[Code of Federal Regulations]
[Title 21, Volume 2]
[Revised as of April 1, 2012]
[CITE: 21CFR120]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION
PART 120 HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

Subpart A--General Provisions

Sec. 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. The requirements of this part shall apply to any juice regardless of whether the juice, or any of its ingredients, is or has been shipped in interstate commerce (as defined in section 201(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(b)). Raw agricultural ingredients of juice are not subject to the requirements of this part. Processors should apply existing agency guidance to minimize microbial food safety hazards for fresh fruits and vegetables in handling raw agricultural products.

(b) The regulations in this part shall be effective January 22, 2002. 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 on January 21, 2003.

(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 on January 20, 2004.

Sec. 120.3 Definitions.

The definitions 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:

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) Offsite storage of processing records required by paragraphs (a)(1) and (a)(4) of this section is permitted after 6 months following the date that the monitoring occurred, if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location and comply with paragraph (g) of this section.

(3) 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 review and copying at reasonable times.

(f) *Public disclosure.* (1) 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 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 computerized records, in accordance with part 11 of this chapter, is acceptable.

Sec. 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) Verifying and modifying the HACCP plan in accordance with the corrective action procedures specified in 120.10(b)(5) and the validation activities specified in 120.11(b) and (c); and 120.7;

(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

RECORDKEEPING

§416.16 Recordkeeping Requirement

(a) *Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOPs and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOPs as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOPs shall authenticate these records with his or her initials and the date.*

(b) Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data.

(c) Records required by this part shall be maintained for at least 6 months and made accessible available to FSIS. All such records shall be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

1. Establishment Responsibilities

§416.16 require the establishment to maintain **daily** records sufficient to document the implementation and monitoring of the SSOPs and any corrective actions taken. The establishment must have records documenting that monitoring has been conducted daily for each of the procedures specified in the SSOPs. If the establishment has specified a monitoring frequency in the SSOP that is more frequent than daily, the documentation would have to reflect that the monitoring activities had been conducted at the specified frequencies. The establishment employee specified in the SSOPs as being responsible for the implementation and monitoring of the procedures shall authenticate these records with initials or signature and the date.

There must also be a written record of any corrective actions required by §416.15. These records must be maintained daily. **The establishment has until the beginning of the same shift the following business day to complete these records.**

§416.16(b) provides the establishment the flexibility to maintain these records on a computer system provided the establishment implements appropriate controls to ensure the integrity of the electronic data.

The records must be kept on-site for 48 hours and must be maintained for at least 6 months. After the initial 48 hours, the records may be kept off-site as long as they can be retrieved for a program employee within 24 hours of the request.

FDA HACCP Plan
Description & Terms
Tennessee Cook Chill
Nashville, TN
FDA Reg. #14717076194

CCP #	Description
1C	Cook Temperatures – Product cooking temperatures for Kettles, Cook Tank, Conventional, & Bakery

Thermometer Calibration - QA personnel or designee will be responsible for calibrating all hand held thermometers used for the purpose of HACCP procedures. Should the thermometer be dropped during the shift, it must be re-calibrated.

Record Keeping Procedures – All completed monitoring, corrective actions etc…will be turned into the QA Lab at the end of each shift. It is the responsibility of the QA Supervisor or designee to review all records for completeness within 24 hours of receipt. All completed paperwork will be held in the QA Lab for a period of at least 24 hours. After which time, the records can be relocated into a storage room, located upstairs next to the conference room. Records will be held in the records room for a period of at least 24 months. (Plant maintains the option to store records in an outside holding area where they can be retrieved within 24 hours of request.) After a period of 24 months, all records are subject to be destroyed. A destruction log will be maintained and available in the QA Lab.

Pre-shipment Review – A member of the QA staff will check all CCP's for completeness, check for any SSOP's written, and verify that pre-op has been completed for the production date being released. This team member will also ensure that all in-house microbial data has passed or corrective actions taken for any product failing micro has been completed prior to releasing product for shipping.

HACCP plan Reassessment (reanalysis) – A reassessment (reanalysis) will be performed when: (1) a significant change in the procedures, ingredients, equipment, or other plant changes occur, (2) in the event of a system failure, (3) in the event an "Unforeseen Hazard" occurs and/or (4) not less frequent than every 3 years. Upon completion of the reassessment, the plant official with overall site authority or designee shall sign the HACCP plan.

Batch Code

All labels will bear a batch code upon packaging. The label shoul contain a batch code which should look similar to the following: ex) A0110305K
The first letter (A) = month of the year
The first four number (0110) = the two digit numerical day followed by the two digit numerical year
The last three numbers (305) = product number
The last letter (K) = Department (except when a "D" is present which signifies specialty items produced for a particular site)

Shipped – Product that has been billed and meets the requirements for Pre-shipment Review.

In-Commerce – the moment in which product leaves the premises of Tennessee Cook Chill, Nashville Tn., and is no longer in direct control of the facility.

Pre-shipment Review – is a review of all HACCP paperwork prior to the product entering commerce in reference to the batches associated with the product on a trailer.

