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Guidance for Industry

Testing for *Salmonella* Species in Human Foods and Direct-Human-Contact Animal Foods

Note: The title page of this document was corrected on April 30, 2012 to provide information on how to obtain additional copies from the Center for Veterinary Medicine.

Additional copies are available from:

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Center for Food Safety and Applied Nutrition
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5100 Paint Branch Parkway
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<http://www.fda.gov/FoodGuidances>*

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You may submit either electronic or written comments regarding this guidance at any time. Submit electronic comments to <http://www.regulations.gov>. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the Federal Register.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition**

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Guidance for Industry¹

Testing for *Salmonella* Species in Human Foods and Direct-Human-Contact Animal Foods²

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

I. Introduction

This guidance is intended for firms that manufacture, process, pack or hold human foods or direct-human-contact animal foods intended for distribution to consumers, institutions, or food processors. This guidance does not apply to egg producers and other persons who are covered by FDA's final rule "Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation" (July 9, 2009, 74 FR 33030). FDA has issued two separate guidances that in part, address environmental and egg testing for *Salmonella* Enteritidis as required by this final rule. These guidances are entitled "Guidance for Industry: Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage and Transportation," (Ref. 1) issued in December 2011, which provides guidance to egg producers on how to comply with certain provisions contained in the final rule, including provisions for environmental and egg testing for *Salmonella* Enteritidis; and "Draft Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation," (Ref. 2) issued in July 2011, which responds to questions FDA has received on the final rule since its publication and includes guidance on environmental and egg testing for *Salmonella* Enteritidis.

The purpose of this guidance is to address testing procedures for *Salmonella* species (*Salmonella* spp.) in human foods and direct-human-contact animal foods, and the interpretation of test results, when the presence of *Salmonella* spp. in the food may render the food injurious to human

¹ This guidance has been prepared by the Division of Plant and Dairy Food Safety in the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine at the U.S. Food and Drug Administration.

² Direct-human-contact foods are animal foods that are intended for use in feeding animals in homes, petting zoos, agricultural fairs, and similar venues where they are likely to be directly handled or ingested by humans.

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health.³ Under section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 342(a)(1)), a food is deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health. FDA may take enforcement action where food has tested positive for *Salmonella* spp. (Refs. 3, 4 and 5). Prohibitions applicable to adulterated food are contained in section 301 (21 U.S.C. § 331) of the FD&C Act.

Consequences for violations of the FD&C Act may include seizure, injunction, and criminal prosecution (See, e.g., sections 302, 303 and 304 of the FD&C Act (21 U.S.C. §§ 332, 333 and 334)).

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 spp. can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Healthy persons infected with *Salmonella* spp. often experience fever, diarrhea (which may be bloody), nausea, vomiting, and abdominal pain. In rare circumstances, infection with *Salmonella* spp. can result in the organism getting into the blood stream and producing more severe illnesses such as arterial infections (i.e., infected aneurysms), endocarditis, and arthritis. In addition, direct-human-contact animal foods contaminated with *Salmonella* spp. pose a significant health risk to humans who have direct contact with the foods at homes, petting zoos, agricultural fairs, or similar venues.

III. Discussion

Many firms that manufacture, process, pack or hold human foods or direct-human-contact animal foods test the food for the presence of *Salmonella* spp. Where the presence of *Salmonella* spp. in the food may render the food injurious to human health, FDA recommends that firms that test their food for the presence of *Salmonella* spp.:

- Maintain control of a food that is being tested for the presence of *Salmonella* spp., pending the final outcome of that testing, to ensure that the food could be reconditioned, destroyed, or diverted (e.g., to a use in which the food will not be consumed by humans but is fed to animals (as long as such diversion would not adulterate the animal food, and such diversion is not to direct-human-contact animal foods)). For the purposes of this guidance, FDA considers that a firm maintains control of a food if the food has not been transferred to another person (Ref. 6).

³ This guidance does not address how to obtain a representative sample from a designated lot of food. Readers should refer to the discussion of sampling plans in Chapter 1 of Reference 7 for guidance about sampling procedures.

