

L.N. 381 of 2012

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

**Control and Eradication of the Bluetongue Disease
(Amendment) Rules, 2012**

IN EXERCISE of the powers conferred by article 5 of the Veterinary Services Act, the Minister for Resources and Rural Affairs has made the following rules:-

Citation.

S.L. 437.80

Amends rule 2
of the principal
rules.

1. The title of these rules is the Control and Eradication of the Bluetongue Disease (Amendment) Rules, 2012 and these regulations shall be read and construed as one with the Control and Eradication of the Bluetongue Disease Rules, hereinafter referred to as "the principal rules".

2. Rule 2 of the principal rules shall be amended as follows:

(a) immediately before the definition "animal", there shall be added the following new definition:

Cap. 437. " "the Act" means the Veterinary Services Act;"

(b) in the definition "animal" for the words "in accordance with the procedure laid down in rule 20(2)" there shall be substituted the words "in accordance with the procedure provided in the definition "Standing Committee on the Food Chain and Animal Health" under this rule";

(c) immediately after the definition "animal" there shall be added the following new definitions:

" "bluetongue disease" means a non-contagious insect-borne viral disease of ruminants, mainly sheep and less frequently cattle, such as goats, buffalos, and antelope, caused by the bluetongue virus which is transmitted by an insect of the species *Culicoides imicola* and any other *Culicoides* insects, hereinafter referred to as "vectors";

"the Commission" means the European Commission;

"the Community" means the European Community

as established by the Treaty on the European Union as amended by subsequent treaties;";

(d) the definition "the competent authority" shall be substituted by the following new definition:

" "the competent authority" means the Department of Veterinary Services in Malta as established by article 2 of the Act;";

(e) immediately after the definition "holding" there shall be added the following new definitions:

" "intra-Community trade" means trade between Member States in animals and their products, a business or occupation to make profit or gain, particularly in retail or wholesale sales and includes dealings in a particular business activity;

"live attenuated vaccines" means vaccines which are produced by adapting bluetongue virus field isolate through serial passages in tissue culture or in embryonated hens' eggs;

"Member State" means a state which is a member of the European Union;

"national crisis unit" means an animal disease crises management unit or a facility which provides animal disease analysis and information, and which deploys or sets up international resources to prevent and contain dangerous animal diseases. Such unit aims at:

(a) strengthening of disease intelligence and emergency preparedness;

(b) supporting broad awareness creation and risk communication;

(c) analyzing the social and economic consequences of both the disease and its control;

(d) strengthening field surveillance, laboratory capabilities, global surveillance and early warning capabilities;

(e) advising the government and building capacities on disease surveillance prevention and

control programmes";

(f) immediately after the definition " "owner" or "holder" " there shall be added the following new definitions:

" "person" means any natural or legal person;

"Scientific Veterinary Committee" means a committee within the Commission which monitors matters of a scientific nature and which aim and scope is *inter alia* to:

(a) protect and raise the health status and condition of animals in the Community, in particular food-producing animals, while promoting intra-Community trade and imports of animals and animal products in accordance with the appropriate health and zootechnical standards' improvement and technology of animal husbandry and international obligations;

(b) analyse scientific and technical questions concerning all aspects of animal health, hygiene, and animal diseases;

"Standing Committee on the Food Chain and Animal Health" or "the Committee" means a Committee made up of the representatives of Member States, named committee members, who assist and consult the Commission by delivering an Opinion regarding safety measures with respect to animal health issues to be then formally adopted by the Commission in accordance with the appropriate procedure. Such committee procedure covers the entire food supply chain, ranging from animal health issues on the farm to the product which arrives to the final consumer, therefore significantly enhancing its ability to target risks to health wherever they arise in the production of food"; and

(g) in the definition "vector" for the words "according to the procedure laid down in rule 20(2)" there shall be substituted the words "in accordance with the procedure provided in the definition "Standing Committee on the Food Chain and Animal Health" under rule 2".

3. Rule 4 of the principal rules shall be amended as follows:

Amends rule 4 of the principal rules.

- (a) in paragraph (d)(iv) of sub-rule (2) thereof, for the words "in accordance with Council Directive 90/667/EEC of the 27th November, 1990 laying down the veterinary rules for the disposal and processing of animal waste, for its placing on the market and for the prevention of pathogens in feeding stuffs of animal or fish origin, and amending Directive 90/425/EEC" there shall be substituted the words "in accordance with Regulation EC 1069/2009 laying down Health Rules as regards Animal By-products and Derived Products not Intended for Human Consumption and repealing Regulation EC 1774/2002 (Animal by-products Regulation), which provisions shall be read without prejudice to the Waste Regulations"; and
- S.L. 504.37

- (b) in sub-rule (4) thereof, for the words "according to the procedure laid down in rule 20(2)" there shall be substituted the words "in accordance with the procedure provided in the definition "Standing Committee on the Food Chain and Animal Health" under rule 2".

4. Rule 5 of the principal rules shall be substituted by the following:

Substitutes rule 5 of the principal rules.

"5. (1) The competent authority may decide to allow the use of vaccines against bluetongue provided that:

- (a) such decision is based on the result of a specific risk assessment carried out by the competent authority;

- (b) the Commission is informed before such vaccination is carried out.

(2) Whenever live attenuated vaccines are used, the competent authority shall demarcate:

- (a) a protection zone, consisting of at least the vaccination area;

- (b) a surveillance zone, consisting of a part of the Maltese territory with a depth of at least 50 kilometres extending beyond the limits of the protection zone."

B 3772

Amends rule 6
of the principal
rules.

