

**L.N. 316 of 2005**

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

**Bivalve Molluscs (Minimum Measures for the  
Control of 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, with the concurrence of the Prime Minister and Minister of Finance, made the following rules:-

1. (1) The title of these rules is Bivalve Molluscs (Minimum Measures for the Control of Diseases) Rules, 2005. Title, scope and definitions.

(2) The scope of these rules is to implement the rules found under European Union Council Directive 95/70/EEC on the Introduction of Minimum European Community Measures for the Control of certain Diseases affecting Bivalve Molluscs, and in accordance with article 5 (1) of the Veterinary Services Act.

(3) These rules establish minimum measures for the control of the diseases affecting bivalve molluscs referred to in these rules.

(4) For the purposes of these rules, the definitions laid down in Article 2 of European Union Council Directive 91/67/EEC and Article 2 of European Union Council Directive 91/492/EEC shall apply as necessary.

(5) In addition, 'observed abnormal mortality' shall mean sudden mortality affecting approximately 15 % of stocks and occurring over a short period between two inspections (confirmed within 15 days). In hatchery a mortality shall be considered abnormal when the farmer cannot obtain larvae during a period which included successive spawns from different brood-stocks. In nursery a mortality shall be considered abnormal when a sudden sizeable mortality occurs in a short time on a number of tubes.

2. (1) All farms rearing bivalve molluscs in Malta shall be registered by the official service. Such registration must be kept constantly up to date. Registration and records to be kept by bivalve molluscs farms.

(2) All farms rearing bivalve molluscs in Malta shall keep a record of:

(a) live bivalve molluscs entering the farm, containing all information relating to their delivery, their number or weight, their size and their origin;

(b) bivalve molluscs leaving the farm for re-immersion, containing all information relating to their dispatch, their number or weight, their size and destination;

(c) observed abnormal mortality. This record, which shall be open to scrutiny by the official service at all times, on demand, shall be updated regularly and kept for four years.

Monitoring and  
sampling in bivalve  
molluscs farms.

**3.** (1) A monitoring and sampling programme shall be applied in bivalve mollusc farms, farming areas and harvested natural beds in order to observe whether there is an abnormal mortality and keep track of the health situation of stocks. In addition, the official service may apply the above programme to purification centres and storage tanks which discharge water into the sea. If, during application of this programme, any abnormal mortality is observed, or if the official service has information giving it reason to suspect the presence of diseases, the following measures shall be taken:

(a) a list shall be drawn up of the sites where the diseases referred to in Schedule A, list II to European Union Council Directive 91/67/EEC are present, provided that such diseases are not the subject of a programme approved pursuant to the said European Union Council Directive,

(b) a list shall be drawn up of the sites at which abnormal mortality has been observed as a result of the presence of the diseases referred to in Schedule B, or on which the official service has information giving it reason to suspect the presence of diseases,

(c) monitoring of the evolution and geographical spread of the diseases referred to in sub-rule (1) (a) and (b) hereof.

(2) The detailed rules for implementing this rule, and inter alia the rules to be applied for establishing the programme referred to in sub-rule 1 of this rule, particularly as regards the frequency and timetable of monitoring, procedures for taking samples (statistically representative volume) and methods of diagnosis, shall be adopted, if necessary, in accordance with the requirements of the European Community and under the procedure provided for in article 5(1) of the Veterinary Services Act.

4. (1) The suspected presence of any diseases referred to in rule 3 and any abnormal mortality rate observed in bivalve molluscs in farms, in farming areas or in harvested natural beds or in purification centres or storage tanks which discharge water into the sea shall be notified as soon as possible to the official service by the shellfish-farmers or any other person who has made such observations.

Measures to be taken in the event of suspicion of diseases.

(2) In the case referred to in sub-rule 5 (1), the official service shall ensure that:

(a) samples are taken for examination in an approved laboratory;

(b) pending the result of the examination referred to in paragraph (a), no molluscs leave the affected farm, farming area or harvested natural beds or purification centres or storage tanks which discharge water into the sea for relaying or re-immersion in another farm or in the aquatic environment, unless authorized by the official service.

(3) If the examination referred to in sub-rule 5(2)(a) fails to demonstrate the presence of a pathogen, the restrictions referred to in sub-rule 5(2)(b) shall be lifted.

(4) (a) If the examination referred to in sub-rule 5(2) shows the presence of a pathogen causing the observed abnormal mortality capable of being the cause of that mortality, or of a pathogen of one of the diseases referred to in rule 4, an epizootic investigation must be carried out by the official service in order to determine the possible means of contamination and to investigate whether molluscs have left the farm, the farming area or the harvested natural beds for relaying or re-immersion elsewhere during the period preceding observation of the abnormal mortality.

