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Guidance for Industry

Measures to Address the Risk for Contamination by *Salmonella* Species in Food Containing a Pistachio-Derived Product as an Ingredient

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**U.S. Department of Health and Human Services
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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 manufacturers who use a pistachio-derived product as an ingredient in a food product. Pistachio-derived products include roasted in-shell pistachios and shelled pistachios (also called kernels) that are roasted or raw. We are issuing this guidance in light of a recent investigation by FDA and the California Department of Public Health of *Salmonella* species (*Salmonella* spp.) contamination in pistachio-derived products (Refs. 1 and 2). The producer issued a voluntary recall involving a substantial quantity of its products. Because the recalled pistachio-derived products were used as ingredients in a variety of foods, this recall affected many products and resulted in additional recalls.

Salmonella 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* often experience fever, diarrhea (which may be bloody), nausea, vomiting, and abdominal pain. In rare circumstances, infection with *Salmonella* 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.

FDA may take enforcement action, including pursuing product seizure, where food has tested positive for *Salmonella* spp. (Refs. 3 and 4). The circumstances under which food is deemed adulterated are set forth in section 402 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and related prohibitions applicable to adulterated food are contained in section 301 (21

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

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U.S.C. 342 & 331). Consequences for violations of the FD&C Act include seizure, injunction, and criminal prosecution. (See, e.g., sections 301(a) through (c) and section 303(a) of the FD&C Act).

This guidance does not provide recommendations for producers of pistachio-derived products. Importantly, this guidance does not diminish the responsibility of producers of pistachio-derived products to ensure that foods that they produce are not adulterated under the FD&C Act or otherwise in violation of the law. FDA has contacted producers of pistachio-derived products to remind them that our current good manufacturing practice (CGMP) regulations apply to them (Ref. 5).

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. Discussion

A. Considerations for Evaluating the Effectiveness of Certain *Salmonella* Control Measures

Salmonella spp. are bacteria that ordinarily are sensitive to heat and high acidity. This sensitivity is often the basis for food processing used to control the presence of the organism. For example, it takes only 3 seconds to achieve a 5-log reduction in *Salmonella* at 71 °C (equivalent to 160 °F) in fruit juices (Ref. 6).

While considered heat sensitive, *Salmonella* spp. can become heat resistant in dry food products such as powdered milk (Ref. 7) or in low water activity products such as chocolate syrup and peanut butter (Refs. 8 and 9). The water activity of pistachios is generally low; for example, pistachios may be dried to a water activity of 0.82 for short-term storage or 0.70 for long-term storage to prevent mold growth and aflatoxin contamination (Ref. 10). The relationship of *Salmonella* heat resistance to water activity has been well-studied at water activities between 0.99 and 0.85. Generally, *Salmonella* becomes more heat resistant as the water activity of a food becomes lower (Refs. 11 and 12). For example, it takes less than 5 minutes to achieve a 5-log reduction of *Salmonella* at 140 °F in a food with a water activity of 0.99 (Ref. 13). However, it takes 50 minutes to achieve the same reduction of *Salmonella* at 140 °F in a food with a water activity of 0.85 (Ref. 14).

The effectiveness of processing conditions used to reduce *Salmonella* spp. in a particular food containing a pistachio-derived product as an ingredient may depend on whether, and to what extent, the water activity of the pistachio-derived product changes within the food matrix to which it is added. Any *Salmonella* in the pistachio-derived product would be expected to become relatively less heat resistant if the ingredient attained a higher water activity within the food matrix, whereas it would not be expected to respond in this manner if the pistachio-derived

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product retained its initial water activity. Similarly, any *Salmonella* that might move into a higher water activity portion of the food matrix and rehydrate would be expected to become less heat resistant. Therefore, the heat resistance of *Salmonella* spp. introduced through a pistachio-derived product will, upon incorporation into a food matrix, depend upon the nature of the food and the way in which the food is handled during manufacture. For example, *Salmonella* spp. originally present in a pistachio-derived product, which is added and thoroughly mixed into a food such as a bakery product mix, has the potential to move uniformly in the mix, rehydrate, and become less resistant to heat. However, factors affecting the rehydration, such as the amount of time between preparing the bakery product mix and cooking it, could affect the susceptibility to heat of the *Salmonella* spp. during the baking process. In addition, knowing that a baked good is heated at an oven temperature such as 375 °F for a fixed time (such as 10 minutes) does not provide information about the temperature actually achieved at the coldest point in the bakery product, the uniformity of the temperature achieved in the bakery product, and the actual duration of time that the bakery product experienced its maximum temperature.

