



DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2018-0033]

Availability of Two Revised Guidelines for Minimizing the Risk of Shiga Toxin-Producing *Escherichia Coli* (STEC) in Beef Slaughter and Processing Operations

AGENCY: Food Safety and Inspection Service, Agriculture (USDA).

ACTION: Notice of availability and response to comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing that it has updated two of its guidelines for minimizing the risk of Shiga toxin-producing *Escherichia coli* (STEC) in beef slaughter (including veal) and processing operations. Additionally, FSIS is responding to comments on the guidelines.

ADDRESSES: Downloadable versions of the guidelines are available to view and print at

<https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/guidelines>. No hard copies of the guidelines have been published.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development by telephone at (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

On March 3, 2017, FSIS announced in the *Constituent Update*¹ the availability of the *FSIS Compliance Guideline for Minimizing the Risk of Shiga Toxin-producing Escherichia coli (STEC) and Salmonella in Beef (including Veal) Slaughter Operations* (hereafter referred to as the beef slaughter guideline). On September 6, 2017, FSIS announced in the **Federal Register** the availability of the *FSIS Compliance Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef (including Veal) Processing Operations* (hereafter referred to as the beef processing guideline).² FSIS published these guidelines to advise small and very small establishments on the best practices for beef slaughter and processing to prevent, eliminate, or reduce levels of fecal and associated microbiological contamination. The guidelines provided information on addressing contamination with STEC and *Salmonella* in raw non-intact beef products and beef products intended for non-intact use. FSIS requested comments on these guidelines.

After review and consideration of all comments, FSIS has made changes to and clarified certain aspects of the guidelines. For example, FSIS removed the word "compliance" from the titles of the guidelines to help clarify that the guidelines are recommendations and do not create any new regulatory requirements. The other revisions are summarized below and are

¹ The March 3, 2017 Constituent Update is located at: <https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-march-3-2017>.

² *FSIS Compliance Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef (including Veal) Processing Operations* can be found at: <https://www.govinfo.gov/app/details/FR-2017-09-06/2017-18847>.

discussed in more detail in the Agency's responses to comments. The revised guidelines are available at the FSIS guidance web page.³ Although comments on these guidelines will no longer be accepted through www.regulations.gov, FSIS will continue to update these documents, as necessary.

Summary of Changes to the Guidelines

Beef Slaughter Guideline

- FSIS clarified that the Agency's recommendations are not regulatory requirements;
- FSIS removed the information pertaining to lymph node harborage of *Salmonella* and will make that information available in other Agency documents that focus on controlling *Salmonella* as a foodborne hazard;
- FSIS removed best practice recommendations on the use of chlorophyll to detect contamination on carcasses and air inflation for binging;
- FSIS clarified the Agency's recommendations on washing cattle to reduce pathogen transfer and added more information on humane handling during cattle washing;
- FSIS added more information on pre-harvest interventions;
- FSIS clarified the Agency's recommendations about when feet, eardrums, and bruises should be removed;

³The FSIS guidance web page can be found at:
<https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/guidelines>.

- FSIS provided more information to support its recommendations on chilling and storage of carcasses and parts;
- FSIS emphasized that it considers the presence of certain STEC strains to be adulterants when they are present in raw non-intact beef products and raw intact beef source materials intended for use in such non-intact beef products or when the intended use is unclear. These adulterant STEC strains include *E. coli* O157:H7 as well as strains that have certain O groups (O26, O45, O103, O111, O121, and O145) and contain two specific virulence genes (stx and eae). This addition was created to clarify FSIS policy regarding STEC in relation to product recalls; and
- FSIS added a section on how “dry aging” can be used as an intervention to reduce pathogens, including STEC.

Beef Processing Guideline

- FSIS clarified throughout the document that the recommendations in the guideline are not regulatory requirements;
- FSIS removed the section on lymph node removal;
- FSIS removed all references to *Salmonella*;
- FSIS added additional examples and scenarios using supplier-based verification programs to illustrate additional verification options for establishments;
- FSIS added a brief question and answer section addressing antimicrobial interventions and retained water in beef trim

intended for grinding, based on concerns expressed by stakeholders to Agency leadership; and

- FSIS added language from FSIS' Microbiology Laboratory Guidebook (MLG), stating that, when testing for STEC, if the initial screen test result is negative for the Shiga toxin gene (stx) or the intimin gene (eae), then the test result is considered to be negative for an adulterant. This addition was created to clarify FSIS policy regarding STEC in relation to product recalls.

Comments and Responses

FSIS received three comments on the beef slaughter guideline from an industry group, a consumer group, and a consumer. FSIS received six comments on the beef processing guideline from three industry groups, two consumers, and a very small establishment. Comment summaries and Agency responses follow.

General

Comment: Multiple industry groups suggested that FSIS revise the guidelines to clarify that the recommendations in the guidelines are not regulatory requirements. The same industry groups stated that FSIS inspectors could incorrectly interpret the guidelines as regulatory requirements instead of best practice recommendations. These same commenters requested that FSIS change the titles of the guidelines to remove the phrase "compliance guidelines" and replace it with "guidance" or "industry guidance" to avoid potential misuse.

Response: As FSIS mentioned above, the Agency removed the word "compliance" from the guidelines' titles. FSIS also included additional text throughout the documents to clarify that the best practices in the documents are not regulatory requirements.

