

## The Juice HACCP Program: An Overview<sup>1</sup>

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### Juice HACCP Background

Juice HACCP commonly refers to the use of HACCP systems to minimize food safety risks in the juice processing, packaging, and transportation industries. The acronym HACCP stands for *Hazard Analysis Critical Control Point* (pronounced 'hás•sip'). Significant hazards for a particular juice, puree, or concentrate are identified, based upon scientific information. The steps at which these hazards can be controlled within the process are identified, and the critical limits at each of the key process steps are set. Monitoring procedures are implemented to evaluate conformance with these critical limits. Should the process fall outside these limits, pre-planned corrective actions are taken to prevent the potentially defective product from entering the commerce stream. In addition, the HACCP system relies on extensive verification and documentation to assure that food safety has not been compromised. Thus, HACCP provides a structure for assessing risks or what could go wrong, and for putting the controls in place to minimize such risks.

Under the federal Juice HACCP rule published in 2001, juice processors must comply with two

requirements: (1) Subpart A of the rule requires use of HACCP principles and systems in their operations. (2) Subpart B of the rule requires that processors implement treatment(s) to reduce a theoretical population of “pertinent” microorganisms in the juice by 99.999% or 5-log cycles. The “pertinent” microorganism is defined as the most resistant microorganism of public health significance that is likely to occur in the juice. At the present time, *Salmonella* is generally recognized as the pertinent organism for citrus juices, and *E. coli* O157:H7 and *Cryptosporidium parvum* are accepted as the pertinent organisms for apple juice. Juices that have not been involved in disease outbreaks may use *Listeria monocytogenes* as the pertinent microorganism. Additionally, other juices with pH levels of 4.6 or less may use the phrase “vegetative bacterial pathogens” as the pertinent microorganisms.

The 2001 rule was implemented after various juice products were implicated in significant foodborne disease outbreaks in the 1990s. In 1995, a fresh citrus juice producer was implicated in a salmonellosis outbreak that sickened over 140 juice consumers. In 1996, *E. coli* O157:H7 contamination

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of apple juice was responsible for over 70 illnesses in the Northwest, including a child who died from hemolytic uremic syndrome (HUS) caused by the contamination. Other *Salmonella* outbreaks in the late 1990s and 2000 led to increased focus on juice-related food safety issues and subsequent rule-making by authorities to enhance public health.

Juice processors that meet the definition of “retail” establishments are not covered by the federal juice HACCP regulation but must comply with other federal and state rules that regulate juice production. Retail establishments are manufacturers that prepare and provide all of their juice production directly to consumers and do not sell or distribute (wholesale) juice to other businesses. For example, supermarkets that produce, package, and sell juice directly to consumers but do not sell juice to wholesalers or other businesses are not covered by the federal juice HACCP rule.

## Juice HACCP and the FDA

The regulation of food safety by implementing HACCP programs has precedent. The US Food and Drug Administration (FDA) used HACCP-based principles when setting up their low-acid food canning regulations in the 1970s. HACCP systems are already federally required for seafood, meat, and poultry processors. In 1995, the FDA issued regulations that made HACCP mandatory for fish and seafood products, and in 2001 they issued regulations for mandatory HACCP in juice processing and packaging plants. In addition, a voluntary HACCP program was implemented in 2001 for Grade A fluid milk and milk product manufacturers under the cooperative federal/state National Conference on Interstate Milk Shipments (NCIMS) program. The FDA has also implemented pilot HACCP programs for a variety of other food processing segments as well as for retail foods

## What Hazards Need to be Controlled by Juice Processors

Foodborne hazards controlled through HACCP include physical, chemical, and microbiological agents that have the potential to cause an adverse

health effect when a juice containing them is consumed, and that are reasonable likely to occur if not controlled. While consumers have historically been most concerned with chemical hazards such as pesticide residues and heavy metal contamination, microbiological contaminants have caused widespread problems in the industry, as noted above. The FDA has published a *Hazards and Controls Guide* that has extensive information on juice-related hazards, including some hazards that *must* be controlled by the HACCP plan.

