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COUNCIL DIRECTIVE 95/69/EC

of 22 December 1995

laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector and amending Directives 70/524/EEC, 74/63/EEC, 79/373/EEC and 82/471/EEC

(OJ L 332, 30.12.1995, p. 15)

Amended by:

	Official Journal		
	No	page	date
►**M1** Council Directive 98/92/EC of 14 December 1998	L 346	49	22.12.1998

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THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 43 thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the European Parliament [2],

Having regard to the opinion of the Economic and Social Committee [3],

1. Whereas Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs [4], lays down the minimum conditions to be met by manufacturers of certain additives, premixtures and compound feedingstuffs containing such additives;

2. Whereas these rules restrict the manufacture or use of certain categories of additives, premixtures and compound feedingstuffs containing such additives and premixtures to those manufacturers who are included on a national list;

3. Whereas individuals holding goods covered by this Directive for the sole purposes of their trade promotion or their transport are not regarded as being intermediaries as defined in this Directive;

4. Whereas with the operation of the internal market in mind, some optional provisions which still allow the Member States to derogate from the Community provisions applying to the sector in question should be abolished and the criteria for approving or registering manufacturers or intermediaries should be specified so as to avoid distortions of competition caused by the MemberStates' different ways of applying and interpreting pre-existing approval conditions and to forestall any potentially adverse effects on animals, humans or the environment, given the risks inherent in using certain additives;

5. Whereas, to forestall certain particularly undesirable substances occurring in feedingstuffs, Council Directive 74/63/EEC of 17 December 1973 on undesirable substances and products in animal nutrition [5], aims to limit their presence in raw materials to an acceptable level; whereas these rules also restrict the use of those raw materials to those persons who have the necessary qualifications, facilities and equipment for the dilution operations which ensure that the maximum levels laid down in the Directive as regards the various types of compound feedingstuffs are complied with;

6. Whereas establishments producing certain substances listed in Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition [6], should also be subject to approval, as should intermediaries;

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(1) OJ No C 348, 28. 12. 1983, p. 18.
(2) OJ No C 91, 28. 3. 1994, p. 296.
(3) OJ No C 148, 30. 5. 1994, p. 21.
(4) OJ No L 270, 14. 12. 1970, p. 1. Directive as last amended by Commission Directive 95/37/EC (OJ No L 172 an 22. 7. 1995, p. 21).
(5) OJ No L 38, 11. 2. 1974, p. 31. Directive as last amended by Commission Directive 94/16/EC (OJ No L 104, 23. 4. 1994, p. 32).
(6) OJ No L 213, 21. 7. 1982, p. 8. Directive as last amended by Commission Directive 95/33/EC (OJ No L 167, 18. 7. 1995, p. 17).

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7. Whereas, with a view to ensuring the quality of the product and preventing the occurrence of residues of certain additives in animal products or of high levels of certain undesirable substances which might result from defective manufacture, all manufacturers of additives, premixtures, compound feedingstuffs and certain products covered by Directive 82/471/EEC, and intermediaries should be approved or registered on the basis of standard, specific criteria;

8. Whereas the level of requirements for the exercise of activities laid down in this Directive must be in proportion to the risks involved in the manufacture or use by establishments of additives and premixtures listed in Directive 70/524/EEC, products covered by Directive 82/471/EEC or raw materials containing undesirable substances or products listed in Directive 74/63/EEC;

9. Whereas establishments which intend to manufacture or use products deemed sensitive under the Directive must receive prior approval on the basis of very strict conditions that should safeguard animals, humans and the environment, whereas, however, in exceptional cases Member States may decide not to approve a specific category of establishment, provided such measures do not hinder the free movement of agricultural products in the territory of the Member States; whereas, conversely, for establishments using less sensitive products, mere registration based on an undertaking by the establishment to comply with a number of conditions will suffice; whereas this distinction must also apply to intermediaries which wrap, package, store or put into circulation additives, premixtures of additives or products covered by Directive 82/471/EEC;

