New Juice Regulations Underway

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Each year Americans experience 16,000 to 48,000 cases of foodborne illness from fruit and vegetable juices, according to Food and Drug Administration (FDA) estimates. Increasing public concern and recent outbreaks from bacteria such as *E. coli* O157:H7 have led to new regulations designed to reduce the risk of juice contamination.

In October 1996, at least 66 people in the Western United States and Canada became ill and a 16-month-old girl died after drinking unpasteurized apple juice contaminated with *E. coli* O157:H7. The company that produced the juice pleaded guilty to violating Federal food safety laws and will pay a record $1.5 million fine.

The outbreaks from contaminated juice, particularly this 1996 *E. coli* O157:H7 outbreak, led regulators to examine the safety of juice. In April 1998, FDA proposed two regulations to increase the safety of fresh and processed juices. The first would require all domestic and foreign fruit and vegetable juice processors to use Hazard Analysis and Critical Control Point (HACCP) procedures to prevent, reduce, or eliminate hazards in juice. The second rule, requiring warning labels on all juice that has not been pasteurized or otherwise treated to control illness-causing pathogens, was finalized by FDA in July 1998. Its purpose is to provide consumers with information to lessen their risk until the HACCP rule is enacted.

Are All Juices Equally Safe?

Juice consumption in the United States has steadily increased from 5.8 billion gallons in 1987 to 7.5 billion gallons in 1997. Currently, almost all juice sold in the United States is heat pasteurized, a process that raises the temperature of the juice high enough to kill pathogenic bacteria. Only about 2 percent of juices are not pasteurized. In addition to killing pathogens, pasteurization or equivalent heat treatments destroy enzymes and naturally occurring spoilage organisms, thus making the product more shelf-stable.

Most refrigerated juice sold in bottles or cartons at grocery stores and other outlets is pasteurized. Unrefrigerated juice in bottles, cans, and laminated paperboard boxes has been heat-treated and is therefore generally considered safe. Frozen, concentrated juices are generally pasteurized during the concentration process.

Farmer's markets and cider mills often sell unpasteurized apple cider. Fresh-squeezed or pressed juice likely has not been processed to specifically control pathogens and therefore may pose some risk, despite a common belief that less-processed products are healthier. A handful of *E. coli* O157:H7 outbreaks have been linked to apple cider. *E. coli* O157:H7, which primarily strikes children, causes a wide range of health outcomes, from mild cases of diarrhea to secondary complications and sometimes premature death. The most serious complication is hemolytic uremic syndrome (HUS), which is essentially kidney failure that may require dialysis and kidney transplants and which may lead to permanent kidney failure and other health problems. Cider made from apple "drops," apples that have fallen to the ground and that might have come into contact with animal feces, such as from cattle or deer, could pose a higher food safety risk than cider made from tree-picked apples.

In 1995 and 1999, there were outbreaks of salmonellosis from unpasteurized orange juice, a product normally considered safe from such bacteria because of its high acidity. Over time, bacteria can develop

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resistance to inhibitory environments (for example, more acid resistance), making food safety precautions even more essential. Most juice-related outbreaks have been from fruit juices, though a 1993 illness from *Clostridium botulinum* in homemade carrot juice was reported in Washington State.

Prior to July 1998, the only mandatory identification for juices was a labeling requirement for pasteurized orange juice; no other juices had to be marked as pasteurized. Consumers of unlabeled juice had not known if they and their families were taking the risk of drinking an unpasteurized product.

Two Regulations Designed To Make Juice Safer

In December 1996, FDA held a 2-day public meeting to review manufacturing practices, science, and technology relating to fresh juices and to consider measures to provide safer fruit juices to the public. After this meeting, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), an independent advisory panel guiding FDA and the U.S. Department of Agriculture on food issues, concluded that juice, particularly unpasteurized juice, poses some safety concerns. The panel recommended that juice processors adopt Hazard Analysis and Critical Control Point (HACCP) procedures.

HACCP procedures use science to identify the steps in the food production chain where food hazards are most likely and to put controls in place to prevent contaminated food from going to the marketplace. The seven principles of HACCP are to (1) conduct a hazard analysis, (2) determine the critical control points, (3) establish critical limits for hazards, (4) establish monitoring procedures, (5) establish corrective actions, (6) establish verification procedures, and (7) establish recordkeeping and documentation procedures.

FDA used the NACMCF input and additional comments from the public and the juice industry to propose two regulations to increase the safety of both fresh and processed fruit and vegetable juices. These proposals were released in April 1998. The first proposed regulation requires all fruit and vegetable juice processors to use HACCP systems to control hazards in juice. There are already existing and soon-to-be-implemented HACCP regulations in the United States for meat, poultry, fish, and fishery products. FDA will evaluate all comments on the proposal and use this information to develop a final HACCP rule for juice, if such a rule is supported by the record.

