

Guidance for FDA Staff

Compliance Policy Guide

Sec. 690.800 *Salmonella* in Food for Animals

Additional copies are available from:
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http://www.fda.gov/ora/compliance_ref/cpg/default.htm

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Center for Veterinary Medicine
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I. Introduction:

The purpose of this document is to provide guidance for FDA staff on the presence of *Salmonella* in food for animals. This document supersedes CPG Sec. 690.700 *Salmonella* Contamination of Dry Dog Food.

Food is defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). In keeping with this statutory definition, the term “food for animals” is used in this document to mean: (1) articles used for food or drink for animals other than humans; and (2) articles used for ingredients of any such articles. In this document, “animal feed” is used to mean food for animals other than pet food. Furthermore, for purposes of this document, pet food is used to mean food for pets and includes treats and chews for pets. The policies in this guidance apply to finished animal feed and pet food and the ingredients used to manufacture these products.

This guidance document does not address *Salmonella* in human food. Contact the Center for Food Safety and Applied Nutrition (CFSAN) when *Salmonella* contamination is associated with human food.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word “should” in FDA guidances means that something is suggested or recommended, but not required.

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II. Background:

Salmonella is a rod-shaped, nonspore-forming, gram-negative microorganism consisting of over 2,500 different serotypes (serovars). *Salmonella* has widespread occurrence in animals, especially in poultry and swine. Environmental sources of *Salmonella* include water, soil, insects, factory surfaces, kitchen surfaces, animal feces, raw meats, raw poultry, and raw seafood.

When consumed by humans, *Salmonella* can cause salmonellosis. The symptoms of salmonellosis include nausea, vomiting, abdominal cramps, minimal diarrhea, fever, and headache. Additional information about *Salmonella* can be found in the FDA Bad Bug Book, located on the FDA's website at:

<http://www.fda.gov/Food/FoodSafety/FoodborneIllness/FoodborneIllnessFoodbornePathogensNaturalToxins/BadBugBook/ucm069966.htm>.

Certain food for animals, such as pet food, poses a significant risk to human health when contaminated with *Salmonella*, because humans come in direct contact with these foods. *Salmonella* from such pet food may be ingested directly by humans from their hands or utensils that are contaminated when they feed their pets. Certain vulnerable populations, such as children, the elderly, and individuals with compromised immune systems, are particularly susceptible to acquiring salmonellosis from pet food and may experience more severe symptoms. Additionally, animals may become infected, either asymptotically or clinically, with *Salmonella* from the pet food, thus increasing the potential human exposure.

The association between human outbreaks of salmonellosis and *Salmonella*-contaminated pet foods is well established. The Centers for Disease Control and Prevention reported that from January 1, 2006 to October 31, 2008, 79 human cases of salmonellosis were linked to *Salmonella* Schwarzengrund in dry dog food manufactured by a company in the United States. Health Canada reported that in 2005, cases of salmonellosis in Canada and the United States caused by *Salmonella* Thompson were linked to pet treats contaminated with *Salmonella* Thompson. In addition, Health Canada informed FDA of Canadian outbreaks of human salmonellosis that were linked to *Salmonella* Newport in beefsteak-patty dog treats that were manufactured in Texas in 2002 and to *Salmonella* Infantis in pig-ear dog treats that were manufactured in Canada in 1999.

Salmonella-contaminated animal feed can cause illness in animals that consume the feed. Whether *Salmonella* causes illness in an animal depends on the serotype. Different animal species typically develop disease in response to different serotypes. *Salmonella* serotypes that cause disease in a particular species are referred to as pathogenic for that animal species.

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III. Policy:

FDA considers an animal feed or pet food that may be injurious to health because it is contaminated with *Salmonella* to be adulterated under section 402(a)(1) of the FD&C Act (21 U.S.C. 342(a)(1)). Given the variability in the potential risk that such contamination may pose to human and animal health, FDA's policy for prioritizing regulatory action takes into account certain risk-based criteria, including the type of food for animals that is involved.

