



Best Practices for Pathogen Control During Tenderizing/Enhancing of Whole-Muscle Cuts

Revised: Spring 2017

Table of Contents

I.	PURPOSE	3
II.	INTRODUCTION	3
III.	HACCP SYSTEM	4
IV.	RAW MATERIAL CONTROL	5
V.	SUPPLIER EVALUATIONS	6
VI.	PRODUCT STORAGE AND TEMPERATURE CONTROL.....	6
VII.	PROCESS CONTROLS	7
A.	NEEDLE TENDERIZED PRODUCTS	7
B.	BRINE-INJECTED AND SUSPENSION PRODUCTS	7
VIII.	LOTING AND TRACEABILITY	8
IX.	SANITATION AND FACILITIES.....	9
X.	INTERVENTIONS/INHIBITORS	11
XI.	MICROBIOLOGICAL TESTING	11
XII.	PACKAGING AND LABELING	12
XIII.	SUPPORTING DOCUMENTATION FOR HAZARD ANALYSIS	13
XIV.	REFERENCES	16
XV.	APPENDICES	19
A.	APPENDIX A. EXAMPLE RECEIVING LOG	19
B.	APPENDIX B. EXAMPLE APPROVED RAW MATERIAL SUPPLIER LOG	20
C.	APPENDIX C. STANDARD OPERATING PROCEDURE FOR EQUIPMENT SANITATION	21
D.	APPENDIX D. EXAMPLE NON-INTACT RAW MATERIAL TRACKING LOG.....	25

This is not a regulatory document. This Best Practices document represents the current thinking of Beef Industry Food Safety Council (BIFSCo) members based on available shared knowledge and experiences. However, this Best Practices document does not create or confer any rights or obligations for or on any person and does not bind NCBA, BIFSCo, its members, or the public. BIFSCo Best Practices documents are not universal in scope or application and do not establish legally enforceable responsibilities. (Section added June 1, 2020)

I. Purpose

This document is designed to share Best Practices demonstrated by Industry within processes involving raw, non-intact beef products other than ground beef. Non-intact/non-ground beef products may include needle marinating, needle tenderizing or novel applications designed for penetrating within the beef muscle as a matter of tenderizing or flavor-enhancing the product. The scope of the non-intact process must be considered individually, as well as in concert with cleaning and sanitizing operations, to assess the risks of interior cross-contamination with potential pathogens that may occur (specifically *E. coli* O157:H7 and non *E. coli* O157:H7 Shiga toxin-producing *E. coli* [collectively STEC] as well as *Salmonella* or other biological pathogens of concern). There are multiple ways to reach the optimal end-result, and each operator should consider the practices and procedures detailed here as they best fit an individual operation. This document is not designed to mandate the use of any specific system or technology, but rather, to provide a framework of tools for application within non-intact beef processes to reduce the risk of microbiological contamination.

II. Introduction

The US Department of Agriculture's Food Safety Inspection Service (USDA-FSIS) defines non-intact beef products as *"beef that has been injected with solutions, mechanically tenderized by needling, cubing, Frenching, or pounding devices, or reconstructed into formed entrees (e.g., beef that has been scored to incorporate a marinade, beef that has a solution of proteolytic enzymes applied to or injected into the cut of meat, or a formed and shaped product such as beef gyros)"* (FSIS, 1999). Suspension marinating or "static" marinades without a vacuum are not recognized by FSIS as non-intact products (askFSIS, 2013). Additionally, FSIS added diced beef less than ¾" as another category of non-intact non-ground raw beef products (FSIS, 2014).

Whole-muscle cuts (e.g., from the chuck, rib, tenderloin, strip loin, top sirloin butt, and round) may be treated to increase tenderness or to add ingredients for quality purposes. Treatments may include solid-needle tenderizing or tenderizing with blades, such as cubing or hollow-needle tenderizing where a solution is pumped into the whole muscle. In some cases, the solution may be a pumping solution subject to a reuse application. In these types of marinade reuse applications, it is important to employ means to ensure the reduction of potential physical, biological and chemical contaminants.

Producers of raw, non-intact whole-muscle 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; Luchansky et al., 2008; Ray et al., 2010; Luchansky et al., 2011; Catford et al., 2013) and the product is not cooked adequately to destroy the pathogens inside the meat product (Luchansky et al., 2009; Luchansky et al., 2011; Swartz et al., 2015). Therefore, a

prudent establishment would consider a litany of possible controls to be evaluated and, upon sound decision making, use them to mitigate this potential risk.

III. HACCP System

Non-intact products will be produced under FSIS or state inspection, thereby being required to meet all Federal or State (equal to) requirements pertaining to HACCP systems (9 CFR 417), Sanitation SOPs (9 CFR 416) and prerequisite programs. All processors need to be prepared to support the decisions that are made in the HACCP program and to use the documentation generated from the program to demonstrate product safety (Refer to the Supporting Documentation for Hazard Analysis section of this paper).

As far as the authors know, there are no data to suggest that through a HACCP Plan hazard analysis, *E. coli* O157:H7/STEC, *Salmonella* or other biological hazards should be considered hazards reasonably likely to occur in tenderizing or enhancing operations. It is important, however, 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) and be specific to the process. This may include ¹Purchase Specification as stipulated by FSIS (2002), which may include ²Certificates of Analysis for STEC pathogen negative results, routine ³Third Party Audit Results and/or other Supplier STEC Verification data such as ⁴Trim Test Verification Results.

¹Purchase specifications should include documented evidence (e.g., Food Safety Letter of Guarantee including detailing of validated interventions and a statistically-based High Event Period Program that is utilized to determine suitability of subprimals and other raw material products for commerce) that the supplier has validated food safety controls effective in the reduction of STEC. Purchase specifications should also indicate whether a single vacuum package can be considered a microbiologically independent lot based on lack of comingling. Lots can be rationalized to consist of a single subprimal provided there is substantiation that the subprimal is microbiologically independent of other subprimals.

²Certificates of Analysis should be from certified laboratories (e.g., ISO 17025).

³Third Party Audit Results should include Global Food Safety Initiative-compliant certificates of compliance or actual audit results of a third party independent audit agency complete with STEC/*E. coli* O157:H7 assessment sections or addendums to the audits.

⁴Trim Test Verification Results should include supplier documentation of acceptable verification activities to demonstrate the trim testing protocol is valid in the case where trim testing is used to support ongoing verification of purchase specification requirements

If a supplier prerequisite program is established, together with supporting supplier documents showing traceability (e.g., P.O. Number), other food safety program elements such as in-house antimicrobial application on raw material received or in-house pathogen screening may not be required, but will need to be supported for FSIS or other regulatory agencies.

