



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFI-35

Public Health Service
Food and Drug Administration

g1018d

March 20, 2001

1990 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L 31-01

Ms. Nurit Berger,
Operations Manager/Owner
Kowalke Family Sprouts
1956 Old Topanga Road
Topanga, CA 91304

Dear Ms. Berger:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your sprout growing facility located at 21217 Chase Avenue, Canoga Park, CA on July 17 and 19, 2000. The inspection revealed that your sprouts are adulterated within the meaning of 402 (a)(4) of the Federal Food, Drug and Cosmetic Act (the Act) in that they have been prepared, packed or held under insanitary conditions whereby they may have been contaminated with filth or whereby they may have been rendered injurious to health. The sprouts are considered adulterated since effective controls, particularly microbial testing for pathogens, have not been adopted and implemented by your firm.

In the case of ready-to-eat sprouts, the agency has determined that microbial testing for *Salmonella* and *Escherichia coli* 0157:H7 is necessary and should be conducted (and found negative) prior to release of these food products into domestic commerce, and that this testing is an appropriate quality control operation. Our current guidance recommends that this testing should be conducted on each lot of sprouts at specific growing periods, and is the most effective means to detect these harmful bacteria in the food. A production lot or batch is defined as sprouts from a single lot of seed that was started at the same time in a single growing unit (e.g. a single drum, or rack of trays).

During our inspection, you questioned whether the FDA considers your "salad greens" (Daikon radish, safflower, pea sprouts, and wheat grass) to be sprouts that should adopt current guidance to enhance their safety. FDA considers these soil-grown products to be sprouts, as Daikon (white radish), peas, and wheat grass were specifically identified in the National Advisory Committee on Microbiological Criteria for Food's (NACMCF) evaluations and recommendations on sprouted seeds.

In the guidance document, "Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production," FDA provides information to assist sprouters on how to sample and test sprouts when testing of spent irrigation water is not practicable, as may be the case with soil-grown sprouts. All sprouters should implement appropriate practices to ensure that sprouts are not produced in violation

of the Food, Drug, and Cosmetic Act which prohibits the production of food under insanitary conditions which may render food injurious to health.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, such as seizure and/or injunction.

For your information, a number of observations made during the referenced inspection of your sprout facility could deem the food products produced at your facility adulterated with the meaning of the Act. These conditions include:

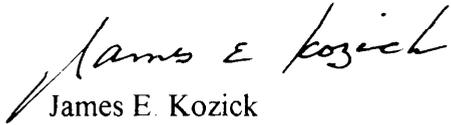
- Use of non-sterile soil for your soil-grown sprouts. Your soil consists of both composted soil prepared on-site and prepackaged, non-sterile potting soil. Current guidance recommends the use of sterilized growing soil for use with soil-grown sprouts to reduce the possibility of contamination with pathogenic bacteria.
- Failure to perform a sanitizing pre-treatment to your sprout seeds before germination. This pre-treatment could reduce the number of pathogenic bacteria in contaminated seed lots.
- Utensils (e.g. shovels) used to mix and spread soil into growing trays are stored directly on the greenhouse floor. This floor is composed of packed soil with mud and rotting vegetative matter.
- Equipment such as buckets and growing trays are stored directly on the greenhouse floor. This floor is composed of packed soil with mud and rotting vegetative matter. In addition, soil preparation takes place directly on these dirt floors. These practices could contribute to contamination of your sprouts.
- Plastic growing trays used in production or ready-to-eat sprouts are stored in a manner that could contribute to contamination. Specifically, these trays were observed stored uncovered in the open grounds of the facilities adjacent to greenhouses.
- The area behind the northernmost greenhouse has accumulated debris and plant matter that could contribute to contamination of your sprouts by providing harborage areas for vermin such as rodents and insects.
- Your sprout growing facilities are not enclosed to provide an adequate barrier to exclude vermin from entering and possibly contaminating your ready-to-eat sprouts. Live birds and numerous insects (both alive and dead) were observed inside your greenhouses containing exposed, growing sprouts.
- No hot water is available to employees handling your ready-to-eat sprouts. Thus, you do not have adequate hand washing and sanitizing facilities in your sprout growing operations. In addition, no hand drying devices (e.g. single service paper towels) were observed at the current handwashing station.

The FDA considers ready-to-eat sprouts a food commodity that is unique from other raw agricultural products due to the foodborne illness outbreaks that have been associated with these products. As such, we hope that you will work with the agency and fellow sprout growers in adopting and implementing the FDA's guidance in their production and handling. We apologize for the delay in issuance of this letter, but feel that the issues brought forth during the inspection are of such significance that issuance is necessary for the protection of the sprout-consuming public.

Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your written reply should be directed to the Director, Compliance Branch, U.S. Food & Drug Administration, 19900 MacArthur Blvd, Suite 300, Irvine, CA 92612-2445.

Sincerely,



James E. Kozick
Acting District Director

cc: California Department of Health Services, Food & Drug Branch
601 N. 7th Street
Sacramento, California 94234-7320
Attn: Stuart Richardson, Jr., Chief