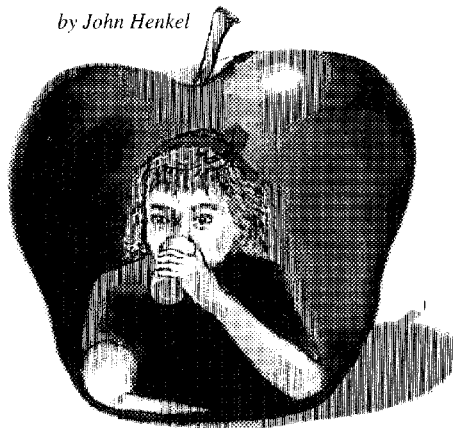




## Juice Maker Fined Record Amount For *E. Coli*-Tainted Product

by John Henkel



A California juice company was fined \$1.5 million after pleading guilty to 16 misdemeanor criminal charges related to a 1996 outbreak of dangerous *Escherichia coli* O157:H7 bacteria. One child died and 14 other children were seriously sickened after drinking the company's fresh, unpasteurized apple juice.

The fine is one of the largest ever imposed in FDA history for a food injury case, and the criminal conviction by federal prosecutors is one of the first ever obtained in a large-scale outbreak of infectious pathogens.

Odwalla Inc., of Half Moon Bay, agreed in a criminal plea bargain in July to pay the fine and serve five years of court-supervised probation. The plea agreement, filed in the U.S. District Court for the Eastern District of California, also requires Odwalla to implement a Hazard Analysis and Critical Control Point (HACCP) plan in its facility. HACCP is a food safety system that identifies potential food safety hazards

and specifies controls for preventing these hazards.

A \$250,000 portion of the fine will be divided between a charitable organization, Safe Tables Our Priority (STOP), and the food safety research centers of the University of Maryland and Pennsylvania State University. The funds will be used to raise consumer food safety awareness and research the safety of fresh produce.

The tainted juice affected consumers in Colorado, California, Washington state, and British Columbia: Fifteen children who drank the juice developed the life-threatening condition hemolytic uremic syndrome (HUS), a leading cause of kidney failure in children. One of the children, a 16-month-old Colorado girl, died from HUS-related multiple organ failure. At least 51 others were sickened, but to a lesser degree. Food safety experts say survivors of this strain of *E. coli* may have significant health problems for years.

In late October 1996, FDA received

word that the health departments from the three affected states had identified an *E. coli* O157:H7 outbreak. Washington state health officials also told FDA that using DNA "fingerprinting" methods, they had clustered 15 related cases of *E. coli* infection in which all the victims had reported drinking Odwalla apple juice.

When notified of these findings, Odwalla began a recall Oct. 31 of all its apple juice products. At the same time, FDA launched a 14-month investigation. An investigator with FDA's San Francisco district office, Helen Hamaoka, inspected the Odwalla plant and collected apple juice samples, which were shipped to FDA's analytical laboratory in Seattle. Tests showed the samples were negative for *E. coli* O157:H7. Hamaoka noted, however, that the company had ignored safety standards by centering its product testing more on shelf life than bacterial contamination.

On Nov. 5, 1996, FDA's Seattle district laboratory analyzed samples of juice found in an Odwalla warehouse in Washington state. One sample that came from juice processed around Oct. 7, 1996, tested positive for *E. coli* O157:H7. The laboratory analysis enabled FDA to link the *E. coli* outbreak positively to Odwalla juice.

As part of its criminal investigation of Odwalla, FDA's Office of Criminal Investigations began interviewing former

Odwalla employees, suppliers, and others familiar with company operations. Their comments indicated that Odwalla had in the past had numerous deficiencies in its sanitation procedures. For example, accepted industry practice calls for use of a chlorine solution for washing and sanitizing fruit, but Odwalla had stopped using chlorine and was instead using phosphoric acid, which may not be effective as a fruit wash.

OCI also learned that the U.S. Army had rejected a contract with Odwalla in June 1996 after Army analysis identified a high bacterial count in an Odwalla product.

OCI also discovered that a consultant hired by the company had uncovered *Listeria* and other bacterial contamination in the processing plant during weekly microbiological tests he conducted between May 1994 and December 1995. OCI learned that Odwalla initially tried to identify and eliminate the source of the *Listeria* contamination but ultimately focused on extending shelf life without ever conclusively solving the contamination problem. Records showed that Odwalla had used an inferior grade of apples, which may have made the juice more prone to contamination.

After determining that Odwalla's operations created an environment within which *E. coli* O157:H7 could exist, OCI's investigation centered on deter-

mining the source of the contamination. Though officials could not pinpoint the exact source, several theories emerged. Among them:

- The apples used to make the juice were contaminated with animal fecal material.
- The wooden crates used to ship the apples were contaminated.
- Odwalla employees failed to wash their hands properly after using the bathroom and before returning to production areas.

As part of the consent decree, Odwalla implemented a HACCP plan whose provisions include:

- maintaining sanitary conditions to avoid food contamination
- a written sanitation control program run by a qualified manager
- a comprehensive employee training program in areas such as proper food handling and personal hygiene.

In June 1997, Hamaoka inspected Odwalla again and took juice samples and swabs from the company's equipment for analysis. The samples proved negative for *E. coli*, and Hamaoka noted that the company had begun using more effective sanitation methods.

FDA will continue to inspect Odwalla regularly to ensure HACCP compliance.

*John Henkel is a staff writer for FDA Consumer.*

## Phony Doc Sentenced To Real Jail Time

A man who posed as a doctor and claimed to have hundreds of thousands of patients worldwide was put out of business after FDA officials discovered the impostor had been diagnosing and treating nonexistent conditions and pur-

chasing and selling unapproved drugs since 1989.

Edwin E. Kokes, owner of Independent Testing Labs of Grand Island, Neb., was sentenced Aug. 19, 1998, in the U.S. District Court for the District of Nebraska to two and a half years in prison and three years of supervised release for sending unapproved drugs and

diagnostic analyses through the mail. He also was fined \$5,000 and ordered to pay \$80,000 in restitution to his victims.

According to the case agent in FDA's Office of Criminal Investigations, the 63-year-old Kokes generated nearly \$1 million in seven years by claiming that he could diagnose and treat such medical conditions as AIDS, cancer and aller-