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Legislation

Contents

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Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other Acts are printed in bold type and preceded by an asterisk.

I

(Acts whose publication is obligatory)

COUNCIL REGULATION (EC) No 894/96

of 29 April 1996

amending Regulation (EEC) No 805/68 on the common organization of the market in beef and veal, with regard to penalties

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],

Whereas the European Parliament has delivered several opinions, in which it stated its support for both maintaining the total ban on growth promoters in stockfarming and reinforcing supervision, monitoring and penalties in connection with the ban;

Whereas the administration of substances or products not authorized under the relevant Community regulations in the veterinary sector, in particular hormonal substances, presents a serious risk for human health; whereas experience acquired shows that as they are likely to affect the public perception of products obtained from bovine animals, the use of such substances or products may also disrupt the balance on the beef and veal market; whereas, taking into account its effects on meat yield, the illegal use of such substances is also likely to confer on the producers in question economic advantages liable to lead to market distortions; whereas a detailed examination of the current situation has revealed that the measures taken to date against the use of the said substances or products are insufficient to ensure compliance with the provisions on the matter; whereas the penalties in particular should be increased;

Whereas each producer must take full responsibility for ensuring that the animals on his holding are not the subject of illegal administration of the aforementioned substances or products; whereas in order better to accentuate the importance of that responsibility, it is necessary to lay down, that if prohibited substances or products, or authorized substances or products used illegally are detected in any of a producer's bovine animals, the producer should be excluded for one year from the granting of any premium and/or compensatory allowance linked with his animals of the bovine species, with the possibility of the exclusion period being extended up to five years in the event of a repeated infringement; whereas in order not to compromise the effectiveness of such penalties, they should also be applied where unauthorized substances or products, or authorized substances or products which are illegally held are found on the holding, or where the producer impedes the performance of veterinary checks;

Whereas Regulation (EEC) No 805/68 [4], should therefore be amended,

HAS ADOPTED THIS REGULATION:

Article 1

Article 4 j of Regulation (EEC) No 805/68 is hereby replaced by the following:

'Article 4 j

1. Where residues of substances prohibited under Council Directives 81/602/EEC, 88/146/EEC, 88/299/EEC and 96/22/EC(*), or residues of substances authorized under the aforementioned acts but used illegally, are detected pursuant to the relevant provisions of Directives 85/358/EEC,

(1) OJ No C 302, 9. 11. 1993, p. 25 and OJ No C 222, 10. 8. 1994, p. 17.
(2) OJ No C 128, 9. 5. 1994, p. 101.
(3) OJ No C 52, 19. 2. 1994, p. 30.
(4) OJ No L 148, 28. 6. 1968, p. 24. Regulation as last amended by Commission Regulation (EC) No 2417/95 (OJ No L 248, 14. 10. 1995, p. 39).

86/469/EEC and 96/23/EC(**) on monitoring, in an animal belonging to the bovine herd of a producer, or where an authorized substance or product, or a substance or product authorized under the Directive on prohibition but held illegally is found on the producer's holding in any form, the producer shall be excluded, for the calendar year of that discovery, from receiving the amounts provided for under this section and the compensatory allowances provided for in Title VI of Regulation (EEC) No 2328/91 for animals of the bovine species.

In the event of a repeated infringement, the length of the exclusion period may, according to the seriousness of the offence, be extended to five years as from the year in which the repeated infringement was discovered.

2. In the event of obstruction on the part of the owner or holder of the animals when inspections are being carried out and the samples taken which are necessary for the application of national residue-monitoring plans as well as at the time of the investigations and checks provided for under the Directives on monitoring referred to in paragraph 1, the penalties provided for in paragraph 1 shall apply.

3. The Commission shall adopt the detailed arrangements for applying this Article in accordance with the procedure laid down in Article 27.

(*) Council Directive 96/22/EC of 29 April 1996, concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC (OJ No L 125, 23. 5. 1996, p. 3).

(**) Council Directive 96/23/EC of 29 April 1996, on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ No L 125, 23, 5. 1996, p. 10).'

Article 2

This Regulation shall enter into force on the seventh day following that of its publication in the *Official Journal of the European Communities*.

It shall apply as from 1 July 1996.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Luxembourg, 29 April 1996.

For the Council
The President
W. LUCHETTI

COUNCIL DIRECTIVE 96/22/EC

of 29 April 1996

concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC

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 Directive 81/602/EEC [4] prohibits certain substances having a hormonal action and any substances having a thyrostatic action and whereas Directive 88/146/EEC [5] prohibits the use in stockfarming of certain substances having a hormonal action, whilst conceding derogations;

(2) Whereas Council Directive 88/299/EEC [6] lays down the conditions for applying the derogations provided for in Article 7 of Directive 88/146/EEC from the prohibition on trade in certain categories of animals and their meat;

(3) Whereas, on account of the residues they leave in meat and other foodstuffs of animal origin, certain substances having a thyrostatic, oestrogenic, androgenic or gestagenic action may be dangerous for consumers and may also affect the quality of foodstuffs of animal origin;

(4) Whereas new substances having an anabolizing action such as beta-agonists are used illegally in livestock-rearing with a view to stimulating the growth and yield of animals;

(5) Whereas the results of an enquiry conducted by the Commission in the Member States from 1990 to 1992 show that beta-agonists are widely available in the livestock-rearing sector, leading to their illegal use;

(6) Whereas the improper use of beta-agonists can be a serious risk to human health; whereas, in the interests of the consumer, the holding, administering to animals of any species and the placing on the market for that purpose of beta-agonists should be prohibited; whereas, moreover, the holding, administering to animals of any species and the placing on the market of stilbenes and thyrostatic substances should be prohibited and the use of other substances regulated;

(7) Whereas, however, the administering of medicinal products based on beta-agonists may be authorized for well-defined therapeutic purposes, in the case of certain categories of bovine animals, *equidae* and pets;

(8) Whereas, moreover, it is necessary to ensure that all consumers are able to acquire meat and foodstuffs derived therefrom under the same conditions of supply and that those products correspond as closely as possible to their concerns and expectations; whereas, given consumer sensitivity, this can only bring about an increase in the consumption of the products in question;

(9) Whereas the prohibition on the use of hormonal substances for fattening purposes should continue to apply; whereas the use of certain substances for therapeutic or zootechnical purposes may be authorized but must be strictly controlled in order to prevent any misuse;

(10) Whereas withdrawal periods are not harmonized at Community level and there are considerable differences between Member States, particularly as regards authorized veterinary medicinal products containing hormonal substances or beta-agonists; whereas, in the interests of harmonization, maximum withdrawal periods should therefore be set for such medicinal products;

(11) Whereas, furthermore, live animals so treated for therapeutic or zootechnical purposes and the meat

[1] OJ No C 302, 9. 11. 1993, p. 8 and OJ No C 222, 10. 8. 1994, p. 16.
[2] OJ No C 128, 9. 5. 1994, p. 107.
[3] OJ No C 52, 19. 2. 1994, p. 30.
[4] OJ No L 222, 7. 8. 1981, p. 32. Directive as amended by Directive 85/358/EEC (OJ No L 191, 23. 7. 1985, p. 46).
[5] OJ No L 70, 16. 3. 1988, p. 16. Directive as amended by the 1994 Act of Accession.
[6] OJ No L 128, 21. 5. 1988, p. 36.

from such animals should not as a general rule be traded, since this could impair the effectiveness of the control arrangements of the scheme as a whole; whereas, however, derogations from the prohibition may, subject to certain conditions, be provided for in respect of intra-Community trade and imports from third countries of animals intended for breeding and breeding animals at the end of their reproductive life;

(12) Whereas such derogations may be authorized where adequate guarantees are provided so as to prevent distortion of trade; whereas such guarantees must cover the products which may be used, the conditions governing their use and the checks to ensure that the conditions are complied with, particularly with regard to the necessary withdrawal period;

(13) Whereas provision should be made for the effective verification of application of the provisions deriving from this Directive;

(14) Whereas Directives 81/602/EEC, 88/146/EEC and 88/299/EEC should be repealed;

(15) Whereas, if the illegal use of growth and productivity promoters in stockfarming is to be combated effectively in all Member States, action will have to be organized at Community level;

(16) Whereas, on 18 January 1996, the European Parliament asked the Commission and the Council to continue opposing the importation into the Community of meat treated with hormones, requested the maintenance of the total ban on the use of growth promoters in stockfarming and, to that end, asked the Council to adopt without delay the Commission proposal on which the European Parliament had delivered its opinion on 19 April 1994,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. For the purposes of this Directive, the definitions of meat and meat products given in Directives 64/433/EEC[1], 71/118/EEC[2], 77/99/EEC[3], and 91/495/EEC[4], the definitions of aquaculture products given in Directive 91/493/EEC[5] and the definitions of veterinary medicinal products given in Directives 81/851/EEC[6] and 81/852/EEC[7] shall apply.

2. In addition, the following definitions shall apply:

(a) 'farm animals' shall mean domestic animals of the bovine, porcine, ovine and caprine species, domestic solipeds, poultry and rabbits, as well as wild animals of those species and wild ruminants which have been raised on a holding;

(b) 'therapeutic treatment' shall mean the administering — under Article 4 of this Directive — to an individual farm animal of an authorized substance to treat, after examination by a veterinarian, a fertility problem — including the termination of unwanted gestation — and, in the case of beta-agonists, to induce tocolysis in cows when calving and to treat respiratory problems and to induce tocolysis in *equidae* raised for purposes other than meat production;

(c) 'zootechnical treatment' shall mean the administering:

(i) to an individual farm animal of any substance authorized under Article 5 of this Directive for synchronizing oestrus and preparing donors and recipients for the implantation of embryos, after examination of the animal by a veterinarian or, in accordance with the second paragraph of Article 5, under his responsibility;

(ii) in the case of aquaculture animals, to a group of breeding animals for sex inversion, on a veterinarian's prescription and under his responsibility;

(d) 'illegal treatment' shall mean the use of unauthorized substances or products or the use of substances or products authorized under Community legislation for purposes or under conditions other than those laid down in Community legislation.

Article 2

Member States shall prohibit:

(a) the placing on the market of stilbenes, stilbene derivatives, their salts and esters and thyrostatic substances for administering to animals of all species;

(b) the placing on the market of beta-agonists for administering to animals the flesh and products of

(1) OJ No 121, 29. 7. 1964, p. 2012/64. Directive as last amended by Directive 95/23/EC (OJ No L 243, 11. 10. 1995, p. 7).
(2) OJ No L 55, 8. 3. 1971, p. 23. Directive as last amended by the 1994 Act of Accession.
(3) OJ No L 26, 31. 1. 1977, p. 85. Directive as last amended by Directive 85/68/EC (OJ No L 332, 30. 12. 1995, p. 10).
(4) OJ No L 268, 24. 9. 1991, p. 41. Directive as last amended by the 1994 Act of Accession.
(5) OJ No L 268, 24. 9. 1991, p. 15. Directive as last amended by Directive 95/71/EC (OJ No L 332, 30. 12. 1995, p. 40).
(6) OJ No L 317, 6. 11. 1981, p. 1. Directive as last amended by Directive 93/40/EEC (OJ No L 214, 24. 8. 1993, p. 31).
(7) OJ No L 317, 6. 11. 1981, p. 16. Directive as last amended by Directive 93/40/EEC (OJ No L 214, 24. 8. 1993, p. 31).

which are intended for human consumption for purposes other than those provided for in point 2 of Article 4.

Article 3

Member States shall prohibit:

(a) the administering to a farm or aquaculture animal, by any means whatsoever, of substances having a thyrostatic, oestrogenic, androgenic or gestagenic action and of beta-agonists;

(b) the holding, except under official control, of animals referred to in (a) on a farm, the placing on the market or slaughter for human consumption of farm animals or of aquaculture animals which contain the substances referred to in (a) or in which the presence of such substances has been established, unless proof can be given that the animals in question have been treated in accordance with Articles 4 or 5;

(c) the placing on the market for human consumption of aquaculture animals to which substances referred to in (a) have been administered and of processed products derived from such animals;

(d) the placing on the market of meat of the animals referred to in (b);

(e) the processing of the meat referred to in (d).

Article 4

Notwithstanding Articles 2 and 3, Member States may authorize:

1. the administering to farm animals, for therapeutic purposes, of oestradiol 17 β, testosterone and progesterone and derivatives which readily yield the parent compound on hydrolysis after absorption at the site of application. Veterinary medicinal products used for therapeutic treatment must comply with the requirements for placing on the market laid down in Directive 81/851/EEC and be administered only by a veterinarian, by injection or for the treatment of ovarian dysfunction in the form of vaginal spirals, but not by implant, to farm animals which have been clearly identified. Treatment of identified animals must be registered by the veterinarian responsible. The latter must record at least the following details in a register, which may be the one provided for in Directive 81/851/EEC:

   — type of treatment,

   — the type of products authorized,

   — the date of treatment,

   — the identity of the animals treated.

   The register must be made available to the competent authority at its request;

2. the administering for therapeutic purposes of authorized veterinary medicinal products containing:

   (i) allyl trenbolone, administered orally, or beta-agonists to *equidae* and pets, provided they are used in accordance with the manufacturer's instructions;

   (ii) beta-agonists, in the form of an injection to induce tocolysis in cows when calving.

   Such substances must be administered by a veterinarian or, in the case of the veterinary medicinal products referred to in (i), under his direct responsibility; treatment must be registered by the veterinarian responsible, who shall record at least the details referred to in point 1.

   Farmers shall be prohibited from holding veterinary medicinal products containing beta-agonists which may be used for induction purposes in the treatment of tocolysis.

However, without prejudice to the first subparagraph of point 2 (ii), therapeutic treatment of production animals, including breeding animals at the end of their reproductive life, shall be prohibited.