5. Sub-rule (1) of rule 6 of the principal rules shall be amended as follows:

(a) in paragraph (b) thereof, for the words "in accordance with Directive 90/667/EEC" there shall be substituted the words "in accordance with Regulation EC 1069/2009, which provisions shall be read without prejudice to the Waste Regulations";

S.L. 504.37

(b) paragraph (d) thereof shall be substituted by the following:

"(d) implement the measures adopted in accordance with the procedure provided in the definition "Standing Committee on the Food Chain and Animal Health" under rule 2, in particular with regard to the introduction of any vaccination programme or other alternative measures;" and

(c) in paragraph (e) thereof, for the words "in accordance with the procedure laid down in rule 20(2)" there shall be substituted the words "in accordance with the procedure provided in the definition "Standing Committee on the Food Chain and Animal Health" under rule 2".

Amends rule 7
of the principal
rules.

6. The proviso to sub-rule (2) of rule 7 of the principal rules shall be substituted by the following:

"Provided that general rules concerning the national crisis unit shall be laid down according to the procedure provided in the definition "Standing Committee on the Food Chain and Animal Health" under rule 2".

Amends rule 8
of the principal
rules.

7. Rule 8 of the principal rules shall be amended as follows:

(a) in paragraph (a) of sub-rule (2) thereof, for the words "part of the Community territory" there shall be substituted the words "part of the Maltese territory";

(b) paragraph (b) of sub-rule (2) thereof shall be substituted by the following:

"(b) The surveillance zone shall consist of a part of the Maltese territory with a depth of at least 50 kilometres extending beyond the limits of the protection zone and in which no vaccination against bluetongue with live attenuated vaccines has been carried out during the

previous twelve months.";

(c) in paragraph (d) of sub-rule (2) thereof, for the words "according to the procedure laid down in rule 20(2)" there shall be substituted the words "in accordance with the procedure provided in the definition "Standing Committee on the Food Chain and Animal Health" under rule 2"; and

(d) in sub-rule (3) thereof, for the words "in accordance with the procedure laid down in rule 20(2)" there shall be substituted the words "in accordance with the procedure provided in the definition "Standing Committee on the Food Chain and Animal Health" under rule 2".

8. Sub-rule (2) of rule 10 of the principal rules shall be substituted by the following: Amends rule 10 of the principal rules.

"(2) The competent authority shall prohibit any vaccination against bluetongue using live attenuated vaccines in the surveillance zone."

9. Rule 15 of the principal rules shall be substituted by the following: Substitutes rule 15 of the principal rules.

"National
Reference
Laboratory.

15. (1) The competent authority shall designate a National Reference Laboratory responsible for carrying out the laboratory tests provided for by these rules, and shall make the details of such laboratory, and any subsequent changes thereto, available to other Member States and to the public. Detailed rules for the uniform application of this sub-rule shall be adopted in accordance with the procedure provided in the definition "Standing Committee on the Food Chain and Animal Health" under rule 2.

(2) The tasks of the national reference laboratory indicated in Annex I(A), as designated by the competent authority in accordance with sub-rule (1) are listed in Annex I(B). Such laboratory shall liaise with the Community Reference Laboratory referred to in rule 16."

10. Rule 16 of the principal rules shall be substituted by the Substitutes rule 16 of the principal rules.

B 3774

following:

"Community
Reference
Laboratory.

16. The Community Reference Laboratory for bluetongue is indicated in Annex II(A) and the tasks of such laboratory are set out in Annex II(B).".

Amends rule 17
of the principal
rules.

11. Rule 17 of the principal rules shall be amended as follows:

(a) in sub-rule (1) thereof, for the words "of the Directive 2000/75/EC transposed by these rules" there shall be substituted the words "of these rules"; and

(b) sub-rule (2) thereof shall be substituted by the following:

"(2) If the Commission carries out a check in accordance with sub-rule (1), the competent authority shall provide the experts with all the necessary assistance in the performance of their task. The general implementing provisions for this rule shall be laid down in accordance with the procedure provided in the definition "Standing Committee on the Food Chain and Animal Health" under rule 2.".

Amends rule 18
of the principal
rules.

12. Rule 18 shall be amended as follows:

(a) in sub-rule (2) thereof, for the words "this Directive" there shall be substituted the words "these rules"; and

(b) sub-rule (3) thereof shall be deleted.

Amends rules 9,
11, 12, 13 and
19 of the
principal rules.

13. In rules 9, 11, 12, 13, and 19 of the principal rules, for the words "the procedure laid down in rule 20(2)" wherever they occur, there shall be substituted the words "the procedure provided in the definition "Standing Committee on the Food Chain and Animal Health" under rule 2".

Deletes rule 20
of the principal
rules.

14. Rule 20 of the principal rules shall be deleted.

Substitutes
Annex I to the
principal rules.

15. Annex I to the principal rules shall be substituted by the following:

"Annex I

A. NATIONAL REFERENCE LABORATORY FOR
BLUETONGUE DISEASE

The National Reference Laboratory for Bluetongue disease in Malta is the National Veterinary Laboratory situated in Abattoir Street, Albertown, Marsa.

B. TASKS OF THE NATIONAL REFERENCE LABORATORY
FOR BLUETONGUE

The National Reference Laboratory for bluetongue shall be responsible for the co-ordination of the standards and diagnostic methods prescribed by the Community Reference Laboratory, the use of reagents and the testing of vaccines. To this end such National Reference Laboratory:

- (a) may supply diagnostic reagents to the Community Reference Laboratory when the latter so requests;
 - (b) shall check the quality of all the diagnostic reagents used in Malta;
 - (c) shall organise comparative tests at regular intervals;
 - (d) shall preserve isolates of the bluetongue virus taken from confirmed cases in Malta;
 - (e) shall ensure the confirmation of positive results obtained."
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