10. Whereas, on grounds of equal treatment, the fundamental principles of these new rules must apply both to establishments which put products into circulation and to manufacturers/stock farmers who manufacture feedingstuffs solely for the requirements of their own farms, without any distinction; whereas, nonetheless, some relief should be allowed the latter on account of the particular circumstances in which they exercise their activity;

11. Whereas provision should be made for amending or withdrawing approval if an establishment changes or ceases its activities or if it no longer fulfils one of the essential conditions applicable to its activity; whereas the same rules should apply, *mutatis mutandis*, to registration;

12. Whereas Member States may be entitled to levy fees for granting approval; whereas the levels of such fees should subsequently be harmonized in order to obviate distortion of competition; whereas such harmonization will fall within the general framework of future Community rules on fees or charges to be levied in the animal feed sector;

13. Whereas it is necessary to give the Commission the task of adopting detailed rules for the application of this Directive, including the conditions for approval and registration of establishments in third countries;

14. Whereas, should the Council confer on the Commission responsibility for implementing the rules laid down on the conditions and arrangements for approving and registering the establishments in question, provision should be made for close cooperation between the Member States and the Commission within the Standing Committee for Feedingstuffs established by Decision 70/372/EEC ([1]);

15. Whereas to ensure greater transparency the conditions and arrangements relating to the approval and registration of estab-

([1]) OJ No L 170, 3. 8. 1970, p. 1.

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lishments in the animal feed sector should be brought together in a single text; whereas this entails adapting existing legislation;

16. Whereas the requirement for manufacturers to be approved or registered will make it possible for Member States to check on manufacturers and intervene, if necessary, where substances are being used illegally, in particular where prohibited substances such as hormones or beta-agonists are in use; whereas Member States have a duty to check beforehand that establishments requiring approval actually meet the minimum conditions which the Directive lays down for exercise of the relevant activity; whereas national supervisory authorities must also ensure subsequently, by means of appropriate checks, that approved or registered establishments and intermediaries are indeed complying with the conditions imposed upon them; whereas these provisions must apply without prejudice to Community rules governing the organization of official checks on animal feed;

17. Whereas it is necessary to adopt these measures at Community level in order better to achieve the objectives of guaranteeing the quality and safety of feedingstuffs,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

SCOPE AND DEFINITIONS

Article 1

1. This Directive lays down the conditions and arrangements applicable to certain categories of establishments and intermediaries in the animal feedsector to allow them to exercise the activities described in Articles 2 and 7 and Articles 3 and 8 respectively.

2. This Directive shall apply without prejudice to the Community provisions concerning the organization of official checks on animal feed.

3. For the purposes of this Directive:

(a) ‘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;

(b) ‘establishment’ means any unit producing or manufacturing additives, premixtures prepared from additives, compound feedingstuffs or products covered by Directive 82/471/EEC and referred to in Chapter I.1 (a) of the Annex to this Directive;

(c) ‘intermediary’ means any person other than the manufacturer or the person producing for the exclusive requirements of his holding, compound feedingstuffs, who holds additives, premixtures prepared from additives, or one of the products covered by Directive 82/471/EEC and referred to in Chapter I.1 (a) of the Annex to this Directive at an intermediate stage between production and use.

4. The definitions laid down in Community legislation on animal feed shall apply where necessary.

CHAPTER II

APPROVAL OF ESTABLISHMENTS AND INTERMEDIARIES

Article 2

Approval of establishments

1. An establishment wishing to exercise one or more of the activities referred to in paragraph 2 must receive approval for each of its activities. A Member State may decide not to approve establishments referred to in paragraph 2 (f).

