L.N. 80 of 2005

VETERINARY SERVICES ACT
(CAP. 437)

Measures to monitor certain Substances and Residues thereof in Live Animals and Animal Product Rules, 2005

IN exercise of the powers conferred by article 13 of the Veterinary Services Act, the Minister for Rural Affairs and the Environment has made the following rules:-

Title and scope.

1. (1) The title of these rules is the Measures to monitor certain Substances and Residues thereof in Live Animals and Animal Products Rules, 2005.

(2) The scope of these rules is to implement the provisions found under European Union Council Directive 96/023/EEC on the measures to monitor certain substances and residues thereof in live animals and animal products and in accordance with article 13 of the Veterinary Services Act.

(3) These rules are intended to implement measures in order to monitor certain substances and residues thereof in live animals and animal products.

Definitions.

2. For the purposes of these rules, the definitions in Directive 96/22/EC shall apply. In addition:

(1) 'animal' means the species covered by Directive 90/425/EEC (1);

(2) 'approved laboratory' means a laboratory approved by the competent authorities of the Territory of Malta for the purposes of examining an official sample in order to detect the presence of residues;

(3) 'batch of animals' means a group of animals of the same species, in the same age range, reared on the same holding, at the same time and under the same conditions of rearing;

(4) 'beta-agonist' means a beta adrenoceptor agonist.

(5) 'the Community' means the European Community as established under the Treaty establishing the European Community;

(6) 'the Commission' means the European Commission.

(7) 'The competent authority' means within the territory of Malta, the Veterinary Services as provided under article 2 of the Veterinary Services Act;

(8) 'illegal treatment' means the use of unauthorized substances or products or the use of substances or products authorized under Community legislation for purposes or under conditions other than those laid down in Community legislation or, where appropriate, in the various national legislations;

(9) 'official sample' means a sample taken by the competent authority which bears, for the purposes of examination of the residues or substances listed in Schedule I, a reference to the species, the type, the quantity concerned, the method of collection and particulars identifying the sex of the animal and the origin of the animal or of the animal product;

(10) 'Member State' means a State which is a Member within the European Community;

(11) 'residue' means a residue of substances having a pharmacological action, of their metabolites and of other substances transmitted to animal products and likely to be harmful to human health;

(12) 'Third Country' means a State which is not a Member within the European Community;

(13) 'unauthorized substances or products' means substances or products the administering of which to animals is prohibited under Community legislation.

Monitoring plans for the detection of residues or substances.

3. The production process of animals and primary products of animal origin shall be monitored in accordance with this Chapter for the purpose of detecting the presence of the residues and substances listed in Schedule I in live animals, their excrement and body fluids and in tissue, animal products, animal feed and drinking water.

Co-ordination of inspections.

4. (1) The Veterinary Services shall assign the task of coordinating the implementation of the inspections provided for in this Chapter, which are carried out within Malta, to a central public department or body.

(2) The Veterinary Services shall be responsible for:

(a) drawing up the plan provided for in rule 5 to enable the competent departments to carry out the required inspections;

(b) coordinating the activities of the central and regional departments responsible for monitoring the various residues. Such coordination shall extend to all departments working to prevent the fraudulent use of substances or products on stock farms;

(c) collecting the data needed to evaluate the means used and the results obtained in carrying out the measures provided for in this Chapter;

(d) sending the Commission, by not later than 31 March of each year, the data and results referred to in (c), including the results of any surveys undertaken.

(3) This rule shall not affect more specific rules applicable to the monitoring of animal nutrition.

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English marginal note Please

5. (1) The Veterinary Services shall submit a plan to the Commission setting out the national measures to be implemented during the initial year of the plan and subsequently any update of plans previously approved in accordance with rule 8 on the basis of the experience of the preceding year, or years by 31 March at the latest of the year of the update.

(2) The plan provided for in sub-rule (1) shall:

(a) provide for detection of groups of residues or substances according to type of animal, in accordance with Schedule II;

(b) specify in particular the measures for detection of the presence of:

(i) the substances referred to in paragraph (a) in the animals, in the drinking water of the animals and in all places where the animals are bred or kept;

(ii) residues of the aforementioned substances in live animals, their excrement and body fluids and in animal tissues and products such as meat, milk, eggs and honey;

(c) comply with the sampling rules and levels laid down in Schedules III and IV.

Sampling levels and frequencies.

6. (1) The plan must conform to the sampling levels and frequencies laid down in Schedule IV. However, at the request of the Veterinary Services the Commission may, in accordance with the procedure provided for in rule 32, adjust the minimum control requirements laid down in Schedule IV provided that it is clearly established that such adjustments increase the overall effectiveness of the plan in respect of the territory of Malta and in no way reduce its ability to identify residues of, or cases of illegal treatment with, substances listed in Schedule I.

(2) Re-examination of the groups of residues to be checked for in accordance with Schedule II and determination of the sampling levels and frequencies covering the animals and products referred to in rule 3 and not already laid down in Schedule IV shall take place in accordance with the procedure provided for in rule 33 and on the first occasion within a maximum of 18 months of the adoption of these rules. In doing so, account shall be taken of experience gained under existing national measures and information forwarded to the Commission under existing Community requirements making such specific product groups subject to monitoring for residues.

Initial plan.

7. The initial plan shall take into account the specific situation of Malta and specify in particular:

(1) legislation on the use of the substances listed in Schedule I and, in particular, provisions on their prohibition or authorization, distribution and placing on the market and the rules governing their administration, in so far as such legislation is not harmonized.

