

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0091]

Draft Guidance for Industry: Testing for Salmonella Species in Human Foods and Direct-Human-Contact Animal Foods; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Testing for *Salmonella* Species in Human Foods and Direct-Human-Contact Animal Foods." The draft guidance, when finalized, is intended for firms that manufacture, process, pack, or hold human foods or direct-human-contact animal foods intended for distribution to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. The draft guidance does not apply to egg producers and other persons who are covered by FDA's final rule "Prevention of *Salmonella* Enteritidis in Shell Eggs During Production,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." The draft guidance addresses testing procedures for *Salmonella* species (spp.) in human foods (except shell eggs) 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 health.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments concerning the draft guidance by June 21, 2011.

ADDRESSES: Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the draft guidance to the Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY**

INFORMATION section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2022.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Testing for *Salmonella* Species in Human Foods and Direct-Human-Contact Animal Foods." The draft guidance, when finalized, 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. The draft 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" (21 CFR part 118; the shell egg final rule). The draft guidance addresses testing procedures for *Salmonella* spp. in human foods (except shell eggs) 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 health. FDA intends to issue a separate guidance document responding to questions FDA has received on the shell egg final rule since its publication and include in that document guidance on environmental and egg testing for *Salmonella* Enteritidis.

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.

The draft guidance represents the Agency's current thinking on testing for *Salmonella* spp. in human foods and direct-human-contact animal foods. It

does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Always access an FDA guidance document by using the Web sites listed previously to find the most current version of the guidance.

Dated: March 17, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0028]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Ovarian Adnexal Mass Assessment Score Test System; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the special controls guidance entitled "Class II Special Controls Guidance Document: Ovarian Adnexal Mass Assessment Score Test System." This guidance document describes a means by which the ovarian adnexal mass assessment score test system may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify these device types into class II (special controls). This