Comment: Multiple industry groups expressed concern regarding the mention of cooking non-intact raw beef products to a level of "doneness" (i.e., rare, medium rare, and well-done), instead of listing recommended internal cooking temperatures. The commenters argued that doneness is not a reliable indicator for food safety and that the guideline would be improved if the levels of doneness were replaced with temperatures and descriptions.

Response: The Agency agrees that visual observation is not a scientifically reliable indicator of food safety. The use of the term "doneness" is to explain to the reader, using plain language, why STEC is an adulterant in some, but not all beef products. Because "rare" and "medium rare" are common descriptive terms describing levels of doneness that indicate non-intact beef products have not been cooked to a validated time/temperature combination sufficient to destroy STEC throughout a product, FSIS did remove the term from the guidance. When describing products that are customarily cooked by the consumer to a well-done state, FSIS made specific reference to validated time and temperature combinations sufficient to destroy STEC throughout the product.

STEC Slaughter Guideline

Comment: One consumer group suggested that the beef slaughter guideline should include more information on veal products and that FSIS should develop outreach materials that focus on the challenges associated with preparing veal products. The consumer group cited recent recalls of veal products to support their argument that FSIS should provide more guidance on veal products.

Response: The Agency maintains that minimizing contamination of the carcass and maximizing decontamination efforts during the slaughter process are the best ways to reduce STEC and *Salmonella* contamination in all classes of beef, including veal. Many of the examples in the beef slaughter guideline should be helpful to establishments that slaughter veal.

FSIS has already published a best-practices document specific for veal slaughter sanitary dressing procedures and antimicrobial interventions.⁴ A reference to the veal slaughter sanitary dressing document has been added to the beef slaughter guideline. FSIS believes that information provided in the beef slaughter guideline and the 2015 best practices document properly addresses concerns over recent recalls associated with STEC in veal. FSIS is not revising the guideline in response to this comment.

⁴ *Antimicrobial Intervention Implementation and Veal Slaughter Establishments: Identified Issues and Best Practices* can be found at: <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/guidelines/2015-0018>.

Salmonella

Comment: A consumer group argued that FSIS should do more to protect consumers from *Salmonella* in beef. The same consumer group argued that FSIS should declare antibiotic resistant (ABR) *Salmonella* strains to be adulterants, just as it declared the six strains of STEC to be adulterants in 2011. Additionally, the consumer group suggested that FSIS update its performance standards for *Salmonella* in ground beef because the current standards are based on outdated studies.

Response: In 2011, the Agency received a petition from the Center of Science in the Public Interest (CSPI) requesting that the Agency declare certain strains of ABR *Salmonella* to be *per se* adulterants, i.e. adulterants in all meat and poultry products, including raw products. FSIS denied the petition without prejudice after determining that the data submitted with the petition was insufficient to support CSPI's request. In 2014, CSPI submitted another petition on the same matter, which FSIS also denied without prejudice.⁵

In the Agency's final response to the 2014 petition, FSIS explained that while the 2014 petition included expanded factual and legal support, the data did not support giving any of the ABR *Salmonella* strains identified in the petition a different status as adulterants than is given to *Salmonella* strains that are susceptible to antibiotics under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) and the Poultry Products

⁵ The link to the CSPI petitions and the Agency's responses is located at <https://www.fsis.usda.gov/policy/petitions>.

Inspection Act (PPIA) (21 U.S.C. 453 et seq.). FSIS also explained in the petition response that the data show that numerous factors, including genetic, environmental, and host-specific factors interact to make a particular strain pathogenic and virulent. Because of this complexity, FSIS concluded that antibiotic resistance alone is not an appropriate basis for determining whether a strain of *Salmonella* should be considered an adulterant in raw meat and poultry products. FSIS further explained that the Agency does not consider ABR *Salmonella* to be an "added substance" within the meaning of the adulteration provisions of the FMIA or PPIA.

More recently, on January 18, 2020, FSIS received a petition submitted on behalf of consumer advocacy groups and private individuals requesting that FSIS issue an interpretive rule to declare certain *Salmonella* serotypes to be *per se* adulterants in meat and poultry products. The petition is available on FSIS' website.⁶ FSIS requested that interested persons submit comments on the petition.⁷ The comment period closed on May 22, 2020. FSIS is analyzing the comments and developing a response to the petition, which it will post on its website.

Regarding the comment on *Salmonella* performance standards for ground beef, FSIS published a **Federal Register** notice on October 28, 2019, to announce and request comments on proposed

⁶ The link to the FSIS Petitions web page is located at: <https://www.fsis.usda.gov/policy/petitions>.

⁷ The link to the January 18, 2020 petition can be found at: <https://www.regulations.gov/document/FSIS-2020-0007-0001>.

pathogen reduction performance standards for *Salmonella* in raw ground beef and beef manufacturing trimmings.⁸ The comment period closed January 27, 2020. The Agency is currently reviewing the comments it received on the notice and intends to respond to comments and announce the final performance standards in a future **Federal Register** document. FSIS is not revising the guidance documents in response to this comment.

Sampling

Comment: An individual consumer submitted questions about FSIS' sampling and testing methods for STEC and *Salmonella*.

Response: FSIS did not address these topics in the beef slaughter guideline. However, more information on sampling and testing methodologies can be found in the *FSIS Compliance Guideline for Controlling Meat and Poultry Products Pending FSIS Test Results*,⁹ *Foodborne Pathogen Test Kits Validated by Independent Organizations*,¹⁰ and the *FSIS Microbiology Laboratory Guidebook (MLG)*.¹¹ FSIS is not revising the guidance documents in response to this comment.

