DRAFT - NOT FOR FILING

901:11-3-01 Definitions.

As used in rules 901:11-3-01 to 901:11-3-11 of the Administrative Code:

(A) "Critical limit" means the maximum or minimum value to which a physical, biological or chemical parameter must be held to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard.

(B) "Critical control point" means a point, step or procedure in food processing at which appropriate measures may be taken to prevent, eliminate or reduce to acceptable levels a food safety hazard.

(C) "Drug" means:

(1) Articles recognized in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, or official national formulary;

(2) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animal;

(3) Articles ~~(~~other than food~~)~~ intended to affect the structure or any function of the body of man or other animals; and,

(4) Articles intended for use as a component of any articles specified in paragraph (C)(1), (C)(2), or (C)(3) of this rule, but does not include devices or their components, parts, or accessories.

(D) ~~–~~"Food safety hazard" means any biological, chemical, or physical property that may cause food to be unsafe for human consumption.

(E) "Hazard analysis critical control point" and its acronym "HACCP" mean a systematic approach to the identification of food safety hazards that are reasonably likely to occur in conjunction with the manufacture of frozen dessert and the measures necessary to prevent or correct the occurrence.

(F) "Hazard analysis critical control point plan" and "HACCP plan" mean a detailed written program implementing the HACCP findings.

(G) "Official Methods" means the "Official Methods of Analysis of the AOAC International (OMA)" 18th edition , Dr. William Horsitz, editor, published by AOAC International, Suite 500, 481 North Frederick Ave., Gaithersburg, Maryland 20877-2417 USA.

(H) "PMO" means the grade "A" pasteurized milk ordinance as adopted in rules 901:11-1-01 to 901:11-1-05 of the Administrative Code.

(I) "Reasonably likely to occur" when used in conjunction with ~~"~~food safety hazard~~"~~ means a food safety hazard which a prudent frozen dessert manufacturer would foresee as having an appreciable risk of happening unless appropriate measures are taken.

(J) "Standard Methods" means the "Standard Methods for the Examination of Dairy Products (SMEDP)", 17th edition 2004, edited by H. Michael Wehr, PhD and Joseph F. Frank, PhD, American Public Health Association, 800 I Street, N.W., Washington, DC 02001.

DRAFT - NOT FOR FILING

901:11-3-02 Standard of identity.

Frozen dessert means those articles of food denominated in 21 C.F.R. 135 Subpart B (April 2014) and shall conform to the descriptions contained therein.

901:11-3-03 Frozen dessert labeling.

(A) When a frozen dessert is made from ~~goat~~ the milk of an animal other than a cow, the animal species~~word "goat"~~ shall precede or follow the name of the product on the label.

(B) Retail packaged frozen desserts shall be legibly labeled in accordance with the applicable requirements of the Federal Food Drug and Cosmetic Act (FFD&CA), the Nutrition Labeling and Education Act (NLEA) of 1990, regulations developed there under, and with:

(1) The name of the product;

(2) The net weight;

(3) The name and address of the manufacturer or the federal information processing standards (FIPS) number; and,

(4) Any other identification that may be required by the director.

(C) All commercial bulk packages of frozen desserts ~~manufactured under the provisions of rules 901:11-3-01 to 901:11-3-11 of the Administrative Code~~ shall be adequately and legibly marked with:

(1) The name of the product;

(2) The net weight;

(3) The production code or date of manufacture, lot number;

(4) The name and address of the manufacturer or the federal information processing standards (FIPS) number; and,

~~(4) The federal information processing standards (FIPS) number or the name and address of the manufacturer; and,~~

(5) Any other identification that may be required by the director.

901:11-3-04 Chemical, bacteriological, and temperature standards.

(A) Raw milk or milk products intended for use in the manufacturer of frozen desserts shall not be accepted by the frozen dessert manufacturer unless the milk and milk products meet the following standards at the time of delivery:

(1) Temperature. The milk and milk products must be received at forty-five degrees Fahrenheit (seven degrees Celsius) or less.

