

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 HACCP plans in accordance with paragraph ~~(B)~~(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.

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Certification

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Date

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