed to confirm that this is the case, and multiple variables may be contributing to this effect.

Next steps: Additional validation work will be repeated with meat extract added to evaluate effects of meat components on bactericidal activity and with inoculated meat exposed to the pickle solution.

Study #2

Objective: To determine the prevalence of *E. coli* O157:H7 in injection solutions used to enhance various beef products.

Sampling Procedures: One-quart samples of injection solutions were taken from the brine return, before the brine entered the reservoir for recycling with fresh solution, before filtration. Samples were collected at least 20 minutes into production, with each sample set of three samples spaced throughout the scheduled production run. Samples were then sealed and sent to the laboratory for testing.

Results: In total, 19 sample sets (57 samples) were collected through July and August 2003. All samples (Table 1) tested negative for the presence of *E. coli* O157:H7. Preliminary investigation into the recovery of *E. coli* O157:H7 that were inoculated into brine samples indicated that the organism could be recovered from the brine solution, if present.

Table 1. Injection Solution Results for Study #2

Date	Meat Cut	<i>E. coli</i> O157:H7 Result 1	<i>E. coli</i> O157:H7 Result 2	<i>E. coli</i> O157:H7 Result 3
29-Jul-03	Flat	NEG	NEG	NEG
29-Jul-03	Flat	NEG	NEG	NEG
29-Jul-03	Ribeye	NEG	NEG	NEG
30-Jul-03	Capoff Inside	NEG	NEG	NEG
30-Jul-03	Flat	NEG	NEG	NEG
30-Jul-03	Ribeye	NEG	NEG	NEG
31-Jul-03	Ribeye	NEG	NEG	NEG
05-Aug-03	Capoff Inside	NEG	NEG	NEG
05-Aug-03	Ribeye	NEG	NEG	NEG
05-Aug-03	Capoff Inside	NEG	NEG	NEG
06-Aug-03	Ribeye	NEG	NEG	NEG
06-Aug-03	Capoff Inside	NEG	NEG	NEG
06-Aug-03	Inside	NEG	NEG	NEG
11-Aug-03	Ribeye	NEG	NEG	NEG
13-Aug-03	Ribeye	NEG	NEG	NEG
20-Aug-03	Inside	NEG	NEG	NEG
20-Aug-03	Capoff Inside	NEG	NEG	NEG
20-Aug-03	Capoff Inside	NEG	NEG	NEG
20-Aug-03	Inside	NEG	NEG	NEG

Appendix D. An Example Standard Operating Procedure for Cleaning & Sanitizing Injector Assembly

Purpose: To effectively clean and sanitize the injector assembly

Program: At the end of each production day, production personnel will perform the following tasks:

Injector Needles

1. Open the needle assembly and inspect for cleanliness. If any residual brine residue remains, rinse the housing and needles completely.
2. Remove all needles and carefully place the needles in a clean meat lug that has not been used during that day's production.
3. Rinse housing after needles are removed to ensure that all areas of the head are free of visible residue.
4. Add clean & soak chemicals to the meat lug to a level that completely submerges all needles in the container. Needles must soak for a minimum of 6 hours or as recommended by the sanitation chemical manufacture. If necessary, use a second set of cleaned and sanitized needles to ensure adequate cleaning while meeting production requirements.
5. After the needles have soaked for a minimum of 6 hours, each needle must be "blown out" with clean air before being replaced in the injector assembly.
6. Once clean needles have been placed in the injector assembly, they must be sanitized and rinsed before being used in production.

Cleaning and Sanitizing Solutions

1. The composition of the cleaning solution used for nightly cleaning can be used for cleaning the needles and assembly parts unless other solutions have been validated for efficacy.
2. The cleaning and sanitizing chemicals should be rotated periodically.
3. The amount of chemical solution used and the soak time for cleaning should be documented, and verified periodically, e.g., quarterly.

Monitoring & Verification: QA and Production Management will monitor the cleaning and sanitizing process during cleanup hours to ensure proper compliance. QA will verify sanitation daily during pre-operational inspections. An authorized person verifies solution composition and chemical strength nightly. Microbial sampling of cleaned and sanitized surfaces will be conducted as per the documented microbiological sampling schedule.