

L.N. 354 of 2005

**VETERINARY SERVICES ACT
(CAP. 437)**

Measures for the Control of Fish Diseases Rules, 2005

IN exercise of the powers conferred by article 5(1) of the Veterinary Services Act, the Minister for Rural Affairs and the Environment has made the following rules:-

1. (1) The title of these rules is Measures for the Control of Certain Fish Diseases Rules, 2005. Title, scope and applicability.

(2) The scope of these rules is to implement the rules contained in the European Union Council Directive 93/53/EEC introducing minimum Community measures for the control of certain fish diseases.

(3) These rules define the minimum measures to be carried out in the territory of Malta for the control of the fish diseases referred to in Schedule A, lists I and II, to European Union Council Directive 91/67/EEC.

2. (1) For the purpose of these rules – Definitions.

“farm suspected of being infected” means a farm containing fish suspected of being infected;

“fish suspected of being infected” means fish showing clinical signs or post-mortem lesions or dubious reactions in laboratory tests giving rise to reasonable suspicion of the presence of a list I or list II disease;

“infected farm” means a farm containing infected fish and a farm which has been evacuated but not yet disinfected.

“infected fish” means fish in which the presence of a list I or list II disease has been officially confirmed as the result of a laboratory examination or, in the case of ISA, as the result of a clinical examination and a post-mortem examination;

“list I diseases” means fish diseases referred to in Schedule A, list I, to European Union Council Directive 91/67/EEC;

“list II diseases” means fish diseases referred to in Schedule A, list II, to European Union Council Directive 91/67/EEC;

“Member State” means a State which is a Member within the European Community;

“the Community” means the European Community as established under the Treaty establishing the European Community;

“the official service” means the Veterinary Services within Malta as provided under article 2 of the Veterinary Services Act;

“third country” means a state which is not a Member within the European Community.

(2) The definitions laid down in Article 2 of European Union Council Directive 91/67/EEC shall apply as necessary.

CHAPTER I

General Provisions

Fish susceptible to list I or list II diseases.

3. (1) All farms rearing or keeping fish susceptible to list I or list II diseases shall-

(a) be registered by the official service; this registration must be kept constantly up to date;

(b) keep a record of:

(a) live fish, eggs and gametes entering the farm, containing all information relating to their delivery, their number or weight, their size, their source and their suppliers;

(b) live fish, eggs and gametes leaving the farm, containing all information relating to their dispatch, their number or weight, their size and destination;

(c) observed mortality:

Provided that this record, which shall be open to scrutiny by the official service whenever the latter so requests, must be regularly updated and shall be kept for four years.

4. It is compulsory for the suspected presence of any of the list I and list II diseases to be notified as soon as possible to the official service.

Notification in case of suspected presence of disease.

CHAPTER II

Control Measures for List I Diseases

5. (1) When fish on a farm are suspected of being infected with a list I disease, the official service shall immediately activate official investigation arrangements to confirm or rule out the presence of the disease, including clinical examination; in particular, it must take, or have taken, the samples necessary for laboratory examination.

Measures to be taken in case of suspected presence of list I disease.

(2) As soon as the suspected presence of the disease is notified, the official service shall have the farm placed under official surveillance and shall in particular require that:

(a) an official census be made of all species and categories of fish and that, in respect of each of these, the number of fish already dead, infected or suspected of being infected or contaminated be recorded; the census must be kept up to date by the owner or keeper to take account of the increase in the population or new mortality observed during the period of suspected infection; the information in the census must be produced on request and may be checked at each inspection;

(b) no fish, whether alive or dead, or eggs or gametes enter or leave the farm without the authorization of the official service;

(c) the disposal of dead fish or their offal be carried out under the supervision of the official service;

(d) the entry or exit of feedingstuffs, utensils, objects or other substances such as waste, liable to transmit disease must be subject, if necessary, to authorization by the official service, which shall lay down the conditions required to prevent the spread of the pathogen;

(e) the movement of persons to or from the farm be made subject to authorization by the official service;

(f) the entry or exit of vehicles to or from the farm be made subject to authorization by the official service, which shall lay down the conditions required to prevent the spread of the pathogen;

(g) appropriate means of disinfection be used at the entrances and exits of the farm;

(h) an epizootic investigation be carried out in accordance with rule 8 (1);

(i) all of the farms situated in the same water catchment area or coastal area be placed under official surveillance, and no fish, eggs or gametes leave these farms without the authorization of the official service:

Provided that in the case of extensive water catchment areas or coastal areas, the official service may decide to limit this measure to a less extensive area close to the farm suspected of being infected, if it considers that this area affords maximum guarantees for the prevention of the spread of the disease:

Provided further that, if the necessity arises, the official services of neighbouring Member States or third countries must be informed of the suspected case; in that event, the official services of the Member States involved shall take appropriate action to apply the measures laid down in this rule.

