Directions Governing Management of Fishery Products Exported to the European Union

[Chronicle of Promulgation and Amendments]

Adopted and promulgated by the Bureau of Standards, Metrology and Inspection, Ministry of Economics Affairs on 23 April 2007; effective on 1 May 2007.

Amended and promulgated by the Bureau of Standards, Metrology and Inspection, Ministry of Economics Affairs on 8 July, 2008; effective on amended date.

Chapter I Goal and Scope

1. The Bureau of Standards, Metrology and Inspection of the Ministry of Economic Affairs (hereinafter referred to as the authority) establishes these Directions to ensure that fishery products exported to the EU comply with EU regulations and health requirements.

2. The scope of these Directions includes the inspection and management of production establishments, the hygiene management of fishery products and the issuance of health certificates.

   An establishment of processing fishery products (hereinafter referred to as the establishment) must first obtain the authority's approval, be registered with the EU, and have their products undergo testing for compliance with health and safety requirements of the EU regulations before it may apply for the issuance of health certificates that permit it to export fishery products to the EU.

Chapter II The Management of Establishments

3. An establishment must meet the following requirements before it may apply to be registered as an establishment exporting fishery products to the EU:

   (1) It shall be a legally established food processing plant.

   (2) It shall assign one person to assume the responsibility of a managerial representative of an EU-registered establishment. The managerial representative must receive at least thirty hours of training on the EU's requirements pertaining to fishery products and receive at least twelve hours of re-training every three years.

   (3) It shall establish a self-management system in compliance with relevant EU regulations.

   An establishment may also apply for certification on Hazard Analysis and Critical Control Point (HACCP) in fishery products at the same time when it submits the above application.

4. An establishment that applies for registration as an establishment exporting fishery products to the EU is required to submit its application to the authority or its branches (hereinafter referred to as the inspection authority) with the following documents attached:

   (1) A completed Application Form for Registration as an Establishment Exporting Fishery Products to the EU and General Information.

   (2) Copies of documents demonstrating that it is a legal entity.

   (3) Copies of documents demonstrating that its designated managerial representative has received training on EU regulations relating to fishery products.

   (4) The copy of its hygiene management manual for fishery products, in compliance with the EU requirements.

5. An establishment that applies for registration as an establishment exporting fishery products to the EU shall undergo documentary review and on-site inspection before it is registered as such.

6. The inspection authority may reject the application if any of the following situations occurs:

   (1) The establishment does not take corrective actions within 15 days of being notified that its documents do not conform to the requirements of Item 4 of these Directions.

   (2) The establishment is not able to cooperate with the on-site inspection arrangement within six months after submission of its application. However, an establishment may apply for a single extension of the period to no more than six months if it has a reasonable explanation.

7. The inspection authority shall arrange for an on-site inspection after the establishment passes the documentary review. The scope of the inspection shall include all stages of production, processing and transportation of fishery products. An establishment that the inspection finds in compliance with relevant EU requirements shall be approved by the authority for registration as an establishment exporting fishery products to the EU.

8. The establishment that the inspection finds not in compliance with relevant EU requirements may apply to the inspection authority for re-inspection within two months of receiving notification of non-compliance. The application for re-inspection is limited to one time and the re-inspection shall be conducted within six months

from the date of application. The application for re-inspection shall be rejected if the establishment is not able to cooperate with the re-inspection arrangement by that deadline. The establishment may apply for a single extension of the deadline of re-inspection to no more than six months, if it has a reasonable explanation.

9. The establishment that the inspection finds not in compliance with relevant EU requirements may re-apply for registration two months after receiving notification that its application for re-inspection is rejected.

10. The inspection authority shall conduct surveillance inspections and product sampling on the establishments that have approved for registration (hereinafter referred to as the registered establishment). The frequency of surveillance shall be adjusted depending on the risk to public and animal health, the type of processing, the establishments' record of violations and the trustworthiness of the establishments' self-management.

11. The establishment of which the surveillance inspection discovers non-compliance with EU regulations shall submit a plan for correction within one month after receiving the notification. The inspection authority may, depending on the severity of the situation, enhance its product inspections within the correction period or temporarily suspend acceptance of the establishment's applications for health certificates required for exporting to the EU. The correction period is limited to one year, and after the correction period expires, a follow-up inspection shall be conducted. The original management method of the establishment will become applicable again only after determination of its compliance.

12. Where there are changes to the content of the "Application Form for Registration as an Establishment Exporting Fishery Products to the EU & General Information," a registered establishment shall apply to the inspection authority for approval of such changes with relevant documents attached. The inspection authority may conduct a follow-up inspection to verify the changes and approve them if they are in compliance with Taiwan and EU requirements. Processing of non-complied changes shall be done in accordance with the provisions of Item 11 of these Directions.

13. Registered establishments that suspend production or business for more than one month shall notify the authority within one month of the suspension.

    The period of suspension mentioned in the preceding paragraph shall not exceed six months, unless a reasonable explanation is provided as to why production or business is unable to resume within the reported period. A registered establishment

may apply in advance for a single extension of the suspension period for a period of no longer than six months.

