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The Gazette of the Democratic Socialist Republic of Sri Lanka

EXTRAORDINARY

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PART I : SECTION (I) — GENERAL

Government Notifications

L.D.B. 4/96 II.

FISHERIES AND AQUATIC RESOURCES ACT, No. 2 OF 1996

REGULATIONS made by the Minister of Fisheries and Ocean Resources under paragraph (*q*) of Sub-section (1) of Section 61 of the Fisheries and Aquatic Resources Act, No. 2 of 1996.

MAHINDA WIJESEKARA,
Minister of Fisheries and Ocean Resources.

Colombo,
21st May, 2002.

Regulations

1. These regulations may be cited as Aquaculture (Monitoring of Residues) Regulations, 2002.

2. All enterprises and establishments processing aquaculture products shall be monitored in accordance with the provisions of these regulations, for the purpose of detecting the presence of the residues of substances specified in Schedule I to these regulations.

3. It shall be the responsibility of the Competent Authority to :

(*a*) Draw up a national residue monitoring plan to enable him to carry out inspections required to be carried out under these regulations and

(*b*) Collect periodically all relevant data necessary to evaluate the resources used and the results obtained in carrying out the measures provided for in these regulations.

4. The national residue monitoring plan referred to in paragraph (*a*) of Regulation 3, shall set out the :

(*a*) National measures to be implemented for the detection of the residues of substances specified in Schedule I to these regulations ;

(*b*) Sampling rules and sampling levels and frequencies to be adopted for the detection of the residues of substances specified in Schedule I to these regulations based on the requirements specified in Schedule II and Schedule III to these regulations ;

(*c*) National tolerances for authorized substances ;

(*d*) List of approved laboratories. with details of their capacities for processing official samples ;

(*e*) List of substances to be detected, methods for their analysis, standards for interpreting the findings and the number of official samples to be taken, giving reasons for selecting such number ;

(*f*) Number of official samples needed to be taken in relation to the number of fish of a particular species concerned, produced or slaughtered in preceding years, in accordance with the sample levels and frequencies specified in Schedule III ;

(*g*) Details of rules governing the collection of official samples, including rules concerning the particulars that should appear on such official samples ; and

(*h*) Type of measures to be adopted with regard to fish products in which residues have been detected.

5. All enterprises and establishments shall be required to abide by and comply with the plan drawn up and made available to such enterprise or establishment by the Competent Authority.

6. Every licensee of an enterprise or establishment shall take all necessary measures to carry out its own checks in order to ensure that :—

(*a*) It accepts (whether by direct delivery or delivery through an intermediary) only fish, for which the supplier is able to guarantee that the appropriate withdrawal periods as determined by the Competent Authority, have been observed ; and

(*b*) Fish brought for processing purpose :—

(i) Does not contain residue levels which exceed the maximum permitted limits;

(ii) Does not contain traces of any unauthorized substances ; and

(iii) Have not been administered with any illegal treatment.

7. Where any fish or fish product is intended to be exported by a licensee of any enterprise or any establishment such licensee shall export only :

(*a*) Fish to which no unauthorized substances have been administered or which have not undergone any illegal treatment ; and

(*b*) Fish in respect of which where authorized substances have been administered. The appropriate withdrawal periods as determined by the Competent Authority for such substances have been observed.

8. Where any fish are being provided for, processing purposes to an establishment by any person ; other than a licensee of any enterprise. The provisions of these regulations pertaining to requirements imposed on any enterprise, shall also be applicable in respect of that person.

9. (1) Inspectors entrusted with the responsibility of monitoring enterprises shall —

(*a*) Monitor the breeding and rearing conditions and forms of treatments referred to in these regulations being adopted within such enterprises ; and

(*b*) Enter in a register kept at the enterprises for that purpose. The dates on which inspections were carried out and the nature of any treatment prescribed or administered, the identification of fish treated and the corresponding withdrawal periods.