(2) the infrastructure of the relevant departments (in particular, giving details of the type and size of the bodies involved in implementing the plans),

(3) a list of approved laboratories with details of their capacity for processing samples,

(4) national tolerances for authorized substances where no maximum Community residue levels have been set under Regulation (EEC) No 2377/90 and Directive 86/363/EEC (1),

(5) a list of the substances to be detected, methods of analysis, standards for interpreting the findings and, in the case of the substances listed in Schedule I, the number of samples to be taken, giving reasons for this number,

(6) the number of official samples to be taken in relation to the number of animals of the species concerned slaughtered in preceding years in accordance with the sampling levels and frequencies laid down in Schedule IV,

(7) details of the rules governing the collection of official samples, and in particular the rules concerning the particulars to appear on such official samples,

(8) the type of measures laid down by the competent authorities with regard to animals or products in which residues have been detected.

Commission to examine initial plans.

8. (1) The Commission shall examine the initial plans forwarded pursuant to Article 5 (1) to ascertain whether they conform to these rules. The Commission may ask Malta to modify or supplement these plans to make them conform.

Once the Commission has established their conformity, it shall submit the plans approval in accordance with the procedure provided for in rule 32.

In order to take account of changes in the situation in Malta or in a region thereof, of the results of national surveys or of investigations carried out in the framework of rules 16 and 17, the Commission may, at the request of Malta or on its own initiative, decide, in accordance with the procedure provided for in rule 32, to approve an amendment or addition to a plan previously approved pursuant to sub-rule 2.

(2) Annual amendments to the initial plans communicated by Malta, in particular in the light of the results referred to in rule 4 (2) (d), shall be forwarded by the Commission to the other Member States once the Commission has established their conformity with these rules.

Member States shall have 10 working days from receipt of those amendments in which to inform the Commission of any comments.

If there are no comments from Member States, the amendments to the plans shall be deemed to be approved.

The Commission shall inform the territory of Malta and the other Member States of such approval immediately.

Where there are comments from Member States or where the Commission deems the update not to be in conformity or insufficient, the Commission shall submit the updated plans to the Standing

Veterinary Committee, which must act under the procedure laid down in rule 33.

The provisions laid down in sub-rule (3) and (4) shall apply to the updated plans.

(3) Every six months, Malta shall inform the Commission and the other Member States within the Standing Veterinary Committee of the implementation of plans approved pursuant to sub-rule (2) or of the development of the situation. Where necessary, sub-rule (4) shall apply. By not later than 31 March each year, Malta shall forward to the Commission the results of their residue and substance detection plans and of their control measures.

Malta shall, for the first time by 31 March 2005, forward to the Commission the results of their residue and substance detection plans and of their control measures.

The territory of Malta shall make public the outcome of the implementation of the plans.

The Commission shall inform Malta and other Member States, within the Standing Veterinary Committee, of developments in the situation in the various regions of the Community.

(4) Each year, or whenever it deems it necessary on public health grounds, the Commission shall report to Malta and other Member States within the Standing Veterinary Committee on the outcome of the checks and surveys referred to in sub-rule (3), in particular on:

— the implementation of national plans,

— developments in the situation in the various regions of the Community.

(5) The Commission shall send the European Parliament and the Council a communication each year on the results of action taken at regional, national or Community level, in consideration of the report and comments made by Member States on it.

Self-monitoring and co-responsibility on the part of operators.

9. (1) Malta shall ensure that:

(a) any farms which place farm animals on the market and any natural or legal person engaged in trade in such animals register beforehand with the competent authorities and undertake to abide by the relevant Community and national rules, in particular the

provisions laid down in Articles 5 and 12 of Directive 90/425/EEC;

(b) the owners or persons in charge of the establishment of initial processing of primary products of animal origin take all necessary measures, in particular by carrying out their own checks, to:

(i) accept — whether by direct delivery or through an intermediary — only those animals for which the producer is able to guarantee that withdrawal times have been observed;

(ii) satisfy themselves that the farm animals or products brought into the establishment:

(1) do not contain residue levels which exceed maximum permitted limits;

(2) do not contain any trace of prohibited substances or products;

(c) (i) the producers or persons in charge referred to in paragraphs (1) and (2) place on the market only:

(a) animals to which no unauthorized substances or products have been administered or which have not undergone illegal treatment within the meaning of these rules;

(b) animals in respect of which, where authorized products or substances have been administered, the withdrawal periods prescribed for these products or substances have been observed;

(c) products derived from the animals referred to in subparagraph (a) (i) and (ii);

(ii) where an animal is presented at a first-stage processing establishment by a natural or legal person other than the producer, the obligations laid down in (a) are incumbent on the latter.

(2) For the purposes of applying sub-rule A, Malta shall ensure, without prejudice to compliance with the rules laid down in the Directives governing the placing on the market of the various products in question, that:

(a) the principle of quality monitoring of the production chain by the different parties involved is established in its legislation,

(b) the self-monitoring measures to be included in the specifications for trade marks or labels are stepped up.

It shall inform the Commission and the other Member States, at their request, of provisions laid down in this regard and in particular of provisions adopted for checks on sub-rule A (3) (a) (i) and (ii).

Monitoring of forms by veterinarians.

10. Malta shall ensure that the terms of reference and responsibilities of veterinarians monitoring farms are extended to monitoring the rearing conditions and the forms of treatment referred to in these rules.

Within this framework, the veterinarian shall enter in a register kept on the farm the date and nature of any treatment prescribed or administered, the identification of the animals treated and the corresponding withdrawal periods.

The stockfarmer shall enter in the register, which may be the register provided for in Directive 90/676/EEC (1), the date and nature of the treatment administered. He shall satisfy himself that withdrawal periods have been observed and keep the prescriptions to prove it for five years.

Stockfarmers and veterinarians shall be required to supply any information to the competent authority, at its request, and in particular supply information to the official veterinarian of the slaughterhouse, regarding a given farm's compliance with the requirements of these rules.

