L.N. 100 of 2005

VETERINARY SERVICES ACT
(CAP. 437)

Conditions for the Registering of Establishments operating in the Animal Feed Sector Rules, 2005

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

Title and scope

1. (1) The title of these rules is the Conditions for the Registering of Establishments operating in the Animal Feed Sector Rules, 2005.

(2) The scope of these rules is to implement the provisions under European Union Council Directive 95/69/EEC laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector to allow them to exercise the activities described in rules 3 and 8 and in rules 4 and 9 respectively, and in accordance with article 23(b) of the Veterinary Services Act.

(3) These rules shall apply without prejudice to the legislative provisions concerning the organization of official checks on animal feed.

Definitions

2. (1) For the purposes of these rules:

"establishment" means any unit producing or manufacturing additives, pre-mixtures prepared from additives, compound feeding stuffs or products covered by Directive 82/471/EEC and referred to in Chapter I.1 (a) of the Schedule to these rules;

"intermediary" means any person other than the manufacturer or the person producing for the exclusive requirements of his holding, compound feeding stuffs, who holds additives, pre-

mixtures prepared from additives, or one of the products covered by Directive 82/471/ EEC and referred to in Chapter I.1 (a) of the Schedule to these rules at an intermediate stage between production and use;

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

"trading partner" shall have the same meaning as provided under article 2 of the Veterinary Services Act, and shall include trading partners of the European Union.

(2) The definitions laid down in legislation on animal feed shall apply where necessary.

CHAPTER I

APPROVAL OF ESTABLISHMENTS AND INTERMEDIARIES

Approval of establishments

3. (1) An establishment wishing to exercise one or more of the activities referred to in sub-rule (2) must receive approval for each of its activities. It may be decided not to approve establishments referred to in sub-rule (2)(f).

(2) To be approved by the competent authorities an establishment:

(a) manufacturing additives or products covered by Directive 82/471/EEC and referred to in Chapter I.1 (a) of the Schedule to these rules with a view to putting them into circulation, must meet the minimum conditions laid down in Chapter I.1 (b) of the said Schedule;

(b) manufacturing pre-mixtures prepared from additives referred to in Chapter I.2 (a) of the Schedule, with a view to putting them into circulation, must meet the minimum conditions laid down in Chapter I.2 (b) of the said Schedule;

(c) manufacturing compound feeding stuffs containing pre-mixtures prepared from additives referred to in Chapter I.3 (a) of the Schedule, with a view to putting them into circulation, must

meet the minimum conditions laid down in Chapter I.3 (b) of the Schedule;

(d) manufacturing compound feeding stuffs, with a view to putting them into circulation, from raw materials referred to in Article 5 of Directive 1999/29/EEC which contain high levels of undesirable substances or products, must meet the minimum conditions laid down in Chapter I.4 of the Schedule to these rules;

(e) producing, for the exclusive requirements of its holding, compound feeding stuffs containing pre-mixtures which include additives referred to in Chapter I.3 (a) of the Schedule must meet the minimum conditions laid down in Chapter I.3 (b) of the Schedule, with the exception of the requirements set out in point 7 thereof;

(f) producing, for the exclusive requirements of its holding, compound feeding stuffs which contain raw materials referred to in Article 5 of Directive 1999/29/EEC containing high levels of undesirable substances or products, must meet the minimum conditions laid down in Chapter 1.4 of the Schedule to these rules, with the exception of the requirements set out in point 7 thereof.

(3) Approval shall be:

withdrawn if an establishment ceases its activities or if it is shown that it no longer fulfils an essential condition applicable to its activities and does not comply with that requirement within a reasonable time, amended if the establishment has demonstrated its ability to engage in activities which are additional to those for which it was first approved or which replace them.

Approval of intermediaries

4. (1) Where additives, products covered by Directive 82/471/EEC or pre-mixtures of additives referred to in Chapters I.1 (a) and I.2 (a) of the Schedule respectively are put into circulation, intermediaries must be approved. The provisions laid down in point 7 of Chapter I.1 8 (b) or Chapter I.2(b) of the Schedule shall apply, as appropriate, to intermediaries which wrap, package, store or put into circulation additives, pre-mixtures of additives or products covered by Directive 82/471/EEC.

(2) Approval shall be:

withdrawn if an intermediary ceases its activities or if it is shown that it no longer fulfils an essential condition applicable to its activities and does not comply with that requirement within a reasonable time;

amended if the intermediary has demonstrated its ability to engage in activities which are additional to those for which it was first approved or which replace them.

Approval procedure for establishments and intermediaries

5. (1) To obtain approval, establishments referred to in rule 3 and intermediaries referred to in rule 4 which intend to exercise for the first time one or more of the activities referred to in rules 3 and 4, shall submit an application to the competent authority in which their facilities are located.

(2) The competent authority shall ensure that a decision is taken on applications for approval mentioned in sub-rule (1) within six months of their submission.

Register of approved establishments and intermediaries

6. (1) (a) For each activity, the competent authority shall enter the establishments and intermediaries it has approved in accordance with rules 3 and 4 in a register under an individual approval number which identifies them, once it has established by means of on-the-spot verification that they satisfy the conditions laid down by these rules.