Returned Product - a finished product, which may have been damaged or does not meet the customer's specification which is sent back to our facility from the customer

Received Product - product is considered received when the truck seal (if applicable) has been broken by the shipping department for the purpose of unloading, and the product has been physically brought into the plant for processing or storage.

Cross Docking - product that was produced at another facility that is removed from one truck at this facility and placed onto another truck for the purpose of shipping when no production will occur on the product at this location. Also referred to as *Pass Through Items*

Corrective Action- procedures to be followed when a deviation occurs

Critical Control Point- a point, step, or procedure is a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels

Critical Limits – the maximum or minimum value to which a physical, biological or chemical hazard must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

Food Safety Hazard – any biological, chemical, or physical property that may cause a food to be unsafe for human consumption

HACCP system - the HACCP plan in operation, including the HACCP plan itself

Hazard - SEE food safety hazard

Preventive measure - physical, chemical, or other means that can be used to control an identified food safety hazard

Process-monitoring instrument – an instrument or device used to indicate conditions during processing at a critical control point

Responsible establishment official - the individual with overall authority on-site or a higher level official of the establishment

in accordance with § 417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of § 417.2(c) of this part.

(b) *Reassessment of the hazard analysis.* Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

§ 417.5 Records.

(a) The establishment shall maintain the following records documenting the establishment's HACCP plan:

(1) The written hazard analysis prescribed in § 417.2(a) of this part, including all supporting documentation;

(2) The written HACCP plan, including decisionmaking documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

(3) Records documenting the monitoring of CCP's and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.

(b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.

(c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with § 417.7 of this part, or the responsible establishment official.

(d) *Records maintained on computers.* The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

(e) *Record retention.* (1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated product, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years.

(2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.

(f) *Official review.* All records required by this part and all plans and procedures required by this part shall be available for official review and copying.

§ 417.6 Inadequate HACCP Systems.

A HACCP system may be found to be inadequate if:

(a) The HACCP plan in operation does not meet the requirements set forth in this part;

(b) Establishment personnel are not performing tasks specified in the HACCP plan;

(c) The establishment fails to take corrective actions, as required by § 417.3 of this part;

(d) HACCP records are not being maintained as required in § 417.5 of this part; or

(e) Adulterated product is produced or shipped.

§ 417.7 Training.

(a) Only an individual who has met the requirements of paragraph (b) of this section, but who need not be an employee of the establishment, shall be permitted to perform the following functions:

(1) Development of the HACCP plan, in accordance with § 417.2(b) of this part, which could include adapting a generic model that is appropriate for the specific product; and

(2) Reassessment and modification of the HACCP plan, in accordance with § 417.3 of this part.

(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.

§ 417.8 Agency verification.

FSIS will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the requirements of this part and all other applicable regulations. Such verification may include:

(a) Reviewing the HACCP plan;

(b) Reviewing the CCP records;

(c) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs;

(d) Reviewing the critical limits;

(e) Reviewing other records pertaining to the HACCP plan or system;

(f) Direct observation or measurement at a CCP;

(g) Sample collection and analysis to determine the product meets all safety standards; and

(h) On-site observations and record review.

PART 424—PREPARATION AND PROCESSING OPERATIONS

Subpart A—General

Sec.

Subpart C—Food Ingredients and Sources of Radiation

AUTHORITY: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

SOURCE: 64 FR 72175, Dec. 23, 1999, unless otherwise noted.

Subpart A—General

§ 424.1 Purpose and scope.

This part of the regulations prescribes rules for the preparation of meat and the processing of poultry products. The rules in this part further the purposes of the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) by, among other things, preventing the adulteration or misbranding of meat and poultry products at official establishments. 9 CFR Chapter III, Subchapter A, Parts 318 and 319, Subpart C of this part, and 21 CFR Chapter I, Subchapter A or Subchapter B, specify rules for the use of certain food ingredients (e.g., food additives and color additives) and sources of radiation that may render meat or poultry products adulterated or misbranded.

Subpart C—Food Ingredients and Sources of Radiation

§ 424.21 Use of food ingredients and sources of radiation.

(a)(1) *General.* No meat or poultry product shall bear or contain any food ingredient that would render it adulterated or misbranded, or which is not approved in this part, part 318 or part 319 of this chapter, or by the Administrator in specific cases.

(2)(i) Poultry products and poultry broth used in the processing of poultry products shall have been processed in the United States only in an official establishment or imported from a foreign country listed in § 381.196(b), and have been inspected and passed in accordance with the regulations. Detached ova and offal shall not be used in the processing of any poultry products, except that poultry feet may be processed

in accordance with §417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of §417.2(c) of this part.

(b) *Reassessment of the hazard analysis.* Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

§ 417.5 Records.

(a) The establishment shall maintain the following records documenting the establishment's HACCP plan:

(1) The written hazard analysis prescribed in §417.2(a) of this part, including all supporting documentation;

(2) The written HACCP plan, including decisionmaking documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures se-

(c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with §417.7 of this part, or the responsible establishment official.

(d) *Records maintained on computers.* The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

(e) *Record retention.* (1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated product, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years.

(2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.

(f) *Official review.* All records required