



## **FALKLAND ISLANDS**

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### **Fishery Products (Examination for Contaminants, Residues and Maximum Residue Levels) Regulations 2015**

(S.R. & O. No: 10 of 2015)



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### Fishery Products (Examination for Contaminants, Residues and Maximum Residue Levels) Regulations 2015

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I make the following regulations under sections 37 and 47 of the Fishery Products Ordinance (No. 21 of 2006).

#### PART 1 – INTRODUCTION

##### 1. Title

These regulations are the Fishery Products (Examination for Residues and Maximum Residue Levels) Regulations 2015.

##### 2. Commencement

These regulations come into force on publication in the *Gazette*.

##### 3. Interpretation

(1) In these regulations —

“**aquaculture fish**” means all live fish or shellfish coming from a farm, or coming from the wild and intended for a farm;

“**approved laboratory**” means a laboratory approved by the food authority for the purpose of examining official samples;

“**competent authority**” means the food authority as defined under the Ordinance;

“**contaminants**” in relation to maximum levels in fish and fishery products means any of the substances referred to in the relevant EU legislation specified under Schedule 5;

**“feed” or “feedingstuff”** means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to fish;

**“fish”** means all seawater or freshwater fish (except for live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods, and all mammals, reptiles and frogs) whether wild or farmed and including all edible forms, parts and products of such fish;

**“illegal treatment”** means the use of unauthorised substances or products and includes the use of authorised products or substances for purposes other than those lawfully permitted;

**“inspector”** means a person who is designated in writing under regulation 13 by the Director, either generally or specifically, to carry out inspections under these regulations;

**“fisheries officer”** has the same meaning as in the Fisheries (Conservation and Management) Ordinance 2005, but includes an examiner appointed by the Director under section 20 of the Fish Farming Ordinance, either generally or specifically, to carry out inspections under these regulations;

**“maximum residue limits”** means, in relation to a substance or product specified under these regulations or the relevant EU legislation, its concentration in the tissues or body fluids of a fish or fishery products, the limit of which is specified in the relevant EU legislation appearing under Schedule 5;

**“official controls”** means checks, audits and corrective procedures made by the competent authority to verify and ensure there is compliance with feed and food requirements and fish health and welfare rules for the protection of public health;

**“official sample”** means a sample taken by the competent authority under Part 4;

**“operator”** means —

(a) the operator of a designated vessel, establishment or installation; and

(b) the holder of a licence for fish farming;

**“pesticide residues”** means residues including active substances, their metabolites, and the breakdown or reaction products of the active substances specified in the relevant EU legislation under Part B of Schedule 5 (in so far as they are present in fish and fishery products);

**“relevant EU legislation”** means (to the extent that it relates to residue limits in fish and fishery products) the legislation specified in the Schedule to the Ordinance;

**“residue”** means the residue of a substance that has a pharmacological action, of its metabolites and of any other substances transmitted to fish or fishery products which is likely to be harmful to human health;

**“therapeutic purposes”** means the administering of an authorised substance or product to a fish;

**“traceability”** means the ability to trace and follow a feed, or substance intended to be,

or expected to be incorporated into a feed, through all stages of production, processing and distribution;

**“unauthorised substances or products”** means the substances or products specified under Schedule 2 which are prohibited under these regulations and relevant EU legislation;

**“veterinary medicinal product”** means —

(a) any substance or combination of substances presented as having properties for treating or preventing disease in fish; or

(b) any substance or combination of substances that may be used in, or administered to, fish with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;

**“withdrawal period”** in relation to an authorised veterinary medicinal product administered to an fish or batch of fish, means the period specified for that product (either in the marketing authorisation relating to that product or as prescribed by the official veterinarian) which is required to be observed from the time the product is administered to the fish and the time the fish can be placed on the market for slaughter for human consumption; and

(2) In these regulations any reference to the ‘licenced use’ of a substance or product means any use of a substance or product that the manufacturer has permitted or approved.

(3) The relevant EU legislation specified under Schedule 5 setting out the maximum residue limits apply to fish and fishery products intended for human consumption.

(4) For purposes of ascertaining whether the maximum residue limits have been exceeded the competent authority must test for the presence of the substance (the drug, drug metabolite or a combination of both) as specified in Schedule 5 (in relation to contaminants) or as specified in the relevant EU legislation listed under Schedule 6 (in particular Regulation 37/2010 of 22 December 2009 in relation to pharmacologically active substances) and measure the levels of that substance.