(b) In respect of intermediaries who act solely as dealers without ever holding the product in their facilities, it is not needed to carry out on-the-sport verification of compliance with the conditions under point 7 of Chapters I.1 (b) or I.2 (b) of the Schedule, providing that those intermediaries lodge with the competent authority a declaration to the effect that they meet the requirements laid down under point 6.2 in the Schedule for the exercise of their activity.

(2) The competent authority shall update the entries of establishments and intermediaries in the register in accordance with the decisions referred to in sub-rule 3 (3) and sub-rule 4 (2) to withdraw or amend approval.

Publication and communication of the list of approved establishments and intermediaries

7. (1) A list of the establishments and intermediaries approved in accordance with rules 3 and 4 shall be published, and then each year, by the 30th November at the latest, the list of amendments made during the year; every five years, a consolidated list shall be published.

(2) Before the 31st December of each year, the competent authority shall send to the Commission the list referred to in sub-rule (1). Before the 31st December each year, the competent authority shall send the trading partners a list of the establishments referred to in sub-rule 3(2)(a) and (b) and of the intermediaries approved in accordance with sub-rule 4(1) and a list of corresponding establishments and intermediaries referred to in sub-rule 5(2) which have submitted

applications for approval on which the competent authority has not yet taken a decision. On request, the competent authority shall send the trading partners all, or part of the list of establishments referred to in sub-rule 3(2)(c) to (f) and all or part of the list of corresponding establishments referred to in sub-rule 5(2) which have submitted applications for approval on which the competent authority has not yet taken a decision.

CHAPTER II

REGISTRATION OF ESTABLISHMENTS AND INTERMEDIARIES

Registration of establishments

8. (1) An establishment wishing to exercise one or more of the activities referred to in sub-rule (2) must be registered by the competent authority for each activity in accordance with these rules.

(2) In order to be registered by the competent authorities an establishment:

(a) manufacturing additives for which a prescribed maximum level is set and which are not included in Chapter I.1 (a) of the Schedule, with a view to putting them into circulation, must meet the minimum conditions laid down in Chapter II (c) of the Schedule;

(b) manufacturing pre-mixtures containing additives referred to in Chapter II (a) of the Schedule, with a view to putting them into circulation, must meet the minimum conditions laid down in Chapter II(c) of the Schedule;

(c) manufacturing compound feeding stuffs containing pre-mixtures of additives referred to in Chapter II (b) of the Schedule or additives referred to in Chapter II (a) of the Schedule with a view to putting them into circulation, must met the minimum conditions laid down in Chapter II (c) of the Schedule;

(d) manufacturing, for the exclusive requirements of its holding, compound feeding stuffs containing pre-mixtures of additives referred to in Chapter II (b) of the Schedule or containing additives referred to in Chapter II (a) of the Schedule, must met the minimum conditions laid down in Chapter II (c) of the Schedule.

(3) Approved establishments exercising the corresponding activities referred to in sub-rule 3 (2) (a), (b), (c) and (e) shall be regarded

as satisfying de facto the conditions laid down in sub-rule (2)(a), (b), (c) and (d).

(4) Registration shall be:

withdrawn if an establishment ceases its activities or if it is shown that it no longer fulfils an essential condition applicable to its activities and does not comply with that requirement within a reasonable time,

amended if the establishment declares that it is engaged in activities which are additional to those for which it was first registered or which replace them.

Registration of intermediaries

9. (1) Where additives for which a prescribed maximum level is set other than those referred to in Chapter I.1 (a) of the Schedule or pre-mixtures of additives referred to in Chapter II (a) of the Schedule are put into circulation, intermediaries must be registered. The provisions laid down in point 7 of Chapter II (c) of the Schedule shall apply, as appropriate, to intermediaries which wrap, package, store or put into circulation additives or pre-mixtures of additives.

(2) Intermediaries approved in accordance with rule 4 shall be regarded as meeting de facto the conditions laid down in sub-rule (1) hereof.

(3) Registration shall be:

(a) withdrawn if an intermediary ceases its activities or if it is shown that it no longer fulfils an essential condition applicable to its activities and does not comply with that requirement within a reasonable time,

(b) amended if the intermediary has declared that it is engaged in activities which are additional to those for which it was first registered or which replace them.

Registration procedure for establishments and intermediaries

10. In order to be registered, the establishments referred to in sub-rule 8 (2) and the intermediaries referred to in sub-rule 9 (1) shall submit a declaration to the competent authority of the trading partner in which they intend to exercise their activities.

List of registered establishments and intermediaries

11. (1) For each activity, the competent authority shall enter the establishments and intermediaries which it has registered in accordance with rules 8 and 9 on a list under an individual registration number which identifies them.

(2) The entries of establishments and intermediaries on the list shall be updated in accordance with the decisions referred to in sub-rules 8 (4) and 9 (3) to withdraw or amend registration.

Communication of the list of registered establishments and intermediaries

12. (1) Before the 31st December of each year, the list of establishments and intermediaries registered during the year in accordance with rules 8 and 9 shall be sent to the Commission and, every five years, a consolidated list thereof shall be sent.

