LEGAL NOTICE No 64/2003

AQACULTURE PRODUCT REGULATIONS

PART I

PRELIMINARY

Art. 1 Short Title

These Regulations may be cited as the "Aquaculture Product Regulations Legal Notice No. 64/ 2003".

Art. 2 Scope of Application

These Regulations lay down measures to monitor the substances and groups of residues listed in Annex 1 hereof.

Art. 3 Definitions

In these Regulations, unless the context otherwise requires:

(1) "unauthorized substances or products" means substances or products the use of which in aquaculture animals and/or products is prohibited under these Regulations;

(2) "illegal treatment" means the use of unauthorized substances or products or the use of substances or products authorized under these Regulations for purposes or under conditions other than those laid down in these Regulations;

(3) "residue" means the remains of substances having a pharmacological action or of their metabolites and of other substances transmitted to animal products and likely to be harmful to human health;

(4) "Competent Authority" means the fish inspection, quality control and safety assurance service of the Ministry of Fisheries of the state of Eritrea;

(5) "official sample" means a sample taken by the Competent Authority which bears, for the purposes of examination of the residues or substances listed in Annex 1 hereof, a reference to the species, the type, the quantity concerned, the method of collection and particulars identifying the sex and the origin of the aquaculture product;

(6) "approved laboratory" means a laboratory approved by the Competent Authority of The Ministry of Fisheries for the purposes of examining an official sample in order to detect the presence of residues;

(7) "aquaculture product" means all fishery products born and raised in controlled conditions until placed on the market as a foodstuff. However, seawater or fresh water fish or crustaceans caught in their natural environment when juvenile and kept until they reach the desired commercial size for human consumption are also considered to be aquaculture products. Fish and crustaceans of commercial size caught in their natural environment and kept alive to be sold at later date are not considered to be aquaculture products if they are merely kept alive without any attempt to increase their size or weight;

(8) "batch of animals" means a group of aquaculture animals of the same species, in the same age range, reared on the same holding, at the same time and under the same conditions of rearing;
(9) "beta-agonist" means a beta adrenoceptor agonist;
(10) "marine aquaculture" means the culture of salt tolerant aquatic species (flora or fauna) under natural or artificial conditions in tidal waters and coastal ponds including but not limited to fish or crustaceans farming utilizing pens, tanks, ponds; the culture of shellfish on the seafloor, in cages, or suspended from structures in the water; and the culturing of halophyte crops or plants and aquatic plants (algae, seaweed etc.);
(11) "freshwater aquaculture" means the culture of aquatic species under natural or artificial conditions in freshwater tanks, ponds, dams, or other freshwater reservoir located further inland or in the coastal zones throughout the country;
(12) "transient or mobile aquaculture" means the culture of aquatic species in cages that are periodically moved about within a specified area so as to reduce user conflicts. This is typically in the form of wire cages that are either individually marked with a surface buoy or strung together in trawls with end buoys to identify the location of the gear;
(13) "Minister" means the Minister of Fisheries;
(14) "Ministry" means the Ministry of Fisheries of the State of Eritrea;
(15) "seawater farming" means the culture of halophyte crops and/or plants using seawater irrigation;
(16) "integrated seawater farming" means the combined operation of aquaculture and seawater agriculture;
(17) "aquaculture farm" means the aquaculture facilities set up to do marine, freshwater or mobile aquaculture;
(18) "monitoring plan" means the activity set up for the detection of a substance or residue in a specimen (water, animal, sediment or food); and
(19) "monitoring program" means the sum of all monitoring plans set-up for a certain period.

PART II

MONITORING PROGRAMME FOR THE DETECTION OF RESIDUES OR SUBSTANCES

Art. 4 Monitoring of the production process

The production process of aquaculture products and primary products of animal origin shall be monitored for the presence of residues and substances listed in Annex I hereof in their body fluids, tissues, feed and culture water in accordance with part II hereof.

Art. 5 Coordination of the inspections

(1) The Ministry of Fisheries shall assign the task of coordinating the implementation of the inspections provided for in this part of the Regulations to the Competent Authority.

(2) The Competent Authority shall be responsible for:
   (a) drawing up the program provided for in Article 6 hereof to enable the competent units to carry out the required inspections;
   (b) co-ordinating the activities of the central and regional units responsible for monitoring the various residues. Such coordination shall extend to all units working to prevent the fraudulent use of substances or products on stock farms;
   (c) collecting the data needed to evaluate the means used and the results obtained in carrying out the measures provided for in this part of the Regulations; and
   (d) sending the data and results referred to in (c) hereof (including the results of any other surveys undertaken) to the importing countries each year.