#### **4. Application**

These regulations apply to fish and fishery products which are to be placed on the market for human consumption produced —

(a) on vessels, establishments and installations designated under the Fishery Products (Vessels, Establishment and Installations) Regulations 2014; and

*[Revision w.e.f. 31/07/2017]*

(b) in fish farming establishments licenced under the Fish Farming Ordinance.

*[Revision w.e.f. 31/07/2017]*

## **PART 2 – PROHIBITIONS ON IMPORT, SALE AND USE OF CERTAIN PRODUCTS AND SUBSTANCES ON FISH**

### **5. General prohibition of import, sale and use of unauthorised substances**

(1) Subject to the provisions of these regulations, a person commits an offence who —

(a) imports into the Falkland Islands any of the unauthorised substances or products specified under Schedule 2;

(b) places on the market for sale any of the unauthorised substances or products specified under Schedule 2;

(c) administers to any fish any of the unauthorised substances or products specified under Schedule 2;

(d) places on the market for slaughter any fish to which any of the substances specified under Schedule 2 has been administered; or

(e) processes or places on the market for sale any fish or fishery products (intended for human consumption) from a fish to which any of the substances specified under Schedule 2 has been administered.

(2) A person convicted of an offence under this regulation is liable to a term of imprisonment not exceeding 12 months or to a fine not exceeding level 8 on the standard scale.

(3) The competent authority may import any of the unauthorised substances or products for zootechnical purposes or any other purposes as may be necessary.

### **6. Prohibitions on the import, sale or administration of certain substances**

(1) A person commits an offence who imports into the Falkland Islands or places on the market for sale for administration to fish any of the following substances —

(a) stilbenes, stilbene derivatives including their salts and esters;

(b) oestradiol 17  $\beta$  and its ester-like derivatives; or

(c) malachite green, crystal violet or their derivatives.

(2) Subject to regulation 7, a person commits an offence who administers to a fish intended for human consumption any of the following substances —

(a) stilbenes, stilbene derivatives including their salts and esters;

(b) oestradiol 17  $\beta$  and its ester-like derivatives; or

(c) malachite green, crystal violet or their derivatives.

(3) A person convicted of an offence under this regulation is liable to a term of imprisonment not exceeding 12 months or to a fine not exceeding level 6 on the standard scale.

## **7. Prohibition of possession of unauthorised substances and substances under regulation 6**

(1) A person commits an offence who is in possession of any unauthorised substances or any of the substances specified under regulation 6.

(2) It is a defence for a person charged with an offence under sub-regulation (1) in relation to the substances specified under regulation 6 that the person had an authorisation from the competent authority to use the substance for its licenced use.

(3) A person convicted of an offence under this regulation is liable to a term of imprisonment not exceeding 12 months or to a fine not exceeding level 6 on the standard scale.

## **8. Fish and fishery products with levels in excess of the maximum residue limits**

(1) A person commits an offence who places on the market for sale any fish and fishery products intended for human consumption which contains –

(a) residue levels that exceed the maximum residue limits specified under Part A of Schedule 5 in relation to pharmacologically active substances;

(b) pesticides residue levels that exceed the maximum residue limits specified under Part B of Schedule 5;

(c) levels that exceed the maximum levels for certain contaminants as specified under Part C of Schedule 5;

(d) levels that exceed the maximum limits specified under Part D of Schedule 5 in relation to microbiological contaminants; or

(e) levels that exceed the maximum limits in relation to relevant EU legislation specified under Schedule 5.

(2) A person convicted of an offence under this regulation is liable to a term of imprisonment not exceeding 6 months or to a fine not exceeding level 4 on the standard scale.

## **PART 3 – GENERAL CONTROL AND MONITORING ON PRODUCTION AND PLACING ON THE MARKET**

### **9. Controls and monitoring of fish going for slaughter**

(1) A person in control of fish going for slaughter must take all reasonable steps to ensure that the fish which are to be taken for slaughter —

(a) are constantly monitored for the purpose of detecting the level of residues from substances or products specified under Schedule 1; and

(b) are not treated with any of the unauthorised substances or products specified under Schedule 2.

(2) The reasonable steps may include the following —

- (a) the correct and appropriate use of veterinary medicinal products (to avoid illegal treatment);
- (b) the keeping of records of all the veterinary medicinal products administered to fish;
- (c) the correct and appropriate use of feed (and additives) and ensuring their traceability; and
- (d) the correct storage of feed (to avoid contamination); and
- (e) ensuring as far as possible that fish which had been administered with authorised substances or products are sent for slaughter only after the applicable withdrawal periods which have been prescribed for those substances or products have elapsed.