Alternatively, *E. coli* O157:H7/STEC testing results of raw materials or finished product may be undertaken, but will need to have adequate testing power and product controls to demonstrate the meaningfulness of results. 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. If routine microbiological testing is being conducted for *E. coli* O157:H7 and/or STEC, it is critical that the sampling method, aseptic collection technique, laboratory analysis and confirmatory testing is completely understood. Certain test methodologies may have less sensitivity or specificity than a more advanced technology due to its accessibility, ease of use and cost. Cultural confirmation of all supplier-induced presumptive *E. coli* O157:H7/STEC test results is recommended. For best practices and limitations on product lotting and microbiological sampling and testing, refer to the BIFSCo guidance document [Sampling, Lotting, and Sample Analysis Guidance](#).

Additionally, because the process involves raw meat processing operations, consideration should be given to *E. coli* O157:H7/STEC as a potential, sporadic contaminant. FSIS gave notice that all processors must reassess their HACCP systems to consider three foodborne outbreaks of *E. coli* O157:H7 that may have been linked to enhanced/tenderized beef steaks in their hazard analysis (FSIS, 2005). Non-intact beef 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/STEC if present as a process contaminant or as a highly unlikely contaminant of subprimals. These strategies typically involve prevention of harborages and niches through cleaning and sanitation of equipment, maintaining cold temperatures, and using antimicrobial interventions on the beef subprimals prior to processing and during recirculation of enhancement solutions.

Routine, risk-based verification that bacteria are not being harbored in the plant environment by swabbing equipment and the processing environment is recommended (e.g., Aerobic Plate Count or other suitable indicator microorganisms). To the authors' knowledge, the most prevalent and practical HACCP approach for justifying that *E. coli* O157:H7/STEC is not a hazard reasonably likely to occur, is a combination of raw material controls supported with a validated (FSIS 2015b) intervention for raw materials intended for non-intact whole-muscle production. This does not necessarily include cubed products for the intervention application given the previously mentioned uniqueness of these products in their appearance and end-product usage.

IV. Raw Material Control

Non-intact, raw beef operations must identify requirements for raw material suppliers and have a system for verification that the requirements are being met, thus achieving the goals of the food safety purchasing specification program. After establishing supplier program essentials, the receiving framework should include identifying approved raw materials at the time of receipt. Considerations within this process step would include documenting approved suppliers on receiving documentation in addition to designating any raw material product approved only for intact production via marking on the product boxes (color coding or specific wording). If products are received for both raw, non-intact beef processes and other uses (i.e., intact steaks and roasts) and different levels of requirements are identified for different processes, product segregation should be considered. Alternatively, dependent on the type of HACCP support required, if a COA is used as a supporting document, one supplier may be approved to provide some products intended for non-intact production, and others that are not. Any product from unapproved suppliers needs to be either rejected upon receipt or placed on HOLD pending adequate supplier approval documentation or risk assessment. Placing product on HOLD does run the

risk that the operation will fail to obtain adequate documentation for the product and will be unable to use the product. See Appendix A for an example of a Receiving Log that includes checks for approved suppliers.

As a note, raw material suppliers for non-intact production must be able to demonstrate validated process interventions and/or validated critical control points (CCPs) are in place to prevent, eliminate or reduce *E. coli* O157:H7/STEC to a non-detectable level. As always, multiple interventions (hurdles) are preferable to single microbial interventions. Validation may include scientific literature and/or plant-specific validation using surrogate or indicator microorganisms with a demonstration that key processing parameters of any supporting science are being met, and it is specific to the process being applied at the establishment. The purchase specifications should have a means to ensure they are being met. Examples of such verification tools include, but are not limited to, third party audits, beef harvest/processing food safety websites, and written supplier explanations of food safety processes.

V. 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 procedures be established to evaluate the raw material supply whether from an internal or external vendor source. Guidelines developed for Purchase Specification Best Practices can be used to help design a system for evaluating supply sources for non-intact raw materials. A more detailed discussion of supplier evaluations can be found in the 2016 BIFSCo [*Guidance for Purchasers of Raw Beef for Non-Intact Use*](#) document. See Appendix B for an example of an Approved Raw Material Supplier Log (*the supplier requirement must be the same whether domestic or imported production*).

VI. Product Storage and 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). This same science demonstrates a 50-hour time period for a one log growth of these pathogens at 50°F. If cold chain control is violated at any point in the chain for an appreciable amount of time, product safety and quality may be compromised. Best practice indicates that, on the conservative side, product temperature should not be above 45°F for more than four hours (US Army 2006), while, as a worst-case scenario, product temperature should not exceed 50°F for 50 hours, as described in ICMSF, 1996.

Cold chain management is especially important at the tenderizing or enhancing operation. Specific points where temperature must 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 less.
- Processing raw materials using a “First In, Oldest Date Out” rotation.
- Monitoring raw materials and finished products using a process room/cooler control program.
- Reuse of solution over more than one batch/lot should be considered in lotting and traceability program.

- Maintaining processing areas at sufficient temperature to maintain product in process at a maximum of 45°F.
- Maintaining finished product temperatures at 45°F or less throughout their shelf life.
- Pre-chilling shipping containers with consideration of seasonal and regional impact.
- Maintaining temperature control throughout shipment.

While temperatures are specified at 45°F or less in the above list, scenario dependent, it is generally recognized that the colder the better to limit all microbial growth, enteric pathogens, and the generally mesophilic spoilage bacteria to reduce any impact of temperature abuse variation imparted to downstream users or end consumers.

VII. Process Controls

There are three general types of specific processing that are recognized within tenderizing and enhancing operations. These include needle tenderizing, brine-injecting (marinating) and suspension marinating with a vacuum. Suspension marinating or “static” marinades without a vacuum are not recognized by FSIS as non-intact products (askFSIS, 2013). Should product be subject to vacuum marinating, it is considered by FSIS as equivalent to needle-enhanced non-intact product.

Specific Best Practices will be presented for each of these categories due to unique differences between the processes. Example Standard Operating Procedures (SOP) are provided in the appendix as a reference for cleaning and sanitizing of injector assembly (Best Practices: Appendix C). Every process and enhancement system is unique and appropriate SOPs must be in place depending on the situation.

A. NEEDLE TENDERIZED PRODUCTS

- Documented Good Manufacturing Practices (GMPs), including sanitation and needle integrity checks, exist for tenderizing operations.
- If possible, needle the product from the side opposite of the external surface of the carcass to minimize any bacterial translocation.
- Develop a traceability program for all finished products.