(3) These Regulations shall not affect more specific rules applicable to the monitoring of animal nutrition.

Art. 6 Monitoring or surveillance program

(1) A program shall be installed setting out the national measures to be implemented during the initial year of the program. Subsequently, the approved program can be updated in accordance with Article 8 hereof on the basis of the experience of the preceding year or years.

(2) The program provided for in sub-article (1) hereof shall:
   (a) provide for the detection of groups of residues or substances according to type of the aquaculture product (monitoring plans) in accordance with Annex II hereof;
   (b) specify in particular the measures for the detection of the presence of:
      (i) the substance referred to in (a) in the aquaculture products and in water;
      (ii) residues of the aforementioned substances in live animals, body fluids and in tissues;
   (c) comply with the sampling rules and levels laid down in Annexes III and IV hereof.

(3) Annual amendments to the initial program, in particular in the light of the results referred to in Article 5 hereof, shall be elaborated.

Art. 7 Sampling levels and frequencies of the monitoring program

The program shall conform to the sampling levels and frequencies laid down in Annex IV hereof. However, at the request of the aquaculture industry, the Competent Authority may adjust the minimum control requirements laid down in Annex IV hereof, provided that it is clearly established that such adjustments increase the overall effectiveness of the plan and in no way reduce its ability to identify residues of or cases of illegal treatment with substances listed in Annex I hereof.

Art. 8 Initial Program

The initial program shall take into account the specific situation of the aquaculture industry and the Competent Authority and specify in particular:

(1) legislation on the use of the substances listed in Annex I hereof and in particular provisions on their prohibition or authorization, distribution and placing on the market and the rules governing their administration;
(2) the infrastructure of the relevant units (in particular, giving details of the type and size of the bodies involved in implementing the plans and programs);
(3) a list of approved laboratories with details of their capacity for analyzing samples listed in Annex V hereof;
(4) national tolerances for authorized substances and maximum residue levels (MRLs), as laid down in Annex VII hereof;
(5) a list of the substances to be detected, methods of analysis, standards for interpreting the findings and, in the case of the substances listed in Annex I hereof the number of samples to be taken, giving reasons for this number;
(6) the number of official samples to be taken in relation to the annual production;
(7) details of the rules governing the collection of official samples and in particular the rules concerning the particulars to appear on such official samples; and
(8) the type of measures laid down by the competent authorities with regard to aquaculture products in which residues have been detected.

Art. 9 Evaluation of the program

(1) The Competent Authority shall evaluate the initial program to ascertain whether it conforms to these Regulations and whether it provides sufficient guarantee to detect the presence of the residues and substances listed in Annex I hereof.
(2) The Competent Authority shall elaborate annual amendments to the initial program in particular in the light of the results referred to in Article 5 hereof.
(3) The Competent Authority shall evaluate the situation mentioned in sub-article 1 hereof every six months.
(4) Every year, the Competent Authority shall prepare a report containing the results of the residue and substance detection plans and control measures and makes public the outcome of the implementation of the program.
(5) On request of the competent authorities of importing countries the residue monitoring programs and the results of the previous monitoring programs shall be presented.

PART III

SELF MONITORING AND CO-RESPONSIBILITY ON THE PART OF OPERATORS

Art. 10 Auto-control and own checks

I) The Competent Authority shall ensure that:

(1) any aquaculture farm which places aquaculture products on the market and any natural or legal person engaged in trade in such animals shall register beforehand with the competent authorities;

(2) the owners or persons in charge of the establishment of initial preparation/ processing of primary aquaculture products take all necessary measures, in particular by carrying out their own checks, to:

(a) accept – whether by direct delivery or through an intermediary – only those products for which the producer is able to guarantee that withdrawal times have been observed; and

(b) satisfy themselves that the aquaculture products brought into the establishment do not contain:

(i) residue levels which exceed maximum permitted limits; and

(ii) any trace of prohibited substances or products; and

(3) the producers or persons in charge referred to in sub-articles (1) and (2) hereof place on the market only:

a) animals to which no unauthorized substances or products have been administered or which have not undergone illegal treatment within the meaning of these Regulations;

b) animals where authorized products or substances have been administered and the withdrawal periods prescribed for these products or substances have been observed; and

c) products derived from the animals referred to in (a) and (b) of this sub-article.