(2) Upon request, the competent authority shall send to the trading partners all or part of the lists referred to in sub-rule (1) hereof.

CHAPTER III

COMMON PROVISIONS

Simplified procedure

13. Where an establishment manufacturing an additive is already authorized to manufacture the same active substance as a veterinary medicinal product within the meaning of article 29 of the Veterinary Services Act, the competent authority shall not be obliged to verify that the conditions laid down in Article 3 (2) (a) and contained in Chapter I.1 (b) of the Schedule to these rules have been fulfilled, with the exception of the requirements set out in points 4, 5, 6.2 and 7.

Checks

14. The competent authority shall ensure, by means of appropriate checks carried out in establishments and at the premises of intermediaries which they have approved or registered, that the requirements imposed by these rules are met.

Fees

15. According to the procedure laid down in article 28(b) of the Veterinary Services Act, the rules for calculating the level of the fee to be charged for the approval of establishments and their intermediaries shall be adopted.

Detailed arrangements, amendment of the Annex and imports from non-member countries

16. The following shall be adopted in accordance with the procedure laid down in Article 16 of Directive 95/69/EEC:

(a) practical arrangements for the approval pursuant to rule 3 and registration pursuant to rule 8 of establishments located in a third country and putting additives, pre-mixtures, products covered by Directive 82/471/EEC as referred to in Chapter 1.1 (a) of the Schedule to these rules or feeding stuffs into circulation within Malta or a trading partner, so that safeguards are provided equivalent to those supplied by establishments located in Malta or in the territory of a trading partner.

These arrangements shall comprise:

(i) publication of the list established and updated by the Commission, of third countries able to provide safeguards equivalent to those offered by Malta or the territory of a trading partner in respect of their own establishments and able to perform the checks referred to in rule 14,

(ii) publication of the list established and updated by the Commission of establishments which have been found by the third countries on the list referred to in paragraph (i) above to fulfil the conditions laid down in these rules,

(iii) the possibility that experts from the Commission, Malta and the territory of trading partners may carry out on-the-spot checks if necessary;

(b) measures for implementing the Schedule to these rules;

(c) the amendments to be made to the Schedule to these rules.

SCHEDULE

CHAPTER 1

Minimum conditions which must be fulfilled by establishments and intermediaries referred to in rules 3 and 4 (subject to approval)

CHAPTER I.1. (a)
Additives and products covered by Directive 82/471/EEC ('products') and referred to in sub-rule 3 (2) (a) and sub-rule 4 (1) of these rules

Additives

— Antibiotics:	all additives in the group
— Coccidiostats and other medicinal substances:	all additives in the group
— Growthpromoters:	all additives in the group
— Vitamins, provitamins and chemically well-defined substances having a similar effect:	all additives in the group
— Trace elements:	all additives in the group
— Enzymes:	all additives in the group
— Micro-organisms:	all additives in the group
— Carotenoids and xanthophylls:	all additives in the group
— Substances with antioxidant effects:	only those with a fixed maximum content

Products covered by Directive 82/471/EEC

— Proteins obtained from microorganisms belonging to the group of bacteria, yeasts, algae, lower fungi:	all products in the group (except for sub-group 1.2.1)
— Co-products of the manufacture of amino acids by fermentation:	all products in the group
— Amino acids and their salts:	all products in the group

— Hydroxy analogues of amino acids: all products in the group

CHAPTER I.1. (b)
Minimum conditions which must be fulfilled by establishments referred to in sub-rule 3 (2) (a) and intermediaries referred to in sub-rule 4 (1) ('products' referred to in Chapter I.1(a))

1. ***Facilities and equipment***

Facilities and manufacturing equipment must be located, designed, constructed and maintained to suit the manufacture of the 'products' concerned. The lay-out, design and operation of the facilities and equipment must be such as to minimize the risk of error and permit effective cleaning and maintenance in order to avoid contamination, cross-contamination and any adverse effects generally on the quality of the products. Facilities and equipment to be used for manufacturing operations which are essential for the quality of the products must undergo appropriate and regular checks, in accordance with written procedures pre-established by the manufacturer for production of the products.

2. ***Personnel***

The manufacturer must have sufficient staff possessing the skills and qualifications necessary for the manufacture of the 'products' concerned. An organizational chart setting out the qualifications (diplomas, professional experience) and responsibilities of the supervisory staff must be drawn up and made available to the competent authorities of the supervisory staff must be drawn up and made available to the competent authorities responsible for inspection. All the staff must be informed clearly in writing of their duties, responsibilities and powers, especially when any change is made, in such a way as to obtain the desired quality of the 'products' concerned.

3. ***Production***

A qualified person responsible for production must be designated. The manufacturer must ensure that the different stages of production are carried out according to pre-established written procedures and instructions aimed at defining, checking and mastering the critical points in the manufacturing process.

Technical or organizational measures must be taken to avoid cross-contamination and errors. There must be sufficient and appropriate means of carrying out checks in the course of manufacture.

4. ***Quality control***

A qualified person responsible for quality control must be designated.

The manufacturer must have access to a quality control laboratory having adequate staff and equipment to guarantee and check, before the release of the 'products' concerned with a view to putting them into circulation, that they comply with the specifications defined by the manufacturer and are in conformity with the provisions laid down in Directive 70/524/EEC or Directive 82/741/EEC. The use of an outside laboratory is permitted.