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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 Annex to this Directive with a view to putting them into circulation, must meet the minimum conditions laid down in Chapter I.1 (b) of the said Annex 1;

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

(c) manufacturing compound feedingstuffs containing premixtures prepared from additives referred to in Chapter I.3 (a) of the Annex, with a view to putting them into circulation, must meet the minimum conditions laid down in Chapter I.3 (b) of the Annex;

(d) manufacturing compound feedingstuffs, with a view to putting them into circulation, from raw materials referred to in Article 3a (2) of Directive 74/63/EEC which contain high levels of undesirable substances or products, must meet the minimum conditions laid down in Chapter I.4 of the Annex to this Directive;

(e) producing, for the exclusive requirements of its holding, compound feedingstuffs containing premixtures which include additives referred to in Chapter I.3 (a) of the Annex must meet the minimum conditions laid down in Chapter I.3 (b) of the Annex, with the exception of the requirements set out in point 7;

(f) producing, for the exclusive requirements of its holding, compound feedingstuffs which contain raw materials referred to in Article 3a (2) of Directive 74/63/EEC containing high levels of undesirable substances or products, must meet the minimum conditions laid down in Chapter 1.4 of the Annex to this Directive, with the exception of the requirements set out in point 7.

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.

Article 3

Approval of intermediaries

1. Where additives, products covered by Directive 82/471/EEC or premixtures of additives referred to in Chapters I.1 (a) and I.2 (a) of the Annex 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 Annex shall apply, as appropriate, to intermediaries which wrap, package, store or put into circulation additives, premixtures 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.

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Article 4

Approval procedure for establishments and intermediaries

1. To obtain approval, establishments referred to in Article 2 and intermediaries referred to in Article 3 which intend to exercise for the first time one or more of the activities referred to in Article 2 and 3 shall, as from 1 April 1998 submit an application to the competent authority of the Member State in which their facilities are located.

Member States shall ensure that a decision is taken on applications for approval mentioned in the first subparagraph within six months of their submission.

2. Establishments and intermediaries which, on 1 April 1998, were exercising one or more of the activities referred to in Articles 2 and 3 respectively, may continue their activities until a decision has been taken on their application for approval, on condition that they submit the application before 1 September 1998.

Member States shall act on applications for approval from he establishments and intermediaries referred to in the first paragraph before 1 April 2001.

Article 5

Register of approved establishments and intermediaries

1. For each activity, the competent authority shall enter the establishments and intermediaries it has approved in accordance with Articles 2 and 3 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 this Directive.

In respect of intermediaries who act solely as dealers without ever holding the product in their facilities, Member States need not 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 Annex, 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 Annex for the exercise of their activity.

2. Member States shall update the entries of establishments and intermediaries in the register in accordance with the decisions referred to in Article 2 (3) and Article 3 (2) to withdraw or amend approval.

Article 6

Publication and communication of the list of approved establishments and intermediaries

1. Each Member State shall publish a list of the establishments and intermediaries approved in accordance with Articles 2 and 3 for the first time in November 2001, and then each year, by 30 November at the latest, the list of amendments made during the year; every five years, it shall publish a consolidated list.

2. Before 31 December each year, Member States shall send the Commission the list referred to in paragraph 1.

Before 31 December each year, Member States shall send the other Member States a list of the establishments referred to in Article 2 (2) (a) and (b) and of the intermediaries approved in accordance with Article 3 (1).

Upon request, Member States shall send the other Member States all or part of the list of establishments referred to in Article 2 (2) (c) to (f).

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CHAPTER III

REGISTRATION OF ESTABLISHMENTS AND INTERMEDIARIES

Article 7

Registration of establishments

1. An establishment wishing to exercise one or more of the activities referred to in paragraph 2 must be registered by a Member State for each activity in accordance with this Directive.

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 Annex, with a view to putting them into circulation, must meet the minimum conditions laid down in Chapter II (c) of the Annex;

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

(c) manufacturing compound feedingstuffs containing premixtures of additives referred to in Chapter II (b) of the Annex or additives referred to in Chapter II (a) of the Annex with a view to putting them into circulation, must met the minimum conditions laid down in Chapter II (c) of the Annex;

(d) manufacturing, for the exclusive requirements of its holding, compound feedingstuffs containing premixtures of additives referred to in Chapter II (b) of the Annex or containing additives referred to in Chapter II (a) of the Annex, must met the minimum conditions laid down in Chapter II (c) of the Annex.

3. Approved establishments exercising the corresponding activities referred to in Article 2 (2) (a), (b), (c) and (e) shall be regarded as satisfying *de facto* the conditions laid down in paragraph 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.