#### **10. Official controls – competent authority**

(1) The competent authority must put in place measures aimed at ensuring compliance with official controls and these measures may include —

- (a) the control of contaminants such as mycotoxins, heavy metals and radioactive material;
- (b) the use of water as specified under Part 2 of the Fishery Products Ordinance;
- (c) organic waste and fertilisers;
- (d) the correct and appropriate use of plant protection products and biocides and their traceability;
- (e) the correct and appropriate use of veterinary medicinal products;
- (f) the keeping of records of all the veterinary medicinal products administered to fish;
- (g) the correct and appropriate use of feed additives and their traceability;
- (h) frequent monitoring to ensure that fish do not contain —
  - (i) residue levels which exceed maximum residue limits specified under these regulations;  
or
  - (ii) any trace of prohibited substances or products.

(2) The competent authority must put in place a monitoring plan and must ensure that inspections are carried out as often as possible for the proper monitoring of the use of substances or products in fish and to check the residues listed under the Schedules to these regulations.

(3) The competent authority must ensure that —

- (a) the residue monitoring plan complies with the requirements under Part 4; and
- (b) the data collected and all the results are sent to the Commission not later than 31<sup>st</sup> March in each year.

## **11. Controls at slaughter - placing on the market for human consumption**

(1) In this Part —

(a) to “process fish” means to alter the initial product by heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes

(b) to “produce fish” means to kill, bleed, skin, clean, slice, trim, part, sever, bone, mince, grind, freeze or thaw a fish or a combination of these procedures.

(2) An operator must take the necessary steps to ensure that fish that are processed for slaughter for human consumption do not contain residues in excess of the maximum limits and that they do not contain any trace of prohibited substances or products as set out under these regulations and the relevant EU legislation.

(3) Any fish or fishery product which is produced and processed to be placed on the market for human consumption must —

(a) be authorised by the competent authority to ensure that it does not contain residues in excess of the levels set out under these regulations and the relevant EU legislation;

(b) in the case of fish which were used for breeding purposes or come from fish which have undergone treatment using authorised products or substances, that the fish were only slaughtered after the lapse of the specified withdrawal periods prescribed for those substances or products;

(c) be thoroughly checked to ensure compliance with the applicable measures relating to fish health and welfare that have implications for human health, including programmes for the monitoring and control of zoonoses and zoonotic agents.

## **12. Checks and approval by competent authority before fish or fishery products is placed on the market**

(1) An operator must ensure that all fresh fish to be placed on the market is produced and processed in compliance with the Fishery Products (Hygiene) Regulations.

*[Revision w.e.f. 31/07/2017]*

(2) An official veterinarian must carry out the official controls referred to in Part 4 to ensure that fish and fishery products placed on the market comply with the residue and contaminant levels set out in these regulations and the relevant EU legislation.

(3) The competent authority must also carry out the official checks aimed at detecting the presence of unauthorised or prohibited substances (which may be used for fattening or for other illegal treatment).

## **PART 4 – OFFICIAL CONTROLS (SAMPLING, TESTING, EXAMINATIONS, INSPECTIONS AND AUDITS)**

### **13. Designation of Inspectors**

(1) The Director of Natural Resources may designate official veterinarians and fishery officers as inspectors for purposes of carrying out all the checks, sampling, monitoring and other official control measures required under these regulations.

(2) An inspector designated under these regulations is responsible for —

(a) carrying out inspections for detecting the presence of unauthorised substances or products intended to be administered to fish for purposes of fattening or for any illegal treatment;

(b) checking the records or registers kept at farms in relation to treatment administered to fish;

(c) taking of samples, registering, preparing and organising the transportation of official control samples; and

(d) any other duties as may be specified in the designation.

### **14. Inspections at fish farms**

(1) The operator must cooperate with the inspectors to facilitate inspections and in particular assist the inspectors or any other authorised staff to carry out any official controls required under these regulations.

(2) The inspectors must check all the records and registers kept in terms of regulation 32.

(3) Where there is any suspicion that fish have been treated with illegal or unauthorised substances or products the competent authority must ensure that inspections or checks are carried out as soon as possible.