A quality control plan must be drawn up in writing and implemented, to include, in particular, checks on the critical points in the manufacturing process, sampling procedures and frequencies, methods of analysis and their frequency, compliance with the specifications — and the destination in the event of non-compliance — of raw materials, active substances, carrier substances and 'products'.

Samples of the active substance and of each batch of 'product' put into circulation or of each specific portion of production in the case of continuous production must be taken in sufficient quantity by a procedure pre-established by the manufacturer and be retained in order to ensure traceability. The samples must be sealed and labelled for ease of identification; they must be stored under conditions which prevent any abnormal change in the composition of the sample or any abnormal adulteration. They must be kept at the disposal of the competent authorities at least until the guarantee date of the finished product.

5. ***Storage***

Raw materials, active substances, carrier substances, 'products' which meet the specifications — and those which do not — must be stored in suitable containers in places designed, adapted and maintained in order to ensure good storage conditions, to which only persons authorized by the manufacturer have access.

They must be stored in such a way as to be easily identifiable and to avoid any confusion or cross-contamination between the different products mentioned above and with medicinal substances. Additives must be packaged and labelled in particular in compliance with the provisions laid down in Directive 70/524/EEC. Products covered by Directive 82/471/EEC must be labelled in compliance with the provisions of those rules.

6. ***Documentation***

6.1. Documentation relating to the manufacturing process and controls

The manufacturer must have a system of documentation designed to define and ensure mastery of the critical points in the manufacturing process and to establish and implement a quality control plan. The manufacturer must keep the results of the relevant controls. This set of documents must be kept so that it is possible to trace the manufacturing history of each batch of 'product' put into circulation and to establish responsibility if complaints arise.

6.2. Register

The manufacturer must record the following information in order to ensure traceability:

(a) *register of additives:*

— the nature and quantity of the additives produced, the respective dates of manufacture and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous manufacture, and the names and addresses of the intermediaries or manufacturers to whom the additives have been delivered,
— indication of the nature and quantity of the additives delivered and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous manufacture;

(b) *register of products covered by Directive 82/471/EEC:*

— the nature of the products and the quantity produced, the respective dates of manufacture and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous manufacture,
— the names and addresses of the intermediaries or users (manufacturers or stock breeders) to whom these products have been delivered, together with an indication of the nature and quantity of the products delivered and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous manufacture.

7. ***Intermediaries referred to in Article 4 (1)***

Where the manufacturer delivers additives to a person other than a manufacturer or products referred to in Directive 82/471/EEC to a person other than a user (manufacturer or stock breeder), that person and any subsequent intermediary by whom they are wrapped, packaged, stored or put into circulation shall be equally bound, as appropriate, by the obligations laid down in points 4, 5, 6.2 and 8 and, in the case of wrapping, by those referred to in point 3.

8. ***Complaints and product recall***

The manufacturer or any intermediary putting a product into circulation under his own name must implement a system for registering and processing complaints. Likewise, he must be in a position to introduce, where this proves necessary, a system for prompt recall of products in the distribution network. The manufacturer must define by means of written procedures the destination of any recalled products, and before such products are put back into circulation they must undergo a quality-control reassessment.

CHAPTER I.2. (a)
Additives referred to in sub-rule 3 (2) (b) and sub-rule 4 (1)

— Antibiotics: all additives in the group

— Coccidiostats and other medicinal substances:	all additives in the group
— Growth promoters:	all additives in the group
— Vitamins, provitamins and chemically well-defined substances having a similar effect:	A and D
— Trace elements:	Cu and Se

CHAPTER I.2. (b)
Minimum conditions which must be fulfilled by establishments referred to in sub-rule 3 (2) (b) and intermediaries referred to in sub-rule 4 (1) (pre-mixtures of additives referred to in Chapter I.2 (a))

1. ***Facilities and equipment***

Facilities and manufacturing equipment must be located, designed, constructed and maintained to suit the manufacture of the pre-mixtures concerned. The layout, design and operation of the facilities and equipment must be such as to minimize the risk of error and permit effective cleaning and maintenance in order to avoid contamination, cross-contamination and any adverse effects generally on the quality of the products. Facilities and equipment to be used for operations which are essential for the quality of the products must undergo appropriate and regular checks in accordance with the written procedures pre-established by the manufacturer.

Preventive measures must be taken to avoid, as far as possible, the presence of harmful organisms, with the introduction of a control plan if necessary.

2. ***Personnel***

The manufacturer must have sufficient staff possessing the skills and qualifications necessary for the manufacture of the pre-mixtures concerned. An organizational chart setting out the qualifications (diplomas, professional experience) and responsibilities of the supervisory staff must be drawn up and made available to the competent authorities responsible for inspection. All the staff must be informed clearly in writing of their duties, responsibilities and powers, especially when any change is made, in such a way as to obtain the desired quality of the pre-mixtures concerned.

3. ***Production***

A qualified person responsible for production must be designated.