II) Where an animal is presented at a first-stage preparation/processing establishment by a legal person other than the producer, the obligations laid down in sub-articles (1)-(3) hereof are incumbent on the latter.

Art. 11 General monitoring of production chains

(1) For the purposes of applying Article 10 hereof, the Competent Authority shall ensure, without prejudice to compliance with the rules laid down in Regulations governing the placing on the market of the various products in question, that:

(a) the principle of quality and safety monitoring of the production chain by the different parties involved laid down in the Fishery Product Regulations, Legal Notice No. 40/1998 is established; and

(b) the self-monitoring measures to be included in the specifications for trade marks or labels are stepped up.

(2) The Competent Authority shall inform the importing states, at their request, of provisions laid down in this regard and in particular of provisions adopted for checks on Article 10 I (3) (a) and (b) hereof.

Art. 12 Monitoring by the Competent Authority of the own checks

(1) Competent authorities shall ensure that the terms of reference and responsibilities of inspectors monitoring aquaculture farms are extended to monitoring the rearing conditions and the forms of treatment referred to in these Regulations.

(2) Within this framework, the inspectors or fish pathologists shall enter in a register kept on the farm (specified in Annex VI hereof) the date

and nature of any treatment prescribed, the identification of the animals treated and the corresponding withdrawal periods.

(3) The stock-farmer shall enter in the register the date and nature of the treatment administered. He shall ensure that withdrawal periods have been observed and the records of the prescriptions are kept as a proof for five years.

(4) Stock-farmers, inspectors and fish pathologists shall provide any information to the Competent Authority when requested.

PART IV
OFFICIAL CONTROL MEASURES
Chapter 1: Official Random Checks

Art. 13 Establishment of random checks

(1) Without prejudice to the checks carried out in connection with implementation of the surveillance program referred to in Article 6 hereof or to the checks provided for in specific Regulations, the Competent Authority may conduct official random checks:
   (a) during the manufacture of the substances included in Group A of Annex 1 hereof and during their handling, storage, transport, distribution and sale or acquisition;
   (b) at any point in the feed production and distribution chain; and
   (c) throughout the production chain of aquaculture products covered by these Regulations.

(2) The checks provided for in sub-article (1) hereof shall be conducted with a view of detecting the possession or presence of prohibited substances or products intended to be administered to animals for the purposes of fast growth or illegal treatment.

(3) Where fraud is suspected, and in the case of a positive result from any of the checks referred to in sub-article (1) hereof, the provisions of Articles 23 to 31 hereof shall apply respectively.

(4) The checks provided for on the first sale of aquaculture products and fishery products can be reduced if the farm of origin or departure belongs to an epidemiological surveillance network or a quality and safety monitoring system as referred to in Article 11 hereof.

Art. 14 Circumstances, facilitation and collaboration

(1) The competent national authorities shall carry out the checks provided for in these Regulations without prior notice.

(2) The owner, the person empowered to dispose of the aquaculture products or their representative shall be obliged to facilitate inspection operations on the first sale of aquaculture products and in particular to assist the official inspector or the authorized staff in any activity deemed necessary.

Chapter 2: Illegal Treatment

Art. 15 Provision of documentation

The Competent Authority shall, where illegal treatment is suspected, ask the owner or the person having charge of the animals or the inspector in

charge of the farm to provide any documentation justifying the nature of the treatment.

Art. 16 Measures to be taken by the Competent Authority in case of illegal treatment

(1) The Competent Authority shall, where the inquiry confirms illegal treatment or where unauthorized substances or products have been used or where there are grounds for suspecting their use, conduct:

(a) spot-checks, including official sampling where necessary, on animals at the farm of origin or departure, in particular with a view to detecting such use;

(b) checks to detect substances, the use of which is prohibited or is unauthorized on the farms where the animals are reared and kept (including on holdings administratively connected with such farms);

(c) spot-checks on animals' feeding-stuffs on their farms of origin or departure, and from the waters in which they are caught;

(d) the checks during the manufacture of the substances included in group A in Annex I hereof and during their handling, storage, transport, distribution and sale or acquisition; and

(e) any check required to clarify the origin of the unauthorized substances or products or that of the treated animals.

