L.N. 147 of 2005

VETERINARY SERVICES ACT
(CAP. 437)

Animal Nutrition (Organisation of Official Inspections), 2005

IN exercise of the powers conferred by article 23 of the Veterinary Services Act, the Minister for Rural Affairs and the Environment has made the following rules:-

CHAPTER I

INTRODUCTORY PROVISIONS

Title and scope.

1. (1) The title of these rules is the Animal Nutrition (Organisation of Official Inspections) Rules, 2005.

(2) These rules set out the principles governing the organisation of official inspections in the field of animal nutrition.

(3) These rules shall apply without prejudice to more specific European Community legislative rules, in particular European Community customs and veterinary rules.

(4) The scope of these rules is the implementation of European Union Council Directive 95/53/EC fixing the principles governing the organization of official inspections in the field of animal nutrition.

Definitions.

2. (1) For the purposes of these rules the following definitions shall apply -

"the Commission" means the European Commission;

"the Community" means the European Community;

"documentary check" means verification of the documents accompanying a product or of any other information provided on the product;

"establishment" means any undertaking which produces or manufactures a product or which holds the product at an intermediate stage before marketing or which markets the products;

"identity check" means verification, by visual inspection only, for consistency between the documents, the labelling and the products;

"Member State" means a State which is a Member within the European Community;

"official inspection in the field of animal nutrition", hereinafter called "inspection", means an inspection by the competent authorities to check compliance with the legislative provisions laid down in –

(i) any other rules in the field of animal nutrition in which provision is made for official inspections to be carried out in accordance with the provisions of these rules,

(ii) European Union Council Directive 2002/32/EC on undesirable substances and products in animal nutrition,

(iii) European Union Council Directive 70/524/EEC concerning additives in feedingstuffs,

(iv) European Union Council Directive 79/373/EEC on the marketing of compound feedingstuffs,

(v) European Union Council Directive 82/471/EEC concerning certain products used in animal nutrition,

(vi) European Union Council Directive 93/74/EEC on feedingstuffs intended for particular nutritional purposes, and

(vii) European Union Council Directive 96/25/EC on the circulation of feed materials rules;

"physical check" means a check of the product itself, including, where appropriate, sampling and laboratory testing;

"product intended for animal nutrition" or '"product" means animal feed or any substance used in animal nutrition;

"putting into circulation" or "circulation" means the holding of any product intended for animal nutrition for the purposes of sale, including offering for sale, or any other form of transfer, whether free or not, to third parties, and the sale and other forms of transfer themselves;

"Third Country" means a State which is not a Member within the European Community;

"Veterinary Services" is the competent authority as established under article 2 of the Veterinary Services Act and for the purposes of these rules is responsible for carrying out official checks in the field of animal nutrition.

(2) The definitions given in European Community legislation relating to the field of animal nutrition shall apply where appropriate.

Criteria for the carrying out of official inspections in the field of animal nutrition.

3. (1) Inspections in the field of animal nutrition are carried out in accordance with these rules.

(2) A product shall not be excluded from appropriate inspection on the grounds that it is intended for export.

Nature and frequency of inspections in the field of animal nutrition.

4. (1) Inspections shall be carried out -

(a) at regular intervals;

(b) where non-compliance is suspected;

(c) using means proportionate to the desired objective and particularly in the light of the risks and of experience gained.

(2) Inspections shall cover all stages of production and manufacture, the intermediate stages prior to marketing, including importation, and the use of products. The Veterinary Services shall select the stage or stages most appropriate for the intended purpose of the inspection.

(3) As a general rule, inspections shall be carried out without prior warning.

(4) Inspections shall also cover uses prohibited in relation to animal nutrition.

Contingency operational plans.

5. (1) The Veterinary Services shall draw up contingency operational plans setting out measures to be implemented without delay where a product for animal nutrition has been found to pose a serious risk to human health, animal health or to the environment and specifying powers and responsibilities as well as channels for transmitting information. The Veterinary Services shall review these plans as appropriate, particularly in the light of changes in the organisation of

the inspection services and of the experience gained, including that gained in any simulation exercises.

(2) The Veterinary Services shall forward to the European Commission the contingency operational plans drawn up by them and also any amendments thereto.

(3) The Veterinary Services shall take due account of any suggestion of amendment issued by the European Commission which would help to ensure that Maltese contingency operation plans offer equivalent guarantees of efficiency as those of Member States.