Article 5

Notwithstanding Article 3 (a) and without prejudice to Article 2, Member States may authorize the administering to farm animals, for the purpose of zootechnical treatment, of veterinary medicinal products having an oestrogenic, androgenic or gestagenic action which are authorized in accordance with Directives 81/851/EEC and 81/852/EEC. Such veterinary medicinal products must be administered by a veterinarian to clearly identified animals; the treatment must be recorded by the veterinarian responsible in accordance with point 1 of Article 4.

However, Member States may allow the synchronization of oestrus and the preparation of donors and recipients for the implantation of embryos to be effected not by the veterinarian direct, but under his responsibility.

With regard to aquaculture animals young fish may be treated for the first three months for the purpose of sex inversion with veterinary medicinal products that have an androgenous action and are authorized in accordance with Directives 81/851/EEC and 81/852/EEC.

In the cases provided for in this Article, the veterinarian shall make out a non-renewable prescription, specifying the treatment in question and the quantity of the product required and shall record the products prescribed.

However, zootechnical treatment of production animals, including during the fattening period for breeding

animals at the end of their reproductive life, shall be prohibited.

Article 6

1. Hormonal products and beta-agonists the administration of which to farm animals is authorized in accordance with Articles 4 and 5 must meet the requirements of Directives 81/851/EEC and 81/852/EEC.

2. The following may not, however, be authorized in accordance with paragraph 1:

(a) the following hormonal products:

(i) products acting as a deposit;

(ii) products with a withdrawal period of more than 15 days after the end of treatment;

(iii) products:

— which were authorized under rules that preceded the amendment made by Regulation (EEC) No 2309/93 [1],

— whose conditions of use are not known,

— for which no reagents or equipment exist for use in the analytical techniques for detecting the presence of residues in excess of the permitted limits,

(b) veterinary medicinal products containing beta-agonists which have a withdrawal period of more than 28 days after the end of treatment.

Article 7

1. For the purpose of trade, Member States may authorize the placing on the market of animals for breeding and breeding animals at the end of their reproductive life which, during the latter period, have undergone a treatment referred to in Articles 4 and 5 and may authorize the affixing of the Community stamp to meat from such animals where the conditions laid down in Articles 4 and 5 and the minimum withdrawal periods laid down in Article 6 (2), under (a) (ii) or (b) respectively or the withdrawal periods provided for in the authorization to place on the market are complied with.

However, trade in high-value horses, and in particular racehorses, competition horses, circus horses or horses intended for stud purposes or for exhibitions, including registered *equidae* to which veterinary medicinal products containing allyl trenbolone or beta-agonists have been administered for the purposes referred to in Article 4, may take place before the end of the withdrawal period, provided that the conditions governing administration are fulfilled and that the type and date of treatment are entered on the certificate or passport accompanying these animals.

2. Meat or products from animals to which substances having an oestrogenic, androgenic or gestagenic action or beta-agonists have been administered in accordance with the dispensatory provisions of this Directive may not be placed on the market for human consumption unless the animals in question have been treated with veterinary medicinal products complying with the requirements of Article 6 and in so far as the withdrawal period laid down was observed before the animals were slaughtered.

Article 8

Member States shall ensure that:

1. at the time of the import, manufacture, storage, distribution, sale and use of the substances referred to in Articles 2 and 3 (a), their possession is restricted to the persons authorized by national legislation in accordance with Article 1 of Directive 90/676/EEC [2];

2. in addition to the checks provided for in the Directives governing the placing on the market of the various products in question, the official checks provided for in Article 11 of Directive 96/23/EC [3] are carried out by the competent national authorities without prior notice, with a view to ascertaining:

(a) the possession or presence of substances or products prohibited under Article 2, intended to be administered to animals for the purpose of fattening;

(b) the illegal treatment of animals;

(c) failure to observe the withdrawal periods provided for in Article 6;

(d) failure to observe the restrictions on the use of certain substances or products laid down in Articles 4 and 5;

3. the tests for the presence of:

(a) the substances referred to in point 1 in animals, in the drinking water of animals and in all places where animals are bred or kept;

(b) residues of the aforementioned substances in live animals, their excrement and body fluids and in animal tissues and products

are carried out in accordance with Annexes III and IV to Directive 96/23/EC;

4. where the checks provided for in points 2 and 3 reveal:

(a) the presence of substances or products the use or possession of which is prohibited, or the presence of residues of substances the administering of which comes under the heading of illegal treatment, such substances or products are confiscated, while any animals treated or the meat therefrom is placed under official

[1] OJ No L 214, 24. 8. 1993, p. 1.

[2] OJ No L 373, 31. 12. 1990, p. 15.

[3] See p. 10 of this Official Journal.

supervision until the requisite penalties have been applied;

(b) failure to comply with the requirements of points 2 (b) and (c), the competent authority takes appropriate measures consistent with the gravity of the infringement.

Article 9

Without prejudice to Directive 81/851/EEC, undertakings buying or producing substances having a thyrostatic, oestrogenic, androgenic or gestagenic action and beta-agonists, undertakings authorized in any capacity to market such substances and undertakings buying or producing pharmaceutical and veterinary medicinal products from such substances shall be required to keep registers detailing, in chronological order, quantities produced or acquired and those sold or used for the production of pharmaceutical and veterinary medicinal products and the names of the persons to whom such quantities were sold or from whom they were purchased.

The above information must be made available to the competent authority at its request and, in the case of computerized records, in the form of a printout.

Article 10

Where the results of checks carried out in a Member State show failure to comply with the requirements of this Directive in the country of origin of the animals or products, the competent authority of that Member State shall have recourse to Council Directive 89/608/EEC of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of legislation on veterinary and zootechnical matters [1].

Article 11

1. Third countries whose legislation authorizes the placing on the market and administration of stilbenes, stilbene derivatives, their salts and esters, or of thyrostatic substances for administering to animals of all species may not appear on any of the lists of countries provided for under Community legislation from which Member States are authorized to import farm or aquaculture animals or meat or products obtained from such animals.

2. Member States shall also prohibit the importation from third countries on any of the lists referred to in paragraph 1 of:

(a) farm or aquaculture animals

(i) to which products or substances referred to in point (a) of Article 2 have been administered by any means whatsoever;

(ii) to which substances or products referred to in point (a) of Article 3 have been administered, unless those substances or products were administered in compliance with the provisions and requirements laid down in Articles 4, 5 and 7 and the withdrawal periods allowed in international recommendations have been observed;

(b) meat or products obtained from animals the importation of which is prohibited under point (a).

3. However, animals intended for breeding, breeding animals at the end of their reproductive life, or meat therefrom, from third countries may be imported subject to their affording guarantees at least equivalent to those laid down in this Directive, which have been established in accordance with the procedure laid down in Article 33 of Directive 96/23/EC for the purpose of giving effect to Chapter V of that Directive.

4. Checks on imports from third countries shall be carried out in accordance with Article 4 (2) (c) of Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries [2] and Article 8 (2) of Council Directive 90/675/EEC of 10 December 1990 laying down the principles governing the organization of veterinary checks on products entering the Community from third countries [3].

Article 12

The Council, acting by a qualified majority on a proposal from the Commission, may adopt transitional measures necessary for the introduction of the arrangements provided for in this Directive.

Article 13

1. Directives 81/602/EEC, 88/146/EEC and 88/299/EEC are hereby repealed as from 1 July 1997.

2. References made to the repealed Directives shall be construed as being made to this Directive and should be read in accordance with the correlation table in the Annex.

Article 14

1. Member States shall bring into force the laws, regulations and administrative provisions, including any

[1] OJ No L 351, 2. 12. 1989, p. 34.

[2] OJ No L 268, 24. 9. 1991, p. 56. Directive as last amended by Commission Decision 95/157/EC (OJ No L 103, 6. 5. 1995, p. 40).

[3] OJ No L 373, 31. 12. 1990, p. 1. Directive as last amended by Directive 95/52/EC (OJ No L 265, 8. 11. 1995, p. 16).

penalties, necessary to comply with this Directive on 1 July 1997, and, for beta-agonists, by 1 July 1997 at the latest. They shall forthwith inform the Commission thereof.

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 Member States.

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

3. Pending application of the provisions of this Directive as regards beta-agonists, the relevant national rules shall continue to apply in compliance with the general provisions of the Treaty.

Article 15

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

Article 16

This Directive is addressed to the Member States.

Done at Luxembourg, 29 April 1996.

For the Council
The President
W. LUCHETTI

ANNEX

Correlation table

This Directive	Directives 81/602/EEC, 88/146/EEC and 88/299/EEC	
Article 1 (1)	Article 1 (1)	81/602/EEC
	Article 1 (1)	88/146/EEC
Article 1 (2) (a) and (b)	Article 1 (2)	81/602/EEC
	Article 1 (2)	88/146/EEC
	Article 2 (1) (b)	88/299/EEC
Article 2 (a)	Article 3	81/602/EEC
Article 2 (b)	—	
Article 3	Article 2	81/602/EEC
Article 4 (1)	Article 4	81/602/EEC
	Article 2 and Article 3 (b)	88/146/EEC
	Article 2 (1) (a) and (2) (4)	88/299/EEC
Article 4 (2)	—	
Article 5	Article 4	81/602/EEC
	Article 2 (1) (b) and (2) (4)	88/299/EEC
Article 6	Article 2 (3)	88/299/EEC
Article 7 (1)	Article 7	88/146/EEC
	Article 2 and 3	88/299/EEC
Article 7 (2)	Article 4	88/299/EEC
Article 8	Article 7	81/602/EEC
Article 9	Article 4	88/146/EEC
Article 10	—	
Article 11 (1)	—	
Article 11 (2)	Article 6 (1) and 6 (2)	88/146/EEC
Article 11 (3)	Article 5	88/299/EEC
Article 11 (4)	Article 6 (7)	88/146/EEC
Article 12	—	
Article 13	—	
Article 14	—	
Article 15	—	
Article 16	—	
Annex	—	

COUNCIL DIRECTIVE 96/23/EC

of 29 April 1996

on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC

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 by Directive 96/22/EC [4] the Council decided to maintain the prohibition on the use of certain substances having a hormonal or thyrostatic action, by extending it to beta-agonists having an anabolic effect;

(2) Whereas on 9 March 1995 the European Parliament pointed out, *inter alia,* that the Community urgently needed an effective and uniform monitoring system and asked the Member States to reinforce supervision and monitoring with regard to the use of illegal substances in meat;

(3) Whereas, by Directive 85/358/EEC [5], the Council adopted certain rules on the detection and monitoring of substances having a hormonal or thyrostatic action; whereas those rules should be extended to cover other substances which are used in stockfarming to promote growth and productivity in livestock or for therapeutic purposes and which may prove dangerous to the consumer on account of their residues;

(4) Whereas by Directive 86/469/EEC [6], the Council introduced certain rules on the monitoring of a certain number of residues of pharmacological substances and of environmental contaminants in farm animals and in the fresh meat obtained from such animals; whereas such monitoring should be extended to cover other animal species and all animal products for human consumption;

(5) Whereas Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin [7] laid down in its Annexes limits for certain veterinary medicinal products;

(6) Whereas the Community legislation on monitoring residues in meat lacks clarity, giving rise to varying interpretations in the different Member States;

(7) Whereas there is a need to reinforce the controls carried out by and in the Member States;

(8) Whereas producers and others involved in the stockfarming industry should take greater responsibility in future for the quality and safety of meat for human consumption;

(9) Whereas the specific penalties in respect of stockfarmers not complying with Community legislation in particular prohibiting the use of certain hormonal and anabolic substances in stockfarming are to be incorporated in the separate provisions governing particular product groups;

(10) Whereas Article 4 of Directive 71/118/EEC [8] requires Member States to ensure that checks are conducted to detect residues of substances having a pharmacological action, their derivatives and other substances which may be transmitted to poultrymeat and which may make the consumption of fresh poultrymeat dangerous or harmful to human health;

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[1] OJ No C 302, 9. 11. 1993, p. 12, and OJ No C 222, 10. 8. 1994, p. 17.
[2] OJ No C 128, 9. 5. 1994, p. 100.
[3] OJ No C 52, 19. 2. 1994, p. 30.
[4] See p. 3 of this Official Journal.
[5] OJ No L 191, 23. 7. 1985, p. 46. Directive as last amended by the 1994 Act of Accession.
[6] OJ No L 275, 26. 9. 1986, p. 36. Directive as amended by the 1994 Act of Accession.
[7] OJ No L 224, 18. 8. 1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 282/96 (OJ No L 37, 15. 2. 1996, p. 12).
[8] OJ No L 55, 8. 3. 1971, p. 23. Directive as last amended by the 1994 Act of Accession.

(11) Whereas Directive 91/493/EEC[1] requires a monitoring system to be established by the Member States to detect contaminants present in the aquatic environment;

(12) Whereas Directive 92/46/EEC[2] provides that, by 30 June 1993 at the latest, national measures for the detection of residues in raw milk, heat-treated milk and milk-based products shall have been submitted to the Commission by the Member States, the residues to be detected being those in Part A, group III, and Part B, group II, of Annex I to Directive 86/469/EEC;

(13) Whereas Directive 89/437/EEC[3] requires Member States to ensure that checks are conducted to detect residues of substances having a pharmacological or hormonal action, antibiotics, pesticides, detergents and other substances harmful or likely to alter the organoleptic characteristics of egg products or make the consumption of such products dangerous or harmful to human health;

(14) Whereas Directive 92/45/EEC[4] requires Member States to extend their residue detection plans in order to make wild-game meat subject, where necessary, to sampling checks with a view to detecting the presence of contaminants from the environment and to include rabbits and farmed game in such monitoring;

(15) Whereas, if the illegal use of growth and productivity promoters in stockfarming is to be combated effectively in all Member States, action will have to be organized at Community level;

(16) Whereas systems of self-regulation by producer groups can play an important role in combating the illegal use of growth promoters; whereas it is essential for consumers that these systems adequately guarantee the absence of such promoters and whereas a general European approach is essential to safeguard and support self-regulation systems;

(17) Whereas, to that end, producer groups should be assisted in developing self-regulation systems to ensure that their meat is free of unauthorized substances or products;

(18) Whereas a certain number of provisions of Directives 86/469/EEC and 85/358/EEC and of Decisions 89/187/EEC[5] and 91/664/EEC[6] require clarification in the interests of the effective application of controls and residue detection in the Community; whereas, with a view to immediate and uniform application of the controls provided for, the present rules and amendments to them should be assembled in a single text repealing the aforesaid instruments,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

Scope and definitions

Article 1

This Directive lays down measures to monitor the substances and groups of residues listed in Annex I.