(2) Where examination of an official sample reveals illegal treatment, the provisions of Articles 23 to 31 hereof shall apply respectively together with the measures laid down in Part V hereof.

Art. 17 Measures to be taken by the Competent Authority when maximum levels are exceeded

The Competent Authority shall:

(1) Where the maximum levels laid down in Annex VII hereof exceed, carry out any measure or investigation deemed appropriate in relation to the finding in question.

(2) Where the examination reveals the presence of residues of unauthorized substances or contaminants exceeding the maximum limits, the measures laid down in Articles 28 to 31 hereof shall apply respectively.

Chapter 3: Reference Laboratories

Art. 18 National Reference Laboratories

(1) The Competent Authority shall designate at least one National Reference Laboratory (NRL). A given residue or residue group may be assigned to more than one National Reference Laboratories.

(2) A list of such designated laboratories shall be drawn up. These laboratories shall be responsible for:

- Coordinating the work of the other national laboratories responsible for residue analysis, in particular by coordinating the standards and methods of analysis for each residue or residue group concerned.
- Assisting the Competent Authority in organizing the plan for monitoring residues.
- Periodically organizing comparative tests for each residue or residue group assigned to them.
- Ensuring that national laboratories comply with the limits laid down.
- Disseminating information supplied by other reference laboratories in the world.
- Ensuring that their staff members are able to participate in further training courses.

Art. 19 Other reference laboratories

Where no National Reference Laboratory is in operation, other laboratories abroad such as those listed in Chapter 1 of Annex V hereof, can be designated as National Reference Laboratories for the detection of residues in aquaculture products.

Art. 20 The Function of the Reference Laboratories

The functions of the reference laboratories shall be as defined in Chapter 2 of Annex V hereof.

Chapter 4: Sampling and Analyses

Art. 21 Official samples

(1) Official samples shall be taken in accordance with Annexes III and IV hereof in order to be examined in approved laboratories.

(2) The Competent Authority shall specify the detailed rules for taking official samples and the routine and reference methods to be employed for the analysis of such official samples.

(3) Whenever an authorization is issued for the placing on the market of a veterinary medicinal product intended for administration to animals, the end product of which is intended for human consumption, the competent authorities shall forward the routine analysis methods.

Art. 22 Confirmation by reference laboratories

(1) For Group A substances, all positive findings recorded following the application of a routine method instead of a reference method shall be confirmed by an approved laboratory using the reference methods laid down in accordance with Article 21 hereof.

(2) For all substances, if claimed on the basis of a contradictory analysis, those results shall be confirmed by the National Reference Laboratory designated in accordance with Articles 18 and 19 hereof for the substance or residue in question. Such confirmation shall be carried out at the claimant's cost in the event of confirmation.

Chapter 5: Investigation Measures in case positive results are obtained

Art. 23 Information

Where positive results are obtained as described in Articles 15, 16 and 17 hereof, the Competent Authority shall obtain without delay:

(a) all the information required to identify the animal and farm of origin or departure; and

(b) full details of the examination and the results.

Art. 24 Investigation

Where positive results are obtained, the Competent Authority shall conduct:

(a) an investigation on the farm of origin or departure as appropriate to determine the reasons for the presence of residues;

(b) in the case of illegal treatment, an investigation of the source or sources of the substances or products concerned at the stage of manufacture, handling, storage, transport, administration, distribution or sale, as appropriate; and

(c) any other further investigations which the authority considers necessary.

Art. 25 Identification of products

Where positive results are obtained, aquaculture products from which samples have been taken shall be clearly identified. The products may not, under any circumstance, leave the farm until the results of the checks are available.

Chapter 6: Immediate actions to be taken after illegal treatment

Art. 26 Placing under official control

Where illegal treatment is established, the Competent Authority shall ensure that the aquaculture stock concerned in the investigations referred to in Article 16 (1) hereof is immediately placed under official control.

Art. 27 Official samples to be taken

The Competent Authority shall furthermore ensure that all the aquaculture products concerned are identified and that, as a first step, a statistically representative official sample is taken from a given lot.

Chapter 7: Residues of authorised substances exceeding the maximum limit

Art. 28 Investigation and necessary measures

(1) Where there is evidence of residues of authorized substances or products of a level exceeding the maximum limit, the Competent Authority shall carry out an investigation on the farm of origin or departure, as applicable, to determine why the above limit have been exceeded.