Official control measures.

11. (1) Without prejudice to the checks carried out in connection with implementation of the surveillance plans referred to in rule 5 or to the checks provided for in specific Directives, Malta may have official random checks conducted:

(a) during the manufacture of the substances included in Group A in Schedule I and during their handling, storage, transport, distribution and sale or acquisition;

(b) at any point in the animal feedingstuffs production and distribution chain;

(c) throughout the production chain of animals and raw materials of animal origin covered by these rules.

(2) The checks provided for in sub-rule (1) must be conducted with a view in particular to detecting the possession or presence of prohibited substances or products which it is intended to administer to animals for the purposes of fattening or illegal treatment.

(3) Where fraud is suspected, and in the case of a positive result from any of the checks referred to in sub-rule (1), rules 16 to 19 and the measures provided for in Chapter V shall apply.

The checks provided for at the slaughterhouse or on the first sale of aquaculture animals and fishery products can be reduced to take account of the fact that the farm of origin or departure belongs to an epidemiological surveillance network or a quality monitoring system as referred to in the first indent of the first subparagraph of rule 9 (B).

Checks by the competent authority.

12. The checks provided for in these rules must be carried out by the competent authority without prior notice.

The owner, the person empowered to dispose of the animals or their representative shall be obliged to facilitate pre-slaughter inspection operations, and in particular to assist the official veterinarian or the authorized staff in any manipulation judged necessary.

Illegal treatment.

13. The competent authority shall:

(a) where illegal treatment is suspected, ask the owner or person having charge of the animals or the veterinarian in charge of the farm to provide any documentation justifying the nature of the treatment;

(b) where this inquiry confirms illegal treatment or where unauthorized substances or products have been used, or where there are grounds for suspecting their use, conduct or have conducted:

(i) spot checks on animals on their farms of origin or departure, in particular with a view to detecting such use and in particular any traces of implants; these checks may include official sampling,

(ii) checks to detect substances the use of which is prohibited or of unauthorized substances or products on the farms where the animals are being reared, kept or fattened (including holdings administratively connected with such farms) or on the animals' farms of origin or departure. Official samples of drinking water and feedingstuffs are necessary for that purpose.

(iii) spot checks on animals' feedingstuffs on their farms of origin or departure, and on their drinking water or — for aquaculture animals — from the waters in which they are caught,

(iv) the checks provided for in rule 11 (1) (a),

(v) any check required to clarify the origin of the unauthorized substances or products or that of the treated animals;

(c) where the maximum levels laid down by Community rules or, pending such legislation, the levels set by national legislation have been exceeded, carry out any measure or investigation which it may deem appropriate in relation to the finding in question.

National reference laboratory.

14. (1) Malta shall designate at least one national reference laboratory. A given residue or residue group may not be assigned to more than one national reference laboratory.

A list of such designated laboratories shall be drawn up in accordance with the procedure laid down in rule 33. These laboratories shall be responsible for:

(a) coordinating the work of the other national laboratories responsible for residue analysis, in particular by coordinating the standards and methods of analysis for each residue or residue group concerned,

(b) assisting the competent authority in organizing the plan for monitoring residues,

(c) periodically organizing comparative tests for each residue or residue group assigned to them,

(d) ensuring that national laboratories observe the limits laid down,

(e) disseminating information supplied by Community reference laboratories,

(f) ensuring that their staff are able to take part in further training courses organized by the Commission or by Commission reference laboratories.

(2) The Community reference laboratories shall be those designated in Chapter 1 of Schedule V.

The powers and working conditions of the laboratories shall be as defined in Chapter 2 of Schedule V.

15. (1) Official samples must be taken in accordance with Schedules III and IV in order to be examined in approved laboratories. Official Samples.

The detailed rules for the taking of official samples and the routine and reference methods to be employed for the analysis of such official samples shall be specified in accordance with the procedure laid down in rule 33.

Whenever an authorization is issued for the placing on the market of a veterinary medicinal product intended for administration to a species the meat or product of which is intended for human consumption, the competent authorities shall forward the routine analysis methods as laid down in Article 5, second subparagraph, point 8 of Directive 81/851/EEC (1) and Article 7 of Regulation (EEC) No 2377/90 to the Community and national reference laboratories for detection of residues.

(2) For Group A substances, all positive findings recorded following the application of a routine method instead of a reference method must be confirmed by an approved laboratory using the reference methods laid down in accordance with sub-rule 1.

For all substances, if challenged on the basis of a contradictory analysis, those results must be confirmed by the national reference laboratory designated in accordance with rule 14 (1) for the substance or residue in question. Such confirmation must be carried out at the plaintiff's cost in the event of confirmation.

(3) Where examination of an official sample reveals illegal treatment, rules 16 to 19 shall apply, together with the measures laid down in Chapter V.

Where the examination reveals the presence of residues of authorized substances or contaminants exceeding the levels set by Community rules or, pending such legislation, the levels set by national legislation, rules 18 and 19 shall apply.

Where the examination referred to in this sub-rule covers animals or products of animal origin from another Member State, the competent authority of the Member State of origin shall apply rules 16 (2), 17, 18 and 19 and the measures provided for in Chapter V to the farm or

establishment of origin or departure, following the reasoned request of the competent authority having carried out the examination.

Where the examination covers products or animals imported from a third country, the competent authority having carried out that examination shall refer the matter to the Commission, which shall take the measures provided for in rule 30.

Positive results of samples.

