

Guidance for FDA Staff

Compliance Policy Guide Sec. 690.800 *Salmonella* in Animal Feed *Draft Guidance*

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
Office of Regulatory Affairs**

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Table of Contents

I. Introduction

II. Background

III. Policy

IV. Regulatory Action Guidance

V. Specimen Charges

Guidance for FDA Staff

Draft Compliance Policy Guide Sec. 690.800 *Salmonella* in Animal Feed

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I. Introduction:

The purpose of this document is to provide guidance for FDA staff on *Salmonella* in animal feed. In this document, “animal feed” is used to mean “food”, as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act (the Act), for animals. This includes, but is not limited to, “animal feed” as defined in section 201(w) of the Act. This draft guidance document does not address *Salmonella* in human food.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 the Agency’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 Agency guidances means that something is suggested or recommended, but not required.

II. Background:

Salmonella is a rod-shaped, nonspore-forming, Gram-negative pathogenic microorganism consisting of over 2,400 different types or 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.

A. *Salmonella*-Contaminated Animal Feed – Direct Human Contact

When consumed by humans, *Salmonella* can cause an infection, salmonellosis. The

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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 animal feed, such as pet treats and pet food, that come in direct contact with humans and do not undergo a commercial heat treatment or other commercial process to eliminate *Salmonella* or become contaminated with *Salmonella* after a process microbial kill step, pose a significant risk to human health. *Salmonella* from such feed may be ingested directly by humans from their hands or utensils that are contaminated when they feed their pets or from intentional ingestion of the animal feed. Certain vulnerable populations, such as children, the elderly, and individuals with compromised immune systems, are particularly susceptible to acquiring salmonellosis from such feed and may experience more severe symptoms. Additionally, animals may become infected, either asymptotically or clinically, with *Salmonella* from the feed, thus multiplying the number of bacteria to which humans are exposed.

The association between human outbreaks of salmonellosis and direct human contact with *Salmonella*-contaminated pet food and pet treats is well established. Notably, Health Canada informed FDA of Canadian outbreaks of human salmonellosis that were linked to *Salmonella* Infantis in pig-ear dog treats that were manufactured in Canada in 1999 and to *Salmonella* Newport in beefsteak-patty dog treats that were manufactured in Texas in 2002. 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, the Centers for Disease Control and Prevention (CDC) reported that, between January 1, 2006 and December 11, 2007, 70 human cases of salmonellosis were linked to *Salmonella* Schwarzengrund in dry dog food manufactured by a company in the United States.

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

Salmonella-contaminated animal feed and feed ingredients can cause illness in animals that consume the feed. Young animals are generally the most susceptible to salmonellosis. Salmonellosis infections in these populations are mainly enteric but may become systemic. Salmonellosis infections in adult animals, however, are less common and more likely to be enteric and asymptomatic. Species-adapted *Salmonella* serotypes are much more likely to cause a more severe, systemic disease.

III. Policy:

A. *Salmonella*-Contaminated Animal Feed – Direct Human Contact

When a direct human contact animal feed or feed ingredient may be injurious to health because it is contaminated with *Salmonella* and will not subsequently undergo a commercial heat step or other commercial process that will kill the *Salmonella* (e.g.,

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rendering, pelleting, extrusion, irradiation), that animal feed or feed ingredient should be considered adulterated under section 402(a)(1) (21 U.S.C. 342(a)(1)) of the Federal Food, Drug, and Cosmetic Act (the Act, FD&C Act).

“Direct human contact animal feed” includes animal feed, such as pet food and pet treats, that are intended to be fed to animals in homes, petting zoos, agricultural fairs, and similar venues where the food is likely to be directly handled or may be ingested by children, the elderly, and individuals with compromised immune systems. As examples, direct human contact animal feed includes:

1. Pet treats or chews (e.g., rawhide bones, pig ears, dog biscuits);
2. Pet food (e.g., puppy food, kitten food, aquarium fish flakes, raw meat, and raw poultry formulations for pets);
3. Vitamins, minerals, and other supplements or treats – in the form of pills, boluses, solutions or powders – that are intended for dogs, cats, and other household pets; and
4. Feed intended to be given as food or treats to animals at petting zoos or agricultural fairs by the general public.

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

When an animal feed or feed ingredient may be rendered injurious to health because it is contaminated with a *Salmonella* serotype that is pathogenic to the animal intended to consume the animal feed or feed ingredient, and will not subsequently undergo a commercial heat step or other commercial process that will kill the *Salmonella* (e.g., rendering, pelleting, extrusion, irradiation), that animal feed or feed ingredient should be considered adulterated under section 402(a)(1) of the Act.

Animal feed and feed ingredients that may serve as vehicles for *Salmonella* serotypes that are pathogenic to the animal consuming the animal feed or feed ingredients and *Salmonella* serotypes that are pathogenic to the specific animal include, but are not limited to, the following:

1. Poultry feed with *Salmonella Pullorum*, *Salmonella Gallinarum*, or *Salmonella Enteritidis*;
2. Swine feed with *Salmonella Choleraesuis*;
3. Sheep feed with *Salmonella Abortusovis*;
4. Horse feed with *Salmonella Abortusequi*; and
5. Dairy and beef feed(s) with *Salmonella Newport* or *Salmonella Dublin*.

Young animals are generally the most susceptible to salmonellosis. Milk replacer contaminated with any *Salmonella* serotype may be pathogenic to these populations.

IV. Regulatory Action Guidance:

The following criteria should be considered in deciding whether to recommend seizure or import detention of an animal feed or feed ingredient to CVM, Office of Compliance and Surveillance, Division of Compliance (HFV-230):

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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 it 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* in the animal feed or feed ingredient may be transmitted directly to humans who handle or ingest the animal feed or feed ingredient (see III.A.), or the *Salmonella* is of a serotype that is pathogenic to the target animal for which the animal feed or feed ingredient is intended (see III.B.).

Contact CFSAN in cases involving human food contaminated with *Salmonella*.

V. Specimen Charges:

A. Domestic Seizure

The article of food was adulterated when introduced into and while in interstate commerce and is 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 Detention

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 and deleterious substance, namely *Salmonella*, which may render it injurious to health.

Issued: