DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 120

RIN 0910–AA43

[Docket No. 97N–0511]

Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to adopt regulations to ensure the safe and sanitary processing of fruit and vegetable juices and juice products. The proposed regulation, if adopted, will mandate the application of Hazard Analysis and Critical Control Point (HACCP) principles to the processing of these foods. HACCP is a preventive system of hazard control. FDA is proposing these regulations because there have been a number of outbreaks of illness, including some directly affecting children, associated with juice products and because a system of preventive control measures is the most effective and efficient way to ensure that these products will be safe. Elsewhere in this issue of the **Federal Register**, FDA is publishing a warning label proposal for packaged juice.

DATES: Submit written comments by July 8, 1998. For information on the proposed compliance dates for small businesses and very small businesses see the **SUPPLEMENTARY INFORMATION** section of this document.

Submit written comments on the information collection requirements by May 26, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Submit written comments regarding information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attention: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Shellee A. Davis, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4681.

SUPPLEMENTARY INFORMATION:

The agency proposes to make any final rule based upon this proposal effective 1 year after its date of publication in the **Federal Register**. However, by its terms, the final rule will not be binding on small businesses as defined in proposed § 120.1(b)(1) until 2 years after the date of publication of a final rule in the **Federal Register**; and for very small businesses as defined in proposed § 120.1(b)(2), the final rule will not be binding until 3 years after the date of its publication in the **Federal Register**.

I. Concerns With Juice

A. Microbial Outbreaks

The Seattle-King County Department of Public Health and the Washington State Department of Health reported on October 30, 1996, an outbreak of *Escherichia coli* O157:H7 infections epidemiologically associated with drinking a particular brand of unpasteurized apple juice, or juice mixtures containing unpasteurized apple juice, purchased from a coffee shop chain, grocery stores, and other locations (Ref. 1). A case was defined as hemolytic uremic syndrome (HUS) or a stool culture yielding *E. coli* O157:H7 in a person who became ill after September 30, 1996, after drinking the particular brand of juice within 10 days before illness onset. There were at least 66 cases of illness, with 14 cases of HUS and the death of one child, associated with this outbreak (Ref. 2). Cases occurred in British Columbia, California, Colorado, and Washington. *E. coli* O157:H7 isolates cultured from a previously unopened container of the particular brand of apple juice had a deoxyribonucleic acid (DNA) ''fingerprint'' pattern (restriction fragment length polymorphism) indistinguishable from case-related isolates (Ref. 1).

Various juices have been documented as vehicles for causing outbreaks from microorganisms. A 1967 outbreak from contaminated water added to orange juice concentrate affected approximately 5,200 persons and was caused by an unidentified virus and possibly other contaminants (Refs. 3 and 4). About 300 people became ill from *Salmonella typhimurium* in cider made from apples, including some that had been picked up from the ground in an orchard fertilized with manure, in a 1974 outbreak in New Jersey (Ref. 5). A 1991 outbreak of *Vibrio cholerae* was associated with coconut milk contaminated during manufacturing in Thailand (Ref. 6). There have been two *Cryptosporidium* outbreaks related to drinking apple cider, the first in Maine in 1993 and the other in New York State in 1996. In the first case, the apples used for cider came from trees near a cow pasture (Ref. 7), and in the second case, water used for rinsing came from a well that tested positive for coliforms (Ref. 8). In 1995 there was an outbreak in Florida that was caused by *Salmonella hartford* in unpasteurized orange juice (Ref. 9).

E. coli O157:H7 has been recognized relatively recently as a human pathogen and has been a source of a number of outbreaks related to juice. Thirteen and possibly 14 children had bloody diarrhea and developed HUS in Toronto, Canada, between September 15 and 25, 1980. The children's illnesses were associated with drinking fresh apple juice. The children's stools were examined for enteropathogenic *E. coli*, *Campylobacter*, *Salmonella*, *Shigella*, and *Yersinia*. None of these organisms were found. *E. coli* O157:H7 is the suspected causative organism. Conclusive testing for that organism was not done because *E. coli* O157:H7 was not recognized as a human pathogen before 1982 (Ref. 10).

A 1991 *E. coli* O157:H7 outbreak in southeast Massachusetts conclusively showed that fresh-pressed unpasteurized apple juice can transmit *E. coli* O157:H7 bacteria. In this outbreak, 23 individuals had diarrhea, 16 had bloody diarrhea, and 4 developed HUS (Ref. 11).

In Connecticut, a 1996 outbreak of *E. coli* O157:H7 illness was associated with drinking a particular brand of apple cider. There were 14 cases of illness (including 7 hospitalized), with 3 cases of HUS associated with the outbreak (Ref. 8).

There was a small outbreak of *E. coli* O157:H7 illness in Washington State in 1996 that was related to apple cider made at a church event. This outbreak occurred during the same time as the unpasteurized apple juice outbreak described in previous paragraphs. The apples were washed in a chlorine solution, but it was not reported how much chlorine was used. Six people became ill, but no estimate was given on how many people may have drunk the apple cider (Ref. 12).

FDA's recall data also provide evidence of microbial hazards in juice. There were 85 cases of illness in 1994 resulting in a recall of orange juice that had fermented and contained *Bacillus cereus* and yeast (Ref. 13).

State investigations provide additional evidence of microbial hazards in juice. A 1989 outbreak in New York was caused by the presence in orange juice of *Salmonella typhi* that originated from an infected worker and

resulted in 69 illnesses with 21 individuals hospitalized (Ref. 14). The State of Washington reported that in 1993 one individual was hospitalized from home-made carrot juice found to contain *Clostridium botulinum* (Ref. 15). A 1993 Ohio outbreak caused by yeast or some other unknown toxicant in orange juice resulted in 23 illnesses (Ref. 16). A home-made watermelon drink contaminated with *Salmonella* spp. caused illness in 18 individuals in a 1993 Florida outbreak (Ref. 17). The State of Colorado reported two outbreaks of gastrointestinal illness from fresh squeezed orange juice at a mountain resort (Ref. 18). There were food handlers that were ill in both Colorado instances, and a virus was suspected as the causative agent.

The evidence shows that certain juices have been the vehicle for outbreaks of foodborne illnesses. Although fruit juice is acidic, and thus would generally be considered to inhibit the growth of most microorganisms, most juice-related outbreaks have been associated with fruit juices.

B. Illnesses From Nonheat-treatable Hazards

Illnesses that have been caused by hazards that can not be reduced to acceptable levels by heat treatments have also been associated with juice. Tin in canned tomato juice caused illness in 113 individuals in 1969 (Ref. 19). Soil nitrate had resulted in a high nitrate content in the tomatoes, and this high nitrate content accelerated detinning in the cans. In 1984, 11 persons became ill from consuming elderberry juice prepared by staff of a religious/philosophic group that contained poisonous parts of the plant (Ref. 20). A 1990 guanabana juice outbreak was caused by the presence of toxic guanabana seed material and caused illness in nine individuals (Ref. 21). A 1997 outbreak was caused by tin in pineapple juice (Ref. 22).

In 1992 an 18-month-old child with a blood lead level of 36 micrograms per deciliter (µg/dL) was found in a routine county health department blood lead monitoring program. Investigation of this incident by the county health department revealed that the only significant source of lead exposure for this child was lead in imported fruit juice packed in 12-ounce, lead-soldered cans (Ref. 23). Analysis by the State health department of multiple flavors of the fruit juices in lead-soldered cans available to the child found lead levels ranging from 160 to 810 parts per billion (ppb). An exposure assessment performed by the county health department estimated that the child consumed about three cans of these fruit juices per day and estimated that the child's daily lead intake from these fruit juices was approximately 600 µg/day (Ref. 23). As a result of this incident, FDA announced an emergency action level of 80 ppb for lead in fruit beverages (such as juices, nectars, and drinks) packed in lead-soldered cans (58 FR 17233, April 1, 1993). The agency subsequently banned the use of lead-soldered cans (60 FR 33106, June 27, 1995).

Recalls also provide evidence of nonheat-treatable hazards in juice. In 1988 a fruit punch drink was recalled because of the presence of tin caused by the acidity of the drink reacting with the tin coating of the cans (Ref. 24). The product had been packaged in the wrong container.

There were 10 recalls between 1990 and 1995 for fruit juice or beverages containing fruit juice because of the presence of food ingredients that were inadvertently added to the product, not declared on the label, or not suitable for the food. Food ingredients involved with these recalls were natamycin (Ref. 25), sulfites (Ref. 26), FD&C yellow No. 5 (Refs. 27 through 33), and salt (Ref. 34).

Five recalls between 1991 and 1997 were caused by improper sanitation procedures or faulty equipment. In 1991 sodium hydroxide from a clean-in-place system contaminated the caps of a citrus punch drink (Ref. 35). In 1992 three persons became ill, with 1 hospitalized, from a sodium hydroxide sanitizing agent that got into fruit drink product containers during cleaning (Ref. 36). In 1993 cracks in a heat exchanger allowed an orange flavored soft drink containing pear juice to come in contact with copper pipe fittings and, thus, to become contaminated with copper (Ref. 37). In 1994 milk was found in orange juice from filler lines that were not cleaned between milk and juice production (Ref. 38). In 1997 the presence of an alkaline cleaning solution in a berry juice caused gastrointestinal distress in several persons (Ref. 39).

Companies have recalled fruit drinks because pieces of glass or plastic were found in their products. The presence of glass in products is typically caused by the use of glass bottles, which can chip or shatter during the production process (Refs. 40 through 42). The plastic was present from the company's practice of draping plastic bags over the side of the bottle loading bin (Ref. 43).

One company recalled apple-prune juice and prune juice in 1996 because of unacceptable levels of lead (Refs. 46 and 47). The cause was contaminated imported prune juice.

In response to the establishment of maximum levels for patulin in apple juice by several foreign governments, FDA initiated a sampling survey to determine the levels commonly found in domestic and imported apple juice. Patulin may be present in juice made from moldy apples. In March 1997 the agency found inordinately high levels of patulin in apple juice from a processor in Washington State (Ref. 48). The level of patulin found in the product was sufficient to pose a health hazard, especially considering the fact that apple juice is commonly used by infants and young children (Ref. 49). All affected products that had left the plant had been used in the manufacture of fermented apple cider. Patulin could not be detected in fermented product, and it was assumed that the patulin was destroyed through the fermentation process.

Therefore, as the foregoing discussion reveals, the evidence demonstrates that juice and juice beverages are susceptible to chemical and physical hazards as well as microbiological hazards.

C. Underreporting

There is wide agreement that the laboratory-confirmed cases from outbreaks and recalls understate the actual number of juice-related cases, but no consensus exists on the size of the understatement. Individuals may not manifest all symptoms or have severe enough symptoms to necessitate medical attention. Medical personnel may simply treat an individual's symptoms without determining the underlying cause. The laboratory-confirmed cases only represent those cases where individuals sought medical attention, and where medical personnel performed the necessary testing and reported the case to a government agency.

While the actual number of juice-related illnesses is unknown, FDA has derived an estimate of the total number by multiplying the average number of laboratory-confirmed cases by factors that account for under-reporting. The factors are based on the relationships between annual outbreak cases and published estimates of the number of foodborne illnesses. For example, using these adjustment factors, it is estimated that the average 16 annual laboratory-confirmed cases of *Salmonella* represents 4,900 to 7,600 actual cases (Ref. 50). For *E. coli* O157:H7, an average 22 laboratory-confirmed cases per year may actually represent 2,200 to 4,300 total juice-related cases (Ref. 50). Therefore, the agency assumes that the

actual number of illnesses from the outbreaks described in sections I.A and I.B of this document is much greater than the confirmed number of illnesses. (For a more complete discussion of these estimates, see the agency's preliminary regulatory impact analysis and Ref. 50)

D. Pesticides

Pesticides are usually applied to plants to combat insects, plant diseases, and weed growth to assist in the growth of the fruit or vegetable. A food is considered adulterated under section 402(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 342(a)(2)(B) if pesticide residues are present above the Environmental Protection Agency (EPA) established tolerances, or if EPA has not established a tolerance for use of the pesticide on the particular plant. FDA annually monitors a wide variety of foods for pesticide residues.

In 1994 FDA sampled 1,411 domestic fruits and fruit products, including apple juice and other fruit juices, for pesticide residues and found that less than 1 percent were violative for being over tolerance and less than 1 percent were violative for having no tolerance (Ref. 51). None of the 122 samples of apple juice or 44 samples of other fruit juices were violative. Out of 1,795 samples of domestic vegetables and vegetable products tested, FDA found that less than 1 percent of samples were over tolerance, and that 2 percent were violative for having no tolerance.

FDA also tested 1,940 imported fruits and fruit products in its 1994 pesticide residue monitoring program. Less than 1 percent of the items tested were over tolerance and 3 percent were violative for having no tolerance. None of the 110 fruit juices sampled were violative. The agency sampled 2,460 imported vegetables and vegetable products and found that less than 1 percent were violative for being over tolerance and 4 percent for having no tolerance.

In its 1995 pesticide monitoring program FDA found less than 1 percent of 1,437 samples of domestic fruits and fruit products to be violative for being over tolerance and 1 percent to be violative for having no tolerance (Ref. 52). Of the 110 apple juices and 22 other fruit juices sampled, only a single apple juice sample was found to be violative, because of the presence of a pesticide with no established tolerance. Analysis of 1,585 samples of domestic vegetable and vegetable product produced results similar to the results found in 1994, i.e., less than 1 percent of samples were over tolerance, and approximately 2 percent were violative because there were no tolerances for the pesticide residues that FDA found.

The agency sampled 1,757 imported fruits and fruit products for pesticides in 1995 and found that less than 1 percent were violative for being over tolerance, and that 3 percent were violative for having no tolerance. Of the 19 apple juices and 52 other fruit juices tested, 2 apple juice samples were violative because they contained pesticides for which there were no established tolerances. The agency sampled 2,535 imported vegetables and vegetable products and found that 1 percent were violative for being over tolerance, and that 3 percent were violative for having pesticide residues for which there was no tolerance. Some of these samples contained both residues over tolerance and residues with no tolerance.

Although there are no documented outbreaks caused by unlawful pesticide residues, chronic exposure to pesticide residues that do not conform to EPA tolerances increase risks to the public health. Therefore, juice processors must determine whether the possible presence of unlawful pesticide residues is a hazard that is reasonably likely to occur.

E. FDA's Public Meeting

As a result of the October 1996 apple juice outbreak from *E. coli* O157:H7, FDA held a public meeting on December 16 and 17, 1996 (hereafter referred to as the juice meeting) (see notice of meeting (61 FR 60290, November 27, 1996)), to review the current science, including technological and safety factors, relating to fresh juices and to consider measures necessary to provide safe fruit juices to the public. Interested persons were given until January 3, 1997, to submit written comments on the notice. On January 2, 1997 (62 FR 102), FDA extended the comment period to February 3, 1997, in response to several requests for an extension.

The purpose of the juice meeting was to provide a forum for an information exchange on current industry practices for the production of juice products and on developments in the science underlying the production of safe juices. Experts from industry, academia, and the regulatory and consumer sectors presented information on illnesses and the epidemiology of outbreaks arising from contaminated juices; concerns about emerging pathogens; the *E. coli* O157:H7 outbreak in October 1996 caused by contaminated apple juice; procedures for processing juices; and new and existing technology to remove or decrease the number of pathogens or other contaminating microorganisms. Time was available for questions and comments from all attendees.

The meeting provided an opportunity to: (1) Consider how FDA's regulatory program for fresh juice and juice products should be revised,(2) discuss and exchange information on relevant safety issues, (3) to identify research needs where appropriate, (4) consider whether additional consumer education is necessary, and (5) consider whether other measures are needed to reduce the risk of future outbreaks of illness from juice.

FDA received over 180 comments from industry (with a number of these describing themselves as small businesses), consumers, consumer organizations, trade organizations, scientific/technical companies, academic institutions or organizations, State agencies, a local government agency, and members of Congress. Although most of the comments concerned apple juice specifically, many comments pertained to juices in general, and some referred only to citrus juices. Most comments were concerned with changes in processing to improve the safety of juices. Among the changes suggested were requiring pasteurization of juices, requiring HACCP, or establishing current good manufacturing practices (CGMP's) in juice processing. The agency has attempted to address the comments made at the meeting or submitted in response to the **Federal Register** notice in this proposal. If there are any significant concerns that the agency has not addressed, these concerns should be brought to the agency's attention in comments on this proposal.

The Fresh Produce Subcommittee (FPS) of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) attended the public meeting. The FPS met after the public meeting and made recommendations to the NACMCF. The NACMCF subsequently met to discuss the issues that were raised at the meeting. Based on information that was presented at the meeting and on the FPS's expertise, the full NACMCF made several recommendations (Ref. 53). The NACMCF stated that there are many aspects that affect pathogen control, such as agricultural practices; product handling; equipment used; growing location, including produce obtained from below ground (carrots), on ground (e.g., tree drops), or picked from trees; pH; acidulants; method of processing; degree of animal contact; refrigeration; packaging; and the distribution system. It stated that, in determining the best control mechanisms, it is important to remember that the conditions for

microbial survival differ from those for growth. The NACMCF recognized that, while the risks associated with specific juices vary, there are safety concerns associated with juices, especially unpasteurized juices.

The NACMCF concluded that: (1) The history of public health problems associated with fresh juices indicates a need for active safety interventions, and (2) for some fruit (e.g., oranges), the need for intervention may be limited to surface treatment, but for others, additional interventions may be required (e.g., pasteurization of the juice).

The NACMCF recommended to FDA the use of safety performance criteria instead of mandating the use of a specific intervention technology. In the absence of known specific pathogen-product associations, the NACMCF recommended the use of *E. coli* O157:H7 or *Listeria monocytogenes* as the target organism, as appropriate. This recommendation was based on the premise that these organisms are two of the most difficult to control (i.e., by juice acidity or heat lethality), and that, by controlling them, other pathogenic organisms will likely be controlled. The NACMCF suggested that a tolerable level of risk may be achieved by requiring interventions that have been validated to achieve a cumulative 5 log reduction in the target pathogen or a reduction in yearly risk of illness to less than 10^{-5}, assuming consumption of 100 milliliters (mL) of juice daily.

In addition, the NACMCF stated that HACCP and safety performance criteria should form the general conceptual framework to ensure the safety of juices, and that control measures should be based on a thorough hazard analysis. The NACMCF also stated that validation of the process must be an integral part of this framework. The NACMCF recommended mandatory HACCP for all juice products, and that processors should implement and strictly adhere to industry CGMP's. The NACMCF also recommended industry education programs addressing basic food microbiology, the principles of cleaning and sanitizing equipment, CGMP's, and HACCP.

The NACMCF recommended further study in several areas:

(1) The efficacy of new technologies and intervention strategies for safety;

(2) The contamination, survival, and growth of pathogens on produce with or without breaks in skin, with or without areas of rot, and within the core;

(3) How produce becomes contaminated with human pathogens, including the relevant microbial ecology during production and processing of juice. In particular, the NACMCF stated that there is an urgent need for these types of studies on *E. coli* O157:H7 in apple juice;

(4) The baseline incidence of human pathogens on fruits and vegetables, particularly on those used in juice processing; and

(5) Labeling information needed for consumer understanding and choice of safer juices and juice products.

On the basis of all the testimony presented at the December 16 and 17, 1996, meeting, the NACMCF agreed that there is a need to understand the differences among all juice and juice products (e.g., citrus versus other). A significant problem identified by the NACMCF is that consumers presently do not have a means to clearly differentiate between unpasteurized and pasteurized products, and that terms used to refer to juice products do not always have universal meanings. For example, the term ''cider'' is perceived to be an unpasteurized product whereas the term ''juice'' is often perceived to be pasteurized.

The NACMCF also stated that traditional heat treatments given to juices and juice products have been designed to achieve shelf stability, to remove water (i.e., concentration), or to affect other quality-related factors, and that these treatments, commonly referred to as ''pasteurization,'' are greatly in excess of a process needed to inactivate foodborne pathogens.

Because of the lack of sufficient data to evaluate the effectiveness of labeling statements as safety interventions or to inform consumer choice, the NACMCF stated that it could not strongly endorse labeling as an interim safety measure.

Although the NACMCF did not endorse labeling as an interim safety measure, elsewhere in this issue of the **Federal Register** FDA is proposing interim labeling measures for packaged juice. The agency sets forth its reasons for proposing to adopt these measures in that proposal.

II. Consideration of How to Address Problems

A. Current Regulation of Juice

FDA has established labeling regulations and standards of identity for a number of juices. 21 CFR 101.30 pertains to percentage juice declaration for beverages that contain fruit or vegetable juice. Common or usual name regulations for nonstandardized beverages that contain fruit or vegetable juice are found in 21 CFR 102.33. Standards of identity are found in part 146 (21 CFR part 146) for a number of fruit juices and beverages and in part 156 (21 CFR part 156) for tomato juice. The standard of identity for pasteurized orange juice (§ 146.140) states that ''The orange juice is so treated by heat as to reduce substantially the enzymatic activity and the number of viable microorganisms.'' Pasteurized orange juice must be labeled as such.

In the 1997 Food Code, FDA articulated its policy regarding unpasteurized apple juice (Ref. 54). The code states that food establishments (e.g., nursing homes) that serve apple juice, apple cider, or other beverages that contain apple juice to segments of the population that are highly susceptible to disease (e.g., the elderly) should serve juice that has been pasteurized or that is in a commercially sterile, shelf-stable form, in a hermetically sealed container.

B. The Current Inspection System

Juice processors, like other food processors, are subject to periodic unannounced, mandatory inspection by FDA. This inspection system provides the agency with a picture of conditions at a facility at the time of the inspection. However, assumptions must be made about conditions at the facility before and after that inspection, as well as about important factors beyond the facility that have a bearing on the safety of the finished product. The reliability of these assumptions over the intervals between inspections can create questions about the adequacy of the system.

FDA's inspections are based, in part, upon its regulations on CGMP in the manufacturing, packing, or holding human food in part 110 (21 CFR part 110). For the most part, these regulations set out broad statements of general applicability to all food processing on matters such as sanitation, facilities, equipment and utensils, processes, and controls. HACCP-type controls are listed as one of several options available to prevent food contamination (§ 110.80(b)(13)(i)), but they are not integral to the controls outlined in the regulations.

The inspection and surveillance strategies that FDA uses ascertain a manufacturer's knowledge of hazards and preventive control measures largely by inference (i.e., based on whether a company's products are in fact adulterated, or whether conditions in a plant are consistent with CGMP). It is the manufacturer's responsibility to ensure that its products are in compliance with the act. However, in the face of new pathogens, such as *E. coli* O157:H7, and the risk of illness associated with these pathogens, especially for children, the elderly, and

the immunocompromised, FDA tentatively concludes that, at least for juices, new measures to control microbial, chemical, and physical hazards are necessary to ensure that finished products comply with the act's standards.

C. Alternatives

Comments from the juice meeting suggested several alternatives to ensure that juice products are safe. These alternatives are discussed in sections II.C.1 through II.C.6 of this document along with their impact on the current situation with juice.

1. Increased Inspection

Continuous visual inspection of juice production is not a viable alternative because few hazards associated with juice are detectable through visual inspection.

Another possibility is to direct significant additional resources toward increasing the frequency of FDA's inspection of juice manufacturers, as well as increasing the agency's sampling, laboratory analysis, and related regulatory activities with respect to these products. While many samples of domestic and imported juice products are collected each year for analysis in FDA laboratories, and this sampling is designed to represent a broad range of products and to target known problems, the product sampled represents only a small fraction of the total poundage of the juice products consumed in this country. Substantially more expenditures would be needed to increase laboratory analyses to statistically significant levels.

Even if the funds for increased FDA inspection and increased sampling and analysis were available, this approach alone would not likely be the best way for the agency to spend its limited resources to protect the public health. Reliance on end-product testing involves a certain amount of inefficiency and enormous sample sizes and testing on a lot-by-lot basis are necessary to overcome that inefficiency. Therefore, this option has significant limitations.

Some comments from the juice meeting stated that juice safety would be improved through more local/State inspection rather than Federal inspection.

FDA agrees that more local/State inspection would help to ensure the safety of juices, particularly where because FDA lacks jurisdiction, there is no connection between the juice products and interstate commerce. However, FDA is not in a position to mandate that State and local regulatory agencies conduct additional inspections with their limited resources. Further, FDA cannot mandate that a State ensure that a firm is complying with FDA's regulations. Therefore, increased local/State inspection for juice is not an option upon which FDA can rely.

2. CGMP's

Many comments from the juice meeting urged the implementation of industry CGMP's or sanitation standards to increase the safety of juices. Some comments provided State rules, model CGMP's, or sanitation guidelines for FDA's consideration. Other comments stated that there is a need for more industry education on sanitation and hygiene.

CGMP regulations have a twofold purpose: (1) To provide guidance on how to reduce insanitary manufacturing practices and on how to protect against food becoming contaminated, and (2) to set out objective requirements that enable industry to know what FDA expects an investigator to find when he or she visits a food plant (51 FR 22458 at 22459, June 19, 1986). CGMP's consist generally of broad statements on sanitation, facilities, equipment and utensils, processes, and controls that are of general applicability to food processing. Therefore, FDA issuance of CGMP's for juice would be an approach that could assist manufacturers in the production of safe juices.

FDA encourages the juice industry to use CGMP's to help ensure the safety of their juices. As stated previously, the NACMCF recommended that processors implement and strictly adhere to industry CGMP's. However, the use of CGMP's alone may not be adequate to ensure that juices are safe because of the broad based nature of CGMP's. CGMP's are directed at plantwide operating procedures and do not concentrate on the identification and prevention of food hazards. Therefore, the agency tentatively concludes that CGMP's, although useful, will not be adequate, without additional measures, to ensure the safety of juices.

3. Mandatory Pasteurization

The majority of the comments from the juice public meeting pertained to pasteurization of juice. A number of comments urged FDA to mandate pasteurization or other equivalent treatment of fruit juice to ensure its safety. One person who commented reported that customers of his apple cider had not complained about a difference in flavor when he implemented pasteurization. One comment requested a 2-year grace period for small businesses before implementation if pasteurization were to be required. Another suggested that pasteurization be required for apple cider only if CGMP's and HACCP fail. One comment suggested that pasteurization be required only for apple juice, because of the difficulty in cleaning apples as compared to other fruits.

However, most comments opposed mandatory pasteurization of juices because of: (1) The expense of pasteurization equipment, (2) preference by some consumers for the flavor of unpasteurized over pasteurized juice, (3) the safety record of juices, and (4) degradation of nutritional value from heat treatment. Many comments from small businesses claimed that they would be forced to close their operations if pasteurization were required. Some comments also stated an economic need for the use of dropped apples (''drops''), with one recommending the use of only hand-picked (rather than machine-picked) drops. Other comments stated that the use of drops should be prohibited, at least in unpasteurized juices.

FDA is aware of the significant safety advantages of pasteurizing juice as well as of the reasons that some processors choose not to pasteurize their products. Pasteurization is a heat treatment used to kill the vegetative forms of specific bacteria in liquid or semi-liquid food products. Pasteurization is an effective and proven technology to ensure that juice does not contain pathogens. However, there may be other methods that are equally effective. Thus, the NACMCF recommended the establishment of safety performance criteria for appropriate target organisms rather than the establishment of a specific intervention technology. The NACMCF stated that safety performance criteria would be most effective.

For example, whole oranges with an intact skin may be processed so that pathogens on the surface of the fruit are destroyed. Because pathogens are not reasonably likely to be present in the interior of an orange, surface treatment could be adequate to ensure the safety of the juice. This example illustrates that if FDA were to mandate pasteurization, such action could have the effect of limiting the development of new technologies that are as effective as pasteurization in particular circumstances but less intrusive and less expensive.

Therefore, the agency tentatively concludes that relying on safety performance criteria, as recommended by the NACMCF, is an approach preferable to pasteurization. However, if the use of safety performance criteria

does not significantly decrease the number of microbial outbreaks caused by juice, the agency may consider adopting a regulation that mandates pasteurization.

The agency disagrees with the comments that stated that it should require that apple juice be pasteurized because apples can be difficult to clean. FDA recognizes that pastuerization is a process that has been validated to meet NACMCF's recommendations. Manufacturers may be able to use other technologies and practices provided that their process is validated to achieve a 5-log reduction in the target pathogen. Therefore, reliance on safety performance criteria is a better long-term approach because it provides for the development of new technologies.

A number of comments at the juice meeting urged FDA to consider alternatives to pasteurization to increase the safety of juices. Alternatives suggested by the comments included extreme isostatic pressure, high pressure sterilization, ultra short time-heat exchanger processing, ohmic heating, aseptic packaging, modified atmosphere packaging, ultrafiltration, high temperature and high pH adjustment of wash-water, ultrahigh hydrostatic pressure, electric pulses, electromagnetic field, pulsed light, ultraviolet (UV) water treatment, UV treatment with photoreactivation, electron beam sterilization, irradiation, ozonated water treatment, microbiocidal additives (benzoate, sorbate), and pH adjustment. The comments recommended that sanitizers or ingredients for washes include use of chlorine, chlorous acid, chlorine with emulsifiers, trisodium phosphate, peroxyacetic acid, peracetic acid, or dimethyl dicarbonate.

The agency agrees that there may be a number of agents that can reduce the number of microorganisms present in juice. As the NACMCF recommended, a tolerable level of risk may be achieved by interventions that have been validated to achieve a cumulative 5 log reduction in the target pathogens or a reduction in yearly risk of illness to less than 10^{-5}, assuming consumption of 100 mL of juice daily. However, the NACMCF did not specify the manner in which this risk reduction should be accomplished, only the target that must be reached. In section IV.M of this document the agency will discuss its proposed approach as to how this performance standard will apply to juice.

4. Labeling

A number of comments suggested that labeling to distinguish pasteurized from unpasteurized juice would enable consumers to make an informed choice. One of the comments requested warnings to those ''at-risk,'' one urged the publication of warnings in the newspaper, and another wanted labeling with no warning. Rather than labeling, one comment suggested point of sale information. One comment urged FDA not to require labeling to distinguish pasteurized from unpasteurized juices.

The NACMCF recommended research on labeling information needed for consumer understanding and choice of safer juice products. The NACMCF concluded that, while the risks associated with specific juices vary, there are safety concerns associated with juices generally, especially unpasteurized juices.

Labeling whether a product is pasteurized or unpasteurized is useful information that the agency encourages processors to place on labels. However, such labeling would not inform purchasers of unpasteurized product that children, the elderly, and the immunocompromised are ''at-risk'' from consuming the product. Without effective consumer education, the label statements ''pasteurized'' and ''unpasteurized'' are likely to have relatively little meaning to consumers and could even cause confusion because some consumers might select unpasteurized juice, considering it more ''healthy'' because it is less processed. Finally, a labeling requirement that focuses only on whether a product is pasteurized or unpasteurized does not take into account technologies other than pasteurization that are adequate to control pathogens, and, thus, such a requirement could be viewed as restricting the development of new technologies.

The agency outlined interim measures in a notice published August 28, 1997 (62 FR 45593), and elsewhere in this issue of the **Federal Register**, FDA is issuing a proposal on labeling for packaged juice. These labeling measures attempt to provide information on the risks that juice that has not been processed to control for pathogens poses to children, the elderly, and the immunocompromised. The agency is proposing that the labeling measures be superseded when these juice products are processed under adequate HACCP programs or are otherwise processed to destroy pathogens (e.g., pasteurization).

It is possible for firms that manufacture juice to control for pathogens. Labeling a product to alert consumers to possible harmful effects from its consumption must not substitute for a manufacturer adequately addressing those concerns during processing. FDA is reluctant to rely on labeling as a safety measure and does so only when its analysis of the countervailing factors reveals that, on balance, labeling provides the most reasonable approach to protecting the public health. Juice is a product that is typically consumed by children, as well as adults. Therefore, FDA tentatively concludes that, for juice, manufacturers need to implement controls for pathogens to ensure that their products are safe and not rely solely on labeling, except as an interim measure. FDA requests comment on this tentative conclusion.

5. Education

Other comments from the juice meeting suggested that education would increase the awareness associated with the safety of juices and of all foods. Some comments suggested that more industry education or training was needed. Other comments wanted more consumer education, especially for those at highest risk from foodborne disease.

The NACMCF recommended that the industry be educated on basic food microbiology, the principles of cleaning and sanitizing equipment, CGMP's, and HACCP. FDA agrees that industry education can serve a valuable role in controlling potential food hazards and encourages the industry to take an active part in educating its employees and utilizing up-to-date technologies. The agency will assist the industry in its education effort.

Concerning consumer education, the agency has launched several initiatives to inform consumers about the potential hazards presented by juice to at-risk individuals (see 62 FR 45593, August 28, 1997). However, no matter how extensive a consumer education initiative the agency undertakes, it is doubtful that consumer education will reach all at-risk consumers. Therefore, consumer education alone will not be adequate to inform the at-risk population of the potential hazards of consumption of juice that has not been processed to control pathogens. Given that effective processing methods are available, primary reliance needs to be placed on them to ensure the safety of juice.

6. The HACCP Option

Many of the attendees at the juice meeting urged FDA to mandate HACCP for juice processors, whereas others were opposed. A number of the attendees urged use of CGMP's together with HACCP. Some attendees at the juice meeting recommended that microbiological criteria or performance

standards be used in addition to HACCP, with two suggesting a 5 log reduction for *E. coli* O157:H7.

The NACMCF concluded that HACCP and safety performance criteria can provide the general conceptual framework needed to ensure the safety of juices, and that validation of the HACCP plan for the juice process (i.e., ensuring that the process is adequate to control hazards) must be an integral part of this framework. The NACMCF stated that processors should establish HACCP control measures based on a thorough hazard analysis.

HACCP is a preventive system of hazard control that places the responsibility for identifying safety problems with the manufacturer. Use of the HACCP system means that a firm is engaged in continuous problem prevention and problem solving, rather than relying on facility inspections by regulatory agencies or consumer complaints to detect a loss of control. HACCP provides for real time monitoring to assess the effectiveness of control. A HACCP system put in place by a manufacturer for a particular facility is unique and must reflect the type of juice, its method of processing, its packaging, the facility in which it is prepared, and the intended consumers.

As discussed previously, there is sufficient evidence to demonstrate that there are significant problems with the presence of pathogens in some juice products. Pathogens in juice can be controlled by heat treatment. However, there may be other treatments that meet the same performance standard that are equally effective (e.g., multiple barriers, surface treatment of intact fruit). The use of a HACCP system provides flexibility to a processor to use alternative pathogen control methods and, thus, encourages the development of new technologies but does not dictate either their development or use. Moreover, not only is HACCP effective in controlling microbiological hazards, it also is effective in preventing chemical and physical hazards. Thus, HACCP is particularly well-suited for the juice industry given, as discussed previously, the range of hazards that must be addressed in processing juice.

The agency agrees with the comments that urged use of CGMP's together with HACCP. CGMP's form the foundation upon which a HACCP system is built. Therefore, CGMP's are integral to the HACCP approach.

Because there are significant concerns with the microbial safety of juices, HACCP systems must control pathogens. As will be discussed in section IV.M of this document, FDA is proposing a 5 log reduction in target pathogens, as the NACMCF recommended, as a necessary step in a HACCP plan for juice. Validation of a HACCP system must ensure that the process that is employed is adequate to control the relevant pathogens, in addition to chemical and physical hazards. Validation of performance standards consists of determining the ability of the pathogens in question to resist acid and other chemical or heat treatment and the ability of the process applied to overcome that resistance. The agency requests comment on this approach to safety performance criteria. FDA also requests comment on the benefits of requiring a general HACCP approach as opposed to those of specifically requiring pasteurization.

7. Alternative Approach

An alternative approach to mandating HACCP would be to draw a distinction between untreated apple cider and all other juices. Manufacturers of apple cider would be provided a permanent option choosing between labeling or implementing a HACCP program with a 5-log pathogen reduction. All juices other than untreated apple cider would be provided a permanent option of choosing between labeling, implementing a HACCP system, or achieving a 5-log pathogen reduction as discussed in section M of this document, entitled ''Pathogen Reduction.'' The agency requests comments on this alternative approach to a mandatory HACCP program.

D. Decision to Propose HACCP

The evidence discussed in section I.A of this document shows that juices have been a vehicle for pathogens that have caused a number of foodborne illnesses. Pathogens can be controlled through heat treatment. Information set forth in sections I.B and I.D of this document, however, demonstrates that there are many hazards that can occur with juice and juice beverages that cannot be controlled through heat treatment. Although not all of the problems discussed in section I of this document are caused by hazards that could be considered reasonably likely to occur in many juice operations, through the use of HACCP programs, a firm can evaluate its process to determine if the problem could have been controlled.

As discussed in section I.E of this document, the NACMCF stated that HACCP and safety performance criteria can form the general conceptual framework needed to ensure the safety of juices. FDA has evaluated each of the seven alternatives that have been suggested for dealing with the problems with juice. While the agency finds that these alternatives are by no means mutually exclusive, FDA has tentatively concluded that a preventive system, such as HACCP, appears to offer the most effective way to control the significant microbial hazards, along with other hazards, that have become a problem with juice.

Increased inspection, while having some beneficial impact on the safety of juices, is resource intensive to the agency. Even if funds were available to the agency for this purpose, increased inspection would likely not be the best way for the agency to utilize its resources to protect the public health. It is ultimately the responsibility of manufacturers to ensure that their products are safe. A preventive approach, such as HACCP, on the other hand, enhances a processor's ability to make safe products because HACCP concentrates on examining all aspects of production, identifying hazards that are reasonably likely to occur in that production process, and establishing measures that will control or minimize those hazards. HACCP also enhances FDA's inspections because it allows the agency to inspect the production facility more efficiently and then to verify that the firm is operating in accordance with the firm's HACCP plan, and it provides some assurance that any problems that have occurred have been identified and appropriately addressed.

CGMP's, the second alternative to HACCP, are plantwide operating procedures. Although FDA supports the use of CGMP's, it tentatively concludes that use of CGMP's alone would not be sufficient to control the problems with juices because CGMP's do not concentrate on the identification and prevention of food hazards. Nonetheless, CGMP's are necessary to provide the foundation on which a HACCP system is built. Therefore, the agency tentatively concludes that, while CGMP's are important to a HACCP system, they are not an adequate alternative to HACCP.

Mandating pasteurization, the third suggested alternative to HACCP, would reduce many microbial hazards in juices but would eliminate the incentive to develop alternative methods (e.g., use of multiple barriers, surface treatment of fruit) that can accomplish the same purpose. FDA does not want to limit innovative approaches to achieving food safety. HACCP, on the other hand, allows and encourages firms to explore more technologically efficient and more cost-efficient ways of managing all of the hazards that they face. Moreover, pasteurization only controls microbial hazards. HACCP systems can control all

food hazards that are reasonably likely to occur.

Labeling was also suggested as an alternative. FDA acknowledges that, from a public health protection standpoint, there are certain advantages to labeling. Elsewhere in this issue of the **Federal Register**, FDA is proposing to require certain labeling, in the form of a warning statement, for packaged juice products that have not been processed to control, reduce, or eliminate pathogenic microorganisms that may be present in such juices. Such labeling will serve to reduce the risk of foodborne illness. However, such reduction will occur only to the extent that consumers read and understand the labeling. Accordingly, the agency has tentatively concluded that mandating HACCP for most juice products will provide more comprehensive public health protection by greatly reducing the number of juice products that contain dangerous pathogens.

Importantly, manufacturers do have the ability to process juice to control pathogens. Labeling a product to alert consumers to possible harmful effects from its consumption is not a substitute for a manufacturer adequately addressing those concerns during processing. Juice is a product consumed by children, as well as by adults. FDA is reluctant to rely on labeling as a safety measure and does so only when its analysis of the countervailing factors reveals that, on balance, labeling provides the most reasonable approach to protect the public health. Here, a situation in which HACCP offers a real long-term solution to controlling, if not eliminating, hazards in juice, the agency tentatively believes that labeling is not a reasonable long-term approach. The agency is soliciting comment on the appropriateness of this tentative conclusion.

The fifth alternative to HACCP that was suggested is education. Industry education can play a valuable role in the production of safe juices. Consumer education can play an important part in consumer purchasing choices. However, education is only effective if people understand and use the information conveyed. Moreover, even an extensive education program may not reach all consumers. Conversely, mandatory HACCP would ensure that industry produces safe juice, and that the product that reaches consumers is safe.

For the foregoing reasons, FDA has tentatively concluded that HACCP represents the appropriate system of controls that is necessary for producing safe juice products. Therefore, FDA is proposing to add part 120 to its regulations to establish procedures for implementing HACCP systems for fruit and vegetable juices. As the agency did with seafood, it is proposing to issue these HACCP regulations under various sections of the the act, including, most significantly, sections 402(a)(1) and (a)(4) and 701(a) of the act (21 U.S.C. 371(a)).

Section 402(a)(1) of the act states that a food is adulterated if it bears or contains any poisonous or deleterious substance that may render the food injurious to health. Section 402(a)(4) of the act states that a food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health. It is important to recognize that section 402(a)(4) of the act addresses conditions that may render a food injurious to health, rather than conditions that have actually caused the food to be injurious (see *United States* v. *1,200 Cans, Pasteurized Whole Eggs, etc.*, 339 F. Supp. 131, 141 (N.D. Ga. 1972)). The question is whether the conditions under which the food is processed and held are insanitary and may render the food injurious to health. The agency tentatively finds that, if a processor of juice products does not incorporate certain basic controls into its procedures for preparing, packing, and holding food, it is operating under insanitary conditions that may render the juice that is produced injurious to health and, therefore, adulterated under the act. Section 701(a) of the act authorizes the agency to adopt regulations for the efficient enforcement of the act.

The legal basis for mandating HACCP systems for juice processors is the same as that for seafood. Additional discussion of the legal basis is set out in the proposed rule (59 FR 4142 at 4150, January 28, 1994) and final rule (60 FR 65096 at 65098) for fish and fishery products.

E. Notice of Intent

FDA published a notice of intent on August 28, 1997 (62 FR 45593), that announced a comprehensive program to address the incidence of foodborne illness related to consumption of fresh juice and to address ultimately the safety aspects of all juice products. The agency invited comment on the appropriateness of its strategy to: (1) Initiate rulemaking on a mandatory HACCP program for some or all juice products, (2) propose that the labels and labeling of some or all juice products not specifically processed to prevent or eliminate the presence of harmful bacteria bear a warning statement informing consumers of the risk of illness associated with consumption of the product, and (3) initiate several educational programs to minimize the hazards associated with fresh juice. The agency stated that it would consider comments received within 15 days of publication of the notice prior to publication of any proposed rule.

Some comments on the notice suggested that FDA mandate HACCP only for fresh juice processors. One comment stated that HACCP should be mandated only for firms that process large quantities of fresh juice. Other comments supported mandatory pasteurization or equivalent treatment of juice, especially apple cider. One comment added that pasteurization and use of CGMP would preclude the need for the mandatory use of HACCP.

In section II.D of this document the agency has already discussed its reasons for proposing HACCP. The illnesses discussed in sections I.A and I.B of this document did not pinpoint problems related solely to fresh juice processors or to the amount of fresh juice that a firm produced. The comments have not provided any new information to alter the agency's tentative conclusion that HACCP is necessary to ensure the safe production of juice. However, FDA requests information on whether there are categories of juice that should be excluded from the proposed regulation.

FDA has reviewed all of the comments received within 15 days of publication of the notice and has determined that the comments provided no information that would cause the agency to conclude that this proposal is inappropriate. The agency has attempted to address these comments to the extent that they are relevant to this proposal. All comments received in response to the notice that address the issues in this proposal will be considered either in this proposal or in any final rule published in response to this proposal.

F. Fresh Produce Guidance

FDA, working with the U.S. Department of Agriculture (USDA) and the agricultural community, has developed voluntary good agricultural practice (GAP) and GMP guidance for fruits and vegetables that has been issued in draft for comment. The guidance, which is a science-based evaluation of risks, will address potential food safety problems throughout the food production and distribution system such as sanitation, worker health, and water quality. This voluntary guidance can be used by both domestic and foreign fresh fruit and vegetable producers to help ensure the safety of their produce.

III. The HACCP System

The HACCP concept is a systematic approach to the identification and assessment of the risk (likelihood of occurrence and severity) of biological, chemical, and physical hazards from a particular food production process or practice and the control of those hazards. HACCP is a preventive strategy for food safety. Under it, the food producer develops a plan that anticipates and identifies the points in the production process where a failure would likely result in a food hazard being created or allowed to persist. These points are referred to as critical control points (CCP's). Under HACCP, identified CCP's are systematically monitored to ensure that critical limits (CL's) are not exceeded, and records are kept of that monitoring. Corrective actions are taken when control of a CCP is lost, including proper disposition of the food produced during that period, and these actions are documented. The effectiveness of HACCP is also systematically verified by the processor.

HACCP has been endorsed by the NACMCF as an effective and rational means of ensuring food safety. HACCP also is recognized in the international food safety community as the state-of-the-art means to ensure the safety and integrity of food. In particular, the Committee on Food Hygiene of the United Nations' Codex Alimentarius Commission (Codex) has endorsed the HACCP concept as a worldwide guideline. The European Union (EU) and other countries around the world have begun to require that foods produced within their borders be processed in a HACCP system. HACCP also is required for shipment of some foods (e.g., seafood) into EU countries.

A. Five Preliminary Steps of HACCP

The NACMCF recommends a process for developing a HACCP system that includes: (1) Assembling a HACCP team, (2) describing the food and its distribution, (3) identifying the intended use and consumers of the food, (4) developing a flow diagram, and (5) verifying the flow diagram (Ref. 55). These steps have been identified by the NACMCF as the ''five preliminary steps'' of HACCP. Although the agency is not proposing to mandate that processors use these preliminary steps, processors will greatly benefit from using these preliminary steps in developing their HACCP systems. The NACMCF advises that the preliminary tasks should be accomplished before the application of HACCP principles to a specific process (Ref. 55).

B. The Seven Principles of HACCP

The NACMCF has developed the following seven principles that describe the HACCP concept:

1. Conduct a Hazard Analysis

The first step in the establishment of a HACCP system for a food production process or practice is the identification of the hazards associated with the product. The NACMCF defines a hazard as a biological, chemical, or physical factor that may cause a food to be unsafe for consumption. The hazard analysis step should include not only a written identification of the hazard but a written assessment of the likelihood that the hazard will occur and its severity if it does occur. This analysis should also involve the identification of CCP's along with control measures for each identified hazard.

2. Determine the CCP's

A CCP is a point, step, or procedure at which control can be applied, so that a potential food hazard can be prevented, eliminated, or reduced to acceptable levels. Points in the manufacturing process that may be CCP's include heat treatment, chilling, specific sanitation procedures, product formulation control, prevention of cross contamination, and certain aspects of employee and environmental hygiene.

3. Establish Critical Limits

This step involves establishing parameters that must not be exceeded for each control measure associated with a CCP. Critical limits (CL's) can be thought of as boundaries of safety for each CCP and may be set for control measures such as temperature, time, physical dimensions, moisture level, water activity, pH, and available chlorine. A CL is used to distinguish between safe and unsafe operating conditions at a CCP. For example, the minimum temperature and time combination that will kill pathogens in a heat treatment step is the CL for that CCP.

4. Establish Monitoring Procedures

Monitoring is a planned sequence of observations or measurements to assess whether a CCP is under control (i.e., operating within its CL) and to produce an accurate record of the monitoring for use in future verification procedures. An unsafe food may result if a process is not properly controlled and a deviation occurs. Because of the potentially serious consequences of a CL deviation, monitoring procedures must be effective. Continuous monitoring is possible with many types of physical and chemical methods. When it is not possible to monitor a CL on a continuous basis, monitoring intervals must be established that are frequent enough to permit the manufacturer to determine whether the step/process/procedure designed to control the hazard is working.

5. Establish Corrective Actions

While the HACCP system is intended to prevent deviations in a planned process from occurring, total prevention can rarely, if ever, be achieved. Therefore, there needs to be a corrective action plan in place to fix or correct the cause of the deviation to ensure that the CCP is brought under control, to ensure that there is appropriate disposition of any food produced during a deviation, and to ensure that records are made of the corrective actions taken. Out of control situations should be used to identify opportunities for improvement of the process to prevent future occurrences.

6. Establish Verification Procedures

This process involves the application of methods, procedures, tests, and evaluations, other than monitoring, to determine the adequacy of, and compliance with, the HACCP system. The major infusion of science in a HACCP system centers on proper identification of the hazards, CCP's, and CL's and the institution of proper verification procedures.

7. Establish Recordkeeping and Documentation Procedures

This principle requires the preparation and maintenance of written HACCP records that list the hazards, CCP's, and CL's identified by the firm, as well as the monitoring, recordkeeping, and other procedures that the firm intends to use to implement the system. This principle also requires the maintenance of records generated during the operation of the HACCP system.

C. History of the Use of HACCP

1. HACCP for Fish and Fishery Products

On December 18, 1995, FDA published a final rule in the **Federal Register** (60 FR 65096) on procedures for the safe and sanitary processing and importing of fish and fishery products (part 123 (21 CFR part 123)) (seafood final rule). The regulations require that seafood processors develop, implement, and document sanitation control procedures and mandate the application of HACCP principles to the processing of seafood. The effective date for the seafood final rule was December 18, 1997.

The regulations proposed herein are based on the seafood final rule with some modification to reflect the differences between seafood and juice products and to reflect recent developments in the application of HACCP. An extensive administrative record was compiled in the seafood proceeding. FDA is incorporating that record as support for the current proposal. Although the regulations proposed herein differ in some aspects from part 123, they are not intended to supersede or otherwise alter the seafood final rule.

2. Advance Notice of Proposed Rulemaking for the Development of HACCP for the Food Industry

In the **Federal Register** of August 4, 1994 (59 FR 39888), FDA published an advance notice of proposed rulemaking (ANPRM) requesting public comment about whether and how the agency should develop regulations that would establish requirements for a new comprehensive food safety assurance program, based on HACCP, for both domestically produced and imported foods. The agency stated its tentative view that, if such regulations were issued, they would enhance FDA's ability to ensure the safety of the U.S. food supply. FDA requested comments on a number of specific issues, as well as on all aspects of such a food safety program.

3. HACCP Pilot Programs

In addition to the ANPRM, FDA also published in the **Federal Register** on August 4, 1994 (59 FR 39771), a notice announcing that it intended to conduct a pilot program in which volunteers from the food manufacturing industry would use a HACCP system that FDA would audit. The pilot program was intended to provide information that FDA could use in deciding whether to propose to adopt regulations and in developing and implementing a regulatory system in which food manufacturers are required to perform the food safety aspects of their operations based on HACCP principles. In the notice, FDA invited individual firms that wished to participate in the program to submit letters of interest. Approximately 50 firms expressed initial interest in participating in the pilot program, and 11 firms were selected to participate. In 1997 FDA completed the pilot program at six firms and published a second interim report.

4. HACCP for Meat and Poultry

On July 25, 1996, USDA published a final rule (61 FR 38806) that, among other things, required that each meat and poultry establishment develop and implement written sanitation standard operating procedures (Sanitation SOP's) and a system of HACCP controls designed to improve the safety of their products. The effective date for the Sanitation SOP's was January 27, 1997, and for the HACCP regulations was January 26, 1998. FDA has reviewed the meat and poultry HACCP regulations and has incorporated portions of them as appropriate in the proposed HACCP regulations for juice.

D. Issues from the ANPRM

FDA received approximately 150 comments in response to the August 4, 1994, ANPRM. The comments represented the views of consumers, consumer organizations, health professionals, academicians, food industry officials, trade associations, and foreign, State, and local government agencies. The agency has attempted to address these comments to the extent that they are relevant to this proposal.

1. The agency asked in the ANPRM how the responsibility for food safety should be shared between the food industry and government. Comments generally agreed that the food industry is responsible for producing safe food products. All respondents on this issue recognized that the Government's role is to verify industry compliance with any applicable safety regulations.

FDA agrees that it is the manufacturer's responsibility to ensure that the food that it produces is safe, and that it is the Government's role to verify that manufacturers are fulfilling their responsibility. Through use of a HACCP system, both the firm and FDA are able to better fulfill their roles. The proposed regulation in part 120 underscores the division of roles. Under the proposed regulation, industry is charged with examining all aspects of production, identifying hazards that are reasonably likely to occur, and establishing measures that will control or minimize those hazards. HACCP records enable the agency to inspect the production facility more efficiently and to verify that the firm is operating in accordance with its HACCP plan. They also give the agency insight into whether any problems that have occurred have been identified and appropriately addressed.

It is important that the juice industry focus on its responsibility to produce safe food. Recent outbreaks evidence that some members of the industry have not kept up with the need to evaluate the hazards presented by juice and to design processes to address those hazards. Firms need to be aware of the emerging problems presented by their raw materials and to decide whether, and if so what, steps are necessary to address these problems. Firms may decide that it is necessary to incorporate a step designed to kill bacteria into their process (e.g., pasteurization), that there are alternative steps that they can take to ensure the safety of their products, or that, given the nature of the raw materials, no steps are necessary. Firms also need to monitor the process that they decide to employ to ensure that it is functioning adequately and appropriately. FDA notes that some firms have already addressed food safety concerns and have implemented HACCP systems.

Moreover, given the heightened concerns about these products, Government needs to be in a position to fulfill its role of verifying that industry is doing its job. Given the sporadic and variable way in which the problems that have been associated with juice arise, sampling and end-product testing of juice products will not enable it to do so. Other steps that will give Government insights into the production itself appear to be in order.

2. FDA requested comment in the ANPRM about the likelihood of occurrence of a hazard that would warrant HACCP-type control. Generally, the comments consistently identified two features that would characterize a properly formulated definition of likelihood: Processing conditions and nature of hazard. The majority of comments offered by the food industry stipulated that the necessary condition for likelihood of occurrence of the hazard appropriate to trigger HACCP control must not be speculative, as in worst-case scenarios, but be real, practical, and intrinsic to the processing or hazards demonstrably present for specific commodities. Several responses recommended that the question be referred to broadly based expert panels to establish the likelihood of risk.

According to the NACMCF, each potential hazard is evaluated based on the severity of the potential hazard and its likely occurrence (Ref. 55). Severity is the seriousness of the consequences of exposure to the hazard. Considerations of severity (e.g., impact of sequelae and magnitude and duration of illness or injury) can be helpful in understanding the public health impact of the hazard. Likelihood of occurrence of a hazard is generally judged based on processing experience, epidemiological data, and information in the technical literature.

The agency agrees with the comments that stated that the processing conditions and the nature of the hazard are key elements in assessing the

likelihood of a hazard occurring. It would be futile for processors to attempt to control for every theoretical hazard because doing so would entail assessing hazards that the processor could not reasonably anticipate would actually occur. The assessment of the likelihood of risk of illness or injury to consumers should be practical for the specific commodity and not be speculative. For example, use of pesticides on fruits and vegetables is a common practice while these foods grow. The presence of pesticides on fruits or vegetables used to make juice is considered a hazard if: (1) The pesticide is not approved for use on the fruit or vegetable, or (2) it is found in amounts above its EPA established tolerance. If a pesticide is applied to fruits or vegetables in conformance with EPA regulations, and the appropriate period of time has elapsed between application and harvest, the presence of the pesticide is not considered to present a hazard that is reasonably likely to occur.

The agency disagrees that it should rely on broadly based expert panels to establish likelihood of occurrence of a hazard. Although such committees could provide insight into the issue, on balance, the insights that they would be likely to provide would not justify the expenditure of resources that convening such committees would require. However, interested persons are welcome to consider voluntarily the question and to submit the results of their consideration to the agency.

3. Comments on the ANPRM stated that because epidemiological studies consistently show that microbial pathogens are the most significant source of food hazards, issues such as pesticides, heavy metals, filth, physical contaminants, and others pale by comparison with the immediate health consequences of foodborne microbial pathogens. They stated that HACCP is best suited for preventing microbial hazards rather than physical or chemical hazards because CCP monitoring can be readily established in a timely fashion for pathogens and, particularly, for the unsanitary conditions that promote their growth.

The comments added that effects that result from events that occur after the food has left the processor's HACCP system are not controllable by the processor. The comments said that this fact is significant because food service establishments and the lack of consumer education have contributed to the majority of incidences of foodborne illness reported in current epidemiological data. They stated that HACCP systems are essentially localized management tools that will not permit any measurable improvement in national or international food safety effectiveness and have been implemented voluntarily solely as a corporate practice to provide strategic business advantages in increasingly competitive markets.

The comments stated that regulation may be premature because of the adequacy and feasibility of presently available analytical tests to control all hazards. They stated that, consequently, HACCP is an excellent tool but only in the very specific case of high-risk food processing that is focused on controlling microbiological risks. The comments stated that, instead of misdirecting its efforts, FDA needs to look to itself to reinforce food preparation safety awareness at food service establishments and to pursue vigorously an enhanced consumer education policy on unsafe food practices as the best preventative food risk control program.

FDA agrees that microbial hazards are a significant source of food hazards. FDA also agrees that HACCP is an ideal mechanism to deal with microbial hazards because it is a system of prevention. Prevention makes up for the inadequacies of end-product testing. For example, for maximum quality, nonshelf stable juice must be distributed quickly, and end-product testing usually takes at least several days to obtain results. If pathogens are discovered in the juice after distribution, the product must be recalled, and consumers may have already ingested product. Finally, the particular samples taken in end product testing may not contain pathogens because the pathogens may not be ubiquitous in the lot (i.e., there may be low level or sporadic contamination) and thus produce false negatives.

A system of preventive controls, like HACCP, on the other hand, is designed to identify and manage conditions where pathogens could be present in juice while it is still being processed. HACCP is designed to ensure that there is early discovery, and timely correction, of any problems that may develop. Although HACCP is well suited for preventing microbial hazards, this does not mean, as some of the comments asserted, that it is not useful for other types of hazards. As the NACMCF has recognized, it is well suited for preventing chemical and physical hazards. For example, processors can establish CCP's to prevent pieces of glass from contaminating a product when glass bottles are used.

The NACMCF endorses HACCP as an effective and rational means of assuring food safety (Ref. 55). According to the NACMCF, its use will likely result in measurable improvement in food safety. Under HACCP, processors view the processing plant from a prevention perspective and thus are in a position to react appropriately to new hazards if they arise. In preparing this proposal, FDA has reviewed the history of juice related outbreaks. All of these outbreaks might have been prevented if a HACCP system of the type that FDA is proposing herein had been in use.

The agency agrees that there are hazards that can occur after food has left the processing plant that the processor cannot control. The agency has established the Food Code to assist State agencies and food workers in retail food establishments and has addressed handling of high risk foods in the Food Code. FDA also provides consumer information on food safety through a consumer hotline, public affairs specialists in FDA's district offices, and various brochures and other publications. These efforts are intended to educate consumers on safe handling of foods at home. In addition, as described in the interim notice, the agency has initiated a consumer education program concerning juice that is not treated to prevent or eliminate the presence of harmful bacteria.

4. The agency requested information in the ANPRM on its possible role in assisting the food industry in the development of HACCP plans. Comments stated that FDA preparation of general background materials on HACCP would be beneficial in establishing a common approach to plan development, in assisting hazard identification analysis, and in using consistent language. They stated that FDA could provide informational resources such as examples of HACCP plans adaptable to the individual circumstances of a business' operations or consultative documents that could serve to guide plan development.

However, some comments urged that FDA avoid over-regulation. They stated that an excessively ambitious regulatory approach will limit the effectiveness of any HACCP program.

The agency agrees that it should avoid over-regulation because such an approach can inhibit future developments and new technology in HACCP systems and in safe food processing. FDA is proposing a HACCP regulation that, if adopted, will be mandatory for juice processors (as defined at proposed § 120.3(i)) but that can be used as a model for other foods in that it outlines the minimum essential components of a HACCP system. To the extent possible, the proposed regulation is in harmony with

the existing HACCP regulations for seafood and meat and poultry.

FDA has developed the ''Fish & Fisheries Products Hazards & Controls Guide'' to assist manufacturers in the implementation of HACCP for seafood. The Federal Safety and Inspection Service (FSIS) has developed, in conjunction with the International Meat and Poultry HACCP Alliance, 13 HACCP models for meat and poultry products, a ''Guidebook for the Preparation of HACCP Plans,'' and the ''Meat and Poultry Products Hazards and Control Guide.'' However, it is not clear whether FDA will be able to provide such detailed information for juice. Therefore, in this rulemaking, the agency will attempt to provide guidance, to the extent possible, concerning the application of the regulation to juice.

5. Some comments on the ANPRM stated that, if EPA tolerances for pesticides in agricultural commodities become HACCP-focused safety issues in food processing and service industries, then explicit coordination by FDA with EPA is needed to define truly significant hazards. They stated that this effort would greatly assist HACCP development in such circumstances, so that duplication of effort would be avoided, consistency among regulatory requirements would be achieved, and impediments to international commerce would be removed.

FDA has attempted to harmonize its regulations with those of other Federal agencies and with Codex. EPA establishes regulations for pesticide use and tolerances for pesticide residues, and FDA and USDA enforce those tolerances on foods.

Under section 402(a)(2)(B) of the act, a food is deemed to be adulterated if it bears or contains a pesticide chemical residue unless a tolerance or an exemption for such pesticide has been established, and the quantity of such pesticide on the commodity is within the tolerance limits. Pesticide chemical residues for which there is no tolerance or exemption are deemed to be unsafe as a matter of law. HACCP is intended to protect against unsafe products. Thus, there is no reason why pesticide residues and similar types of food safety measures should be outside the scope of HACCP.

6. In the ANPRM, the agency asked if there was a need for microbiological criteria in HACCP regulations. Some comments favored inclusion of microbiological criteria for known high risk foods because such criteria are practical, efficient, and cost effective. However, most comments maintained that microbiological criteria, set as national standards, are not warranted because: (1) Criteria are discordant with HACCP purposes because they depend on end product testing, (2) criteria possess inadequate scientific basis, and (3) criteria are preemptive of localized development of HACCP systems.

The agency tentatively agrees with those comments that stated that microbiological criteria in HACCP regulations are warranted for some foods. Contrary to what many of the comments asserted, effective microbial controls depend not on end product testing but on processing controls and the establishment of CL's. For example, juice made from apples that have fallen on the ground must be processed in some manner to destroy pathogens because pathogens are likely to be present and, as discussed previously, end product testing may produce false negatives. If a regulation is flexible, it should not ''preempt'' the processor's development of HACCP, but it can provide the CL's needed for the safe processing of food under a HACCP system. However, the agency agrees that the decision on which processing controls are to be used must have a valid scientific basis.

Microbial pathogens have emerged as a significant problem in unpasteurized juice in recent years. The NACMCF recommended that safety performance criteria, rather than a specific intervention technology, be mandated for juice (Ref. 53). The safety performance criteria recommended by the NACMCF is whether the measures that a juice processor employs have been validated to achieve a cumulative 5 log reduction in the target organisms or a reduction in yearly risk of illness to less than 10^{-5}, assuming consumption of 100 mL of juice daily. As will be discussed in section IV.M of this document, FDA is proposing to require that firms include in their HACCP plans measures that will produce, at a minimum, a 5 log reduction in target pathogens.

7. Comments on the ANPRM stated that FDA should require end product testing records to provide information as to the effectiveness of a HACCP program. These comments stated that end product testing was practical because mandated testing was a necessary, continuing, and recordable validation of the completeness of a HACCP system, thereby ensuring that 100 percent control is manifested.

Comments from the juice meeting also supported the use of end product testing. One of the these comments proposed using testing to decide whether to pasteurize each lot. Several comments pointed to new rapid testing technologies and testing kits for pathogens.

However, other comments maintained that information generated from end product tests would not be useful. One comment stated that end product testing activities were counterproductive to a well-planned HACCP system. Furthermore, these comments added, any requirements that FDA puts forward must be practical, and no process can be regulated into 100 percent certainty.

The agency is not proposing to require end product testing. End product testing is most useful where there are high levels of the substance being tested, and there is uniformity throughout the lot being sampled. Product sampled for testing for microbial hazards, where a pathogen (e.g., *E. coli* O157:H7) is hazardous even at very low levels, or for physical hazards (e.g., glass), where the hazard is the presence of a discrete unit, may not contain the hazard even under the best sampling procedure. In these cases end product testing is likely to produce false negatives and, thus, to provide scant protection. It is prohibitive to use end product testing adequately in these situations because of the amount of testing that is necessary for a statistically valid test, and because it would be necessary to channel a significant portion of the product for that testing. Therefore, the agency has tentatively concluded that use of control measures under a HACCP system to prevent hazards from occurring, with subsequent monitoring, verification, validation, and recordkeeping, is more effective than end product testing in ensuring that food is safe. Thus, FDA has not included a requirement for end product testing in this proposed rule on juice products.

8. The agency asked in the ANPRM whether it should mandate HACCP for all segments of the food industry. Many comments stated that mandatory HACCP regulations for low-risk foods would be inappropriate because trying to manage low risk hazards through HACCP would dilute agency resources and therefore the effectiveness of HACCP. The comments stated that FDA could utilize its resources most efficiently by focusing on those high-risk food processing operations identified in its 1993 model Food Code as ''Potentially Hazardous.'' They stated that the U.S. food supply is already demonstrably the world's safest, so that there is no valid reason for requiring HACCP plans of the entire industry. The comments stated that enforcement mechanisms in the act are, and will continue to be, sufficient without adding to the regulatory burden on

industry. They added that incorporation of HACCP into food industry operations should be permitted to proceed on a voluntary basis, unless a well-defined need requires implementation through specific authority provisions of the act into specific high-risk segments of the food industry.

However, some comments stated that unless all segments of the food chain are mandatorily included, adoption of HACCP is unlikely to result in measurable enhancement of the safety of the food supply. They stated that less than universal coverage would create confusion about what should be excluded. The comments stated that any attempt to limit HACCP to identified ''high-risk'' processors would hinder efforts to address significant public health problems that may arise in the future. They concluded that it is not unduly burdensome to mandate HACCP for all. The comments maintained that HACCP regulations should be as comprehensive as practicable and applied throughout the food chain to the fullest extent possible and reasonable, and that HACCP principles must be applied from farm to fork.

FDA disagrees with the comments that stated that HACCP is inappropriate for low-risk foods. Both food processors and government regulatory agencies would benefit from the use of HACCP systems. The U.S.'s excellent record for having a safe food supply does not mean that this country should not consider ways of improving on that record. In the face of emerging pathogens and other new food hazards, HACCP provides a flexible system in which processors reassess their procedures on an on-going basis. HACCP also enables processors to meet future demands.

The use of HACCP allows food processors to concentrate their efforts on the aspects of the processes that they use where risks are highest and provides regulatory agencies with assurance that processors are observing prudent processing practices. HACCP also provides assurance that problems in the process are likely to be discovered, and that unsafe product is unlikely to leave the firm. The complexity of HACCP is a function of the number of hazards that must be controlled and the nature of the controls for each hazard. Foods that involve few hazards will tend to have fewer CCP's, and, conversely, those that have multiple hazards will tend to have more complex HACCP plans and monitoring requirements.

FDA is proposing a regulation that will mandate HACCP for juices. The agency has tentatively concluded that there is a safety basis to require that processors use HACCP systems in the processing of juice. As the agency gains experience and additional information from the pilot program and from seafood HACCP implementation, it will examine the appropriateness of expanding the scope of proposed part 120 (if the agency adopts it) to include other foods. Clearly, the agency will consider HACCP's use with foods that it has identified as presenting likely hazards, as it is doing in this proposal.

In developing the proposed regulations for juice, FDA came to recognize that the elements of a HACCP regulation for juice are really no different than those for seafood. This insight suggests that part 120 can act as a model for HACCP for other parts of the food industry should the agency become aware of facts that would justify extending the coverage of the regulation. Firms that are interested in voluntarily instituting HACCP can use the regulations in part 120 as a guide for doing so.

9. The ANPRM requested information on the criteria that FDA should use in deciding whether to cover some or all segments of the food industry with a mandatory HACCP rule. Some of the comments stated that exclusions cannot be justified on the basis of business size because about 75 percent of the food industry would be considered to be small businesses. The comments asserted that exclusions can only be judged with respect to properly defined risks for the food hazards involved in producing the end-product.

FDA agrees that exemptions from HACCP regulations cannot be justified on the basis that a business is small because food hazards that are reasonably likely to occur in the production of most foods occur regardless of the size of the firm. The agency also agrees that any exceptions to mandatory HACCP systems must be based on instances in which risks are not reasonably likely to occur. However, FDA is required by law to consider ways to assist small businesses when it implements regulations. While FDA does not propose to exempt any small businesses from the food safety requirements in this proposed rule, FDA is considering ways to provide regulatory options that will serve to reduce the burden of compliance on such small businesses.

IV. FDA's Proposal

A. Applicability

1. Scope

The agency tentatively concludes that HACCP is necessary for the safe and sanitary production of fruit and vegetable juices to address the special concerns discussed previously. Therefore, FDA is proposing new § 120.1(a), which states that part 120 applies to juice and defines what juice means for purposes of this regulation.

Fruit and vegetable juices may be used as ingredients in other beverages (e.g., flavored bottled waters; juice beverages and cocktails). These products often resemble juices, are processed in a manner that is similar to juices, and handled by consumers similarly to juices. Thus, they can present the same food hazards as juices. Therefore, FDA is proposing to require that any juice sold as such or used as an ingredient in beverages be processed in accordance with the requirements of part 120.

As stated in section II of this document, FDA has established standards of identity for a number of fruit juices in part 146 and for tomato juice in § 156.145. These standardized juices are generally described as the liquid extracted or expressed from a fruit or vegetable. However, prune juice (§ 146.187) is prepared from a water extract of dried prunes.

A typical dictionary definition of the term ''juice'' is a fluid naturally contained in plant or animal tissue (Ref. 56). As described above, the present situation has demonstrated a need to control food hazards associated with fruit and vegetable juices. The present situation does not include oil extracts of fruits and vegetables (e.g., olive oil) because these are not traditionally considered juice. Some juices (e.g., banana juice) and fruit nectars, when purees of the fruit used, need to be included in any definition FDA proposes because such purees are often blended with other juices. If there are food hazards associated with extractives of a fruit or vegetable, those food hazards will be present in purees of that fruit or vegetable. Concentrates of juice and purees also need to be included in the definition because, if a hazard is present in the juice or puree, it could also likely be present in the juice concentrate. Therefore, the agency is tentatively defining ''juice'' as the aqueous liquid expressed or extracted from a fruit or vegetable, purees of the edible portions of a fruit or vegetable, or any concentrates of such liquid or puree.

The agency requests comments on the definition of ''juice.'' FDA also requests comments on the scope of the regulation and on whether it should mandate HACCP for all types of juices, or whether it would be sufficient to mandate HACCP for certain types of juices.

2. Effective Date

The seafood final rule provided processors 2 years to implement HACCP. This was done to: (1) Allow time for training of industry personnel and regulatory personnel; (2) provide the States with the time to have a full opportunity to understand and respond to the effects of these regulations; (3) increase the likelihood that more agreements with other countries will exist; (4) increase the opportunity for processors to engage in ''voluntary'' HACCP inspections in advance of the effective date to obtain preliminary, informal feedback from the agency on their progress; and (5) allow incorporation of modifications made in the final rule and publication of FDA assistance materials for the seafood industry (60 FR 65096 at 65169).

The period of time between publication of the final rule and the effective dates of the HACCP regulations for meat and poultry issued by FSIS are: (1) Eighteen months for large establishments with 500 or more employees, (2) Thirty months for smaller establishments with 10 or more employees but fewer than 500, and (3) Forty-two months for very small establishments with fewer than 10 employees or annual sales of less than $2.5 million (61 FR 38806).

A comment from a fresh juice trade association submitted to the agency in response to the NACMCF recommendations to FDA on the safety of juices, requested that FDA mandate HACCP for all juice products and phase this requirement in over a 3-year period from the publication of the final rule in a manner similar to the FSIS HACCP regulation. The comment requested that FDA consider annual inspections of fresh juice firms until the regulation is effective. It stated that the delay in implementing HACCP requirements would allow FDA and juice processors the ability to review conclusions of specific research and establish performance standards based on this research.

Comments on FDA's notice of intent (62 FR 45593) generally supported a phased-in approach for small firms taking 3 to 4 years. However, one comment expected that a phase-in approach would take no more than 2 years.

The agency is considering the significant issues surrounding orderly implementation of HACCP. FDA must balance the need for immediate implementation of HACCP, because of its associated food safety benefits, against the costs of implementation and consider options to minimize the burden to small businesses. The proposed timeframe for implementation of these regulations attempts to balance these competing concerns. The implementation of HACCP may be more burdensome for small firms than for large firms. Large firms tend to have quality control personnel already in place. In addition, many regulatory requirements are less burdensome for a large firm in proportion to output than they are for a small firm.

FDA recognizes that HACCP systems cannot be developed and implemented overnight. The HACCP system of controls can involve new ways of thinking and performing on a routine basis.

The agency issued a notice on August 28, 1997 (62 FR 45593), that provided interim measures, and elsewhere in this issue of the **Federal Register**, FDA is proposing to require labeling for juice to address the agency's immediate public health concerns. If finalized, these measures will require labeling on juice to provide information that juice unprocessed to control pathogens poses risks to children, the elderly, and the immunocompromised. The agency is proposing that the labeling measures be superseded once packaged juice products are processed under adequate HACCP programs, or are otherwise processed in a manner to destroy pathogens (e.g., pasteurization). Therefore, as proposed, before the applicable effective date, juice will be processed to control for pathogens or, if not, will bear labeling to alert consumers that such processing has not occurred. After any applicable effective date, processors will use HACCP systems in the production of juice.

The agency has considered the precedents established by other HACCP regulations and the comments submitted on juice. There are two significant differences between the HACCP regulation that FDA is proposing for juice and the HACCP regulations for seafood and for meat and poultry. First, FDA has issued interim guidance suggesting that juice that has not been processed to control pathogens be labeled accordingly. Elsewhere in this issue of the **Federal Register**, the agency is proposing to require such labeling. Second, at the present time, FDA's available resources would make it very difficult, if not impossible, to implement a comprehensive inspection program for the entire juice industry. A phased in approach for compliance will thus ease the burden not only on small businesses but also on the agency itself. Accordingly, FDA is proposing that the regulations proposed herein generally be effective 1 year after the date of publication of the final rule, with special provisions that will extend the phase-in to up to 3 years after publication of the final rule. This proposed phase-in approach will permit the regulated industry time to accomplish the training of personnel and adjust its activities to include necessary HACCP activities and takes into account the needs of smaller businesses.

The agency proposes to establish a timetable for phasing in HACCP based on business size. FDA proposes in § 120.1(b) that the effective date be 1 year following publication of the final rule. The agency is proposing that, by its terms, the regulation will not be binding until 2 years following the date of publication of the final rule for small businesses employing fewer than 500 persons (§ 120.1(b)(1)). This is based on the definition of a small business used by the Small Business Administration. In addition, the agency is proposing that, by its terms, the regulation will not be binding until 3 years following the date of publication of the final rule for very small businesses that have either total annual sales of less than $500,000, or that have total annual sales that are greater than $500,000 but total annual food sales of less than $50,000, or that employ fewer than an average of 100 full-time equivalent employees and that sold fewer than 100,000 units of the product in the United States (§ 120.1(b)(2)). These criteria are consistent with those that the agency has used in its regulation on small firms and compliance with the nutrition labeling rules that implement the Nutrition Labeling and Education Act (the 1990 amendments) (61 FR 40963) (see § 101.9(j)(1) and (j)(18)) (21 CFR 101.9(j)(1) and (j)(18)). In the 1990 amendments context, these criteria represent the outcome of three hearings in different parts of the country, an act of Congress, and informal rulemaking by FDA. Thus, FDA tentatively concludes that food manufacturers agree with and understand the definition of very small businesses. As discussed in the next section of this document, for purposes of this proposed rule, the agency has tentatively decided that a retail establishment as set out in proposed § 120.3(h)(2)(iii) includes a very small processor that makes juice on its premises and directly sells this juice both to consumers and other retailers provided that total juice sales do not exceed 40,000 gallons per year.

In implementing proposed § 120.1(b)(2), FDA intends to use the definitions for the terms ''unit,'' ''food product,'' ''person,'' and ''full-time equivalent employee'' in

§ 101.9(j)(18)(vi). These definitions are as follows: (1) ''Unit'' means the packaging or, if there is no packaging, the form in which a food product is offered for sale to consumers; (2) ''food product'' means food in any size package that is manufactured by a single manufacturer or that bears the same brand name, that bears the same statement of identity, and that has similar preparation methods; (3) ''person'' means all domestic and foreign affiliates, as defined in 13 CFR 121.401, of the corporation, in the case of a corporation, and all affiliates, as defined in 13 CFR 121.401, of a firm or other entity, when referring to a firm or other entity that is not a corporation; and (4) ''full-time equivalent employee'' means all individuals employed by the person claiming the exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the person and of all of its affiliates by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours x 52 weeks).

FDA is committed to its mission of ensuring that food is safe and not misbranded. This commitment is the basis for proposing interim labeling measures. The agency tentatively finds that a phase-in HACCP implementation is necessary because of the logistical effort required to manage a fundamental change in work processes, roles, and responsibilities for smaller processors. The proposed implementation schedule reflects the abilities of processors of varying sizes to implement HACCP, and the time needed by industry to develop HACCP plans and train employees.

Upon the proposed implementation date, processors must be ready to operate their HACCP system, and FDA will conduct inspection activities according to HACCP principles to ensure that the HACCP system is operating acceptably. FDA requests comment on its proposed phased-in implementation of HACCP.

B. Definitions

FDA is proposing in the introductory paragraph of § 120.3 that the definitions and interpretations of terms in section 201 of the act (21 U.S.C. 321), in § 101.9(j)(18)(vi), and in part 110 be applicable to such terms when used in part 120, except where they are redefined in § 120.3.

The agency is proposing to include in § 120.3 all definitions applicable to juice that are in the seafood HACCP regulation. The following terms have proposed definitions that are the same as their definitions in § 123.3: ''critical limit'' (§ 120.3(d)), ''food hazard'' (§ 120.3(e)), ''importer'' (§ 120.3(f)), ''shall'' (§ 120.3(j)), and ''should'' § 120.3(k)).

However, FDA is proposing to modify the term ''preventive measure'' to ''control measure'' (§ 120.3(b)) and to modify its definition from that used in the seafood HACCP regulation (§ 123.3(i)) to conform with recent NACMCF changes in terminology (Ref. 55). The term ''control measure'' is used because not all hazards can be prevented, but virtually all can be controlled to some degree. The new NACMCF definition describes the control measures as actions or activities rather than as chemical, physical, or other factors. Further, the term ''control'' is clarified to mean prevention, elimination, or reduction of hazards. The agency tentatively concludes that the recent NACMCF definition better describes the measures that processors must take. Therefore, FDA is proposing that ''control measure'' means any action or activity that can be used to prevent, eliminate, or reduce a hazard.

The NACMCF also recently modified its definition for ''critical control point'' (Ref. 55). The modified definition incorporates the new definition of ''control measure'' and emphasizes the essential or critical nature of the step. Thus, FDA tentatively concludes that the recent NACMCF definition better characterizes the term. Therefore, the agency is proposing in § 120.3(c) that ''critical control point'' means a point, step, or procedure in a food process at which a control measure can be applied and at which control is essential to reduce an identified food hazard to an acceptable level.

The seafood HACCP regulation defines ''processing'' in § 123.3(k) with specific product application. To apply these definitions to juice and to avoid listing specific processes, the agency is proposing in § 120.3(h)(1) to define ''processing'' as activities that are conducted by a processor that are directly related to the production of juice products.

As with the seafood HACCP regulation, there are certain handlers of juice products that are not covered by the proposed definition. FDA has tentatively concluded that harvesting, picking, or transporting raw agricultural ingredients of juice products, without otherwise engaging in processing, should not be included in the term ''processing'' (§ 120.3(h)(2)(i)). FDA has developed voluntary GAP guidance that has been issued in draft for comment and will apply to these activities. The agency believes that growers will find GAP's useful and that the regulations that it is proposing in this rulemaking will, if adopted, reinforce use of both FDA and specific industry GAP's, thus affecting harvesting, picking, or transporting indirectly through processor and importer controls over raw materials and imported shipments (e.g., preventive controls such as the purchasing of raw materials only from farms that engage in proper handling of produce).

The agency notes that, with FSIS, it published an ANPRM (61 FR 59372, November 22, 1996) concerning transportation and storage requirements for potentially hazardous foods. In that ANPRM, FDA and FSIS requested information and comments on approaches that the two agencies should take to foster food safety improvements in the transportation and storage of potentially hazardous foods. While juice has not historically been considered a potentially hazardous food, recent illnesses associated with juice necessitate reconsideration of whether this food should not be included in that category. FSIS and FDA are reviewing the comments received in response to the joint transportation notice and will decide whether rulemaking is warranted. FDA invites comment on whether its approach to transportation is adequate.

The agency has also tentatively decided to exclude the operation of a retail establishment from the definition of ''processing'' (§ 120.3(g)(2)(ii)). For purposes of this rule, the agency has tentatively decided that a retail establishment as set out in proposed § 120.3(h)(2)(iii) includes a very small processor that makes juice on its premises and directly sells juice to consumers and other retailers provided that total juice sales do not exceed 40,000 gallons per year.

FDA has traditionally refrained from directly regulating retail establishments, although it has authority to do so. FDA provides training and other forms of technical assistance to States and local governments who inspect retail food establishments through the agency's retail Federal/State cooperative program. A major part of that cooperative program involves the development of model codes, some of which have been widely adopted by States and local governments. FDA has consolidated those model codes into a single, updated food code for the retail sector. Appropriate controls are included in the food code that can be applied to address juice hazards at retail. FDA will continue to operate through the Federal/State cooperative mechanism and, consequently, has not proposed to regulate juice retailers in

this proposal. However, elsewhere in this issue of the **Federal Register**, the agency is proposing to require labeling statements for packaged juice products including those sold by retailers that have not been pasteurized or otherwise processed to reduce, eliminate, or control pathogens. The proposed labeling requirement would apply to packaged untreated juice products produced in retail establishments for immediate consumption (such as grocery stores and very small processors) and would serve to inform consumers of the risk of untreated juices. (Retail processors selling unpackaged juice on-site for immediate consumption, such as restaurants and juice bars, would be exempt from both HACCP and labeling.) FDA notes that 2 of the outbreaks associated with apple cider (an outbreak of E. Coli. 0157:H7 infection and an outbreak of cryptosporidosis involving very small apple cider mills, refs. 8, 8A, and 11) would have fallen under the retail exclusion. Under the proposed labeling rule, the cider mills would have been required to label their apple cider. FDA seeks comment on whether the provisions of the food code in combination with the labeling statements will provide adequate public health protection. In addition, in formulating its proposal to include in the definition of retailer a processor that sells less than 40,000 gallons per year, the agency considered two other alternatives on which it requests comments. The first alternative would be to subject these establishments to the HACCP requirements and to provide a 3-year effective date. The second alternative would be to subject these establishments to the HACCP requirements and to provide a 5-year effective date. The agency is also soliciting comment on the appropriateness of including these establishments in the retail exemption as well as the appropriateness of the other two options considered.

The agency is proposing to define the term ''control,'' even though it was not included in § 123.3. FDA is proposing in § 120.3(a), that ''control'' means to prevent, eliminate, or reduce. This definition is consistent with the use of the term ''control'' in the definition for ''control measure'' (§ 120.3(b)) and describes more specifically what is to be accomplished in the control of food hazards.

FDA is also proposing to define the term ''monitor,'' even though it was not included in § 123.3. FDA is proposing in § 120.3(g) to define ''monitor'' as conducting a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and producing an accurate record of those observations or measurements for use in verification. This definition is identical with that of the NACMCF (Ref. 55). The agency tentatively concludes that defining this term will assist juice processors to be aware of what activities constitute monitoring of the various components of the HACCP system and prerequisite programs; and comply with the monitoring and recordkeeping requirements necessary for acceptable verification of HACCP.

C. CGMP's

Section 120.5 of the proposed regulations references the umbrella CGMP regulations in part 110 as providing general guidance to such matters as facility design, materials, personnel practices, and cleaning and sanitation procedures. Because part 110 provides guidance of general applicability to all foods, including juice, the agency intends that this guidance will continue to apply to juice processors even if FDA adopts the proposed regulations in part 120.

D. Prerequisite Program Standard Operating Procedures

The available evidence, including FDA's experience with the HACCP pilot programs, points to the effectiveness of two programs that do not fall within the parameters of traditional HACCP. FDA will refer to these programs in this document as ''prerequisite programs.'' The first of these programs is that the firm have in place SOP's designed to ensure plant sanitation.

The seafood final rule requires in § 123.11 that the processor monitor certain sanitation measures and document both the monitoring activities and any corrective actions taken when such monitoring finds an insanitary condition that may contribute to the likelihood of product becoming hazardous. While seafood processors are not required under § 123.11(a) to develop and implement written sanitation or prerequisite program SOP's, processors must maintain sanitation control records that, at a minimum, document that certain monitoring requirements have been met, and that corrective actions are taken when necessary (§ 123.11(c)). Section 123.11(b) sets forth requirements for sanitation monitoring.

FSIS's regulations for meat and poultry require that official establishments develop, implement, and maintain written SOP's for sanitation (9 CFR 416.11). Each official establishment must take appropriate corrective action when it or FSIS determines that the SOP's have failed to prevent direct contamination or adulteration of product (9 CFR 416.15). Each establishment must maintain daily records that are initialed and dated to document the implementation and monitoring of the SOP's and any corrective actions taken (9 CFR 416.16). Finally, FSIS verifies the adequacy and effectiveness of the SOP's (9 CFR 416.17).

Insanitary facilities or equipment, poor food handling, improper personal hygiene, and similar insanitary conditions create an environment in which products may become contaminated with microorganisms, including pathogens. However, sanitation controls may be difficult to fit into HACCP plans. Sanitation covers the whole processing environment, not just CCP's. A prerequisite program is an appropriate mechanism for a situation, such as sanitation, that does not lend itself well to HACCP controls. Therefore, sanitation SOP's are a type of prerequisite program that is essential to provide a solid foundation for HACCP systems. The agency tentatively concludes that sanitation SOP's are an essential foundation for HACCP systems for juice.

The second prerequisite program is one that provides control over materials that are entering the plant. The SOP requirements of both the seafood and FSIS regulations are limited to sanitation. However, the pilot program experience has suggested the utility of controls on incoming material. A processor could use incoming material prerequisite program SOP's, in a manner similar to the sanitation SOP's, i.e., to cover a range of processing factors, not just CCP's. Although use of incoming material SOP's may not obviate the need for some CCP's in a HACCP plan, FDA anticipates that their use could help to ensure the safety of the food produced.

Incoming material controls for raw produce could be invaluable in establishing the conditions under which produce needs to be grown (including pesticide application) and harvested to provide assurance to the processor that the raw produce will not present hazards that the processor will otherwise need to control. For example, the processor's incoming material SOP's could specify that the processor will only purchase carrots that have not been fertilized with manure during growth. Another example is that the incoming material control could specify that the processor will only accept apples that have been picked from the tree, and that dropped apples are unacceptable. A simple solution to control the possible

presence of unlawful pesticide residues on fruits and vegetables is to establish SOP's for incoming material control that ensure that any pesticides that have been used on the produce are approved for that use, are used at the appropriate level, and that appropriate time has elapsed between application and harvest.

As discussed previously, FDA is developing GAP and GMP guidance that has been issued in draft for comment. The guidance will address potential food safety problems throughout the food production and distribution system such as sanitation, worker health, and water quality.

A manufacturer also could use controls on the packaging materials that it receives. Proper packaging is essential if a processor is to minimize the possibility of the occurrence of hazards after juice has been processed. Juice that is not packed in hermetically sealed containers may be subject to contamination from a number of sources. The processor also needs to ensure that the container coating that it uses will not deteriorate through reasonable storage. Evidence in section I.B of this document showed examples where the acid content of some juices corroded the tin lining of the container, and the tin was present in sufficient concentration to be toxic. Incoming material controls will mean that the processor will act to ensure that packaging materials are safe and suitable before accepting them.

Incoming material controls for ingredients that a processor may add to juice can also be helpful. For example, if a processor is purchasing juice or juice concentrate from a supplier for use in a multi-juice beverage, it is essential that that juice have been processed under an adequate HACCP system and have not been contaminated during transportation. Thus, incoming material SOP's will lead the processor to establish controls on ingredients as criteria for acceptance in the plant.

However, the agency is not proposing to provide for the use of incoming materials SOP's in part 120 at this time and requests comment on this issue. FDA is seeking comment on whether incoming material SOP's can be utilized in a similar relationship to the HACCP system as the sanitation SOP's. Do interested persons see value in FDA requiring that these SOP's be written, monitored, and verified? How do these SOP's relate to FDA's draft guidance on fresh produce? What are reasonable procedures for acceptance of incoming materials that could be incorporated into SOP's?

1. Sanitation SOP's

FDA is proposing in § 120.6(a)(1) to require that processors have and implement SOP's that address sanitary conditions and practices before, during, and after processing. Good sanitation practices are critical to the prevention of microbiologically related foodborne illnesses. FDA's CGMP regulations for food in part 110 set out general principles of sanitation that should be followed in plants that manufacture, package, label, or hold human food. They address such matters as personal hygiene and cleanliness among workers who handle food, the suitability of the plant design to sanitary operations, and the cleaning of food-contact surfaces. The proposed sanitation SOP's relate to the entire facility, not just to a limited number of CCP's. FDA tentatively concludes that this step is necessary to fully implement section 402(a)(4) of the act and yet at the same time not overload the HACCP system. FDA invites comments on this approach.

FDA did not elect to make the development of a written sanitation SOP mandatory for seafood because it recognized that some processors may be able to achieve satisfactory sanitary conditions and practices without having to commit their sanitary control procedures to writing (60 FR 65096 at 65149). In the seafood final rule, FDA concluded that as long as there were records demonstrating that the plant was being kept in sanitary condition, it was not necessary to require written sanitation SOP's, even though the agency strongly recommended that a processor have them. The agency requests comment on whether it should require for juice HACCP that sanitation SOP's be written.

In the evidence discussed in section I.A of this document, there were several instances where contaminated water was the cause of the outbreak. The water that the processor used was contaminated and when produce was washed with it before juicemaking, the water contaminated the produce, resulting in contaminated juice. Therefore, the safety of the water that comes into contact with food or food contact surfaces is an important factor that a processor must consider to maintain proper sanitation and prevent contamination of the product and plant. The seafood HACCP regulation in § 123.11(b) lists eight sanitary conditions and practices that processors must monitor, and monitoring the safety of the water that comes into the plant is one of them (§ 123.11(b)(1)). Based on the foregoing, FDA is proposing a similar requirement in § 120.6(a)(1).

In section I.B of this document, FDA recounted the evidence demonstrating, that several outbreaks were caused by cleaning solution directly contaminating the juice. Sanitation SOP's for seafood in § 123.11(b)(5) require that processors protect food from adulteration with cleaning compounds. Given that cleaning compounds, sanitizing agents, pesticides, and other materials can pose a similar threat if not properly used in a juice processing facility, FDA is proposing a parallel requirement in § 120.6(a)(5).

The other provisions of § 123.11(b) are based on CGMP and encompass basic sanitation principles. Based on its consideration of the factors that it cited in arriving at § 123.11(b), the agency tentatively concludes that it is appropriate to require in § 120.6(a) that juice processors address the same sanitary conditions and practices in their SOP that must be monitored by seafood processors. FDA requests comment on the proposed matters that must be addressed in the sanitation SOP, and whether others are necessary for juice.

2. Other Requirements for Prerequisite Program SOP's

FDA is proposing in § 120.6(b) that processors monitor sanitation conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 that are appropriate both to the plant and to the food being processed. The seafood HACCP regulation requires sanitation monitoring (§ 123.11(b)). Because prerequisite programs potentially include facility-wide control points and provide a foundation for HACCP systems, processors need to monitor the performance of the SOP's to ensure that they are functioning as designed, and that they are corrected if there is a problem.

The agency is proposing in § 120.6(c) that processors maintain records that document the monitoring that they do under the prerequisite program SOP's and any corrections to those SOP's that they make. Monitoring and recording of conditions and practices under the prerequisite program SOP's are as much keys to the success in improving those conditions as is the development by a processor of the SOP's. As in the case of HACCP records, FDA is proposing to require that processors engage in systematic monitoring of their own sanitation practices and conditions. This proposed requirement is similar to what is required for sanitation SOP's for seafood (§ 123.11(c)). Monitoring to

ensure that sanitation is under control is the responsibility of all processors. Monitoring records help processors to see trends, and also allow the regulator to assess a processor's compliance over a period of time, not just at the time of an inspection.

FDA believes that the records bearing on the monitoring of relevant sanitation conditions and practices and the agency's access to such records are essential if proposed § 120.6 is to be an effective regulatory strategy. Therefore, as with HACCP records, the agency tentatively concludes that these records be subject to the recordkeeping requirements in proposed § 120.12.

Proposed § 120.6(d) provides the option to juice processors to include prerequisite program SOP controls in the HACCP plan. However, if these controls are implemented as part of the prerequisite program SOP's, there is no need to include them in the HACCP plan. The control must be in the HACCP plan or in the prerequisite program SOP but need not be in both places. This proposed provision is similar to § 123.11(d) for seafood. It is intended to provide manufacturers with flexibility in how they address the issues involved in the prerequisite controls.

The agency requests comment on its proposed approach to prerequisite program SOP's.

E. Hazard Analysis

1. The Hazard Analysis

The seafood HACCP regulation in § 123.6(a) requires that every processor conduct, or have conducted for it, a hazard analysis to determine whether there are food hazards that are reasonably likely to occur for each kind of fish and fishery product processed by that processor and to identify the preventive (i.e., control) measures that the processor can apply to control those hazards. Section 123.6(a) reflects the fact that food hazards can be introduced both within and outside the processing plant environment, including before, during, and after harvest. A food hazard that is reasonably likely to occur is one that, based on the evidence and insights provided by experience, illness data, scientific reports, and other information, has a reasonable possibility of occurring in the particular food if appropriate controls to protect against the hazard are not put in place. Thus, ensuring that a food will be safe involves identifying these hazards and preparing for them. The FSIS HACCP regulation for meat and poultry, in 9 CFR 417.2(a)(1), also requires that a hazard analysis be done.

According to the NACMCF, a thorough hazard analysis is the key to preparing an effective HACCP plan (Ref. 55). If the hazard analysis is not done correctly, and the hazards warranting control within the HACCP system are not identified, the plan will not be effective regardless of how well it is followed.

The hazard analysis involves hazard identification and evaluation. According to the NACMCF, each potential hazard is evaluated based on the severity of the potential hazard and the likelihood of its occurrence (Ref. 55). The NACMCF defined severity as the seriousness of the consequences of exposure to the hazard. They stated that consideration of the likelihood of its occurrence is usually based upon a combination of experience, epidemiological data, and information in the technical literature, and that when conducting the hazard evaluation, it is helpful to consider the likelihood of exposure and the severity of the potential consequences if the hazard is not properly controlled. The NACMCF also stated that consideration should be given to the effects of short term, as well as long term, exposure to the potential hazard.

The seafood HACCP regulation does not differentiate between hazards that cause acute harm and hazards that cause harm through chronic exposure. FDA stated in the seafood final rule that:

> HACCP should be the norm, rather than the exception, for controlling safety related hazards in the seafood industry. Existing standards for such contaminants as drug residues, pesticides, and industrial contaminants, are established to ensure that their presence in foods does not render the food unsafe. Processors of fish and fishery products are obliged to produce foods that meet these standards.
>
> Processors are obliged to exercise control over all food safety hazards that are reasonably likely to occur.

An important principle is that the processor has the burden of determining the reasonable likelihood of a hazard's occurrence, regardless of whether it is a chronic or an acute exposure hazard. In determining whether a chronic hazard is reasonably likely to occur, a processor should consider whether it is reasonably likely that, without some form of control, the food will contain a contaminant in sufficient quantity to cause it to be adulterated under the act (e.g., it exceeds a Federal tolerance for a pesticide residue).

The agency tentatively concludes that the requirement for a processor to conduct a hazard analysis is appropriate for juice processors. The evidence presented in section I of this proposal demonstrates that hazards are reasonably likely to occur in the processing of juice. Therefore, FDA is proposing to require in § 120.7 that processors develop a hazard analysis to determine whether there are food hazards that are reasonably likely to occur for each type of juice processed and to identify the control measures that the processor can employ to control those hazards. The agency requests comments on how processors should consider the severity of the hazard, as the NACMCF discussed, along with its likelihood of occurrence, in a hazard analysis.

FDA is also proposing in § 120.7 to require that juice processors use the same considerations in their hazard analysis as required of seafood and meat and poultry processors (i.e., that they determine where hazards are introduced, and which hazards need to be controlled) because these considerations raise the fundamental issues that must be considered in identifying the hazards present in any processing operation.

Finally, under the proposed regulation, the hazard analysis must be developed by an individual trained in HACCP. Training is critical to the successful implementation of HACCP systems. A trained individual will be able to understand and apply HACCP principles to the hazard analysis.

The hazard analysis serves several purposes. It can identify any modifications to a process or product that are necessary to ensure or improve the product's safety. It can also provide the basis for determining CCP's. A specific analysis of a process is necessary because aspects of the process that represent significant hazards in one operation may not present significant hazards in another operation even though the two operations produce the same or a similar product. Differences in equipment and incoming materials are generally the basis for these variations. For example, processors will use different equipment and incoming materials if producing juice from concentrate than if they are producing the same juice from raw materials.

A summary of the deliberations and the rationale developed during the hazard analysis should be kept for future reference. This information will be useful during reviews and updates of the hazard analysis and the HACCP plan.

Although under both seafood HACCP and meat and poultry HACCP a hazard analysis is required, a written hazard analysis is only required under the meat and poultry regulation. In the seafood HACCP final rule, the agency presented its reasons for not requiring a written hazard analysis (60 FR 65096 at 65118). It stated:

The agency recognizes that the best way for it to verify a processor's hazard analysis is indirectly, through its own evaluations of whether a processor ought to have a HACCP plan, and whether a HACCP plan appropriately identifies the food safety hazards and CCP's that are reasonably likely to occur. In other words, it is the end product of the hazard analysis, the HACCP plan and its implementation, that should be judged by the regulator. For this reason, the agency is not requiring that hazard analyses be performed according to a standardized regimen, or that they be documented in writing for FDA review.

Even though FDA is not requiring that the hazard analysis be available to the agency, there may be cases in which it would be to the processor's advantage to have a carefully documented written hazard analysis to show to FDA. Such documentation may prove useful in resolving differences between the processor and the agency about whether a HACCP plan is needed and about the selection of hazards, CCP's, and CL's. Written hazard analyses may also be useful to processors in that they may help provide the rationale for the establishment of CL's and other plan components. Having the basis for these decisions available may be helpful when processors experience changes in personnel, especially those associated with the HACCP process, and in responding to unanticipated CL deviations.

FDA believes that the position taken in the seafood HACCP regulation continues to be appropriate for seafood. The agency notes that the ''Fish & Fisheries Products Hazards & Controls Guide'' assists processors in the development of their HACCP plans, including the hazard analysis. It lists numerous potential hazards and guides seafood processors through the hazard analysis. However, as discussed previously, it is not clear whether, given the limitations on its resources, FDA will be able to provide such detailed information for juice. Therefore, the agency tentatively concludes that a requirement for a written hazard analysis is appropriate for juice.

Moreover, most firms in the FDA pilot program reported that preparing a written hazard analysis, including a list of preventive measures, helped them conduct a more scientific analysis rather than just a qualitative one; they also reported that the written hazard analysis provided a means of communicating to employees the public health significance of the hazards that were being controlled (Ref. 57). Thus, FDA believes that processors likely will conduct a more appropriate hazard analysis if they have to document it. If the hazard analysis has not been conducted properly, the HACCP plan will likely be inadequate. Therefore, FDA tentatively concludes that HACCP plans alone may not be adequate without a documented hazard analysis.

Accordingly, FDA is proposing to include in § 120.7 that the hazard analysis be written and maintained as a record in accordance with proposed recordkeeping requirements (§ 120.12). The agency requests comments on its approach of requiring a written hazard analysis.

2. Evaluation of Hazards

Section 123.6(c) requires that processors consider in the hazard analysis whether any food safety hazards are reasonably likely to occur as a result of natural toxins, microbiological contamination, chemical contamination, pesticides, drug residues, decomposition, parasites, unapproved use of direct or indirect food or color additives, and physical hazards. In 9 CFR 417.2(a)(3), FSIS lists these same considerations where food safety hazards might be expected to arise and adds zoonotic diseases to the list.

FDA has reviewed the food hazards that are reasonably likely to occur in juice. For the most part, the hazards that processors should consider in doing a hazard analysis for this type of food are the same as those that FDA and USDA have listed in the regulations for seafood, meat, and poultry (Ref. 58). However, unlike seafood, meat, and poultry, pesticides may be intentionally applied to fruits, vegetables, and other plant products during their growth. All pesticides applied to produce must be approved for use on that plant, and the residue levels of the pesticides at the time of harvest must be within tolerances. Therefore, processors must ensure that any pesticide residues on plant foods are lawful for that food and are within tolerances.

The presence of possible allergens in foods is a second possible hazard that was not considered in HACCP regulations for seafood or meat and poultry. Food ingredients must be declared on the label in accordance with § 101.4, and individuals sensitive to particular ingredients may avoid consuming them by checking the ingredient list. However, there is a possibility that traces of undeclared food materials could be present in food products from foods run previously on the same equipment as used for the juice or on nearby equipment. The presence of even traces of certain food ingredients can cause life threatening reactions in sensitive individuals. For example, dairies may process juice using the same equipment that they use to process milk. Therefore, dairies processing juice in this manner must consider whether traces of milk are present in the juice. The same principle holds for processors producing several types of juices on the same equipment. A hazard analysis should determine whether a food hazard is created as a result. FDA tentatively concludes that a hazard analysis should consider the potential presence of undeclared food ingredients that could be possible allergens.

Therefore, FDA is proposing in § 120.7(a) that in evaluating which food hazards are reasonably likely to occur, consideration should be given, at a minimum, to the following: (1) Microbiological contamination, (2) parasites, (3) chemical contamination, (4) unlawful pesticide residues, (5) decomposition in food where a food hazard has been associated with decomposition, (6) natural toxins, (7) unapproved use of direct or indirect food or color additives, (8) presence of undeclared allergens, and (9) physical hazards. The agency requests comment on these hazards and any others that should be included in the regulation.

3. Other Considerations

The agency is proposing in § 120.7(b) that processors should evaluate product ingredients, processing procedures, packaging, storage, and intended use; facility and equipment function and design; and plant sanitation, including employee hygiene, to determine the potential effect of each on the safety of the finished food for the intended consumer. These are factors that a prudent processor should consider in conducting a hazard analysis. The seafood HACCP regulations at § 123.6(a) did not list specific items or factors that processors should consider when conducting a hazard analysis. The preamble to the final rule for those regulations stated that, as of December 1995, the methodology for conducting a hazard analysis was not sufficiently standardized to justify mandating what the hazard analysis must include. The preamble encouraged processors to study the NACMCF guidance on the subject. The agency tentatively concludes, however, that including in the codified text the minimum elements that the processor should consider in developing a hazard analysis will assist processors. This material is included to be helpful and does not constitute a substantive change from the seafood HACCP regulation. FDA requests comment on proposed § 120.7(b).

F. HACCP Plan

1. The HACCP Plan

The seafood HACCP regulation requires in § 123.6(b) that processors have and implement a written HACCP

plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur. FSIS has established a similar requirement for meat and poultry (9 CFR 417.2(b)).

FDA is proposing to require in § 120.8(a) that every juice processor have and implement a written HACCP plan whenever a hazard analysis reveals that one or more food hazards are reasonably likely to occur during processing, as described in § 120.7. This could include adapting a model or generic-type plan to a processor's specific situation. This proposed requirement is in keeping with Principle 7 of the NACMCF guidelines that firms prepare and maintain written HACCP records (Ref. 55).

The agency is also proposing in § 120.8(a)(1) and (a)(2) that a HACCP plan be specific to each location where juice is, and to each type of juice that is, processed by that processor. The plan may group types of juice products together, or group types of production methods together, if the food hazards, CCP's, CL's, and procedures required to be identified and performed are essentially the same for the products or methods being grouped, provided that any required features of the plan that are unique to a specific product or method are clearly delineated in the plan and are observed in practice. Proposed § 120.8(a) is similar to provisions in both § 123.6(b) of the seafood HACCP regulation and 9 CFR 417.2(b) of the HACCP regulation for meat and poultry.

A plan is specific to each location because the likely hazards, CCP's, CL's, and monitoring procedures can vary from one facility to another depending on such factors as type of equipment, conditions and procedures, personnel, and location. A plan also should be specific to each type of juice for the same kinds of reasons. Hazards can vary depending on the type of fruit or vegetable used to make the juice, pH, and other factors. The agency has tentatively concluded, however, that some types of juices can be grouped together in a HACCP plan if the hazard analysis reveals that the juices present similar hazards, their processing includes the same CCP's, or there are other appropriate commonalities in their production. Grouping would reduce the paperwork burden on some processors without altering the benefits attainable through HACCP. The agency requests comment on this approach.

A valid HACCP plan delineates the procedures to be followed in processing the juice. Thus, FDA tentatively concludes that the HACCP plan needs to be developed by individuals who not only are knowledgeable in juice processing but who have been trained in HACCP. This activity requires specialized training in the principles of HACCP, various aspects of food science, and the knowledge of criteria of existing regulations and guidelines. Therefore, the agency is proposing in § 120.8(a) that the HACCP plan be developed by an individual or individuals who have been trained in accordance with proposed § 120.13.

Seafood and meat and poultry processors are required to have a written HACCP plan that is subject to certain recordkeeping requirements. An adequate recordkeeping system is the key to HACCP. In addition, adequate records allow the processor to be able to reference the HACCP plan as necessary. Thus, FDA tentatively concludes that, because of the plan's importance in a HACCP system, the HACCP plan for juice must also be subject to certain recordkeeping requirements. Therefore, the agency is also proposing in § 120.8 that the HACCP plan be maintained in accordance with the recordkeeping requirements of § 120.12.

2. The Contents of the HACCP Plan

As discussed previously, the NACMCF has developed seven principles that describe the HACCP concept and what constitutes a HACCP plan. Both § 123.6(c) and 9 CFR 417.2(c) include minimum requirements for the contents of HACCP plans for seafood and meat and poultry, respectively, that are based on these seven principles. FDA is proposing to require similar minimum criteria for HACCP plans for juice products.

The agency is proposing in § 120.8(b)(1) to require that the plan list the food hazards that are reasonably likely to occur as identified in accordance with § 120.7 and that thus must be controlled for each type of product. This list identifies the hazards that will be controlled by adhering to the HACCP plan in the processing of that type of juice.

Consistent with the HACCP principles identified by the NACMCF, FDA is proposing in § 120.8(b)(2) that processors list the CCP's for each of the identified food hazards, including, as appropriate, CCP's designed to control hazards that could occur or be introduced inside the processing plant environment, and CCP's designed to control food hazards introduced outside the processing plant environment, including hazards that occur before, during, or after harvest. Complete and accurate identification of CCP's is fundamental to controlling food hazards (Ref. 55). Hazards may be caused by improper processing or by events outside the processor's direct control. These hazards are controlled by the CL's, monitoring, control procedures, and recordkeeping that are done as part of HACCP.

In § 120.8(b)(3), FDA is proposing, consistent with the NACMCF principles, that processors list the CL's that must be met at each of the CCP's. CL's must be met to ensure that the relevant hazard is controlled or avoided. According to the NACMCF, each CCP will have one or more control measures to ensure that the identified hazards are prevented, eliminated, or reduced to acceptable levels (Ref. 55). Each control measure has one or more associated CL's. Thus, some CL's can be set to reflect regulatory levels established by FDA or EPA in the form of action levels, regulatory limits, or tolerances for contaminants such as pesticide residues, natural toxins, and other contaminants.

According to the NACMCF, monitoring serves three main purposes (Ref. 55). First, monitoring is essential to food safety management in that it facilitates tracking of the operation. If monitoring indicates that there is a trend towards loss of control, then action can be taken to bring the process back into control before a deviation from a critical limit occurs. Second, monitoring is used to determine when there is loss of control and thus a deviation at a CCP (i.e., exceeding or not meeting a CL). When a deviation occurs, an appropriate corrective action must be taken. Third, it provides written documentation for use in verification.

Proposed § 120.8(b)(4) requires that processors list the procedures, and the frequency with which they are to be performed, that will be used to monitor each of the CCP's to ensure compliance with the CL's. Monitoring steps are necessary to ensure that the CCP is in fact under control and to produce an accurate record of what has occurred at the CCP. The frequency of monitoring affects the level of confidence that a firm has in the safety of its product, with continuous monitoring providing the highest level of confidence.

The agency is proposing in § 120.8(b)(5) that processors include in their HACCP plan any corrective action plans that have been developed in accordance with proposed § 120.10(a), and that are to be followed in response to deviations from CL's at CCP's. As explained in more detail in the ''Corrective Actions'' section of this preamble, FDA has tentatively concluded that these regulations should provide the processor with the option of predetermining corrective actions. Predetermined corrective action

procedures have the potential to facilitate faster action when a deviation occurs than would be possible in the absence of such procedures and to enable a processor to make a more timely response to the deviation when trained or otherwise qualified individuals are not readily available.

Consistent with the NACMCF principles, the agency is proposing in § 120.8(b)(6) that processors list the verification and validation procedures, and the frequency with which they are to be performed, that the processor will use in accordance with proposed § 120.11. As explained in more detail in the ''Verification and Validation'' section of this preamble, FDA has tentatively concluded that a processor must specify in its HACCP plan the verification and validation procedures that it will use and the frequency with which it will use those procedures. FDA tentatively finds that inclusion of this information in the plan is necessary to underscore that a processor has an ongoing obligation to ensure that the verification and validation steps it has determined are necessary are readily ascertainable by its employees as well as by regulatory officials.

Finally, in § 120.8(b)(7), FDA is proposing that processors provide for a recordkeeping system that documents the monitoring of the CCP's, and that the records contain the actual values and observations obtained during monitoring. Implementing a HACCP system depends on adequate records to document the controls at each CCP and the corrective actions taken in response to any deviations. FDA has tentatively concluded that it is neither possible for processors to derive the full benefits of a HACCP system, nor to verify or validate the operation of the system, without actual measurement values. Notations that heat treatment temperatures are ''satisfactory'' or ''unsatisfactory,'' without recording the actual times and temperatures, are vague and subject to varying interpretations and thus, will not ensure that controls are working properly. Also, it is not possible to discern trends without actual measurement values.

The agency requests comments on developing a HACCP plan based on the NACMCF principles.

3. Products Subject to Other Regulations

FDA has already established HACCP type regulations for acidified and low acid canned foods. FDA examined this issue in the seafood final rule (60 FR 65096 at 65124) and acknowledged that there is no need for a processor to restate in its HACCP plan the requirements of part 113 or 114 (21 CFR part 113 or 114).

Parts 113 and 114 dictate that low-acid canned foods and acidified foods be processed in a manner to become commercially sterile. Commercial sterility of thermally processed food is defined in § 113.3(e)(1) as a process that renders the food free of: (1) Microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution, and (2) viable microorganisms (including spores) of public health significance. Consequently, juice processors who must comply with the requirements of part 113 or 114 need not address these particular hazards at all in their HACCP plans.

However, it is important to note that other hazards may be reasonably likely to occur in an acidified or low-acid canned juice. FDA is proposing to require that these hazards be addressed in the HACCP plan, as appropriate. For example, FDA anticipates that the possible presence of glass in carrot juice packed in glass containers is a hazard that is reasonably likely to occur and thus the agency expects this hazard to be addressed in the HACCP plan. Accordingly, to clarify what is required of processors of acidified and low-acid canned juice products, FDA is proposing to adopt § 120.8(c) for juice products subject to other regulations.

4. Relationship to Prerequisite Programs

All hazards identified during the hazard analysis as being reasonably likely to occur need to be addressed by control measures that a processor can apply. Determining how the control measures, in turn, are to be addressed is a primary consideration in developing the HACCP plan. Control measures involve identifying the relevant CCP's and CL's as part of the HACCP plan, or, in those limited circumstances specified in proposed § 120.6, making appropriate provision in a prerequisite program SOP. The safety of the product can be compromised if control measures are not properly monitored and addressed.

As it required for seafood HACCP, FDA is proposing to require that processors address plant sanitation by monitoring certain key sanitary conditions and practices apart from CCP monitoring activities, either by including sanitation controls as part of the HACCP plan, or as part of an SOP in accordance with § 120.6, or by adopting some combination of these two approaches, at the option of the processor.

To reflect this approach, the agency is proposing in § 120.8(d) to state that sanitation controls may be included in the HACCP plan, but that, to the extent that they are monitored in accordance with § 120.6, they need not be included in the HACCP plan.

FDA recognizes that many processing operation sanitation controls, such as hand and equipment washing and sanitizing, are critical to the safety of the food because they serve to minimize the risk of pathogen introduction into finished products that may not be further heat treated before consumption. For this reason, some processors may elect to include in their HACCP plan the control of sanitation through standardized practices in addition to, or in place of, monitoring of sanitation conditions and control practices apart from the HACCP plan. However, FDA also recognizes that sanitation controls may be difficult to fit into HACCP plans, with appropriate CL's and corrective actions sometimes being elusive. For this reason, some processors may elect to rely exclusively on sanitation controls that are not part of the HACCP plan. Either approach is likely to be acceptable, so long as whatever approach is chosen is fully implemented and followed. FDA requests comment on this view.

G. Legal Basis

The seafood HACCP regulation states that the failure of a processor to have and to implement a HACCP plan that complies with § 123.6(g), whenever a HACCP plan is necessary, or otherwise to operate in accordance with the requirements of part 123, will render the fish or fishery products of that processor adulterated under section 402(a)(4) of the act, and potentially section 402(a)(1). Whether a processor's actions are consistent with ensuring the safety of food will be determined through an evaluation of the processor's overall implementation of its HACCP plan, if one is required. The legal basis for FDA's proposed mandatory HACCP systems for juice processors is the same as that for seafood processors. Additional discussion of the legal basis may be found in the proposed rule (59 FR 4142 at 4150) and final rule (60 FR 65096 at 65098) for fish and fishery products.

The agency is proposing in § 120.9 that failure of a juice processor to have and to implement a HACCP system that complies with § 120.8 or otherwise to operate in accordance with the requirements of this part, will have similar consequences as a failure to comply with the seafood HACCP regulations. FDA has tentatively determined that the hazards, especially microbial hazards, inherent in juice

processing are such that, unless there is adherence to HACCP principles, there cannot be assurance that the product is safe. Thus, failure to operate a juice processing operation in accordance with HACCP is itself an insanitary condition that may render the juice product injurious to health.

H. Corrective Actions

The fifth HACCP principle, as articulated by the NACMCF, is that processors establish the corrective actions that they will take should monitoring show a CL deviation. The NACMCF's expectation is that these corrective actions should be predetermined and written into the processor's HACCP plan. Where there is a deviation from established CL's, corrective actions are necessary (Ref. 55).

Section 123.7 of the seafood regulation permits, but does not require, processors to include in their HACCP plans any written corrective action plans that they develop. When a deviation from a CL occurs, § 123.7(a) requires that the processor either: (1) Follow a corrective action plan that is appropriate for the particular deviation, or (2) follow the series of actions provided in § 123.7(c). The steps in § 123.7(c) constitute a minimum generic model for corrective actions.

Section 123.7(b) of the seafood HACCP regulation defines an appropriate action plan as one that addresses both the safety of the product that was being processed when the CL failure occurred and the cause of the deviation. In this respect, the contents of the corrective action plan are consistent with the views of the NACMCF (Ref. 55).

Action necessary to correct the potential hazard may involve one or more of the following steps: Immediately reprocessing the product; diverting the product to another use for which it is safe; segregating, holding, and having the product evaluated by a competent expert; or destroying the product (60 FR 65096 at 65127). To ensure that subsequent product is not subjected to the same deviation, the corrective action must be sufficient to bring the process back under control. FDA advised in the preamble to the seafood final rule (60 FR 65096 at 65127) that such action may involve, where appropriate, adjustments to those process parameters that have an effect on the relevant CL (e.g., flow rate, temperature, source of raw materials); temporarily diverting product around a point in the process at which problems are being encountered; or temporarily stopping production until the problem can be corrected.

Section 123.7(c) of the seafood HACCP regulation describes the steps that a processor must take whenever there is a deviation from a CL, but the processor has not prepared a corrective action plan for that situation. If the processor does not have a corrective action plan for a particular deviation, then the processor must: (1) Segregate and hold the affected product for as long as necessary, (2) perform or obtain a review by a trained individual to determine the affected product's acceptability for distribution, (3) take corrective action to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation, (4) take corrective action to correct the cause of the deviation, and (5) have a trained individual perform a timely reassessment to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation and modify the HACCP plan as necessary.

As stated in a previous paragraph , these steps constitute a minimum generic-type corrective action plan. The objectives of these steps are the same as those of a preconceived plan: To ensure that adulterated product does not enter commerce and to correct the cause of the deviation. Because it is a generic-type plan that is intended to be applicable to any situation, some of the steps, such as segregating and holding the affected product (§ 123.7(c)(1)), might not be necessary if the corrective action had been predetermined. This aspect of the generic-type plan may provide processors with an incentive to predetermine corrective actions whenever practical.

FDA is proposing essentially the same requirements in § 120.10 that it requires in § 123.7 of the seafood HACCP regulation because the agency is not aware that a juice processor has any options other than those that are available to the seafood processor. The processor can either follow its own established corrective action plan, as appropriate for the particular deviation, or follow the generic provisions of the regulation that are applicable to any food. Thus, FDA tentatively concludes that the seafood HACCP requirements for corrective actions are applicable to juice processing.

Proposed § 120.10 sets forth the corrective action procedures that a processor must take whenever a deviation from a CL occurs. A processor may take corrective action either by following: (1) A corrective action plan as identified in the HACCP plan (see proposed § 120.8(b)(5)), or (2) the procedures outlined in proposed § 120.10(b). Predetermined plans provide processors with benefits, such as faster action when a deviation occurs, less need to justify to management the appropriateness of the corrective action after it has been taken, and a more timely response to the deviation than is possible when trained or otherwise qualified individuals are not readily available to make determinations, and a plan is not available.

The agency is proposing to provide in § 120.10(a) that processors may develop written corrective action plans, which become part of their HACCP plans in accordance with § 120.8(b)(5), by which they predetermine the corrective actions that they will take whenever there is a deviation from a CL. According to the NACMCF, specific corrective actions should be developed in advance for each CCP and included in the HACCP plan (Ref. 55). The agency is also proposing in § 120.10(a) that a corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that: (1) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation, and (2) the cause of the deviation is corrected. These two considerations are essential because they represent the reasons for taking corrective actions (i.e., protecting the public health and correcting the problem at hand).

In § 120.10(b), FDA is proposing the steps that processors must take when a deviation from a CL occurs, and they do not have a corrective action plan that is appropriate for that deviation. First, under proposed § 120.10(b)(1), any CL deviation will require the segregation and holding of the affected product until the significance of the deviation can be determined. FDA tentatively finds that this step is necessary to ensure that products that may be injurious to health do not enter commerce until the deviation's impact on safety has been determined.

Proposed § 120.10(b)(2) requires that processors perform or obtain a review to determine the acceptability of the affected product for distribution. This is fundamental to determining the final outcome of the affected product. In some instances product may simply need to be reprocessed, while at other times, the product may not be considered adulterated. For example, if the pasteurization process did not reach the minimum temperature specified by the CL, the juice can be diverted and rerouted through the pasteurizer for

reprocessing at acceptable temperatures. However, if the juice contains a pesticide above an established tolerance level, the juice is deemed to be adulterated.

FDA is also proposing to require in § 120.10(b)(2) that the safety determination be made by an individual who has adequate training or experience to perform such a review. Adequate training may or may not include training in accordance with proposed § 120.13, but the individual's training must be sufficient to qualify him or her to make the public health determinations of this nature. For example, an individual must have some training to understand that pasteurized juice must have been processed to reach a minimum time and temperature combination and know methods of reprocessing to remedy problem situations. Adequate training in this context requires only knowledge of how to perform the particular operation responsibility rather than training in the concepts of HACCP.

Under proposed § 120.10(b)(3), processors must take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation. Under proposed § 120.10(b)(4) processors must take corrective action, when necessary, to correct the cause of the deviation. As discussed for proposed § 120.10(a), the actions called for under these two provisions are essential to any corrective action plan because they address one of the two reasons for taking corrective actions, that is, correcting the problem at hand.

FDA is proposing in § 120.10(b)(5) to require that a trained person validate the HACCP plan that was in use at the time of the deviation to determine whether it needs to be modified to reduce the risk of recurrence of the deviation and to modify the HACCP plan as necessary. It is critically important that processors learn as much as possible from the occurrence of a deviation, and that they take the steps necessary to ensure that such deviation will not be repeated. Proposed § 120.10(b)(5) reflects these principles.

Finally, proposed § 120.10(c) requires that processors maintain records of all corrective actions that they take following either the corrective action procedures in the HACCP plan or those specified in § 120.10(b). The agency is proposing that these records be subject to the verification requirements in proposed § 120.11(a) and the recordkeeping requirements of § 120.12. The records need to reflect all actions taken in response to a deviation (i.e., provide the specifics about the actions taken and not simply refer to a written procedure). Such information helps the processor to determine if there are recurring problems that it needs to address. The information also will enable both the processor and the regulator to identify factors that may help prevent problems in the future.

The agency requests comments on its proposed approach to corrective actions.

I. Verification and Validation

The seafood HACCP regulation requires that every processor verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented (§ 123.8(a)). Section 123.8 includes requirements for reassessment of the HACCP plan and for various other verification activities, including reviewing monitoring records, reviewing records of corrective actions, and reviewing calibration records. Section 123.8 also requires, in certain circumstances, that processors who had concluded that no HACCP plan was necessary reassess that judgment and reevaluate their HACCP analysis.

The meat and poultry HACCP regulation requires that every establishment validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis and verify that the plan is being effectively implemented (9 CFR 417.4(a)). Section 417.4 includes requirements for initial validation, ongoing verification activities, reassessment of the HACCP plan, and reassessment of the hazard analysis for processors that do not need a HACCP plan.

According to the NACMCF (Ref. 55), there are four aspects to verification. One is verifying whether the facility's HACCP system is functioning according to the HACCP plan. Another aspect is the initial validation of the HACCP plan to determine whether the significant hazards have been identified, and whether, if the HACCP plan is properly implemented, these hazards will be effectively controlled. The third aspect consists of documented validations that are done after the initial development and implementation of the HACCP plan. The fourth aspect of verification deals with a periodic verification of the HACCP system by an unbiased, independent authority.

1. Verification

The agency is proposing in § 120.11(a) to require that every processor verify that the HACCP system is being implemented according to design. According to the NACMCF, a functioning HACCP system requires little end-product sampling because appropriate monitored safeguards are inherent to the process. Therefore, rather than relying on end-product sampling, firms need to conduct frequent reviews of their HACCP plan to verify that it is being correctly followed, to review CCP records, and to ensure that appropriate risk management decisions and product dispositions are made when process deviations occur.

Proposed § 120.11(a) sets forth the minimum requirements for verification activities. Proposed § 120.11(a)(1) deals with ongoing verification activities. These ongoing activities are in keeping with the NACMCF's view that verification needs to take the form of ''frequent reviews.'' Frequent reviews relate primarily to whether the HACCP plan is functioning effectively on a day-to-day basis.

The agency is proposing to require in § 120.11(a)(1)(i) that a processor review any consumer complaint that it receives to determine whether the complaint relates to the performance of the HACCP plan or reveal the existence of unidentified CCP's. Although the absence of consumer complaints does not, by itself, verify the adequacy of a HACCP system, those consumer complaints alleging a safety problem that a processor does receive can be of value as a verification tool and should be used for that purpose.

Proposed § 120.11(a)(1)(ii) provides for the calibration of process-monitoring instruments as a verification activity. Calibration provides assurance that an instrument is measuring correctly. Calibration is an important activity and involves readily defined procedures, usually provided by the instrument manufacturer, that can easily be included in the plan.

Proposed § 120.11(a)(1)(iii) provides that the processor may perform periodic end-product or in-process testing. FDA acknowledges the shortcomings of product testing, especially microbiological testing, as a process control. However, the agency recognizes that many processors will find that product testing may be included in their verification activities, and the agency encourages incorporation of testing into HACCP systems, where appropriate. For example, in cases where a processor is obtaining fruits and vegetables from unknown sources, and there is no assurance that pesticides have been correctly applied, product testing for pesticide residues is an appropriate step in a HACCP plan.

Proposed § 120.11(a)(1)(iv) provides for a review by a trained individual of all records that document monitoring of CCP's, the taking of corrective actions, the calibration of any process control instruments, and the performance of any end-product or in-process testing. As proposed, the review must include signing and dating of the records. The primary purpose of the record review is the periodic verification that the HACCP plan is appropriate and is being properly implemented. This review of these records must occur with sufficient frequency so as to ensure that any problems in the design and implementation of the HACCP plan will be promptly uncovered, and that modifications to the plan or process will be promptly made.

FDA tentatively concludes that a weekly review of HACCP monitoring and corrective action records (§ 120.11(a)(1)(iv)(A) would provide the industry with the necessary flexibility to handle a highly perishable commodity like fresh juice without interruption, while still facilitating timely feedback of information. FDA's experience with low-acid canned foods and acidified foods has demonstrated that timely review of these kinds of records is a critical verification tool.

However, this principle need not apply to the review of records of such verification activities as process control instrument calibration and product testing. The frequency of these activities will be variable and dependent upon the HACCP plan. For example, pesticide testing of fruits and vegetables may only need to be done when the source of the produce is new or unfamiliar to the firm. Consequently, the agency tentatively concludes that setting a specific review frequency for these records is not warranted and thus is only proposing that the review be conducted within a reasonable time after the records are made (see proposed § 120.11(a)(iv)(C)).

Proposed § 120.11(a)(1)(v) requires that processors take appropriate corrective action whenever any verification procedure, including the review of a consumer complaint, reveals the need to do so. This proposed provision is essentially a reminder to processors that information obtained through verification may require a corrective action.

FDA is proposing in § 120.11(a)(2) that processors document, in records that are subject to the recordkeeping requirements of § 120.12, the calibration of process-monitoring instruments and the performance of any periodic end-product and in-process testing, in accordance with paragraphs (a)(1)(iv)(B) and (a)(1)(iv)(C). For a processor's HACCP controls to work, the instruments and equipment that it relies upon in monitoring CCP's, such as thermometers, temperature-recording devices, and computer software, must be accurate and reliable. FDA has tentatively concluded that the best way to ensure such accuracy and reliability for juice is to require that the processor's monitoring procedures include steps necessary to verify the reliability of these instruments and devices. The proposed requirement that records of end-product testing be kept is consistent with the general recordkeeping principles of HACCP.

The agency requests comment on its proposed verification procedures for juice.

2. Validation of the HACCP Plan

The agency is proposing, in § 120.11(b) to require that juice processors validate that their HACCP plan is adequate to control the food hazards that are reasonably likely to occur in their products; this validation is required at least once during the year after implementation and at least annually thereafter or whenever any changes occur that could affect the hazard analysis or alter the HACCP plan and prerequisite program SOP's in any significant way. The proposed requirement that HACCP plan validation be conducted at least once during the year after implementation is based on a recommendation from the NACMCF (Ref. 55). This process consists of reviewing the CL's to verify that the limits at CCP's are adequate to control the hazards that are likely to occur.

The proposed requirement that the HACCP plan be validated at least annually, or whenever any relevant changes occur, is based on the NACMCF view that validation must occur on a regular basis (Ref. 55), although the NACMCF does not specify timeframes. Validation should be conducted on a regular basis, even in the absence of a recognized change, to ensure that the plan continues to address all of the reasonably likely food hazards with appropriate control limits and monitoring procedures. Processors should conduct the review at intervals that are appropriate for their processes, although FDA is proposing to require that this interval not exceed 1 year.

Proposed § 120.11(b) provides examples of changes that could trigger a validation. These include changes in raw materials or source of raw materials; product formulation; processing methods or systems, including computers and their software; packaging; finished product distribution systems; or the intended use or consumers of the finished product. These examples are derived from the NACMCF materials on the ''five preliminary steps'' that form the basis for the HACCP plan (Ref. 55). A change in any of these areas could necessitate a change in the plan to respond to any new hazards that may have been introduced or to maintain preventive control over existing ones. It is important to recognize that this list is not all inclusive.

Proposed § 120.11(b) requires that the plan validation be performed by an individual or individuals who have been trained in accordance with § 120.13. The validation is fundamental in determining whether the HACCP plan is adequate to control food hazards that are reasonably likely to occur. HACCP plan validation may result in a need to alter other aspects of the HACCP system and the prerequisite program SOP's. The activities involved in plan validation are not routine activities but require an understanding of the principles of HACCP and of plan development. This understanding is obtained through training.

Initial validation of the HACCP plan is necessary to ensure that all significant hazards have been identified, and that, if the HACCP plan is properly implemented, these hazards will be effectively controlled. Subsequent validation of the HACCP plan ensures that the plan continues to be effective.

Validation is especially important whenever any changes occur that could affect the hazard analysis or alter the HACCP plan and prerequisite program SOP's in any way. Without these assessments and subsequent changes, the HACCP plan may not control the hazards that it should, and unsafe juice may be distributed. Therefore, the agency tentatively concludes that validation of the HACCP plan is necessary to ensure that juice processed in accordance with the plan will not have been processed under conditions whereby it may have been rendered injurious to health.

The NACMCF states that the HACCP plan should be updated and revised as needed (Ref. 55). Changes in sources of incoming materials, formulations, processing, distribution, and consumer use usually occur over time. New technologies may be developed. New concerns that previously were not considered hazards reasonably likely to occur may become apparent. For example, *E. coli* O157:H7 was not recognized as a human pathogen before 1982 (Ref. 10), and the impact of its acid tolerance was not well understood.

Therefore, the agency tentatively concludes that processors must maintain records demonstrating that they have been diligent in keeping their HACCP plans current. Thus, FDA is proposing to require in § 120.11(b) that records of the plan validation be subject to the requirements of § 120.12.

Proposed § 120.11(b) also requires that, where validation shows that the HACCP plan is inadequate, the processor modify immediately the plan. Failure of a processor to modify immediately its HACCP plan after the processor has determined that the plan is inadequate would result in the processor operating under insanitary conditions that may render the food prepared under the inadequate plan injurious to health and thus would render the food adulterated.

FDA requests comments on its proposed approach to validation of HACCP plans for juice.

3. Validation of the Hazard Analysis

Proposed § 120.11(c) requires that, whenever a juice processor has no HACCP plan because a hazard analysis has revealed no food hazards that are reasonably likely to occur, the processor reassess the adequacy of that hazard analysis whenever there are any changes that could reasonably affect whether a food hazard exists. FDA has proposed to include examples of such changes in § 120.11(c). The list is identical to that proposed in § 120.11(b), on when a plan must be validated. Any change in these factors could warrant a validation to be certain that a plan is still not needed because, as stated in the discussion of proposed § 120.11(b), such changes could introduce new hazards.

FDA has tentatively concluded that, under a mandatory HACCP system for juice, the principle of validation applies equally to a decision that a HACCP plan is not necessary as it does to a decision that the plan is adequate. Circumstances change, and processors must be alert to whether factors that effectively exempt them from the requirement to have a plan continue to apply.

The agency is proposing in § 120.11(c) that the validation be performed by an individual or individuals who have been trained in accordance with proposed § 120.13. The validation is fundamental in determining whether the hazard analysis considers all food hazards that are reasonably likely to occur. The hazard analysis validation may result in a need to alter other aspects of the HACCP system and the prerequisite program SOP's. These kinds of activities are not routine but require an understanding of the principles of HACCP that is obtained through appropriate training.

The agency requests comment on its proposed approach to validation requirements of a hazard analysis in the absence of a HACCP plan.

J. Records

Implementing a HACCP program involves engaging in adequate monitoring of CCP's and documenting the results of that monitoring through records. It also involves the taking of appropriate corrective actions in response to any deviations and, again, documenting the results. HACCP records also include the hazard analysis, the HACCP plan itself, and documentation of verification and validation activities. Records of prerequisite program SOP's, although not a part of the HACCP system, are significant records in a HACCP program in that the SOP's may be used in place of HACCP controls. Record systems used by the pilot firms in FDA's pilot program included hand written logs, filing systems for continuous recording charts and inspection sheets, and computer files of data of monitoring results and followup corrective actions.

In § 123.9 of the seafood regulation, FDA established requirements for HACCP records. Under this provision, all required records must include: (1) The name and location of the processor or importer; (2) the date and time of the activity that the record reflects; (3) the signature or initials of the person performing the operation; and (4) where appropriate, the identity of the product and the production code, if any. Processing and other information must be entered on records at the time that it is observed (§ 123.9(a)(4)). Records must be retained for at least 1 year for refrigerated foods and for at least 2 years for all other foods, similarly, records relating to the general adequacy of equipment or processes being used by a processor must be retained for 2 years (§ 123.9(b)). Off site provisions for storage of records from processing facilities that seasonally pack are allowed, provided that the records are reasonably accessible (§ 123.9(b)(3)). All records must be available for official review (§ 123.9(c)). Section 123.9 also provides information concerning public disclosure of records and maintenance of records on computers.

According to the NACMCF, maintenance of appropriate records is fundamental to the success of a HACCP system (Ref. 55). In recognition of this fact, FDA is proposing to require in § 120.12 that specific records be kept; that HACCP records contain certain necessary information; that records be maintained for specific periods of time; and that records be available for FDA review.

The agency is proposing in § 120.12(a) to list the records that the processor is required to maintain to document its HACCP system. FDA has discussed the basis for requiring that these records be kept in the sections addressing each particular provision. The proposed sections also state that records shall be maintained. The list of records that juice processors are required to maintain is included in § 120.12(a), although this list is included simply for simplicity, in that the list reflects the record requirements that are set out in other sections of the proposed regulation.

Proposed § 120.12(b) describes the general requirements for records. The purpose of the proposed requirements in this provision is to ensure that records maintained under part 120 can be readily linked to a product and to the timeframe in which the product was manufactured. Linking a record to a specific product will be especially important when there has been a deviation at a CCP and will enable processors to isolate product that has not been processed properly, thereby preventing the product from reaching consumers. These records will also benefit processors in that only those lots that were processed inadequately will need to be recalled or isolated. The agency has tentatively concluded that including the name and location of the processor or importer; the date and time of the activity that the record reflects; the signature or initials of the person performing the operation or creating the record; and, where appropriate, the identity of the product and the production code, if any, are the minimum information necessary to enable the processor to determine what product may have been affected by a deviation and to take any appropriate actions with respect to that product.

Proposed § 120.12(b)(3) requires that the record include the signature or initials of the person performing the operation or creating the record. Requiring that the record be signed by the individual who made the observation will ensure responsibility and accountability. Also, if there is a question about the record, a signature ensures that the source of the record will be known.

Proposed § 120.12(b)(4) requires that processing and other information be entered on records at the time that it is observed and that the records contain the actual values and observations obtained during monitoring. It is important that information relating to observations be recorded immediately

and that the records contain the actual values and observations to enhance accuracy.

Both the HACCP regulations for seafood and for meat and poultry require that the HACCP plan be signed and dated. In the seafood final rule (60 FR 65096 at 65124), FDA emphasized the importance of signing and dating the HACCP plan. The agency stated that:

> Such a signature would provide direct evidence of management's acceptance of the plan for implementation. FDA cannot stress enough that for HACCP to succeed, there must be a clear commitment to it from the top of the firm on down. Management must set a strong example in this regard. A signature requirement will remind management of this important responsibility and will signal to all employees that the firm regards the HACCP plan as a document to be taken seriously. Additionally, the representative's signature, along with the date of signing, would serve to minimize potential confusion over the authenticity of any differing versions or editions of the document that might exist.

The agency tentatively concludes that this same reasoning applies to HACCP plans for juice processing, and that there are significant benefits of requiring similar steps for the HACCP plan for juice.

The agency is also proposing to require that the hazard analysis for juice be written (see proposed § 120.7). FDA tentatively concludes that the hazard analysis shall be signed and dated in a manner similar to what is required for the HACCP plan because of its relationship to and importance in the development of an adequate HACCP plan.

Therefore, the agency is proposing to require in § 120.12(c)(1) that the hazard analysis and the HACCP plan be signed and dated by the most responsible individual on-site at the processing facility or by a higher level official of the processor. Proposed § 120.12(c)(1) provides that the signatures signify that these records have been accepted for incorporation into the HACCP system by the firm.

In § 120.12(c)(2)(i) through (c)(2)(iii), FDA is proposing to require that the hazard analysis and the HACCP plan be dated and signed upon initial acceptance, upon any modification, and upon verification and validation of the plan in accordance with proposed § 120.11(d)(1). As was discussed fully in the ''Verification and Validation'' section of this preamble, FDA is proposing in § 120.11 that the adequacy of the HACCP plan, or, in the absence of a HACCP plan, the hazard analysis, be validated at least once during the year after implementation and at least annually thereafter or whenever any changes occur that could affect the hazard analysis or that could alter the HACCP plan and prerequisite program SOP's in any way. These verifications, validations, and modifications are necessary to ensure that the HACCP program remains current, and that it is responsive to emerging problems. The signature of the firm representative will document that these validations and modifications are performed as required. The requirements for documentation are the same as those required for the HACCP plan in the seafood regulation (§ 123.6(d)).

The agency is proposing in § 120.12(d) requirements for record retention. Proposed § 120.12(d)(1) states that, in the case of perishable or refrigerated products, all required records shall be retained at the processing facility or importer's place of business in the United States for at least 1 year after the date that they were prepared and in the case of frozen, preserved, or shelf-stable products, 2 years after the date that they were prepared. These timeframes are based on the length of time that these products can be expected to be in commercial distribution plus a reasonable time thereafter to ensure that the records are available for the processor's and FDA's verification activities.

FDA is proposing in § 120.12(d)(2) that records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, be retained at the processing facility or the importer's place of business in the United States for at least 2 years after the date that the processor last used that equipment or process. Under § 120.12(a)(5) processors are required to maintain records documenting validation of the HACCP plan. If the firm is relying on equipment or processes to control hazards that are reasonably likely to occur then the firm must have some assurance that the equipment or process is adequate for that purpose. Should FDA adopt proposed § 120.12(d)(2), a written certification from the equipment manufacturer will likely generally be sufficient to establish equipment adequacy. However, the processor may need to obtain a written scientific evaluation of a process, especially in cases where two or more treatments are used to accomplish a 5 log reduction in the target pathogen, to ensure that the process is adequate to destroy microorganisms of public health significance or to prevent their growth. Such an evaluation may also be necessary to ensure the adequacy of the pasteurization or refrigerating equipment that the processor is using. As with processing records, these records are required to be retained for a period of time that reflects the period that the products to which they relate can be expected to be in commercial distribution.

The agency realizes that under the proposed requirements for recordkeeping, some juice processors may be required to store a significant quantity of records, and that there may not be adequate storage space in the processing facility for all of these records. However, if HACCP is to work, these records must be available for the processor's verification activities and for FDA inspections. Therefore, the agency is proposing to provide some relief to processors in § 120.12(d)(3), which allows for off-site storage of the prerequisite program SOP records and records documenting the ongoing application of the HACCP plan (i.e., monitoring of CCP's and their CL's and corrective actions) 6 months after the date that the monitoring occurred, if such records can be retrieved and provided on-site within 24 hours of request for official review. The records for which FDA is proposing to allow off-site storage are the more routine processing operation records and thus are of the type that are likely to be generated in the greatest numbers. FDA tentatively concludes that the proposed relief will benefit processors but will not interfere with the purpose for record retention because the records will be readily available.

The use of computers in the food processing industry is increasing. Computerized systems within large corporations can be networked, allowing for the sending and receiving of information in a secure fashion to all of the different food processing facilities of that corporation worldwide. This type of system can easily be used to maintain all of the processing records from each of the processing facilities at corporate headquarters. Therefore, for clarity, FDA is proposing in § 120.12(d)(3) that electronic records are considered to be on-site if they are accessible from an on-site location and comply with proposed § 120.12(g).

FDA recognizes that some juice processing plants may be closed on a seasonal basis. Given the nature of the HACCP system, however, FDA may choose to inspect at least the records of a plant even if the plant is not in operation. Therefore, FDA is providing in proposed § 120.12(d)(4) that, if the processing facility is closed for a prolonged period between seasonal packs, the records may be transferred to some other reasonably accessible

location at the end of the seasonal pack but shall be immediately returned for official review upon request. This proposed provision will give the juice processor some relief, yet will serve to ensure that the records in question will be readily available.

Proposed § 120.12(e) requires that all records required under part 120 be available for official review and copying at reasonable times. The agency's access to HACCP records is essential to ensure that the HACCP system is working, and that the safety of juice is being ensured by design. FDA's authority to require maintenance of these records, and to provide for agency access to them, was fully discussed in the rulemaking on seafood HACCP (60 FR 65096 at 65139). The importance of the records in ensuring that juice will not be rendered injurious to health has been fully discussed. FDA access to these records will expedite the agency's efforts to ensure that the juice products in interstate commerce are not adulterated and to identify any such products that are. The agency points out that the proposed language in § 120.12(e) is intended to be flexible enough to cover State officials if their agency adopts any final regulation by reference.

Proposed § 120.12(f) sets forth information concerning public disclosure of processing records. The agency concluded in the seafood final rule (60 FR 65096 at 65139):

> that records and plans should be protected to the extent possible in order to promote the implementation of HACCP across the seafood industry. FDA has concluded that the public will benefit from the protection of records because it will actually strengthen the HACCP system. So long as the legitimate public need to be able to evaluate the system can be met through other means, the confidentiality of HACCP records and plans generally will foster the industry's acceptance of HACCP. Even though HACCP may be mandatory under these regulations, in order for it to succeed, processors must be committed to it because they see value in it for themselves. Fear of public disclosure of matters that have long been regarded as confidential business matters could significantly undermine that commitment. FDA concludes, therefore, that it is in the public interest to foster tailored HACCP plans that demonstrate understanding and thought, rather than promote the use of rote plans and minimally acceptable standards due to fear of public disclosure.
>
> FDA understands that it cannot make promises of confidentiality that exceed the permissible boundaries established under the Freedom of Information Act, nor does the agency wish to do so in this case. The agency still does not expect that it will be in possession of a large volume of plans and records at any given moment. However, given the significant interest in this subject as conveyed by the comments, FDA has concluded that the final regulations should reflect the fact that the HACCP plans and records that do come into FDA's possession will generally meet the definition of either trade secret or commercial confidential materials.

The agency is not aware of any circumstances that would warrant different conditions for public disclosure for records for juice HACCP than those required for seafood HACCP. Therefore, FDA is proposing the same provisions for § 120.12(f) as are found in § 123.9(d).

In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA issued regulations at part 11 (21 CFR part 11) that provide criteria for acceptance by FDA, under certain circumstances, of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper. Proposed § 120.12(g) allows for the maintenance of records on computers in accordance with part 11. This provision simply makes clear the fact that records can be maintained on computers.

The agency requests comments on its proposed approach to recordkeeping for juice processors.

K. Training

In § 123.10 of the seafood HACCP regulation, FDA required that certain functions relating to the operation of a HACCP system be conducted by an individual who has successfully completed training in the application of HACCP principles to fish and fishery product processing that is at least equivalent to that received under a standardized curriculum recognized as adequate by FDA. Job experience that has provided equivalent knowledge is also acceptable. The trained individual need not be an employee of the company.

Training is essential to the effective implementation of a HACCP system for juice. Only a trained individual is capable of effectively executing certain activities, such as identifying appropriate CCP's, how to establish CL's, control measures, corrective actions, and recordkeeping procedures. The often seasonal nature, remote location, and small size of many juice processors also support the need for formalized training.

However, these conditions also create difficulty recruiting highly qualified management and supervisory staff. Given these factors, particularly in light of what FDA learned in its pilot program, the agency is concerned that a significant portion of the juice industry will be unprepared to meet the requirements of a mandatory HACCP program without some training (Ref. 59).

Therefore, FDA is proposing in § 120.13(a) that only an individual who has met specified training requirements can be responsible for certain functions. Those functions are listed in proposed § 120.13(a)(1) through (a)(4). FDA has discussed the basis for requiring that a trained individual perform these functions in the sections addressing each particular proposed provision. The agency is listing the functions that shall be performed by a trained individual in § 120.13(a) for simplicity and is not imposing any additional requirement through this list.

Proposed § 120.13(b) requires that the individual performing the functions listed in proposed § 120.13(a) have successfully completed training in the application of HACCP principles to food processing. The agency anticipates that 2- or 3-day training sessions, modeled after the Better Process Control Schools currently in place for low acid canned food and acidified food manufacturers, will be provided by various private organizations and through academia. FDA does not intend to run HACCP-training courses for the industry.

FDA has been extensively involved with a consortium called the ''Seafood HACCP Alliance'' (the Alliance) consisting of representatives from Federal and State agencies, industry, and academia, who have worked to create a uniform, core training program that will meet the requirements of the seafood HACCP regulations and that will cost very little. The training program that has been developed by the Alliance is based on the recommendations of the NACMCF. The core curriculum for the course consists of basic HACCP principles that are applicable to any food and, thus, are also applicable to juice. It is the agency's intent to utilize the Alliance materials, as applicable, as the standard against which other course materials may be judged. Therefore, the agency is proposing in § 120.13(b) that the training be at least equivalent to that received under standardized curriculum recognized as adequate by FDA.

FDA is also proposing in § 120.13(b) that job experience may qualify an individual to perform these functions if such experience has provided knowledge at least equivalent to that provided through the standardized curriculum. FDA acknowledges that a short course in HACCP has its limitations. For example, a 3-day course might not have anything important to offer to an individual who has had significant job experience working with or for an individual who is well-versed

in HACCP. Where a job experience has imparted a level of knowledge at least equivalent to that that could be provided by short course training, that individual would qualify as a trained individual. FDA requests comments on how processors will be able to determine whether job experience has provided the individual with the specific knowledge and expertise to develop and implement a HACCP program.

FDA is proposing to provide in § 120.13(b) that the trained individual need not be an employee of the processor. Processors may utilize consultants or other trained individuals to perform these functions if they so choose.

L. Application of Requirements to Imported Products

The seafood HACCP regulation sets forth requirements for importers of fish and fishery products in § 123.12. According to § 123.12(a), the importer must either: (1) Obtain fish or fishery products from a country that has an active memorandum of understanding or similar agreement with FDA that documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system relative to the products being imported, or (2) have and implement written verification procedures, as described in the regulation, for ensuring that the products being imported were processed in accordance with the requirements of part 123. If the importer must engage in affirmative verification steps, records of the taking of these steps must be made in English and be on file with the importer, and available for inspection by FDA (§ 123.12(c)). In the absence of assurances that the imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors, the product will appear to be adulterated under section 402(a)(4) of the act, and FDA will deny the product entry (§ 123.12(d)) under section 801(a) of the act (21 U.S.C. 381(a)).

Many types of juice are imported into the United States. FDA's inspection system for imports consists largely of reviewing the customs entries for products being offered for entry into the United States, engaging in wharf examinations and sample collections for laboratory analysis, and automatically detaining products with a history of problems (e.g., tamarind and tamarind products, including juice and juice concentrate). The same problems that are present in domestically produced juice can be present in imported juice and may not be apparent from the import review currently conducted by FDA. Consequently, the agency tentatively concludes that HACCP controls for juice should apply to imported products as well as to domestic products.

FDA also tentatively concludes that the importer should share responsibility with the foreign processor for safety. More often than not, it is the U.S. importer, rather than the foreign processor, who actually offers imported juice for entry into the United States. While many importers are conscientious about the safety of the products that they import, others have little understanding of the potential hazards associated with their products.

In the rulemaking process for seafood HACCP, the agency considered many options for compliance with HACCP requirements and carefully crafted the final regulation to incorporate a number of them. These options provide great flexibility for importers to achieve compliance and thus, would appear to be suitable for a wide variety of foods. FDA tentatively concludes that importer requirements for fish and fishery products in § 123.12 are appropriate for and applicable to juice, and is proposing the same requirements in § 120.14 because the agency is not aware of any circumstances that would necessitate any differences in treatment between juice imports and seafood imports. Thus, while the agency has made some minor editorial revisions for clarity, proposed § 120.14 essentially tracks § 123.12. FDA requests comments on the proposed import requirements for juice.

M. Pathogen Reduction

As discussed previously, one of the NACMCF's recommendations to FDA was the use of safety performance criteria instead of mandating the use of a specific intervention technology (Ref. 53). Performance standards set forth requirements in terms of what is to be achieved by a given regulatory requirement, and represent a shift in focus from ''command-and-control'' regulations because they specify the ends to be achieved (producing safe juice products), not the means to achieve those ends.

The NACMCF suggested that a tolerable level of risk would be achieved by requiring interventions that have been validated to achieve a cumulative 5 log reduction in the target pathogen or a reduction in yearly risk of illness to less than 10^{-5}, assuming consumption of 100 ml of juice daily. In addition, the NACMCF stated that HACCP and safety performance criteria should form the general conceptual framework needed to ensure the safety of juices, and that control measures should be based on a thorough hazard analysis. The NACMCF stated that validation of the process must be an integral part of this framework.

Based on the evidence of microbial outbreaks discussed in section I.A of this document, FDA tentatively concludes that processors must establish controls for pathogen reduction in juice. The requirements of parts 113 and 114 mandate a process that exceeds the proposed provision, and, therefore, it is not necessary to require that juices subject to part 113 or 114 meet the 5 log reduction requirement in proposed § 120.24.

FDA is proposing to require in part 120, subpart B, that juice processors, except those subject to the requirements of part 113 or 114, include in their HACCP plans control measures that are known, or can be shown, to produce, at a minimum, a 5 log (i.e., 10^5) reduction in the most resistant microorganism of public health significance that is likely to occur in the juice for at least as long as the shelf life of the product under normal and moderate abuse conditions. The agency requests comment on the appropriateness of the 5 log reduction performance standard and if other approaches, such as establishing a minimal acceptable risk standard for juices, could be used that would ensure the safety of the juice. The agency requests comments on what such a minimal acceptable risk standard should be and how it would be implemented. The agency also invites interested persons to submit scientific data concerning the acceptability of a 5 log reduction requirement or whether a more or less stringent performance standard (e.g., 3 or 7 log reduction) for specific juices would be more appropriate or whether different approaches consistent with a minimal acceptable risk standard for juices might be appropriate for specific juices based on their unique characteristics.

In the absence of known specific pathogen-product associations, the NACMCF recommended the use of *E. coli* O157:H7 or *L. monocytogenes* as the target organism, as appropriate. This recommendation is based on the number of known outbreaks of *E.coli* in juice as described in section I.A of this document and the ubiquitous nature of *L. monocytogenes*. *E. coli* is known to be unusually acid resistant (Refs. 60 and 61), and *L. monocytogenes* is relatively heat resistant (Refs. 62 and 63). Therefore, depending on the type of juice, one of the two NACMCF recommended target organisms will likely be the most resistant microorganism of public health

significance. In controlling the target microorganism, other pathogenic organisms will likely also be controlled.

However, because FDA is proposing a performance standard for pathogen reduction in lieu of a time/temperature requirement and is providing for a cumulative pathogen reduction process, the agency recognizes that other microorganisms may be more appropriate targets for juice processing. For example, control measures other than pasteurization may be more effective for reducing *E. coli* O157:H7 and less effective for another pathogen, and, thus, the most resistant pathogen under the circumstances must be the target pathogen.

Pasteurization is one process that will achieve the 5 log reduction performance standard. However, other interventions (e.g., surface treatments) may be adequate for some types of produce (e.g., citrus fruits). As discussed previously in section I.E of this document, the NACMCF concluded that: (1) The history of public health problems associated with fresh juices indicates a need for active safety interventions; and (2) for some fruit (e.g., oranges), the need for intervention may be limited to surface treatment, but for others, additional interventions may be required (e.g., pasteurization of the juice). Pathogens are not reasonably likely to be present in the interior of sound whole oranges or other citrus fruits. In addition, the acidic nature of citrus fruits may further inactivate any pathogens that may be present. Therefore, any contamination being introduced into the juice will come from the surface of the fruit or the food contact surfaces of the equipment.

There are two possible means by which contamination on the surface of the fruit can be introduced into the juice. First, the skin of the fruit can be damaged allowing any pathogens present to migrate inside the orange. An appropriate HACCP program can control this means of contamination through grading and culling. This step may be the first CCP in a HACCP plan for fresh orange juice production with a critical limit of zero defectives.

Secondly, contamination on the surface of the skin can be introduced from cutting into the orange to extract the juice. This source may be controlled by washing, brushing, and sanitizing the fruit prior to cutting. This step may be a CCP in the processing of fresh orange juice with processors establishing critical limits for the associated parameters (e.g., temperature of water, type and strength of sanitizers, effectiveness of equipment).

Proper implementation of these two CCP's (i.e., zero defects and washing, brushing, and sanitizing the fruit) could potentially achieve a three log reduction in microorganisms (Ref. 64). However, as proposed, processors must validate that such a reduction in the target pathogen is occurring.

In addition to the two CCP's, processors must implement CGMP's (proposed § 120.5) and sanitation SOP's (proposed § 120.6) to ensure that the working area and equipment are clean. The most important step is sanitation of the extraction equipment which may harbor yeasts, molds, and acid tolerant bacteria (Ref. 65). The 1995 outbreak of *Salmonella hartford* associated with fresh orange juice was most likely related to poor CGMP's (Ref. 9). However, CGMP's and sanitation SOP's alone are not sufficient to ensure a 5 log reduction.

Extraction of orange juice and other citrus juices is generally done by either a machine which scores and cores the fruit before squeezing or by cutting the fruit in half and reaming out each side. In the first instance, the only part of the peel which is exposed to the fruit is the cut core. In the second instance, the edge of the knife will make contact with the peel and could potentially contaminate the fruit through the first half of the cut (in the second half of the cut, the knife leaves the fruit after making contact with the peel). If most of the surface of the skin of the orange does not contact the interior (juice) during extraction and the peel is discarded, such an extraction technique may be considered a CCP contributing towards the reduction of the potential pathogenic load.

For purposes of illustration, FDA has simplified some of the extraction methods in order to calculate the possible log reduction in pathogens that might occur from different methods of extraction. In the ''coring'' extraction method, using an example of an orange that is 4 inches in diameter with a ½ inch core cut, there could potentially be a 2 log reduction by only allowing contact with the surface area contained by a ½-inch circle of the outside of the peel. That is, a 4-inch orange has about 50 square inches of peel and a ½-inch circle contains an area of 0.78 inches so that only 1.6 percent (.78/50) of the outside would be potentially in contact with the inner part of the orange. However, FDA points out that under proposed part 120, processors must be able to validate that the reduction in the target pathogen is occurring.

In the cutting method of extraction, there would also be a considerable reduction in the amount of potentially contaminated produce discarded. If, for example the knives used were 0.01 inch thick, the area of the exterior part of the orange that would make contact with the interior would be the top half of the circumference of the orange multiplied by the width of the knife, or about 0.06 square inches with a 4-inch (diameter) orange. Thus, the reduction of pathogens could be approximately 3 log (0.06/50) just by discarding the orange peel. Again, under proposed part 120, processors must be able to validate that this reduction is occurring in the target pathogen.

Thus, it may be feasible that a processor use a combination of CGMP's, sanitation SOP's, and at least the three CCP's discussed previously ((1) Culling and grading; (2) washing, brushing, and sanitizing; and (3) appropriate methods of extraction) and achieve a 5 log reduction in a target pathogen for orange juice. If so, it is unlikely that processors of fresh orange juice, and perhaps other fresh citrus fruit juices, will have to implement pasteurization in order to achieve a 5 log reduction in pathogenic bacteria. In addition, FDA anticipates that manufacturers of other juices, such as apple juice, may be able to use other technologies and practices in lieu of pasteurization (such as a combination of eliminating use of drops, brushing, washing, and using sanitizers) provided that the process is validated to achieve the 5 log reduction in the target pathogen. However, the agency points out that under the proposed rule, processors must establish CL's for each CCP, monitor CL's to ensure compliance, conduct verification and validation procedures, and maintain records of these actions. In addition, the 5 log reduction must be of a target organism.

Each type of control measure used in a cumulative process introduces a unique variable in attaining the overall target of pathogen reduction. The physical parameters of the juice and how the product will be handled after it leaves the processing plant, and before it is consumed, must be considered in the selection of the target organism. Processors must take into consideration time, temperature, pH, and Brix parameters and other matters for juice products in order to provide adequate pathogen control. Time, temperature, juice pH, and Brix directly affect the rate of growth and the types of microorganisms.

The proposed 5 log reduction standard of proposed § 120.24 requires that this reduction be achieved and persist for at least the shelf life of the product when the product is stored under normal and moderate abuse

conditions. Normal handling of juice includes the movement of the juice from the plant to retail (e.g., transportation, warehouse storage) and consumer handling after purchase (e.g., transport home, setting out on a counter or table). Moderate abuse may occur when unusual circumstances arise during regular handling. For example, unloading a truck on a hot day where the product may sit on a loading dock for a short period of time could constitute moderate abuse. In addition, moderate abuse could occur if consumers purchase a product on a warm day, place it in their car, and run errands before refrigerating the product. In FDA's view, moderate abuse does not include exposure to high temperatures for extended periods of time.

The proposed requirement mandates that processors validate that the control measures are both appropriate to their operation and scientifically sound. In many cases, processors may rely on a written certification from the equipment manufacturer or may obtain a written scientific evaluation of a process, especially in cases where two or more control measures are used to accomplish the 5 log reduction in the target pathogen, to ensure that the process is adequate to destroy microorganisms of public health significance or to prevent their growth. Such an evaluation may also be necessary to ensure the adequacy of the pasteurization or refrigerating equipment used by the processor.

Comments on the notice of intent (62 FR 45593, August 28, 1997) addressed the issue of pathogen reduction. One comment stated that a 2 1/2 log reduction in fruit surface microflora from washing was adequate. Some comments asked from what point the 5 log reduction would be measured (e.g., washing of produce).

FDA tentatively concludes that the cumulative 5 log reduction could be measured from the point of the processors' initial treatment of the intact fruit or vegetable. If pathogens are meaningfully reduced on the raw produce through washing or other treatment, and the product is processed under an adequate HACCP program, the hazard from the presence of pathogens may be controlled. However, this control measure may not be adequate or appropriate for all types of produce because of differences in surfaces, areas that are difficult to clean, inclusion of peel or outer layer in the juice, and tissue fragility.

The agency requests comments on its approach to pathogen reduction. In particular, the agency requests comments on whether all juices should be subject to proposed § 120.24, or whether such a requirement may not be necessary for certain juices or types of juices. FDA also requests comments on whether a 5 log reduction is appropriate for all juices, or whether a higher or lower requirement would be adequate for some types of juice.

V. The Paperwork Reduction Act of 1995

This proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collections are shown below with an estimate of the annual recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate or other forms of information technology.

Title: Hazard Analysis and Critical Control Point (HACCP) Systems—Reporting and recordkeeping requirements for processors of fruit and vegetable juices under the provisions of 21 CFR part 120.

Description: Section 402(a)(1) (21 U.S.C. 342(a)(1)) of the Federal Food, Drug, and Cosmetic Act (the act) states that a food shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health. Section 402(a)(4) (21 U.S.C. 342(a)(4)) of the act states that a food shall be deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The proposed regulation set forth in this proposed rule would require processors to use Hazard Analysis and Critical Control Point (HACCP) methodology to ensure that fruit and vegetable juices are safe under the act. HACCP is a preventive system of hazard control.

Description of Respondents: Businesses or other for profit organizations.

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Sections	No. of Recordkeepers	Annual Frequency	Hours per Recordkeeper	Total Hours
120.6(c)	600	1[2]	4	4,800[2]
120.12(a)(1) and (a)(2), 120.6(c)-(d), and 120.12(a)(5)	600	1	2	1,200
120.7 and 120.12(a)(2) and (c)(1)	600	1[2]	8	4,800[2]
120.8(a) and 120.12(a)(3) and (c)	600	1[2]	8	4,800[2]
120.8(b)(7) and 120.12(a)(4)(i)	600	14,600	0.01	87,600
120.11(b) and 120.12(a)(5)	600	1	4	2,400
120.11(a)(1)(iv)	600	52	0.1	3,120
120.10(c) and 120.12(a)(4)(ii)	600	12	0.1	720
120.14(a)(2)	308	1	4	1,232
120.12(e)	182[3]	1	4	728

Totals:

First year 111,400
Subsequent years 97,000

There are no operating and maintenance cost or capital costs associated with this collection of information.
[2] First year only.
[3] Assuming that producers and importers are subject to official review on a 5-year cycle.

The burden for these activities will vary considerably among processors and importers of juice and juice products, depending on the type and number of products involved, and the nature of the equipment or instruments required to monitor critical control points. The burdens have been estimated based on the estimated average annual information collection burden for seafood HACCP (60 FR 65096 at 65178; December 18, 1995). As noted in the preliminary regulatory impact analysis for this proposal, FDA estimates that there are at least 600 firms producing juice products of the type affected by this proposed rulemaking.

In compliance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to submit comments regarding information collection by May 26, 1998, to the OMB (address above), Attention: Desk Officer for FDA.

VI. Environmental Impact

The agency has determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Analysis of Impacts

A. Preliminary Regulatory Impact Analysis

In accordance with Executive Order 12886, FDA has developed a single preliminary regulatory impact analysis (PRIA) that estimates benefits and costs associated with both this HACCP proposal and the warning label proposal for juice. The agency will promptly publish the PRIA in the **Federal Register.**

B. Small Entity Analysis

In accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), FDA has developed a single small entity analysis that estimates benefits and costs associated with both this HACCP proposal and the warning label proposal for juice. The agency will promptly publish the small entity analysis in the **Federal Register**.

VIII. Request for Comments

Interested persons may, on or before July 8, 1998, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

IX. References

The following information has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday.

1. Centers for Disease Control and Prevention, ''Outbreak of *Escherichia coli* O157:H7 Infections Associated With Drinking Unpasteurized Commercial Apple Juice—British Columbia, California, Colorado, and Washington,'' October 1996, MMWR, 45(44):875, November 8, 1996.

2. Griffin, P. M., ''Report of O157:H7 Outbreaks Caused by Juices,'' Current Science and Technology on Fresh Juices, Transcript of Public Meeting, vol. 1:15–27, December 16 and 17, 1996.

3. Tabershaw, I. R., L. L. Schmelzer, and H. B. Bruyn, ''Gastroenteritis From an Orange Juice Preparation I, Clinical and Epidemiological Aspects,'' *Archives of Environmental Health* 15:72–77, 1967.

4. Schmelzer, L. L., J. M. Gates, M. S. Redfearn, and I. R. Tabershaw, ''Gastroenteritis From an Orange Juice Preparation II, Field and Laboratory Investigation,'' *Archives of Environmental Health*, 15:78–82, 1967.

5. Centers for Disease Control, ''*Salmonella typhimurium* Outbreak Traced to a Commercial Apple Cider— New Jersey,'' MMWR 24:87–88, 1975

6. Centers for Disease Control and Prevention, ''Cholera Associated With Imported Frozen Coconut Milk—Maryland,'' MMWR 40(49):844–843, 1991.

7. Millard, P. S., K. R. Gensheimer, D. G. Addiss, D. M. Sosin, G. A. Beckett, A. Houck-Jankoski, and A. Hudson, ''An Outbreak of Cryptosporidiosis From Fresh-pressed Apple Cider,'' *JAMA* 272(20):1592–1596, 1994.

8. Centers for Disease Control and Prevention, 1997, ''Outbreaks of *Escherichia coli* O157:H7 Infection and Cryptosporidiosis Associated With Drinking Unpasteurized Apple Cider—Connecticut and New York,'' MMWR 46(1):4–8, October 1996.

8A. Memorandum of telephone conversation between Mike Cambridge, New York State Health Department, and Clark Nardinelli, FDA, April 20, 1998.

9. Cook, K. A., 1996, EPI–AID 95–62 Trip Report: ''Outbreak of *Salmonella* Hartford Infections Among Travelers to Orlando, Florida,'' Centers for Disease Control and Prevention Memorandum, October 1, 1995.

10. Steele, B. T., N. Murphy, G. S. Arbus, and C. P. Rance, ''An Outbreak of Hemolytic Uremic Syndrome Associated With Ingestions of Fresh Apple Juice,'' *Journal of Pediatrics* 101(6):963–965, 1982.

11. Besser, R. E., S. M. Lett, J. T. Weber, M. P. Doyle, T. J. Barrett, J. G. Wells, and P. M. Griffin, ''An Outbreak of Diarrhea and Hemolytic Uremic Syndrome From *Escherichia coli* O157:H7 in Fresh-pressed Apple Cider, *JAMA* 269(17):2217–2220, 1993.

12. Whatcom County (Washington) Health Department, Summary of a Suspected Outbreak of *E. coli* O157:H7 Associated With Consumption of Unpasteurized Apple Cider, 2 pages, 1996.

13. Webb, R. W., ''Gastroenteritis in Elementary School Students after Drinking Orange Juice, Mobile County,'' Note to Epidemiology File, May 10, 1994.

14. Memorandum of telephone conversation between Mike Cambridge, New York State Health Department, and Debra Street, FDA, January 22, 1997.

15.Memorandum of telephone conversation between Patty Walker, Washington State Health Department, and Debra Street, FDA, January 15, 1997.

16.Memorandum of telephone conversation between Susan Karam, Ohio State Health Department, and Debra Street, FDA, January 21, 1997.

17. Memorandum of telephone conversation between Roberta Hammond, Florida State Health Department, and Debra Street, FDA, January 21, 1997.

18. Memorandum of telephone conversation between Pam Shillam, Colorado State Health Department, and Debra Street, FDA, January 17, 1997.

19. Barker, W. H., and V. Runte, 1972, ''Tomato Juice-associated Gastroenteritis, Washington and Oregon,'' *American Journal of Epidemiology* 96(2):219–226, 1969.

20. Centers for Disease Control, ''Poisoning From Elderberry Juice —California,'' MMWR 33(13):173–174, 1984.

21. Memorandum of telephone conversation between Dr. K. Hendricks, Texas State Health Department, and Debra Street, FDA, January 16, 1997.

22. FDA, Health hazard evaluation, classification, and FDA Enforcement Report for firm-initiated recall #F–680–7, August 12 and 27, 1997.

23. FDA, Health hazard evaluation, classification, and FDA Enforcement Report for firm-initiated recall #F–411/420–2, July 14 and 30, 1992, and August 12, 1992.

24. FDA, Health hazard evaluation, classification, and FDA Enforcement Report for firm-initiated recall #F–346–8, July 14, 20, and 27, 1988.

25. FDA, Health hazard evaluation, classification, and FDA Enforcement Report

for firm-initiated recall #F–400/421–1, May 23, 1991, and June 6 and 19, 1991.
26. FDA, Health hazard evaluation, classification, and FDA Enforcement Report for firm-initiated recall #F–189/190–5, January 6 and 25, 1995.
27. FDA, Health hazard evaluation, classification, and FDA Enforcement Report for recall #F–338/339–8, July 6, 7, and 27, 1988.
28. FDA, Health hazard evaluation, classification, and FDA Enforcement Report for firm-initiated recall #F–68–9, November 16, 1988, and December 6 and 14, 1988.
29. FDA, Health hazard evaluation, classification, and FDA Enforcement Report for recall #F–092/093–0, October 19, 1989, and November 1, 1989.
30. FDA, Health hazard evaluation, classification, and FDA Enforcement Report for recall #F–523–0, June 27, 1990, and July 10 and 18, 1990.
31. FDA, Health hazard evaluation, classification, and FDA Enforcement Report for recall #F–107–1, November 14, 1990; December 31, 1990; January 9, 1991; and February 6, 1991.
32. FDA, Health hazard evaluation, classification, and FDA Enforcement Report for recall #F–421–2, July 8, 10, and 22, 1992.
33. FDA, Health hazard evaluation, classification, and FDA Enforcement Report for recall #F–285–3, April 1 and 21, 1993.
34. FDA, Health hazard evaluation, classification and FDA Enforcement Report for recall #F–665–5, May 16, 18, and 31, 1995.
35. FDA, Health hazard evaluation, classification, and FDA Enforcement Report for recall #F–529–1, September 4, 5, and 18, 1991.
36. FDA, Health hazard evaluation, classification, and FDA Enforcement Report for recall #F–364–2, June 23, 1992, and July 2, 1992.
37. FDA, Health hazard evaluation, classification, and FDA Enforcement Report for firm initiated recall #F–319–3, May 4 and 19, 1993.
38. FDA, Health hazard evaluation, classification, and FDA Enforcement Report for recall #F–250–4, January 13 and 27, 1994, and February 9, 1994.
39. FDA, Health hazard evaluations, classification, and FDA Enforcement Report for recall #F–492–7, June 27, 1997, and July 2 and 16, 1997.
40. FDA, Health hazard evaluation, classification, and FDA Enforcement Report for firm-initiated recall #F–427–1, June 3, 11, and 19, 1991.
41. FDA, Health hazard evaluation, classification, and FDA Enforcement Report for firm-initiated recall #F–781–4, August 9, 10, and 24, 1994.
42. FDA, Health hazard evaluation, classification, and Enforcement Report for recall #F–406–7, May 1 and 7, 1997
43. FDA, Health hazard evaluation, classification, and FDA Enforcement Report for firm-initiated recall #F–584/596–6, June 6, 7, and 26, 1996.
44. FDA, Health hazard evaluation, classification, and FDA Enforcement Report for recall #F–023–7, October 24 and 30, 1996.
45. FDA, Health hazard evaluation, classification, and FDA Enforcement Report for recall #F–036–7, October 23 and 30, 1996, and November 13, 1996.
46. FDA, Health hazard evaluation, classification, and FDA Enforcement Report for recall #F–072–7, November 14 and 20, 1996.
47. FDA, Health hazard evaluation, classification, and FDA Enforcement Report for recall #F–073–7, November 14 and 20, 1996.
48. Trucksess, M. W., memorandum to Martin J. Stutsman on Patulin—97–688–239, Apple Juice Concentrate, March 31, 1997.
49. Wagstaff, J., memorandum to M. J. Stutsman, and T. C. Troxell on the hazard of patulin in apple juice concentrate sample 97–688–239, April 2, 1997, and July 18, 1997.
50. Williams, R. T. Wilcox, B. Timbo, D. Street, C. Nardinelli, P. McCarthy, G. Jackson, M. T. Hendricks, and E. Elliot, ''Preliminary Investigation Into the Morbidity and Mortality Effects Associated With the Consumption of Fruit and Vegetable Juices,'' October 31, 1997.
51. FDA, ''Pesticide Program Residue Monitoring 1994,'' J. AOAC International, vol. 78, September/October 1995.
52. FDA, 1996, ''Pesticide Program Residue Monitoring 1995.''
53. National Advisory Committee on Microbiological Criteria for Foods, ''NACMCF Recommendations on Fresh Juice,'' April 9, 1997.
54. U.S. Public Health Service, ''Food Code, 1997 Recommendations of the United States Public Health Service, Food and Drug Administration,'' National Technical Information Service Publication PB95–265492, p. 73.
55. National Advisory Committee on Microbiological Criteria for Foods, ''Hazard Analysis and Critical Control Point Principles and Application Guidelines,'' August 14, 1997.
56. Webster's II New Riverside University Dictionary, The Riverside Publishing Co., p. 657, 1994.
57. FDA, ''Hazard Analysis and Critical Control Point (HACCP) Pilot Program for Selected Food Manufacturers: Second Interim Report of Observations and Comments,'' October 31, 1997.
58. Davis, S. A., memorandum to file: '' Hazard Analysis and Critical Control Point (HACCP) Systems for Juice; Consideration of Hazards that are Reasonably Likely to Occur,'' October 21, 1997.
59. FDA, Hazard Analysis Critical Control Point (HACCP) Pilot Program for Selected Food Manufacturers: Interim Report of Observations and Comments, June 19, 1996.
60. Zhao, T., M. P. Doyle, and R. E. Besser, ''Fate of Enterohemorrhagic *Escherichia coli* O157:H7 in Apple Cider With and Without Preservatives,'' *Applied and Environmental Microbiology*, 59(8):2526–2530.
61. Miller, L. G., and C. W. Kaspar, ''*Escherichia coli* O157:H7 Acid Tolerance and Survival in Apple Cider,'' *Journal of Food Protection*, 57(6):460–464, 1994.
62. Bradshaw, J. G., J. T. Peeler, J. J. Corwin, J. M. Hunt, J. T. Tierney, E. P. Larkin, and R. M. Twedt, ''Thermal Resistance of *Listeria monocytogenes* in Milk,'' *Journal of Food Protection*, 48:743–745, 1985.
63. Doyle, M. P., K. A. Glass, J. T. Beery, G. A. Garcia, D. J. Pollard, and R. D. Schultz, ''Survival of *Listeria monocytogenes* in Milk During High-Temperature, Short-Time Pasteurization,'' *Applied and Environmental Microbiology*, 53(7):1433–1438, 1987.
64. Memorandum of telephone conversation between Mickey Parish, University of Florida, and Richard Williams, FDA, December 31, 1997.
65. Winniczuk, P. P., and M. E. Parish, ''Minimum Inhibitory Concentrations of Antimicrobials Against Microorganisms Related to Juice,'' *Food Microbiol.*, 14(4):373–381, 1997.

List of Subjects in 21 CFR Part 120

Fruit and vegetable juice, Food, Imports, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, under the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that title 21 CFR chapter I be amended as follows:

1. Part 120 is added to read as follows:

PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

Subpart A—General Provisions

Sec.

Subpart B—Pathogen Reduction

Authority: 21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393; 42 U.S.C. 241, 242l, 264.

Subpart A—General Provisions

§ 120.1 Applicability.

(a) Any juice sold as such or used as an ingredient in beverages shall be processed in accordance with the requirements of this part. Juice means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree.

(b) The regulations in this part shall be effective 1 year after the date of publication of the final rule in the **Federal Register**. However, by its terms, this part is not binding on small and very small businesses until the dates listed in paragraphs (b)(1) and (b)(2) of this section.

(1) For small businesses employing fewer than 500 persons the regulations in this part are binding 2 years after the date of publication of the final rule in the **Federal Register**.

(2) For very small businesses that have either total annual sales of less than $500,000, or if their total annual sales are greater than $500,000 but their total food sales are less than $50,000; or the person claiming this exemption employed fewer than an average of 100 full-time equivalent employees and fewer than 100,000 units of juice were sold in the United States, the regulations are binding 3 years after the date of publication of the final rule in the **Federal Register**.

§ 120.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act, § 101.9(j)(18)(vi), and part 110 of this chapter are applicable to such terms when used in this part, except where redefined in this part. The following definitions shall also apply:

(a) *Control* means to prevent, eliminate, or reduce.

(b) *Control measure* means any action or activity that can be used to prevent, eliminate, or reduce a hazard.

(c) *Critical control point* means a point, step, or procedure in a food process at which a control measure can be applied and at which control is essential to reduce an identified food hazard to an acceptable level.

(d) *Critical limit* means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food hazard.

(e) *Food hazard* means any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

(f) *Importer* means either the U.S. owner or consignee at the time of entry of a food product into the United States, or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States. The importer is responsible for ensuring that goods being offered for entry into the United States are in compliance with all applicable laws. For the purposes of this definition, the importer is ordinarily not the custom house broker, the freight forwarder, the carrier, or the steamship representative.

(g) *Monitor* means to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification.

(h)(1) *Processing* means activities that are directly related to the production of juice products.

(2) For purposes of this part, processing does not include:

(i) Harvesting, picking, or transporting raw agricultural ingredients of juice products, without otherwise engaging in processing.

(ii) The operation of a retail establishment; and

(iii) The operation of a retail establishment that is a very small business and that makes juice on its premises, provided that the establishment's total sales of juice and juice products do not exceed 40,000 gallons per year, and that sells such juice:

(A) Directly to consumers or

(B) directly to consumers and other retail establishments.

(i) *Processor* means any person engaged in commercial, custom, or institutional processing of juice products, either in the United States or in a foreign country. A processor includes any person engaged in the processing of juice products that are intended for use in market or consumer tests.

(j) *Shall* is used to state mandatory requirements.

(k) *Should* is used to state recommended or advisory procedures or to identify recommended equipment.

§ 120.5 Current good manufacturing practice.

Part 110 of this chapter applies in determining whether the facilities, methods, practices, and controls used to process food are safe, and whether the food has been processed under sanitary conditions.

§ 120.6 Prerequisite program standard operating procedures.

(a) *Sanitation controls.* Each processor shall have and implement a sanitation standard operating procedure (SOP) that addresses sanitation conditions and practices before, during, and after processing and relates to the following:

(1) Safety of the water that comes into contact with food or food contact surfaces or that is used in the manufacture of ice;

(2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;

(3) Prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to processed product;

(4) Maintenance of hand washing, hand sanitizing, and toilet facilities;

(5) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;

(6) Proper labeling, storage, and use of toxic compounds;

(7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and

(8) Exclusion of pests from the food plant.

(b) *Monitoring.* The processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 of this chapter that are appropriate both to the plant and to the food being processed. Each processor shall correct, in a timely manner, those conditions and practices that are not met.

(c) *Records.* Each processor shall maintain prerequisite program SOP records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b) of this section. These records are subject to the recordkeeping requirements of § 120.12.

(d) *Relationship to Hazard Analysis and Critical Control Point (HACCP) plan.* Prerequisite program SOP controls may be included in the HACCP plan required under § 120.8(b). However, to the extent that they are implemented in accordance with this section, they need not be included in the HACCP plan.

§ 120.7 Hazard analysis.

Each processor shall develop, or have developed for it, a written hazard analysis to determine whether there are food hazards that are reasonably likely to occur for each type of juice processed by that processor and to identify the control measures that the processor can apply to control those hazards. The hazard analysis shall include food hazards that can be introduced both within and outside the processing plant environment, including food hazards that can occur before, during, and after harvest. A food hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience,

illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that, in the absence of those controls, the food hazard will occur in the particular type of product being processed. The hazard analysis shall be developed by an individual or individuals who have been trained in accordance with § 120.13 and shall be subject to the recordkeeping requirements of § 120.12.

(a) In evaluating what food hazards are reasonably likely to occur, consideration should be given, at a minimum, to the following:

(1) Microbiological contamination;

(2) Parasites;

(3) Chemical contamination;

(4) Unlawful pesticides residues;

(5) Decomposition in food where a food hazard has been associated with decomposition;

(6) Natural toxins;

(7) Unapproved use of food or color additives;

(8) Presence of undeclared ingredients that may be allergens; and

(9) Physical hazards.

(b) Processors should evaluate product ingredients, processing procedures, packaging, storage, and intended use; facility and equipment function and design; and plant sanitation including employee hygiene to determine the potential effect of each on the safety of the finished food for the intended consumer.

§ 120.8 Hazard Analysis Critical Control Point (HACCP) plan.

(a) *HACCP plan.* Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food hazards that are reasonably likely to occur during processing, as described in § 120.7. The HACCP plan shall be developed by an individual or individuals who have been trained in accordance with § 120.13 and shall be subject to the recordkeeping requirements of § 120.12. A HACCP plan shall be specific to:

(1) Each location where juice is processed by that processor; and

(2) Each type of juice processed by the processor. The plan may group types of juice products together, or group types of production methods together, if the food hazards, critical control points, critical limits, and procedures required to be identified and performed by paragraph (b) of this section are essentially identical, provided that any required features of the plan that are unique to a specific product or method are clearly delineated in the plan and are observed in practice.

(b) *The contents of the HACCP plan.* The HACCP plan shall, at a minimum:

(1) List all food hazards that are reasonably likely to occur as identified in accordance with § 120.7, and that thus must be controlled for each type of product.

(2) List the critical control points for each of the identified food hazards, including as appropriate:

(i) Critical control points designed to control food hazards that could occur or could be introduced inside the processing plant environment; and

(ii) Critical control points designed to control food hazards introduced outside the processing plant environment, including food hazards that occur before, during, and after harvest;

(3) List the critical limits that shall be met at each of the critical control points;

(4) List the procedures, and the frequency with which they are to be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include any corrective action plans that have been developed in accordance with § 120.10(a), and that are to be followed in response to deviations from critical limits at critical control points;

(6) List the validation and verification procedures, and the frequency with which they are to be performed, that the processor will use in accordance with § 120.11; and

(7) Provide for a recordkeeping system that documents the monitoring of the critical control points in accordance with § 120.12. The records shall contain the actual values and observations obtained during monitoring.

(c) *Products subject to other regulations.* HACCP plans for juice need not address the food hazards associated with microorganisms and microbial toxins that are controlled by the requirements of part 113 or 114 of this chapter. A HACCP plan for such juice shall address any other food hazards that are reasonably likely to occur.

(d) *Sanitation.* Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with § 120.6, they are not required to be included in the HACCP plan.

§ 120.9 Legal basis.

Failure of a processor to have and to implement a Hazard Analysis and Critical Control Point (HACCP) system that complies with §§ 120.6, 120.7, and 120.8, or otherwise to operate in accordance with the requirements of this part, shall render the juice products of that processor adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. Whether a processor's actions are consistent with ensuring the safety of juice will be determined through an evaluation of the processor's overall implementation of its HACCP system.

§ 120.10 Corrective actions.

Whenever a deviation from a critical limit occurs, a processor shall take corrective action by following the procedures set forth in paragraph (a) or paragraph (b) of this section.

(a) Processors may develop written corrective action plans, which become part of their Hazard Analysis and Critical Control Point (HACCP) plans in accordance with § 120.8(b)(5), by which processors predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

(1) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and

(2) The cause of the deviation is corrected.

(b) When a deviation from a critical limit occurs, and the processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;

(2) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such review. Adequate training may or may not include training in accordance with § 120.13;

(3) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;

(4) Take corrective action, when necessary, to correct the cause of the deviation; and

(5) Perform or obtain timely validation in accordance with § 120.11, by an individual or individuals who have been trained in accordance with § 120.13, to determine whether modification of the HACCP plan is required to reduce the risk of recurrence of the deviation, and to modify the HACCP plan as necessary.

(c) All corrective actions taken in accordance with this section shall be fully documented in records that are

subject to verification in accordance with § 120.11(a)(1)(iv)(B) and the recordkeeping requirements of § 120.12.

§ 120.11 Verification and validation.

(a) *Verification*. Every processor shall verify that the Hazard Analysis and Critical Control Point (HACCP) system is being implemented according to design.

(1) Verification activities shall include:

(i) A review of any consumer complaints that have been received by the processor to determine whether such complaints relate to the performance of the HACCP plan or reveal previously unidentified critical control points;

(ii) The calibration of process-monitoring instruments;

(iii) At the option of the processor, the performance of periodic end-product or in-process testing;

(iv) A review, including signing and dating, by an individual who has been trained in accordance with § 120.13, of the records that document:

(A) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that the records document values that are within the critical limits. This review shall occur within 1 week (7 days) of the day that the records are made;

(B) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with § 120.10. This review shall occur within 1 week (7 days) of the day that the records are made; and

(C) The calibrating of any process monitoring instruments used at critical control points and the performance of any periodic end-product or in-process testing that is part of the processor's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made; and

(v) The following of procedures in § 120.10 whenever any verification procedure, including the review of consumer complaints, establishes the need to take a corrective action.

(2) The calibration of process-monitoring instruments, and the performance of any periodic end-product and in-process testing, in accordance with paragraphs (a)(1)(iv)(B) through (a)(1)(iv)(C) of this section, shall be documented in records that are subject to the recordkeeping requirements of § 120.12.

(b) *Validation of the HACCP plan*. Every processor shall validate that the HACCP plan is adequate to control food hazards that are reasonably likely to occur; this validation shall occur at least once within 12 months after implementation and at least annually thereafter or whenever any changes in the process occur that could affect the hazard analysis or alter the HACCP plan and prerequisite program of the standard operating procedures (SOP's) in any way. Such changes may include changes in the following: Raw materials or source of raw materials; product formulation; processing methods or systems, including computers and their software; packaging; finished product distribution systems; or the intended use or consumers of the finished product. The validation shall be performed by an individual or individuals who have been trained in accordance with § 120.13 and shall be subject to the recordkeeping requirements of § 120.12. The HACCP plan shall be modified immediately whenever a validation reveals that the plan is no longer adequate to fully meet the requirements of this part.

(c) *Validation of the hazard analysis*. Whenever a juice processor has no HACCP plan because a hazard analysis has revealed no food hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes in the process that could reasonably affect whether a food hazard exists. Such changes may include changes in the following: Raw materials or source of raw materials; product formulation; processing methods or systems, including computers and their software; packaging; finished product distribution systems; or the intended use or intended consumers of the finished product. The validation shall be performed by an individual or individuals who have been trained in accordance with § 120.13 and shall be subject to the recordkeeping requirements of § 120.12.

§ 120.12 Records.

(a) *Required records*. Processors shall maintain the following records documenting the processor's Hazard Analysis and Critical Control Point (HACCP) system:

(1) Records documenting the implementation of the prerequisite program of the standard operating procedures (SOP's) (see § 120.6);

(2) The written hazard analysis required by § 120.7;

(3) The written HACCP plan required by § 120.8;

(4) Records documenting the ongoing application of the HACCP plan that include:

(i) Monitoring of critical control points and their critical limits, including the recording of actual times, temperatures, or other measurements, as prescribed in the establishment's HACCP plan; and

(ii) Corrective actions, including all actions taken in response to a deviation; and

(5) Records documenting verification of the HACCP system and validation of the HACCP plan or hazard analysis.

(b) *General requirements*. All records required by this part shall include:

(1) The name and location of the processor or importer;

(2) The date and time of the activity that the record reflects;

(3) The signature or initials of the person performing the operation or creating the record; and

(4) Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed. The records shall contain the actual values and observations obtained during monitoring.

(c) *Documentation*. (1) The records in paragraphs (a)(2) and (a)(3) of this section shall be signed and dated by the most responsible individual onsite at the processing facility or by a higher level official of the processor. These signatures shall signify that these records have been accepted by the firm.

(2) The records in paragraphs (a)(2) and (a)(3) of this section shall be signed and dated:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) Upon verification and validation in accordance with § 120.11.

(d) *Record retention*. (1) All records required by this part shall be retained at the processing facility or at the importer's place of business in the United States for, in the case of perishable or refrigerated juices, at least 1 year after the date that such products were prepared, and for, in the case of frozen, preserved, or shelf-stable products, 2 years or the shelf life of the product, whichever is greater, after the date that the products were prepared.

(2) Records that relate to the general adequacy of equipment or processes used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing facility or at the importer's place of business in the United States for at least 2 years after the date that the

processor last used such equipment or process.

(3) Off-site storage of processing records required by paragraphs (a)(1) and (a)(3) of this section is permitted after 6 months following the date that the monitoring occurred, if such records can be retrieved and provided on-site within 24 hours of request for official review. Electronic records are considered to be on-site if they are accessible from an on-site location and comply with § 120.12(g).

(4) If the processing facility is closed for a prolonged period between seasonal packs, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack but shall be immediately returned to the processing facility for official review upon request.

(e) *Official review*. All records required by this part shall be available for official review and copying at reasonable times.

(f) *Public disclosure*. (1) Subject to the limitations in paragraph (d)(2) of this section, all records required by this part are not available for public disclosure unless they have been previously disclosed to the public, as defined in § 20.81 of this chapter, or unless they relate to a product or ingredient that has been abandoned and thus, no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter.

(2) Records required to be maintained by this part are subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic-type HACCP plans that reflect standard industry practices.

(g) *Records maintained on computers*. The maintenance of records on computers, in accordance with part 11 of this chapter, is acceptable.

§ 120.13 Training.

(a) Only an individual who has met the requirements of paragraph (b) of this section shall be responsible for the following functions:

(1) Developing the hazard analysis, including delineating control measures, as required by § 120.7;

(2) Developing a Hazard Analysis and Critical Control Point (HACCP) plan that is appropriate for a specific processor, in order to meet the requirements of § 120.8;

(3) Validating and modifying the HACCP plan in accordance with the corrective action procedures specified in § 120.10(c)(5) and the validation activities specified in § 120.11(b) and (c); and

(4) Performing the record review required by § 120.11(a)(1)(iv).

(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed training in the application of HACCP principles to juice processing at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration or shall be otherwise qualified through job experience to perform these functions. Job experience may qualify an individual to perform these functions if such experience has provided knowledge at least equivalent to that provided through the standardized curriculum. The trained individual need not be an employee of the processor.

§ 120.14 Application of requirements to imported products.

This section sets forth specific requirements for imported food.

(a) *Importer requirements*. Every importer of food shall either:

(1) Obtain the food from a country that has an active memorandum of understanding (MOU) or similar agreement with the Food and Drug Administration, that covers the food and documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system, accurately reflects the relationship between the signing parties, and is functioning and enforceable in its entirety; or

(2) Have and implement written procedures for ensuring that the food that such importer receives for import into the United States was processed in accordance with the requirements of this part. The procedures shall provide, at a minimum:

(i) Product specifications that are designed to ensure that the product is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act because it may be injurious to health or because it may have been processed under insanitary conditions; and

(ii) Affirmative steps to ensure that the products being offered for entry were processed under controls that meet the requirements of this part. These steps may include any of the following:

(A) Obtaining from the foreign processor the Hazard Analysis and Critical Control Point (HACCP) plan and prerequisite program of the standard operating procedure (SOP) records required by this part that relate to the specific lot of food being offered for import;

(B) Obtaining either a continuing or lot specific certificate from an appropriate foreign government inspection authority or competent third party certifying that the imported food has been processed in accordance with the requirements of this part;

(C) Regularly inspecting the foreign processor's facilities to ensure that the imported food is being processed in accordance with the requirements of this part;

(D) Maintaining on file a copy, in English, of the foreign processor's hazard analysis and HACCP plan, and a written guarantee from the foreign processor that the imported food is processed in accordance with the requirements of this part;

(E) Periodically testing the imported food, and maintaining on file a copy, in English, of a written guarantee from the foreign processor that the imported food is processed in accordance with the requirements of this part; or

(F) Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part.

(b) *Competent third party*. An importer may hire a competent third party to assist with or perform any or all of the verification activities specified in paragraph (a)(2) of this section, including writing the importer's verification procedures on the importer's behalf.

(c) *Records*. The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in paragraph (a)(2)(ii) of this section. These records shall be subject to the applicable provisions of § 120.12.

(d) *Determination of compliance*. The importer shall provide evidence that all food offered for entry into the United States has been processed under conditions that comply with this part. If assurances do not exist that an imported food has been processed under conditions that are equivalent to those required of domestic processors under this part, the product will appear to be adulterated and will be denied entry.

Subpart B—Pathogen Reduction

§ 120.20 General.

This subpart augments subpart A of this part by setting forth specific requirements for process controls.

§ 120.24 Process controls.

In order to meet the requirements of subpart A of this part, processors of juice products, except those subject to the requirements of part 113 or 114 of

this chapter, shall include in their Hazard Analysis and Critical Control Point (HACCP) plans control measures that will produce, at a minimum, a 5 log (i.e., 10^5) reduction, for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions, in the pertinent microorganism. For the purposes of this regulation, the ''pertinent microorganism'' is the most resistant microorganism of public health significance that is likely to occur in the juice.

Dated: April 17, 1998.

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 98–11025 Filed 4–22–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 97N–0524]

RIN 0910–AA43

Food Labeling: Warning and Notice Statements; Labeling of Juice Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require warning statements on packaged fruit and vegetable juice products that have not been processed to destroy pathogenic microorganisms that may be present. FDA is taking this action because of the recent outbreaks of foodborne illness and deaths caused by consumption of juice products that were not pasteurized or otherwise processed to control pathogenic microorganisms. This requirement for warning labels will serve to reduce the risk of foodborne illness. Elsewhere in this issue of the **Federal Register**, FDA is proposing to require that juice be processed under a Hazard Analysis and Critical Control Point program (HACCP).

DATES: Submit written comments by May 26, 1998. See section V of the **SUPPLEMENTARY INFORMATION** section of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Geraldine A. June, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

SUPPLEMENTARY INFORMATION:

I. Background

There recently have been outbreaks of foodborne illness associated with the consumption of juice and beverages containing juice, i.e., juice products, that have not been pasteurized or otherwise treated to destroy pathogenic microorganisms.[1] On October 30, 1996, the Seattle-King County Department of Public Health and the Washington State Department of Health reported an outbreak of *Escherichia coli* O157:H7 infections epidemiologically associated with consumption of unpasteurized apple juice. The outbreak resulted in at least 66 cases of illness in 3 western States and British Columbia, and the death of 1 child (Refs. 1 and 2).

Pathogens other than *E. coli* O157:H7 may be present in apple and other types of juice products and have been documented as the cause of foodborne illness. In particular, outbreaks caused by *Salmonella typhimurium* and *Cryptosporidium* in apple cider (Refs. 3, 4, and 5) and *Vibrio cholerae* in coconut milk (Ref. 6) have been reported. In addition, outbreaks caused by consumption of unpasteurized orange juice contaminated with *S. hartford* (Ref. 7), orange juice drink contaminated with *S. agona* (Ref. 8), orange juice contaminated with *Bacillus cereus* (Ref. 9), and home-made carrot juice contaminated with *Clostridium botulinum* (Ref. 10) have been reported.

Because of the agency's concern that its regulatory program for fresh juices may not be adequate to ensure the production of safe juice and juice products, and because of the severity of the recent outbreak of *E. coli* O157:H7 associated with apple juice, the agency held a public meeting on December 16 and 17, 1996, to discuss safety issues presented by juice products. At that meeting, FDA met with interested parties to review the current science, including technological and safety factors, relating to fresh juice production and to consider the measures that would be necessary to provide safe fruit and vegetable juices. Experts from industry, academia, and the regulatory and consumer sectors presented information on illnesses and the epidemiology of outbreaks arising from microbially contaminated juices; concerns with emerging pathogens; procedures for processing juices; and new and existing technology to control pathogens in juice products.

In light of the information developed at the public meeting and in comments received by the agency, as well as other information available to the agency, FDA has developed a strategy that it believes will address both the immediate goal of reducing the risk of foodborne illness associated with juice products and the long-term goal of ensuring that juice products are safe. In the **Federal Register** of August 28, 1997 (62 FR 45593), the agency published a notice of intent (''the notice of intent'') that announced a comprehensive program to address the incidence of foodborne illness related to consumption of fresh juice and ultimately to address the safety aspects of all juice products. The agency invited comment on the appropriateness of its strategy to: (1) Initiate rulemaking on a mandatory HACCP program for some or all juice products; (2) propose that the labels or labeling of juice products not specifically processed to prevent, reduce, or eliminate the presence of harmful bacteria bear a warning statement informing consumers of the risk of illness associated with consumption of the product; and (3) initiate several educational programs to minimize the hazards associated with fresh juice. FDA stated that it would consider comments received within 15 days of publication of the notice of intent as part of any rule proposed by the agency.

This document addresses the warning statements for labels of packaged juice products that have not been specifically processed to prevent, reduce, or eliminate the presence of harmful pathogens. FDA has reviewed all the comments received within 15 days of publication of the notice of intent and has determined that the comments provide no information that would cause the agency to conclude that this proposal is inappropriate. In this document, the agency addresses these comments to the extent that they are relevant to this proposal. Comments in response to the notice of intent received more than 15 days after publication of that notice that address issues in this

[1] In this proposal, the terms ''juice'' and ''juice products'' are used interchangeably. Thus, ''juice'' refers both to beverages that are composed exclusively of an aqueous liquid or liquids extracted from one or more fruits or vegetables and those beverages that contain other ingredients in addition to juice. Similarly, ''juice product'' refers both to beverages that contain only juice and beverages that are composed of juice and other ingredients.