

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER Center for Food Safety and Applied Nutrition, Office of Compliance, Division of Enforcement, FDA 5100 Paint Branch Parkway, College Park, MD 20740 Phone: (301) 436-2361 Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>	DATE(S) OF INSPECTION April 19 - 24, 2012 <hr/> FEI NUMBER 3006530291
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
**TO:** Mr. Dominic Sebastian, Managing Director

FIRM NAME Moon Fishery (India) Pvt. Ltd	STREET ADDRESS 11/722/D, Chemical Industrial Estate
CITY, STATE AND ZIP CODE Aroor, Alleppy 688534 Kerala India	TYPE OF ESTABLISHMENT INSPECTED Food Manufacturer

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:  
 Observation # 1

Your HACCP plan does not list one or more critical control points that are necessary for each of the identified food safety hazards.

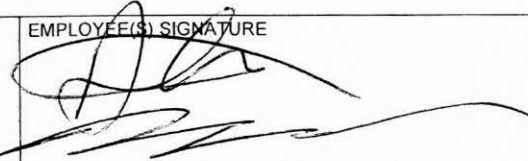
Specifically, your HACCP plan for raw tuna does not list critical control points at the following process step to control the hazards of Clostridium Botulinum, histamine and allergens.

A- There is no Critical Control Point listed on your HACCP plan for the processing steps of cutting, scraping, and vacuum packaging performed in your processing room, kept at a temperature of [REDACTED] s C, to control the hazard of pathogen growth and histamine formation.

B- There is no Critical Control Point listed on your HACCP plan for C. botulinum and allergen labeling applied to the primary packaging.

C- There is no Critical Control Point listed on your HACCP plan for metal detection.

D- In your HACCP plan for receiving tuna, the only critical limit listed is temperature, with no critical limit listed for vessel monitoring and histamine testing records to show that tuna was not temperature abused on the harvesting vessel.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Dipesh Shah, Investigator Michael Charles, Investigator	DATE ISSUED 04/24/2012
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Observation # 2

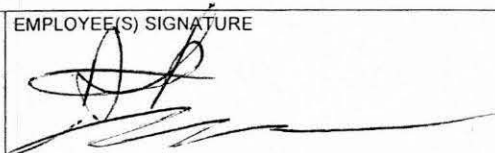
You are not monitoring the sanitation conditions and practices with sufficient frequency to assure conformance with Current Good Manufacturing Practices including safety of water that comes into contact with food or food contact surfaces, including water used to manufacture ice, condition and cleanliness of food contact surfaces, maintenance of hand washing, hand sanitizing, and toilet facilities, and protection of food, food packaging material, and food contact surfaces from adulteration.

A- You are not monitoring the safety of water as evidenced by:

1- Tanks used for storage of process waters have apparent visible debris, filth, and microbiological contamination. Sand and activated carbon filter units used in manufacturing of water are not sanitized, and ventilation for tanks is not filtered to protect against contamination. There is no laboratory analysis for water used in ice manufacturing at the (b) (4) facility to show the water used to make ice is potable. Ice manufacturing lacks sanitary controls: ice manufacturing equipment at the Moon Fishery facility is located outside and is susceptible to adulteration from pests and the environment. Apparent bird feces were observed on the ice manufacturing equipment at Moon Fishery; insects and filth were observed in and on the equipment. Ice manufacturing equipment at your (b) (4) facility is rusty and situated so that the ice can not be protected against adulteration, as the ice manufacturing process is constructed into the flooring of the ice facility. Tuna processed at your facility, which is consumed raw or cooked, comes in direct contact with water and ice.

B- You are not monitoring the condition or cleanliness of food contact surfaces as evidenced by:

- 1-Some of the floor and wall tiles in the tuna processing area are broken and cracked, not allowing for proper cleaning.
- 2- After cleaning, the ceiling directly above the in-process tuna line was observed to have visible product residue.

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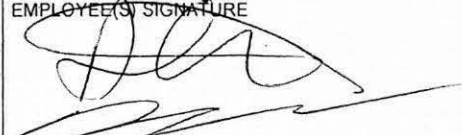
3- After cleaning, product residues and rust were observed on knives and utensil storage boxes. These knives are used to cut raw tuna.

C- You are not monitoring protection from adulterants as evidenced by:

1-Peeling paint was observed directly above the in-process tuna line.

D- You are not monitoring hand washing, hand sanitizing and toilet facilities as evidenced by:

1-There were no hand drying devices available in the employee rest rooms on the first floor.

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