(2) In accordance with the results of that investigation, the Competent Authority shall take all necessary measures to safeguard public health.

This may include prohibiting aquaculture products from leaving the farm or establishment concerned for a set period.

Art. 29 Repeated infringements

(1) In the event of repeated infringements of maximum residue limits when animals and/or aquaculture products are placed on the market by a farmer or a processing establishment, intensified checks on the animals and products from the farm and/or establishment in question shall be carried out by the Competent Authority for a period of at least six months. Products would be impounded pending the results of analysis of the samples.

(2) Any results showing that the maximum residue limit had been exceeded shall lead to animals and/or aquaculture products concerned being declared unfit for human consumption.

Chapter 8: Costs

Art. 30 Costs of investigations/checks and analyses

(1) The costs of the investigations and checks referred to in Articles 23, 24 and 25 hereof shall be borne by the owner or the person in charge of the animals.

(2) Where the investigation confirms that suspicion was justified, the costs of analyses carried out under Articles 26, 27, 28 and 29 hereof shall be borne by the owner or the person in charge of the animals.

Art. 31 Cost of destroying animals and/or aquaculture products

Without prejudice to criminal or administrative penalties, the cost of destroying animals and/or aquaculture products with positive results or animals that have been deemed positive in accordance with Article 33 hereof shall be borne by the owner or the person in charge of the animals without compensation.

PART V
MEASURES TO BE TAKEN IN THE EVENT OF INFRINGEMENT

Art. 32 Placing substances or products under official control

Where unauthorized substances or products or substances listed in Group A and Group B (1) and (2) of Annex 1 hereof are discovered in possession of non-authorized persons, without prejudice to the possible imposition of penalties on the offender(s), those unauthorized substances or products shall be placed under official control until appropriate measures are taken by the Competent Authority,

Art. 33 Actions and measures to be taken

(1) During the period in which animals and/or aquaculture products are impounded as provided for in Articles 26 and 27 hereof, animals from the farm in question may not leave the farm of origin or be handed over to any other person except under official control. The Competent Authority shall take appropriate precautionary measures

in accordance with the nature of the substance or substances identified.

(2) After sampling has been carried out in accordance with Articles 26 and 27 hereof, if there is confirmation of a case of illegal treatment, the animal or animals found to be positive shall be taken to the designated knacker's yard or high risk processing plant under cover of an official inspection certificate in order to be destroyed there.

In addition, samples shall be taken for analysis at the farm's expense from the entire batch of animals belonging to the farm where illegal treatment is suspected.

(3) However, if half or more of the samples taken by representative sampling in accordance with Articles 26 and 27 hereof are positive, the farmer may be made to choose between a check on all the animals present on the farm which are suspected or a destruction of all the aquaculture products.

(4) For a further period of at least 12 months, the farm(s) belonging to the same owner shall be subject to more stringent checks for the residues in question. Where an organized system of self-monitoring has been set up, this facility shall be withdrawn from the farmer for that period.

(5) In view of the infringement recorded, the farms or establishments supplying the holding concerned shall be subject to checks in addition to those provided for in Article 13(1) hereof to determine the origin of the substance in question. The same shall apply to all farms and establishments in the same supply chain of animals and animal feed as the farm of origin or departure.

Art. 34 Suspension of approval arrangements

(1) Without prejudice to criminal penalties, laid down in Articles 17 and 18 of the Fishery Product Proclamation No. 105/1998, where the possession, use or manufacture of unauthorized substances or products in a manufacturing establishment is confirmed, any authorizations or official approval arrangements enjoyed by the establishment concerned shall be suspended for a period during which the establishment shall be subjected to more stringent checks.

(2) In the case of a repeated offence, such authorizations or approval arrangements shall be permanently withdrawn.

Art. 35 Administrative measures

Without prejudice to criminal penalties of the Fishery Product Proclamation No 105/1998 or penalties imposed by professional bodies, appropriate administrative measures shall be taken against any person where he is responsible, as the case may be, for the use or administering of prohibited substances or products or for the administering of authorized substances or products for purposes other than those laid down in these Regulations.

Art. 36 Failure to cooperate

Any failure to cooperate with the Competent Authority during inspection and sampling as required for the implementation of national programs for monitoring residues and during the investigations and checks provided for in these Regulations, shall be liable to criminal and/or administrative punishment.