(2) It shall be the duty of the licensee of an enterprise, to maintain a record of dates on which inspections were carried out by an inspector, nature of any treatment administered and dates of administering the same, and satisfy himself that the appropriate withdrawal periods as determined by the Competent Authority have been observed. He shall further keep in safe custody the prescriptions as proof of administration of treatment, for a period of not less than five years from the date of administering the same.

10. All licensees of enterprises and inspectors carrying out inspections in such enterprises, shall be required to furnish any information requested for, by the Competent Authority, and in particular supply to any establishment on request, information relating to compliance by such enterprise with the requirements under these regulations.

11. (1) Without prejudice to any self-monitoring carried out in connection with the implementation of the national residue monitoring plan drawn up under Regulation 3, the Competent Authority may have official random inspections carried out at any enterprise throughout the fish breeding and rearing process, for the purpose of, detecting the possession or presence of any unauthorized substances which has been used or is intended to be used, to, promote the growth of fish or for purposes of administering any illegal treatments.

(2) The random inspections referred to in paragraph (1) shall be carried out without giving any prior notice to the enterprise concerned.

(3) It shall be the duty of the licensee of any enterprise or any person in charge of such an enterprise, to render all necessary assistance to the Competent Authority or to any person, authorized in that behalf by the Competent Authority, in carrying out the random inspections.

12. (1) Where administration of any illegal treatment is being suspected, the Competent Authority shall request the licensee or the person in charge of the enterprise, to provide documentary proof to justify the nature of the treatment administered.

(2) Where documentary proof confirms that any illegal treatment had been administered or there is sufficient reason to suspect their use, and the licensee of the enterprise is unable to justify such act, the Competent Authority shall conduct—

(*a*) Spot checks (including official sampling) on fish in the enterprise with a view to detecting the administration of any illegal treatment or use of any unauthorized substances ;

(*b*) Spot checks on fish feed being used and the water in which such fish is being reared ; and

(*c*) Any other appropriate checks to clarify the origin of the unauthorized substance or the fish, which were subjected to the illegal treatment.

13. The Competent Authority may for the purpose of carrying out laboratory tests on official samples of fish, approve any one or more laboratories, provided that a given residue or residue group shall not be assigned to more than one approved laboratory. Such official samples shall be taken and examined in accordance with the requirements specified in Schedules II and III to these regulations.

14. Any one of the laboratories approved under Regulation 13 which is designated for such purpose by the Competent Authority, shall be responsible for :

(*a*) Co-ordinating the work of other laboratories responsible for residue analysis, with particular emphasis on co-ordinating the standards and methods of analysis adopted for the detection of each residue or residue group concerned ;

(*b*) Assisting the Competent Authority in organizing the plan for monitoring residues ;

(*c*) Periodically organizing comparative tests for each residue or residue group assigned to it ; and

(*d*) Ensuring the observance of limits lay down.

15. Procedure for obtaining official samples and treatment of such official samples shall be as specified in Schedule IV to these regulations.

16. Where positive results are recorded in the analysis of any official sample, it shall be the duty of the Competent Authority to forthwith —

(*a*) Obtain all relevant information for the purpose of identifying the fish in which the residue was found ;

(*b*) Obtain full details of the analysis carried out by the approved laboratory and the result of such analysis ;

(*c*) Designate an inspector to carry out an investigation on the enterprise concerned, to determine the reasons for the presence of such residue ; and

(*d*) Carry out further investigations, which the Competent Authority may consider appropriate.

17. (1) Where any illegal treatment has been established, the Competent Authority shall ensure that —

(*a*) The fish under investigation is kept under his official control ;

(*b*) The fish bears an official mark or any other form of an identification mark ; and

(*c*) An official sample is taken from a statistically representative sample on an internationally recognized scientific basis.

(2) During the period in which any fish are placed under the official control of the Competent Authority, no fish from the enterprise concerned shall, under any circumstances whatsoever, be removed or taken out or be handed over to any other person, except under the official supervision of the Competent Authority.