Where necessary, specific measures may be taken in accordance with the relevant procedure of the European Community.

(3) Until such time as the official measures laid down in sub-rule (2) are enforced, the owner or keeper of any fish in which disease is suspected shall take every appropriate measure to ensure compliance with sub-rule (2), except for (h) and (i) thereof.

(4) The measures referred to in sub-rule (2) shall not be withdrawn until the suspicion of disease has been officially ruled out.

Measures to be taken when presence of list I disease is confirmed.

6. As soon as the presence of a list I disease has been officially confirmed, the official service shall order that, in addition to the measures listed in rule 5 (2), of the following measures be applied:

(a) in an infected farm:

(i) all fish shall be withdrawn in accordance with a scheme established by the official service and approved by the Commission in accordance with the relevant procedure of the European Community;

(ii) in the case of inland farms all pools must be drained for the purposes of cleaning and disinfection;

(iii) all eggs and gametes, dead fish and fish showing clinical signs of disease shall be regarded as high-risk material and must be destroyed under the supervision of the official service, in accordance with European Union Council Directive 90/667/EEC;

(iv) all live fish shall either be killed and destroyed under the supervision of the official service in accordance with European Union Council Directive 90/667/EEC, or else, in the case of fish which have reached commercial size and show no clinical sign of disease, be slaughtered under the supervision of the official service for marketing or processing for human consumption:

Provided that in the latter case, the official service shall ensure that the fish are immediately slaughtered and gutted, that these operations are carried out in conditions such as to prevent the spread of pathogens, that the fish waste and offal are regarded as highrisk material and are submitted to a treatment to destroy pathogens in accordance with European Union Council Directive 90/667/EEC and that the used water is submitted to a treatment which inactivates any pathogens it may contain;

(v) after removal of the fish, eggs and gametes, ponds, equipment and any material liable to be contaminated must be cleaned and disinfected as soon as possible following the instructions established by the official service in such a way as to eliminate any risk of the agent of the disease spreading or surviving. The procedures for cleaning and disinfecting an infected farm shall be determined in accordance with the relevant procedure of the European Community;

(vi) any substances which might be contaminated, referred to in rule 5 (2) (d), must be destroyed or treated in such a way as to ensure the destruction of any pathogen present;

(vii) an epizootic investigation must be carried out in accordance with rule 8 (1) and the provisions of rule 8 (4) must be applied; this investigation must include the taking of samples for laboratory examination;

(b) all farms situated in the water catchment area or in the coastal zone in which the infected farm is situated shall undergo health inspections. If these inspections reveal positive cases, the measures provided for under paragraph (a) of this rule shall be applied;

(c) the repopulation of the farm shall be authorized by the official service following satisfactory inspection of the cleaning and disinfection operations and at the end of a period deemed adequate by the official service to ensure eradication of the pathogen, and of other possible infections in the same water catchment area;

(d) if application of the measures laid down under paragraphs (a), (b), (c) and (d) of rule 5 (2) requires the cooperation of the official services of other Member States, the official services of the Member States concerned shall collaborate to ensure compliance with the measures laid down in this rule.

Where necessary, appropriate additional measures shall be adopted in accordance with the relevant procedure of the European Community.

Fish from the wild or fish in lakes, ponds and other installations.

7. (1) Where fish from the wild and not belonging to any farm or fish in lakes, ponds or other installations intended for angling or holding ornamental fish are infected or suspected of being infected, appropriate measures shall be taken by the official service.

(2) The official service shall inform the Commission and the other Member States of the measures they have taken.

Epizootic investigation.

8. (1) The epizootic investigation shall deal with:

(a) the likely length of time during which the disease may have existed on the farm before being notified or suspected;

(b) the possible origin of the disease on the farm and the identification of other farms on which there are eggs and gametes and fish of susceptible species which may have become infected;

(c) the movement of fish, eggs or gametes, vehicles or substances and persons likely to have carried the agent of the disease to or from the farms in question;

(d) the possible existence of carriers of the disease, and their distribution.