The manufacturer must ensure that the different stages in production are carried out according to pre-established written procedures and instructions aimed at defining,

checking and mastering the critical points in the manufacturing process, such as in corporation of the additive in the pre-mixture, chronological order of production, meters and weighing apparatus, mixer and returns, in such a way as to obtain the desired quality of the pre-mixtures concerned in accordance with the provisions of Directive 70/524/EEC.

Technical or organizational measures must be taken to avoid cross-contamination and errors.

4. ***Quality control***

A qualified person responsible for quality control must be designated.

The manufacturer must have access to a quality control laboratory having adequate staff and equipment to guarantee and check that the pre-mixtures concerned comply with the specifications defined by the manufacturer and which will guarantee and check, in particular, the nature, content, homogeneity and stability of the additives in the pre-mixture, and as low a level of cross-contamination as possible. The use of an outside laboratory is permitted.

A quality control plan must be drawn up in writing and implemented, to include, in particular, checks on the critical points in the manufacturing process, sampling procedures and frequencies, methods of analysis and their frequency, compliance with the specifications — and destination in the event of non-compliance — for carrier substances, additives and pre- mixtures (‘products’).

Samples of each batch of pre-mixture put into circulation must be taken in sufficient quantity by a procedure pre-established by the manufacturer and be retained in order to ensure traceability. These samples must be sealed and labelled for ease of identification; they must be stored under conditions which prevent any abnormal change in the composition of the sample or any abnormal adulteration. They must be kept at the disposal of the competent authorities at least until the guarantee date of the pre-mixture.

5. ***Storage***

‘Products’ which meet the specifications — and those which do not — must be stored in suitable containers or in places designed, adapted and maintained in order to ensure good storage conditions, to which only persons authorized by the manufacturer have access.

Preventive measures must be taken to avoid, as far as possible, the presence of harmful organisms, with the introduction of a control plan if necessary. The ‘products’ must be stored in such a way as to be easily identifiable and to avoid any confusion or cross-contamination between the different products and with medicinal substances. Pre-mixtures must be wrapped and labelled in accordance with the provisions of Directive 70/524/EEC.

6. ***Documentation***

6.1. Documentation relating to the manufacturing process and controls

The manufacturer must have a system of documentation designed to define and ensure the mastery of the critical points in the manufacturing process, and to establish and implement a quality control plan. The manufacturer must keep the results of the relevant controls. This set of documents must be kept in such a way as to make it possible to trace the manufacturing history of each pre-mixture batch put into circulation and to establish responsibility if complaints arise.

6.2. Register of pre-mixtures

The manufacturer must record the following information in order to ensure traceability:

— the names and addresses of manufacturers of additives or of intermediaries, the nature and quantity of the additives used and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous manufacture,

— the date of manufacture of the pre-mixture, the batch number where appropriate,

— the names and addresses of the intermediaries or manufacturers of compound feeding stuffs to whom the pre-mixture is delivered, the delivery date, the nature and quantity of the pre-mixture is delivered, and the batch number where appropriate.

7. ***Intermediaries referred to in sub-rule 4 (1)***
Where the manufacturer delivers pre-mixtures to a person other than a manufacturer of compound feeding stuffs, that person and any subsequent intermediary by whom they are wrapped, packaged, stored our put into circulation shall be equally bound, as appropriate, by the obligations laid down in points 4, 5, 6.2 and 8 and, in the case of wrapping, by those referred to in point 3.

8. ***Complaints and product recall***

The manufacturer or any intermediary putting a product into circulation under his own name must implement a system for registering and processing complaints. Likewise, he must be in a position to introduce, where this proves necessary, a system for prompt recall of products in the distribution network. The manufacturer must define by means of written procedures the destination of any recalled products, and before such products are put back into circulation they must undergo a quality-control reassessment.

CHAPTER I.3. (a)
Additives referred to in sub-rules 3 (2) (c) and (e)

— Antibiotics:	all additives in the group

— Coccidiostats and other medicinal substances:	all additives in the group
— Growthpromoters:	all additives in the group

CHAPTER I.3. (b)
Minimum conditions which must be fulfilled by establishments referred to in sub-rule 3 (2) (c) and (e) (compound feeding stuffs containing pre-mixtures of additives referred to in Chapter I.3 (a))

1. ***Facilities and equipment***

Facilities and manufacturing equipment must be located, designed, constructed and maintained to suit the manufacture of compound feeding stuffs containing pre-mixtures. The layout, design and operation of the facilities and equipment must be such as to minimize the risk of error and permit effective cleaning and maintenance in order to avoid, as far as possible, contamination, cross-contamination and any adverse effects generally on the quality of the products.

Facilities and equipment to be used for manufacturing operations which are essential for the quality of the products must undergo appropriate and regular checks, in accordance with the written procedures pre-established by the manufacturer, or possibly, in the case of manufacture solely for the manufacturer's own needs, pre-established by a qualified outside person acting at the request and under the responsibility of the manufacturer. Preventive measures must be taken to avoid, as far as possible, the presence of harmful organisms, with the introduction of a control plan if necessary.