Art. 37 Effective Date

These Regulations shall come into force on the date of their publication in the Gazette of Eritrean Laws.

Done at Asmara, this 30th day of April, 2003
Ahmed Haj Ali,
Minister of Fisheries.

ANNEX 1

Residues and Substances, Veterinary Drugs and Contaminants

GROUP A – Substances having anabolic effect and unauthorized substances

(1) Stilbenes, stilbene derivatives, and their salts and esters
(2) Antithyroid agents
(3) Steroids
(4) Resorcylic acid lactones including zeranol
(5) Beta-agonists
(6) Pharmacologically active substances with *zero tolerance*

- Aristolochia spp
- Chlooramfenicol
- Chloroform
- Chloropromazine
- Colchicine
- Dapson
- Dimetrinidazole
- Metronidazole
- Nitrofuranes (inclus. Furazolidon)
- Ronidazole

GROUP B – Veterinary drugs (including unlicensed substances that could be used for veterinary purposes) and contaminants.

(1) Antibacterial substances, including *sulphonomides*, quinolones
(2) Other veterinary drugs
    (a) Antihelmintics
    (b) Anticoccidials, including nitroimidazoles
    (c) Cabamates and pyrethroids
    (d) Sedatives
    (e) Non- steroidal anti-inflammatory drugs (NSAIDs)
    (f) Other pharmacologically active substances
(3) Other substances and environmental contaminants
    (a) Organochlorine compounds including PCBs
    (b) Organophosphorus compounds
    (c) Chemical elements
    (d) Mycotoxins
    (e) Dyes
    (f) Others

ANNEX II

Residue or Substance Groups to be detected in Aquaculture animals and/or Products, their Feed and Primary Animal Products

Aquaculture Products, Feeding-stuffs or Animal Products (Substance Groups as listed in Annex I)	**Aquaculture Animals**
A 1	X
2	
3	X
4	
5	
6	X
B 1	X
2 a	X
b	
c	
d	
e	
f	
3 a	X
b	
c	X
d	X
e	X
f	

ANNEX III
Sampling Strategy

(1) The residue control program and plans are aimed at surveying and revealing the reasons for residue hazards in aquaculture animals and/or products on farms, fish processing plants and packing stations. Official samples are to be taken in accordance with chapter of Annex IV hereof.

Wherever official samples are taken, sampling shall be unforeseen, unexpected and effected at no fixed time and on no particular day of the week. The Competent Authority shall take all the precautions necessary to ensure that random checks are constantly maintained.

2. For Group A substances, surveillance should be aimed at detecting the illegal use of prohibited ,substances and the abusive administration of approved substances, respectively. The emphasis of such sampling shall be concentrated according to Annex IV hereof.

The samples shall be targeted taking into account the following minimum criteria: sex, age, species, rearing condition, 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 (MRLs) for residues of veterinary medicinal products fixed in Annexes I and III hereof to Regulation (EEC) No 2377/90, and the maximum levels of pesticides fixed in Annex III hereof to Directive 86/363/EEC, and monitoring the concentration of environmental contaminants.

ANNEX IV

Sampling Levels and Frequency of Sampling for Aquaculture animals and/or Products

The purpose of this Annex is to define the minimum number of animals from which the samples shall be taken.

Each sample can be analyzed for detecting the presence of one or more substances.

1. **Finfish farming products**

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 Competent Authority shall comply with the minimum sampling levels and frequencies given below, depending on the production of farmed fish (expressed in tones).

The minimum number of samples to be collected each year shall be at least 1 per 100 tones 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 shall be complied with:

Group A: one third of the total samples:

All the samples shall be taken at farm level, on fish at all stages of farming [1], including aquaculture products that are ready to be placed on the market for consumption.

Group B: two thirds of the total samples:

The sampling should be carried out:

(a) preferably at the farm, on fish ready to be placed on the market for consumption; and

(b) either at the processing plant, or at wholesale level, on fresh fish, on condition that tracing-back to the farm of origin, in the event of positive results, can be done. In all cases, samples taken at farm level should be from a minimum of 10% of registered sites of production.

2. **Other aquaculture products**

When the Competent Authority has reason to believe that veterinary medicine or chemicals are being used in other aquaculture animals and/or products, or when environmental contamination is suspected, then these animals and/or products shall be included in the sampling plan in proportion to their production as additional samples to those taken for finfish farming products.