B. BRINE-INJECTED AND SUSPENSION PRODUCTS

- Letters of Guarantee and Certificates of Analysis or an appropriate hazard analysis that considers the ingredients used and the appropriate actions to address them (e.g. irradiated, steam-treated spices, etc.) exist for ingredients used in pumping solution (brine or pickle solution).
- Documented GMPs (including needle integrity checks) exist for injecting operations.
- Verifying the potability of process water is necessary.
- Chilled water system is preferable to complete chilling of brine.
- Maximum age is established for reuse brine (pickle) solutions (e.g., 12, 24, 48, etc. hours), with a mandatory break in the use cycle (e.g., every 12, 24, 48, etc. hours), if the reuse and break time can be substantiated.
- Determine if use of an antimicrobial intervention (e.g., filtration, UV) for reuse enhancement solution is applicable and practical if deemed necessary by the hazard analysis and if the characteristics of the solution lend to efficacy of use.

- Use of bacteriostatic ingredients in the enhancement solution (e.g., lactate, diacetate, sodium metasilicate) are recommended when applicable.
- If possible, inject the product from the side opposite of the external surface to minimize any bacterial translocation.
- As determined by your hazard analysis and historical data, require daily needle removal, a thorough cleaning of each needle upon removal, and a soaking of the needles in a sanitizing solution. If anything less than daily removal and cleaning is practiced, the frequency should be justified by validation of the alternative cleaning protocol.
- Established protocols exist for managing rework, including traceability and a time frame for incorporation into manufacturing.
- Establish a traceability program for all finished products.

VIII. Lotting and Traceability

All non-intact processors need to 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 the lot definition.

In the instance of raw materials, this cannot just be reduced to a clean up to clean up at the further process as definition of the lot (e.g., production date). There must be more to substantiate the definition of a raw material lot (FSIS 2013). Lots can be rationalized to consist of a single subprimal provided there is substantiation that the subprimal is microbiologically independent of other subprimals.

The term “comingling” has been used by FSIS to define a situation where subprimals are not microbiologically independent. Comingling consists of subprimals packaged together in a vacuum package, stacked together, stored in a combo together and not vacuum-packed, or stored in containers, such as a stainless-steel container (e.g., sausage cart) or a plastic lugger without going through a validated intervention.

Establishing a single subprimal as the lot of raw materials is extremely important with the advent of FSIS STEC testing of beef subprimal raw materials, as a part of the FSIS MT65 Bench Trim microbiological testing program. The MT65 program is targeted at the raw material prior to processing rather than the finished non-intact products such as mechanically tenderized or enhanced products. Per USDA FSIS Directive 10,010.1 Rev 4, an MT65 sample should be collected from raw materials intended for non-intact production after the application of an antimicrobial surface treatment (if used in the process) and before the product is tenderized. This includes trimmings from subprimal processing where those trimmings are intended for ground beef manufacturing and subprimals intended for non-intact whole-muscle products. To establish a single subprimal as the lot of raw materials there must be documentation from the supplier (e.g., food safety letter) demonstrating that vacuum-packaged subprimals are not comingled, and documentation and demonstration at the further processing facility that comingling of subprimals does not occur from the point of debagging through the tenderization process or validated intervention process just prior to tenderization.

In the event of FSIS MT65 testing, it should be strongly considered that the lot be defined as a subprimal. In the event of FSIS MT65 testing of raw materials intended for non-intact whole-muscle production, all food contact surfaces touched by that tested raw material must be cleaned and sanitized

both before and after the testing with documentation of the cleaning and subsequent inspection of the area.

Finished product lotting systems can range from very simplistic, e.g., handwritten numbering, to very elaborate, e.g., computerized, automated bar coding. They can also be substantiated by a clean up to clean up rationale, absent any carry over product. 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. 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, which would potentially minimize the volume of product implicated in the event a recall is ever required. If lots are intended to be broken at some frequency by needle rotation, accompanying sanitation of the feed-in area (debugging tables, conveyors) is also necessary. However, it is important to note that unless the recirculation and/or duration of use of a brine or marinade is considered, this is not feasible for injected products.

Ideally, carry-over product already rendered non-intact would be eliminated as an option from the operation and all products should be run into a finished product state on the date they are originally exposed to the processing area. Partially completed finished product, finished product cases, or raw materials already rendered non-intact that carry over from one production day to another should be identified with either in-house labels on the in-progress product or codes on the finished product (e.g., an “X” following the finished product production date). These identified products must have been produced in no more than two consecutive production days and prevented from comingling with other products run on different production dates. In the event carry-over product is run on non-consecutive days, it should be the last run in the production day and that fact documented, preferably on an Operational Sanitation log.

Establishments must maintain records associated with all production lots. Information to be recorded is dependent on the individual system; however, the following data typically are recorded for lot identification:

- Raw material vendor, vendor plant, vendor lot, date and time of entry into processing
- Equipment or line of production
- Finished product process date and potentially, time of production
- Raw material, brine, processing room and product temperature
- Microbiological data

A more detailed discussion of lotting can be found in the BIFSCo [Best Practices for Raw Ground Products](#) document. Appendix D includes an example Non-Intact Raw Material Tracking Log.

IX. 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), the equipment used must meet sanitary operating guidelines, and all food contact substances must be verified and documented to meet sanitary standards, including water potability. Establishments should meet all regulatory requirements of the Sanitation Standard Operating Procedures and should consider the guidelines presented in the Sanitation Performance Standards.

For optimal operation, the entire system should be process engineered. The idea of process engineering encompasses facility design, equipment design, product movement, supply movement and employee movement to create an environment that minimizes microbial contamination. The North American Meat Institute's *Sanitary Equipment Design Principles* (NAMI, 2014) serves as a good reference. A checklist and a fact sheet, can be accessed in the Data and Resources section at <https://www.meatinstitute.org/>.

Proper sanitation is the single most important control measure available to processors of mechanically tenderized and enhanced products to prevent foodborne outbreaks. Specifically, enhanced and mechanically tenderized processors should follow sanitation practices much like those adhered to by ready-to-eat (RTE) operations. A comprehensive review of RTE sanitation and practices is found in the *Guidelines for Developing Good Manufacturing Practices (GMPs), Standard Operating Procedures (SOPs) and Environmental Sampling/Testing Recommendations (ESTRs) in Ready to Eat (RTE) Products* (NMA, 1999).

When making non-intact whole-muscle products, considerations for general sanitation controls include Pre-Operational and Operational best practices. A thorough daily inspection of all equipment used to render intact products into non-intact products with a detailed documentation of that inspection is a necessary Pre-Operational best practice. Additionally, the equipment should be included regularly in plant environmental testing programs at a frequency greater than that of other processing equipment. Both practices should document corrective actions for any failures with follow up observation or testing to verify the effectiveness of the corrective actions. Furthermore, the physical removal of protein and fat inside needles by blowing out with air should happen before cleaning and sanitation and a thorough soak of the actual tenderizing pieces of the equipment (needles, blades) overnight (or between idle shifts) in a sanitizer solution should be considered. Needle sets can be rotated daily to allow for effective cleaning and sanitation.