⁸ *Changes to the Salmonella Verification Testing Program: Proposed Performance Standards for Salmonella in Raw Ground Beef and Beef Manufacturing Trimmings and Related Agency Verification Procedures* can be found at <https://www.federalregister.gov/documents/2019/10/28/2019-23473/changes-to-the-salmonella-verification-testing-program-proposed-performance-standards-for-salmonella>.

⁹ The FSIS Compliance Guideline for Controlling Meat and Poultry Products Pending FSIS Test Results can be found at: <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/guidelines/2013-0003>.

¹⁰ The list of test kits that have been validated for detection of relevant foodborne pathogens can be found at: <https://www.fsis.usda.gov/guidelines/2019-0008>.

¹¹ FSIS Microbiology Laboratory Guidebook: <https://www.fsis.usda.gov/news-events/publications/microbiology-laboratory-guidebook>.

Comment: Multiple establishments have sent inquiries to the askFSIS questioning whether the required generic *E. coli* testing under 9 CFR 310.25 is equivalent to STEC testing conducted for HACCP verification. Although these questions were not submitted specifically as comments on the guidelines, we have addressed the issue in the revisions to the guidelines, as they are the best vehicle to communicate guidance to industry stakeholders.

Response: FSIS has added a text box to the verification sections of the slaughter and processing guidelines to explain the differences between STEC testing conducted for HACCP verification and the required generic *E. coli* testing under 9 CFR 310.25. The text box explains how each serves a separate function, and neither is a supportable substitute for the other.

Best Practices

Comment: One consumer group suggested that the beef slaughter guideline emphasize the importance of preventing aerosolization of contamination during "up-pulling" of hides, which is the action generated by a machine that pulls the hide away from the carcass.

Response: The beef slaughter guideline's best practice section on dehiding as posted on September 6, 2017 already included information on preventing aerosolization due to the excessive forces that occur when using mechanical hide pullers. During this process, best practices in preventing cross-contamination include establishing a maintenance program for the mechanical pullers that involves monitoring pullers on an

on-going basis for proper adjustment, installing shields or devoting an employee to holding up a shield, and directing air flow away from the carcasses being skinned to prevent contamination of carcasses with the aerosols created at this step. Because the requested information is already in the guideline, FSIS did not make additional changes to the guidance in response to this comment.

Comment: An industry group argued that the recommendation in the "Best Practices during Cattle Transport, Receiving and Holding" section on washing incoming cattle is flawed. The commenter agreed that washing cattle reduces visual contamination but argued that the guideline provides no support showing that the practice effectively reduces *Salmonella* and STEC contamination.

Response: FSIS has revised the beef slaughter guideline to clarify that washing cattle may be considered a means to reduce visible contamination, but this practice may not necessarily reduce pathogen transfer to the carcass. In addition, FSIS specified that if an establishment decides to wash livestock pre-slaughter, it should ensure the washing is done in a humane manner.

Comment: An industry group questioned language in the beef slaughter guideline suggesting that industry-source cattle from "farms or feedlots that employ one or more production system or feedlot controls [are] shown to reduce the carriage of STEC and *Salmonella*." The commenter also opposed language in the

guideline stating that “effective farm and feedlot management and control can reduce fecal shedding of the organism, as well as reduce the microbial load on the animals in the intestinal tract.” The commenter pointed out that FSIS does not cite any data to support the conclusion that sourcing such cattle will cause a meaningful reduction in the overall prevalence of *Salmonella* and STEC on carcasses or their final products and stated that FSIS should remove the section from the guideline.

Response: FSIS has revised the beef slaughter guideline to add a reference to the 2014 FSIS guideline on preharvest controls for STEC.¹² The 2014 guideline addresses the commenter’s concerns, including the concern about FSIS’ supporting data for its recommendations on pre-harvest interventions.

Comment: An industry group expressed concern about language in the beef slaughter guideline about removing the front and hind feet before making any incisions to remove the hide. The industry group stated that the practice is unnecessary if cattle are not being cradled for skinning. The industry group stated that FSIS inspectors may consider that the best practice recommendation is a regulatory requirement.

Response: FSIS revised the “Best Practices during Hide Removal” section of the beef slaughter guideline to clarify that establishments are not required to remove an animal’s feet first. However, FSIS continues to recommend that when

¹² The 2014 guideline, Pre-Harvest Management Controls and Intervention Options for Reducing Shiga Toxin-Producing *Escherichia coli* Shedding in Cattle: An Overview of Current Research can be found at: <https://www.fsis.usda.gov/guidelines/2014-0012>.

establishments use a bed or cradle for hide removal, establishments remove the front and hind feet before making any other incisions through the hide. These procedures should reduce the potential for cross-contamination of the carcass.

Comment: An industry group expressed concern regarding recommended practices in the beef slaughter guideline related to clamping, bagging tails, bunging before hide removal, and using paper towels to protect the exposed carcass surfaces. While the commenter agreed that it is important to ensure the hide, tail, and bung do not contact the carcass surface, the commenter noted that the recommendations appear to be regulatory requirements and that there are additional methods to protect carcasses from insanitary conditions than FSIS provides in the guideline.