16. Member States shall ensure that, where positive results are obtained as described in rule 15:

(1) the competent authority shall obtain without delay:

(a) all the information required to identify the animal and farm of origin or departure;

(b) full details of the examination and its result. If the controls carried out in Malta demonstrate the need for an investigation or other action in one or more Member States or third countries, Malta shall inform the other Member States and the Commission. The Commission shall coordinate the appropriate measures taken in Member States where an investigation or other action proves necessary;

(2) the appropriate authority shall carry out:

(a) an investigation on the farm of origin or departure, as appropriate, to determine the reasons for the presence of residues;

(b) in the case of illegal treatment, an investigation of the source or sources of the substances or products concerned at the stage of manufacture, handling, storage, transport, administration, distribution or sale, as appropriate;

(c) any other further investigations which the authority considers necessary;

(3) animals from which sample shave been taken are clearly identified. They may not in any circumstances leave the farm until the results of the checks are available.

Illegal treatment.

17. Where illegal treatment is established, the competent authority must ensure that the livestock concerned in the investigations referred to in paragraph (b) of rule 13 is immediately placed under official control. It must furthermore ensure that all the animals concerned bear an official mark or identification and that, as a first step, an official

sample is taken from a statistically representative sample, on internationally recognized scientific bases.

Evidence of residues.

18. (1) Where there is evidence of residues of authorized substances or products of a level exceeding the maximum limit for residues, the competent authority shall carry out an investigation in the farm of origin or departure, as applicable, to determine why the above limit was exceeded.

In accordance with the results of that investigation, the competent authority shall take all necessary measures to safeguard public health which may include prohibiting animals from leaving the farm concerned or products from leaving the farm or establishment concerned for a set period.

(2) In the event of repeated infringements of maximum residue limits when animals are placed on the market by a farmer or products are placed on the market by a farmer or a processing establishment, intensified checks on the animals and products from the farm and, or establishment in question must be carried out by the competent authorities for a period of at least six months, products or carcasses being impounded pending the results of analysis of the samples. Any results showing that the maximum residue limit has been exceeded must lead to the carcasses or products concerned being declared unfit for human consumption.

Costs.

19. (1) The costs of the investigations and checks referred to in rule 16 shall be borne by the owner or person having charge of the animals.

Where the investigation confirms that suspicion was justified, the costs of analyses carried out under rules 17 and 18 shall be borne by the owner or person having charge of the animals.

(2) Without prejudice to criminal or administrative penalties, the cost of destroying animals which have given a positive result or animals which have been deemed positive in accordance with rule 23 shall be borne by the owner of the animals without indemnity or compensation.

Mutual Assistance.

20. (1) Council Directive 89/608/EEC of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of legislation on veterinary and zootechnical matters, shall apply for the purposes of these regulations.

(2) Where the competent authority considers that, in another Member State, the controls provided for in these regulations are not being, or have ceased to be, carried out, it shall inform the competent central authority of that State accordingly. Following an investigation carried out in accordance with paragraph 2 of rule 16, that authority shall take all necessary measures and shall, at the earliest opportunity notify the competent central authority of Malta of the decisions taken and the reasons for those decisions.

If the competent authority fears that such measures are not being taken or are inadequate, it shall, together with the Member State which has been challenged, seek ways and means of remedying the situation; if appropriate, this may involve an on-the-spot inspection. Malta shall inform the Commission of disputes and of solutions arrived at.

If Malta is involved in a dispute and is unable to reach agreement, it shall bring the matter to the notice of the Commission within reasonable period of time, and the latter shall instruct one or more experts to deliver an opinion.

Pending that opinion, Malta may carry out checks on products coming from any establishment or holding to which the dispute relates and, if the result is positive, take measures similar to those provided for in Article 7 (1) (b) of Directive 89/662/EEC(2).

In the light of the experts' opinion, appropriate measures may be taken in accordance with the procedure provided for in rule 32. Those measures may be reviewed in accordance with the same procedure, in the light of a new expert opinion delivered within 15 days.

Uniform implementation of plans.

21. (1) To the extent necessary to ensure uniform application of these regulations, and in cooperation with the competent authorities of Malta, the Commission's veterinary experts may verify on the spot that the plans and the system for checking the plans by the competent authorities have been uniformly implemented. Malta, within whose territory a verification is being carried out, shall give all necessary assistance to the experts in carrying out their duties. The Commission shall inform Malta of the results of the verifications carried out.

Malta shall take the measures necessary to take account of the results of these verifications and shall notify the Commission of the measures taken. Where the Commission considers that the measures taken are insufficient, it shall, after consultation with Malta in question and having regard to the measures necessary to safeguard public health, take appropriate measures in accordance with the procedure laid down in rule 32.

(2) The general rules for implementing this rule, especially as regards the frequency and method of carrying out the verifications referred to in the first subparagraph of sub-rule (1) (including cooperation with the competent authorities), shall be determined in accordance with the procedure laid down in rule 33.

Measures to be taken in the event of infringement.

22. Where unauthorized substances or products or substances listed in Group A and Group B (1) and (2) of Schedule I are discovered in the possession of non-authorized persons, those unauthorized substances or products must be placed under official control until appropriate measures are taken by the competent authority, without prejudice to the possible imposition of penalties on any offender.

Impounded animals.

23. (1) During the period in which animals are impounded as provided for in rule 17, animals from the farm in question may not leave the farm of origin or be handed over to any other person except under official control. The competent authority shall take appropriate precautionary measures in accordance with the nature of the substance or substances identified.

(2) After sampling has been carried out in accordance with rule 17, if there is confirmation of a case of illegal treatment, the animal or animals found to be positive shall be slaughtered immediately on the spot or taken immediately to the designated slaughterhouse or to the knacker's yard under cover of an official veterinary certificate in order to be slaughtered there. Animals so slaughtered shall be sent to a high-risk processing plant as defined by Directive 90/667/EEC.