(4) An inspection carried out under this regulation may include —

(a) official sampling of the fish feeding stuff or water in which the fish are kept;

(b) a search within the farm for the presence of the unauthorised substances or products or where there are unauthorised substances or products found checks to establish the origin of those substances or products;

(c) a requirement for the owner of the fish to detain a certain number of fish to enable the fish to be inspected for the purposes of checking for unauthorised substances or the residue levels of authorised substances; or

(d) any other action as may be appropriate in the circumstances.

(5) Where further samples or checks are to be carried out in compliance with sub-regulation (3) or if the sampling is carried out on a specific batch of fish the competent authority must give the owner of the fish or the person in control of the fish 7 days' notice in writing as to when the further sampling and checks are to take place.

(6) The owner or person in control of the fish must allow further sampling and checks to take place within 7 days of the notification.

(7) Where an inspection under this section reveals any positive results the competent authority must take any action as specified under Part 5.

### **15. Inspections at vessels, establishments or installations**

(1) An operator must cooperate with the inspectors by facilitating pre- and post-slaughter inspection operations and offer any assistance as necessary so that official controls to be carried out by the inspectors and the competent authority can be performed effectively.

(2) The operator must in particular —

(a) give access to all buildings, premises, installations or other infrastructures where fish production or processing is done; and

(b) make available any documentation and records required or considered necessary by an inspector.

(3) Where an inspection under this section reveals any positive results the competent authority must take action as specified under Part 5.

#### *Residue Monitoring Plans – Fish and fishery products for Export Purposes*

### **16. Residue monitoring plans**

(1) The competent authority must prepare and transmit to the Community a residue monitoring plan for all fish and fishery products produced and processed for export to the Community annually as required under regulation 10.

(2) The residue monitoring plan must comply with the requirements of the relevant EU legislation and must take into account the following —

(a) the legal requirements on the use of substances or products specified under these regulations and the relevant EU legislation;

(b) the capacity of all the relevant parties involved in implementing the plan;

(c) the laboratories approved for processing samples;

(d) the number of official samples to be taken (in relation to the number of fish of the species slaughtered in preceding years) in accordance with the sampling levels and frequencies laid down under Schedule 4;

(e) the legal requirements for collection of samples and the information provided with samples; and

(f) measures to be taken with regard to fish or fishery products which are found to contain residues in excess of the prescribed maximum limits.

## **17. Monitoring**

(1) The competent authority must monitor fish production and the overall processing and production of fish and fishery products for detecting the presence of any residues and substances listed under these regulations and the relevant EU legislation.

(2) The competent authority must ensure that all samples are collected in accordance with these regulations and the relevant EU legislation in particular by —

(a) drawing up a monitoring plan to enable inspections to be carried out as and when necessary;

(b) collecting all the data needed to evaluate the methods used to collect samples and the results obtained from carrying out any measures taken; and

(c) sending to the Commission, not later than 31 March in each year the data and the results (including the results of any surveys taken during the course of that year).

(3) The competent authority may introduce separate monitoring and sampling procedures for fish and fishery products that are for domestic human consumption in the interests of public food safety.

## **18. Contents of the monitoring plan**

The monitoring plan must —

(a) provide, according to the category of fish, for detection of groups of residues or substances specified under Schedule 3;

(b) specify the measures for detection of the presence of the substances referred to under paragraph (a) (and where necessary in the feeding stuffs and in the water where the fish are kept);

(c) comply with the sampling rules and levels laid down under Schedule 4.

### *Sampling and Sampling Reports*

## **19. Requirements for taking samples**

(1) The competent authority must ensure that samples are taken frequently or as routinely as possible throughout the course of the year to detect the possession or presence of prohibited substances or products or to determine the levels of residues or contaminants from products of substances.

(2) The taking of samples may be unscheduled and must be done as often as necessary to detect the possession or presence of prohibited substances or products.

(3) The taking of official samples must be done in accordance with the requirements of Schedule 4 and the competent authority must ensure the establishments take samples at a frequency appropriate to production.

## **20. Transport and storage of samples**

- (1) Residue control plans must specify suitable storage and transport conditions for each analyte or matrix combination to ensure analyte stability and sample integrity.
- (2) The competent authority may impose additional conditions under which official control samples are transported in relation to the temperature and the storage of the samples.

