



Republic of the Philippines
Department of Agriculture
Elliptical Road, Diliman, Quezon City

FISHERIES ADMINISTRATIVE)
ORDER NO. 234 :
Series of 2010)

SUBJECT: ACCREDITATION OF MARINE BIOTOXIN TESTING CENTERS

In line with Articles 6 and 17 of RA 7394, this order for the accreditation of marine biotoxin testing laboratories for monitoring and regulatory purposes is hereby issued pursuant to Section 67 (1 & 2) of the IRR for RA 8550 for guidance of all concerned.

Section 1. The term “accreditation “ as used in this order shall be construed as the official recognition of satellite laboratories in analyzing marine biotoxins and identifying toxic phytoplankton and other microalgae species.

Section 2. Scope and coverage. – The laboratory of the Marine Biotoxin Monitoring Section, FRMD of the BFAR shall be the Central Laboratory, while other satellite shall be those of Fisheries Regional Offices and of the local government units duly accredited which shall monitor the incidence of marine biotoxins in their jurisdictional areas subject to verification by the Central Laboratory.

Section 3. Accreditation panel. – An accreditation panel shall be created and presided by the Chief of FRMD with the Marine Biotoxin Section Chief and three other members, which shall determine the competence and capability of the laboratories applying for accreditation and recommend the same to the BFAR Director whether for approval or otherwise.

Section 4. Evaluation. – Application for accreditation shall undergo the preliminary assessment and on-site evaluation.

- a. Preliminary assessment shall require submission to the panel of the following documents:
- 1) Application form embodying the letter of intent addressed to the BFAR Director;
 - 2) Analysis reports for the preceding three (3) months for independent analysis by the Central Laboratory; and
 - 3) Certified true copy of applicant laboratory’s Manuals.
- b. On-site evaluation of the laboratory shall be conducted based on the documents submitted and its compliance to the protocols.

Section 5. Levels of accreditation. – Depending on the capability of the applicant laboratory, accreditation shall be on the following levels:

- a. Level I – Capable of microscopic analysis of PSP causative organisms

Requirement: Ability to identify and quantify the following organisms;

Paralytic Shellfish Poison

Pyrodinium bahamense variety compressum

Alexandrium tamiyavanichii

Alexandrium minutum

Gymnodinium catenatum

Diarrhetic Shellfish Poison

Dinophysis caudata

Dinophysis fortii

Dinophysis miles

Dinophysis rotundata

Prorocentrum concavum

Prorocentrum lima

Amnesic Shellfish Poison

Pseudonitzschia spp.

Nitzschia spp.

Ciguatera Fish Poison
Gambierdiscus toxicus
Microalgae associated with Fish Kills
Chatonella marina
Cochlodinium polydrikoides
Gonyaulax polygramma
Gymnodinium sanguineum
Gyrodinium galatheanum
Heterosigma akashiwo
Noctiluca scintillans
Prorocentrum micans
Prorocentrum minimum

Level II - Full level accreditation is for the capability to analyze PSP, TTX and CFP but shall be further categorized depending on present capacity of the laboratory

Level II-A - Capable of PSP and TTX analysis by mouse assay

Requirements:

- Level I accreditation
- Test kits readily in the laboratory

Level III - Full level accreditation is for the capability to analyze DSP and ASP (domoic acid) but shall be further categorized depending on present capacity of the laboratory

Level III-A- Capable of ASP analysis commercially available assay methods

Requirements:

- Levels I and II accreditation
- Availability of required test kit/materials if employing assay method other than bioassay

Level III-B- Capable of DSP analysis by mouse assay or commercially available assay methods

Requirements:

- Levels I and II accreditation
- Availability of required test kit/materials if employing assay method other than bioassay

Level IV - Capable of analyzing PSP, ASP, DSP, TTX & CFP

Requirements:

- Levels I and II accreditation
- Capable of ASP analysis by High Performance Liquid Chromatography
- Availability of required test kit/materials if employing assay method other than bioassay

Laboratories may apply for accreditation upgrading upon meeting the requirements.

Section 6. Benefits of accredited marine biotoxin testing laboratories

a. The analysis result of an accredited biotoxin laboratory shall be recognized and accepted at the national level which shall be the basis for issuance of appropriate shellfish bulletins and advisories.

b. The personnel of accredited marine biotoxin testing laboratories shall have access to advanced training by BFAR.

c. Laboratories applying for accreditation shall be provided with the initial set of breeders, a supply of test mice and the saxitoxin standard needed for the required mouse calibration.

d. Laboratories applying for accreditation shall be provided with the basic reagents needed for their analysis.

e. An accredited marine biotoxin testing center in any given locality will increase the confidence of the local community with regards to its food safety.

Section 7. Duties and responsibilities of an accredited marine biotoxin testing center.

- a. To conform with established monitoring protocols. Conformance shall be checked through the following documents to be furnished by BFAR.
 - 1) Weekly analysis results if the area within the jurisdiction of the subject center has been placed under shellfish advisory.
 - 2) Monthly analysis results if the area under the jurisdiction of the center is free from toxic red tide.
- b. Calibration of mice within the specified time period.
- c. Shall be subject to periodic audit by accreditation panel.

Section 8. Terms of accreditation. –

- a. First time accreditation shall have a validity of two (2) years only from date of issuance to the end of the second calendar year.
- b. Extended validity of accreditation may be granted with consistent conformity to established protocols.
- c. Upon expiry of accreditation, renewal shall follow the same procedure in Section 4 hereof.
- d. Mouse calibration is waived for the first accreditation but shall be mandatory to be performed within the first year. Failure on this aspect shall automatically result to non-renewal of accreditation.
- e. Accreditation shall be subject to revocation for non-compliance with the terms thereof.
- f. Guidelines for monitoring processes and analytical methods shall be provided the accredited laboratories.
- g. Periodic review of guidelines and analytical methods shall be regularly conducted by the Central Laboratory.

Section 9. Effectivity. – This Order shall take effect fifteen (15) days after its publication in the Official Gazette and/or in two (2) newspapers of general circulation and fifteen (15) days after registration with the office of the National Administrative Register.

ISSUED this 28th day of April 2010 at Quezon City, Metropolitan Manila, Philippines.

(SIGNED)

ATTY. BERNIE G. FONDEVILLA
Secretary

Recommended by:

(SIGNED)

MALCOLM I. SARMIENTO, JR.
Director
Bureau of Fisheries & Aquatic Resources

(SIGNED)

SALVADOR S. SALACUP
OIC, Undersecretary for Fisheries and Livestock
Chairman, NFARMC