Article 2

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

(a) 'unauthorized substances or products' shall mean substances or products the administering of which to animals is prohibited under Community legislation;

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

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

(d) 'competent authority' shall mean the central authority of a Member State competent in veterinary matters or any authority to which such central authority has delegated such competence;

(e) 'official sample' shall mean a sample taken by the competent authority which bears, for the purposes of examination of the residues or substances listed in

(1) OJ No L 268, 24. 9. 1991, p. 15. Directive as last amended by Directive 95/71/EC (OJ No L 332, 30. 12. 1995, p. 40).
(2) OJ No L 268, 14. 9. 1992, p. 1. Directive as last amended by the 1994 Act of Accession.
(3) OJ No L 212, 22. 7. 1989, p. 87. Directive as last amended by the 1994 Act of Accession.
(4) OJ No L 268, 14. 9. 1992, p. 35. Directive as last amended by the 1994 Act of Accession.
(5) OJ No L 66, 10. 3. 1989, p. 37.
(6) OJ No L 368, 31. 12. 1991, p. 17.

Annex I, a reference to the species, the type, the quantity concerned, the method of collection and particulars identifying the sex of the animal and the origin of the animal or of the animal product;

(f) 'approved laboratory' shall mean a laboratory approved by the competent authorities of a Member State for the purposes of examining an official sample in order to detect the presence of residues;

(g) 'animal' shall mean the species covered by Directive 90/425/EEC(1);

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

(i) 'beta-agonist' shall mean a beta adrenoceptor agonist.

CHAPTER II

Monitoring plans for the detection of residues or substances

Article 3

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

Article 4

1. Member States shall assign the task of coordinating the implementation of the inspections provided for in this Chapter, which are carried out within their national territory, to a central public department or body.

2. The department or body referred to in paragraph 1 shall be responsible for:

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

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

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

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

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

Article 5

1. By 30 June 1997 at the latest, Member States shall submit a plan to the Commission setting out the national measures to be implemented during the initial year of the plan and subsequently any update of plans previously approved in accordance with Article 8 on the basis of the experience of the preceding year, or years by 31 March at the latest of the year of the update.

2. The plan provided for in paragraph 1 shall:

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

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

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

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

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

Article 6

1. The plan must conform to the sampling levels and frequencies laid down in Annex IV. However, at the request of a Member State the Commission may, in accordance with the procedure provided for in Article 32, adjust the minimum control requirements laid down in Annex IV provided that it is clearly established that such adjustments increase the overall effectiveness of the plan in respect of the Member State concerned and in no way reduce its ability to identify residues of, or cases of illegal treatment with, substances listed in Annex I.

2. Re-examination of the groups of residues to be checked for in accordance with Annex II and determination of the sampling levels and frequencies covering the animals and products referred to in Article 3 and not already laid down in Annex IV shall take place in accordance with the procedure provided for in Article 33 and on the first occasion within a maximum of 18 months of the adoption of this Directive. In doing so, account shall be taken of experience gained under

(1) OJ No L 224, 18. 8. 1990, p. 29. Directive as last amended by Directive 92/65/EEC (OJ No L 268, 14. 9. 1992, p. 54).

existing national measures and information forwarded to the Commission under existing Community requirements making such specific product groups subject to monitoring for residues.

Article 7

The initial plan shall take into account the specific situation of each Member State and specify in particular:

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

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

— a list of approved laboratories with details of their capacity for processing samples,

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

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

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

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

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

Article 8

1. The Commission shall examine the initial plans forwarded pursuant to Article 5 (1) to ascertain whether they conform to this Directive. The Commission may ask a Member State to modify or supplement these plans to make them conform.

Once the Commission has established their conformity, it shall submit the plans for approval in accordance with the procedure provided for in Article 33.

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

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

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

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

The Commission shall inform the Member States of such approval immediately.

Where there are comments from Member States or where the Commission deems the update not to be in conformity or insufficient, the Commission shall submit the updated plans to the Standing Veterinary Committee, which must act under the procedure laid down in Article 33.

The provisions laid down in paragraph 3 and 4 shall apply to the updated plans.

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

Member States shall make public the outcome of the implementation of the plans.

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

4. Each year, or whenever it deems it necessary on public health grounds, the Commission shall report to Member States within the Standing Veterinary Committee on the outcome of the checks and surveys referred to in paragraph 3, in particular on:

[1] OJ No L 221, 7. 8. 1986, p. 43. Directive as last amended by Directive 95/39/EC (OJ No L 197, 22. 8. 1995, p. 29).

— the implementation of national plans,

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

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

CHAPTER III

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

Article 9

A. Member States shall ensure that:

1. any farms which place farm animals on the market and any natural or legal person engaged in trade in such animals register beforehand with the competent authorities and undertake to abide by the relevant Community and national rules, in particular the provisions laid down in Articles 5 and 12 of Directive 90/425/EEC;

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

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

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

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

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

3. (a) the producers or persons in charge referred to in points 1 and 2 place on the market only:

      (i) animals to which no unauthorized substances or products have been administered or which have not undergone illegal treatment within the meaning of this Directive;

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

      (iii) products derived from the animals referred to in (i) and (ii);

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

B. For the purposes of applying point A, Member States shall ensure, without prejudice to compliance with the rules laid down in the Directives governing the placing on the market of the various products in question, that:

— the principle of quality monitoring of the production chain by the different parties involved is established in their legislation,

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

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

Article 10

Member States shall ensure that the terms of reference and responsibilities of veterinarians monitoring farms are extended to monitoring the rearing conditions and the forms of treatment referred to in this Directive.

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

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

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

[1] OJ No L 373, 31. 12. 1990, p. 15.

CHAPTER IV

Official control measures

Article 11

1. Without prejudice to the checks carried out in connection with implementation of the surveillance plans referred to in Article 5 or to the checks provided for in specific Directives, Member States may have official random checks conducted:

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

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

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

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

3. Where fraud is suspected, and in the case of a positive result from any of the checks referred to in paragraph 1, Articles 16 to 19 and the measures provided for in Chapter V shall apply.

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

Article 12

The checks provided for in this Directive must be carried out by the competent national authorities without prior notice.

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

Article 13

The competent authority shall:

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

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

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

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

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

— the checks provided for in Article 11 (1) (a),

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

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

Article 14

1. Each Member State shall designate at least one national reference laboratory. A given residue or residue group may not be assigned to more than one national reference laboratory.

However, until 31 December 2000, Member States may continue to entrust testing for the same residue or residue group to several national laboratories which they designated prior to the date of adoption of this Directive.

A list of such designated laboratories shall be drawn up in accordance with the procedure laid down in Article 33.

These laboratories shall be responsible for:

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

— assisting the competent authority in organizing the plan for monitoring residues,

— periodically organizing comparative tests for each residue or residue group assigned to them,

— ensuring that national laboratories observe the limits laid down,

— disseminating information supplied by Community reference laboratories,

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

2. The Community reference laboratories shall be those designated in Chapter 1 of Annex V.

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

Article 15

1. Official samples must be taken in accordance with Annexes III and IV in order to be examined in approved laboratories.

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

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

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

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

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

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

Where the examination referred to in this paragraph covers animals or products of animal origin from another Member State, the competent authority of the Member State of origin shall apply Articles 16 (2), 17, 18 and 19 and the measures provided for in Chapter V to the farm or establishment of origin or departure, following the reasoned request of the competent authority having carried out the examination.

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

Article 16

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

1. the competent authority shall obtain without delay:

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

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

2. the appropriate authority shall carry out:

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

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

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

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

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

Article 17

Where illegal treatment is established, the competent authority must ensure that the livestock concerned in the investigations referred to in point (b) of Article 13 is immediately placed under official control. It must furthermore ensure that all the animals concerned bear an official mark or identification and that, as a first step, an official sample is taken from a statistically representative sample, on internationally recognized scientific bases.

Article 18

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

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

2. In the event of repeated infringements of maximum residue limits when animals are placed on the market by a farmer or products are placed on the market by a farmer or a processing establishment, intensified checks on the animals and products from the farm and/or establishment in question must be carried out by the competent authorities for a period of at least six months, products or carcases being impounded pending the results of analysis of the samples.

Any results showing that the maximum residue limit has been exceeded must lead to the carcases or products concerned being declared unfit for human consumption.

Article 19

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

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

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

Article 20

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

2. Where a Member State considers that, in another Member State, the controls provided for in this Directive are not being, or have ceased to be, carried out, it shall inform the competent central authority of that State accordingly. Following an investigation carried out in accordance with point 2 of Article 16, that authority shall take all necessary measures and shall, at the earliest opportunity notify the competent central authority, of the first Member State of the decisions taken and the reasons for those decisions.

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

Member States shall inform the Commission of disputes and of solutions arrived at.

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

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

In the light of the experts' opinion, appropriate measures may be taken in accordance with the procedure provided for in Article 32.

(1) OJ No L 351, 2. 12. 1989, p. 34.
(2) OJ No L 395, 30. 12. 1989, p. 13. Directive as last amended by Directive 92/67/EEC (OJ No L 268, 14. 9. 1992, p. 73).

Those measures may be reviewed in accordance with the same procedure, in the light of a new expert opinion delivered within 15 days.

Article 21

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

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

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

CHAPTER V

Measures to be taken in the event of infringement

Article 22

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

Article 23

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

2. After sampling has been carried out in accordance with Article 17, if there is confirmation of a case of illegal treatment, the animal or animals found to be positive shall be slaughtered immediately on the spot or taken immediately to the designated slaughterhouse or to the knacker's yard under cover of an official veterinary certificate in order to be slaughtered there. Animals so slaughtered shall be sent to a high-risk processing plant as defined by Directive 90/667/EEC [1].

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

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

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

5. In view of the infringement recorded, the farms or establishments supplying the holding concerned shall be subject to checks in addition to those provided for in Article 11 (1) to determine the origin of the substance in question. The same shall apply to all farms and establishments in the same supply chain of animals and animal feed as the farm of origin or departure.

Article 24

The official veterinarian of a slaughterhouse must:

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

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

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

[1] OJ No L 363, 27. 12. 1990, p. 51. Directive as last amended by the 1994 Act of Accession.

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

In that event, Articles 20 to 23 shall apply;

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

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

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

3. declare unfit for human consumption carcases and products in which the residue level exceeds the levels authorized by Community or national regulations.

Article 25

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

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

Article 26

Rights of appeal allowed by national legislation in force in the Member States against decisions taken by the competent authorities under Articles 23 and 24 shall not be affected by this Directive.

Article 27

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

Article 28

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

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

CHAPTER VI

Imports from third countries

Article 29

1. Inclusion and retention on the lists of third countries provided for in Community legislation from which Member States are authorized to import animals and animal products covered by this Directive shall be subject to submission by the third country concerned of a plan setting out the guarantees which it offers as regards the monitoring of the groups of residues and substances referred to in Annex I. This plan must be updated at the request of the Commission, particularly when the checks referred to in paragraph 3 render it necessary.

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

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

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

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

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

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

Article 30

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

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

— the Member States shall carry out more stringent checks on all batches of animals or products from the same source. In particular, the next 10 batches from the same source must be impounded — and a deposit lodged against inspection costs — at the frontier inspection post for a check on residues by taking a representative sample of each batch or of the part of the batch.

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

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

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

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

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

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

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

(1) OJ No L 302, 31. 12. 1972, p. 28. Directive as last amended by the 1994 Act of Accession.
(2) OJ No L 373, 31. 12. 1990, p. 1. Directive as last amended by Directive 92/52/EC (OJ No L 265, 8. 11. 1995, p. 16).
(3) OJ No L 268, 24. 9. 1991, p. 56. Directive as last amended by the 1994 Act of Accession.

CHAPTER VII

General provisions

Article 31

The Council, acting on a proposal from the Commission, shall amend Directive 85/73/EEC[1] before 1 July 1997 in order to provide for the charging of a fee to cover monitoring carried out pursuant to this Directive.

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

Article 32

1. Where the procedure laid down in this Article is to be followed, matters shall be referred without delay to the Standing Veterinary Committee set up by Decision 68/361/EEC[2], by its Chairman, either on his own initiative or at the request of a Member State.

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

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

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

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

Article 33

1. Where the procedure laid down in this Article is to be followed, matters shall be referred without delay to the Standing Veterinary Committee, by its Chairman, either on his own initiative or at the request of a Member State.

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

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

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

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

Article 34

Without prejudice to Article 6 (2), Annexes I, III, IV and V may be amended or supplemented by the Council acting by a qualified majority on a proposal from the Commission.

In particular, the aforementioned Annexes may be amended within three years of the date of adoption of this Directive, with a view to risk assessment of the following factors:

— potential toxicity of residues in foodstuffs of animal origin,

— likelihood of residues occurring in foodstuffs of animal origin.

Article 35

The Council, acting by a qualified majority on a proposal from the Commission, may adopt transitional measures required for the implementation of the arrangements laid down by this Directive.

Article 36

1. Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC are hereby repealed as from 1 July 1997.

