

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

- (1) For a currently licensed manufacturer; submit a copy of their HACCP plan to the director no later than one year and ninety days from the effective date of this rule; and,
- (2) For any manufacturer licensed after the effective date of this rule; submit a copy of their HACCP plan to the director no later than one year after licensing.
- (3) 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.
- (4) 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.
- (5) The HACCP plan shall be implemented by the frozen dessert manufacturer within six 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.

(F) 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 (F)(1)(a) to (F)(1)(e) and (F)(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.

(G) A frozen dessert manufacturer that meets the requirements of paragraphs (F)(1)(a) to (F)(1)(e) and (F)(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.

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