U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Food

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Guidance for Industry: Reducing Microbial Food Safety Hazards For Sprouted Seeds

Contains Nonbinding Recommendations

October 27, 1999

GUIDANCE[1]

All parties involved in the production of sprouts -- seed producers, seed conditioners, and distributors, and sprout producers -- should be aware that seeds and sprouted seeds have been recognized as an important cause of foodborne illness. The following recommendations identify the preventive controls that the Food and Drug Administration (FDA) believes should be taken immediately to reduce the risk of raw sprouts serving as a vehicle for foodborne illness and ensure sprouts are not adulterated under the food safety provisions of the Food, Drug, and Cosmetic Act (the act). Failure to adopt effective preventive controls can be considered insanitary conditions which may render food injurious to health. Food produced under such conditions is adulterated under the act (21 U.S.C. 342(a)(4)). FDA will consider enforcement actions against any party who does not have effective preventive controls in place, in particular, microbial testing.

These recommendations are based on the recommendations of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF, 1999) and elaborate on Compliance Policy Guide 7120.28 (CPG 7120.28).

Seed Production: Seeds for sprout production should be grown under good agricultural practices (GAPs) in order to minimize the likelihood that they will contain pathogenic bacteria. For more information on GAPs, see FDA's 1998 "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables [1]".

Seed Conditioning, Storage, and Transportation: Seeds that may be used for sprouting should be conditioned, stored, and transported in a manner that minimizes the likelihood that the seeds will be contaminated with pathogens. For example, seed should be stored in closed or covered containers in a clean dry area dedicated to seed storage. Containers should be positioned off the floor and away from walls to reduce the possibility of contamination by rodents or other pests and to facilitate regular monitoring for pest problems.

Sprout Production: Sprouters should implement appropriate practices to ensure that sprouts are not produced in violation of the act which prohibits the production of food under insanitary conditions which may render food injurious to health (21 U.S.C. 342(a)(4)). In addition to seed treatment and testing for pathogens (see below), sprouters should maintain facilities and equipment in a condition that will protect against contamination. Facilities with poor sanitation can significantly increase the risk of contaminating product. Sprouters should employ good sanitation practices as a standard operating procedure to maintain control throughout all stages of sprout production. Inadequate water quality and poor health and hygienic practices can all increase the risk of food becoming contaminated with pathogens. Sprouters may wish to review 21 CFR Part 110 which sets forth good manufacturing practices (GMPs) in manufacturing, packaging, or holding human food that cover these aspects of food production.

Seed Treatment: Seeds for sprouting should be treated with one or more treatments (such as 20,000 ppm calcium hypochlorite[2]) that have been approved for reduction of pathogens in seeds or sprouts. Some treatments can be applied at the sprouting facility while others will have to be applied earlier in the seed

production process. However, at least one approved antimicrobial treatment should be applied immediately before sprouting[(3)] . Sprouters should carefully follow all label directions when mixing and using antimicrobial chemicals.

Testing for Pathogens: Because currently approved antimicrobials have not been shown to be capable of eliminating all pathogens from seed, sprout producers should conduct microbiological testing of spent irrigation water from each production lot to ensure that contaminated product is not distributed. Because testing for pathogens can be done with irrigation water as early as 48 hours into what is generally a 3 to 10 day growing period, producers who plan accordingly can obtain test results before shipping product without losing product shelf-life. Testing, whether done by the producer or contracted out, should be done by trained personnel, in a qualified laboratory, using validated methods. Additional information on sample collection and microbial testing, including how to sample and test sprouts when testing spent irrigation water is not practicable (as may be the case with soil-grown sprouts), can be found in a companion guidance document referenced below.

Traceback: Traceback cannot prevent a foodborne illness outbreak from occurring. However, being able to trace a food back to it's source quickly can limit the public health and economic impacts of an outbreak, if it occurs. Information gained in traceback investigations may also help prevent future outbreaks. Sprout producers, seed producers, conditioners and distributors should develop and implement systems to facilitate traceback and recalls in the event of a problem. All parties should test their systems in advance of a real problem.

References and resources

1. Food and Drug Administration. 1982. Compliance Policy Guide Sec. 555.750 Seeds for Sprouting Prior to Food Use, i.e., Dried Mung Beans, Alfalfa Seeds, etc. (CPG 7120.28) can be viewed and printed from the WWW at the following address http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg555-750.html (Updated web reference:CPG Sec. 555.750[2])

2. Food and Drug Administration. 1998. Guidance for Industry -- Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables[3] may be obtained by calling 202-401-9725.

3. Food and Drug Administration, 1999. Press Release -- Consumers Advised of Risks Associated with Raw Sprouts. P99 - 13. http://www.fda.gov/bbs/topics/NEWS/NEW00684.html

4. FDA, 1999. "Guidance for Industry: Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production"[4] can be viewed and printed from the WWW at http://www.cfsan.fda.gov/~dms/sprougd2.htm.

5. National Advisory Committee on Microbiological Criteria for Foods. 1999a. Microbiological Safety Evaluations and Recommendations on Sprouted Seeds[5]. http://www.cfsan.fda.gov/~mow/sprouts2.htm.

6. National Advisory Committee on Microbiological Criteria for Foods. 1999b. Microbiological Safety Evaluations and Recommendations on Fresh Produce. Food Control. 10:117 - 143.

7. Copies of Federal regulations in the Code of Federal Regulations (CFR) may be purchased from the U.S. Government Printing Office or by telephone at (202) 512 - 1800. The CFR is also available at local branches of U.S. Government Printing Office Bookstores. Information on location of regional branches is available on the WWW at the following address: http://www.cfsan.fda.gov/~lrd/ob-reg.html

8. Sections of the CFR, such as 21 CFR Part 110 Current Good Manufacturing Practices in Manufacturing, Packing, or Holding Human Food, can be viewed and printed from the WWW at the following address: http://www.access.gpo.gov/nara/cfr/index.html[6].

Footnotes:

1. This guidance has been prepared by the Office of Plant and Dairy Foods and Beverages in the Center for Food Safety and Applied Nutrition at the Food and Drug Administration. This guidance represents the agency's current thinking on reducing microbial food safety hazards for sprouted seeds. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations. Following the recommendations in this guidance will not shield any person or any food from appropriate enforcement under the Federal Food, Drug, and Cosmetic Act if adulterated food is distributed in interstate commerce.

2. In 1998, the Environmental Protection Agency issued a "section 18" for the temporary use of 20,000 ppm calcium hypochlorite to disinfect seed for sprouting. In the fall of 1999, the exemption was renewed for another year. However, in order to ensure continued availability of this treatment, registrants should be actively pursuing a full registration under section 3 in 2000.

3. Antimicrobials are either pesticides chemicals or food additives, depending on where they are used. As such their use on seeds for sprouting must be approved by EPA or FDA. To find out what antimicrobials have been approved by EPA or FDA for use on seeds for sprouting, you can call 202-418-3098.

For questions regarding this document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1700).

Federal Register Notice of Availability, 64 FR 57893, Guidance for Industry: Reducing Microbial Food Safety Hazards for Sprouted Seeds and Guidance for Industry: Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production October 27, 1999