CHAPTER II

IMPORTS FROM THIRD COUNTRIES

Documentary and random identity checks.

6. (1) Notwithstanding the provisions of rule 4 (1), when products are introduced into the customs territory of Malta they are subjected by the Veterinary Services to a documentary check of each batch and to random identity checks in order to verify -

(a) their nature,

(b) their origin,

(c) their geographical destination,

so as determine the customs procedure applicable to them.

(2) Where appropriate, detailed rules for the application of this rule shall be adopted in accordance with the procedure laid down in article 23 of European Union Council Directive 95/53/EEC.

Designation of entry points in Malta.

7. For the purpose of the checks provided for in rule 6, the Veterinary Services may designate particular entry points in Malta for the various types of products. To the same end it may require notice to be given to it of arrival of products at a particular entry point.

Random physical checks.

8. (1) Conformity of products will be ensured by means of random physical checks before they are marketed.

(2) Where appropriate, detailed rules for the application of this rule shall be adopted in accordance with the procedure laid down in article 23 of European Union Council Directive 95/53/EEC.

Non-compliant products imported from third countries.

9. (1) Where the checks show that products do not meet the requirements of these rules, their entry or marketing shall be prohibited and order their re-dispatch out of European Community territory shall be ordered by the Veterinary Services; it shall immediately inform the European Union Commission and Member States that it has rejected the products, indicating the infringements found.

(2) Notwithstanding sub-rule (1), Malta may authorise the carrying out, under the conditions laid down by the Veterinary Services, of one of the following operations -

(a) bringing the products into line with the requirements within a deadline to be determined, or

(b) decontamination where appropriate, or

(c) processing in any other suitable manner, or

(d) use for other purposes, or

(e) destruction of the products.

(3) The Veterinary Services shall ensure that the operations listed in sub-rule (2) do not give rise to any adverse effects on human and animal health or on the environment.

(4) The costs incurred in the measures taken in accordance with sub-rules (1) and (2) shall be borne by the authorisation holder or his representative.

Documents to be issued by the Veterinary Services.

10. (1) Where products are not marketed in Malta of which the Veterinary Services carries out the checks referred to in rule 6 and, where appropriate, a physical check, the Veterinary Services shall provide the person concerned with a document indicating the type of check carried out and its outcome. Commercial documents shall contain a reference to this document.

(2) The right of the Member State of destination to carry out random checks on products shall not be affected.

(3) A standard document and, where appropriate, detailed rules for the application of sub-rule (1) shall be adopted in accordance with the procedure laid down in article 23 of European Union Council Directive 95/53/EC.

11. (1) Where a problem likely to pose a serious risk to human or animal health or the environment appears or spreads on the territory of a third country, the European Union Commission, on its own initiative or at the request of a Member State, shall immediately depending on the gravity of the situation take the following measures, in accordance with the procedure laid down in article 23a of European Union Council Directive 95/53/EC - Emergency measures adopted regarding imports originating from a third country.

(a) suspend imports of products from all or part of the third country concerned or from one or more specific production establishments and, where appropriate, any third country of transit; and, or

(b) lay down special conditions for products intended for import from all or part of the third country concerned.

Where the Veterinary Services adopts such temporary protective measures, it shall immediately inform the Member States and the European Commission.

(2) However, where, the measures referred to in sub-rule (1) are provisionally adopted by the European Commission after informing the Veterinary Services of Malta, these measures shall be applied by Malta and, until they have not been replaced by another legal act, they shall continue to apply.

12. (1) Where necessary, on-the-spot inspections may be carried out by European Union Commission and Member States' experts in third countries to verify whether guarantees, offered by those countries, regarding the conditions for the production and putting into circulation of products can be considered as at least equivalent to those required by the European Community. On-the-spot inspections in third countries.

CHAPTER III

TRADE WITHIN THE EUROPEAN COMMUNITY

13. Products intended for dispatch to a Member State are inspected with the same care as those intended to be marketed in Malta. Inspection of products intended for dispatch to a Member State.

14. (1) The Veterinary Services shall carry out checks on establishments in order to satisfy itself that they meet their obligations under European Community legal rules and that products intended to be marketed comply with European Community requirements. Checks at source.

(2) Where there are grounds for suspecting that requirements are not being met, the Veterinary Services shall carry out the necessary checks and, if the suspicion is confirmed, take the appropriate measures.

Control at destination.