(b) If the epizootic investigation shows that the disease has been introduced into one or more farms, farming areas or harvested natural beds as a result *inter alia* of molluscs being moved, the provisions of sub-rule 5(2) shall apply. However, by way of derogation from article 3 (1) (c) of European Union Council Directive 91/67/EEC, the official service may, within its territory, authorize the movement of live bivalve molluscs to other farms, farming areas or harvested natural beds which are infected with the same disease.

(c) If necessary, further appropriate measures may be decided by the official service in accordance with the requirements of

the European Community and under the procedure laid down in article 5(1) of the Veterinary Services Act.

(5) The official service shall ensure that the European Commission and the other European Union Member States are immediately informed, in accordance with the current European Community procedures, of any cases of abnormal mortality rates observed involving a pathogen, of any measures taken to analyse and control the situation and of the cause of the mortality.

Sampling and testing.

**5.** (1) Sampling and laboratory testing for the determination of the cause of abnormal mortality of bivalve molluscs shall be carried out using the methods established by the European Community.

(2) A national reference laboratory for Malta is designated in Schedule A of these rules, with facilities and expert personnel enabling it to carry out the testing referred to in sub-rule 6(1).

(3) National reference laboratories shall cooperate with the European Community reference laboratory for molluscs diseases.

Spot-checks by European Commission experts.

**6.** (1) European Commission experts may, to the extent necessary to ensure uniform application of European Union Council Directive 95/70/EEC, carry out on-the-spot checks. In so doing, they may carry out random, non-discriminatory checks to ensure that the official service in charge of molluscs diseases is monitoring compliance with the said Directive.

(2) The checks referred to in sub-rule (1) shall be carried out in collaboration with the official service in charge of molluscs diseases in Malta.

(3) The official service in charge of molluscs diseases in Malta shall provide the experts with any assistance they require to accomplish their task.

**SCHEDULE A**

**MALTA NATIONAL REFERENCE LABORATORY  
FOR DISEASES OF BIVALVE MOLLUSCS**

*ISTITUTO ZOOPROFILATTICO SPERIMENTALE DELLE VENEZIE,*  
Area Ittiopatologia Laboratorio Patologia Molluschi,  
Via della Roggia, 94  
I-33030 Basaldella di Campoformido (UD)  
Italy.

**SCHEDULE B****DISEASES OF BIVALVE MOLLUSCS AND THE SUSCEPTIBLE HOST SPECIES**

<b>Disease</b>	<b>Pathogen</b>	<b>Susceptible Host Species</b>
Bonamiosis	<i>Bonamia exitiosus</i>	<i>Tiostrea chilensis</i> and <i>Ostrea angasi</i>
	<i>Mikrocytos roughleyi</i>	<i>Saccostrea (Crassostrea) Commercialis</i>
Marteiliosis	<i>Marteilia sydneyi</i>	Marteiliosis <i>Saccostrea (Crassostrea) commercialis</i>
Microcytosis	<i>Mikrocytos mackini</i>	<i>Crassostrea gigas</i> ; <i>C. virginica</i> ; <i>Ostrea edulis</i> ; <i>O. conchaphila</i>
Perkinsosis	<i>Perkinsus marinus</i>	<i>Crassostrea virginica</i> and <i>C. gigas</i>
	<i>Perkinsus olseni/ atlanticus</i>	<i>Haliotis ruber</i> ; <i>H. cyclobates</i> ; <i>H. scalaris</i> ; <i>H. laevigata</i> ; <i>Ruditapes philippinarum</i> and <i>R. decussates</i>
MSX disease	<i>Haplosporidium nelsoni</i>	<i>Crassostrea virginica</i> and <i>C. gigas</i>
SSO disease	<i>Haplosporidium costale</i>	<i>Crassostrea virginica</i>
Withering syndrome of abalones	<i>Candidatus Xenohaliotis californiensis</i>	Members of the genus <i>Haliotis</i> including black abalone ( <i>H. cracherodii</i> ), red abalone ( <i>H. rufescens</i> ), pink abalone ( <i>H. corrugata</i> ), green abalone ( <i>H. fulgens</i> ) and white abalone ( <i>H. sorenseni</i> )

*Note:* Susceptible host species also includes any other species specified, for the pathogen in question, in the International Office of Epizooties' (OIE) most recent edition of the International Aquatic Animal Health Code.