(2) If the epizootic investigation reveals that the disease could have been introduced from another water catchment area or another coastal area, or could have been transferred to another water catchment area or another coastal area as a result of a contact arising from the movement of fish, eggs or gametes, animals, vehicles or persons, or in any other way, the farms belonging to such water catchment areas and coastal areas shall be considered suspect and the measures laid down in rule 5 shall apply. If the presence of the disease is confirmed, the measures laid down in rule 6 shall apply.

(3) If the epizootic investigation reveals that the cooperation of the official services of other Member States is required, the official service of Malta shall take all necessary measures to ensure compliance with the provisions of these rules.

(4) A crisis unit shall be established by the official service in order to provide full coordination of all measures necessary to ensure eradication of the disease as quickly as possible and for the purpose of carrying out the epizootic investigation:

Provided that the general rules concerning national crisis unit in the territory of Malta in accordance with the requirements of the European Community.

CHAPTER III

Control Measures for List II Diseases

9. (1) Where a list II disease is suspected and/or confirmed in an approved zone or on an approved farm situated in a non-approved zone, an epizootic investigation shall be carried out in accordance with rule 8. In the case where Malta wishes to regain its status defined in accordance with European Union Council Directive 91/67/EEC, Malta must comply with the provisions of Schedules B and C to that Directive.

Epizootic
investigation.

(2) If the epizootic investigation reveals that the disease could have been introduced from an approved zone or from another approved farm, or could have been transferred to another approved farm as a result of the movement of fish, eggs or gametes, vehicles or persons, or in any other way, those zones or farms shall be considered suspect and the appropriate measures shall apply.

(3) The official service may, however, authorize the fattening of fish to be slaughtered until they reach commercial size.

Non-approved farm
in a non-approved
zone.

10. (1) Where a non-approved farm situated in a non-approved zone contains fish suspected of being infected with a list II disease, the official service shall:

(a) immediately sets in motion official means of investigation to confirm or rule out the presence of the disease including, where necessary, the taking of samples for examination in an approved laboratory;

(b) carries out or causes to be carried out an official census of the infected farms, this census being regularly updated;

(c) places, or causes to be placed, the infected farms under official supervision, in order to ensure that, by way of derogation from Article 3 (1) (c) of European Union Council Directive 91/67/EEC, the only movements authorized from infected farms are live fish or eggs or gametes intended either for other farms infected by the same disease or for slaughter for human consumption.

(2) For a fixed period, an optional or compulsory programme for the eradication of list II diseases in non-approved farms or in nonapproved zones may be set up in the territory of Malta, under the supervision of the official service and subject to the following provisions:

(a) during this period, the introduction into a zone or farm subject to such a programme of live fish, eggs or gametes from infected farms or farms of unknown health status shall be forbidden;

(b) these programmes, which will be set up on the basis of general criteria determined by the European Community, and will be submitted to the Commission for scrutiny, and approved and where necessary amended in accordance with the relevant procedure of the European Community.

CHAPTER IV

Final Provisions

Sampling and
laboratory testing.

11. (1) Sampling and laboratory testing for the presence of list I and list II diseases shall be carried out using the methods established in accordance with Article 15 of European Union Council Directive 91/67/EEC.

(2) Testing for the presence of disease or pathogens shall be carried out by a laboratory approved by the official service. Laboratory testing shall, if necessary and especially on the first appearance of the disease, identify the type, sub-type or the variant of the relevant pathogen, which must be confirmed by the national reference laboratory and may be confirmed, if necessary, by the Community reference laboratory on fish diseases.

12. (1) A national reference laboratory shall be designated in Malta, with facilities and expert personnel enabling it to show at all times, and especially when the disease in question first appears, the type, sub-type and variant of the relevant pathogen and to confirm results obtained by diagnostic laboratories. National reference laboratory.

(2) The national laboratory designated for the diseases in question shall be responsible for coordinating diagnostic standards and methods, and for the use of reagents.

(3) The national laboratory designated for the diseases in question shall be responsible for coordinating the diagnostic standards and methods in Malta. To this end, they:

- (a) may provide diagnostic reagents to laboratories approved by the official service;
- (b) shall control the quality of all diagnostic reagents used in Malta;
- (c) shall periodically arrange comparative tests;
- (d) shall hold isolates of the pathogen of the disease from cases confirmed in Malta;
- (e) shall ensure confirmation of positive results obtained in diagnostic laboratories approved by the official service.