15. (1) The competent authority of the Member State of destination may, at places of destination, check the compliance of products with the provisions of rule 2 (1) (a) by means of non-discriminatory random checks. In particular, and only to the extent necessary for carrying out these random checks, the Veterinary Services may ask operators to report the arrival of the products to it. The Veterinary Services shall inform the European Commission when they avail themselves of this action.

(2) Without prejudice to sub-rule (1), where the Veterinary Services in case of transit trough Malta or at destination has information leading it to suspect an infringement, checks may also be carried out during the transport of products in the territory.

Measures to be taken in an event of non-compliance.

16. (1) If, during a check carried out at the place of destination of a consignment or during transport, the Veterinary Services establishes the non-compliance of the products with the provisions of rule 2 (1) (a), it shall take the appropriate measures and formally require the consignor, the consignee or any other person entitled to carry out, under the conditions laid down by the Veterinary Services, one of the following operations -

(a) bringing of the products into compliance within a deadline to be determined, or

(b) rendering the products harmless where appropriate, or

(c) processing in any other suitable manner, or

(d) use for other purposes, or

(e) re-dispatch to the country of origin, after informing the Veterinary Services of the country of the establishment of origin, or

(f) destruction of the products.

(2) The costs incurred in the measures taken in accordance with sub-rule (1) shall be borne by the consignor or any other person entitled, including where appropriate the consignee.

Co-operation in the event of infringements.

17. (1) In the event of the destruction, use for other purposes, re-dispatch to the country of origin or rendering harmless of the products, as provided for in rule 16 (1), Malta as the Member State of destination shall contact the Member State of dispatch without delay. If the Member State of destination fears that such measures are inadequate, it shall together with the Member State of dispatch seek ways and means of remedying the situation; if appropriate this may involve a joint on-the-spot inspection.

(2) Where the checks carried out in accordance with rule 15 show repeated irregularities, the Veterinary Services as the competent authority of the Member State of destination shall inform the European Commission and the other Member States.

(3) In the event of the destruction, use for other purposes, re-dispatch to Malta or rendering harmless of products originating from Malta, as provided for in rule 16 (1), the Veterinary Services of Malta shall take all necessary measures and notify the Member State of destination of the nature and outcome of the checks carried out, the decisions taken and the reasons for such decisions. If the Member State of destination fears that such measures are inadequate, the Veterinary Services and the Member State of destination shall seek ways and means of remedying the situation; if appropriate this may involve a joint on-the-spot inspection.

Co-operation with the European Commission in case of infringements.

18. (1) At the request of the Member State of destination or on its own initiative, taking into account the nature of the infringements established, the European Commission may -

(a) send representatives, in co-operation with the Veterinary Services and the Member State concerned, to the establishment in question,

(b) request the Member State of dispatch to intensify its checks on the products of the establishment concerned.

(2) The Member State of destination may, for its part, intensify checks at destination on products coming from the same establishment.

(3) In case of products where Malta is the Member State of dispatch, where at the request of the Member State of destination or on its own initiative, taking into account the nature of the infringements established, the European Commission sends representatives to the establishment of origin, the Veterinary Services shall afford them all the assistance necessary for carrying out their duty. Pending the

representatives' findings, the Veterinary Services must, if so requested by the European Commission, intensify checks on products coming from the establishment in question.

Safeguard clause.

19. (1) Where a problem due to a product to be used in animal nutrition, likely to pose a serious risk to human health, animal health or to the environment, appears in one or more Member States and cannot be contained satisfactorily by means of the measures taken by any Member State concerned, the Veterinary Services, acting in accordance with the procedure provided for in Article 23a of European Union Council Directive 95/53/EC, shall immediately, depending on the seriousness of the situation adopt the following measures -

(a) suspend the putting into circulation within Malta, the use in animal nutrition or exports to third countries of products from all or part of any Member State concerned or from one or more establishments situated in the territory of any Member State, or

(b) lay down special conditions for the putting into circulation in Malta, the use in animal nutrition or exports to third countries of products from all or part of any Member State concerned or from one or more establishments situated in territory of Member States.

(2) Where the Veterinary Services adopts such temporary protective measures referred to in sub-rule (1), it shall immediately inform the Member States and the European Commission.

(3) However, where the measures referred to in sub-rule (1) are adopted by the European Commission after informing the Veterinary Services of Malta these measures shall be applied by Malta.

Inspections on holdings.

20. The Veterinary Services shall have access to places where agricultural production is carried on and where the products are manufactured or used in order to carry out the prescribed checks.