Response: FSIS revised the beef slaughter guideline to convey that FSIS' recommendations are not regulatory requirements and that there are more ways to prevent insanitary conditions than were mentioned in the 2017 guideline. For example, FSIS revised the guideline to state that using hide clips is just one way to prevent hide flaps from contacting the carcass.

Comment: An industry group mentioned that using chlorophyll detection equipment to identify fecal material is outdated and most equipment used for this purpose is no longer commercially available.

Response: FSIS removed the best practice recommendations on the use of chlorophyll to detect contamination on carcasses from the beef slaughter guideline.

Comment: An industry group pointed out that in the "Best Practices during Bunging" section, FSIS recommends that establishments remove the bung during the final part of rumping. While the commenter acknowledged that it is important to ensure the bung is not a source of fecal contamination to the carcass, the commenter questioned why FSIS recommends that bunging be performed at this step. The commenter argued that bunging should happen whenever an establishment can best minimize the risk of contamination.

Response: FSIS modified the beef slaughter guideline to reflect that an establishment could do bunging at other points in the process, besides the final part of rumping, if the establishment minimized the contamination.

Comment: An industry group opposed the guideline's recommendation of using air inflation around the anus/vulvar area to assist in bunging, because, according to the commenter, this practice is not typically performed and could cause greater contamination.

Response: FSIS removed the recommendation of using air inflation.

Comment: An industry group expressed concern regarding the "Best Practices during Head Removal" section of the guideline. The commenter pointed out that FSIS suggests removing the

eardrums before head washing but provides no explanation or documentation as to why any establishment should perform this process before washing and not after.

Response: FSIS revised the text in the beef slaughter guideline to state, "remove horns, pieces of hide and ear drums in a manner to minimize contamination."

Comment: An industry group expressed concern regarding the "Best Practices during Carcass Splitting" section of the guideline. According to the commenter, FSIS recommends removing bruises before carcass splitting, but provides no justification for how removing this material before or after splitting minimizes the risk of STEC and *Salmonella* contamination. The commenter suggested that bruises should be removed at the step in the harvest process most suitable to each individual facility.

Response: In the Agency's experience during inspection, removing organic material, bruises, grubs, and tissue damaged by grubs from the middle area of the back before splitting reduces potential contamination to the split saw, bone, and surrounding tissues. Therefore, FSIS is not making the requested revision.

Comment: An industry group opposed FSIS' recommendation that industry "sanitize saws and knives between each carcass," because, according to the commenter, FSIS provides no explanation as to why this practice effectively reduces STEC and *Salmonella* contamination.

Response: FSIS modified the guideline to clarify that the

practice should be done as necessary instead of between each carcass. FSIS recommends that establishments disinfect the splitting saw after each use on suspect, retained, or diseased carcasses to prevent contamination.

Comment: An industry group stated that the best practices in the chilling section of the beef slaughter guideline are outdated and lack a scientific foundation. The commenter noted that the guideline asserts a carcass should begin chilling within one hour of bleed-out to limit pathogen multiplication but does not provide an explanation or supporting data to demonstrate that this practice will effectively minimize STEC or *Salmonella* contamination.

Response: FSIS revised the guideline to clarify that the one-hour timeline is a recommendation and not a regulatory requirement. The recommended one-hour period from bleed-out to the start of chilling corresponds to a period of slower bacterial growth due to new environmental conditions and is based on the ComBase Growth Predictor Model for generic *E. coli*. According to the ComBase Growth Predictor Model for *E. coli*, if the establishment begins chilling the carcass within this time period, then the establishment may be able to minimize microbial growth during the overall chilling process.¹³

¹³ ComBase Growth Predictor Model for *E. coli* was used to predict the growth of *E. coli* if the bacterium was deposited onto the sterile carcass surface during the hide removal/dressing steps. The Growth Predictor Model predicts the response of a range of pathogens and spoilage microorganisms characterizing the food environment. The parameters selected were left at the ComBase default values of initial level = 3 log₁₀, pH 7, physiological state as recommended by ComBase, and either water activity at 0.997, or 0.6% NaCl.

Comment: An industry group opposed the guideline's recommendations that hot-boning rooms be maintained at 50°F or lower and that product should be chilled and maintained at 40°F or lower. The industry group argued that both recommendations are provided without scientific justification and should be removed from the guideline.

Response: FSIS revised the "Best Practices During Chilling" section of the guideline to clarify that establishments may choose to maintain temperatures other than those recommended in the guideline if they have supporting documentation for their chosen temperature limit. The temperature recommended in the guideline of chilling and storage of product at 40°F or lower is based on the Tompkin paper¹⁴ that shows STEC and *Salmonella* will not grow at product temperatures of 40°F or less.

The recommendation for maintaining a temperature of 50°F or less for a hot-boning room is based on minimizing the potential for bacterial growth during processing. Common industry practice has shown that the colder the temperature, the more the risk of bacterial growth decreases. FSIS is not aware of any specific scientific research on environmental temperatures during hot-boning. Establishments are not required to follow this specific temperature recommendation and can use any temperature as long as bacterial growth is prevented.

Comment: An industry group argued that FSIS did not provide

¹⁴ The Tompkin paper can be found at:
https://meathaccp.wisc.edu/Model_Haccp_Plans/assets/raw_ground/TompkinPaper.pdf.

a scientific basis for the beef slaughter guideline's recommendation that packers should not hold aged-beef for longer than seven days. The commenter argued that the best practice ignores several considerations (e.g., weekends and holidays), and opens the door for an inspector to conclude product held more than seven days is out of compliance.