In addition, samples must be taken at the farm's expense from the entire batch of animals belonging to the farm at which checks were carried out and which may be suspect.

(3) However, if half or more of the samples taken by representative sampling in accordance with rule 17 are positive, the farmer may be left a choice between a check on all the animals present on the farm which may be suspect, or slaughter of these animals.

(4) For a further period of at least 12 months, any farm belonging to the same owner shall be subject to more stringent checks for the residues in question. Where an organized system of self-monitoring has been set up, this facility shall be withdrawn from the farmer for that period.

(5) In view of the infringement recorded, the farms or establishments supplying the holding concerned shall be subject to checks in addition to those provided for in rule 11 (1) to determine the

origin of the substance in question. The same shall apply to all farms and establishments in the same supply chain of animals and animal feed as the farm of origin or departure.

Duties of veterinarians in the slaughter-house.

24. The official veterinarian of a slaughterhouse must:

(1) if he suspects or has evidence that the animals concerned have been subjected to illegal treatment or that unauthorized substances or products have been administered to them:

(a) arrange for the animals to be slaughtered separately from other batches of animals arriving at the slaughterhouse;

(b) impound the carcasses and offal and carry out all sampling procedures necessary to detect the substances in question;

(c) if positive results are obtained, send the meat and offal to a high-risk processing plant as defined by Directive 90/667/EEC, without indemnity or compensation.

In that event, rules 20 to 23 shall apply;

(2) if the suspects or has evidence that the animals concerned have been subjected to an authorized treatment but that the withdrawal periods have not been complied with, postpone slaughter of the animals until he can be satisfied that the quantity of residues does not exceed the permitted levels.

This period may in no circumstances be less than the withdrawal period laid down in point (b) of Article 6 (2) of Directive 96/22/EC for the substances in question, or than the withdrawal periods provided for in the marketing authorization.

However, in an emergency or where required for the well-being of the animals, or if the infrastructure or equipment of the slaughterhouse is such that slaughter cannot be deferred, the animals may be slaughtered before the end of the ban or postponement period. The meat and offal shall be impounded pending the outcome of the official checks carried out by the slaughterhouse's official veterinarian. Only meat and offal containing a quantity of residues not exceeding the permitted levels shall be used for human consumption;

(3) declare unfit for human consumption carcasses and products in which the residue level exceeds the levels authorized by Community or local laws.

Unauthorized substances.

25. Without prejudice to criminal penalties, where the holding, use or manufacture of unauthorized substances or products in a manufacturing establishment is confirmed, any authorizations or official approval arrangements enjoyed by the establishment concerned shall be suspended for a period during which the establishment shall be subjected to more stringent checks.

In the case of a repeated offence, such authorizations or approval arrangements shall be permanently withdrawn.

Rights of appeal.

26. Rights of appeal allowed by any law in force in Malta against decisions taken by the competent authorities under rules 23 and 24 shall not be affected by these regulations.

Transfer etc. of prohibited substances.

27. Without prejudice to criminal penalties, or penalties imposed by professional bodies, appropriate administrative measures must be taken against any person where he is responsible, as the case may be, for the transfer or administering of prohibited substances or products or for the administering of authorized substances or products for purposes other than those laid down by law.

Failure to co-operate.

28. Any failure to cooperate with the competent authority and any obstruction by slaughterhouse personnel or the slaughterhouse supervisor or, in the case of a private enterprise, by the slaughterhouse owner or owners, or by the owner of the animals or person having charge of them, during inspection and sampling as required for the implementation of national plans for monitoring residues and during the investigations and checks provided for in this rule, shall result in appropriate criminal and, or administrative penalties being imposed by the competent authority.

If it is proven that a slaughterhouse owner or supervisor is helping to conceal the illegal use of prohibited substances, Malta shall deny the guilty party any opportunity of receiving or applying for Community aid for a period of 12 months.

Imports from third countries.

29. (1) Inclusion and retention on the lists of third countries provided for in Community legislation from which Malta is authorized to import animals and animal products covered by these rules shall be subject to submission by the third country concerned of a plan setting out the guarantees which it offers as regards the monitoring of the groups of residues and substances referred to in Schedule I. This plan must be updated at the request of the Commission, particularly when the checks referred to in sub-rule (3) render it necessary.

The provisions of rule 8 concerning time limits for submission and updating of plans shall apply for plans to be submitted by third countries.

The guarantees must have an effect at least equivalent to those provided or in these rules and must, in particular, meet the requirements of rule 4 and specify the particulars laid down in rule 7 of these rules and meet the requirements of Article 11 (2) of Directive 96/22/EC.

The Commission shall approve the plan in accordance with the procedure laid down in rule 33. Under the same procedure, guarantees alternative to those resulting from the implementation of this rule may be accepted.

(2) Where the requirements of sub-rule (1) are not complied with, inclusion of a third country on the lists of third countries laid down by Community legislation or as a result of the benefit of pre-listing may be suspended in accordance with the procedure laid down in rule 33, at the request of Malta or by the Commission on its own initiative.

(3) Compliance with the requirements of and adherence to the guarantees offered by the plans submitted by third countries shall be verified by means of the checks referred to in Article 5 of Directive 72/462/EEC (1) and the checks provided for in Directives 90/675/EEC (2) and 91/496/EEC (3).

(4) Malta shall inform the Commission each year of the results of residue checks carried out on animals and animal products imported from third countries, in accordance with Directives 90/675/EEC and 91/496/EEC.

Use of unauthorized products or substances.

