State of California—Health and Human Services Agency
California Department of Public Health

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Director

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Dear Sprout Manufacturer:

Three recent sprout recalls involving contaminated sprouts have reaffirmed the potential for foodborne illness from sprouts. The purpose of this letter is to make you aware of the Food and Drug Branch's (FDB)'s concerns with the manufacture of these products and the importance of evaluating and controlling all known hazards in these processes to minimize the risk of adulteration. FDB strongly urges you as a processor of sprouts to immediately conduct a thorough review of your current practices and procedures to ensure the safety of these products. Recent investigations of California sprout processors have identified several critical areas that are cause for concern. These observations include:

1. Lack of understanding and implementation of the current United States Food and Drug Administration's (USFDA) recommended test and release procedures.

   If a manufacturer uses a screening test method and obtains a positive pathogen test result from spent irrigation water or finished product, then manufacturers are advised to either (1) destroy all product from that production lot and thoroughly clean and sanitize sprouting equipment or (2) conduct a confirmatory test using a qualified laboratory and hold all affected product until the confirmatory test results are received. If the FDA approved confirmatory tests are negative using an experienced, qualified laboratory, then the lot may be shipped.

   You may obtain a copy of the USFDA *Guidance for Industry – Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production* (http://www.cfsan.fda.gov/~dms/sprougd2.html)

2. Lack of procedures to thoroughly evaluate, screen or test incoming seed lots before use.

   As you are aware, seeds are considered the most likely source of contamination in most sprout-associated outbreaks. Yet, we continue to see sprouters who purchase seed without requirements or procedures in place to evaluate the seed before use.

Some sprout growers may require or obtain a negative test on each incoming shipment of seed. However, many only require 25 grams of seed to be tested from a lot composed of several thousand pounds of seed. Because the sample size is so small, and pathogens are likely not uniformly distributed throughout the lot, the probability of detecting pathogens in a large seed lot, using a single 25 gram sample, is very low if pathogens are indeed present.

Although there are currently no USFDA guidelines or state statutory requirements in this area, the incoming seed represents a known hazard that should be addressed with an effective and statistically valid procedure for evaluation of seeds prior to use. These procedures should include visual examination of the seed bags and examination of a representative sample of seeds from the lot for evidence of contamination, such as rodent urine or holes in seed bags, rodent droppings, or insects. If evidence of contamination exists at this stage, sprout growers should consider declining the lot. Further assessment should include testing of a statistically valid sample of incoming seed, and/or testing of spent irrigation water from a statistically valid sample of sprouted seeds before acceptance/use of the entire lot.

3. Using untrained and inexperienced staff to oversee the food safety efforts within the sprout manufacturing facility.

   Sprout manufacturers should ensure that supervisors or other employees have adequate knowledge of and receive frequent training in Good Manufacturing Practices and current sprout production guidelines.

4. Inadequate understanding of and inadequately designed laboratory space to conduct microbiological screening tests in-house.

   Sprout manufacturers should not attempt to conduct microbiological screening tests in sprout manufacturing facilities without a well-designed, dedicated laboratory space and thorough training in and understanding of microbiological principles including aseptic sampling, prevention of cross contamination, and positive and negative controls.

5. Lack of adequate documentation pertaining to seed lot use, disinfection, test results, cleaning and sanitizing, and destruction of product that tested positive for pathogens.

   When a recall is requested, we have found that many manufacturers' records are inaccurate or incomplete. Incomplete documentation will frequently result in a much broader recall of all sprouts because the manufacturer was unable to determine which sprout lots were linked to the positive pathogen test result.

Sprout manufacturers should maintain legible, detailed daily records that clearly indicate:

i. The specific seed lot that was used to manufacture each lot of sprouts. This record should include the lot codes of the seed, name, address and telephone number of the seed supplier. This record should also include the results of the seed evaluation conducted prior to use.
ii. The date the seed lot was disinfected, the identification and concentration of the chemical that was used for seed disinfection, the written procedures for disinfection of seed, and a copy of the seed disinfection log.
iii. Initial and confirmatory test results for all spent irrigation water and finished product testing. This documentation should include the sprout lot code (linked to the seed lot used), the test date(s), the test result(s), who completed the testing, and the test method.
iv. Cleaning and sanitizing records thoroughly documenting the steps taken to clean and sanitize sprout equipment and the methods used to verify the effectiveness of the cleaning and sanitation. This is especially important following a positive pathogen test result. These records should include the specific equipment that was cleaned and sanitized, the cleaning methods, the name of the supervisor, and the type of chemical that was used for sanitizing.
v. Records of destruction of lots that tested positive for a pathogen. These records should include the specific sprout lot codes that were destroyed, the seed lots from which the sprouts were produced, the method of destruction, the date of destruction, and the individual for oversight of destruction.

Additional resources for sprout manufacturers include: USFDA *Guidance for Industry – Reducing Microbial Food Safety Hazards for Sprouted Seeds* (http://vm.cfsan.fda.gov/~dms/sprougd1.html)

I urge you to carefully re-evaluate your current food safety efforts. Our investigators will be inspecting sprout production facilities in California during the next several months to ensure compliance with Good Manufacturing Practices.

If you have questions, please feel free to contact me at (714) 558-4595.

Sincerely,

Jane Marie Pettit, M.P.H.
Chief, Food Safety Inspection Unit
Food and Drug Branch