(3) The Competent Authority shall appoint an inspector to carry out an investigation, where appropriate into the source or sources of the substance used in the illegal treatment at the stage of its manufacture, handling, storage, transport and the administration of such substance to the fish.

(4) Where after a sampling has been carried out under paragraph (1) there is confirmation of a case of illegal treatment, the fish found to be positive shall be slaughtered immediately within the premises itself, or be taken to a place outside such premises to be slaughtered under the direct supervision of an inspector appointed for that purpose. Fish slaughtered shall be burned immediately.

(5) Cost incurred in slaughtering and burning of any fish under paragraph (4), shall be borne by the licensee of the enterprise concerned.

18. (1) Where there is evidence of residues of authorized substance of a level exceeding the maximum limit for residues, the Competent Authority shall carry out an investigation within the premises of the enterprise concerned in order to determine the reason why the limit has ben exceeded.

(2) In accordance with the results of an investigation carried out under paragraph (1), the Competent Authority shall, take all necessary measures to safeguard public health and may, among other measures that may be adopted, prohibit the removal of any fish from such enterprise or establishment for a period to be determined by him.

(3) In the event of repeated infringement of the maximum residue limits by a licensee, of an enterprise who place such fish to the market, or by an establishment seeking to export fish products using such contaminated fish, the Competent Authority shall carry out intensified checks on such fish or fish products, as the case may be, for a period not less than six months, and confiscate such products pending the results, of the analysis, and on conformation of the result. The Competent Authority shall, declare such fish or fish products unfit for human consumption or export as the case may be.

19. Cost of carrying out an investigation and analysis under Regulation 18 shall be borne by the licensee of the enterprise or the establishment concerned.

20. Where any unauthorized substance specified in Schedule I to these regulations are found in the possession of any unauthorized person, such substances shall be placed under the official control of the Competent Authority, until any appropriate measures pertaining to the same, are taken by him.

21. (1) Where there is proof that any fish has been subject to authorized treatment but that the appropriate withdrawal periods as determined by the Competent Authority in respect of such fish have not been complied with, the Competent Authority may require the licensee of the enterprise to postpone the slaughter of such fish until he is satisfied that the levels of residues found in them does not exceed the permitted levels.

(2) The postponement period to be determined by the Competent Authority under paragraph (1) shall under no circumstances be less than the appropriate withdrawal period that had been determined in respect of such fish.

22. In these regulations —

"Act" means Fisheries and Aqauatic Resources Act, No. 2 of 1996 ;

"approved laboratory" means a laboratory approved by the Competent Authority under Regulation 13 ;

"authorized substance" means any substance the use or administration of which is not prohibited under these regulations ;

"Competent Authority" means the Director-General of fisheries and Aquatic Resources appointed under the Act ;

"enterprise" means an aquaculture enterprise licensed under the Act ;

"establishment" means a fish processing establishment certified by the Competent Authority as a certified establishment under Regulation 10 of the Fish Products (Export) Regulations, 1998 ;

"fish" means any aquatic organism of animal origin propagated under human control for the purpose of human consumption, to the manipulation of at least one stage of an aquatic organism's life for the purpose of increasing production ;

"fish product" means a product obtained from the processing of fish ;

"illegal treatment" means the use of unauthorized substances or the use of substances authorized for puposes or under conditions other than those permitted under these regulations ;

"official sample" means a sample taken by the Competent Authority which bears, for the purposes of examination of the residues of substances specified in Schedule I to these regulations, a reference to the species, type, quantity concerned, method of collection and particulars identifying the sex of the fish and the origin of the fish or the fish product ;

"residue" means a residue of substances having a pharmacological action, of their metabolites and of other substances transmitted to fish products and likely to be harmful to human health ; and

"unauthorized substance" means the substance specified in Group A of Schedule I to these regulations ;

[Regulation 21]