(4) By way of derogation from sub-rule (1), if a national laboratory is not designated in Malta, competent as regards the disease in question, the official service may use the services of a national laboratory with competence in the matter in another Member State.

(5) The list of national reference laboratories for fish diseases is set out in Schedule A.

Vaccination.

13. (1) Vaccination against list II diseases in approved zones, in approved farms situated in non-approved zones or in zones or farms which have already begun the approval procedures laid down by European Union Council Directive 91/67/EEC and against list I diseases shall be forbidden.

(2) By way of derogation, vaccination may be authorised in the case of an outbreak of list I diseases provided the procedures for vaccination are specified in the approved contingency plans in accordance with rule 15 and account is taken of the criteria set out in Schedule D.

Contingency plan.

14. (1) The official service shall draw up a contingency plan specifying how it will implement the measures laid down in these rules in the event of an outbreak of a list I disease. This plan must allow access to facilities, equipment, personnel and all other appropriate structures necessary for the rapid and efficient eradication of the outbreak.

(2) The general criteria to be applied for drawing up those plans are set out in Schedule C:

Provided that the official service may confine itself to the application of the criteria specific to the diseases concerned, where the general criteria have already been adopted in the context of the submission of plans relating to the application of measures for the control of another disease. Those criteria may be amended or supplemented, taking into account the specific nature of the disease and in accordance with the requirements of the European Community.

(3) Plans drawn up in accordance with the criteria set out in Schedule C shall be submitted to the Commission.

(4) The plans shall be examined by the Commission in order to determine whether they permit the desired objective to be attained and shall suggest to the official service any amendments required, in particular to ensure that they are compatible with the plans of the other Member States.

(5) The plans shall be approved by the Commission and amended, if necessary, in accordance with the relevant procedure of the European Community:

Provided that the plans may subsequently be amended or supplemented, in accordance with the same procedure, to take into account developments in the situation.

15. Commission experts may, in collaboration with the official service, and in so far as is necessary to ensure uniform application of these rules, make on-the-spot checks in Malta, as follows:

On-the-spot checks
by Commission
experts.

(a) they may check a representative percentage of holdings to see whether the official service is checking that these holdings are fulfilling the requirements of these rules;

(b) the official service shall be informed by the Commission of the result of the checks carried out;

(c) when a check is being carried out, the official service shall give all the necessary assistance to the experts in carrying out their duties.

SCHEDULE A

NATIONAL REFERENCE LABORATORIES FOR FISH DISEASES

Belgium: CODA — Centrum voor Onderzoek in Diergeneeskunde en Agrochemie
CERVA — Centre d'étude et de recherches vétérinaires et agrochimiques
Groeselenberg 99 B-1180 Brussel/Bruxelles.

Czech Republic: Výzkumný ústav veterinárního lékařství Hudcova 70 621 32 Brno-Medlánky.

Denmark: Statens Veterinære Serumlaboratorium Fødevareministeriet Høngevej 2 DK-8200 Århus N.

Germany: Bundesforschungsanstalt für Viruskrankheiten der Tiere Boddenblick 5a D-17498 Insel Riems.

Estonia: Veterinaar- ja Toidulaboratoorium Väike-Paala 3 11415 Tallinn.

Greece: Laboratory of Fish Pathology and Bio-Pathology of Aquatic Organisms Centre of Athens
Veterinary Institutes, Institute of Infectious and Parasitic Diseases 25 Neapoleos ST. GR-153 10 Ag.
Paraskevi Attiki.

Spain: Laboratorio Central de Veterinaria de Algete Madrid.

France: Agence française de sécurité sanitaire des aliments (AFSSA) Laboratoire d'études et de recherches
en pathologie des poissons (LERPP) Technopôle Brest Iroise — BP 70 F-29280 Plouzane.

Ireland: Fisheries Research Centre Abbotstown Castleknock Dublin 15 Ireland.

Italy: Istituto zooprofilattico sperimentale delle Venezie Via Romea 14/A I-35020 Legnaro, Padova.

Cyprus: *Εργαστήριο Αναφοράς για τις Ασθένειες των Ζώων, Κτηνιατρικές Υπηρεσίες*, 1417 Λευκωσία
National Reference Laboratory for Animal Health Veterinary Services CY-1417 Nicosia.

Latvia: Valsts veterinārmedicīnas diagnostikas centrs Leļupes iela 3 LV-1076 Rīga.