Response: FSIS revised the guideline to clarify that holding beef for no more than seven days is a recommendation and not a requirement. FSIS chose seven days based on industry practice and Dr. Bruce Tompkin's estimates of the combined effect of temperature and bacterial content on time of spoilage of beef.¹⁵ The revised guideline explains that establishments may hold carcasses for longer than seven days in the cooler before fabrication if they maintain scientific supporting documentation for cooler parameters that take the holding time into account, which may include: temperature, humidity, and air flow (see 9 CFR 417.5(a)(1) or 417.5(a)(2)). In addition, FSIS added a section on "dry aging" of beef to the guideline.

Comment: An industry group suggested that FSIS remove references to antimicrobial interventions, Hazard Analysis and Critical Control Points (HACCP) verification, and HACCP validation. The commenter argued that FSIS should reference FSIS' HACCP systems validation guideline as essential and

¹⁵ Tompkin, R.B. 1996. The Significance of Time-temperature to Growth of Foodborne Pathogens During Refrigeration at 40-50°F. Presented during the Joint FSIS/FDA Conference on Time/Temperature. November 18, 1996 Washington, DC. Available at: https://meathaccp.wisc.edu/Model_Haccp_Plans/assets/raw_ground/TompkinPaper.pdf.

complementary to help reduce the risk of *Salmonella* and STEC contamination.

Response: The beef slaughter guideline provides a link to FSIS' *Compliance Guideline on HACCP Systems Validation*.¹⁶ The validation information provided in the beef slaughter guideline is included as a convenience to the reader and is not a replacement of the HACCP systems validation guideline. No revision was made in response to this comment.

STEC Processing Guideline

General

Comment: An industry group opposed FSIS' recommendation that establishments use a single supplier for each lot. The commenter argued that this is impractical, lacks a scientific basis, and that it does not represent typical or practical industry practices. The commenter argued that this recommendation was included in the guideline to simplify Agency traceback investigations.

Response: FSIS revised the text in the beef processing guideline and removed the wording that suggests using single source material is a "best practice." However, it is important to emphasize that this practice does help in traceback and could limit the scope of a recall.

Comment: A very small establishment stated that it would be too difficult for small and very small establishments to implement the testing recommendations in the guideline because

¹⁶ Available at: <https://www.fsis.usda.gov/guidelines/2015-0011>.

of the costs of lot-by-lot testing. The same commenter also stated that using antimicrobial interventions on a day-to-day basis would be difficult because often the amount of product that needs to be produced is unknown.

Response: The beef processing guideline does not create any new regulatory requirements. Instead, the beef processing guideline presents supportable recommendations that establishments can use to address STEC, including having a purchase specification program to get a Certificate of Analysis (COA) on each lot received. If a COA is not available, then FSIS recommends testing each lot of incoming product, testing each lot of finished product, applying a validated antimicrobial intervention, or treating or washing the product and then trimming the outer surface. There is not one "superior" antimicrobial intervention for STEC. When searching for an antimicrobial treatment to use as an intervention for STEC, establishments should review the supporting documentation available and choose an intervention based on its overall HACCP system. Establishments must effectively control STEC in their production of non-intact beef products. The financial impact of a recall or illness outbreak associated with a failure to control STEC at the establishment could be much greater than the cost of implementing the recommended prevention strategies. FSIS is not revising the guideline in response to this comment.

Comment: An industry group requested that FSIS consider expanding the usability of the guideline for all beef processing

operations, regardless of size.

Response: FSIS has developed these guidelines to help small and very small establishments meet best practice recommendations by FSIS, based on the best scientific and practical considerations. The guidelines are focused on small and very small establishments; however, all FSIS regulated beef slaughter and processing establishments may be able to apply the recommendations in the guidelines. As written, larger establishments may use the guideline. FSIS is not revising the guideline in response to this comment.

Comment: Multiple establishments have sent inquiries to FSIS questioning whether establishments can send product that is positive or presumptive positive for STEC to pet food manufacturers to be processed into animal food product. Although these questions were not submitted specifically as comments on the guidelines, FSIS has addressed the issue in the revisions to the beef processing guideline, as it is the best vehicle to communicate guidance to industry stakeholders.

Response: FSIS has revised the beef processing guidance to clarify that product that is positive or presumptive positive for STEC is eligible to be sent to a pet food manufacturer. FSIS recommends that FSIS-inspected establishments communicate with pet food manufacturers before sending products containing STEC to a pet food manufacturer, so that the pet food manufacturer is aware that the ingredient they are receiving contains a pathogen that will need to be controlled in their finished pet food.

Pet food facilities operate under the jurisdiction of the Food and Drug Administration (FDA). Pet food facilities required to register with the FDA as food facilities must comply with the Preventive Controls for Animal Food (PCAF) regulation, at 21 CFR part 507, unless an exemption applies. Under the PCAF regulation, registered facilities are required, in part, to identify and control any hazards requiring a preventive control that are associated with their incoming ingredients (21 CFR 507.33 and 507.34). As a result, if a pet food facility is receiving ingredients that are or may be positive for STEC, it would be required to identify and evaluate that food safety hazard and implement a preventive control that has been validated to prevent or significantly minimize the hazard (21 CFR 507.34 and 507.47). Pet food facilities exempt from FDA registration requirements or otherwise not subject to the PCAF regulations also have an obligation under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331 and 342) not to introduce adulterated pet food into interstate commerce. As a result, FDA expects such facilities to put in place appropriate processes and procedures to ensure that any animal food they produce using ingredients containing microbiological pathogens is not adulterated.