30. (1) Where the checks provided by Directives 90/675/EEC and 91/496/EEC reveal the use of unauthorized products or substances for the treatment of the animals in a given batch — batch within the meaning of Article 2 (2) (e) of Directive 91/496/EEC — or the presence of such products or substances in all or part of a batch originating in the same establishment, the competent authority shall take the following measures in respect of the animals and products involved in such use:

(a) it shall inform the Commission of the nature of the products used and the batch concerned; the Commission shall forthwith inform all frontier posts,

(b) Malta shall carry out more stringent checks on all batches of animals or products from the same source. In particular, the

next 10 batches from the same source must be impounded — and a deposit lodged against inspection costs — at the frontier inspection post for a check on residues by taking a representative sample of each batch or of the part of the batch.

Where such additional checks demonstrate the presence of unauthorized substances or products or of residues of such substances or products:

(i) the batch or the part of the batch concerned must be returned to the country of origin at the expense of the consignor or his agent with a clear indication on the certificate of the reasons for rejecting the batch;

(ii) depending on the nature of the infringement found and the risk associated with such an infringement, it must be left to the consignor to decide whether to send back the batch or part of the batch concerned, to destroy it or to use it for other purposes authorized by Community legislation, without indemnity or compensation;

(c) the Commission shall be informed of the outcome of the more stringent checks and on the basis of this information shall make all necessary investigations, to identify the reasons for and origins of the infringements found.

(2) Where the checks provided for by Directive 90/675/EEC reveal that the maximum residue limits have been exceeded, use shall be made of the checks referred to in paragraph (b) of sub-rule (1).

(3) If, in cases involving third countries which have concluded equivalence agreements with the Community, the Commission, after making enquiries of the competent authorities of the third countries concerned, concludes that they have failed to fulfill their obligations and the guarantees given by the plans referred to in rule 29 (1), it shall cease to allow that country, under the procedure laid down in rule 32, to benefit from the said agreements for the animals and products in question until the third country in question has made good its shortcomings. The suspension shall be revoked under the same procedure.

If necessary, in order to re-establish the benefit afforded by the said agreements, a Community deputation including experts from the Member States shall visit the country concerned, at that country's expense, in order to verify that such measures have been taken.

General provisions.

31. The Council, acting on a proposal from the Commission, shall amend Directive 85/73/EEC in order to provide for the charging of a fee to cover monitoring carried out pursuant to these rules.

Pending that decision by the Council, Malta shall be authorized to charge national fees to cover the actual costs of such monitoring.

Standing Veterinary Committee.

32. (1) Where the procedure laid down in this rules is to be followed, matters shall be referred without delay to the Standing Veterinary Committee set up by Decision 68/361/EEC , by its Chairman, either on his own initiative or at the request of Malta.

(2) The Commission representative shall submit a draft of the measures to be taken. The Committee shall deliver its opinion on those matters within a time limit which the Chairman may set according to the urgency of the matter submitted. Opinions shall be delivered by a majority of 62 votes.

(3) (a) The Commission shall adopt the measures and implement them immediately where they are in accordance with the opinion of the Committee.

(b) Where they are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall forthwith submit to the Council a proposal concerning the measures to be taken. The Council shall adopt the measures by a qualified majority.

If, 15 days after the proposals were submitted to it, the Council has not adopted any measures, the Commission shall adopt the measures proposed and implement them immediately unless the Council has rejected those measures by a simple majority.

SCHEDULE I

GROUP A — **Substances having anabolic effect and unauthorized Substances**

(1) Stilbenes, stilbene derivatives, and their salts and esters
(2) Antithyroid agents
(3) Steroids
(4) Resorcylic acid lactones including zeranol
(5) Beta-agonists
(6) Compounds included in Annex IV to Council Regulation (EEC) No 2377/90 of 26 June 1990

GROUP B — **Veterinary drugs and contaminants**

(1) Antibacterial substances, including sulphonomides, quinolones
(2) Other veterinary drugs
(a) Anthelmintics
(b) Anticoccidials, including nitroimidazoles
(c) Carbamates and pyrethroids
(d) Sedatives
(e) Non-steroidal anti-inflammatory drugs (NSAIDs)
(f) Other pharmacologically active substances
(3) Other substances and environmental contaminants
(a) Organochlorine compounds including PcBs
(b) Organophosphorus compounds
(d) Chemical elements
(d) Mycotoxins
(e) Dyes
(f) Others

SCHEDULE II

RESIDUE OR SUBSTANCE GROUP TO BE DETECTED BY TYPE OF ANIMAL, THEIR FEEDINGSTUFFS, INCLUDING DRINKING WATER, AND PRIMARY ANIMAL PRODUCTS

Type of animal, feeding-stuffs or animal products Substance groups	Bovine, ovine, caprine, porcine, equine animals	Poultry	Aquacul-ture animals	Milk	Eggs	Rabbit meat and the meat of wild (*) game and farmed game	Honey
Al	X	X	X			X	
2	X	X				X	
3	X	X	X			X	
4	X	X				X	
5	X	X				X	
6	X	X	X	X	X	X	
B 1	X	X	X	X	X	X	X
2a	X	X	X	X		X	
b	X	X			X	X	
c	X	X				X	X
d	X						
e	X	X		X		X	
f							
3a	X	X	X	X	X	X	X
b	X			X			X
c	X	X	X	X		X	X
d	X	X	X	X			
e			X				
f							

SCHEDULE III

SAMPLING STRATEGY

1. The residue control plan is aimed at surveying and revealing the reasons for residue hazards in foods of animal origin on farms, slaughterhouses, dairies, fish processing plants, and egg collecting and packing stations.

   Official samples are to be taken in accordance with the relevant chapter of Schedule IV.

Wherever official samples are taken, sampling must be unforeseen, unexpected and effected at no fixed time and on no particular day of the week. The territory of Malta must take all the precautions necessary to ensure that the element of surprise in the checks is constantly maintained.