2. ***Personnel***

The manufacturer must have sufficient staff possessing the skills and qualifications necessary for the manufacture of compound feeding stuffs containing pre-mixtures. An organizational chart setting out the qualifications (diplomas, professional experience) and responsibilities of the supervisory staff must be drawn up — if appropriate in the case of manufacture solely for the manufacturer's own needs — and made available to the competent authorities responsible for inspection. All the staff must be informed clearly in writing of their duties, responsibilities and powers, especially when any change is made, in such a way as to obtain the desired quality of the compound feeding stuffs containing pre-mixtures.

3. ***Production***

A qualified person responsible for production must be designated who, in the case of manufacture solely for the manufacturer's own needs, may if necessary be from outside, but shall act at the request and under the responsibility of the manufacturer.

The manufacturer must ensure that the different stages in production are carried out according to pre-established written procedures and instructions aimed at defining,

checking and mastering the critical points in the manufacturing process, such as incorporation of the pre-mixture in the feeding stuff, chronological order of production, meters and weighing apparatus, mixer and returns, in such a way as to obtain the desired quality of the compound feeding stuffs in accordance with the provisions of Directive 79/373/EEC.

Technical or organizational measures shall be taken to avoid cross-contamination and errors as far as possible.

4. ***Quality control***

A qualified person responsible for quality control must be designated who, in the case of manufacture solely for the manufacturer's own needs, may if necessary be from outside, but shall act at the request and under the responsibility of the manufacturer.

The manufacturer must have at his disposal a quality control laboratory having adequate staff and equipment to guarantee and check that the compound feeding stuffs containing pre-mixtures comply with the specifications defined by the manufacturer and which will guarantee and check, in particular, the nature, content and homogeneity of the additives concerned in the compound feeding stuffs, and as low a level as possible of cross-contamination, as well as, in the case of feeding stuffs to be put into circulation, the contents as regards analytical constituents (Directive 79/373/EEC). The use of an outside laboratory is permitted.

A quality control plan must be drawn up in writing and implemented, to include, in particular, checks on the critical points in the manufacturing process, sampling procedures and frequencies, methods of analysis and their frequency, compliance with the specifications — and destination in the event of non-compliance — for raw materials, pre-mixtures and compound feeding-stuffs ‘products’.

Samples must be taken in sufficient quantity by a procedure pre-established by the manufacturer on the basis of each batch of compound feeding stuffs or each specific portion of production in the case of continuous manufacture, and be retained in order to ensure traceability where it is put into circulation, or on a regular basis in the case of manufacture solely for the manufacturer's own needs. These samples must be sealed and labelled for ease of identification; they must be stored under conditions which prevent any abnormal change in the composition of the sample or any abnormal adulteration. They must be kept at the disposal of the competent authorities for an appropriate period.

5. ***Storage***

‘Products’ which meet the specifications — and those which do not — must be stored in suitable containers in places designed, adapted and maintained in order to ensure good storage conditions, to which only persons authorized by the manufacturer have access.

Preventive measures must be taken to avoid, as far as possible, the presence of harmful organisms, with the introduction of a control plan if necessary.

The ‘products’ must be stored in such a way as to be easily identifiable and to avoid any confusion or cross-contamination between the different products and with medicinal substances or medicinal feeding stuffs, or with raw materials containing high levels of undesirable substances and products, or with additives. Compound feeding stuffs intended to be put into circulation must comply with the provisions of Directive 79/373/EEC.

6. ***Documentation***

6.1. Documentation relating to the manufacturing process and controls

The manufacturer must have a system of documentation designed to define and ensure the mastery of the critical points in the manufacturing process, and to establish and implement a quality control plan. The manufacturer must keep the results of the relevant controls. This set of documents must be kept in such a way as to make it possible to trace the manufacturing history of each batch produced and, where it is put into circulation, to establish responsibility if complaints arise.

6.2. Register of compound feeding stuffs

The manufacturer must record the following information in order to ensure traceability:

— the names and addresses of pre-mixture manufacturers or intermediaries, with the batch number if appropriate, the nature and quantity of the pre-mixture used,

— the nature and quantity of feeding stuffs manufactured, together with the date of manufacture.

7. ***Complaints and product recall***

The manufacturer must implement a system for registering and processing complaints.

Likewise, he must be in a position to introduce, where this proves necessary, a system for prompt recall of products in the distribution network. The manufacturer must define by means of written procedures the destination of any recalled products, and before such products are put back into circulation they must undergo a quality-control reassessment.

CHAPTER I.4
Minimum conditions which must be fulfilled by establishments referred to in sub-rule 3 (2) (d) and (e) (compound feeding stuffs from raw materials which contain high levels of undesirable substances and products (‘raw materials concerned’))

1. ***Facilities and equipment***

Facilities and manufacturing equipment must be located, designed, constructed and maintained to suit the manufacture of compound feeding stuffs from the ‘raw materials concerned’. The layout, design and operation of the facilities and equipment must be such as to minimize the risk of error and permit effective cleaning and maintenance in order to avoid contamination, as far as possible, contamination, cross-contamination and any adverse effects generally on the quality of the products. Facilities and equipment to be used for manufacturing operations which are essential for the quality of the products must undergo appropriate and regular checks, in accordance with written procedures pre-established by the manufacturer, or possibly, in the case of manufacture solely for the manufacturer's own needs, pre-established by a qualified outside person acting at the request and under the responsibility of the manufacturer.