2. The following are also repealed as from the said date:

(a) Article 4 (3) of Directive 71/118/EEC;

(b) Article 5 (3) and (4) of Directive 89/437/EEC;

(1) OJ No L 32, 5. 2. 1985, p. 14. Directive as last amended by Directive 95/24/EC (OJ No L 243, 11. 10. 1995, p. 14).
(2) OJ No L 255, 18. 10. 1968, p. 23.

(c) the last subparagraph of point II.3.B of Chapter V of the Annex to Directive 91/493/EEC;

(d) Article 11 (1) of Directive 92/45/EEC;

(e) Article 15 (1) of Directive 92/46/EEC.

3. References to Directives and Decisions which have been repealed shall be deemed to be references to this Directive and shall be read in accordance with the correlation table in Annex VI.

Article 37

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 July 1997.

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 Member States.

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

Article 38

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

Article 39

This Directive is addressed to the Member States.

Done at Luxembourg, 29 April 1996.

For the Council
The President
W. LUCHETTI

ANNEX I

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

(1) Stilbenes, stilbene derivatives, and their salts and esters

(2) Antithyroid agents

(3) Steroids

(4) Resorcylic acid lactones including zeranol

(5) Beta-agonists

(6) Compounds included in Annex IV to Council Regulation (EEC) No 2377/90 of 26 June 1990

GROUP B — **Veterinary drugs**[1] **and contaminants**

(1) Antibacterial substances, including sulphonomides, quinolones

(2) Other veterinary drugs

- (a) Anthelmintics
- (b) Anticoccidials, including nitroimidazoles
- (c) Carbamates and pyrethroids
- (d) Sedatives
- (e) Non-steroidal anti-inflammatory drugs (NSAIDs)
- (f) Other pharmacologically active substances

(3) Other substances and environmental contaminants

- (a) Organochlorine compounds including PcBs
- (b) Organophosphorus compounds
- (d) Chemical elements
- (d) Mycotoxins
- (e) Dyes
- (f) Others

[1] Including unlicensed substances which could be used for veterinary purposes.

ANNEX II

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

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

(*) Only chemical elements are relevant where wild game is concerned.

ANNEX III

SAMPLING STRATEGY

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

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

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

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

   The samples must be targeted taking account of the following minimum criteria: sex, age, species, fattening system, all available background information, and all evidence of misuse or abuse of substances of this group.

   The details of these criteria will be laid down in the Commission Decision provided for in Article 15 (1).

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

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

ANNEX IV

SAMPLING LEVELS AND FREQUENCY

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

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

CHAPTER 1

Bovine, porcine, ovine, caprine and equine animals

1. **Bovine animals**

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

Group A: 0,25 % divided as follows:

— one half of the samples are to be taken from live animals on the holding;

(by derogation, 25 % of samples analysed for the research of Group A 5 substances can be taken from appropriate material (feedingstuffs, drinking water, etc.))

— one half of the samples are to be taken at the slaughterhouse.

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

The balance must be allocated according to the experience and background information of the Member State.

Group B: 0,15 %

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

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

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

The balance must be allocated according to the situation of the Member State.

2. **Porcine animals**

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

Group A: 0,02 %

In those Member States which carry out their sampling of animals at the slaughterhouse, in addition analysis of drinking water, feedingstuffs, faeces, or all other appropriate parameters must be undertaken at farm level. In that case, the minimum number of farms to be visited annually must represent at least one farm per 100 000 pigs slaughtered the previous year.

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

The balance will be allocated according to the experience and background information of the Member State.

Group B: 0,03 %

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

3. **Sheep and goats**

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

Group A: 0,01 %

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

The balance will be allocated according to the experience and background information of the Member State.

Group B: 0,04 %

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

4. **Equine animals**

The number of samples is to be determined by each Member State in relation to the problems identified.

CHAPTER 2

Broiler chickens, spent hens, turkeys, other poultry

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

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

The following breakdown must be respected:

Group A: 50 % of the total samples

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

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

The balance will be allocated according to the experience and background information of the Member State.

Group B: 50 % of the total samples,

30 % must be checked for Group B 1 substances,

30 % must be checked for Group B 2 substances,

10 % must be checked for Group B 3 substances.

The balance will be allocated according to the situation of the Member State.

CHAPTER 3

Aquaculture products

1. **Finfish farming products**

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

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

The minimum number of samples to be collected each year must be at least 1 per 100 tonnes of annual production.

The compounds sought and the samples selected for analysis should be selected according to the likely use of these substances.

The following breakdown must be respected:

Group A: one third of the total samples:

all the samples must be taken at farm level, on fish at all stages of farming(1), including fish which is ready to be placed on the market for consumption.

Group B: two thirds of the total samples:

the sampling should be carried out:

(a) preferably at the farm, on fish ready to be placed on the market for consumption;

(b) either at the processing plant, or at wholesale level, on fresh fish, on condition that tracing-back to the farm of origin, in the event of positive results, can be done.

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

2. **Other aquaculture products**

When Member States have reason to believe that veterinary medicine or chemicals are being applied to the other aquaculture products, or when environmental contamination is suspected, then these species must be included in the sampling plan in proportion to their production as additional samples to those taken for finfish farming products.

(1) For sea-farming, in which sampling conditions may be especially difficult, samples may be taken from feed in place of samples from fish.

ANNEX V

Chapter 1

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

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

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

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

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

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

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

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

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

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

Chapter 2

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

1. The functions of Community reference laboratories shall be:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(d) have an adequate administrative infrastructure;

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

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

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

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

ANNEX VI

Correlation table

This Directive	Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC	
Article 1	—	
Article 2	Article 2	86/469/EEC
Article 3	Article 1	86/469/EEC
	Article 2	85/358/EEC
Article 4	Article 3	86/469/EEC
Article 5	Article 4 (1) first and second indents	86/469/EEC
Article 6	—	
Article 7	Article 4 (1) except first and second indents	86/469/EEC
Article 8	Article 4 (2) to 4 (5)	86/469/EEC
	Article 12	86/469/EEC
	Article 9	85/358/EEC
Article 9	—	
Article 10	—	
Article 11	Article 1	85/358/EEC
Article 12	—	
Article 13	Article 3	85/358/EEC
	Article 10	86/469/EEC
Article 14 (1)	Article 8 (1) (b)	86/469/EEC
Article 14 (2)	Article 8 (2)	86/469/EEC
	Decision 91/664/EEC	
	Decision 89/187/EEC	
Article 15 (1)	Article 8 (3)	86/469/EEC
	Article 5 (2)	85/358/EEC
Article 15 (2)	Article 8 (3)	86/469/EEC
	Article 5 (3)	85/358/EEC
Article 15 (3)	Article 9	86/469/EEC
Article 16	Article 9 (1) and Article 9 (2)	86/469/EEC
	Article 6 (1) and Article 6 (2)	85/358/EEC
Article 17	Article 9 (3) (a)	86/469/EEC
	Article 6 (3) (a)	85/358/EEC
Article 18	Article 9 (3) (c) and (d)	86/469/EEC
Article 19	—	
Article 20 (1)	—	
Article 20 (2)	Article 11	86/469/EEC
Article 21	Article 5	86/469/EEC
Article 22	Article 7	85/358/EEC
Article 23	Articles 9 (3) (b) (c) (d) and 9 (4), 9 (5)	86/469/EEC
	Articles 6 (3) (b) (c) (d) and 6 (4)	85/358/EEC
Article 24	Article 4	85/358/EEC
Article 25	—	
Article 26	—	

This Directive	Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC	
Article 27	—	
Article 28	—	
Article 29	Article 7	86/469/EEC
	Article 13	85/358/EEC
Article 30	—	
Article 31	Article 12	85/358/EEC
Article 32	Article 14	86/469/EEC
	Article 11	85/358/EEC
Article 33	Article 15	86/469/EEC
	Article 10	85/358/EEC
Article 34	Article 13	86/469/EEC
Article 35	—	
Article 36	—	
Article 37	—	
Article 38	—	
Article 39	—	
Annex I	Annex I	86/469/EEC
Annex II	—	
Annex III	—	
Annex IV	Annex II	86/469/EEC
Annex V Chapter 1	Decision 91/664/EEC	
Annex V Chapter 2	Decision 89/187/EEC	
Annex VI	—	

COUNCIL DIRECTIVE 96/24/EC

of 29 April 1996

amending Directive 79/373/EEC on the marketing of compound feedingstuffs

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],

Whereas Council Directive 77/101/EEC of 23 November 1976 on the marketing of straight feedingstuffs [4] has been repealed by Council Directive 96/25/EC of 29 April 1996 on the circulation of feed materials, amending Directives 70/524/EEC, 74/63/EEC, 82/471/EEC and 93/74/EEC and repealing Directive 77/101/EEC [5];

Whereas Directive 96/25/EC aims, in particular, to remove differences between the national legislations concerning straight feedingstuffs and raw materials; whereas, to that end, it introduces a common term 'feed materials' and a definition of that term which covers straight feedingstuffs and raw materials; whereas, consequently, those terms and their definitions in Directive 79/373/EEC [6] should be replaced by the new common term and by its definition as given in Directive 96/25/EC; whereas these amendments have an impact on the definition of compound feedingstuffs;

Whereas the list contained in Part B of the Annex to Directive 96/25/EC should be used for the circulation of feed materials whatever their intended use, as well as for the labelling of feed materials used in compound feedingstuffs;

Whereas Commission Directive 92/87/EEC of 26 October 1992 establishing a non-exclusive list of the main ingredients normally used and marketed for the preparation of compound feedingstuffs intended for animals other than pets [7] lays down a list of ingredients for the labelling requirements of compound feedingstuffs; whereas measures should be taken to ensure that Directive 92/87/EEC is repealed with the entry into force of Parts A and B of the Annex to Directive 96/25/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Council Directive 79/373/EEC is hereby amended as follows:

1. in Article 1 (2) (a) the term 'straight feedingstuffs' shall be replaced by the term 'feed materials';

2. the term 'ingredient(s)' shall be replaced by the term 'feed material(s)';

3. Article 2 (b) shall be replaced by the following:

   '(b) compound feedingstuffs: mixtures of feed materials, whether or not containing additives, for oral animal feeding in the form of complete or complementary feedingstuffs;'

4. Article 2 (k) shall be replaced by the following:

   '(k) feed materials: various products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing additives, which are intended for use in oral animal feeding, either directly as such or after processing, in the preparation of compound feedingstuffs or as carriers of premixtures;'

5. Article 10 (b) shall be deleted;

6. in Article 10 (a) (1) the wording 'referred to in Article 10 (b)' shall be replaced by the following: 'of the main feed materials listed in Part B of the Annex to Council Directive 96/25/EC of 29 April 1996 on the

(1) OJ No C 238, 26. 8. 1994, p. 6.
(2) OJ No C 305, 31. 10. 1994, p. 146.
(3) OJ No C 102, 24. 4. 1995, p. 12.
(4) OJ No L 32, 3. 2. 1977, p. 1. Directive as last amended by Directive 90/654/EEC (OJ No L 353, 17. 12. 1990, p. 48).
(5) See page 35 of this edition of the Official Journal.
(6) 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).
(7) OJ No L 319, 4. 11. 1992, p. 19.

circulation of feed materials, amending Directives 70/524/EEC, 74/63/EEC, 82/471/EEC and 93/74/EEC and repealing Directive 77/101/EEC(*).

(*) OJ No L 125, 23. 5. 1996, p. 35';

7. Article 10 (a) (2) shall be replaced by the following:

'2. Member States shall ensure that the provisions of headings (I), (II), (III) and (IV) of Part A "General" of the Annex to Directive 96/25/EC are respected.';

8. Article 11 shall be replaced by the following:

'*Article 11*

For the purposes of marketing within the Community, the indications printed on the accompanying document, on the packaging, on the container or on the label attached thereto shall be written in at least one or several languages which the country of destination shall determine from among the national or official languages of the Community.'

Article 2

Member States shall bring into force not later than 30 June 1998 the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, 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 Member States.

Article 3

The provisions adopted shall apply as from 1 July 1998. Member States shall, however, lay down that compound feedingstuffs marketed before 1 July 1998 which do not comply with this Directive may remain in circulation until 30 June 1999.

Article 4

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

Article 5

This Directive is addressed to the Member States.

Done at Luxembourg, 29 April 1996.

