



United States
Department of
Agriculture



Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness



Food Safety and Inspection Service:

National Advisory Committee on Meat and Poultry Inspection

NACMPI Charge

FSIS Testing of Boxed Beef Primal and Sub-Primal Products
for Shiga toxin-producing *E. coli* (STEC)

September 24, 2020

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Food Safety and Inspection Service: Overview

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Food Safety and Inspection Service: Summary of Charge

“STEC” is an acronym for Shiga toxin-producing *E. coli*. Some strains of STEC may cause severe illness due to the presence of Shiga toxin and other virulence factors.

STEC can reside in the intestinal track, mouth, hide, and hooves of live cattle, and can be transferred to the carcass during the slaughter dressing process.

It is important to understand that STEC is not inside the raw intact muscle itself. STEC contamination occurs when it is transferred to the meat surface during the dressing process.



Food Safety and Inspection Service: Summary of Charge

- STEC has a low infectious dose.
- Exposure to STEC has been linked with serious, life-threatening human illnesses (hemorrhagic colitis and hemolytic uremic syndrome).
- 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 organisms that have been introduced below the product's surface (*e.g.*, ground beef products, tenderized steaks).



Food Safety and Inspection Service: Summary of Charge

To determine what product to sample, FSIS distinguishes between:

- *intact cuts of muscle that are to be distributed for consumption as intact cuts (e.g., steaks, roasts, other intact cuts)*

OR

- *non-intact products (e.g., needle or blade tenderized steaks, ground beef), as well as intact cuts of muscle that are to be further processed into non-intact products prior to consumption (e.g., beef trimmings used for raw ground beef).*



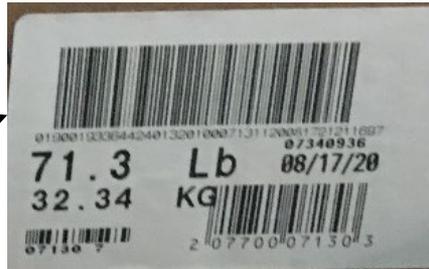
Rare or medium internal state
will eliminate STEC on the **exterior**



Rare or medium internal state
will not eliminate STEC on the **interior**

Food Safety and Inspection Service: Summary of Charge

- Issue:** boxed beef primals intended solely for intact use by the producing establishment are being used to make raw ground beef, resulting in STEC positive ground beef in commerce, illnesses and death.



~2-lb Ground Beef



35-lb Boxed Beef Primal

- Charge:** If an establishment identifies boxed beef primal/subprimal products as intended for intact cuts, should FSIS continue not to sample or test these products?

Food Safety and Inspection Service: Raw Beef and STEC Policy

E. coli O157:H7 and raw beef:

September 1994: In a speech to the American Meat Institute, then-FSIS Administrator, Michael R. Taylor stated,

*“To clarify an important legal point, we consider raw ground beef that is contaminated with E. coli O157:H7 to be adulterated within the meaning of the [FMIA]. We are prepared to use the Act’s enforcement tools, as necessary, to exclude adulterated product from commerce. *** We plan to conduct targeted sampling and testing of raw ground beef at plants and in the marketplace for possible contamination.”* Mr. Taylor further stated, *“We know that the ultimate solution for the E. coli O157:H7 problem lies not in comprehensive end-product testing but rather in the development and implementation of science-based preventive controls, with product testing to verify process controls.”*

FSIS started testing for *E. coli* O157:H7 in ground beef in 1994.

Food Safety and Inspection Service: Raw Beef and STEC Policy

January 19, 1999 *Federal Register*:

- FSIS announced that it would distinguish between:
 - intact cuts of muscle distributed for consumption,
 - non-intact products, and
 - intact cuts of muscle that are to be further processed into non-intact products prior to distribution for consumption.
- *If the latter two types of products are found to be contaminated with E. coli O157:H7, they must be made ready-to-eat (i.e., receive a full lethality treatment), or they will be deemed to be adulterated.*

February 11, 2000 *Federal Register*:

- HACCP regulations require that establishments identify the intended use or consumers of the finished product (9 CFR 417.2(a)(2)).

October 7, 2002 *Federal Register*:

- Even establishments that produce intact product were required to reassess their HACCP plans.

Food Safety and Inspection Service: Raw Beef and STEC Policy

In 2004, FSIS began testing beef manufacturing trimmings and other raw ground beef components for *E. coli* O157:H7 in response to ground beef positives.

In 2007, FSIS began routinely testing beef manufacturing trimmings and other raw ground beef components for *E. coli* O157:H7.

September 20, 2011 *Federal Register*

- FSIS announces that, in addition to *E. coli* O157:H7, six non-O157 STECs (*E. coli* O26, O45, O103, O111, O121, and O145) are adulterants of non-intact raw beef products and raw, intact beef products that are intended for use in raw-non-intact products.

June 2, 2012 - FSIS began analyzing beef manufacturing trimmings samples for non-O157 STEC.