CHAPTER III

INFORMATION SYSTEM FOR HAZARDS FROM FEEDING STUFFS

Obligations of persons responsible for establishments regarding hazards.

21. (1) The persons responsible for the establishments must immediately inform the Veterinary Services if they have evidence that a consignment of products for animal nutrition which they have brought

into the territory from a third country or put into circulation, and which they are holding or own -

(a) exceeds the maximum levels laid down in Section A of Annex II to European Union Council Directive 2002/32/EC beyond which the product must not be fed as such to animals or mixed with other products for animal nutrition, or

(b) does not comply with one of the other provisions referred to in rule 2 (1) (a) to these rules and, owing to that non-compliance and, in view of the purpose for which it is intended, poses a serious risk to human health, animal health or to the environment.

(2) The persons responsible for the establishments shall provide all details enabling precise identification of the relevant product or consignment of products and as full as possible a description of the risk posed by the product or products concerned, as well as all available information useful in tracing the product or products.

(3) The persons responsible for the establishments the Veterinary Services of action taken to prevent risks to human health, animal health or to the environment, describing that action.

(4) The Veterinary Services shall lay down the same information requirements concerning the risks posed by products for animal nutrition for persons carrying out health monitoring of holdings such as those referred to in article 10 of Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products, and for persons responsible for laboratories carrying out analyses.

(5) Where appropriate, the Veterinary Services shall apply the provisions of rules 9, 14 or 16.

Measures to be taken on the basis of risk assessment in the event of hazards.

22. (1) Where the Veterinary Services of Malta have information indicating, on the basis of the risk assessment factors available, that a consignment of products for animal nutrition poses a serious risk to human health, animal health or to the environment they shall verify the information received and, where appropriate, ensure that the necessary measures are taken so that the consignment is not used in animal nutrition, put the consignment under restriction and investigate immediately -

(a) the nature of the hazard and where appropriate the level of undesirable substances,

(b) the possible origin of the undesirable substances or of the hazard, in order to assess the risk more closely.

(2) Where appropriate, the risk assessment shall be extended to other consignments of the same product or to other products in the feed or food chain which might contain undesirable substances or in respect of which such a hazard might exist, taking into account any admixture of the undesirable substances in other products for animal nutrition and possible recycling of dangerous products into the feed chain.

(3) Where the existence of a serious risk is confirmed in accordance with sub-rule (1), the Veterinary Services shall ensure that the final destination of the consignment containing undesirable substances, including possible decontamination, further action to render the products harmless, reprocessing or destruction, cannot have harmful effects on human or animal health or on the environment and where it is possible that the undesirable substances or the risk of such substances being present has extended to other consignments or to the feed or food chain.

(4) Subject to sub-rule (3) the Veterinary Services shall immediately identify and put under control other consignments of the products deemed hazardous and also, where appropriate, identify live animals fed with hazardous products and implement the measures provided for in European Union Council Directive 96/23/EC or in other relevant veterinary provisions relating to animal health or to the food safety of products of animal origin ensuring co-ordination between the relevant control services, in order to avoid the hazardous products being put into circulation and to ensure the enforcement of recall procedures for the products already in circulation.

Rapid alert system.

23. (1) Where the Veterinary Services finds that a product for animal nutrition which has been put into circulation in Malta and in that of Member States, or a product originating in a third country which has been brought into the territory in order to be put into circulation in Malta or in the Member States -

(a) exceeds the maximum levels laid down in Section A of Annex II to Council Directive 2002/32/EC beyond which the product must not be fed as such to animals or mixed with other products for animal nutrition, or

(b) does not comply with one of the other provisions referred to in rule 2 (1) (a) to these rules and, owing to that non-compliance and the purpose for which it is intended, poses a serious risk to

human health, animal health or to the environment, the Veterinary Services shall forthwith alert the European Commission by way of notification.

(2) The Veterinary Services provide sufficient information to identify the products concerned, trace and put them under control and, where appropriate, the live animals fed with them, and shall specify safeguard measures envisaged or already taken, in order to enable the European Commission properly to inform the Member States.

(3) The Veterinary Services shall immediately alert the European Commission of any follow up measure taken in respect of the notified hazards, including information concerning the end of the risk situation.

(4) The Veterinary Services shall participate to the setting up and operational phases of a system for rapid exchange of information under conditions set in accordance with the procedure provided for in article 23 of European Union Council Directive 95/53/EC, with a view to expediting transmission and dissemination of the alerts referred to in sub-rule (1) and the information referred to in rule 9 (1).