During operations, cleaning and thoroughly spraying the tenderizing pieces of equipment with a food contact sanitizer or approved pathogen intervention may be necessary. Segregation of raw materials intended for non-intact whole-muscle production from those intended for intact production must take place upstream of the tenderizing or non-intact rendering equipment. Also, as mentioned earlier in the Lotting section, comingling of the subprimals needs to be prevented upstream of the tenderizing or non-intact rendering equipment. Pre-Operational and Operational sanitation checks and verification of the application of sanitizers to equipment used for rendering whole-muscle intact product into whole-muscle non-intact product, as well as the absence of subprimal comingling and segregation of raw materials intended for intact and non-intact processing, is to be documented on the Pre-Operational Sanitation Log and Operational Sanitation Log or other official facility record subject to routine daily verification.

As the tenderizers/injectors pass through the product they may introduce biological hazards to the interior of the product. Inadequate tenderizing equipment sanitation, particularly injection needle sanitation, poses the greatest risk to spread any microbial contaminants present on the incoming raw materials, thus sanitation is critical. All equipment must be cleaned and sanitized daily, with needles removed at least daily, cleaned out, and soaked in a sanitizing solution prior to inspection and reassembly of the needle injector. Ideally, two sets of needles could be rotated to allow for maximum soaking time and potentially greater sanitation efficacy. Injection systems should be cleaned in place (CIP) using a validated sanitation process of cleaning followed by sanitizing. Standard Operating

Procedures should include the chemical concentration, frequency of cleaning, responsible party, and how it will be verified.

Validation and verification of sanitation practices are always challenging given the nature of tenderizing equipment, especially with small diameter hollow injection needles further compounding this issue. Nevertheless, sanitation of tenderizing equipment should be routinely validated and verified. To validate the efficacy of the sanitation system, needles can be sacrificed (broken) to determine if the cleaning and sanitizing procedures are adequate. This could include sacrificing one needle per set numbers of cleaning cycles to verify internal needle cleanliness.

X. Interventions/Inhibitors

Use of a validated antimicrobial intervention process by the non-intact beef processor provides an element of additional assurance. Industry experiences indicate that it is particularly difficult to substantiate a hazard analysis that does not include both a supplier verification activity and a validated pathogen intervention when rendering whole-muscle intact products into whole-muscle non-intact products.

The most basic intervention is knife trimming and washing of the tissue surface with a validated antimicrobial solution prior to the non-intact process. Other current applied technologies may include:

- Application of antimicrobial solutions or processes such as ultraviolet light or irradiation to the raw materials before processing.
- Treatment of the enhancement solution with an inhibitory process (e.g., ultraviolet and/or filtration).
- Addition of an inhibitory ingredient to solutions.
- Application of an intervention or inhibitor to the finished product or packaging materials. Any intervention or antimicrobial packaging technology applied post-intact processing should be validated to address internalized contamination.

New antimicrobial interventions and inhibitors that may be applicable in tenderizing or enhancing operations continue to be developed. Many of the Safe and Suitable Ingredients listed in [FSIS Directive 7120.1](#) are antimicrobial interventions suitable for use when tenderizing beef. When using an intervention, it is incumbent upon the operation to develop sufficient validation for that intervention (including scientific validation and in-plant validation) and verify its effectiveness on an ongoing basis. [FSIS Compliance Guideline HACCP System Validation April 2015](#) is an excellent guide for this validation.

XI. Microbiological Testing

Most suppliers of raw, intact beef products complete extensive sampling of products intended for raw ground use. Of particular note, *E. coli* O157:H7 testing performed on beef trimmings is a fair and accurate representation of a 'process in control' that represents the carcass disassembly process and the resultant subprimals.

It is the original producer uses of such tests within a High Event Program [HEP] that are most critical to the likelihood of detecting the STEC pathogen on the intact beef subprimal. In addition, suppliers should provide verification testing data to support that a 'process in control' for *E. coli* O157:H7 is a 'process in control' for non-O157 STEC.

Finished product and raw material pathogen microbiological testing is a potential way 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 (BIFSCo 2008 & 2016). However, finished product sampling, and particularly raw material 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 percent confidence that the probability of contamination is no greater than five percent). Furthermore, considerations for finished product testing should include implication of broken lots of raw materials including non-protein ingredients, unused or recirculated brine, and other products made on the same equipment before or after the implicated product was produced. The challenge of testing a multi-ingredient finished product for the presence of the pathogen requires all components of the finished product to be considered as a source of the pathogen, not just the protein raw material. Generally, the economics of testing raw materials and finished products and the high numbers of samples required to have a relatively high degree of confidence that a low level of contamination exists, make such product testing extremely expensive and impractical. Such product testing may have some value in some instances such as for occasional verification activities using indicator microorganisms, or when a process is out-of-control and an assignable cause is being sought, but these should be extremely rare one-off type occurrences.

XII. Packaging and Labeling

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 (North American Meat Institute; 2014).

It is the belief of FSIS that consumers do not understand or expect whole-muscle steaks and roasts to be non-intact. Thus, the agency has mandated through the 2015 Final Rule titled *“Descriptive Designation for Needle-or Blade-Tenderized (Mechanically Tenderized) Beef Products”* (FSIS 2015a) that processors label enhanced and mechanically tenderized products (other than cubed and other similar products where the tenderization clearly changes the products appearance, such as ground beef, hamburger, beef patties, raw corned beef, any fully cooked non-intact products and beef products that are less than 1/8” thick, like beef bacon and carne asada or under 3/4” diced product).

This rule requires that a Descriptive Designation be included in or adjacent to the product description and must include:

“1. “Mechanically Tenderized” or, if needle tenderized the product can be described as “Needle Tenderized,” or if blade tenderized, the product can be described as “Blade Tenderized.”

2. The product name and the descriptive designation must be printed in a single, easy-to-read type style and color and must appear on a single-color contrasting background. The print may appear in upper and lower case letters, with the lower-case letters not smaller than one-third (1/3) the size of the largest letter, and with no intervening text between the identity of the meat and the descriptive designation. The descriptive designation may be above, below, or next to the product name without intervening text or graphic on the principal display panel.”

The Cooking Instructions required on the label include:

- 1. The cooking method (e.g., grill, bake);*
- 2. That these products need to be cooked to a specified minimum internal temperature;*

3. *Whether these products need to be held for a specified time at that temperature or higher before consumption to ensure that potential pathogens are destroyed throughout the product; and*
4. *A statement that the internal temperature should be measured by a thermometer.”*

FSIS has developed a compliance guide for assisting with meeting these requirements (FSIS 2015b). It lists a variety of ways establishments can meet the new requirements. The expectation of FSIS, however, is that any cooking instructions developed by the establishment be validated as to being able to repeatedly achieve the desired temperature and time combination and the desired lethality. It is recommended that a simple statement based on the FDA Food Code 2013 cooking requirements be utilized for the cooking instructions (145°F for 3 minutes, 155°F for 15 seconds or 158°F) as these values are validated. FSIS has suggested the terminology of *“Grill until product reaches 145°F, as measured by a food thermometer, and hold the product at or above that temperature for 3 minutes”* to be acceptable to meet the wording requirements of the cooking instructions (FSIS 2016c).