Article 8

Registration of intermediaries

1. Where additives for which a prescribed maximum level is set other than those referred to in Chapter I.1 (a) of the Annex or premixtures of additives referred to in Chapter II (a) of the Annex are put into circulation, intermediaries must be registered.

The provisions laid down in point 7 of Chapter II (c) of the Annex shall apply, as appropriate, to intermediaries which wrap, package, store or put into circulation additives or premixtures of additives.

2. Intermediaries approved in accordance with Article 3 shall be regarded as meeting *de facto* the conditions laid down in paragraph 1.

3. Registration 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,

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— 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.

Article 9

Registration procedure for establishments and intermediaries

1. In order to be registered, the establishments referred to in Article 7 (2) and the intermediaries referred to in Article 8 (1) shall, as from 1 April 1998, submit a declaration to the competent authority of the Member State in which they intend to exercise their activities.

2. Establishments and intermediaries which, on 1 April 1998, were exercising one or more of the activities referred to in Articles 7 and 8 respectively, may continue their activities on condition that they submitted the declaration referred to in paragraph 1 by 1 September 1998.

Article 10

List of registered establishments and intermediaries

1. For each activity, the competent authority shall enter the establishments and intermediaries which it has registered in accordance with Articles 7 and 8 on a list under an individual registration number which identifies them.

2. Member States shall update the entries of establishments and intermediaries on the list in accordance with the decisions referred to in Articles 7 (4) and 8 (3) to withdraw or amend registration.

Article 11

Communication of the list of registered establishments and intermediaries

1. Before 31 December each year, Member States shall send the Commission the list of establishments and intermediaries registered during the year in accordance with Articles 7 and 8 and, every five years, they shall send a consolidated list.

2. Upon request, Member States shall send to the other Member States all or part of the lists referred to in paragraph 1.

CHAPTER IV

COMMON PROVISIONS

Article 12

Simplified procedure

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 24 of Directive 81/851/EEC [1], Member States shall not be obliged to verify that the conditions laid down in Article 2 (2) (a) and contained in Chapter I.1 (b) of the Annex to this Directive have been fulfilled, with the exception of the requirements set out in points 4, 5, 6.2 and 7.

Article 13

Checks

Member States shall ensure, by means of appropriate checks carried out in establishments and at the premises of intermediaries which they have

[1] OJ No L 317, 6. 11. 1981, p. 16. Directive as last amended by Commission Directive 93/40/EEC (OJ No L 214, 24. 8. 1993, p. 31).

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approved or registered, that the requirements imposed by this Directive are met.

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Article 14

The Council, acting by a qualified majority on a proposal from the Commission, shall, before 1 April 1999, adopt rules for calculating the level of the fee to be charged for the approval of establishments and their intermediaries.

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Article 15

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

The following shall be adopted in accordance with the procedure laid down in Article 16:

(a) before 1 April 1998, practical arrangements for the approval pursuant to Article 2 and registration pursuant to Article 7 of establishments located in a non-member country and putting additives, premixtures, products covered by Directive 82/471/EEC as referred to in Chapter 1.1 (a) of the Annex to this Directive or feedingstuffs into circulation within the Community, so that safeguards are provided equivalent to those supplied by establishments located in the Community.

These arrangements shall comprise:

— establishment and updating of a list of non-member countries able to provide safeguards equivalent to those offered by the Member States in respect of their own establishments and able to perform the checks referred to in Article 13,

— establishment and updating of a list of establishments which have been found by the non-member countries on the list referred to in the first indent to fulfil the conditions laid down in this Directive,

— the possibility that experts from the Commission and the Member States may carry out on-the-spot checks if necessary. Such checks shall be performed on behalf of the Community, which will bear the relevant expenses;

(b) measures for implementing this Directive, in particular the form of the register and approval numbers;

(c) the amendments to be made to the Annexes.

Article 16

Standing Committee for Feedingstuffs

The Commission shall be assisted by the Standing Committee for Feedingstuffs established by Decision 70/372/EEC, hereinafter referred to as 'the Committee'.

The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of Decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee. If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

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If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures by a simple majority.