(2) Bacterial limits. The milk and milk products shall not exceed three-hundred thousand parts per milliliter.

The test for bacterial limits shall be tested in conjunction with the drug residue inhibitory substance test.

(3) Drugs. There shall be no positive results on drug residue detection methods analyzed at an officially designated laboratory using examinations in substantial compliance with the standard methods and the official methods.

(4) These standards shall be maintained by the frozen dessert manufacturer through pasteurization.

(B) Bulk loads of raw milk and milk products shall be pasteurized in accordance with rule 901:11-3-05 of the Administrative Code at the receiving plant prior to use in the manufacturing of finished products.

(C) Bulk loads of pasteurized milk or milk products shall be re-pasteurized in accordance with rule 901:11-3-05 of the Administrative Code at the receiving plant prior to use in the manufacturing of finished products.

(D) Frozen desserts made from pasteurized milk or milk products shall meet the following standards:

(1) Temperature. After pasteurization the milk and milk products shall be cooled to forty-five degrees Fahrenheit (seven degrees Celsius) or less.

(2) Bacterial limits. The milk and milk products shall not exceed three-hundred thousand parts per milliliter. The test for bacterial limits shall be tested in conjunction with the drug residue inhibitory substance test.

(3) Coliform. The milk and milk products shall not exceed ten parts per milliliter.

(4) Drugs. There shall be no positive results on drug residue detection methods analyzed at an officially designated laboratory using examinations in substantial compliance with the standard methods and the official methods.

(5) Phosphatase. The milk and milk products shall not exceed three hundred and fifty milliunits per liter using examinations in substantial compliance with the standard methods and the official methods.

901:11-3-05 Pasteurization.

(A) Frozen desserts shall be pasteurized by holding the mixture continuously at or above the following temperatures for not less than the corresponding time:

Temperature	Time
155 degrees F (69 degrees C).	30 minutes
175 degrees F (80 degrees C).	25 seconds
180 degrees F (83 degrees C).	15 seconds
191 degrees F (89 degrees C).	1.0 second
194 degrees F (90 degrees C).	0.5 second
201 degrees F (94 degrees C).	0.1 second
204 degrees F (96 degrees C).	0.05 second

212 degrees F (100 degrees C)~~.~~	0.01 second

The equipment used and the operation of the equipment shall comply with part II, section 7, ~~items 16p(A), 16p(B), 16p(D) and 16p(E)~~item 16p of the PMO~~.~~, as adopted in chapter 901:11-1~~rules 901:11-1-01 to 901:11-1-05~~ of the Administrative Code.

(B) All milk and milk products, eggs, egg products, cocoa, cocoa products, emulsifiers, stabilizers, vitamins, and liquid sweeteners shall be added to the frozen dessert before it is pasteurized~~. These ingredients,~~ except ~~for dairy products may be added after pasteurization only if~~in cases where:

(1) The processor demonstrates to the director's satisfaction that the addition of these ingredients prior to pasteurization will negatively impact the ability to produce the product or the quality of the product; and~~,~~

(2) Records are maintained to the director's satisfaction showing the science proving the ingredients which are added after pasteurization are safe and suitable; and

(3) The ingredients are safely and sanitarily added to the frozen dessert product.

(C) Flavoring and coloring ingredients may be added after pasteurization when:

(1) The ingredient has been subjected to a prior heat treatment sufficient to destroy pathogenic microorganisms; or,

(2) The ingredient has 0.85 per cent water activity (a_w of 0.85) or less when the water activity is calculated by dividing the water vapor pressure of the ingredient by the vapor pressure of pure water when at the same temperature as the ingredient; or

(3) The ingredient has a high acid content (pH level of 4.6 or below when measured at seventy-five degrees Fahrenheit (twenty-four degrees Celsius)) or high alkalinity (pH level greater than eleven when measured at seventy-five degrees Fahrenheit (twenty-four degrees Celsius)); or,

