



VIA FEDERAL EXPRESS

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

WARNING LETTER

FLA-01-27

January 29, 2001

I. Buddy Levine, President
Collins Fish & Seafood, Inc.
328 NE 70th Street
Miami, Florida 33138

Dear Mr. Levine:

We completed an inspection of your seafood processing plant at the above address on August 29, 2000 and found that you continue to have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your vacuum packaged fresh raw fish and scombrotoxin forming fish products such as tuna to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

If you choose to group kinds of fish and fishery products together in one plan it must comply with the criteria of 21 CFR 123.6(b)(2). However, your generic HACCP plan for refrigerated seafood (fish) products attempts to group products that have different hazards e.g. pathogens, histamine, ciguatera and aquaculture drugs. Where the food safety hazards, critical control points, critical limits, monitoring, verification and record keeping procedures are not identical, separate plans must be prepared.

You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). However, your generic HACCP plan for refrigerated seafood (fish) products does not list the critical control points of raw material and finished product storage to control the food safety hazards of:

- 1) *Clostridium botulinum* toxin formation in vacuum packaged product; and
- 2) Histamine in scombrotoxin-forming fish species such as tuna.

These two hazards may not be common to the same kinds of fish or fishery products and may need to be identified in separate HACCP plans.

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You must have a HACCP plan that lists the critical limits that must be met, in order to comply with 21 CFR 123.6(c)(3). However, your generic HACCP plan for refrigerated seafood (fish) products lists:

- 1) A critical limit of "fish to be received NMT 40 degrees Fahrenheit" at the receiving critical control point that is not adequate to control *Clostridium botulinum* toxin formation ("pathogen growth") in vacuum packaged raw fresh fish.

An appropriate critical limit for this hazard at receiving is a valid time/temperature integrator inserted by the supplier into each vacuum package that indicates that the product never exceeded 38° F throughout transit.

Packaging conditions that exclude oxygen favor the growth of facultative and anaerobic microorganisms, of particular concern is *Clostridium botulinum*. Uncontrolled temperatures could result in growth and toxin formation by the pathogen. This potential food safety hazard is reasonably likely to occur in your raw, non-preserved fish products in vacuum packages. To prevent this hazard from occurring, assurances must be made that the temperature of the raw, vacuum packaged fish is maintained at 38° F or below throughout transport from your supplier to your facility and during the entire period that the product is under your control and remains in the barrier package.

Adjustments to your Plan's monitoring procedures, corrective actions and record keeping procedures would be necessary to reflect corrections to this critical limit.

- 2) A critical limit of a "suppliers certificate" at the receiving critical control point that is not adequate to control histamine formation in scombrotoxin-forming fish species such as tuna. An appropriate critical limit for this hazard at receiving is:
 - a) All lots received are accompanied by transportation records that show that the fish were held at or below 40° F throughout transit; or
 - b) There is an adequate quantity of ice or other cooling media to completely surround the product at the time of delivery.

Adjustments to your Plan's monitoring procedures, corrective actions and record keeping procedures would be necessary to reflect corrections to this critical limit.

- 3) A critical limit that "no histamine producing species will exceed 40 degrees Fahrenheit for more than four hours cumulatively" at the cutting/packing critical control point that is not adequate to control histamine formation in scombrotoxin-forming fish species such as tuna.

The limit is not specific to a portion of the fish. Very large chilled fish may maintain a low backbone temperature for significant periods of time while exterior portions of the fish can become quite warm. Hence, histamine-forming bacteria may remain active on portions of the fish closer to the surface of the fish while internal temperatures of the fish may suggest that the appropriate temperatures were maintained. An appropriate critical limit is that the fish are not to be exposed to **ambient** temperatures above 40° F (4.4° C) for more than 4 hours, cumulatively, if any portion of that time is at temperatures above 70° F (21° C), or the fish are not to be exposed to **ambient** temperatures above 40° F (4.4° C) for more than 8 hours, cumulatively, as long as no portion of that time is above 70° F (21° C).

Alternatively, provided your firm does all of the butchering within the same cooler as that used for storing raw and finished product, appropriate CCPs are established for product storage, and the cooler is continuously monitored at 40° F or below, it may not be reasonably likely for the histamine hazard to occur during your cutting operation. A CCP to control histamine formation at the cutting step would not be necessary in such a case. However, since your product is removed from the cooler for packaging, the packing CCP would still be needed to control the histamine hazard unless product flow is controlled in such a manner as to assure that product exposure outside of the cooler is very brief and product delays or backups do not occur.

You must have a HACCP plan that lists the critical limits that must be met to comply with 21 CFR 123.6(c)(3). However, your firm's generic HACCP plan for refrigerated seafood (fish) products does not list a critical limit at the packing critical control point to control the hazard of *Clostridium botulinum* toxin formation.

Because your firm packages and distributes raw, refrigerated, fresh fish and fishery products in vacuum packaged bags, you need to provide assurances that the recipients of the fish can identify if the product had been temperature abused. Time/temperature integrators should be incorporated into each bag to identify

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product exposures to temperatures above 38° F. Instructions on interpreting the integrator results should be included on the package labeling or on the integrators themselves.

Alternatively, you could distribute the product in a frozen state, including labeling instructions that the product is to be held frozen and is to be thawed under refrigeration immediately before use (e.g., 'Important, keep frozen until used, thaw under refrigeration'); or use an oxygen permeable packaging instead of vacuum packaging.

You must have a HACCP plan that list monitoring procedures for each critical control point, in order to comply with 21 CFR 123.6(c)(4). However, your generic HACCP plan for refrigerated seafood (fish) products lists a monitoring procedure to "monitor production time for histamine producing species" from "each lot" using a "thermometer" that is not adequate to control histamine formation in scombrototoxin-forming fish.

Time is not measured with a thermometer. The exposure of concern is both time and temperature and both must be monitored. The length of time the fish are exposed to non-refrigerated conditions (i.e., above 40° F (4.4° C) and above 70° F (21° C); see the recommended critical limits above) and the ambient temperatures during the exposure period should be monitored. This can be accomplished by making visual observations of time and by use of a dial or digital thermometer to determine ambient air temperature in the processing area at least every two hours. The "lot" measured during processing need not be, and would likely not be the same intact lot as that at receiving. A more specific description of the processed lot may need to be provided if it differs from the original lot received.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your seafood products and/or enjoin your firm from operating.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your firm operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice (GMP) regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

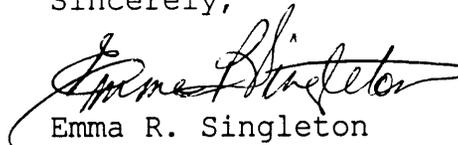
Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to

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include in your response documentation such as copies of your HACCP plans, monitoring records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Jimmy E. Walthall, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Walthall at (407) 475-4731.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton". The signature is fluid and cursive, with a large initial "E" and "S".

Emma R. Singleton
Director, Florida District