Health Canada (2014) has also developed labeling requirements for non-intact whole-muscle products. Those requirements stipulate that the principal display panel of labels of affected products include:

- a) *Identification as mechanically tenderized;*
- b) *Safe cooking instructions “Cook to a minimum internal temperature of 63 °C (145 °F);”*
- c) *And, in the case of steaks, an additional safe cooking instruction to help achieve a consistent temperature throughout “Turn steak over at least twice during cooking.”*

XIII. Supporting Documentation for Hazard Analysis

FSIS (2016a) has published good summary information sheets on basic consumer food safety information and safety research regarding raw, non-intact whole-muscle products. The FSIS paper estimates that 2.7 billion pounds of mechanically tenderized beef representing an estimated 6.7 billion servings are consumed annually in the United States. The paper recommends that consumers cook these products to 145°F as measured by a food thermometer inserted into the center of the cooked cut and to further allow the cut to rest for three minutes following cooking. That cooking temperature and rest time combination is also reflected in the FDA’s 2013 Food Code (FDA 2013).

Perhaps the best overall recent research on the topic of non-intact whole-muscle beef has been led by Dr. John B. Luchansky, Ph.D. of the USDA Agricultural Research Service Eastern Regional Research Center in Wyndmoor, PA. A series of experiments started in 2008, provided a basic understanding of how the translocation of pathogens may occur within raw non-intact beef products. First, mechanical tenderization may transfer pathogens from the exterior to the interior of inoculated beef (Top Sirloins), but at low levels of inoculation (0.6 CFU/g). The majority of the inoculated pathogen load remains near the surface thus making them more susceptible to cooking lethality (Luchansky et al.,2008). Further, it was determined that, in the event that the inoculated pathogens were transferred beneath the original surface, neither the number of passes (one or two) nor the side from which the product was tenderized (fat side or lean side) affected translocation. Additional research demonstrated that translocation of inoculated *E. coli* O157:H7 and non O157:H7 STEC from the exterior to the interior occurred in brine-injected Top Sirloin steaks (Luchansky, 2011). Importantly, demonstrated in both the Luchansky et al. (2011) experiment and another experiment (Luchansky et al.,2009), cooking the respective STEC-inoculated, brine-injected, and mechanically tenderized steaks on a commercial gas grill inactivated the translocated STEC. It was also demonstrated that thicker steaks, when cooked to the same degree of

doneness, resulted in a higher degree of inactivation (presumably due to the increased cooking time to reach a given degree of doneness) (Luchansky et al., 2009). Swartz et al. (2015) similarly reported that 0.3-inch-thick cubed steaks, double passed through a cubing machine and cooked on a griddle heated to 377°F for 3 minutes per side reached a 5 log reduction of inoculated STEC.

While important in establishing the scientific basis of non-intact whole-muscle beef products, it must be strongly noted that inoculation scientific studies are not always reflective of 'real-world' STEC pathogen levels. If STEC pathogens are found on raw meat products, it is typically at very low levels. Scientific studies typically use 3-5 log STEC inoculations to ensure the study method is clearly understood. Industry is doing the exact opposite of the scientific studies, in that intervention technologies are being applied to prevent and/or reduce pathogen contamination at numerous points within the beef harvest/production/enhancement continuum. The likelihood of potential pathogens being transferred to the inside from the outside of raw beef products is extremely low because of a very low prevalence of pathogens on product being tenderized or enhanced, with any remote and sporadic occurrence of STEC and other pathogens being at extremely low contamination load levels.

Several studies indicate that *E. coli* O157:H7 is not a hazard reasonably likely to occur on the surface of intact meat portions. A study was conducted where sponge samples were taken of 1,014 subprimal cuts from six beef processing plants over a five-week period, as a portion of the Heller et al (2007) reported study. Only two samples (<0.2%) tested positive for *E. coli* O157:H7. Enumeration indicated that each of the two positive samples had <3.0 CFU per 200 cm² sampled, which would, in practical terms, equate to a lower value in terms of the standard CFU per gram measurement commonly used in product testing.

Two other studies were conducted by ABC Research Corporation (Kennedy et al., 2006) throughout 2004 to determine the prevalence of *E. coli* O157:H7 and indicator organisms on the surface of beef briskets, rounds, chucks, and middle meats used as raw materials for tenderizing or enhancing operations. The first 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 subprimal 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 subprimal. 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 subprimals was < 0.083% (Kennedy et al., 2006).

These studies are further supported by more recent data from the FSIS testing programs of beef industry products for STEC, specifically in testing results for FSIS's MT65 testing program. The MT65 program (previously MT55 before Sept. 1, 2015) includes testing "Bench Trim" at eligible establishments (including those who produce mechanically tenderized and enhanced products) for *E. coli* O157:H7 and other STECs of concern. FSIS defines Bench Trim as purchased product "...including secondary trimmings, smaller pieces of trim, and chucks, rounds, sirloins, and other primal or subprimal cuts the further processor intends for use in raw non-intact product" (FSIS-USDA, 2014). FSIS instituted testing of beef subprimals intended for non-intact products, such as mechanical tenderization or enhanced beef, in early 2014 in the MT65 (then MT55) program which included excision sampling of subprimal product using an N60 sampling protocol. From that time through December 11, 2016, FSIS had sampled 3,980 samples of Bench Trim with one positive, resulting in a rate of 0.0025% positives (FSIS-USDA, 2016b).

Numerous industry antimicrobial intervention steps, sanitation practices, purchase specification programs, product labeling, proper product segregation, chilling procedures and handling practices are established. In addition, there are practical aspects of the tenderization process relative to pathogen risks on non-solution-added, mechanically tenderized, raw, non-intact beef products other than ground beef. Even during inoculation studies, only three to four percent of surface bacterial populations are translocated to an average interior depth of ¼” of the cuts during processing (Sporing, 1999; Lambert et al., 2001).