## **21. Sampling report**

- (1) The report must contain the following —
  - (a) name of the officer carrying out the sampling;
  - (b) official code of the sample;
  - (c) sampling date;
  - (d) if the sampling is done on farm, the name and address of the owner or the person who has control of the fish farm;
  - (e) in the case of fish and fishery products prepared for placing on the market, the name and address of the fish slaughter establishment;
  - (f) licence number of the fish farm;
  - (g) lot or batch number of the fish;
  - (h) fish species;
  - (i) sample matrix indicating the type of tissue sampled;
  - (j) veterinary medicinal products given to the fish within the last four weeks before the sampling is undertaken;
  - (k) substances or groups of substances which the sampling is to cover; and
  - (l) any other necessary information relevant to the sampling.
- (2) The sampling report must be signed and the original copy filed with the competent authority.

### *Official control checks*

## **22. Official control measures**

- (1) The competent authority must ensure that official control measures are put in place to detect the possession or presence of unauthorised substances or products intended to be administered to fish for any illegal treatment (including fattening).
- (2) The official control measures referred to in sub-regulation (1) may include the following —
  - (a) unscheduled checks carried out as often as necessary;

(b) training of fish farmers or people in charge of fish on the keeping of records and the proper use of veterinary medicinal substances or products.

### **23. Official control checks**

(1) The competent authority must perform periodic unscheduled checks at farms to check any of the following —

(a) the treatment given to fish;

(b) the records of treatments administered on fish;

(c) any traces of implants on the fish and these checks may include official sampling;

(d) the presence of prohibited or unauthorised substances or products; or

(e) the fish's feeding stuffs and water in which they are kept to detect any prohibited or unauthorised substances or products.

(2) The competent authority may perform unscheduled checks on a particular fish farm where there is suspicion that illegal treatment has taken place.

(3) Where the competent authority finds any unauthorised substances or products as a result of a check under sub-regulation (2), it must carry out further checks to clarify the origins of the unauthorised substances or products.

(4) Where the checks under sub-regulation (2) reveal that the maximum limits or levels laid down under Schedule 5 have been exceeded the competent authority must take such action or measures it may deem appropriate in the circumstances.

### *Approved laboratories*

### **24. Designated laboratories**

(1) The competent authority must designate a number of laboratories for purposes of complying with these regulations and the relevant EU legislation.

(2) The designated laboratories must be capable of carrying out the tests required under these regulations for the testing of samples for residues.

### **25. Examination of samples**

Where the examination of a sample reveals that there has been illegal treatment, the competent authority must take such measures and any of the actions laid down under Part 5.

## **PART 5 – ACTION TO BE TAKEN FOR POSITIVE RESULTS**

### **26. Further investigations – competent authority**

(1) Where the results or outcome of the official checks and examinations carried out under Part 4 reveal positive results of the presence of any residues that exceed the maximum limits specified under Schedule 1, the competent authority must carry out a further investigation.

- (2) The competent authority must obtain all the necessary information without delay in order to—
- (a) establish whether the residues are of authorised or unauthorised substances or products;
  - (b) identify the fish and the fish farm or establishment from where the affected fish come; and
  - (c) establish the source of the unauthorised substances or products.
- (3) Depending on the outcome of the investigation and based on its findings, the competent authority may take the appropriate action as set out under regulations 27 and 28.

### **27. Actions by competent authority – maximum levels exceeded**

- (1) Where the results or outcome of the official checks and examinations carried out under Part 4 or a further investigation conducted under regulation 25 reveal that the residue levels of authorised substances or products exceed the maximum levels specified under Schedule 5, the competent authority must carry out a further investigation to determine the reasons of the excess in residue levels.
- (2) Based on the outcome of the further investigation under sub-regulation (1), the competent authority must put in place necessary measures to safeguard public health.
- (3) The measures referred to under sub-regulation (2) may include —
- (a) where the residues which exceed the maximum limits are found in fish, the confiscation and destruction of those fish;
  - (b) the prevention of the placing on the market for slaughter, of fish from that fish farm for a specified period.
- (4) The competent authority must ensure that fish that come from a fish farm, a designated vessel, establishment or installation which have had repeated incidents of exceeding the maximum residue limits go through intensified checks and examinations for a specified period not less than 6 months before fish from that farm can be placed on the market for slaughter; and

### **28. Actions by competent authority – illegal treatment**

- (1) Where the results or outcome of the official checks and examinations carried out under Part 4 or a further investigation conducted under regulation 26 reveal that there has been illegal treatment the competent authority must —
- (a) ensure that all the fish on that fish farm or from a designated vessel, establishment or installation) are checked and the affected fish are immediately placed under official control;
  - (b) cause the pen or tank of the batch of affected fish to be marked to ensure that they are easily identifiable; and
  - (c) cause all the affected fish to be slaughtered separately.