For the Council
The President
W. LUCHETTI

COUNCIL DIRECTIVE 96/25/EC

of 29 April 1996

on the circulation of feed materials, amending Directives 70/524/EEC, 74/63/EEC, 82/471/EEC and 93/74/EEC and repealing Directive 77/101/EEC

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, in the framework of the production, processing and consumption of agricultural products feed materials play an important role in agriculture;

(2) Whereas, in the light of growing interest in quality, efficiency and the environment, the role of feed materials in agriculture will gain in importance;

(3) Whereas, in these circumstances, the rules governing the circulation of feed materials are particularly useful in ensuring sufficient transparency throughout the feed chain while improving the quality of agricultural production, notably livestock production;

(4) Whereas Council Directive 77/101/EEC of 23 November 1976 on the marketing of straight feedingstuffs [4], lays down rules for the marketing of straight feedingstuffs; whereas Member States still have different traditions as regards regulating the marketing of raw materials; whereas for that reason Directive 77/101/EEC permits Member States to provide for derogations in certain cases;

(5) Whereas the result of these derogations is that in some Member States Directive 77/101/EEC governs the marketing of both straight feedingstuffs and raw feed materials and in other Member States only the marketing of straight feedingstuffs, which allows straight feedingstuffs to be sold as raw feed materials not subject to rules;

(6) Whereas, with a view to the smooth functioning of the internal market, the discrepancies which can still be noted among the Member States should be removed; whereas, in view of the extent of the sector under consideration, Directive 77/101/EEC should be replaced by new rules;

(7) Whereas straight feedingstuffs and raw feed materials are so similar and close, that to ensure a consistent integration of the scope of this Directive they should be placed in one category, namely 'feed materials';

(8) Whereas the new definition 'feed materials' includes the intended purpose of these products, namely the use in oral animal feeding, as provided for in the existing definitions for 'feedingstuffs' and 'compound feedingstuffs'; whereas it is thus guaranteed that the term 'feedingstuffs' can now be used as a generic term for all feed materials and compound feedingstuffs;

(9) Whereas this comprehensive definition for 'feedingstuffs' is particularly important for Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs [5] and Council Directive 74/63/EEC of 17 December 1973 on undesirable substances and products in animal nutrition [6]; whereas in certain cases both terms 'feedingstuffs' and 'feed materials' will be used in order to specify the provisions, since in Directive 74/63/EEC certain provisions only apply to feed materials, whereas other provisions apply to all feedingstuffs including feed materials;

(10) Whereas, in order to achieve the desired transparency throughout the entire feed chain, this Directive covers the 'circulation' of feed materials;

[1] OJ No C 236, 24. 8. 1994, p. 7.
[2] OJ No C 305, 31. 10. 1994, p. 147.
[3] OJ No C 102, 24. 4. 1995, p. 10.
[4] OJ No L 32, 3. 2. 1977, p. 1. Directive as last amended by Directive 90/654/EEC (OJ No L 353, 17. 12. 1990, p. 48).
[5] OJ No L 270, 14. 12. 1970, p. 1. Directive as last amended by Commission Directive 95/55/EC (OJ No L 263, 4. 11. 1995, p. 18).
[6] OJ No L 38, 11. 2. 1974, p. 31. Directive as last amended by Directive 93/74/EEC (OJ No L 237, 22. 9. 1993, p. 23).

(11) Whereas satisfactory results in livestock production depend to a large extent on the right use of suitable, good quality feed materials; whereas feed materials must therefore always be sound, genuine and of merchantable quality; whereas they must neither represent a danger to animal or human health nor be marketed in a manner liable to mislead;

(12) Whereas, since many products can have either a feed or a non-feed purpose, the feed purpose must be indicated by compulsory *ad hoc* labelling when the products in question are put into circulation for that purpose;

(13) Whereas the circulation of feed materials in many cases occurs in bulk consignments, whether or not split up into several units; whereas such materials are generally accompanied by documents such as invoices and waybills; whereas these papers may serve as 'accompanying documents' within the meaning of Article 5 of this Directive; whereas this is permitted only if identification of (the units of) the consignment and the existence of a common reference and an accompanying document is properly guaranteed at all stages of circulation, for example by the use of reference numbers or signs;

(14) Whereas, since feed materials can differ in health and nutritional quality, a clear distinction should be made between the different feed materials by subjecting them, when they are put into circulation, to a labelling requirement indicating their specific names;

(15) Whereas the buyers or users of feed materials should throughout the feed chain be given accurate and valid additional information, such as the quantities of analytical constituents having a direct effect on the quality of the feed material; whereas failure by the seller to declare the quantities of analytical constituents should be avoided in order to protect small buyers claiming this information in vain and to avoid the unnecessary costs of a multiplication of analyses immediately before the end of the feed chain; whereas certain Member States experience difficulties in conducting inspections at farm level; whereas under these circumstances it is necessary to adopt provisions requiring the quantities of analytical constituents to be declared at the beginning of the feed chain;

(16) Whereas labelling particulars concerning the analytic composition of feed materials are not required if, before the transaction, the purchaser deems that he has no need of such information; whereas this labelling exemption may apply in particular to products stored until such time as they are the subject of a new transaction;

(17) Whereas the circulation of feed materials between farmers in the great majority of cases consists of products of vegetable or animal origin, in their natural state, fresh or preserved, whether or not subjected to simple physical treatment such as chopping or grinding and not treated with additives, except for preservatives; whereas for general reasons of knowledge of the characteristics of such products and for practical reasons no declaration referred to in this Directive should be required on an accompanying document such as an invoice; whereas this should nevertheless be required where the products in question are treated with additives as such treatment may change the chemical composition and nutritional value of the products;

(18) Whereas feed materials of animal or vegetable origin are sold in small quantities by many retailers, frequently for feeding pet animals; whereas for general reasons of knowledge of the characteristics of such products and for practical reasons no constituent declaration should be required for these products;

(19) Whereas, in certain third countries, there are not always the necessary means of carrying out analyses which make it possible to supply the information required by this Directive on the analytic composition of feed materials; whereas Member States should therefore be allowed, on certain conditions, to permit such materials to be put into circulation in the Community accompanied by provisional composition data;

(20) Whereas, where reliable definitive data on analytical constituents are not available, in particular of feed materials from third countries put into circulation in the Community for the first time, in order to avoid unnecessary clogging of ports and road/rail links there should be the possibility of giving final confirmation of provisionally declared data within 10 working days;

(21) Whereas several basic Community regulations provide for lists of ingredients and straight feedingstuffs;

(22) Whereas, for practical reasons and to ensure the necessary legal consistency and efficiency, a list of

the main feed materials similar to lists already established in comparable areas should be drawn up;

(23) Whereas such a list cannot be exhaustive owing to the great diversity of products and by-products which may be traded and used, the constant development of food technology and the need not to restrict choice for manufacturers and farmers; whereas it is possible to allow the circulation of feed materials other than those included in the abovementioned list provided that they are designated by specific names preventing any confusion with materials qualifying for a name laid down at Community level;

(24) Whereas feed materials containing levels of undesirable substances and products higher than those indicated for straight feedingstuffs in Annex I to Directive 74/63/EEC should be supplied only to compound feed manufacturers approved in accordance with the provisions 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[1]; whereas this should be stated on compulsory specific labelling indicating the intended use of the product; whereas these undesirable substances and products should be included on the list of Part B of Annex II to Directive 74/63/EEC, with certain exceptions relating to aflatoxin, cadmium and arsenic and feed materials containing these substances, which are already listed in Annex II, Part A to Directive 74/63/EEC;

(25) Whereas amendment of the list of the chief feed materials constitutes a scientific measure;

(26) Whereas the list in Part B of the Annex to this Directive should be used for the circulation of feed materials, irrespective of intended use, and for the labelling of feed materials used in compound feeds;

(27) Whereas Commission Directive 92/87/EEC of 26 October 1992 establishing a non-exclusive list of the main ingredients normally used and marketed for the preparation of compound feedingstuffs intended for animals other than pets[2] draws up for labelling purposes a list of ingredients of compound feedingstuffs; whereas the said Directive should be repealed as from the application of Parts A and B of this Directive;

(28) Whereas, in order to improve the unambiguity and comparability at international level of systems for identifying and exchanging data on feed materials, the Commission should be instructed to adopt implementing arrangements, when appropriate, for the introduction of a practical international coding system for feed materials, based on glossaries of the various aspects of feedingstuffs, such as origin, role, process, maturity/quality;

(29) Whereas, in order to facilitate the adoption of implementing measures, the procedure introducing cooperation between the Member States and the Commission within the Standing Committee on Feedingstuffs should be followed;

(30) Whereas it is important to ensure that, in accordance with this Directive, the accuracy of the declarations made can be officially verified in a uniform way throughout the Community, at all stages of circulation of the feed materials;

(31) Whereas the introduction of this Directive entails deletion of the terms 'straight feedingstuffs', 'raw materials (ingredients)', 'raw materials' and 'ingredients'; whereas these terms should be replaced in current Community legislation, in particular in Council Directives 70/524/EEC, 74/63/EEC, 82/471/EEC[3] and 93/74/EEC[4] by the terms 'feed materials', and where appropriate the definition 'feed materials' should be replaced by the definition given in this Directive; whereas this also has an impact on the definition of compound feedingstuffs; whereas Commission Directives 80/511/EEC[5], 82/475/EEC[6] and 91/357/EEC[7] and Commission Decision 91/516/EEC[8] should be amended for the same reason, by means of a Commission act;

(32) Whereas it is necessary to ensure that the provisions of the Annexes are continually adjusted to take account of the latest developments in scientific or technical knowledge; whereas such

[1] OJ No L 332, 30. 12. 1995, p. 15.
[2] OJ No L 319, 4. 11. 1992, p. 19.
[3] OJ No L 213, 21. 7. 1982, p. 8.
[4] OJ No L 237, 22. 9. 1993, p. 23.
[5] OJ No L 126, 21. 5. 1980, p. 14.
[6] OJ No L 213, 21. 7. 1982, p. 27.
[7] OJ No L 193, 17. 7. 1982, p. 34.
[8] OJ No L 281, 9. 10. 1991, p. 23.

amendments will have to be made swiftly using the procedure laid down by this Directive in order to establish close cooperation between Member States and the Commission within the Standing Committee on Feedingstuffs;

(33) Whereas, on grounds of the effective protection of animal and human health and to ensure the smooth functioning of the internal market, action should be taken at Community level,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive shall apply to the circulation of feed materials within the Community.

2. This Directive shall apply without prejudice to other Community provisions in the field of animal nutrition.

Article 2

For the purposes of this Directive the following definitions shall apply:

(a) 'feed materials': various products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing additives, which are intended for use in oral animal feeding either directly as such, or after processing, in the preparation of compound feedingstuffs or as carriers of premixtures;

(b) 'putting into circulation' ('circulation'): the holding of feed materials for the purposes of sale, including offering for sale, or any other form of transfer, whether free or not, to third parties, and the sale and other forms of transfer themselves.

Article 3

Member States shall prescribe that feed materials may circulate in the Community only of they are sound, genuineAA-1 and of merchantable quality. They shall prescribe that such feed materials may represent no danger to animal or human health and may not be put into circulation in a manner liable to mislead.

Article 4

Member States shall prescribe that the general provisions laid down in Part A of the Annex shall apply to the putting into circulation of feed materials.

Article 5

1. Member States shall prescribe that feed materials may not be put into circulation unless the particulars listed below, which must be properly visible, legible and indelible and for which the producer, packer, importer, seller or distributor, established within the Community, shall be held responsible, are shown on an accompanying document or where appropriate on the packaging, on the container or on a label attached thereto:

(a) the words 'feed material';

(b) the name of the feed material and where appropriate the other particulars referred to in Article 7;

(c) for feed materials listed in Part B of the Annex, the particulars provided for in the fourth column of Part B of the Annex;

(d) for feed materials which are not listed in Part B of the Annex, the particulars provided for in the second column of the table in Part C of the Annex;

(e) where appropriate, the particulars provided for in Part A of the Annex;

(f) the net quantity expressed in units of mass in the case of solid products, and in units of mass or volume in the case of liquid products;

(g) the name or business name and the address or registered place of business of the person responsible for the particulars referred to in this paragraph.

2. Other information may be given on packaging, containers, labels and accompanying documents provided that such information relates to objective or quantifiable parameters which can be substantiated and that it cannot mislead the purchaser. This information must be separate from the information referred to in paragraph 1.

3. For quantities of feed materials less than or equal to 10 kg, intended for the final user, the particulars provided for in paragraphs 1 and 2 may be given to the purchaser by means of an appropriate notice at the point of sale.

4. If a batch is divided during circulation, the particulars referred to in paragraph 1, together with a reference to the initial batch, must be repeated on the packaging, container or accompanying document of each division of the batch.

5. Where the composition of a feed material in circulation is changed, the particulars referred to in paragraph 1 must be changed accordingly under the responsibility of the person providing the new particulars.

Article 6

1. By way of derogation from Article 5, the particulars referred to in Article 5 (1) (c) and (d) and points 2 and 3

of heading V of Part A of the Annex shall not be required where:

(a) before each transaction the purchaser has stated in writing that he does not require this information;

(b) without prejudice to Directive 90/667/EEC(1), feed materials of animal or vegetable origin, fresh or preserved, whether or not subject to a simple physical treatment, in quantities less than or equal to 10 kg, intended for pet animals and supplied directly to the final user by a seller established in the same Member State, are put into circulation.

2. Where, in the case of feed materials from a third country put into circulation in the Community for the first time, it has not been possible to provide the guarantees regarding composition required in Article 5 (1) (c) and (d) and points 2 and 3 of heading V of Part A of the Annex owing to the absence of means of assuring the analytic measurements necessary in the country concerned, Member States may allow provisional composition data to be supplied by the person responsible referred to in Article 5 (1) (g) provided that:

(a) the competent authorities responsible for checks are informed in advance of the arrival of the feed material;

(b) the definitive particulars of composition are provided to the purchaser and the competent authorities within 10 working days of the date of its arrival in the Community;

(c) the particulars of composition on the documents are accompanied by the following indications in bold type:

'provisional data to be confirmed by ... (name and address of the laboratory instructed to carry out the analyses) regarding ... (reference number of the sample to be analysed) before ... (date)';

(d) Member States inform the Commission of the circumstances in which they applied the derogation referred to in this paragraph.

3. By way of derogation from Article 5:

(a) the particulars referred to in Article 5 (1) shall not be required, without prejudice to Directive 90/667/EEC, in the case of products of vegetable or animal origin in their natural state, fresh or preserved, whether or not subjected to a simple physical treatment and not treated with additives, except for preservatives, which are provided by a farmer-producer to a breeder-user, both of whom are established in the same Member State;

(b) the particulars referred to in Article 5 (1) (c), (d), (e) and (f) and Part A of the Annex shall not be required where by-products of vegetable or animal origin derived from agro-industrial processing, with a moisture content greater than 50 %, are put into circulation.

4. By way of derogation from Article 5 (1) (a):

— in German the designation 'Futtermittel-Ausgangserzeugnis' may be replaced by 'Einzelfuttermittel',

— in Italian the designation 'materie prime per alimenti degli animali' may be replaced by 'mangime semplice',

— in Greek the designation 'πρώτη ύλη ζωοτροφών' may be replaced by 'απλή ζωοτροφή'.