Lymph Nodes and Salmonella

Comment: Three industry groups commented that the beef processing guideline should focus on STEC, not *Salmonella*. These industry groups suggested that all references to *Salmonella*,

including the section on lymph node removal, be removed from the document, because they may detract from the purpose of the document and confuse the reader.

Response: While *Salmonella* is a pathogen of public health significance and is associated with raw beef products, FSIS agrees with the commenters that the beef processing guideline is designed to describe the best practices for controlling STEC, not *Salmonella*. Therefore, references to controlling *Salmonella*, including the section on lymph nodes, have been removed from this guideline. *Salmonella* control is still addressed in the beef slaughter guideline and additional information may be incorporated into future *Salmonella* specific guidance materials.

Comment: A consumer group asked if FSIS will continue to allow establishments to use lymph nodes taken from meat products for "beef patties" where the ingredients statement discloses that the patties contain byproducts. The commenter urged FSIS to entirely eliminate the exception, or at least require additional disclosure, such as an asterisk on the ingredients statement that is linked to the statement: "beef byproducts have been shown to contain high levels of pathogenic *Salmonella*. Cook thoroughly."

Response: FSIS is not changing its labeling policy. FSIS clarifies in its *Food Standards and Labeling Policy Book*¹⁷ that beef patties may contain beef byproducts if the byproducts are

¹⁷ The FSIS Food Standards and Labeling Policy Book can be found at: <https://www.fsis.usda.gov/wps/wcm/connect/7c48be3e-e516-4ccf-a2d5-b95a128f04ae/Labeling-Policy-Book.pdf?MOD=AJPERES>.

included in the ingredients statement and the ingredients statement immediately follows the product name. Additionally, FSIS already requires establishments to label not ready-to-eat inspected product with safe-handling instructions that state "Cook Thoroughly" (9 CFR 317.2(1)). FSIS is not adopting the commenter's requested warning statement because it could confuse consumers.

Lymph Nodes

Comment: One consumer group suggested that FSIS should conduct more inspection tasks to verify that processors do not mix highly pathogenic lymphatic tissue into beef products because, according to the consumer group, there is research showing that lymphatic tissue harbors high concentrations of *Salmonella* bacteria. One industry group argued that "suggesting/requiring" the removal of "major" lymph nodes lacks sound scientific reasoning, and that a "one size fits all" approach will not work. Rather, the industry group suggested that each packing establishment should use its data to determine the appropriate best practices regarding lymph nodes.

The industry group further argued that there is currently no research showing that lymph nodes are a source of STEC contamination and therefore, requiring their removal would not reduce STEC contamination on carcasses and final products. Additionally, the industry group argued that multiple peer-reviewed scientific studies illustrate that the prevalence of *Salmonella* is not consistent geographically, seasonally, across

production stages, or across individual lymph nodes within each animal. Therefore, the commenter argued that requiring all establishments to remove the six peripheral lymph nodes in all carcasses at all times is not a prudent best practice.

Response: FSIS determined that the inclusion of lymph node removal procedures to assist in the control of *Salmonella* is out of the scope of this document's overall focus on STEC control. Therefore, the Agency removed this section from this document and intends to include it in future guidance materials that focus on *Salmonella* control.

On-going Verification

Comment: Multiple industry groups suggested that the beef processing guideline over-emphasizes the importance of product testing for on-going verification rather than providing detailed options for processors. The commenters stated that this over-emphasis may lead to FSIS inspectors concluding that product testing is mandatory or is the best and only option for on-going verification and that FSIS should clarify, in the guideline, that testing is not a regulatory requirement. One commenter suggested that information about alternatives to testing may be helpful to small and very small establishments and should be included in the guideline. Additionally, the same commenters argued that the guideline should provide more examples of on-going verification besides product testing in the "Scenarios" section of the guideline. Multiple industry groups commented that supplier verification programs should be mentioned as an

alternative to on-going verification.

Response: FSIS did not intend to suggest that testing by the receiving establishment is the only option available. The beef processing guideline was developed to assist small and very small establishments understand STEC controls and verification procedures. The guideline includes detailed discussions on sampling and testing procedures based on the many askFSIS questions that FSIS receives.

In response to comments, FSIS has revised the beef processing guideline to include options for on-going verification other than testing and added an example of on-going verification procedures, other than receiving establishment testing, to Scenario 4. FSIS has modified the "On-going Verification" section and the flowchart to include supplier verification programs as a form of verification.

Comment: An industry group argued that the customary cooking section on page four of the beef processing guideline is confusing and recommended that the words "customary" and "customarily" be removed, as the words have not been adequately defined. The commenter also recommended that the section be segmented into two parts: 1) how the two classes of non-intact products (ground beef and non-intact steak) should be considered regarding cooking instructions and 2) the processing establishment's HACCP plan.