(2) Based on the outcome of the further investigation under sub-regulation (1) and depending on the nature of the unauthorised substances or products identified, the competent authority may put in place necessary precautionary measures to safeguard public health.

(3) The measures referred to under sub-regulation (2) may include —

(a) where any unauthorised substances or products are found in the fish farm or on the establishment, the confiscation of those substances or products;

(b) the prevention of the placing on the market for slaughter, of fish from that fish farm for a period as may be specified by the competent authority; or

(c) cancellation of the fish farming licence.

(4) The owner of the fish farm must bear the following costs —

(a) costs of the checks done on all the fish;

(b) costs of slaughter of the affected fish including the costs of transporting the fish to a processing establishment or approved laboratory.

## **29. Action by official veterinarian – fish farming establishments**

(1) If an official veterinarian at a slaughterhouse has evidence that fish have been treated with unauthorised substances or products or that, after being treated or administered with authorised substances or products, the withdrawal periods were not observed, the official veterinarian must—

(a) in the case of live fish, arrange for the fish to be slaughtered separately from other fish;

(b) if the fish have already been slaughtered, impound all the fish until all the sampling procedures necessary to detect the level of residues for the substances or products in question have been conducted.

(2) The official veterinarian may, where there is suspicion that fish have been illegally treated or that, after being treated or administered with authorised substances or products, the withdrawal periods were not observed —

(a) impound all the carcasses and offal from fish slaughtered until all the sampling procedures necessary to detect the residues have been complied with; or

(b) subject to sub-regulation (3), delay the slaughter of the fish until satisfied that the quality of the residues does not exceed the permitted levels by observing the withdrawal periods to be observed with respect to those substances or products.

(3) If there is an emergency or due to fish welfare reasons it is required that slaughter cannot be delayed the fish must be slaughtered immediately and the fish must be checked before it can be placed on the market for human consumption.

(4) If the sampling procedures undertaken in relation to fish under this regulation show that the residue levels exceed the maximum limits, the fish or any fishery products from that fish must be declared unfit for human consumption and be destroyed.

(5) The competent authority may impose any of the measures specified under these regulations based on the results of the sampling procedures undertaken under this regulation (whether the sampling reveals illegal treatment or exceeding of maximum limits).

## **PART 6 – MISCELLANEOUS PROVISIONS**

### **30. Notices**

Any decision or action to be taken by the competent authority under these Regulations must be given by notice which —

- (a) must be in writing;
- (b) may be subject to conditions; and
- (c) may, depending on the decision or action be amended, suspended or revoked.

### **31. Appeals**

(1) Any person aggrieved by the decision of the competent authority under these regulations may lodge an appeal in writing to the Governor within 14 days from the date of the decision by the competent authority.

(2) An appeal under sub-regulation (1) must be commenced by submitting a notice of appeal to the Governor.

(3) The notice of appeal must be accompanied by supporting documents including a copy of the decision of the competent authority.

(4) Where an appeal is made under this regulation, the Governor may —

- (a) allow the appeal in full;
- (b) dismiss it entirely; or
- (c) reverse or vary one or more parts of the decision made by the competent authority.

### **32. Record keeping**

(1) There must be kept on the fish farm a register on which the following is recorded —

- (a) all the information relating to any treatment prescribed or administered to fish;
- (b) the date when the treatment was administered to the fish;
- (c) the identification of the batch of fish treated;
- (d) the withdrawal periods to be observed for the treatments administered (including information indicating when those periods elapsed); and
- (e) any other relevant information.

(2) A person who owns a fish farm or is in control of fish or is engaged in the placing on the market of fish for slaughter must keep records of the following —

- (a) all veterinary medicinal products or other treatments administered to fish, the dates of administration and withdrawal periods;
- (b) the occurrence of diseases that may affect the safety of the fish and products of fish origin;
- (c) the results of any analyses carried out on samples taken from fish or other samples taken for diagnostic purposes, that have importance for human health; and
- (d) any relevant reports on checks carried out on fish or fishery products.

(3) The inspector, the owner of the fish farm or the person in charge of the fish must enter the details specified under this regulation in the register.