Preventive measures must be taken to avoid, as far as possible, the presence of harmful organisms, with the introduction of a control plan if necessary.

2. ***Personnel***

The manufacturer must have sufficient staff possessing the skills and qualifications necessary for the manufacture of compound feeding stuffs from the ‘raw materials concerned’. An organizational chart setting out the qualifications (diplomas, professional experience) and responsibilities of the supervisory staff must — if appropriate in the case of manufacture solely for the manufacturer's own needs — be drawn up and made available to the competent authorities responsible for inspection. All the staff must be informed clearly in writing of their duties, responsibilities and powers, especially when any change is made, in such a way as to obtain the desired quality of compound feeding stuffs from the ‘raw materials concerned’.

3. ***Production***

A qualified person responsible for production must be designated who, in the case of manufacture solely for the manufacturer's own needs, may if necessary be from outside, but shall act at the request and under the responsibility of the manufacturer.

The manufacture must ensure that the different stages in production are carried out according to pre-established written procedures and instructions aimed at defining, checking and mastering the critical points in the manufacturing process, such as incorporation in the feeding stuff of the ‘raw material concerned’, chronological order of production, meters and weighing apparatus, mixer and returns, in such a way as to obtain the desired quality of the compound feeding stuffs in accordance with the provisions of Directive 79/373/EEC.

Technical or organizational measures shall be taken to avoid cross-contamination and errors as far as possible.

4. ***Quality control***

A qualified person responsible for quality control must be designated who, in the case of manufacture solely for the manufacturer's own needs, may if necessary be from outside, but shall act at the request and under the responsibility of the manufacturer.

The manufacturer must have at his disposal a quality control laboratory having adequate staff and equipment to guarantee and check that the compound feeding stuffs concerned comply with the specifications defined by the manufacturer and which will guarantee and check, in particular, the nature, content and homogeneity of the undesirable substances and products concerned in the compound feeding stuff, and as low a level as possible of cross-contamination as well as compliance with the maximum levels of undesirable substances and products as laid down in Directive 1999/29/EEC and, in the case of feeding stuffs to be put into circulation, contents as regards analytical constituents (Directive 79/373/EEC). The use of an outside laboratory is permitted.

A quality control plan shall be drawn up in writing and implemented, to include, in particular, checks on the critical points in the manufacturing process, sampling procedures and frequencies, methods of analysis and their frequency, compliance with the specifications — and destination in the event of non-compliance — for raw materials, including those with high levels of undesirable substances and products, and compound feeding stuffs.

Samples must be taken sufficient quantity by a procedure pre-established by the manufacturer on the basis of each of compound feeding stuffs or each specific portion of production in the case of continuous manufacture, and be retained in order to ensure traceability where it is put into circulation, or on a regular basis in the case of manufacture solely for the manufacturer's own needs. These samples must be sealed and labelled for ease of identification; they must be stored under conditions which prevent any abnormal change in the composition of the sample or any abnormal adulteration. They must be kept at the disposal of the competent authorities for a period appropriate to the use to which the feeding stuffs are put.

5. ***Storage***

Raw materials, notably those containing high levels of undesirable substances and products and compound feeding stuffs which meet the specifications — and those which do not — must be stored in suitable containers or in places designed, adapted and maintained in order to ensure good storage conditions.

Preventive measures must be taken to avoid, as far as possible, the presence of harmful organisms, with the introduction of a control plan if necessary.

The products must be stored in such a way as to be easily identifiable and to avoid any confusion or cross-contamination between the different products mentioned above and with medicinal substances or medicinal feeding stuffs, or with additives or pre-mixtures of additives. Compound feeding stuffs intended to be put into circulation must comply with the provisions of Directive 79/373/EEC.

6. ***Documentation***

6.1. Documentation relating to the manufacturing process and controls

The manufacturer must have a system of documentation designed to define and ensure the mastery of the critical points in the manufacturing process, and to establish and implement a quality control plan. The manufacturer must in particular keep the results of the relevant controls. This set of documents must be kept in such a way as to make it possible to trace the manufacturing history of each batch produced and, where it is put into circulation, to establish responsibility if complaints arise.

6.2. Register of compound feeding stuffs

The manufacturer must record the following information in order to ensure traceability:

— the names and addresses of suppliers of raw materials containing high level of undesirable substances and products, and

— the nature and level of undesirable substances and products, the delivery date and the nature and quantity of the products manufactured, plus the date of manufacture.

7. ***Complaints and product recall***

The manufacturer must implement a system for registering and processing complaints.

Likewise, he must be in a position to introduce, where this proves necessary, a system for prompt recall of products in the distribution network. The manufacturer must define by means of written procedures the destination of any recalled products, and before such products are put back into circulation they must undergo a quality-control reassessment.