Response: FSIS has revised this section of the guideline, and has divided it into two sections, one on validated cooking

instructions and one on customary cooking practices. The Agency did not remove the words "customary" or "customarily" from the guideline, because they are adequately defined. Additionally, the discussion of customary cooking practices is consistent with the Agency's discussion of customary cooking practices in the January 19, 1999 **Federal Register** notice *Beef Products Contaminated with Escherichia coli O157:H7*.¹⁸ The customary preparation of raw ground beef and non-intact steaks (i.e., cooking to a rare or medium state) does not destroy STEC throughout the product or render the product safe. However, FSIS recognizes that there are some non-intact raw beef products (e.g., raw corned beef) that are customarily cooked by the consumer to a well-done state (i.e., cooked to a time and temperature combination sufficient to destroy STEC throughout the product).

Comment: An industry group suggested that FSIS rewrite the section on outside suppliers to include a more comprehensive discussion of the importance of processing establishments ensuring that their HACCP plans adequately address the use of incoming product for producing non-intact product.

Response: FSIS disagrees with the commenter. The guideline already thoroughly discusses STEC control options for establishments that purchase product slaughtered off-site. For example, the guideline recommends that the receiving establishment have knowledge of the STEC controls applied to the

¹⁸ *Beef Products Contaminated with Escherichia coli O157:H7* can be found at: <https://www.govinfo.gov/content/pkg/FR-1999-01-19/pdf/99-1123.pdf>.

product they are purchasing, as that affects decisions being made in the receiving establishment's HACCP system. FSIS is not revising the guideline in response to this comment.

Comment: Multiple industry groups recommended that FSIS incorporate and reference in the beef processing guideline the recommendations outlined in the November 2016 Beef Industry Food Safety Council (BIFSCO) *Guidance for Purchasers of Raw Beef for Non-Intact Use*. The commenters stated that the BIFSCO Guidance, developed by industry, provides practical guidance to processing establishments producing non-intact product on how to maximize the food safety of raw materials and finished products, as well as how to meet FSIS regulatory requirements. It also includes the components of a supplier verification program.

Response: The beef processing guideline represents FSIS' best practice recommendations and are based on the best scientific and practical considerations. Establishments may choose to adopt different procedures than those outlined in the guideline, such as practices recommended by BIFSCO.¹⁹ FSIS' best practice recommendations are generally consistent with the BIFSCO recommendations. FSIS is not revising the guideline in response to this comment.

Comment: One industry group stated that FSIS should cite the appropriate scientific articles that support the testing frequencies recommended throughout the guideline.

¹⁹ BIFSCO *Guidance for Purchasers of Raw Beef for Non-Intact Use*: https://www.bifSCO.org/Media/BIFSCO/Docs/guidance_for_purchasers_of_raw_beef_for_non-intact_use_final.pdf.

Response: Establishments determine their frequencies for on-going verification procedures based on their specific individual HACCP system. However, the Agency recognizes that small and very small establishments routinely have difficulty in finding scientific support for the frequency of on-going verification procedures as required by 9 CFR 417.5(a)(2). Therefore, the Agency has provided on-going verification frequencies based on past industry practices that provide a safe harbor and starting point for establishments and support for their on-going verification frequency. If an establishment chooses to select an alternative frequency, they may do so if they have supporting documentation for their chosen frequency (see 9 CFR 417.5(a)(2)). As is explained in the guideline, in the absence of an STEC control or preventive measures, establishments cannot rely solely on testing at the frequencies listed in the verification section. FSIS rejects this comment.

Comment: An industry group recommended that FSIS remove the following language from page nine of the beef processing guideline: "Testing of product provides a statistical confidence that the product is not contaminated with STEC. However, negative test results do not provide 100 percent certainty that the product is not contaminated. For that reason, testing is a verification activity that demonstrates that a HACCP system is functioning as intended rather than a control for pathogens." The commenter argued that this language is not pertinent to the discussion on verification testing.

Response: FSIS disagrees with the commenter. The Agency included the information to help small and very small establishments understand that testing alone is not a sufficient control for STEC. FSIS is not revising the guideline in response to this comment.

Comment: An industry group suggested that, on page 10 of the beef processing guideline, FSIS should remove the green call-out box that stated that "In the absence of a control or prevention measures, it is not appropriate for establishments to apply the recommended minimum frequencies. Without a control or preventive measure in place, sampling should occur on a lot-by-lot basis." The commenter argued that there are many options to conduct on-going verification activities that do not include product testing for non-intact products.

Response: The green box was revised to emphasize that, in the absence of an STEC control or preventive measures, establishments cannot rely solely on testing at the frequencies listed in the verification section.

Comment: Multiple industry groups opposed FSIS' recommendation of "frequent sampling at multiple points in the process (e.g., before and after the non-intact processing)." According to the commenters, testing at this frequency may cause confusion or render lotting documentation null and void. The commenters stated that this approach conflicts with downstream verification testing, conducted to verify that the systems in place have been effective in reducing the pathogens of concern

to undetectable levels before the materials are received at the further processor. The commenters further argued that it is unclear how testing before and after non-intact processing provides meaningfully different feedback on supply-side intervention processes and that the establishment should have the flexibility to determine when and where sampling should occur within their HACCP plan to demonstrate process control.

Response: FSIS revised the language in the beef processing guideline to emphasize that sampling and testing should provide evidence regarding the effectiveness of the establishment's HACCP controls.

Comment: An industry group suggested that FSIS revise the last paragraph on page 15 of the beef processing guideline on lotting. The commenter suggested the following revision:

"Following the identification of the affected lot, the establishment is required to ensure that no product that is injurious to health or otherwise adulterated enters commerce. The amount of any additional affected product will be determined based on the establishment's lotting and food safety systems. The implemented corrective actions will depend on whether the positive finding represents a critical control point (CCP) deviation requiring corrective actions per 9 CFR 417.3(a) or an unforeseen hazard requiring corrective actions per 9 CFR 417.3(b)."