(4) An operator must keep all the records relating to fish brought into the fish farm, vessel, establishment or installation including any records relating to fish and fish products produced and processed in the fish farm, vessel, establishment or installation.

(5) A copy of the register or records to be kept under this regulation must be made available to the competent authority when requested.

### **33. Guidance by competent authority**

The competent authority may publish guidance on good record keeping practices as well as on the taking of samples, sampling frequency and strategy as well as on the storage and administration of veterinary medicinal products.

### **34. Obstruction of inspectors and other competent authority officials**

(1) It is an offence to do one or more of the following —

- (a) intentionally to obstruct any person acting in the execution of these regulations;
- (b) knowingly to give any information that is false or misleading to any person acting in the execution of these regulations;
- (c) intentionally to fail to disclose any material particular to any person acting in the execution of these regulations; or
- (d) to fail, without reasonable excuse —
  - (i) to give any assistance that any person acting in the execution of these regulations may require, or
  - (ii) to produce any record that any person acting in the execution of these regulations may require to be produced,

for the performance of that person's functions under these regulations.

(2) A person convicted of an offence under this regulation is liable to a term of imprisonment not exceeding 6 months, or to a fine not exceeding level 6 on the standard scale.

### **35. Offences and penalties**

(1) It is an offence for a person to contravene a provision of these regulations.

(2) A person convicted of an offence under these regulations for which no penalty is provided, is liable to a term of imprisonment not exceeding 6 months, or to a fine not exceeding level 8 on the standard scale.

**SCHEDULE 1**  
**SUBSTANCES OR PRODUCTS TO BE MONITORED**  
**IN FISH AND AQUACULTURE FISH**  
*(regulation 9(1)(a))*

**Group A**

(i) Substances which have anabolic effect and unauthorised substances

(1) Stillbenes, stillbene derivatives, and their salts and esters  
Steroids

(2) The following substances for which no maximum residue levels can be established:

Aristolochia
Chloramphenicol
Chloroform
Chlorpromazine
Colchicine
Dapsone
Dimetridazole
Metronidazole
Nitrofurans (including furazolidone)
Ronidazole

**Group B**

Veterinary drugs and contaminants:

(1) Antibacterial substances including sulphonamides, quinolones

(2) Other veterinary drugs —

(a) Anthelmintics

(3) Other substances and environmental contaminants —

(a) Organochlorine compounds including PCBs

(b) Chemical elements

(c) Mycotoxins

(d) Dyes

**SCHEDULE 2**  
**UNAUTHORISED/PROHIBITED SUBSTANCES**  
*(regulation 5)*

**List A – Prohibited Substances**

Stillbenes, stilbene derivatives, their salts and esters  
Oestradiol 17 $\beta$  and its ester-like derivatives  
Dyes

**List D – Substances for which a maximum safe level in food cannot be established**

The following substances for which no MRL can be established)

Aristolochia
Chloramphenicol
Chloroform
Chlorpromazine
Colchicine
Dapsone
Dimetridazole
Metronidazole
Nitrofurans (including furazolidone)
Ronidazole

**SCHEDULE 3**  
**SUBSTANCES SUBJECT TO MONITORING OR CHECKING**  
*(regulation 18(a))*

The following substances are to be checked in the fish specified (checked in live fish, their excrement and body fluids as well as in the fish's feeding stuffs and drinking water) —

<b>Substances to be checked</b>	<b>Types of fish</b>
Stilbenes Steroids Compounds for which no MRL can be established	aquaculture fish
Antibacterial substances including sulphonamides, quinolones	aquaculture fish
Anthelmintics	aquaculture fish
Organochlorine compounds including PCBs	aquaculture fish
Chemical elements	aquaculture fish and wild caught fish
Mycotoxins <sup>i</sup>	aquaculture fish
Dyes	aquaculture fish
Dioxins	aquaculture fish and wild caught fish
Polyaromatic hydrocarbons	aquaculture fish and wild caught fish <sup>ii</sup>

**SCHEDULE 4**  
*(regulation 16(2)(d))*

**PART A**  
**SAMPLING STRATEGY – RESIDUES**

1. The residue control plan must be aimed at surveying and revealing the reasons for residue hazards in fish and fishery products.
2. The taking of samples must comply with the requirements of Part B of this Schedule.
3. Sampling must be unscheduled and must be carried out as often as is necessary.
4. For Group A substances the sampling must be conducted to check for —
  - (a) illegal treatment of fish using the prohibited/unauthorised substances under paragraph (6); and
  - (b) unlawful use of authorised substances.
5. The samples must be targeted and must check the sex and age of the fish, the fish species, any fattening system in place and any other information relevant to the detection of residue levels or any illegal treatment.
6. For Group B substances the sampling must be aimed at controlling and ensuring that there is compliance with maximum residue limits for the following —
  - (a) residues of veterinary medicinal products specified under EU Regulation 37/2010;
  - (b) levels of pesticides specified under EU Regulation 396/2005; and
  - (c) concentration levels of environmental contaminants.