SCHEDULE I

Group A – unauthorized substances

(1) Chloramphenicol

(2) Nitrofurans (including furazolidone)

(3) Malachite green

Group B – Veterinary drugs and contaminants

(1) Antibacterial substances, including sulphonomides, quinolones ;

(2) Other substances and environmental contaminants

(*a*) Organochlorine compounds including Pc Bs ;
(*b*) Chemical elements ;
(*c*) Mycotoxins

[Regulation 4]

SCHEDULE II

SAMPLING STRATEGY

(1) The plan for monitoring residues is aimed at surveying and revealing the reasons for residue hazards in fish and fish products in enterprises and establishments.

Official samples are to be taken in accordance with the provisions of Schedule III.

Wherever official samples are taken, sampling must be unforeseen, unexpected and effected at no fixed time and on no particular day of the week.

(2) For Group A substances, surveillance should be aimed at detecting the illegal administration of prohibited substances. The emphasis of such sampling must be concentrated according to the provisions of Schedule III.

The samples must be targeted taking into account the following minimum criteria : sex, age, species, fattening system, all available background information, and all evidence of misuse or abuse of substances of this group.

(3) For Group B substances, surveillance should be aimed particularly at controlling the compliance with maximum residue levels for residues of veterinary medicinal products, the maximum levels of pesticides and the concentration of environmental contaminants.

[Regulation 4]

SCHEDULE III

SAMPLING LEVELS AND FREQUENCY

A sample is one or more fish, according to the size of the fish in question and of the requirements of the analytical method.

The minimum number of samples to be collected each year must be at least 1 per 100 tons of annual production.

The compounds sought and the samples selected for analysis should be selected according to the likely use of these substances.

The following breakdown must be respected :

Group A : One third of the total samples ;
All the samples must be taken at the enterprise level, on fish at all stages of farming including fish, which is ready to be placed on the market for consumption.

Group B : Two third of the total samples ;
The sampling should be carried out ;

(*a*) Preferably at the enterprise, on fish ready to be placed on the market for consumption ;

(*b*) Either at the establishment or at wholesale level, on fresh fish, on condition that tracing-back to be enterprise of origin, in the event of positive results, can be done.

In all cases, samples taken at enterprise level should be taken from a minimum of 10% of licensed sites of production.

[Regulation 5]

SCHEDULE IV

RULES FOR OFFICIAL SAMPLING PROCEDURES AND OFFICIAL SAMPLE TREATMENT

(1) Responsibilities :

(*a*) *Inspector :*

Official inspectors shall be appointed by the Competent Authority for taking, registering, preparing and organizing the transport of official control samples under appropriate condition.

(*b*) *Approved laboratories*

The analysis of the samples shall be carried out exclusively by approved laboratories.

(2) Sampling :

(*a*) *Fundamental aspects :*

Whenever official samples are taken, sampling must be unforeseen, unexpected and effected at no fixed time and on no particular day of the week – all precautions must be taken to ensure that the element of surprise in the checks is constantly maintained.

Sampling shall be carried out at variable intervals spread over the whole year. In this context it has to be considered that a number of substances is administered only in particular seasons.

Without prejudice to the contents of the national residue-monitoring plan, other available information shall be taken into consideration when choosing the samples, e.g. The use of presently unknown substances, diseases suddenly appearing in particular regions, indications of fraudulent activities etc.

(*b*) *Sampling strategy :*

The national residue monitoring plan is aimed at :

(i) detecting illegal treatment ;

(ii) controlling the compliance with any national regulations on maximum residue levels for residues of veterinary medicinal products, the maximum levels of pesticides and environmental contaminants ;

(iii) surveying and revealing the reasons for residue in fish.

(c) Collection of the samples :

(i) Definitions

(A) Targeted sample :

Targeted sample is a sample which is taken in accordance with the sampling strategy as defined in item (b) above.

