



APR - 3 2009

Dear Manufacturer:

As you may be aware, an investigation by FDA and the California Department of Public Health (CDPH) of *Salmonella* species (*Salmonella* spp.) contamination in pistachios sold by Setton Pistachio of Terra Bella, Inc., is underway. The company has stopped distribution of, and has issued a voluntary recall involving, a substantial quantity of its products. Because the recalled pistachios were used as ingredients in a variety of foods, this recall affects many products. Further, the investigation may lead to additional recalls.

The contamination involves multiple strains of *Salmonella*. *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. Individuals who are experiencing these symptoms should contact a doctor immediately or go to an emergency room for evaluation.

This letter is to remind you that FDA's current good manufacturing practice (CGMP) regulations apply to processors of pistachio nuts and pistachio products. The CGMP regulations provide in part as follows:

- All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source (21 CFR 110.80).
- Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination (21 CFR 110.80).
- All food that has become contaminated to the extent that it is adulterated within the meaning of the act must be rejected, or if permissible, treated or processed to eliminate the contamination (21 CFR 110.80).
- Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration (21 CFR 110.80(a)(1)).
- Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act (21 CFR 110.80(a)(2)).
- Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling water activity that are taken to destroy or prevent the growth of

undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act (21 CFR 110.80(b)(4)).

The circumstances under which food is deemed adulterated are set forth in section 402 of the Federal Food, Drug, and Cosmetic Act (FFDCA), and related prohibitions applicable to adulterated food are contained in section 301 (21 U.S.C. 342 & 331). Consequences for violations of the act include seizure, injunction, and criminal prosecution. *See, e.g.*, sections 301(a) through (c) and section 303(a) of the FFDCA.

FDA intends to work closely with the pistachio industry to help it understand the risk of *Salmonella* and its regulatory obligations under the laws administered by the agency. Companies may wish to obtain CGMP training from universities, trade associations, or private entities. It is up to companies to evaluate their training needs and decide how best to ensure that they are met. FDA also intends to examine current industry practices to identify and address any practices that may lead to contamination by bacteria of public health significance, and to issue guidance to the industry to provide further information about measures to prevent *Salmonella* contamination.

Sincerely,

A handwritten signature in black ink, appearing to read 'S. Sundlof', written over a horizontal line.

Stephen F. Sundlof, D.V.M., Ph.D.
Director
Center for Food Safety
and Applied Nutrition

Enclosure
Listing of Pistachio Industry Processors

Pistachio Industry Processor List

A&P Growers
26487 North Highway 99
Tulare, CA 93274

Santa Barbara Pistachio Co.
3380 Highway 33
Ventucopa, CA 93252

Arizona Pistachio Company
3865 N Business Center Drive, Suite 115
Tucson, AZ 85705

Setton Pistachios of Terra Bella, Inc.
P.O. Box 11089
Terra Bella, CA 93270

Artois Nut Company
P.O. box 219
Artois, CA 95913

Braga Farms
10668 Road 26 1/2
Madera, CA 93637

California Pistachio Orchards
P.O. Box 569
Kettlehman City, CA 93239

Fiddymment Farms
P.O. Box 245 / 3144 Venture Drive, Suite 500
Lincoln, CA 95648

Keenan Farms, Inc.
P.O. Box 99
Avenal, CA 93204-0099

Monarch Nut Company
786 Road 188
Delano, CA 93215

Nichols Farms
13762 First Ave
Hanford, CA 93230

Paramount Frams
13646 Highway 33
Lost Hills, CA 93249

Pistachio Tree Ranch
7320 U.S. Hwy. 54/70 North
Alamogordo, NM 88310

Primex Farms LLC.
16070 Wildwood Road
Wasco, CA93280