Article 7

1. Member States shall lay down that the feed materials listed in Part B of the Annex may circulate only under the names specified therein and on conditions that they correspond to the descriptions given therein.

2. Member States shall allow the circulation of feed materials other than those on the list referred to in paragraph 1, provided that such materials circulate under names and/or with terms other than those listed in the Annex which cannot mislead the purchaser as to the real identity of the product offered to him.

Article 8

Member States shall prescribe that:

(a) feed materials containing a level of undesirable substances or products in excess of that permitted for feed materials under Directive 74/63/EEC may be put into circulation only if they are intended for approved establishments manufacturing compound feed entered on a national list in accordance with Directive 95/69/EC;

(b) by way of derogation from Article 5 (1) (a), feed materials within the meaning of point (a) of this Article must be labelled 'feed material intended for approved establishments manufacturing compound feed'. Article 6 (4) shall apply.

(1) OJ No L 363, 27. 12. 1990, p. 51.

Article 9

For the purpose of circulation within the Community, the indications printed on the accompanying document, on the packaging, on the container or on a label attached thereto shall be written in at least one or several languages which the country of destination shall determine from among the national or official languages of the Community.

Article 10

Member States shall ensure that feed materials are not subject, for reasons connected with the provisions of this Directive, to restrictions of circulation other than those laid down in this Directive.

Article 11

In accordance with the procedure laid down in Article 14:

(a) a numerical coding system for the listed feed materials based on glossaries concerning the origin, part of the product/by-product used, processing and maturity/quality of the feed materials enabling feed to be identified at international level — in particular by name and description — may be adopted;

(b) the Annex may be amended in the light of advances in scientific and technical knowledge.

Article 12

Member States shall make all necessary arrangements for compliance with the requirements of this Directive to be officially monitored, at least by sampling during circulation.

Article 13

1. The Commission shall be assisted by the Standing Committee on Feedingstuffs, set up by Council Decision 70/372/EEC[1], hereinafter referred to as 'the Committee'.

2. Where the procedure laid down in this Article is to be followed, the Chairman shall, without delay, refer the matter to the Committee, either on his own initiative or at the request of the representative of a Member State.

3. 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 in question. 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.

4. (a) The Commission shall adopt the intended measures when they are in accordance with the Committee's opinion.

(b) When the intended measures are not in accordance with the opinion of the Committee, or in the absence of any opinion, the Commission shall forthwith submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral of the proposal 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.

Article 14

1. Directive 70/524/EEC is hereby amended as follows:

(a) in all cases the term 'straight feedingstuffs' shall be replaced by the term 'feed materials';

(b) Article 2 (f) shall be replaced by the following:

'(f) "feed materials": various products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing additives, which are intended for use in oral animal feeding either directly as such or after processing, in the preparation of compound feedingstuffs or as carriers of premixtures;';

(c) Article 2 (g) shall be replaced by the following:

'(g) "compound feedingstuffs": mixtures of feed materials, whether or not containing additives, which are intended for oral animal feeding as complete or complementary feedingstuffs;'.

2. Directive 74/63/EEC is hereby amended as follows:

(a) in all cases the terms 'straight feedingstuff(s)' shall be replaced by the term 'feed material(s)';

(b) Article 2 (b) shall be replaced by the following:

'(b) "feed materials": various products of vegetable or animal origin, in their natural state, fresh or

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

preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing additives, which are intended for use in oral animal feeding, either directly as such or after processing, in the preparation of compound feedingstuffs or as carriers of premixtures;';

(c) Article 2 (h) shall be replaced by the following:

'(h) "compound feedingstuffs": mixtures of feed materials, whether or not containing additives, which are intended for oral animal feeding as complete or complementary feedingstuffs;';

(d) Article 2 (i) shall be deleted;

(e) in all cases the term 'raw material(s)' shall be replaced by 'feed material(s)'.

3. Article 1 (2) of Directive 82/471/EEC is hereby amended as follows:

(a) the words 'of straight feedingstuffs and' in point (d) shall be deleted;

(b) the following point shall be added:

'(g) the circulation of feed materials.'.

4. Directive 93/74/EEC is hereby amended as follows:

(a) the term 'ingredients' in Article 5 (8) shall in each case be replaced by the term 'feed materials';

(b) Article 2 (b) shall be replaced by the following:

'(b) "compound feedingstuffs": mixtures of feed materials, whether or not containing additives, which are intended for oral animal feeding as complete or complementary feedingstuffs;'.

Article 15

Directive 77/101/EEC shall be repealed as from 1 July 1998.

Article 16

On the basis of information supplied by the Member States, the Commission shall submit a report to the Council before 1 July 2001 on the experience acquired in applying Article 6 (1) (a), (2) and (3) (a) accompanied, when necessary, by appropriate proposals.

Article 17

Member States shall bring into force not later than 30 June 1998 the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, 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 Member States.

Article 18

The provisions adopted shall apply as from 1 July 1998. Member States shall, however, lay down that feed materials put into circulation before 1 July 1998 which do not comply with this Directive may remain in circulation until 30 June 1999.

Article 19

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

Article 20

This Directive is addressed to the Member States.

Done at Luxembourg, 29 April 1996.

For the Council
The President
W. LUCHETTI

ANNEX

PART A

General

I. EXPLANATORY NOTES

1. Feed materials are listed and named in Part B according to the following criteria:

   — the origin of the product/by-product, for example vegetable, animal, mineral,

   — the part of the product/by-product used, for example whole, seeds, tubers, bones,

   — the processing to which the product/by-product has been subjected, for example decortication, extraction, heating and/or the resulting product/by-product, for example flakes, bran, pulp, fat,

   — the maturity of the product/by-product and/or the quality of the product/by-product, for example 'low in glucosinolate', 'rich in fat', 'low in sugar'.

2. The list set out in Part B is divided into 12 chapters.

   1. Cereal grains, their products and by-products
   2. Oil seeds, oil fruits, their products and by-products
   3. Legume seeds, their products and by-products
   4. Tubers, roots, their products and by-products
   5. Other seeds and fruits, their products and by-products
   6. Forages and roughage
   7. Other plants, their products and by-products
   8. Milk products
   9. Land animal products
   10. Fish, other marine animals, their products and by-products
   11. Minerals
   12. Miscellaneous

II. PROVISIONS REGARDING BOTANICAL PURITY

1. The botanical purity of the products and by-products listed in Part B and Part C shall not be less than 95 %, unless a different level has been laid down in Part B or Part C.

2. The following are considered as botanical impurities:

   (a) natural but innocuous impurities (e.g. straw and straw waste, seeds of other cultivated species or weeds);

   (b) harmless residues of other oil seeds or oleaginous fruit derived from a previous manufacturing process, the level of which does not exceed 0,5 %.

3. The levels indicated refer to the weight of the product and by-product as such.

III. PROVISIONS REGARDING NAMING

Where the name of a feed material includes a word or words in brackets, the bracketed word(s) may be included or omitted as an option, for example soy (bean) oil may be declared as soy bean oil or soy oil

IV. PROVISIONS REGARDING THE GLOSSARY

The glossary given below refers to main processes used for the preparation of feed materials mentioned in Part B and Part C of this Annex. When the names of these feed materials include a common name or term from this glossary, the process to be used must be in accordance with the given definition.

Process	Definition	Common name/term
Concentration	Increase in certain contents by removing water or other constituents	Concentrate
Decortication [1]	Removal of outer layers from grains, seeds, fruits, nuts and others	Decorticated
Drying	Dehydration by artificial or natural processes in order to preserve the product	Dried (sun or artificially)
Extraction	Removal either by organic solvent of fat or oil from certain materials or by aqueous solvent of sugar or other water-soluble components. In the case of the use of organic solvent, the resulting product must be technically free of such solvent	Extracted (in case of oil-containing materials) Molasses, pulp (in case of products containing sugar or other water-soluble components)
Extrusion	Pressing, pushing or protrusion of material through orifices under pressure. See also pregelatinization	Extruded
Flaking	Rolling of moist heat-treated material	Flakes
Flour milling	Physical processing of grain to reduce particle size and facilitate separation into constituent fractions (principally flour, bran and middlings)	Flour, bran, middlings
Heat treatment/ heating	General term covering a number of heat treatments carried out under specific conditions to influence the nutritional value or the structure of the material	Toasted, cooked, puffed, heat-treated
Hydrogenation	Treatment of oils and fats to achieve a higher melting point	Hardened
Hydrolysis	Breakdown into simpler chemical constituents by appropriate treatment with water and possibly either enzymes or acid/alkali	Hydrolysed
Pressing	Removal by mechanical extraction (by a screw or other type of press) and possibly some heat, of fat/oil from oil-rich materials or of juice from fruits or other vegetable products	Expeller [2] (in case of oil-containing materials) Pulp, pomace (in case of fruits etc.)
Pelleting	Compression by passage through a die	Pellet
Pregelatinization	Modification of starch to improve markedly its swelling properties in cold water	Pregelatinized
Refining	Removal of impurities in sugars, oils and other natural materials by chemical/physical treatment	Refined
Wet-milling	Mechanical separation of the component parts of kernel/grain after steeping in water, possibly with sulphur dioxide, for the extraction of starch	Germ, gluten, starch

[1] 'Decortication' may be replaced by 'dehulling' or 'dehusking' if appropriate. Therefore the common name/term should be 'dehulled' or 'dehusked'.
[2] When appropriate, the word 'expeller' may be replaced by 'cake'.

V. PROVISIONS REGARDING LEVELS INDICATED OR TO BE DECLARED AS SPECIFIED IN PART B AND C

1. The levels indicated or to be declared relate to the weight of the feed material, unless otherwise stated.

2. Subject to article 3 and article 6 (3) (b) of the Directive and provided that no other level is laid down in Part B of this Annex, the feed material's moisture content must be stated if it exceeds

14,5 % of the weight of the feed material. In the case of feed materials with a moisture content not exceeding the limits indicated above, that content must be declared at the purchaser's request.

3. Subject to Article 3 of the Directive and provided that no other level is laid down in Part B of this Annex the level of ash insoluble in hydrochloric acid of feed materials must be stated if it exceeds 2,2 % in the dry matter.

VI. PROVISIONS REGARDING DENATURING AND BINDING AGENTS

Where the products referred to in column 2 of Part B or column 1 of Part C of this Annex are used to denature or bind feed materials, the following information must be given:

— denaturing agents: nature and quantity of the products used,

— binding agents: nature of the products used.

In the case of binding agents, the quantity of the products used may not exceed 3 % of the total weight.

VII. PROVISIONS REGARDING MINIMUM TOLERATED LEVELS INDICATED OR TO BE DECLARED AS SPECIFIED IN PART B AND C

Where, on official inspection pursuant to Article 12 of the Directive, the composition of a feed material is found to depart from the declared composition in a manner such as to reduce its value, the following minimum tolerances are permitted:

(a) for crude protein:

— 2 units for declared contents of 20 % or more,

— 10 % of the declared content for declared contents of less than 20 % but not less than 10 %,

— 1 unit for declared contents of less than 10 %;

(b) for total sugars, reducing sugars, sucrose, lactose and glucose (dextrose):

— 2 units for declared contents of 20 % or more,

— 10 % of the declared content for declared contents of less than 20 % but not less than 5 %,

— 0,5 unit for declared contents of less than 5 %;

(c) for starch and inulin:

— 3 units for declared contents of 30 % or more,

— 10 % of the declared content for declared contents of less than 30 % but not less than 10 %,

— 1 unit for declared contents of less than 10 %;

(d) for crude oils and fats:

— 1,8 units for declared contents of 15 % or more,

— 12 % of the declared content for declared contents of less than 15 % but not less than 5 %,

— 0,6 unit for declared contents of less than 5 %;

(e) for crude fibre:

— 2,1 units for declared contents of 14 % or more,

— 15 % of the declared content for declared contents of less than 14 % but not less than 6 %,

— 0,9 unit for declared contents of less than 6 %;

(f) for moisture and crude ash:

— 1 unit for declared contents of 10 % or more,

— 10 % of the declared content for declared contents of less than 10 % but not less than 5 %,

— 0,5 unit for declared contents of less than 5 %;

(g) for total phosphorus, sodium, calcium carbonate, calcium, magnesium, acid index and matter insoluble in light petroleum:

— 1,5 units for declared contents (values) of 15 % (15) or more, as appropriate,

— 10 % of the declared content (value) for declared contents (values) of less than 15 % (15), but not less than 2 % (2), as appropriate,

— 0,2 unit for declared contents (values of less than 2 % (2) as appropriate;

(h) for ash insoluble in hydrochloric acid and chlorides expressed as NaCl:

— 10 % of the declared content for declared contents of 3 % or more,

— 0,3 unit for declared contents of less than 3 %;

(i) for carotene, vitamin A and xanthophyll:

— 30 % of the declared content;

(j) for methionine, lysine and volatile nitrogenous bases:

— 20 % of the declared content.