2. For Group A substances, surveillance should be aimed at detecting the illegal administration of prohibited substances and the abusive administration of approved substances, respectively. The emphasis of such sampling must be concentrated according to the relevant chapter of Schedule IV.

The samples must be targeted taking account of the following minimum criteria: sex, age, species, fattening system, all available background information, and all evidence of misuse or abuse of substances of this group. The details of these criteria will be laid down in the Commission Decision provided for in rule 15 (1).

3. For Group B substances, surveillance should be aimed particularly at controlling the compliance with MRLs for residues of veterinary medicinal products fixed in Annexes I and III to Regulation (EEC) No 2377/90, and the maximum levels of pesticides fixed in Annex III to Directive 86/363/EEC, and monitoring the concentration of environmental contaminants.

Unless random sampling can be justified by the territory of Malta when presenting their national plans to the Commission, all the samples shall be targeted according to criteria laid down in the Commission Decision provided for in rule 15 (1).

SCHEDULE IV

SAMPLING LEVELS AND FREQUENCY

The purpose of this Schedule is to define the minimum number of animals from which the samples must be taken.

Each sample can be analysed for detecting the presence of one or more substances.

CHAPTER 1

Bovine, porcine, ovine, caprine and equine animals

1. **Bovine animals**
The minimum number of animals to be controlled each year for all kinds of residues and substances must at least equal 0,4 % of bovine animals slaughtered the previous year, with the following breakdown:

Group A: 0,25 % divided as follows :

— one half of the samples are to be taken from live animals on the holding; (by derogation, 25 % of samples analysed for the research of Group A 5 substances can be taken from appropriate material (feedingstuffs, drinking water, etc.))

— one half of the samples are to be taken at the slaughterhouse. Each sub-group in Group A must be checked each year using a minimum of 5 % of the total number of samples to be collected for Group A.

The balance must be allocated according to the experience and background information of the territory of Malta.

Group B: 0,15 %

30 % of the samples must be checked for Group B 1 substances.
30 % of the samples must be checked for Group B 2 substances.
10 % of the samples must be checked for Group B 3 substances.

The balance must be allocated according to the situation in Malta.

2. **Porcine animals**
The minimum number of animals to be checked each year for all kinds of residues and substances must at least equal 0,05 % of the pigs slaughtered the previous year, with the following breakdown:

Group A: 0,02 %

In Malta which carries out its sampling of animals at the slaughterhouse, in addition analysis of drinking water, feedingstuffs, faeces, or all other appropriate parameters

must be undertaken at farm level. In that case, the minimum number of farms to be visited annually must represent at least one farm per 100 000 pigs slaughtered the previous year.

Each sub-group in Group A must be checked each year using a minimum of 5 % of the total number of samples to be collected for Group A. The balance will be allocated according to the experience and background information about Malta.

Group B: 0,03 %

The same breakdown per sub-group as for bovine animals has to be respected. The balance will be allocated according to the situation in Malta.

3. **Sheep and goats**
The minimum number of animals to be checked for all kind of residues and substances must at least equal 0,05 % of sheep and goats over three months of age slaughtered the previous year, with the following breakdown:

Group A: 0,01 %

Each sub-group of Group A must be checked each year using a minimum of 5 % of the total number of samples to be collected for Group A.

The balance will be allocated according to the experience and background information about Malta.

Group B: 0,04 %

The same breakdown per sub-group as for bovine animals has to be respected. The balance will be allocated according to the experience of Malta.

4. **Equine animals**
The number of samples is to be determined by the territory of Malta in relation to the problems identified.

CHAPTER 2

Broiler chickens, spent hens, turkeys, other poultry

A sample consists of one or more animals depending on the requirements of the analytical methods.

For each category of poultry considered (broiler chickens, spent hens, turkeys, and other poultry), the minimum number of samples to be taken each year must at least equal one per 200 tonnes of annual production (deadweight), with a minimum of 100 samples for each group of substances if the annual production of the category of birds considered is over 5 000 tonnes.

The following breakdown must be respected:

Group A: 50 % of the total samples

The equivalent of one fifth of these samples must be taken at farm level.

Each sub-group of Group A must be checked each year using a minimum of 5 % of the total number of samples to be collected for Group A.

The balance will be allocated according to the experience and background information about Malta.

Group B: 50 % of the total samples,

30 % must be checked for Group B 1 substances,
30 % must be checked for Group B 2 substances,
10 % must be checked for Group B 3 substances.

The balance will be allocated according to the situation in Malta.

CHAPTER 3

Aquaculture products

1. **Finfish farming products**
A sample is one or more fish, according to the size of the fish in question and of the requirements of the analytical method.

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

The minimum number of samples to be collected each year must be at least 1 per 100 tonnes of annual production. 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 farm, on fish ready to be placed on the market for consumption;
(b) either 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.

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

2. **Other aquaculture products**

When Malta 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.

SCHEDULE V

Chapter 1

The following laboratories shall be designated Community reference laboratories for the detection of residues of certain substances:

(a) For the residues listed in Schedule I, Group A 1, 2, 3, 4, Group B 2 (d) and Group B 3 (d)

Rijksinstituut voor Volksgezondheid en Milieuhygiëne (RIVM)
A. van Leeuwenhoeklaan, 9
NL-3720 BA Bilthoven

(b) For the residues listed in Schedule I, Group B 1 and B 3 (e) and carbadox residues and olaquindox residues

Laboratoriesdes médicaments vétérinaires (CNEVA-LMV)
La Haute Marche, Javene
F-35135-Fougères

(c) For the residues listed in Schedule I, Group A 5 and Group B 2 (a), (b), (e)

Bundesinstitut für Gesundheitlichen Verbraucherschutz und Veterinärmedizin (BGVV)
Diedersdorfer Weg, 1
D-12277-Berlin

(d) For the residues listed in Schedule I, Group B 2 (c) and Group B 3 (a), (b), (c):

Istituto Superiore di Sanità
Viale Regina Elena, 299
I-00161-Roma

The compounds included in Group A 6, B 2 (f) and B 3 (f) are allocated to the designated Community reference laboratories, according to their pharmacological action.