(B) Suspect sample :

Suspect sample is a sample, which is taken :

- as a consequence of positive results of sample taken in accordance with the requirements of the national residue monitoring plan ;
- as a consequence of regulation II ;
- as a requirement under regulation 21.

(C) Random sample :

A random sample is a sample, which is taken under statistical consideration to provide representative data.

(ii) On farm targeted sampling

(A) Criteria for the selection of targeted sample

Sampling can be chosen using local knowledge or any other relevant information such as type of fattening system, breed and sex of fish. The inspector then makes an assessment of all the stock on the enterprise to select those fish to be sampled. In making the assessment following criteria should be applied inter alia.

- indication of use of pharmacological active substances,
- secondary sexual characteristics,
- behavioural changes,
- the same level of development in a group of fish of different breed/categories.
- fish with good conformation and little fat.

(B) Type of targeted sample to be collected

For the detection of pharmacological active substances the corresponding suitable samples are taken according to the provisions in the national residue-monitoring plan.

(iii) Targeted sampling at establishments

(a) Criteria for the selection :

In making their assessment on fish and/or fish products to be sampled. An inspector should apply the following criteria inter alias.

- Sex, age, species and breeding system.
- Information about the producer.
- Indication of use of pharmacological active substances.
- Common practice with regards to the administration of particular pharmacological active substances in the respective enterprise.

When taking the samples, efforts should be made to avoid multiple sampling from one enterprise.

(*b*) *Type of samples collected :*

For the detection of pharmacological active substances the corresponding suitable samples are taken according to the provisions in the national residue-monitoring plan.

(*c*) *Sample quantity :*

The minimum sample quantities must be defined in the national residue-monitoring plan. It must be sufficient to enable the approved laboratories to carry out the analytical procedures necessary to complete the screening and the confirmatory analyses.

(*d*) *Division into sub-samples :*

Unless technically impossible, each sample must be divided into at least two equivalent sub-samples each allowing the complete analytical procedure. Sub division can take place at the sampling location or in the laboratory.

(*e*) *Sample containers ;*

Samples must be collected in suitable containers to maintain sample integrity and tractability. In particular, containers must prevent substitution, cross-contamination and degradation. The containers must be officially sealed.

(*f*) *Sampling report :*

A report shall be produced after each sampling procedure.

The inspector collects at least the following data in the sampling report :

- address of the Competent Authority,
- name of the inspector or identification code,
- official code number of the sample,
- sampling date,
- name and address of the licensee of the enterprise or the person having charge of the enterprise or the name and address of the licensee of the establishment,
- name and address of the enterprise (when sampling on the enterprise),
- license number of the establishment,
- fish product identification,
- fish species,
- sample matrix,
- medication within the last four weeks before sampling (when sampling on the establishment),
- substance or substance groups for examination,
- particular remarks,

Copies of the report are to be foreseen depending on the sampling procedure. The inspector in case of enterprise sampling shall sign the sampling report and its copies at least. The licensee of the enterprise or the person having charge of the enterprise may be invited to sign the original sampling report.

The original of the sampling report will remain with the Competent Authority who has to ensure that unauthorized persons shall not have access to the original report.

If necessary, the licensee of the enterprise may be informed of the sampling undertaken.

(*g*) *Laboratory report :*

The laboratory report established by the Competent Authority shall contain at least the following information :

- address of the Competent Authority
- name of inspector or identification code
- official code number of the sample
- sampling date
- fish species
- sample matrix
- substances or substance groups for examination
- particular remarks.

This report shall be handed over to the approved laboratory together with the samples.

(*h*) *Transport and storage :*

National residue monitoring plan shall specify the suitable storage and transport conditions for each analytic/matrix combination to ensure analytic stability and sample integrity. Specific attention must be paid to transport boxes, temperature and delivery times to the responsible approved laboratory.

In case of any non-compliance with the requirements of the national residue-monitoring plan the approved laboratory shall inform of such fact to the Competent Authority without delay.