FDA believes regulatory action is warranted in cases involving pet foods contaminated with any *Salmonella* serotype, due to the heightened human health risk given the high likelihood of direct human contact with such food.

FDA believes the likelihood of direct human contact with animal feed is substantially lower than for pet foods. Therefore, in cases of animal feed contaminated with *Salmonella*, FDA believes regulatory action is warranted when such cases involve *Salmonella* serotypes that are known to cause disease in the animal species for which the feed is intended. Cases of contamination involving other *Salmonella* serotypes should be considered on a case-by-case basis.

A. *Salmonella*-Contaminated Pet Food – All Serotypes

FDA considers a pet food to be adulterated under section 402(a)(1) of the FD&C Act (21 U.S.C. 342(a)(1)) when it is contaminated with *Salmonella* and will not subsequently undergo a commercial heat step or other commercial process that will kill the *Salmonella*.

The following are some examples of pet food:

- Dog and cat food, aquarium fish food, raw meat and raw poultry formulations for pets
- Pet treats or chews (e.g., dog biscuits, rawhide, pig ears)
- Vitamins, minerals, and other nutritional supplements intended for dogs, cats, and other pets
- Pet food ingredients such as animal products, plant protein products, grain products, vitamin and mineral products.

B. *Salmonella*-Contaminated Animal Feed – Serotypes Pathogenic to Animals

FDA considers an animal feed to be adulterated under section 402(a)(1) of the FD&C Act when it is contaminated with a *Salmonella* serotype that is considered pathogenic to the animal intended to consume the animal feed and the animal feed will not subsequently undergo a commercial heat step or other commercial process that will kill the *Salmonella*. FDA should evaluate cases involving contamination of animal feed with other *Salmonella* serotypes on a case-by-case basis.

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The following are some examples of animal feeds and the pathogenic *Salmonella* serotypes that have been associated with disease in the particular animal species consuming these feeds:

- Poultry feed with *Salmonella* Pullorum, *Salmonella* Gallinarum, or *Salmonella* Enteritidis
- Swine feed with *Salmonella* Choleraesuis
- Sheep feed with *Salmonella* Abortusovis
- Horse feed with *Salmonella* Abortusequi
- Dairy and beef feed(s) with *Salmonella* Newport or *Salmonella* Dublin

IV. Regulatory Action Guidance:

The Districts should consider the following risk-based criteria in deciding whether to recommend seizure or import refusal of a pet food, animal feed, or their ingredients to the Center for Veterinary Medicine (CVM), Office of Surveillance and Compliance, Division of Compliance (HFV-230):

A. Pet Food

1. *Salmonella* is present in one or more subsamples of the pet food or pet food ingredient; and
2. The pet food or pet food ingredient will not be, or information is not available to determine whether the pet food or pet food ingredient will be, further processed with a heat treatment or other method during the commercial manufacturing or processing to eliminate the *Salmonella*.
3. The *Salmonella* is of any serotype.

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B. Animal Feed

1. *Salmonella* is present in one or more subsamples of the animal feed or feed ingredient; and
2. The animal feed or feed ingredient will not be, or information is not available to determine whether the animal feed or animal feed ingredient will be, further processed with a heat treatment or other method during the commercial manufacturing or processing to eliminate the *Salmonella*; and
3. The *Salmonella* is of a serotype that is pathogenic to the animal species for which the animal feed or feed ingredient is intended (see section III.B. of this document).

Contact CVM's Division of Compliance in cases involving animal feed that are positive for *Salmonella* serotypes that are not listed in section III.B. of this document before pursuing further action.

V. Specimen Charges:

A. Domestic Seizure

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

B. Import Refusal

The article of food is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act in that it appears to be adulterated within the meaning of section 402(a)(1) of the FD&C Act in that it appears to bear and contain a poisonous or deleterious substance, namely *Salmonella*, which may render it injurious to health.

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