CHAPTER V

ADAPTATION OF LEGISLATION

Article 17

Amendment of Directive 70/524/EEC

Article 13 (1) of Directive 70/524/EEC shall be replaced by the following:

'Article 13

1. Member States shall require that additives covered by this Directive, premixtures prepared from these additives with a view to their being incorporated in compound feedingstuffs and compound feedingstuffs containing these premixtures may be put into circulation or used only by the establishments or intermediaries which meet the conditions laid down, as appropriate, in Council Directive 95/69/EC of 22 December 1995 laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector (*).

(*) OJ No L 332, 30. 12. 1995, p. 15.'

Article 18

Amendment of Directive 74/63/EEC

Point (a) of Article 3a (2) of Directive 74/63/EEC shall be replaces by the following:

'(a) it is intended for use by establishments which meet the conditions of Council Directive 95/69/EC of 22 December 1995 laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector (*).

(*) OJ No L 332, 30. 12. 1995, p. 15.'

Article 19

Amendment of Directive 79/373/EEC

In Council Directive 79/373/EEC of 2 April 1979 on the marketing of compound feedingstuffs ([1]), the following subparagraph shall be added to Article 5 (1):

'(k) the approval number allocated to the establishment in accordance with Article 5 of Council Directive 95/69/EC of 22 December 1995 laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector (*).

(*) OJ No L 332, 30. 12. 1995, p. 15.'

([1]) OJ No L 86, 6. 4. 1979, p. 30. Directive as last amended by Directive 93/74/EEC (OJ No L 237, 22. 9. 1993, p. 23).

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Article 20

Amendment of Directive 82/471/EEC

Directive 82/471/EEC is hereby amended as follows:

1. The following paragraph shall be added to Article 3:

   '3. Member States shall require that products referred to in Chapter I.1 (a) of Council Directive 95/69/EC of 22 December 1995 laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector (*) may be put into circulation only by establishments or intermediaries which meet the conditions laid down in Article 2 or Article 3 of that Directive, as appropriate.

   (*) OJ No L 332, 30. 12. 1995, p. 15.'

2. In the Annex, for the products referred to in Chapter I.1 (a) of this Directive, in column 7 ('special provisions'), the terms 'approval number' shall be added as a final indent to the details to be given on the packaging of the product, on the container or on a label affixed thereto.

CHAPTER VI

FINAL PROVISIONS

Article 21

1. Member States shall adopt, not later than 1 April 1998 the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof. The measures adopted shall be applicable as from 1 April 1998.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by the Member States.

2. Member States shall communicate to the Commission the text of the main provisions of domestic law which they adopt in the field governed by this Directive.

Article 22

Thise Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Communities*.

Article 23

This Directive is addressed to the Member States.

(*) OJ No L 332, 30. 12. 1995, p. 15.

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ANNEX

CHAPTER 1

Minimum conditions which must be fulfilled by establishments and intermediaries referred to in Articles 2 and 3 (subject to approval)

CHAPTER I.1. (a)

Additives and products covered by Directive 82/471/EEC ('products') and referred to in Article 2 (2) (a) and Article 3 (1) of this Directive Additives

Additives

— 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:	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 micro-organisms 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 Article 2 (2) (a) and intermediaries referred to in Article 3 (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 madeavailable 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.

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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 that Directive.

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

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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 3 (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 Article 2 (2) (b) and Article 3 (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 Article 2 (2) (b) and intermediaries referred to in Article 3 (1) (premixtures 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 premixtures 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.

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2. ***Personnel***

The manufacturer must have sufficient staff possessing the skills and qualifications necessary for the manufacture of the premixtures 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 premixtures 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 premixture, chronological order of production, meters and weighing apparatus, mixer and returns, in such a way as to obtain the desired quality of the premixtures 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 premixtures 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 premixture, 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 premixtures (‘products’).

Samples of each batch of premixture 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 premixture.

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. Premixtures 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 sets of

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documents must be kept in such a way as to make it possible to trace the manufacturing history of each premixture batch put into circulation and to establish responsibility if complaints arise.