PART B

Non-exclusive list of the main feed materials

1. CEREAL GRAINS, THEIR PRODUCTS AND BY-PRODUCTS

Number	Name	Description	Compulsory declarations
1	2	3	4
1.01	Oats	Grains of *Avena sativa* L. and other cultivars of oats	
1.02	Oat flakes	Product obtained by steaming and rolling dehusked oats. It may contain a small proportion of oat husks	Starch
1.03	Oat middlings	By-product obtained during the processing of screened, dehusked oats into oat groats and flour. It consists principally of oat bran and some endosperm	Crude fibre
1.04	Oat hulls and bran	By-product obtained during the processing of screened oats into oat groats. It consists principally of oat hulls and bran	Crude fibre
1.05	Barley	Grains of *Hordeum vulgare* L.	
1.06	Barley middlings	By-product obtained during the processing of screened, dehusked barley into pearl barley, semolina or flour	Crude fibre
1.07	Rice, broken	By-product of preparation of polished or glazed rice *Oryza sativa* L. It consists principally of undersized and/or broken grains	Starch
1.08	Rice bran (brown)	By-product of the first polishing of dehusked rice. It consists principally of silvery skins, particles of the aleurone layer, endosperm and germ	Crude fibre
1.09	Rice bran (white)	By-product of the second polishing of dehusked rice. It consists principally of particles of the aleurone layer, endosperm and germ	Crude fibre

Number	Name	Description	Compulsory declarations
1	2	3	4
1.10	Rice bran with calcium carbonate	By-product of the polishing of dehusked rice. It consists principally of silvery skins, particles of the aleurone layer, endosperm, germ and small amounts of calcium carbonate resulting from use in the manufacturing process. (Maximum $CaCO_3$-content 3 %)	Crude fibre
1.11	Fodder meal of precooked rice	By-product of the polishing of dehusked precooked rice. It consists principally of silvery skins, particles of the aleurone layer, endosperm, germ and small amounts of calcium carbonate resulting from use in the manufacturing process. (Maximum $CaCO_3$-content 3 %)	Crude fibre
1.12	Rice germ expeller	By-product of oil manufacture, obtained by pressing the germ of rice to which parts of the endosperm and testa still adhere	Crude protein Crude fat Crude fibre
1.13	Rice germ, extracted	By-product of oil manufacture obtained by extraction of the germ of rice to which parts of the endosperm and testa still adhere	Crude protein
1.14	Rice starch	Technically pure rice starch	Starch
1.15	Millet	Grains of *Panicum miliaceum* L.	
1.16	Rye	Grains of *Secale cereale* L.	
1.17	Rye middlings	By-product of flour manufacture, obtained from screened rye. It consists principally of particles of endosperm, with fine fragments of the outer skins and some grain waste	Crude fibre
1.18	Rye feed	By-product of flour manufacture, obtained from screened rye. It consists principally of fragments of the outer skins, and of particles of grain from which less of the endosperm has been removed than in rye bran	Crude fibre
1.19	Rye bran	By-product of flour manufacture, obtained from screened rye. It consists principally of fragments of the outer skins, and of particles of grain from which most of the endosperm has been removed	Crude fibre
1.20	Sorghum	Grains of *Sorghum bicolor* (L.) Moench s.l.	
1.21	Wheat	Grains of *Triticum aestivum* L., *Triticum durum* Desf. and other cultivars of wheat	
1.22	Wheat middlings	By-product of flour manufacture, obtained from screened grains of wheat or dehusked spelt. It consists principally of particles of endosperm with fine fragments of the outer skins and some grain waste	Crude fibre
1.23	Wheat feed	By-product of flour manufacture, obtained from screened grains of wheat or dehusked spelt. It consists principally of fragments of the outer skins and of particles of grain from which less of the endosperm has been removed than in wheat bran	Crude fibre
1.24	Wheat bran [1]	By-product of flour manufacture, obtained from screened grains of wheat or dehusked spelt. It consists principally of fragments of the outer skins and of particles of grain from which the greater part of the endosperm has been removed	Crude fibre

Number	Name	Description	Compulsory declarations
1	2	3	4
1.25	Wheat germ	By-product of flour milling consisting essentially of wheat germ, rolled or otherwise, to which fragments of endosperm and outer skin may still adhere	Crude protein Crude fat
1.26	Wheat gluten	Dried by-product of the manufacture of wheat starch. It consists principally of gluten obtained during the separation of starch	Crude protein
1.27	Wheat gluten feed	By-product of the manufacture of wheat starch. It is composed of bran and gluten, to which components of the steeping liquor and a small quantity of germ from which the oil has been removed may be added	Crude protein Starch
1.28	Wheat starch	Technically pure wheat starch	Starch
1.29	Spelt	Grains of spelt *Triticum spelta* L., *Triticum dioccum* Schrank, *Triticum monococcum*	
1.30	Triticale	Grains of *Triticum X Secale* hybrid	
1.31	Maize	Grains of *Zea mays* L.	
1.32	Maize middlings	By-product of the manufacture of flour or semolina from maize. It consists principally of fragments of the outer skins and of particles of grain from which less of the endosperm has been removed than in maize bran	Crude fibre
1.33	Maize bran	By-product of the manufacture of flour or semolina from maize. It consists principally of outer skins and some maize germ fragments, with some endosperm particles	Crude fibre
1.34	Maize germ expeller	By-product of oil manufacture, obtained by pressing of dry or wet processed maize germ to which parts of the endosperm and testa may still adhere	Crude protein Crude fat
1.35	Maize germ, extracted	By-product of oil manufacture, obtained by extraction of dry or wet processed maize germ to which parts of the endosperm and testa may still adhere	Crude protein
1.36	Maize gluten feed [2]	By-product of the manufacture of maize starch. It is composed of bran and gluten, to which components of the steeping liquor and a small quanity of germ from which the oil has been removed may be added	Crude protein Starch
1.37	Maize gluten	Dried by-product of manufacture of maize starch. It consists principally of gluten obtained during the separation of the starch	Crude protein
1.38	Maize starch	Technically pure maize starch	
1.39	Pre-gelatinized maize starch [3]	Heat-treated maize starch, having the property of marked swelling on contact with cold water	Starch

Number	Name	Description	Compulsory declarations
1	2	3	4
1.40	Malt culms	By-product of malting, consisting mainly of dried rootlets of germinated cereals	Crude protein
1.41	Brewers' dried grains	By-product of brewing obtained by drying residues of malted and unmalted cereals and other starchy products	Crude protein
1.42	Distillers' dried grains	By-product of alcohol distilling obtained by drying solid residues of fermented grain	Crude protein
1.43	Distillers' dark grains (4)	By-product of alcohol distilling obtained by drying solid residues of fermented grain to which pot ale syrup or evaporated spent wash has been added	Crude protein

(1) When this ingredient has been subjected to a finer milling, the word 'fine' may be added to the name or the name may be replaced by a corresponding denomination.
(2) This name may be replaced by 'corn gluten feed'.
(3) This name may be replaced by 'extruded maize starch'.
(4) This name may be replaced by 'distillers' dried grains and solubles'.

2. OIL SEEDS, OIL FRUITS, THEIR PRODUCTS AND BY-PRODUCTS

Number	Name	Description	Compulsory declarations
1	2	3	4
2.01	Groundnut, partially decorticated, expeller	By-product of oil manufacture, obtained by pressing of partially decorticated groundnuts *Arachis hypogaea* L. and others species of *Arachis*. (Maximum crude fibre content 16 % in the dry matter.)	Crude protein Crude fat Crude fibre
2.02	Groundnut, partially decorticated, extracted	By-product of oil manufacture, obtained by extraction of partially decorticated groundnuts. (Maximum crude fibre content 16 % in the dry matter)	Crude protein Crude fibre
2.03	Groundnut, decorticated, expeller	By-product of oil manufacture, obtained by pressing of decorticated groundnuts	Crude protein Crude fat Crude fibre
2.04	Groundnut, decorticated, extracted	By-product of oil manufacture, obtained by extraction of decorticated groundnuts	Crude protein Crude fibre
2.05	Rape seed (1)	Seeds of rape *Brassica napus* L. ssp. *oleifera* (Metzg.) Sinsk., of Indian sarson *Brassica napus* L. Var. *Glauca* (Roxb.) O. E. Schulz and of rape *Brassica campestris* L. ssp. *oleifera* (Metzg.) Sinsk. (Minimum botanical purity 94 %)	
2.06	Rape seed expeller (1)	By-product of oil manufacture, obtained by pressing of seeds of rape. (Minimum botanical purity 94 %)	Crude protein Crude fat Crude fibre
2.07	Rape seed extracted (1)	By-product of oil manufacture, obtained by extracation of seeds of rape. (Minimum botanical purity 94 %)	Crude protein

Number	Name	Description	Compulsory declarations
1	2	3	4
2.08	Rape seed hulls	By-product obtained during dehulling of rape seeds	Crude fibre
2.09	Safflower seed, partially decorticated, extracted	By-product of oil manufacture, obtained by extraction of partially decorticated seeds of safflower *Carthamus tinctorius* L.	Crude protein Crude fibre
2.10	Copra expeller	By-product of oil manufacture, obtained by pressing the dried kernel (endosperm) and outer husk (tegument) of the seed of the coconut palm *Cocos nucifera* L.	Crude protein Crude fat Crude fibre
2.11	Copra, extracted	By-product of oil manufacture, obtained by extraction of the dried kernel (endosperm) and outer husk (tegument) of the seed of the coconut palm	Crude protein
2.12	Palm kernel expeller	By-product of oil manufacture, obtained by pressing of palm kernels (*Elaeis guineensis* Jacq.), Corozo *oleifera* (HBK) L. H. Bailey (*Elaeis melanococca* auct.) from which as much as possible of the hard shell has been removed	Crude protein Crude fibre Crude fat
2.13	Palm kernel, extracted	By-product of oil manufacture, obtained by extraction of palm kernels from which as much as possible of the hard shell has been removed	Crude protein Crude fibre
2.14	Soya (bean), toasted	Soya beans *Glycine max.* L. *Merr.* subjected to an appropriate heat treatment	
2.15	Soya (bean), extracted, toasted	By-product of oil manufacture, obtained from soya beans after extraction and appropriate heat treatment. (Maximum crude fibre content 8 % in the dry matter)	Crude protein
2.16	Soya (bean), dehulled, extracted, toasted	By-product of oil manufacture, obtained from dehulled soya beans after extraction and appropriate heat treatment	Crude protein Crude fibre
2.17	Soya (bean) protein concentrate	Product obtained from dehulled, fat extracted soya beans	Crude protein
2.18	Soya (bean) oil	Oil obtained from soya beans	
2.19	Soya (bean) hulls	By-product obtained during dehulling of soya beans	Crude fibre
2.20	Cotton seed	Seeds of cotton *Gossypium* ssp. from which the fibres have been removed	Crude protein Crude fibre Crude fat
2.21	Cotton seed, partially decorticated extracted	By-product of oil manufacture, obtained by extraction of seeds of cotton from which the fibres and part of the husks have been removed. (Maximum crude fibre 22,5 % in the dry matter)	Crude protein Crude fibre
2.22	Cotton seed expeller	By-product of oil manufacture, obtained by pressing of seeds of cotton from which the fibres have been removed	Crude protein Crude fibre Crude fat

Number	Name	Description	Compulsory declarations
1	2	3	4
2.23	Niger seed expeller	By-product of oil manufacture, obtained by pressing of seeds of the niger plant *Guizotia abyssinica* (L.F.) *Cass.* (Ash insoluble in HCl: max 3,4 %)	Crude protein Crude fat Crude fibre
2.24	Sunflower seed	Seeds of the sunflower *Helianthus annuus* L.	
2.25	Sunflower seed, extracted	By-product of oil manufacture, obtained by extraction of seeds of the sunflower	Crude protein
2.26	Sunflower seed, partially decorticated, extracted	By-product of oil manufacture, obtained by extraction of seeds of the sunflower from which part of the husks has been removed. (Maximum crude fibre 27,5 % in the dry matter)	Crude protein Crude fibre
2.27	Linseed	Seeds of linseed *Linum usitatissimum* L. (Minimum botanical purity 93 %)	
2.28	Linseed expeller	By-product of oil manufacture, obtained by pressing of linseed. (Minimum botanical purity 93 %)	Crude protein Crude fat Crude fibre
2.29	Linseed, extracted	By-product of oil manufacture, obtained by extraction of linseed. (Minimum botanical purity 93 %)	Crude protein
2.30	Olive pulp	By-product of oil manufacture, obtained by extraction of olives *Olea europea* L. separated as far as possible from parts of the kernel	Crude protein Crude fibre
2.31	Sesame seed expeller	By-product of oil manufacture, obtained by pressing of seeds of the sesame plant *Sesamum indicum* L. (Ash insoluble in HCl: max 5 %)	Crude protein Crude fibre Crude fat
2.32	Cocoa bean, partially decorticated, extracted	By-product of oil manufacture, obtained by extraction of dried and roasted cocoa beans *Theobroma cacao* L. from which part of the husks has been removed	Crude protein

(1) When appropriate 'low in glucosinolate' may be indicated additionally in the name. 'Low in glucosinolate' means as defined in Community legislation.

3. LEGUME SEEDS, THEIR PRODUCTS AND BY-PRODUCTS

Number	Name	Description	Compulsory declarations
1	2	3	4
3.01	Chickpeas	Seeds of *Cicer arietinum* L.	
3.02	Guar meal, extracted	By-product obtained after extraction of the mucilage from seeds of *Cyamopsis tetragonoloba* (L.) *Taub.*	Crude protein
3.03	Ervil	Seeds of *Ervum ervilia* L.	
3.04	Chickling vetch(1)	Seeds of *Lathyrus sativus* L. submitted to an appropriate heat treatment	

Number	Name	Description	Compulsory declarations
1	2	3	4
3.05	Lentils	Seeds of *Lens culinaris a.o.* Medik	
3.06	Sweet lupins	Seeds of *Lupinus* spp. low in bitter seed content.	
3.07	Beans, toasted	Seeds of *Phaseolus* or *Vigna* spp. submitted to an appropriate heat treatment to destroy toxic lectins	
3.08	Peas	Seeds of *Pisum* spp.	
3.09	Pea middlings	By-product obtained during the manufacture of pea-flour. It consists principally of particles of cotyledon, and to a lesser extent, of skins	Crude protein Crude fibre
3.10	Pea bran	By-product obtained during the manufacture of pea meal. It is composed mainly of skins removed during the skinning and cleaning of peas	Crude fibre
3.11	Horse beans	Seeds of *Vicia faba* L. ssp. *faba* var. *equina Pers.* and var. *minuta* (Alef.) Mansf.	
3.12	Monantha vetch	Seeds of *Vicia monanthos* Desf.	
3.13	Vetches	Seeds of *Vicia sativa* L. var. *sativa* and other varieties	

(1) The name must be qualified by an indication of the nature of the heat treatment.