14. The registration status of an establishment becomes immediately invalid when it relocates its plant. In that case, the registered establishment shall take the initiative to notify the inspection authority of its inventory so as to be eligible for applying for Health Certificate for exporting its products produced during the period of validity of the original registration to the EU.

    The above-mentioned invalid establishment, continues to use the same registration number, shall make a new application for registration within six months from the day of relocation according to Item 4 of these Directions. However, if the establishment is not able to cooperate with the on-site inspection arrangement within six months after submission of its application, it may apply for a single extension of the period to no more than six months with a reasonable explanation.

15. The authority shall revoke registration that was acquired through fraudulent means and shall submit the matter to judicial agencies for investigation if it involves criminal responsibility.

16. Registration shall be rescinded under any of the following circumstances:

    (1) If a registered establishment applies for cancellation of registration.

    (2) If the establishment is found not in compliance with the EU requirements during the surveillance inspections and does not complete its corrective actions before the deadline or is not able to guarantee compliance of its products with the requirements in the future.

    (3) If a registered establishment fails to make payments in accordance with related requirements and does not pay within 15 days after receiving a notice to make the overdue payments.

    (4) If a registered establishment fails to report to the authority about its suspension of production or business, and fails to resume production or make the report within 15 days after receiving a notice from the authority.

    (5) If a registered establishment fails to make arrangements to facilitate the conduction of surveillance inspections and the processing of appeals, complaints or disputes, and still does not cooperate after receiving a notice from the authority.

17. If the registration of an establishment has been revoked or rescinded, it may re-apply for registration four months after the revocation or rescission. The

establishment shall be given a new registration number after it passes the inspection.

Chapter III Hygiene Management of Fishery Products and Issuance of Health Certificates

18. A registered establishment shall verify that the production and processing of its fishery products comply with related EU regulations with respect to the following items, for which it shall also retain records:

(1) Origin of the raw material: The origin of fishery products entering the plant as raw materials shall be confirmed those were obtained from approved establishments.

(2) Organoleptic examinations: Random organoleptic checks shall be conducted at all stages of production and transportation to verify freshness of fishery products.

(3) Freshness indicators: When an organoleptic examination reveals any doubt as to the freshness of fishery products, samples may be taken and sent to the inspection authority to test the levels of total volatile basic nitrogen (TVB-N) and trimethylamine nitrogen (TMA-N).

(4) Histamine: When necessary, random samples shall be taken to verify that the histamine level does not exceed the permitted levels set by the EU regulation.

(5) Residues and Contaminants: Compliance with the EU regulations is to be ensured.

(6) Microbes: When necessary, monitoring of microbiological levels is to be conducted in accordance with relevant regulations to ensure compliance with those criteria.

(7) Parasites: Random samples shall be taken and tested for parasites to ensure compliance with the EU requirements.

(8) Poisonous fishery products: Checks shall be made to ensure that toxic fishery product varieties of families *Tetraodontidae*, *Molidae*, *Diodontidae* and *Canthigasteridae*, as well as fishery product varieties containing ciguatera or other toxins dangerous to human health do not enter the market. However, fishery products derived from bivalve mollusks, echinoderms, tunicates and marine gastropods are not subject to this restriction if their marine biotoxins in

total quantities are comply with the standards set by point 2 of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004.

19. When a registered establishment uses imported fishery products for further processing in order to export them to the EU, it shall prepare the following documents and pay for the due for testing goods or other technical service measures, then apply for the inspection of "Imported Raw Materials for Fishery Products Exporting to the EU" to the inspection authority before they process the products. Documents required include:

    (1) Application form for inspection for imported raw materials.

    (2) Original Health Certificate issued by the government of the exporting country demonstrating compliance of the imported fishery products with EU requirements.

    (3) Copy of the Import Permit.

    (4) The marketing records of imported fishery product.

20. A registered establishment shall apply to the inspection authority for the issuance of Health Certificates in EU format with specified language in accordance with the "Regulations Governing Contracted Inspection of Commodities" prior to exporting its fishery products to the EU and provide the following documents:

    (1) the marketing records of fishery product ; application form for inspection for imported raw materials while using imported raw materials.

    (2) the establishment's self-management records.

    The Animal Health Certificate issued by the Bureau of Animal and Plant Health Inspection and Quarantine of the Council of Agriculture, Executive Yuan for the aquaculture products shall be attached to the application, if the section of Part II.2 of health certificate needs to be shown as attestation.

21. After acceptance of the application, the inspection authority shall verify that the origin of the raw materials, and the production process and hygiene management of the establishment comply with EU regulations. When necessary, the inspection authority shall dispatch inspectors to the site to take samples for testing. The Health Certificate shall be issued when the tests verify compliance.

22. A registered establishment shall not be issued a Health Certificate if any of the following situations occurs:

(1) If the product contents, quantity, package labeling, quality or other items does not comply with the EU regulations. Under the circumstances, a contracted testing report, instead of a Health Certificate, shall be issued. If the product does not comply with Taiwan's health standards for food, the health agencies shall be notified for follow-up actions.

(2) If the registration of an establishment is revoked, rescinded or no longer valid, the authority shall immediately stop issuing Health Certificates to this establishment.