Specific to the Juice HACCP regulation is the control of patulin in apple juice. The FDA has deemed patulin (a mold toxin) to be a potential hazard in apple juice, regardless of plant and/or processing specifics. Other hazards of particular interest to juice processors are microbiological hazards; the Hazards and Controls Guide discusses the extent to which these potential hazards must be controlled quite thoroughly. For example, the thermal treatment of pasteurization is commonly used in the citrus processing industry and specific time/temperature profiles are discussed in the guide. Allergens that may be present in the processing environment, as well as metal and glass fragments are additional examples of potential hazards that must be considered by those conducting the hazard analysis step.

## Principles of HACCP

The seven principles of HACCP are:

- Principle 1: Conduct a hazard analysis. Potential hazards associated with a food are identified, along with measures to control those hazards. Potential hazards that must be considered by juice processors and packagers are outlined in FDA's *Hazards and Control Guide*.
- Principle 2: Determine the critical control points (CCPs). CCPs are points in a food's production and processing at which significant hazards can be controlled or eliminated. Generally, the thermal processing steps of concentration and/or pasteurization are key CCPs in a processors/packagers HACCP plan.

- Principle 3: Establish critical limit(s) (CLs) for each CCP. Each CCP must operate within specific parameters to ensure the hazard is being appropriately and effectively controlled.
- Principle 4: Set up systems to monitor each CCP. Monitoring involves defining how the CCPs will be assessed, performing the monitoring at the appropriate time intervals, determining who will perform the monitoring, and finally maintaining the proper monitoring records.
- Principle 5: Establish corrective actions. When a critical limit is not met (a process deviation), proper actions must be taken. These can include reworking product, diverting product to a non-food use, or destruction of product. Corrective actions can be both short- and long-term in nature. Appropriate records must be maintained.
- Principle 6: Establish verification procedures. Verification is used to confirm that the system is working properly and that procedures outlined in the HACCP plan are being followed.
- Principle 7: Record-keeping and documentation. This includes all records required in the various parts of the HACCP plan, as well as other key records such as sanitation logs, supplier agreements, and shipping documents. Electronic records, as long as they meet the FDA's electronic records requirements (21 CFR Part 11), are acceptable.

### **HACCP Plan Validation**

Each Juice HACCP Plan must be validated at least once within 12 months after implementation. The Plan must also be validated at least every year thereafter and also when any process or product changes have occurred that might affect the hazard analysis or the plan itself.

### **The '5-log' Requirement**

In addition to manufacturing juice under a HACCP plan, processors must ensure that products have been treated in a manner that would reduce a

theoretical population of a “pertinent” microorganism by 99.999%, also known as a 5-log cycle or 100,000 times reduction. This treatment must occur in the same facility where the juice is bottled or packaged. This is generally accomplished by pasteurization of juice, although other treatments such as UV light processing of apple juice may also yield the required microbial reduction.

Citrus juice producers who do not want to pasteurize their juices are given an option to apply a cumulative 5-log reduction to fruit surfaces over a series of steps in the manufacturing process. These processors are not exempt from the requirement to package the juice in the same facility where the 5-log reduction occurs.

### **Further Activity**

Juice processors and packagers have implemented juice HACCP in their plants as directed in the regulation. As additional information is gathered and developed, refinements to the practice of juice HACCP will continue. For example, after the Juice HACCP regulation was fully implemented, it became evident that it did not adequately cover the condition of bulk transport of juice concentrate for further blending (a practice common to the industry). Subsequent guidelines conforming to the principles were developed by industry to bridge this gap. There will continue to be activity in the area of juice HACCP in the area of training, program development, and auditing as this program of Juice HACCP becomes a permanent part of the juice processing industry.

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