Lithuania: Nacionalinė veterinarijos laboratorija J. Kairiūkšėio g. 10 LT-2021 Vilnius.

Luxembourg: CODA — Centrum voor Onderzoek in Diergeneeskunde en Agrochemie
CERVA — Centre d'étude et de recherches vétérinaires et agrochimiques
Groeselenberg 99 B-1180 Brussel/Bruxelles.

Hungary: Országos Állategészségügyi Intézet (OÁI), Pf. 2. Tábornok u. 2. HU-1581 Budapest.

Malta: Istituto Zooprofilattico Sperimentale delle Venezie Legnaro (PD) Italy.

Netherlands: Fish Diseases Laboratory ID-Lelystad Institute for Animal Science and Health Edelhertweg
15PO Box 65 8200 AB Lelystad Nederland.

Austria: Institut für Hydrobiologie, Fisch- und Bienenkunde Veterinärmedizinische Universität Wien
Veterinärplatz 1 A-1210 Wien.

Poland: Laboratorium Zakładu Chorób Ryb Państwowego Instytutu Weterynaryjnego Al. Partyzantów 57
PL-24-100 Puławy.

Portugal: Laboratório Nacional de Investigação Veterinária Estrada de Benfica 701 P-1500 Lisboa.

Slovenia: Nacionalni veterinarski inštitut, Gerbičeva 60 SI-1000 Ljubljana.

Slovakia: Štátny veterinárny a potravinový ústav Janoškova 1611/58 026 80 SK-Dolný Kubín.

Finland: Eläinlääkintä- ja elintarvikelaitos (EELA) PL 368 FIN-00231 Helsinki.

Sweden: Statens Veterinärmedicinska Anstalt (SVA) S-751 89 Uppsala.

United Kingdom: CEFAS Weymouth Laboratory Barrack Road Weymouth DT4 8UB United Kingdom.
The Marine Laboratory PO box 101 Victoria Road Aberdeen AB9 8DB United Kingdom.

B 5042

SCHEDULE B

COMMUNITY REFERENCE LABORATORY FOR FISH DISEASES

Statens Veterinære Serumlaboratorium
Landbrugsministeriet
Hangøvej 2
8200 Aarhus N
Denmark.

SCHEDULE C

MINIMUM CRITERIA FOR CONTINGENCY PLANS

Contingency plans shall meet at least the following criteria:

1. the establishment of a national crisis centre which shall coordinate all control measures in the Member State concerned;
2. a list shall be provided of local disease control centres with adequate facilities to coordinate the disease control measures at a local level;
3. detailed information shall be given on the staff involved in control measures, their skills and their responsibilities;
4. each local disease control centre must be able to contact rapidly persons/organizations which are directly or indirectly involved in an outbreak;
5. equipment and materials shall be available to carry out the disease control measures properly;
6. detailed instructions shall be provided on action to be taken on suspicion and confirmation of infection or contamination;
7. training programmes shall be established to maintain and develop skills in field and administrative procedures;
8. where appropriate, diagnostic laboratories must have facilities for postmortem examination, the necessary capacity for serology, histology, etc., and must maintain the skills for rapid diagnosis (to this end, arrangements must be made for rapid transportation of samples);
9. provisions shall be adopted to ensure the legal powers necessary for the implementation of the contingency plans.

SCHEDULE D

CRITERIA FOR VACCINATION PROGRAMMES

Vaccination programmes must contain at least the following information:

1. The nature of the disease calling for a request to be made to vaccinate.
2. Information shall be supplied on the coastal and mainland areas, the sites and farms in which vaccination may be carried out: under no circumstances may vaccination be conducted beyond the limits of the infected area and, if necessary, the buffer zone established around the infected area.
3. Detailed information on the vaccine to be used, including the type(s) of vaccine which may be used.
4. Detailed information on the conditions for use, frequency of vaccination and the limits on use of the vaccine (which fish, which cages, etc.).
5. The criteria for ceasing vaccination.
6. Provisions shall be adopted to ensure that a log is kept of past vaccinations (dates, sites and farms in which vaccination has been conducted, the establishment of a buffer zone, etc.).
7. Measures shall be taken for fish movements to be limited within the vaccination area so as to guarantee that fish can leave the vaccination area only if they are to be killed for human consumption, or if necessary to be destroyed.
8. Any other necessary provisions required for vaccination.