[1] *For mariculture, in which sampling conditions may be especially different, samples may be taken from feed in place of samples from fish.*

ANNEX V

Reference Laboratories

Chapter 1

The following laboratories shall be designated as European Community Reference Laboratories for the detection of residues of certain substances:

(a) For the residues listed in Annex 1 hereof, Group A 1, 2, 3, 4, Group B 2 (d) and Group B 3 (d).

Rijksinstituut voor Volksgezondheid en Milieugygiene (RIVM)
A. Van Leeuwenhoeklaan, 9
NL-3720 BA Bilthoven

(b) For the residues listed in Annex I hereof, Group B 1 and B 3 (e) and carbadox residues and olaquindox residues.

Laboratories des médicaments veterinaries (CNEVA-LMV)
La Haute Marche, Javene
F-35135-Fougéres

(c) For the residues listed in Annex I hereof, Group A 5 and Group B 2 (a), (b), (e).

Bundesintitut fur Gesundheitlichen Verbraucherschutz und Veterinärmedizin (BGVV)
Diedersdorfer Weg, 1
D-12277-Berlin

(d) For the residues listed in Annex 1 hereof, Group B 2 (c) and Group B 3 (a), (b), (c).

Istituto Superiore di Sanita
Viale Regina Elena, 299
1-00161- Roma

The compounds included in Group A 6, B 2 (f) and B 3 (f) are allocated to the designated European Community Reference Laboratories, according to their pharmacological action.

Chapter 2

The functions of the reference laboratories for the detection of residues in live animals, their body fluids and in tissues, animal products, animal feed and drinking water shall be as follows:

1. The functions of Reference Laboratories shall be:
   (a) to promote and coordinate research into new analytical methods and to inform National Reference Laboratories of advances in analytical methods and equipment;

(b) to help the National Reference Laboratories (NRLs) for residues to implement an appropriate quality assurance scheme system based on good laboratory practice (GLP) principles and EN 45,000 criteria;
(c) to approve validated methods as reference methods, to be integrated into a collection of methods;
(d) to provide the National Reference Laboratories with the routine analytical methods accepted during the MRL procedure;
(e) to provide National Reference Laboratories with details of analytical methods and the comparative tests to be conducted, and to inform them of the results of the tests;
(f) to provide National Reference Laboratories, at their request, with technical advice on the analysis of the substances for which they have been designated the reference laboratory;
(g) to organize comparative tests for the benefit of the National Reference Laboratories. Consequently, the reference laboratories shall distribute blank samples and samples containing known amounts of analyte to be analyzed;
(h) to identify residues and determine their concentration in cases where the results of an analysis give rise to a disagreement between tests;
(i) to conduct initial and further training courses for the benefit of analysts from national laboratories;
(j) to provide services, including the standards, measurements and testing program, with technical and scientific assistance;
(k) to compile a report on each year's work; and
(l) to liaise, in the field of analytical methods and equipment, with the National Reference Laboratories in the programs to be submitted in accordance with Article 13 hereof.

(2) In order to perform the functions specified in part 1 of this chapter, reference laboratories shall:
(a) have been designated as a National Reference Laboratory in a State;
(b) have suitable qualified staff who are adequately trained in analytical methods used for the residues for which they have been designated as the reference laboratory;
(c) possess the equipment and substances needed to conduct the analysis for which they are responsible;
(d) have an adequate administrative infrastructure;
(e) have sufficient data-processing capacity to produce statistical data based on their findings and to enable rapid communication of the data and other information to National Reference Laboratories;
(f) ensure that their staff respect the confidential nature of certain issues such as results or communications;
(g) have sufficient knowledge of International Standards and practices; and
(h) have an up-to date list of certified reference material and reference material held by the Institute for Reference Material and Methods, and an up-to date list of manufacturers and vendors of the mater

(Register to be kept at Aquaculture Farm and inspected regularly by CA Inspectors)

Date	Nature of treatment prescribed or administered	Identification of animals (division of the farm)	withdrawal period	signature of the stock farmer	Signature of veterinarian/ pathologist of the farm

Name of Official Inspector: _____ Date: _____ Signature: _____

Remarks: _____

Name of Official Inspector: _____ Date: _____ Signature: _____

Remarks: _____

ANNEX VI

Model Register of Drug Treatment of Aquaculture Products (during cultivation)

