



Billing Code 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2017-0028]

Availability of FSIS Compliance Guideline for Minimizing the Risk of Shiga toxin-producing *Escherichia coli* (STEC) and *Salmonella* in Raw Beef (including Veal) Processing Operations

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of Availability and Request for Comment.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of and requesting comments on the updated compliance guideline for small and very small businesses on reducing STEC and *Salmonella* in beef and veal operations. The new guideline will assist small and very small beef (including veal) processing establishments understand and comply with the regulatory requirements associated with controlling STEC and *Salmonella* in raw non-intact beef products and beef products intended for non-intact use. The guideline also includes information for establishments and retail stores on developing and maintaining records associated with the production of ground beef.

DATES: Submit Comments on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: A downloadable version of the compliance guideline is available to view and print at <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index> once copies of the guideline have been published.

FSIS invites interested persons to submit comments on this guidance. Comments may be submitted by one of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov/>. Follow the on-line instructions at that site for submitting comments.

Mail, including CD-ROMs: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, Room 8-163B, Washington, DC 20250-3700.

Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E Street SW., Room 8-163A, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name, FSIS, and document title: FSIS Compliance Guideline for Minimizing the Risk of Shiga toxin-producing *Escherichia coli* (STEC) and *Salmonella* in Raw

Beef (including Veal) Processing Operations 2017. Comments received will be made available to the public and posted without change, including any personal information, at <http://www.regulations.gov>.

Docket: For access to background documents or to comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E Street SW., Room 164-A, Washington, DC 20250-3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Roberta Wagner, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

STEC and *Salmonella* are pathogens that are associated with foodborne illness from consumption of non-intact beef products (e.g., ground beef, mechanically tenderized steaks). Although the percent positive rates of STEC and *Salmonella* have decreased, outbreaks and illnesses continue to occur from these products (<https://www.cdc.gov/ecoli/2016-outbreaks.html>).

Raw non-intact beef products present a significant public health risk because they are frequently consumed after preparation (e.g., cooking hamburger to a rare or medium rare state) that does not destroy STEC that has been introduced below the product's surface. Given the low infectious dose of STEC

associated with foodborne disease outbreaks and the very severe consequences of an STEC infection, including serious, life-threatening human illnesses (hemorrhagic colitis and hemolytic uremic syndrome), raw non-intact beef products and those beef products intended for non-intact use are adulterated within the meaning of the Federal Meat Inspection Act when contaminated with STEC unless further processed to destroy this pathogen (64 FR 2803). *Salmonella* does not present the same severe health consequences as STEC, and FSIS does not have a zero tolerance for *Salmonella* in raw non-intact beef products. However, because STEC and *Salmonella* are hazards that have historically occurred in the production of non-intact beef products, establishments that produce these products or products intended for non-intact use must conduct a hazard analysis and determine if these pathogens need to be addressed by its Hazard Analysis and Critical Control Point (HACCP) system. FSIS is making available the updated compliance guideline to assist establishments that produce raw non-intact beef products in designing a HACCP system to prevent, control, and reduce STEC and *Salmonella* to acceptable levels in these products. The guideline helps establishments understand the adulterant status of STEC in beef products, how the product's intended use impacts the hazard analysis, and to develop ongoing verification measures to demonstrate that the HACCP system is functioning as

intended to reduce STEC to below detectable levels. In addition, the guideline provides updated information for establishments responding to STEC positive results to strengthen their food safety systems so that additional positive results do not occur in the product. While the guideline focuses primarily on STEC policy, the procedures described in this document to reduce STEC will also assist establishments in reducing *Salmonella*.

FSIS is also providing information in the updated guidance to assist federal establishments and retail facilities to develop and maintain grinding records as required by the final rule, *Records To Be Kept By Official Establishments and Retail Stores That May Grind Raw Beef Products* (80 FR 79231).

This guideline incorporates all of the above policy updates and includes the most current Agency thinking, and combines and replaces information from the following previously issued guidance documents:

- 1) Draft Guidance for Small and Very Small Establishments on Sampling Beef Products for *Escherichia coli* O157:H7 (August 12, 2008);and
- 2) Sanitation Guidance for Beef Grinders (January 2012).

The target audiences for this compliance guideline are small and very small establishments in support of the Small Business Administration's initiative to provide such establishments with compliance assistance under the Small Business Regulatory Flexibility Act (SBRFA). However, all FSIS regulated beef establishments may be able to apply the recommendations in this guideline.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS Web page located at: <http://www.fsis.usda.gov/federal-register>. FSIS also will make 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 constituents and stakeholders. The Constituent Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an e-mail 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

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Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Done, at Washington, DC: August 31, 2017.

Paul Kiecker,

Acting Administrator

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