B. Recommendations

Because procedures used to manufacture finished products containing a pistachio-derived product as an ingredient may or may not adequately reduce² the presence of *Salmonella* spp., FDA recommends that:

- Manufacturers of foods containing a pistachio-derived product as an ingredient obtain pistachio-derived product only from suppliers with processes in place to adequately reduce the presence of *Salmonella* spp.
- Manufacturers purchasing a pistachio-derived product as an ingredient in a form for which no process has been applied to ensure adequate reduction in the presence of *Salmonella* spp. (e.g., raw shelled pistachios), and manufacturers that have purchased a pistachio-derived product about which questions have been raised concerning the potential presence of *Salmonella* spp. in a particular lot or lots, ensure that their own manufacturing process would adequately reduce the presence of *Salmonella* spp. (based upon a combination of time and temperature, or other means). In evaluating the ability of their manufacturing processes to reduce the presence of *Salmonella* spp. in the finished product, such manufacturers should consider the following:
 - Based on the available data and information, the processing conditions appropriate to adequately reduce *Salmonella* spp. in a particular food product vary depending on the specific characteristics of the food product.

² In this document, we use the phrase “adequately reduce” to mean capable of reducing the presence of *Salmonella* to an extent sufficient to prevent illness. The extent of reduction sufficient to prevent illness usually is 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 in the 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.

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- Determining the processing conditions appropriate to adequately reduce *Salmonella* spp. in a particular food product involves considerable expertise in both food microbiology and the physics of heat transfer.
- The most reliable way to determine whether a manufacturing process would reduce the presence of *Salmonella* spp. in a food product containing a pistachio-derived product as an ingredient is to conduct a scientific study to determine the death rate of *Salmonella* spp. in the product using microbiological challenge studies, taking into account properties of the food.
- A history of negative microbiological tests for *Salmonella* spp. in the finished product, while useful in a verification program for a process, is not sufficient, by itself, to determine the adequacy of a process in reducing the presence of *Salmonella*.

FDA is aware that the Grocery Manufacturers Association (GMA), collaborating with other food industry organizations in a *Salmonella* Control Task Force and a Nut Safety Task Force, has recently published two industry guidance documents. The first document reviews and synthesizes information about industry programs in place to control *Salmonella* spp. and help ensure the safety of low-moisture food products (Refs. 15 and 16). The second document (Ref. 17) builds upon the first and provides a comprehensive handbook on the control of food safety hazards for peanut and tree nut shellers, hullers, processors, and manufacturers. Manufacturers that use a pistachio-derived product as an ingredient in a food product may find GMA's documents useful. Please be aware that FDA is not responsible for the content of GMA's documents, which FDA did not create and has not verified.

III. 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. As of August 17, 2011, FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after August 17, 2011.

1. FDA. 2009. [Update on Pistachio Product Recall](#).
2. FDA. 2009. [Pistachio Product Recalls](#).
3. FDA. 2005. Compliance Policy Guide Sec. 527.300, Dairy Products - Microbial Contaminants and Alkaline Phosphatase Activity ([PDF, 103KB](#)).
4. FDA. 1995. [Compliance Policy Guide Sec. 555.300 Foods, Except Dairy Products - Adulteration with *Salmonella* \(7120.20\)](#).
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16. Grocery Manufacturers Association. 2009. Annex to Control of *Salmonella* in Low-Moisture Foods. (available in [PDF](#)).
17. Grocery Manufacturers Association. 2010. Industry Handbook for Safe Processing of Nuts. (available in [PDF](#)).