CHAPTER II
Minimum conditions which must be fulfilled by establishments and intermediaries referred to in rules 8 and 9 (subject to registration)

CHAPTER II (a)
Additives referred to in sub-rule 8 (2) (b), (c) and (d) and in sub-rule 9 (1)

— Vitamins, provitamins and chemically well-defined substances having a similar action:	all additives in the group except for vitamins A and D
— Trace elements:	all additives in the group except for Cu and Se

— Carotenoids and xanthophylls:	all additives in the group
— Enzymes:	all additives in the group
— Micro-organisms:	all additives in the group
— Substances with antioxidant effects:	only those with a fixed maximum content

CHAPTER II (b)
Additives referred to in sub-rule 8 (2) (c) and (d)

— Vitamins, provitamins and chemically well-defined substances having a similar action:	all additives in the group
— Trace elements:	all additives in the group
— Carotenoids and xanthophylls:	all additives in the group
— Enzymes:	all additives in the group
— Micro-organisms:	all additives in the group
— Substances withantioxidant effect:	only those with a fixed maximum content

CHAPTER II (c)
Minimum conditions which must be fulfilled by establishments and intermediaries referred to in sub-rule 8 (2) (a) and (b) and sub-rule 9 (1), (additives for which a prescribed maximum level is set and which are not referred to in Chapter I.1 (a), pre-mixtures of additives referred to in Chapter II (a)) and establishments referred to in sub-rule 8 (2) (c) and (d), (compound feeding stuffs containing pre-mixtures of additives referred to in Chapter II (b) or additives referred to in Chapter II (a)).

1. ***Facilities and equipment***

Facilities and technical equipment must be located, designed, constructed and maintained to suit the manufacture of the additives, pre-mixtures of additives and compound feeding stuffs containing additives or pre-mixtures of additives concerned (‘products concerned’).

2. ***Personnel***

The manufacturer must have sufficient staff possessing the skills and qualifications necessary for the manufacture of the ‘products concerned’.

3. ***Production***

A qualified person responsible for production must be designated who, in the case of manufacture solely for the manufacturer's own needs, may if necessary be from outside, but shall act at the request and under the responsibility of the manufacturer.

The manufacturer must ensure that the different stages of production are carried out in such a way as to obtain the desired quality of the ‘products concerned’ in accordance with the provisions of Directive 70/524/EEC or Directive 79/373/EEC.

4. ***Quality control***
A qualified person responsible for quality control must be designated who, in the case of manufacture solely for the manufacturer's own needs, may if necessary be from outside, but shall act at the request and under the responsibility of the manufacturer.

The manufacturer must draw up and implement a quality control plan to guarantee and check that the ‘products in question’ comply with the specifications defined by the manufacturer and that they comply, as appropriate, with the provisions of Directive 70/524/EEC or Directive 79/373/EEC.

In order to ensure traceability, samples must be taken and kept, where appropriate, from each batch of the product or from each specific portion of production in the case of continuous or regular manufacture. They must be kept at the disposal of the competent authorities for a period appropriate to the use to which the feeding stuffs are put.

5. ***Storage***

Raw materials, active substances, carrier substances, pre-mixtures and compound feeding stuffs must be stored in places designed, adapted and maintained in order to ensure good storage conditions.

The products must be stored in such a way as to be easily identifiable and to avoid any confusion or cross-contamination between the different products mentioned above and with medicinal substances or medicinal feeding stuffs. Products to be put into circulation must be wrapped, where appropriate, and labelled in accordance with the provisions of Directive 70/524/EEC or Directive 79/373/EEC, as appropriate.

6. ***Register***

The manufacturer must record the following information in order to ensure traceability:

(a) *for additives:*

— the nature and quantity of the additives produced, the respective dates of manufacture and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous manufacture,

— the names and addresses of the intermediaries or users (manufacturers or stock breeders) to whom the additives have been delivered, with an indication of the nature and quantity of the additives delivered and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous manufacture.

(b) *for pre-mixtures:*

— the names and addresses of the additive manufacturers or intermediaries, the nature and quantity of the additives used and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous manufacture,

— the date of manufacture of the pre-mixture, the number of the batch where appropriate,

— the names and addresses of the intermediaries or manufacturers to whom the pre-mixtures have been delivered and the nature and quantity of the pre-mixture delivered, and the number of the batch, where appropriate;

(c) *for compound feeding stuffs containing pre-mixtures or additives:*

— the names and addresses of the pre-mixture manufacturers or intermediaries, with the batch number where appropriate, the nature and quantity of the pre-mixture used,

— the names and addresses of the additive manufacturers or intermediaries, the nature and quantity of the additive used and the number of the batch or of the specific portion of production in the event of continuous manufacture,

— the nature and quantity of the feeding stuffs manufactured, with the date of manufacture.

7. ***Intermediaries referred to in sub-rule 8 (1)***

Where the manufacturer delivers additives to a person other than a manufacturer or stock breeder, or pre-mixtures to a person other than a manufacturer, that person and any subsequent intermediary by whom they are wrapped, packaged, stored or put into circulation shall be equally bound, as appropriate, by the obligations laid down in points 4, 5 and 6.2 and, in the case of wrapping, by those laid down in point 3.

Ippubblikat mid-Dipartiment ta' l-Informazzjoni (doi.gov.mt) — Valletta — *Published by the Department of Information (doi.gov.mt) — Valletta*
Mitbugh fl-Istamperija tal-Gvern — *Printed at the Government Printing Press*
Prezz Lm1.16c – *Price Lm1.16c*