Response: FSIS agreed with the commenter and revised the guideline to reflect the commenter's suggestion.

Scenarios

Comment: An industry group recommended that FSIS rewrite Scenario 1 on page 18 to clarify whether the boxed subprimals in the scenario were vacuum packaged and whether the processing establishment went to the supplier's website to determine what food safety documents were available. The commenter argued that these are key points that must be included in the scenario because they reflect the current information the processing establishment would have to consider as they ensure their food safety system is appropriate and meets regulatory requirements. Furthermore, the commenter stated that each of these details would more completely explain the scenario and possibly provide direction to the processing establishment.

Additionally, the same industry group recommended that FSIS should rewrite Scenario 2 on page 18 to clarify whether the boxed beef primals were vacuum packed as it would indicate the supplier did not intend the use to be for non-intact products and whether the certificate of analysis (COA) was received. The industry group noted that intended use of products must be considered by the receiving establishment. The same industry group recommended that FSIS explain in the scenario that no intervention was used. Furthermore, the same industry group stated that if the finished ground beef that tested positive contained trim from these non-intact primals and there was no intervention used to microbially differentiate the non-intact subprimals from the ground beef, FSIS should explain that the

Agency may also investigate the need to recall the non-intact subprimals.

Response: FSIS agreed with the commenter and revised Scenario 1 and Scenario 2 to clarify that the boxed subprimals were vacuum packaged and that the receiving establishment was able to obtain a letter of guarantee from each supplier. FSIS did not specifically mention that the receiving establishment obtained the letter of guarantee from a website because producing establishments can also provide the letter via mail or email.

In Scenario 2, FSIS added additional information indicating that the establishment did not apply any antimicrobial interventions. Lotting and microbiological independence are already addressed in the guideline. The focus of Scenario 2 is on establishments developing a HACCP system that addresses materials from multiple sources used in ground beef product and not the response to positive product or recall potential. The guideline contains a separate section on how establishments should respond to positive product.

Non-intact Classification

Comment: An industry group requested that the beef processing guideline be revised to include cube steak on the list of non-intact products that are "customarily cooked by the consumer to a well-done state." The commenter argued that cubed steak is customarily cooked by consumers to a well-done state and should be included alongside products like meatballs and

"Philly" style steak.

Response: As FSIS explained in the October 7, 2002 **Federal Register** notice *E. coli O157:H7 Contamination of Beef Products*, there is a lack of data on industry and consumer practices for cooking pinned, needled, and blade tenderized steaks and a lack of data on the proportion of industry outlets and consumers that prepare these products according to each of these different methods.²⁰ However, establishments have the option of providing support for how their establishment uses the end-product. The HACCP regulations provide establishments the flexibility to design their HACCP system to fit their procedures, processes, and products. Ultimately, the regulations require the establishment to conduct the hazard analysis (9 CFR 417.2(a)), determine the hazard(s) reasonably likely to occur (9 CFR 417.2(a)(1)), conduct on-going verification (9 CFR 417.4), and support the decisions made (9 CFR 417.5(a)(1)). FSIS is not revising the guideline in response to this comment. *Comment:* An industry group opposed FSIS categorizing diced beef smaller than three-fourths of an inch in any one dimension as non-intact, putting it into a higher risk category. The commenter argued that FSIS did not conduct an assessment to determine the higher risk surrounding diced products smaller than three-fourths of an inch in any one dimension, and that FSIS should not classify this product as non-intact.

Response: The guideline did not create a new classification

²⁰*E. coli O157:H7 Contamination of Beef Products* can be found at: <https://www.govinfo.gov/app/details/FR-2002-10-07/02-25504>.

for diced beef. In 1999, FSIS published the **Federal Register** notice *Beef Products Contaminated with Escherichia coli O157:H7*, which differentiated intact beef cuts from non-intact products.²¹ The meat interior of intact beef cuts remains protected from pathogens migrating below the exterior surface. Pathogens may be introduced below the surface of non-intact beef cut as a result of the processes by which they are made. FSIS considers diced beef products (beef cubes) of less than three-fourths of an inch to exhibit the same food safety characteristics as raw non-intact beef products. Similar to ground beef, when cubes are made smaller-and-smaller, the cubes begin to stick (or clump) together, allowing pathogens previously restricted only to the exterior of the meat to be distributed throughout the mass (or clump) of cubes. FSIS is not revising the guideline in response to this comment.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication online through the FSIS Web page located at: http://www.fsis.usda.gov/federal-register_. FSIS also will make copies of this publication available through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our

²¹*Beef Products Contaminated with Escherichia coli O157:H7* can be found at: <https://www.govinfo.gov/app/details/FR-1999-01-19/99-1123>.

constituents and stakeholders. The *Constituent Update* is available on the FSIS Web page. Through the Web page, FSIS can provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at:

<http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

Congressional Review Act

Pursuant to the Congressional Review Act at 5 U.S.C. 801 et seq., the Office of Information and Regulatory Affairs has determined that this notice is not a "major rule," as defined by 5 U.S.C. 804(2).

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Done in Washington, DC:

Paul Kiecker,
Administrator

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