~~(4) The ingredients are roasted nuts, fruits and vegetables added at the freezer; or,~~

~~(5)~~ (4) There is an alcohol content in the ingredient sufficient to assure that pathogenic microorganisms will not be transferred to the final product; or,

~~(6)~~ (5) The ingredients consist of safe and suitable bacterial cultures; or enzymes; or,

~~(7)~~ (6) The ingredients are dry sugars and salts; or,

~~(8)~~ (7) The ingredients are subjected to any process acceptable to the director which will assure that the ingredient is free of pathogenic microorganisms.

(D) Frozen desserts may be pasteurized at a milk plant other than the milk plant where it is packaged for retail sale provided it is transported to the packaging milk plant in a tote using a single service liner which complies with the following specifications:

(1) Totes used to transport frozen dessert mix shall be:

(a) Constructed and managed to protect their contents from sun, freezing, and contamination;

(b) Constructed for ease of cleaning;

(c) Constructed of smooth, impervious, corrosion-resistant, nontoxic material;

(d) Kept in good repair;

(e) Kept clean; and,

(f) Constructed to be fully enclosed when in transport. Provided, totes of five gallon capacity or less are not required to be fully enclosed.

(2) The single service liner used to transport frozen dessert mix shall:

(a) Be fabricated from material complying with (2007) 21 C.F.R. parts 175 to 178;

(b) Be nontoxic;

(c) Be free from deleterious substances;

(d) Be free of coliform organisms; and,

(e) Have a residual bacteria count not to exceed fifty per container, when the rinse test is used, or not over fifty colonies per eight square inches (one per square centimeter) of product contact surface, when the swab test is used. Testing procedures shall be in substantial compliance with the standard methods as defined in rule 901:11-3-01 of the Administrative Code.

(3) No substance capable of contaminating the frozen dessert mix shall be transported with the product.

901:11-3-06 Hazard analysis and critical control point plan.

(A) Every frozen dessert manufacturer shall conduct, or have conducted for it, an analysis to determine whether there are food safety hazards that are reasonably likely to occur in conjunction with the manufacturing of frozen dessert and to identify the critical control points and preventive measures that apply to control those hazards. The analysis shall include food safety hazards which can occur both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after processing. The frozen dessert manufacturers shall submit their analysis to the director.

(B) If the analysis done under paragraph (A) of this rule discloses that no food safety hazards are reasonably likely to occur, the frozen dessert manufacturer shall comply with rules 901:11-2-19 to 901:11-2-22, 901:11-2-25, 901:11-2-27 to 901:11-2-29, 901:11-2-33, 901:11-2-39, 901:11-2-40, 901:11-2-43 to 901:11-2-44 and 901:11-3-01 to 901:11-3-05 of the Administrative Code and shall be inspected at least once in a twelve month period by the director.

(C) If the analysis completed under paragraph (A) of this rule discloses one or more food safety hazards are reasonably likely to occur the frozen dessert manufacturer shall create and implement a HACCP plan.

(1) The HACCP plan shall be specific to:

(a) Each location where frozen desserts are manufactured; and,

(b) Each kind of frozen dessert manufactured by the processor.

(2) The HACCP plan shall be dated and signed:

(a) List the food safety hazards that are reasonably likely to occur, as identified in accordance with paragraph (A) of this rule, and that thus must be controlled for each frozen dessert. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:

(i) Natural toxins;

(ii) Microbiological contamination;

(iii) Chemical contamination;

(iv) Pesticides;

(v) Drug residues;

(vi) Unapproved use of direct or indirect food or color additives; and,

(vii) Physical hazards.

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

(i) Critical control points designed to control food safety hazards that could be introduced in the processing plant environment; and,

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

(c) List the critical limits that must be met at each of the critical control points;

(d) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(e) Include any corrective action plans that have been developed in accordance with paragraph (B) of rule 901:11-3-07 of the Administrative Code;

(f) List the verification procedures, and frequency thereof, that the processor will use in accordance with paragraph (A) of rule 901:11-3-08 of the Administrative Code;

(g) Provide for a record keeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(D) Signing and dating the HACCP plan.

