

CPG Sec. 555.300 Foods, Except Dairy Products - Adulteration with Salmonella

REGULATORY ACTION GUIDANCE:

The following represent the criteria for direct reference seizure *requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN*:

- a. The lot has been randomly sampled in accordance with the following product categories, as defined in Chapter I of the Bacteriological Analytical Manual:

No. of Sample	Minimum No. of Product Cat. Units Collected	Composite Units Tested
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I	60	4
II	30	2
III	15	1

and

- b. One or more composite units is positive for Salmonella,

and

- c. The sample and analytical controls are negative for Salmonella.

SPECIMEN CHARGE:

The article was adulterated (when introduced into and while in interstate commerce) or (is adulterated while held for sale after shipment in interstate commerce) within the meaning of 21 U.S.C. 342(a)(1), in that it contains a pathogenic microorganism, namely Salmonella, which may render it injurious to health.

NOTES:

1. Direct reference seizures must be based upon samples conforming to the collection criteria established for each specified product category. The criteria of this guide do not preclude examination of lots having fewer containers than the number of sample units specified.
2. Refer to Investigations Operations Manual, Chapter 4, subchapter 400, Sample Schedule - Chart 1 for description of sampling procedures.

3. Test for Salmonella must be in accordance with instructions contained in the Bacteriological Analytical Manual.
4. A copy of the direct reference seizure should be sent to *HFS-605.*
5. Refer to Sec. 527.300 (CPG 7106.08) for compliance guidance on Salmonella in dairy products.

Material between asterisks is new or revised.

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