MICROBIAL TESTING OF SPENT IRRIGATION WATER DURING SPROUT PRODUCTION

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On October 27, 1999, the FDA issued two guidance documents to enhance the safety of sprouts. The first, "Guidance to Industry–Reducing Microbial Food Safety Hazards for Sprouted Seeds," is a broad-based guide, highlighting some of the most important areas of which to be aware, including Good Agricultural Practices (GAPs) for seed production, enhancing sprout production practices, including seed treatment, and microbial testing, where the agency believes immediate action must be taken to reduce the risk of raw sprouts as a vehicle for foodborne illness. The second guide, "Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production," is intended to assist sprouters in implementing one of the principal recommendations in the broader sprout guide; specifically, that producers test spent irrigation water for two pathogens–*Salmonella* and *Escherichia coli* O157:H7–before product enters commerce. Instructions are also provided for the testing of sprouts for those instances when it is not possible to test spent irrigation water. However, for the reasons discussed below, sprouts should not be tested in lieu of water.

WHY TEST?

Salmonella and *Escherichia coli* O157:H7 have been the major causes of at least 14 sprout-associated illness outbreaks in the U.S. since 1995. The number of culture-confirmed cases in each outbreak ranged from eight to more than 500, and more than 1,300 cases have been confirmed overall. Seeds are the likely source of contamination in most outbreaks. Routine use of seed disinfection treatments–such as 20,000 parts per million (ppm) calcium hypochlorite in water–is likely to reduce the level of contamination if pathogens are present in or on seed and, in turn, reduce the risk of foodborne illness from sprouted seed. However, current treatments cannot guarantee total elimination of pathogens. The same conditions that encourage germination and growth of seeds during sprouting–temperature, moisture, available nutrients–also favor growth of bacterial pathogens. If only a few pathogens survive a seed disinfection treatment, they can grow to high levels during sprouting and contaminate the entire batch. Therefore, seed disinfection treatments should be combined with microbial testing to ensure pathogens are not present before sprouts enter the food supply.

SPECIFIC RECOMMENDATIONS

FDA recommends testing of spent irrigation water from every production batch of sprouts. A production lot or batch is defined as sprouts from a single lot of seed that were started at the same time in a single growing unit, such as a single drum or a rack of trays. Spent irrigation water that has flowed over and through sprouts is a good indicator of the types of microorganisms present in the sprouts themselves. The microflora in the irrigation water is fairly uniformly distributed, which simplifies sampling when compared to sampling of sprouts. Spent irrigation water can be used directly in the testing procedures whereas sprouts will require additional preparation. Samples should be collected at least 48 hours after the start of sprouting (including presoak), but preferably not later than 48 hours before harvest. The guide provides information on aseptic sample collection, criteria for who should perform the tests, and corrective actions if a positive presence of *Salmonella* or *Escherichia coli* O157:H7 is found. Sprouters should be aware that the testing program in this guidance involves a number of hazards and should be run only by qualified personnel in a qualified laboratory that is separate from food production facilities.

Contamination of seed is usually low-level and sporadic. Public health officials estimate pathogen levels in contaminated seed to be about four colony-forming units (CFUs)/kilogram of seed. Thus, testing irrigation water from a production lot of sprouts once for each new lot of seed received at a facility, or even occasional testing, is probably insufficient to prevent contaminated product from entering the food supply since the contamination may not be present in the batch tested. In addition, pooling water from different production batches should be avoided, because this may reduce the sensitivity of the tests by diluting the level of pathogens in a contaminated sample with samples that are not contaminated and complicate interpretation of results. Some producers have proposed pooling samples combined with holding back individual samples for analysis if a presumptive positive is found. This may help with interpreting results from pooled samples. However, absent information on the level of pathogens in spent irrigation water that has flowed through naturally contaminated seed and the detection limits of various tests, FDA continues to be concerned about the potential for pooling to reduce the sensitivity of tests.

The testing procedures described in the guide are screening tests. They were chosen to give results as quickly and as simply as possible on the presence or absence of the two previously mentioned pathogens. All of these tests involve an enrichment step to encourage the selec-

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tive growth of pathogens, if they are present, to make their detection possible. Sprouts and their irrigation water have a high level of natural microflora. FDA is not aware of any test kits that will detect pathogens in spent irrigation water when an enrichment step is not performed. If alternative kits are used, they should first be validated either by formal collaborative studies or by comparative studies with standard methods described in the FDA *Bacteriological Analytical Manual* (BAM) using the spent irrigation water or sprouts.

IMPLEMENTATION

Because of the seriousness of public health concerns, FDA implemented its guidance immediately upon publication. As with all guidance, comments may be submitted at any time. This guidance represents FDA's current thinking on reducing microbial food safety hazards for sprouts. An alternative approach may be used if it satisfies the requirements of the applicable statute and regulations.

A number of comments asked for clarification on the types of products covered by the guidance. The guidance covers all raw sprouted seed. In its consideration of the microbial hazards associated with sprouted seed, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) included wheatgrass grown in soil. FDA has no information to exclude sprouts grown in soil from its recommendations. Care must be taken to ensure soil does not introduce additional hazards, however. Although most sprouts are sprouted for an average of three to 10 days, some seeds and beans are sprouted for a shorter time (24 hours) to produce a slightly sprouted product, sometimes called "crunchy salad mix." The conditions that encourage bacterial growth in other sprouting operations (moisture, temperature, available nutrients) also apply to these products. In fact, although peak levels usually occur at about 48 hours after the start of sprouting, the greatest amount of growth likely occurs in the first 24 hours. Producers sprouting product for less than 48 hours should sample as close to 48 hours as possible.

FDA will closely monitor the safety of sprouts and the adoption of enhanced production practices as outlined in the guidance. Failure to adopt effective preventive controls can be considered processing under insanitary conditions that may render food injurious to health. As more effective treatments and other food safety controls are identified and implemented, the current recommendation to test irrigation water from every production batch of sprouts may be changed, such as recommend periodic microbial testing as a tool for validating the effectiveness of food safety systems.

FDA is working with the California Department of Health Services to develop an educational video to assist all interested parties in improving the safety of sprouts. Sprout guidance and information about the video can be found on FDA's web page at http://vm.cfsan.fda.gov.

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