The second rule concerning juice warning labels was proposed to cover the phase-in time necessary to implement the HACCP regulation. Although the time schedule for the HACCP rule was extended, FDA finalized and published the labeling rule in the *Federal Register* on July 8, 1998, in time for the fall apple cider season, the season when most unpasteurized juice is consumed. This rule requires warning labels on all juice that has not been pasteurized or otherwise treated to prevent, reduce, or eliminate illness-causing pathogens. Both rules target microbial pathogens, such as illness-causing bacteria, though the HACCP rule also controls for physical and chemical contamination.

The Proposed HACCP Regulation

The proposed HACCP regulation targets manufacturers of packaged fruit and vegetable juice. Packaged juice is any container of juice intended for retail sale for consumption outside the retail environment. Therefore, the regulation excludes fresh juice squeezed for consumption on a firm's premises (for example, by the glass), such as juice sold and served in juice bars and restaurants. One part of the proposed HACCP rule requires that packaged juice and juice products be processed in a manner that will produce, at a minimum, a five-log reduction (a decrease of the pathogen by 100,000-fold) in the most resistant pathogen of public health significance likely to occur in juice, for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions. The NACMCF recommended the use of *E. coli* O157:H7 or *Listeria monocytogenes* as the target pathogen, though other pathogens such as *Salmonella* may be appropriate. To date, FDA has not stipulated particular pathogens for the proposed regulation; the selection may depend on the type of juice and the growing region. For example, oranges grown in California may be more or less likely to be contaminated with a particular pathogen than those grown in Florida.

Heat pasteurization will achieve the required five-log reduction. However, processors can choose what risk-reducing methods they want to use—pasteurization, another food safety precaution, or a combination of precautions. For example, processors may reach a five-log reduction in citrus juice through careful culling and sanitizing of the fruit followed by appropriate extraction of the juice.

Processors affected by this proposal include both farms and manufacturers that make packaged juice products. Retailers of packaged juice, growers and transporters of raw products, and small retail processors who sell less than 40,000 gallons of fresh juice per year directly to consumers and other retail establishments may be exempt from this rule. The proposed phase-in period for this regulation varies by firm size, with larger firms

expected to comply earlier than smaller firms.

Warning Labels on Unpasteurized Juice

The warning label regulation targets packaged fruit and vegetable juice. Unpasteurized juice or juice that does not meet the five-log reduction must carry the following warning label:

> ***WARNING:*** This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.

People with weakened immune systems include people who have AIDS, organ transplants, cancer, and other significant health problems. As 98 percent of all juice sold in the United States is pasteurized, the labeling regulation affected roughly 2 percent of juice produced. According to a spokesperson at the U.S. Apple Association, small manufacturers were disproportionately affected because of their inability to afford pasteurization equipment.

The compliance dates for warning labels depend on the type of juice. Following publication of the final labeling rule on July 8, 1998, manufacturers of packaged apple juice and apple cider had until September 8, 1998, to comply, whereas manufacturers of all other unpasteurized juices had until July 8, 1999. However, some juice companies filed agreements with FDA requesting additional time, beyond November 5, 1999, to comply with the warning label requirement. All manufacturers of packaged juice, regardless of size, may temporarily comply by using signs or placards posted at the point of sale for up to 1 year from their respective compliance dates. This temporary alternative gives firms time to make label changes and deplete existing label inventories. According to the U.S. Apple Association, many firms producing unpasteurized juices began pasteurizing their juice instead of opting to use the warning label.

What Firms Are Affected?

Both the proposed HACCP rule and the final labeling rule target juice manufacturers that sell packaged juice in the United States. Neither rule covers firms that squeeze and sell fresh juice for consumption on their premises (by the glass), such as juice bars and restaurants. Grocery stores, health food stores, and other retail outlets that sell fresh-squeezed juice for offsite consumption do not have to specifically treat their juice to control pathogens, but they must use warning labels.

FDA estimates that if both rules are adopted, up to 40 million additional gallons of juice would be pasteurized each year. FDA's preliminary regulatory impact analysis (PRIA) estimates that pasteurization would kill all *Salmonella* and *E. coli* O157:H7 in juice and that 14 percent of all unpasteurized juice would be exempt from the proposed HACCP regulation. FDA estimates that 86 percent of the 4,000 *Salmonella* cases and 1,700 *E. coli* O157:H7 illnesses attributed to juice each year would be prevented by the proposed HACCP regulation; however, only 9 percent of the 2,800 annual *Bacillus cereus* cases from juice would be prevented. Pasteurization and other heat treatments are less effective against *Bacillus cereus* as its heat-resistant spores may produce illness-causing toxins. The PRIA also estimates that the interim labeling regulation would result in a 5- to 16-percent decline in juice consumption and associated juice-related foodborne illnesses. The PRIA concludes that the $3 billion-$4 billion in savings from averted medical costs and lost productivity from the proposed rules outweigh the $240 million cost of implementing the rules.

References

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