Chapter 2

The powers and operating conditions of the Community reference laboratories for the detection of residues in live animals, their excrement and body fluids and in tissue, animal products, animal feed and drinking water shall be as follows:

1. The functions of Community reference laboratories shall be:

(a) to promote and coordinate research into new analytical methods and to inform national reference laboratories of advances in analytical methods and equipment;

(b) to help the national reference laboratories (NRLs) for residues to implement an appropriate quality assurance scheme system based on good laboratory practice (GLP) principles and EN 45 000 criteria;

(c) to approve validated methods as reference methods, to be integrated into a collection of methods;

(d) to provide the national reference laboratories with the routine analytical methods accepted during the MRL procedure;

(e) to provide national reference laboratories with details of analytical methods and the comparative tests to be conducted, and to inform them of the results of the tests;

(f) to provide national reference laboratories, at their request, with technical advice on the analysis of the substances for which they have been designated the Community reference laboratory;

(g) to organize comparative tests for the benefit of the national reference laboratories, the frequency of which shall be determined in agreement with the Commission. Consequently, the Community reference laboratories shall distribute blank samples and samples containing known amounts of analyte to be analysed;

(h) to identify residues and determine their concentration in cases where the results of an analysis give rise to a disagreement between Member States;

(i) to conduct initial and further training courses for the benefit of analysts from national laboratories;

(j) to provide the Commission services, including the standards, measurements and testing programme, with technical and scientific assistance;

(k) to compile a report on each year's work and transmit it to the Commission;

(l) to liaise, in the field of analytical methods and equipment, with the national reference laboratories designated by third countries in the plans to be submitted in accordance with rule 11 of these rules.

2. In order to perform the functions specified in paragraph 1, Community reference laboratories must satisfy the following minimum requirements:

(a) have been designated as a national reference laboratory in Malta;

(b) have suitable qualified staff who are adequately trained in analytical methods used for the residues for which they have been designated the Community reference laboratory;

(c) possess the equipment and substances needed to carry out the analysis for which they are responsible;

(d) have an adequate administrative infrastructure;

(e) have sufficient data-processing capacity to produce statistics based on their findings and to enable rapid communication of those statistics and other information to national reference laboratories and the Commission;

(f) ensure that their staff respect the confidential nature of certain issues, results or communications;

(g) have sufficient knowledge of international standards and practices;

(h) have available an up-to-date list of certified reference material and reference material held by the Institute for Reference Material and Methods, and an up-to-date list of manufacturers and vendors of that material.

SCHEDULE VI

Correlation table

These rules	Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC
Rule 1	—
Rule 2	Article 2 86/469/EEC
Rule 3	Article 1 86/469/EEC
	Article 2 85/358/EEC
Rule 4	Article 3 86/469/EEC
Rule 5	Article 4 (1) first and second indents 86/469/EEC
Rule 6	—
Rule 7	Article 4 (1) except first and second indents 86/469/EEC
Rule 8	Article 4 (2) to 4 (5) 86/469/EEC
	Article 12 86/469/EEC
	Article 9 85/358/EEC
Rule 9	—
Rule 10	—
Rule 11	Article 1 85/358/EEC
Rule 12	—
Rule 13	Article 3 85/358/EEC
	Article 10 86/469/EEC
Rule 14 (1)	Article 8 (1) (b) 86/469/EEC
Rule 14 (2)	Article 8 (2) 86/469/EEC
	Decision 91/664/EEC
	Decision 89/187/EEC
Rule 15 (1)	Article 8 (3) 86/469/EEC
	Article 5 (2) 85/358/EEC
Rule 15 (2)	Article 8 (3) 86/469/EEC
	Article 5 (3) 85/358/EEC
Rule 15 (3)	Article 9 86/469/EEC
Rule 16	Article 9 (1) and Article 9 (2) 86/469/EEC
	Article 6 (1) and Article 6 (2) 85/358/EEC
Rule 17	Article 9 (3) (a) 86/469/EEC
	Article 6 (3) (a) 85/358/EEC
Rule 18	Article 9 (3) (c) and (d) 86/469/EEC
Rule 19	—
Rule 20 (1)	—
Rule 20 (2)	Article 11 86/469/EEC
Rule 21	Article 5 86/469/EEC
Rule 22	Article 7 85/358/EEC
Rule 23	Articles9 (3) (b) (c) (d) and 9 (4), 9 (5) 86/469/EEC
	Articles6 (3) (b) (c) (d) and 6 (4) 85/358/EEC
Rule 24	Article 4 85/358/EEC
Rule 25	—

These Rules	Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC	
Rule 26	—	
Rule 27	—	
Rule 28	—	
Rule 29	Article 7	86/469/EEC
	Article 13	85/358/EEC
Rule 30	—	
Rule 31	Article 12	85/358/EEC
Rule 32	Article 14	86/469/EEC
	Article 11	85/358/EEC
Rule 33	Article 15	86/469/EEC
	Article 10	85/358/EEC
Rule 34	Article 13	86/469/EEC
Rule 35	—	
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Schedule I	Annex I	86/469/EEC
Schedule II	—	
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Schedule IV	Annex II	86/469/EEC
Schedule V Chapter 1	Decision 91/664/EEC	
Schedule V Chapter 2	Decision 89/187/EEC	
Schedule VI	—	

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