4. TUBER, ROOTS, THEIR PRODUCTS AND BY-PRODUCTS

Number	Name	Description	Compulsory declarations
1	2	3	4
4.01	(Sugar) Beet pulp	By-product of the manufacture of sugar, consisting of extracted and dried pieces of sugar beet *Beta vulgaris* L. ssp *vulgaris* var. *altissima* Doell. (Maximum content of ash insoluble in HCl: 3,5 % of dry matter)	Total sugar expressed as sucrose
4.02	(sugar) Beet molasses	By-product consisting of the syrupy residue collected during the manufacture or refining of beet sugar. (Maximum humidity content: 25 %)	Total sugar expressed as sucrose
4.03	(Sugar) Beet pulp, molassed	By-product of the manufacture of sugar comprising dried sugar-beet pulp, to which molasses has been added	Total sugar expressed as sucrose
4.04	(Sugar) Beet vinasse	By-product obtained after the fermentation of beet molasses in the production of alcohol, yeast, citric acid and other organic substances	Crude protein NPN
4.05	(Beet) Sugar (1)	Sugar extracted from sugar beet	Sucrose

Number	Name	Description	Compulsory declarations
1	2	3	4
4.06	Sweet potato	Tubers of *Ipomoea batatas* (L.) Poir, regardless of their presentation	Starch
4.07	Manioc	Roots of *Manhiot esculenta* Crantz, regardless of their presentation	Starch
4.08	Manioc, starch, puffed	Starch obtained from manioc roots, greatly expanded by appropriate heat treatment	Starch
4.09	Potato pulp	By-product of the extraction of potato starch *Solanum tuberosum* L.	
4.10	Potato starch	Technically pure potato starch	Starch
4.11	Potato protein	Dried by-product of starch manufacture composed mainly of protein substances obtained after the separation of starch	Crude protein

(1) This name may be replaced by 'sucrose'.

5. OTHER SEEDS AND FRUITS, THEIR PRODUCTS AND BY-PRODUCTS

Number	Name	Description	Compulsory declarations
1	2	3	4
5.01	Carob pods	Product obtained by crushing the dried fruits (pods) of the carob tree *Ceratonia seliqua* L., from which the locust beans have been removed	Crude fibre
5.02	Citrus pulp	By-product obtained by pressing citrus fruits *Citrus* spp. during the production of citrus juice	Crude fibre
5.03	Apple pomace	By-product obtained by pressing apples *Malus* spp. during the production of apple juice	Crude fibre
5.04	Tomato pulp	By-product obtained by pressing tomatoes *Solanum lycopersicum* Karst. during the production of tomato juice	Crude fibre
5.05	Grape pulp	By-product of processing of grapes *Vitis vinifera* L. after the juice has been pressed out	Crude fibre
5.06	Grape pips, extracted	By-product of the processing of grapes composed of extracted pips, practically exempt of other components	Crude fibre

6. FORAGES AND ROUGHAGES

Number	Name	Description	Compulsory declarations
1	2	3	4
6.01	Lucerne meal(1)	Product obtained by drying and milling young lucerne *Medicago sativa* L. and *Medicago* var. *Martyn* (Minimum botanical purity 80 %) (Ash insoluble in HCl: max. 3,4 %)	Crude protein Crude fibre
6.02	Lucerne pomace	Dried by-product obtained by pressing juice from lucerne	Crude protein
6.03	Lucerne protein concentrate	Product obtained by artificially drying fractions of lucerne press juice, which has been centrifuged and heat-treated precipitate proteins	Carotene Crude protein
6.04	Clover meal(1)	Product obtained by drying and milling young clover *Trifolium* spp. (Minimum botanical purity 80 %) (Ash insoluble in HCl: max 3,4 %)	Crude protein Crude fibre
6.05	Grass meal(1)	Product obtained by drying and milling young forage plants (Ash insoluble in HCl: max. 3,4 %)	Crude protein Crude fibre
6.06	Wheat straw	Straw of wheat	
6.07	Cereals straw, treated(2)	Product obtained by an appropriate treatment of cereals straw	Crude protein NPN, if treated with ammonia Sodium, if treated with NaOH

(1) The term 'meal' may be replaced by 'pellets'. The method of drying may be indicated additionally in the name.
(2) The name must be qualified by reference to the nature of chemical treatment carried out.

7. OTHER PLANTS, THEIR PRODUCTS AND BY-PRODUCTS

Number	Name	Description	Compulsory declarations
1	2	3	4
7.01	(Sugar) Cane molasses	By-product consisting of the syrupy residue collected during the manufacture of refining of sugar from sugar cane *Saccharum officinarum* L. (Maximum humidity content: 25 %)	Total sugar expressed as sucrose
7.02	(Sugar) Cane vinasse	By-product obtained after the fermentation of cane molasses in the production of alcohols, yeast, citric acid or other organic substances	Crude protein NPN
7.03	(Cane) Sugar(1)	Sugar extracted from sugar cane	Sucrose
7.04	Seaweed meal	Product obtained by drying and crushing seaweed, in particular brown seaweed. This product may have been washed to reduce the iodine content	Crude ash

(1) This name may be replaced by 'sucrose'.

8. MILK PRODUCTS

Number	Name	Description	Compulsory declarations
1	2	3	4
8.01	Skimmed-milk powder	Product obtained by drying milk from which most of the fat has been separated	Crude protein
8.02	Buttermilk powder	Product obtained by drying the liquid which remains after butter-churning	Crude protein Crude fat Lactose
8.03	Whey powder	Product obtained by drying the liquid which remains after cheese, quark and casein making or similar processes	Crude protein Lactose
8.04	Whey powder, low in sugar	Product obtained by drying whey from which the lactose has been partly removed	Crude protein Lactose
8.05	Whey protein powder (1)	Product obtained by drying the protein compounds extracted from whey or milk by chemical or physical treatment	Crude protein
8.06	Casein powder	Product obtained from skimmed or buttermilk by drying casein precipitated by means of acids or rennet	Crude protein
8.07	Lactose powder	The sugar separated from milk or whey by purification and drying	Lactose

(1) This name may be replaced by 'milk albumin powder'.

9. LAND ANIMAL PRODUCTS

Number	Name	Description	Compulsory declarations
1	2	3	4
9.01	Meat meal (1)	Product obtained by heating, drying and grinding whole or parts of warm-blooded land animals from which the fat may have been partially extracted or physically removed. The product must be substantially free of hooves, horn, bristle, hair and feathers, as well as digestive tract content (Minimum crude protein content 50 % on a dry matter basis) (Ash insoluble in HCl: max. 2,2 %)	Crude protein Crude fat Crude ash
9.02	Meat and bone meal (1)	Product obtained by heating, drying and grinding whole or parts of warm-blooded land animals from which the fat may have been partially extracted or physically removed. The product must be substantially free of hooves, horn, bristle, hair and feathers, as well as digestive tract content	Crude protein Crude fat Crude ash
9.03	Bone meal	Product obtained by drying, heating and finely grinding bones of warm-blooded land animals from which the fat has been largely extracted or physically removed. The product must be substantially free of hooves, horn, bristle, hair and feathers, as well as digestive tract content	Crude protein Crude ash

Number	Name	Description	Compulsory declarations
1	2	3	4
9.04	Greaves	Residual product of the manufacture of tallow and other extracted or physically removed fats of animal origin	Crude protein Crude fat
9.05	Poultry offal meal (1)	Product obtained by drying and grinding waste from slaughtered poultry. The product must be substantially free of feathers (Ash insoluble in HCl: max. 3,3 %)	Crude protein Crude fat Crude ash
9.06	Feather meal, hyrolysed	Product obtained by hydrolysing drying and grinding poultry feathers (Ash insoluble in HCl: max. 3,4 %)	Crude protein
9.07	Blood meal	Product obtained by drying the blood of slaughtered warm-blooded animals. The product must be substantially free of foreign matter	Crude protein
9.08	Animal fat	Product composed of fat from warm-blooded land animals	

(1) Products containing more than 13 % fat in the dry matter must be named as 'rich in fat'.

10. FISH, OTHER MARINE ANIMALS, THEIR PRODUCTS AND BY-PRODUCTS

Number	Name	Description	Compulsory declarations
1	2	3	4
10.01	Fish meal (1)	Product obtained by processing whole or parts of fish from which part of the oil may have been removed and to which fish solubles may have been re-added (Ash insoluble in HCl: max. 2,2 %)	Crude protein Crude fat Crude ash
10.02	Fish solubles, condensed	Stabilized product composed of pressed juice obtained during manufacture of fish meal from which much of the fish oil and some of the water has been removed	Crude protein
10.03	Fish oil	Oil obtained from fish	
10.04	Fish oil, refined, hardened	Oil obtained from fish which has been refined and subjected to hydrogenation	Iodine number

(1) Products containing more than 75 % crude protein in the dry matter may be named as 'rich in protein'.

11. MINERALS

Number	Name	Description	Compulsory declarations
1	2	3	4
11.01	Calcium carbonate (1)	Product obtained by grinding sources of calcium carbonate, such as limestone, oyster or mussel shells, or by precipitation from acid solution (Ash insoluble in HCl: max. 5 %)	Calcium Ash insoluble in HCl
11.02	Calcium and magnesium carbonate	Natural mixture of calcium carbonate and magnesium carbonate	Calcium Magnesium
11.03	Calcareous marine algae (Maerl)	Product of natural origin obtained from calcareous algae, ground or granulated (Ash insoluble in HCl: max. 5 %)	Calcium Ash insoluble in HCl
11.04	Magnesium oxide	Technically pure magnesium oxide (MgO)	Magnesium
11.05	Kieserite	Natural magnesium sulphate ($MgSO_4 \cdot H_2O$)·	Magnesium
11.06	Dicalcium phosphate (2)	Precipitated calcium monohydrogen phosphate from bones or inorganic sources ($CaHPO_4 \cdot xH_2O$)·	Calcium Total phosphorus
11.07	Mono-dicalcium phosphate	Product obtained chemically and composed of equal parts of dicalcium phosphate and mono-calcium phosphate	Total phosphorus Calcium
11.08	Defluorinated rock-phosphate	Product obtained by grinding purified and appropriately defluorinated natural phosphates	Total phosphorus Calcium
11.09	Degelatinized bone, meal	Degelatinized, sterilized and ground bones from which the fat has been removed	Total phosphorus Calcium
11.10	Monocalcium phosphate	Technically pure calcium-bis (dihydrogenphosphate) $[Ca(H_2PO_4)_2 \cdot xH_2O]$·	Total phosphorus Calcium
11.11	Calcium-magnesium phosphate	Technically pure calcium magnesium phosphate	Magnesium Total phosphorus
11.12	Mono-ammonium phosphate	Technically pure mono-ammonium phosphate ($NH_4H_2PO_4$)·	Total nitrogen Total phosphorus
11.13	Sodium chloride (1)	Technically pure sodium chloride or product obtained by grinding natural sources of sodium chloride, such as (rock) and (marine) salt	Sodium
11.14	Magnesium propionate	Technically pure magnesium propionate	Magnesium

(1) The nature of the source may replace or be indicated additionally in the name.
(2) The manufacturing process may be included in the name.

12. MISCELLANEOUS

Number	Name	Description	Compulsory declarations
1	2	3	4
12.01	Bakery and pasta waste	By-product obtained from the manufacture of biscuits, cake, bread or pasta	Starch Total sugar expressed as sucrose
12.02	Confectionery waste	By-product obtained from the manufacture of chocolate, sweets and other confectionery	Starch Total sugar expressed as sucrose
12.03	Fatty acids	By-product obtained during the deacidification, by means of lye or by distillation of oils and fats of unspecified vegetable or animal origin	Crude fat
12.04	Salts of fatty acids (1)	Product obtained by saponification of fatty acids with calcium, sodium or potassium-hydroxide	Crude fat Ca (or Na or K, when appropriate)

(1) The name may be supplemented by an indication of the salt obtained

PART C

Provisions regarding the declaration of certain constituents of non-listed feed materials

For feed materials put into circulation which are not listed in Part B of this Annex a compulsory declaration of the constituents indicated in column 2 of the table below shall be made in accordance with Article 5 (1) (d) of the Directive.

Feed material belonging to	Compulsory declaration of
1	2
Cereal grains	
Products and by-products of cereal grains	Starch, when > 20 % Crude protein, when > 10 % Crude fat, when > 5 % Crude fibre
Oil seeds, oil fruits	
Products and by-products of oil seeds, oil fruits	Crude protein Crude fat, when > 5 % Crude fibre
Legume seeds	
Products and by-products of legume seeds	Crude protein Crude fibre
Tubers, roots	
Products and by-products of tubers, roots	Starch Crude fibre
Products and by-products of the sugar beet processing industry	Crude fibre Total sugar expressed as sucrose

Feed material belonging to	Compulsory declaration of
1	2
Other seeds and fruits, their products and by-products	Crude protein Crude fibre
Forages and roughage	Crude protein Crude fibre
Other plants, their products and by-products	Crude protein Crude fibre
Products and by-products of the sugar cane processing industry	Crude protein Crude fibre Total sugar expressed as sucrose
Milk products	Crude protein
Lactose-rich milk products	Crude protein Lactose
Land animal products	Crude protein, when > 10 % Crude fat, when > 5 %
Fish, other marine animals, their products and by-products	Crude protein, when > 10 % Crude fat, when > 5 %
Minerals	Relevant minerals
Miscellaneous	Crude protein, when > 10 % Crude fibre Crude fat, when > 10 % Starch, when > 30 % Total sugar, expressed as sucrose, when > 10 %