**PART B**  
**SAMPLING LEVELS AND FREQUENCY- RESIDUES**

**General**

1. Sampling must be done only on a specified number of fish.
2. A sample must be analysed for detecting the presence of one or more substances.

**Aquaculture Products**

**1. Finfish farming products**

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

(b) The competent authority must respect the minimum sampling levels and frequencies given below, depending on the production of farmed fish (expressed in tonnes).

(c) The minimum number of samples to be collected each year must be at least 1 per 100 tonnes of annual production.

(d) 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 farm level, on fish at all stages of farming ( 1 ), including fish which is 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 fish farm, on fish ready to be placed on the market for human consumption;  
or

(b) 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.

## **2. Sea-farming**

(a) For sea-farming, in which sampling conditions may be especially difficult, samples may be taken from feed in place of samples from fish.

(b) In all cases, samples taken at farm level should be taken from a minimum of 10 % of registered sites of production.

## **3. Other aquaculture products**

When the competent authority has reason to believe that veterinary medicine or chemicals are being applied to the other aquaculture products, or when environmental contamination is suspected, then these species must be included in the sampling plan in proportion to their production as additional samples to those taken for finfish farming products.

## **4. Wild caught fish**

A sampling strategy must be produced by the competent authority based on realistic cost, logistics and risk assessment.

**SCHEDULE 5**  
**MAXIMUM LEVELS FOR CERTAIN CONTAMINANTS IN FISH**  
*(regulation 23(4))*

**Part A**  
**Pharmacologically active substances**

Council Regulation (EU) 37/2010 sets out the pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of fish origin. The pharmacologically active substances listed are applicable in so far as they relate to fish and fishery products.

**Part B**  
**Pesticide Residues**

Council Regulation (EC) 396/2005 sets the maximum residue levels of pesticides in or on food and feed of plant and fish origin. The maximum residue levels are applicable in so far as they relate to fish and fishery products.

**Part C**

Council Regulation (EC) 1881/2006 sets out the maximum levels for certain contaminants in foodstuffs. The maximum levels for the contaminants are applicable in so far as they relate to fish and fishery products.

**Part D**

Microbiological criteria for fish and fishery products

Food category	Micro-organisms	Sampling plan <sup>iii</sup>		Limits (2)		Analytical reference method (3)	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
cooked crustaceans and molluscan shellfish	<i>Salmonella</i>	5	0	absence in 25g		ISO 6579	Products placed on the market during their shelf-life	Improvements in process hygiene and review of process controls
fishery products from fish species associated with high amount of histamine <sup>iv</sup>	Histamine	9 <sup>v</sup>	2	100mg /kg	200mg /kg	HPLC	Products placed on the market during their shelf life	Review of processing controls

fishery products which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histamine <sup>vi</sup>	Histamine	9 <sup>vii</sup>	2	200mg /kg	400mg / kg	HPLC	Products placed on the market during their shelf-life	Review of processing controls
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<sup>i</sup> Mycotoxins may only be investigated if there are any results over 0

<sup>ii</sup> PAH must be monitored in dried, salted, brined or smoked fish, cephalopods, crustaceans and molluscs and fish fat/oils. PAH must be measured in plain fish if there has been environmental contamination that may increase risk of high PAH levels

<sup>iii</sup> E.coli is used here as an indication of faecal contamination

<sup>iv</sup> Fish species of the families *Scombridae*, *Clupeidae*, *Engraulidae*, *Coryfenidae*, *Pomatomidae*, *Scombresosidae*

<sup>v</sup> Single samples may be taken at retail level. If the result is above M the whole batch is deemed unsafe

<sup>vi</sup> Fish species of the families *Scombridae*, *Clupeidae*, *Engraulidae*, *Coryfenidae*, *Pomatomidae*, *Scombresosidae*

<sup>vii</sup> Single samples may be taken at retail level. If the result is above M the whole batch is deemed unsafe