(1) The HACCP plan shall be signed and dated, either by the most responsible individual on-site at the frozen dessert processing facility or by a higher level official of the processor. This signature shall signify that the HACCP plan has been accepted for implementation by the firm.

(2) The HACCP plan shall be dated and signed:

(a) Upon initial acceptance;

(b) Upon any modification; and,

(c) Upon verification of the plan in accordance with paragraph (A)(1) of rule 901:11-3-08 of the Administrative Code.

(E) Every frozen dessert manufacturer required to create and implement a HACCP plan shall submit a copy of their HACCP plan to the director no later than three months after licensing.

(F) The director shall, within thirty days of receipt of the HACCP plan, either approve or disapprove the HACCP plan. The director shall disapprove the HACCP plan if it does not comply with the requirements of paragraphs (C) and (D) of this rule.

(G) If the director disapproves a HACCP plan he shall return the plan to the licensee with a statement of the changes necessary to bring the plan into compliance. The licensee shall have thirty days from its receipt of the plan to resubmit it to the director for reconsideration.

(H) The HACCP plan shall be implemented by the frozen dessert manufacturer within three months of notice of approval of the plan by the director. Prior to implementation of a HACCP plan, a frozen dessert manufacturer shall be inspected by the director and comply with the requirements listed in paragraph (B) of this rule.

(I) A licensed frozen dessert manufacturer shall be exempt from the requirements of this rule if he requests an exemption in writing and meets the criteria established in paragraphs (I)(1)(a) to (I)(1)(e) and (I)(2) of this rule.

(1) The frozen dessert manufacturer only manufactures frozen dessert mix for sale and no other frozen dessert and all of the following apply;

(a) The frozen dessert manufacturer holds a processor license with a category designation of grade A fluid milk processor, grade A cultured milk processor or grade A condensed milk products processor;

(b) The equipment and facility used to manufacture frozen dessert mix is routinely inspected by the director and used in the processing of grade "A" dairy products;

(c) The temperature requirements for pasteurization in rule 901:11-3-05 of the Administrative Code are met;

(d) The frozen dessert manufacturer maintains the frozen dessert mix in compliance with the requirements of rule 901:3-14-04 of the Administrative Code; and,

(e) The frozen dessert is manufactured in compliance with rules 901:11-3-01 to 901:11-3-05 of the Administrative Code.

(2) The frozen dessert manufacturer produces ten thousand gallons or less of frozen dessert annually.

(J) A frozen dessert manufacturer that meets the requirements of paragraphs (I)(1)(a) to (I)(1)(e) and (I) (2) of this rule shall be inspected at least once in a twelve month period by the director and shall comply with the requirements listed in paragraph (B) of this rule.

901:11-3-07 Corrective actions.

(A) Whenever a deviation from a critical limit occurs, a frozen dessert manufacturer shall take corrective action either by:

(1) Following a corrective action plan that is appropriate for the particular deviation; or,

(2) Following the procedures in paragraph (C) of this rule.

(B) A frozen dessert manufacturer may develop written corrective action plans, which become part of their HAACP plans in accordance with paragraph (C)(2)(e) of rule 901:11-3-06 of the Administrative Code, by which they 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.

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

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (C)(2) and (C)(3) of this rule 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 who is qualified in accordance with rule 901:11-3-11 of the Administrative Code;

(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 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.

(D) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with paragraph (A)(3)(b) of rule 901:11-3-08 of the Administrative Code and the recordkeeping requirements of rule 901:11-3-09 of the Administrative Code.

901:11-3-08 Verification.