CHAPTER IV

GENERAL PROVISIONS AND INSPECTIONS

Considerations when carrying out inspections.

24. (1) In Malta, inspections shall be carried out in such a way that delays in the delivery of products are minimised and that inspections do not result in unjustified obstacles to the marketing thereof.

(2) Officials responsible for inspection are subject to professional confidentiality:

Provided that, this provision shall not affect the possibility for the Veterinary Services of disseminating information necessary to prevent a serious risk to human health, animal health or to the environment.

On-the-spot inspections by European Commission experts.

25. (1) Experts from the European Commission may, make on-the-spot inspections in co-operation with the Veterinary Services of establishments situated in Malta.

(2) The Veterinary Services shall afford the experts referred to in sub-rule (1) all the assistance necessary for carrying out their duties.

Provisions applicable to official sampling for purpose of analysis.

26. (1) Where products are sampled for the purpose of analysis, the Veterinary Services shall adopt the provisions necessary -

(a) to ensure that those subject to checks are entitled to a second opinion,

(b) to ensure that officially sealed reference samples are preserved.

(2) The Veterinary Services shall draw up a list of laboratories responsible for carrying out analyses, and shall ensure that such laboratories are designated on account of their capabilities.

(3) Sampling and analysis are carried out in accordance with European Community rules.

(4) In the absence of European Community rules and methods, the Veterinary Services shall take all necessary steps to satisfy itself that inspections are carried out -

(a) in accordance with standards recognised by international bodies;

(b) in the absence of such standards, in accordance with scientifically recognised rules which comply with the general principles of the agreement with Member States.

(5) Detailed rules for the application of this rule may be adopted in accordance with the procedure laid down in article 23 of European Union Council Directive 95/53/EC.

Penalties in the event of non-compliance.

27. (1) The provisions of these rules shall be applied in full.

(2) Subject to the provisions of these rules and of the Veterinary Service Act, a person who infringes any of the provisions arising from these rules, shall on conviction be liable to a fine *(multa)* of not less than one thousand Malta Liri and not exceeding five thousand Malta liri.

(3) Without prejudice to the provisions in sub-rule (1), the court may also order any person who is found guilty of committing an offence under these rules, to pay for the expenses incurred by the Veterinary Services as a result of the said offence, the revocation of the permit issued under European Union Council Directive 95/69/EC and any other rules in the field of animal nutrition and the confiscation,

retention and disposal of the items not complying with these rules and other rules in the field of animal nutrition.

Rights of appeal in the event of infringement.

28. (1) Rights of appeal existing under the laws in force in Malta against decisions by the Veterinary Services shall not be affected by these rules. Decisions taken by the Veterinary Services where an infringement has been found and the reasons for such decisions must be notified to the operator concerned by such decisions or his representative.

(2) If the operator concerned or his representative so requests, the said decisions and reasons must be communicated to him in writing with details of the rights of appeal which are available to him under the law in force in Malta performing the checks and of the procedure and time limits applicable.

Monitoring Programmes in the Field of Animal Nutrition.

29. (1) The Veterinary Services shall drawn up programmes setting out the measures to be taken to achieve the aim of these rules. These programmes must take into account the specific situation of Malta and specify the type and frequency of the inspections, which must be performed regularly.

(2) Before 1st April of each year, the Veterinary Services shall transmit to the European Commission all relevant information concerning the implementation of the programmes referred to in sub-rule (1) during the previous year, specifying -

(a) the criteria used in drawing up the programmes,

(b) the number and type of inspections carried out,

(c) the results of the inspections, in particular the number and type of infringements found,

(d) action taken where infringements have been found.

(3) The information referred to in sub-rule (2) be presented in the form of annual reports in accordance with the specimen drawn up by the European Commission.

(4) The Veterinary Services shall follow the recommendation concerning a co-ordinated inspection programme drawn up by the European Commission.

(5) Without prejudice to sub-rules (1), (2) and (4), where the protection of human or animal health or the environment requires

the prompt introduction of limited, specific, co-ordinated programmes of inspections, the Veterinary Services, according to the decisions taken by the European Commission, shall take the necessary measures in accordance with the procedure laid down in article 23 of European Union Council Directive 95/53/EC.

(6) The programmes referred to in sub-rule (5) shall in particular serve in situations provoked by any specific incident.

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