The most recent risk assessment completed on non-intact whole-muscle products titled “mechanically tenderized beef” was reported by Catford et al. (2013) and spurred by an *E. coli* O157:H7 associated outbreak, in part including non-intact, whole-muscle steak products produced through needle tenderizing raw beef product at retail without an intervention. Catford’s risk assessment determined that non-intact whole-muscle products subjected to an intervention prior to being rendered non-intact were similar in risk to whole-muscle intact beef. Specifically, the overall risk posed by non-intact whole-muscle beef was five times that of intact beef, however, this risk assessment did not include cubed steaks. Cubed steaks represent a different risk level due to their appearance as non-intact versus non-intact whole-muscle steaks and roasts, which do not appear non-intact. Additionally, the normal preparation and cooking methods using very high heat and the relatively thin steak height of cubed steaks place them in another risk category which is likely why they have not been associated with any appreciable food safety risk or outbreaks. This general fact was recognized by FSIS-USDA in their 2015 Federal Register Notice “*Descriptive Designation for Needle- or Blade-Tenderized (Mechanically Tenderized) Beef Products,*” as cubed steaks were excluded for the labeling requirements spelled out in that notice.

Thus, mechanically tenderized and enhanced products pose no greater risk than intact cuts when the raw materials used for these products have been subjected to adequate prerequisite programs and a validated intervention just prior to being rendered non-intact (Catford et al., 2013), and when the non-intact products are appropriately labeled and cooked to a medium rare degree of doneness (145°F) (FSIS, 2016a). A review of research results relative to mechanically tenderized beef and STEC can be found in the white papers entitled *Beef Industry Addresses the Safety of Non-Intact Beef Products* (NCBA, 2006) and *Findings of the Health Risk Assessment of Escherichia coli O157 in Mechanically Tenderized Beef Products in Canada* (Catford et al., 2013).

While the operating practices at individual companies may vary, producers of non-intact whole-muscle cuts are urged to consider these Best Practices as guidelines for their own internal practices and documentation.

This document was developed by members of the Beef Industry Food Safety Council. Best Practice documents are ever evolving, and as changes or new information becomes available, these documents will be reviewed and updated. Questions or suggestions are welcome and should be addressed to BIFSCO at bifscob@beef.org.

XIV. References

- askFSIS. 2013. Non-intact beef products. FSIS-USDA. Washington, DC.
https://askfsis.custhelp.com/app/answers/detail/a_id/1711/~non-intact-beef-products.
Accessed December 20, 2016.
- BIFSCo. 2016. Beef Industry Food Safety Council. Best Practices for Purchase Specifications.
(www.bifsc.org).
- BIFSCo. 2016. Beef Industry Food Safety Council. Best Practices for Raw Ground Products.
(www.bifsc.org).
- BIFSCo. 2008. Beef Industry Food Safety Council. Best Practices for Using Microbiological Sampling.
(www.bifsc.org).
- BIFSCo. 2016. Beef Industry Food Safety Council. Guidance Document for Sampling and Lotting of Beef Products and Sample Analysis for Pathogens. (www.bifsc.org).
- Catford, A., M. Lavoie B. Smith, E. Buenaventura, H. Couture, A. Fazil, and J. M. Farber. 2013. Findings of the Health Risk Assessment of *Escherichia coli* O157 in Mechanically Tenderized Beef Products in Canada. *Int. Food Risk Anal.* 3:1-12
- FDA. 2013. Food Code 2013. U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, College Park, MD 20740. Chapter 3-401.11 p. 81.
- FSIS. 1999. Federal Register Notice: Beef Products Contaminated with *Escherichia Coli* O157:H7. *Fed. Regist.* 64(11):2803-2808.
- FSIS. 2002. Federal Register Notice: *E. coli* O157:H7 Contamination of Beef Products. *Fed. Regist.* 62325-62334.
- FSIS. 2005. Federal Register Notice: HACCP Plan Reassessment for Mechanically Tenderized Beef Products. *Fed. Regist.* 70(101):30331-30334.
- FSIS. 2013. Compliance Guideline: Controlling Meat and Poultry Products Pending FSIS Test Results. Washington, DC. https://www.fsis.usda.gov/wps/wcm/connect/6b7b5a65-9ad3-4f89-927d-078e564aca24/Compliance_Guide_Test_Hold_020113.pdf?MOD=AJPERES. Accessed December 20, 2016.
- FSIS. 2014. Notice 39-14: Clarification and Expansion of Sampling Eligibility Criteria for the Routine Beef Manufacturing Trimmings (MT60) and Bench Trim (MT55) Sampling Programs.
- FSIS. 2015a. Federal Register Notice: Descriptive Designation for Needle- or Blade-Tenderized (Mechanically Tenderized) Beef Products. *Fed. Regist.* 80(95):28153-28172.
- FSIS. 2015b. Compliance Guideline: FSIS Compliance Guideline for Validating Cooking Instructions for Mechanically Tenderized Beef Products 2015. Washington, DC.
https://www.fsis.usda.gov/wps/wcm/connect/606919b6-5192-40bd-a32b-99a41c75eeb6/Comp_Guide_MTB.pdf?MOD=AJPERES. Accessed December 20, 2016.

- FSIS. 2016a. Mechanically Tenderized Beef. Food Safety Information Fact Sheet. Washington, DC. <https://www.fsis.usda.gov/wps/wcm/connect/88bbcd9c-5295-4b2f-a937-f0d04ba84ee7/Mechanically-Tenderized-Beef.pdf?MOD=AJPERES>. Accessed December 20, 2016.
- FSIS. 2016b. Testing of Raw Ground Beef and Raw Ground Beef Component Samples for *E. coli* O157:H7: Year-to-Date Totals. <https://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/ec/e-coli-o157h7-year-to-date/ecoli-o157-raw-beef-testing-data-ytd>. Accessed December 20, 2016.
- FSIS. 2016c. Questions and Answers on Descriptive Designation for Needle-Or Blade – Tenderized (Mechanically Tenderized) Beef Products FSIS–2008–0017 docket, Final Rule, 9 CFR 317.2(e)(3). Washington, DC. <https://www.fsis.usda.gov/wps/wcm/connect/e42698a1-1949-4828-9909-5ff919f275c6/FAQs-2008-0017.pdf?MOD=AJPERES>. Accessed December 20, 2016.
- Hajmeer, M.N., E. Ceylan, J.L. Marsden, and R.K. Phebus. 2002. Translocation of natural microflora from muscle surface to interior by blade tenderization. Cattlemen’s Day 2002. Report on Progress 850, pp. 125-126. Kansas State University, Manhattan, KS.
- Health Canada. 2014. Guidance on Mandatory Labelling for Mechanically Tenderized Beef. Health Canada Food Directorate, Health Products and Food Branch. Ottawa, ON. <http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/mech-tenderized-beef-boeuf-attendris-meca-eng.php>. Accessed December 20, 2016.
- Heller, C.E., J. A. Scanga, J. N. Sofos, K. E. Belk, W. Warren-Serna, G. R. Bellinger, R. T. Bacon, M. L. Rossman, and G. C. Smith. 2007. Decontamination of Beef Subprimal Cuts Intended for Blade Tenderization or Moisture Enhancement. *J. Food Protect.* 70: 1174-1180
- International Commission on Microbiological Specifications for Foods. 1996. *Microorganisms in Foods: Microbiological Specifications of Food Pathogens*. Blackie Academic & Professional, New York, NY.
- Kennedy Jr., J. E., S. K. Williams, T. Brown, and P. Minerich. 2006. Prevalence of *Escherichia coli* O157:H7 and indicator organisms on the surface of intact subprimal beef cuts prior to further processing. *J. Food Protect.* 69:1514-1517.
- Krizner, K. 1999. Blade-tenderization safe for steaks: Studies suggest process poses little risk of introducing *E. coli* O157:H7 onto beef steaks. *Meat Marketing & Technology* (September Issue) p. 120.
- Lambert, D.L., R.K. Phebus, H. Thippareddi, J.L. Marsden, and C.L. Kastner. 2001. *Salmonella* spp. risk assessment for production and cooking of non-intact pork products. IAFP Annual Meeting Program and Abstract Book. (PO54). p. 60 (Abstr.).
- Luchansky, J.B., A.C.S. Porto-Fett, B.A. Shoyer, J.E. Call, W. Schlosser, W. Shaw, N. Bauer and H. Latimer. 2011. Inactivation of Shiga Toxin–Producing O157:H7 and Non-O157:H7 Shiga Toxin–Producing *Escherichia coli* in Brine-Injected, Gas-Grilled Steaks. 74:1054-1064.
- Luchansky, J.B., R. K. Phebus, H. Thippareddi and J. E. Call. 2008. Translocation of Surface-Inoculated *Escherichia coli* O157:H7 into Beef Subprimals following Blade Tenderization. *J. Food Protect.* 71:2190-2197.