(A) Every frozen dessert manufacturer shall 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. Verification shall include, at a minimum:

(1) A reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. Such changes may include changes in the following: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The HACCP plan shall be modified immediately whenever a reassessment reveals that

the plan is no longer adequate to fully meet the requirements of paragraph (C) of rule 901:11-3-06 of the Administrative Code.

(2) Ongoing verification activities including:

(a) A review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;

(b) The calibration of process-monitoring instruments; and,

(c) The performing of periodic end-product or in-process microbial testing.

(3) A review, including signing and dating, by a responsible individual 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 they document values that are within the critical limits. This review shall occur within one week 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 rule 901:11-3-07 of the Administrative Code. This review shall occur within one week of the day that the records are made; and

(c) The calibrating of any process control instruments used at critical control points and the performing of any periodic end-product or in-process testing that is part of the frozen dessert manufacturer'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 frozen dessert manufacturer's written procedures. These reviews shall occur within a reasonable time after the records are made.

(B) Frozen dessert manufacturers shall immediately follow the procedures in rule 901:11-3-07 of the Administrative Code whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.

(C) Whenever a frozen dessert manufacturer does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur, the frozen dessert manufacturer shall reassess the adequacy of that hazard analysis whenever there are any changes that could reasonably affect whether a food safety hazard now exists. Such changes may include, but are not limited to changes in: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product.

(D) The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing, in accordance with paragraphs (A)(2)(b) and (A)(2)(c) of this rule shall be documented in records that are subject to the recordkeeping requirements of rule 901:11-3-09 of the Administrative Code.

901:11-3-09 Records.

(A) Each frozen dessert manufacturer shall maintain sanitation control records that document the verification and corrections prescribed by rules 901:11-3-07 and 901:11-3-08 of the Administrative Code.

These records shall also include;

(1) The name and location of the processor;

(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 shall be entered on records at the time that it is observed.

(B) Record retention.

(1) All records required by this part shall be retained at the manufacture milk processing facility for at least one year after the date they were prepared.

(2) Records that relate to the general adequacy of equipment or processes being used by a frozen dessert manufacturer, including the results of scientific studies and evaluations, shall be retained at the processing facility for at least one year after their applicability to the product being produced at the facility.

(C) The records may be maintained on computers if appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

901:11-3-10 Sanitation control procedures.

(A) Each frozen dessert manufacturer shall have and implement a written sanitation standard operating procedure (SSOP) that is specific to each location where frozen desserts are processed. The processor shall correct in a timely manner, those conditions and practices that are not met. The SSOP shall detail the practices and procedures implemented to ensure sanitary conditions and practices are maintained in each of the following areas:

(1) Safety of the water that comes into contact with food or food contact surfaces, or 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 unsanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to pasteurized 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 milk processing facility.

(B) The SSOP shall be implemented at the same time as the HACCP plan.

901:11-3-11 Training.

(A) No person shall be qualified either through completion of a training course or through work experience to apply HACCP principles unless the person can establish to the satisfaction of the director of agriculture or his representative the ability to:

(1) Develop a HACCP plan or adapt a generic HACCP plan that meets the requirements of paragraph (B) of rule 901:11-3-06 of the Administrative Code;

(2) Determine, in accordance with rule 901:11-3-07 of the Administrative Code, when a deviation from a critical limit occurs, whether or not the HACCP plan needs to be modified to reduce the risk of reoccurrence of the deviation, and modifying the plan as necessary; and,

(3) Implement the requirements of rule 901:11-3-08 of the Administrative Code by:

(a) Verifying the adequacy of a HACCP plan;

(b) Reassessing the adequacy of a HACCP plan; and,

(c) Conducting a review of the records documenting a HACCP plan.

(B) A person may establish that they meet the requirements of paragraphs (A)(1) to (A)(3) of this rule by:

(1) Submitting evidence of the successful completion of a formal training course in HACCP principles; or,

(2) Submitting a resume of work experience and work product demonstrating their ability to perform the tasks listed in paragraphs (A)(1) to (A)(3) of this rule.