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- Use the cultural method in FDA’s Bacteriological Analytical Manual (BAM) (Ref. 7), or a similarly validated (Ref. 9) non-BAM method, to conduct tests for *Salmonella* spp. in a sample of a food, including safeguards to ensure that the sample is properly taken and handled.
- Be aware that testing for *Salmonella* spp. in food using the cultural method in the BAM (or similarly validated method) can yield one of three results:
 - A presumptive positive result, which is a preliminary result that may or may not ultimately yield a confirmed positive result (i.e., it may yield a negative result). You may perform additional testing, using biochemical and serological methods described in the BAM or similarly validated (Ref. 9) non-BAM methods, on a cultural isolate from any presumed positive sample to obtain a final result. However, you should not have to perform another test or obtain a cultural isolate from a presumed positive sample if you choose to not ship the food based on the presumptive positive result (Ref. 9);
 - A confirmed positive result, which can only be obtained if a presumptive positive result, in the first test stage, is followed by additional testing as described above that results in a confirmed *Salmonella* spp. cultural isolate; or
 - A negative result, which can be obtained if either:
 - The first test stage does not yield a presumptive positive result; or
 - Additional testing, as described above, after a presumptive positive result does not result in confirmation of the presence of *Salmonella* spp.
- Consider any confirmed positive result to be valid (even if subsequent tests on the original sample or other samples from the food are negative), absent other circumstances clearly demonstrating the inaccuracy of the first test result.⁴ There are a number of explanations why a food that is contaminated with *Salmonella* spp. may initially yield a confirmed positive result for *Salmonella* spp. in one test and subsequently yield a negative result for *Salmonella* spp. in one or more additional tests. For example, the distribution of *Salmonella* spp. in the food may not be homogeneous.
- Validate any treatment or process used to adequately reduce⁵ *Salmonella* spp. in a food.

FDA may take enforcement action if we sample a lot of food and one or more composite unit(s) is positive for *Salmonella* spp. (Refs. 3, 4 and 5), even when the manufacturer has previously tested the food and obtained negative results.

⁴ Examples of such circumstances include clear evidence of contamination during sampling (Ref. 8) and clear evidence of laboratory error (such as a test result obtained when a negative control used during the test is positive for *Salmonella* spp.).

⁵ In this document, we use the phrase “adequately reduce” to mean reducing the presence of *Salmonella* spp. to an extent sufficient to prevent illness. The extent of reduction sufficient to prevent illness is usually determined by the estimated extent to which *Salmonella* spp. may be present in the food combined with a safety factor to account for uncertainty in that estimate. For example, if it is estimated that there would be no more than 1000 (i.e., 3 logs) *Salmonella* organisms per gram of food, and a safety factor of 100 (i.e., 2 logs) is employed, a process adequate to reduce *Salmonella* spp. would be a process capable of reducing *Salmonella* spp. by 5 logs per gram of food.

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IV. References

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA. 2011. [Guidance for Industry: Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage and Transportation.](#)
2. FDA. 2011. [Draft Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation.](#)
3. FDA. 2005. Compliance Policy Guide Sec. 527.300, [Dairy Products - Microbial Contaminants and Alkaline Phosphatase Activity.](#)
4. FDA. 1995. [Compliance Policy Guide Sec 555.300, Foods, Except Dairy Products - Adulteration with *Salmonella* \(CPG 7120.20\).](#)
5. [FDA. 1995. Compliance Policy Guide Sec. 690.700, *Salmonella* Contamination of Dry Dog Food \(CPG 7126.17\).](#)
6. FDA. 2010. [Draft Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007 \(Edition 2\).](#)
7. FDA. 2011. [Bacteriological Analytical Manual, November 2011 Version, Chapter 5.](#)
8. ICMSF (International Commission on Microbiological Specifications for Foods) (2002) *Microorganisms in Foods 7. Microbiological Testing in Food Safety Management*, Springer Science + Business Media, LLC, pp. 191-197.
9. FDA. 2011. [Guidelines for the Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods.](#)