- Luchansky J.B., A. C. S. Porto-Fett, B. Shoyer, R.K. Phebus, H. Thippareddi and J.E. Call. 2009. Thermal Inactivation of *Escherichia coli* O157:H7 in Blade-Tenderized Beef Steaks Cooked on a Commercial Open-Flame Gas Grill. *J. Food Protect.* 72: 1404-1411.
- National Cattlemen's Beef Association. 2006. Beef Industry Addresses the Safety of Non-Intact Beef Products. Non-Intact Products Processing Workshop, Dallas, TX.
- National Meat Association. 1999. Guidelines for Developing Good Manufacturing Practices (GMPs), Standard Operating Procedures (SOPs) and Environmental Sampling/Testing Recommendations (ESTRs) in Ready to Eat (RTE) Products. National Meat Association, Oakland, CA.
- North American Meat Institute. 2014. Sanitary Equipment Design Task Force. Sanitary Equipment Design Checklist & Glossary and Fact Sheet. North American Meat Institute, Washington, DC.
- Phebus, R.K., H. Thippareddi, S. Sporing, J.L. Marsden, and C.L. Kastner. 2000. *E. coli* O157:H7 risk assessment for blade-tenderized beef steaks. Cattlemen's Day 2000. Report of Progress 850, pp. 117-118. Kansas State University, Manhattan, KS.
- Ray, A. N., M. E. Dikeman, B. A. Crow, R. K. Phebus, J. P. Grobbel, and L. C. Hollis. 2010. Microbial translocation of needle-free versus traditional needle injection-enhanced beef strip loins. *Meat Sci.* 84(1):208-211.
- Sporing, S.B. 1999. *E. coli* O157:H7 Risk Assessment for Production and Cooking of Blade Tenderized Beef Steaks. Master Thesis. Kansas State University, Manhattan, Kan.
- Swartz, R. S., J. B. Luchansky,² M. Kulas,³ B. A. Shoyer, L. E. Shane, H. Strasser, M. Munson, and A.C. S. Porto-Fett. 2015. Thermal Inactivation of Shiga Toxin–Producing *Escherichia coli* Cells within Cubed Beef Steaks following Cooking on a Griddle. *J. Food Protect.* 78:1013-1017.
- US Army. 2006. Medical Services U.S. Army Veterinary Command Guidelines and Procedures. Department of the Army Headquarters, US Army Medical Command, Fort Sam Houston, TX. MEDCOM 40-13, Chapter 5:48-59

XV. Appendices

A. APPENDIX A. EXAMPLE RECEIVING LOG

Receiving Log

Date

TIME	SUPPLIER	EST #	PO #	LOT CODE, PACK DATE, BEST BY, USE BY DATE	PRODUCT DESCRIPTION	PRODUCT SURFACE TEMP °F	APPROVED SUPPLIER NON- INTACT Y/N	INTACT SUPPLIER COLOR CODED Y/N	INITIALS	CORRECTIVE ACTION / COMMENTS
						Front:				
						Middle:				
						Back:				
						Front:				
						Middle:				
						Back:				
						Front:				
						Middle:				
						Back:				
						Front:				
						Middle:				
						Back:				

Verified By:

Date:



B. APPENDIX B. EXAMPLE APPROVED RAW MATERIAL SUPPLIER LOG

Raw Non-Intact Beef Supplier Approval Log

Calendar Quarter/Year _____

Supplier Company Name	Est. Number	LOG Current Letter of Guarantee on File (Dated for quarter covered or later) Yes/No	AUDIT & ADDENDUM 3 rd Party Audit Certificate w <i>E. coli</i> Control Verification/ Addendum (For Previous Calendar Year) Yes/No	TRIM TESTING VERIFICATION RESULTS (Only required if supplying raw materials for grinding) (For Previous Calendar Year Quarter) Yes/No	Does Supplier Qualify as Active for Supplying Raw Beef Products for Whole-Muscle Non-Intact production? Yes/No

Verified By: _____

Date: _____

C. APPENDIX C. STANDARD OPERATING PROCEDURE FOR EQUIPMENT SANITATION

Standard Operating Procedures for Cleaning and Sanitizing Injector Assembly: Example I

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. Each needle must be "blown out" with clean air before being replaced in the injector assembly" to remove fat, lean, oils and concentrates prior to soaking.
5. Add clean and 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.
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.

Standard Operating Procedure Clean in Place System Cleaning: Example II

PURPOSE: To minimize bacterial growth.

PROGRAM: A CIP cleaning solution will be ran through the injection process to ensure proper cleaning of the injection process.

PROCEDURE:

1. Drain all brine material from lines, pumps, and tanks. During the draining process production personnel will continue to rinse all six tanks with potable water until all visible brine residue has disappeared.
2. Fill the two mixing tanks (# 3 & # 6) with 200 Gal. of cold potable water each.
3. Flush 100 Gal. from the line 1 mixing tank (#3) to each of the rear holding tanks (#2 & #1).
4. Flush 100 Gal. from the line 2 mixing tank (#6) to each of the rear holding tanks (#5 & #4).
5. Flush all water from all holding tanks through the CIP system and a minimum of 50 Gal. through each of the injectors (line 1 and line 2).
6. Fill mixing tanks (#3) and (#6) again with 200 Gal. of cold potable water and add appropriate amount of the approved CIP cleaning solution.
7. Mix thoroughly.
8. Flush 100 Gal. of the mixed cleaning solution from the line 1 mixing tank (#3) to each of the rear holding tanks (#2 & #1).
9. Flush 100 Gal. of the mixed cleaning solution from the line 2 mixing tank (#6) to each of the rear holding tanks (#5 & #4).
10. Flush all cleaning solution from all holding tanks through the CIP system pumping from each tank a minimum of 5 minutes.
11. A minimum of 50 Gal. will be pumped from one of the holding tanks of each line through its designated injector (line 1 and line 2).
12. Fill the two mixing tanks (# 3 & # 6) with 200 Gal. of cold potable water each.
13. Flush 100 Gal. from the line 1 mixing tank (#3) to each of the rear holding tanks (#1 & #2).
14. Flush 100 Gal. from the line 2 mixing tank (#6) to each of the rear holding tanks (#5 & #4).
15. Flush all water from all holding tanks through the CIP system and a minimum of 50 Gal. through each of the injectors (line 1 and line 2).

The currently used cleaning solution is STERIS brand Process Klenz alkaline cleaner used at 2.5% by volume. (5 gallons Process Klenz mixed with 200 gallons' potable water.)

CORRECTIVE ACTION: Production will not be allowed to start until CIP cleaning has taken place.

RELATED FORMS: CIP System Cleaning Verification Process Check

MATERIALS NEEDED: Steris brand process klenz alkaline cleaner.

FREQUENCY: Daily

MONITORED BY: QA and Production Management will routinely monitor to ensure proper compliance.

General Manager

Date

QA Manager

Date

Standard Operating Procedure Clean in Place System Sanitizing: Example III

PURPOSE: To minimize bacterial growth.

PROGRAM: A CIP Sanitizing solution will be ran through the injection process to ensure proper cleaning of the injection process.

PROCEDURE:

1. Fill the two mixing tanks (# 3 & # 6) with 200 Gal. of cold potable water each.
2. Flush 100 Gal. from the line 1 mixing tank (#3) to each of the rear holding tanks (#2 & #1).
3. Flush 100 Gal. from the line 2 mixing tank (#6) to each of the rear holding tanks (#6 & #4).
4. Flush all water from all holding tanks through the CIP system and a minimum of 50 Gal. through each of the injectors (line 1 and line 2).
5. Fill mixing tanks #3 and #6 again with 200 Gal. of cold potable water and add appropriate amount of the approved CIP sanitizing solution.
6. Mix thoroughly.
7. Flush 100 Gal. of the mixed sanitizing solution from the line 1 mixing tank (#3) to each of the rear holding tanks (#2 & #1).
8. Flush 100 Gal. of the mixed sanitizing solution from the line 2 mixing tank (#6) to each of the rear holding tanks (#5 & #4).
9. Flush all sanitizing solution from all holding tanks through the CIP system pumping from each tank a minimum of 5 minutes.
10. A minimum of 50 Gal. will be pumped from one of the holding tanks of each line through its designated injector (line 1 and line 2).
11. Fill the two mixing tanks (# 3& # 6) with 200 Gal. of cold potable water each.
12. Flush 100 Gal. from the line 1 mixing tank (#3) to each of the rear holding tanks (#2 & #1).
13. Flush 100 Gal. from the line 2 mixing tank (#6) to each of the rear holding tanks (#5 & #4).
14. Flush all water from all holding tanks through the CIP system and a minimum of 50 Gal. through each of the injectors (line 1 and line 2).

The currently used cleaning solution is STERIS brand Process LCS liquid chlorinating sanitizer used at .25 ounce per gallon. (50 ounces mixed with 200 gallons’ potable water.) Chlorine Days Monday, Wednesday, Friday, Saturday, Sunday. Quat Days: Tuesday, Thursday.

CORRECTIVE ACTION: Production will not be allowed to start until sanitizing has taken place.

RELATED FORMS: NA

MATERIALS NEEDED: Quat or Chlorine

FREQUENCY: Daily

MONITORED BY: QA and Production Management will routinely monitor to ensure proper compliance.

General Manager

Date

QA Manager

Date

Standard Operating Procedure Operational Cleaning of Injector Reservoir In-Line Filters: Example IV

PURPOSE: To minimize bacterial growth.

PROGRAM: Injection filters will be cleaned on a regular basis to ensure the injectors operate at an optimal level.

PROCEDURE:

1. Remove the machine side in-line final filter by rotating its holding cylinder to the vertical position where it will latch against the wall of the reservoir.
2. From this position the end cap can be threaded back and spun out of the way so the filter may be removed for cleaning.
3. Remove filter and clean with tempered water of sufficient pressure to remove any built-up residue.
4. Replace filter into its holding cylinder and thread back its end cap to secure filter in the cylinder.
5. Return filter assembly to the horizontal position inside the reservoir tank.
6. Remove the off side in-line final filter by rotating its holding cylinder to the vertical position where it will latch against the wall of the reservoir.
7. From this position the end cap can be threaded back and spun out of the way so the filter may be removed for cleaning.
8. Remove filter and clean with tempered water of sufficient pressure to remove any built-up residue.
9. Replace filter into its holding cylinder and thread back its end cap to secure filter in the cylinder.
10. Return filter assembly to the horizontal position inside the reservoir tank.

CORRECTIVE ACTION: NA

RELATED FORMS: NA

MATERIALS NEEDED: Tempered Water

FREQUENCY: Operational cleaning of injector reservoir filters should be conducted on the hourly basis to maintain consistent pump settings.

NOTE: Each employee who handles injector equipment must change gloves before and after as well as clean any additional utensils needed for the tasks. This ten-step process will be used for the reservoir tanks of both line one and line two injectors. If filters are cleaned one at a time than the injector does not need to be shut down for this SOP.

MONITORED BY: QA and Production Management will routinely monitor to ensure proper compliance.

General Manager: _____

Date: _____

QA Manager: _____

Date: _____

D. APPENDIX D. EXAMPLE NON-INTACT RAW MATERIAL TRACKING LOG

Non-Intact Raw Material Tracking Log

Date

TIME	SUPPLIER	EST #	PRODUCT DESCRIPTION	LOT CODE, PACK DATE, BEST BY, USE BY DATE	NUMBER OF PIECES	PROCESSING LINE	INITIALS	CORRECTIVE ACTION / COMMENTS

Verified By: _____

Date: _____