Food Safety and Inspection Service: HACCP and Intended Use

Eligible products that the establishment **intends for use in raw non-intact product or when the intended use is unclear** include:

- **Beef parts of boneless beef of any size in boxes or in combos the producing slaughter establishment intends for raw non-intact use;**
- **Primal cuts the producing slaughter establishment intends for raw non-intact use;**
- **Two piece chucks (i.e., the blade portion and an arm roast from the forequarter individually packaged and placed in to the same container); and**
- **Smaller pieces of trimmings from subprimal cuts.**

Inspection Program Personnel (IPP) are not to sample product that the establishment intends for use in intact or ready-to-eat product, or product that will receive other full lethality treatment at another federally inspected establishment. If the product is to receive a full lethality treatment at another federally inspected establishment, IPP are to verify that the establishment's hazard analysis and flow chart show that the product is intended for one of these controlled uses, and that the establishment has controls that ensure that the product is used as intended. If not, IPP are to collect the sample.

Food Safety and Inspection Service: HACCP and Intended Use

FSIS primarily relies on the establishment to identify each product's intended use, and then FSIS determines FSIS sampling and testing eligibility.

[9 CFR 417.2\(a\)\(2\)](#)

(2) A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified.

A webpage statement or statement on an invoice may read:

[Establishment Name] produces primal products packaged in vacuum bags intended solely for intact use. [Establishment Name] expects any customer who purchases vacuum packaged primals for other than intact product, address that specific usage in their HACCP plan.

14-oz steak



35-lb Primal

Food Safety and Inspection Service:

Food Safety Impact

FSIS finds retailers to be unaware of the intended use of raw beef primals or the risk of grinding such products.

- The statements (webpage or invoice) do not describe the risks associated with grinding boxed beef;
- Retailers do not have HACCP plans;
- Retailers aren't aware boxed beef has an intended use; and
- Retailers do not always buy directly from the establishment.



In 2019, FSIS began collecting intended use data for each retail ground beef sample. The data is entered by FSIS personnel on a questionnaire, for each retail ground beef sample collected. Data show:

- 82% used vacuum packaged primals (in whole or trim thereof) to make the ground beef;
- 83% of the retailers were not aware of the source material's intended use; and
- 93% of the retailers did not apply any STEC controls.

Food Safety and Inspection Service:

Food Safety Impact

Webpage and invoice statements identify boxed beef to be solely for intact use, and FSIS does not sample and test boxed beef intended for intact use for STEC. Evidence shows retailers use boxed beef to make ground beef and do not apply any additional STEC controls.

FSIS does not take action against the producing establishment or retailer when the intended use is not followed. FSIS does take action when an illness occurs or a retail ground beef sample tests positive for STEC.

- Currently, there are over 98,000 retail firms, and FSIS collects ~500 retail ground beef samples each year.

Food Safety and Inspection Service: Food Safety Impact



Intended for
Intact Use

 *Intact cuts of muscle with surface contamination are customarily cooked in a manner that ensures that these products are not contaminated with STEC when consumed. These products are not eligible for FSIS STEC sampling.*



Intended for
Non-Intact Use



Intact products intended for non-intact use are eligible for FSIS STEC sampling.



Fresh
Ground
Beef



Food Safety and Inspection Service:

Food Safety Impact

Since 2014, there have been:

- 3 ground beef positives identified through FSIS retail ground beef sampling, resulting in 3 recalls.
 - In each case, the trace-back revealed the retailers made ground beef from source materials intended for intact use.
- 2 ground beef positives identified through FSIS in-plant testing, resulting in 1 recall.
- 3 illness outbreak investigations (including 1 death), resulting in 3 recalls.
 - In each case, the trace-back revealed the retailers made ground beef from source materials intended for intact use.



In each case described here, the intact products were not eligible for FSIS sampling at the producer and did not remain intact.

Food Safety and Inspection Service:

Summary of Charge

When considering consumer-ready intact steaks and roasts, FSIS is confident that many of the products will remain intact when sold at retail (e.g., individually vacuum packaged steaks). However, larger primals that are intended solely for intact use (i.e., vacuum packaged primals) are being used to make ground beef for sale to consumers.

FSIS is seeking input on how FSIS can reduce STEC positives, outbreaks, recalls, and deaths that occur when downstream processors are commonly unaware of the producer's intended intact use or the risks of grinding such products. FSIS is requesting the Committee's comments and recommendations in response to the following questions:

If an establishment identifies boxed beef primal/sub-primal products as intended for intact cuts, should FSIS continue not to sample or test these products?

Food Safety and Inspection Service:

Summary of Charge (continued)

If Yes, how can the current system be strengthened?

For example:

- What are all of the options producing establishments should have to communicate their intended use to customers?
- What steps should producing establishments take to verify the intended use was both understood, and followed by further processors/grinders? How should this be documented or tracked, so that the establishment and FSIS know the product was used as intended?
- What steps should further processors/grinders take to seek out the intended use information from the producing establishment?
- In addition to verifying HACCP plan reassessment, what actions should FSIS take at the producing establishment when products intended for intact use are used to make raw non-intact beef?

If No, what criteria should FSIS use to determine which products should be subject to sampling and testing for STEC?

For example:

- What are the size/dimension thresholds, cuts or product characteristics (grade, individual v. bulk packaged, etc.) FSIS should use to be confident the product intended for intact use will remain intact through consumer cooking?

For both options:

- What changes to FSIS sampling and testing, HACCP verification instructions, or regulations does the Committee believe would help effect the Committee's recommendations?
- What outreach methods and messages would be most effective to Federal establishments and retail firms?

Food Safety and Inspection Service: Questions?