6.2. Register of premixtures

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 premixture, the batch number where appropriate,

— the names and addresses of the intermediaries or manufacturers of compound feedingstuffs to whom the premixture is delivered, the delivery date, the nature and quantity of the premixture is delivered, and the batch number where appropriate.

7. ***Intermediaries referred to in Article 3 (1)***

Where the manufacturer delivers premixtures to a person other than a manufacturer of compound feedingstuffs, 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 Article 2 (2) (c) and (e)

— Antibiotics:	all additives in the group
— Coccidiostats and other medicinal substances:	all additives in the group
— Growth promoters:	all additives in the group

CHAPTER I.3. (b)

Minimum conditions which must be fulfilled by establishments referred to in Article 2 (2) (c) and (e) (compound feedingstuffs containing premixtures 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 feedingstuffs containing premixtures. 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.

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2. ***Personnel***

The manufacturer must have sufficient staff possessing the skills and qualifications necessary for the manufacture of compound feedingstuffs containing premixtures. 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 feedingstuffs containing premixtures.

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 premixture in the feedingstuff, chronological order of production, meters and weighing apparatus, mixer and returns, in such a way as to obtain the desired quality of the compound feedingstuffs 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 feedingstuffs containing premixtures 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 feedingstuffs, and as low a level as possible of cross-contamination, as well as, in the case of feedingstuffs 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, premixtures and compound feedingstuffs 'products'.

Samples must be taken in sufficient quantity by a procedure pre-established by the manufacturer on the basis of each batch of compound feedingstuffs 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 feedingstuffs, or with raw materials containing high levels of undesirable substances and

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products, or with additives. Compound feedingstuffs 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 feedingstuffs

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

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

— the nature and quantity of feedingstuffs 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 Article 2 (2) (d) and (e) (compound feedingstuffs 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 feeedingstuffs 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 feedingstuffs 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 feedingstuffs from the 'raw materials concerned'.

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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 feedingstuff 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 feedingstuffs 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 feedingstuffs 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 feedingstuff, 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 74/63/EEC and, in the case of feedingstuffs 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 feedingstuffs.

Samples must be taken sufficient quantity by a procedure pre-established by the manufacturer on the basis of each of compound feedingstuffs 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 feedingstuffs are put.

5. ***Storage***

Raw materials, notably those containing high levels of undesirable substances and products and compound feedingstuffs 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 feedingstuffs, or with additives or premixtures of additives. Compound feedingstuffs intended to be put into circulation must comply with the provisions of Directive 79/373/EEC.

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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 feedingstuffs

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 Articles 7 and 8 (subject to registration)

CHAPTER II (a)

Additives referred to in Article 7 (2) (b), (c) and (d) and in Article 8 (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 Article 7 (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 with antioxidant effect:	only those with a fixed maximum content

CHAPTER II (c)

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Minimum conditions which must be fulfilled by establishments and intermediaries referred to in Article 7 (2) (a) and (b) and Article 8 (1), (additives for which a prescribed maximum level is set and which are not referred to in Chapter I.1 (a), premixtures of additives referred to in Chapter II (a)) and establishments referred to in Article 7 (2) (c) and (d), (compound feedingstuffs containing premixtures 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, premixtures of additives and compound feedingstuffs containing additives or premixtures 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 feedingstuffs are put.

5. ***Storage***

   Raw materials, active substances, carrier substances, premixtures and compound feedingstuffs 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 feedingstuffs. 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.

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(b) *for premixtures:*

— 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 premixture, the number of the batch where appropriate,

— the names and addresses of the intermediaries or manufacturers to whom the premixtures have been delivered and the nature and quantity of the premixture delivered, and the number of the batch, where appropriate;

(c) *for compound feedingstuffs containing premixtures or additives:*

— the names and addresses of the premixture manufacturers or intermediaries, with the batch number where appropriate, the nature and quantity of the premixture 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 feedingstuffs manufactured, with the date of manufacture.

7. ***Intermediaries referred to in Article 8 (1)***

Where the manufacturer delivers additives to a person other than a manufacturer or stock breeder, or premixtures 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.