

Mr. Juan Ballarin Pons
President
Pesquera Torres del Paine S.A.
Km. 8 Norte s/n
Punta Arenas, Chile

AUG 28 2003

Warning Letter

Dear Mr. Ballarin Pons:

On November 11-12, 2002 we inspected your seafood processing facility, located at Km. 8 Norte s/n, Punta Arenas, Chile. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) Regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section, or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). Accordingly your frozen block centollon crabmeat is adulterated, in that the product has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You may find the Act and the Seafood HACCP Regulations through links in FDA's home page at www.fda.gov.

In response to the observations listed in the form FDA-483, Mr. José Miguel Burgos, Head of Fisheries Health Department, SERNAPESCA, provided us with a copy of your document entitled [REDACTED]. We note that critical control points for cooking and meat storage were added to your HACCP plan.

Upon further evaluation of the documentation provided to us from the inspection and the subsequent response to the deviations, we find the following deviations concerning the HACCP plan for the Frozen Crab Lines:

- You must have a HACCP plan that at a minimum lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for frozen crab lines does not list the monitoring frequency at the Cooking and Chilling critical control point that is adequate to control pathogen growth and toxin formation. Specifically, your firm monitors the cooking times and chilling temperature every [REDACTED] for processing [REDACTED] crabmeat. In addition to monitoring the [REDACTED], FDA recommends monitoring and documenting the cooking temperature continuously (e.g., temperature monitoring instrument) with a visual check of the monitoring instrument at least once per day or whenever the cooking temperature is adjusted. In addition, we recommend visual check of the conveyor belt speed whenever it is adjusted.

Moreover, the monitoring frequencies for the Storage (Meats) and Meat Storage critical control points are inadequate. Specifically, your firm monitors the storage temperatures [REDACTED]

[REDACTED] during the work shift. FDA recommends monitoring and documenting the cold storage temperature continuously (e.g., temperature monitoring instrument) with a visual check of the monitoring instrument at least once per day or whenever temperature of the cold storage room is adjusted

Please refer to the Fish and Fisheries Products Hazards and Controls Guidance: Third Edition, Chapter 12 (Pathogen Growth/Toxin Formation) and Chapter 16 (Pathogen Survival Through Cooking), found at www.cfsan.fda.gov/~comm/haccp4.html for specific guidance.

- You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.(6)(3). A critical limit is defined in 21 CFR 123.3(c) as “the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.” However, your firm’s HACCP plan for Frozen Crab Lines lists a critical limit of a storage temperature of [REDACTED] at the meat storage critical control point that is not adequate to control pathogen growth and toxin formation. FDA recommends maintenance of 4.4°C (40°F). For more specific information please refer to the Fish and Fisheries Products Hazards & Controls Guidance: Third Edition, Chapter 12 (Pathogen Growth/Toxin Formation).

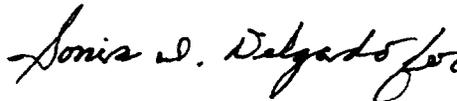
Please respond in writing within six (6) weeks from receipt of this letter. Your response should outline the specific thing you are doing to correct these deviations. You should include in your response documentation such as a copy of your revised HACCP plan reflecting the changes you made, 5 consecutive working days of records after the changes to the HACCP plan are made and other useful information that will assist us in evaluating your corrections. If you cannot complete the correction before you respond, we expect that you will explain the reason for your delay and state when you will correct this deviation.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP Regulations and the Good Manufacturing Practices regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Failure to respond adequately will result in your firm being placed on Detention Without Physical Examination.

Please send your reply to Food and Drug Administration, Attention: Giselle Jordan, Consumer Safety Officer, Office of Compliance, Division of Enforcement, Import Branch HFS-606, 5100 Paint Branch Parkway, College Park, MD 20740 U.S.A. If you have questions regarding any issue in this letter, you may contact Ms. Jordan at (301) 436-1576 or at her e-mail address gjordan@cfsan.fda.gov.

Sincerely,



Judith A. Gushee
Director
Division of Enforcement
Office of Compliance
Center for Food Safety
and Applied Nutrition