ANNEX VII

Maximum Levels

LIST 1

List of pharmacologically active substances with Maximum Residue Levels (MRL) for fishery products:

Pharmacologically active substances	**Indicator residue**	**MRL**	**Tissues**	**Other Provisions**
All products of the sulfonamide group	original drug	100 µg/kg	Muscle & skin in natural proportion	the total Residue level of all substances of the sulfonamide group shall not be more than 100 µg/kg
Trimethoprim	Trimethoprim	50 µg/kg	"	
Penicillines				
Amoxicilline	Amoxicilline	50 µg/kg	"	
Ampicilline	Ampicilline	50 µg/kg	"	
Benzylpenicilline	Benzylpenicilline	50 µg/kg	"	
Cloxacilline	Cloxacilline	300 µg/kg	"	
Dicloxacilline	Dicloxacilline	300 µg/kg	"	
Oxacilline	Oxacilline	300 µg/kg	"	
Quinolones				
Sarafloxacin	Sarafloxacin	30 µg/kg	"	
Tetracyclines	sum of original drug + 4 – epimere		"	
Chlorotetracycline	"	100 µg/kg	"	
Tetracycline	"	100 µg/kg	"	
Oxytetracycline	"	100 µg/kg	"	

ANNEX VII
Maximum Levels

LIST 2
List of pharmacologically active substances present in drugs for veterinary use, with preliminary Maximum Residue Levels (MRL).

Pharmacologically active substance	Indicator residue	MRL	Tissues	Other Provisions
Quinolones				
Flumequine	Flumequine	150 µg/kg	"	
Florfenicol and related substances				
Florfenicol	total content of florfenicol and metabolites expressed in florfenicolamine	1000 µg/kg	"	
Organic phosphates				
Azamethifos		100 µg/kg	"	
Acylureum derivatives				
Teflubenzuron	Teflubenzuron	500 µg/kg		

ANNEX VIII

GUIDELINE FOR THE PRESENTATION AND EVALUATION OF THE RESIDUE MONITORING PROGRAMME ON NATIONAL LEVEL AQUACULTURE PRODUCT REGULATIONS, 2002			
Date of Evaluation:	**Period Covered:**		
List of Animals/Products covered in the present program: (tick the appropriate categories)			
Aquaculture		**Suf.**	**Insuf.**
1. GENERAL INFORMATION			
1.1	Legislation concerning the use of substances of Annex I (Article 8 (1)) hereof.		
1.2	Infrastructure of the official service; information on co-ordination of the activities of central and regional departments (Article 5 and 8(2) hereof)		
1.3	List of Official laboratories (Article 8(3)) hereof.		
1.4	Level of competence of the National Reference Laboratory(s), as well as routin Laboratories, particularly as regards the implementation of Quality Assuranc or GLPs.		
1.5	National tolerance limits (MRLs) for authorized substances and environmental contaminants (Article 8(4)) hereof.		
1.6	Official sampling procedures in the field, including information on how samples are secured after collection (using flow charts)		
1.7	Description of measures taken by the competent authorities where residues are detected (Article 8(7) and (8) hereof.		
2. BACKGROUND INFORMATION ON PRODUCTION			
2.1	Animal species, products and total figures of production.		
2.2	Type of production of 2.1. (intensive, extensive, wild or mixed systems) (Annex IV hereof)		
2.3	Aquaculture products and total number of production planned to be packed in approved establishments and to be exported.		
3. SCOPE OF THE RESIDUE MONITORING PROGRAMME			
3.1	Groups of residues covered (as listed in Annex I hereof); Breakdown of substances monitored in each group by animal species and product (table) (Article 8(5) hereof).		
3.2	Details of analysis methods-screening/routine and confirmation, with action levels and detection limits (Article 8(5) hereof).		
4. FREQUENCIES AND LEVELS OF THE CONTROLS			
4.1	Numbe of samples to be taken for each sub-group of substances in the case of each species/product by reference to volume of product output of animal origin in the previous year (Annex IV hereof). For Eritrea, the figures could only refer to exports; in that case, guarantees for appropriate segregation and control must be given (Article 8(6) hereof). See check table.		
5. TARGETING CRITERIA			
5.1	Results from pervious year		
5.2	Changes based on analysis of the residue plan of the previous year (whereas such plans exists), particularly as regards problem areas identified (referred to in Article 9(2)) hereof.		