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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 L 125, 23.5.1996, p. 3)

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COUNCIL DIRECTIVE 96/22/EC

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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) hereas 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;

([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.

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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 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

([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).

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medicinal products given in Directives 81/851/EEC [1] and 81/852/EEC [2] 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.

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Article 2

Member States shall prohibit:

(a) the placing on the market of the substances listed in Annex II, list A, for administering to animals of all species;

(b) the placing on the market of the substances listed in Annex II, list B, for administering to animals, the flesh and products of which are intended for human consumption, for purposes other than those provided for in point 2 of Article 4 and in Article 5a.

Article 3

Member States shall prohibit, for substances listed in Annex II, and shall provisionally prohibit, for substances listed in Annex III:

(a) the administering of those substances to farm or aquaculture animals, by any means whatsoever;

(b) — the holding, except under official control, of animals referred to in point (a) on a farm, and

— the placing on the market or the slaughter for human consumption of farm animals,

which contain the substances referred to in Annex II and Annex III 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, 5 or 5a;

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

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[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).

[2] 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).

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

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

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Article 4

Notwithstanding Articles 2 and 3, Member States may authorize:

1. the administering to farm animals, for therapeutic purposes, of ►M1 ———— ◄ 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

►M1 Notwithstanding Article 3(a) and without prejudice to Article 2, Member States may authorise the administering to farm animals, for the purpose of zootechnical treatment, of veterinary medicinal products having an oestrogenic (other than oestradiol 17β and its ester-like derivatives), androgenic or gestagenic action which are authorised in accordance with Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products ([1]). ◄ 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

([1]) OJ L 311, 28.11.2001, p. 1.

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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.

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Article 5a

1. Notwithstanding Article 3(a) and without prejudice to Articles 2 and 11a, Member States may authorise the administering to farm animals of veterinary medicinal products containing oestradiol 17β or its ester-like derivatives for:

— the treatment of foetus maceration or mummification in cattle, or

— the treatment of pyometra in cattle,

in accordance with Directive 2001/82/EC.

2. Notwithstanding Article 3(a) and without prejudice to Article 2, Member States may authorise the administering to farm animals of veterinary medicinal products containing oestradiol 17β or its ester-like derivatives for oestrus induction in cattle, horses, sheep or goats until 14 October 2006, in accordance with Directive 2001/82/EC.

3. The treatment must be carried out by the veterinarian himself or herself on farm animals which have been clearly identified. This treatment must be registered by the veterinarian responsible. The latter must record at least the following details in a register, which may be that provided for in Directive 2001/82/EC:

— the type of product administered,

— the nature of the treatment,

— the date of treatment,

— the identity of the animals treated,

— the date of expiry of the withdrawal period.

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

Stockfarmers shall be prohibited from holding on their farms veterinary medicinal products containing oestradiol 17β or its ester-like derivatives.

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Article 6

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1. Hormonal products and beta-agonists the administration of which to farm animals is authorised in accordance with Articles 4, 5 or 5a must meet the requirements of Directive 2001/82/EC.

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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;

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(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

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1. For the purpose of trade, Member States may authorise 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, 5 or 5a and may authorise the affixing of the Community stamp to meat from such animals where the conditions laid down in Articles 4, 5 or 5a and the withdrawal periods provided for in the authorisation to place on the market are complied with.

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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:

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1. at the time of the import, manufacture, storage, distribution, sale and use of the substances referred to in Articles 2 and 3, their possession is restricted to the persons authorised by national legislation in accordance with Article 68 of Directive 2001/82/EC.

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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 ([2]) 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 ►M1 Articles 2 and 3 ◄, intended to be administered to animals for the purpose of fattening;

(b) the illegal treatment of animals;

([1]) OJ No L 214, 24. 8. 1993, p. 1.
([2]) See p. 10 of this Official Journal.

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(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 ►M1 in Articles 4, 5 and 5a ◄;

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 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.

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

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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 ►M1 Annex II, List A, ◄ have been administered by any means whatsoever;

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(ii) to which substances referred to in Annex II, List B, and Annex III have been administered, unless those substances were administered in compliance with the provisions and requirements laid down in Articles 4, 5, 5a and 7 and the withdrawal periods allowed in international recommendations have been observed;

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(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 [1] 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 [2].

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Article 11a

The Commission shall present within two years from 14 October 2003 to the European Parliament and to the Council, a report on the availability of alternative veterinary medicinal products to those containing oestradiol 17β or its ester-like derivatives for the treatment of foetus maceration or mummification in cattle, and for the treatment of pyometra in cattle, and present to them the following year any necessary proposals intending to replace these substances in due time.

Likewise, with regard to the substances listed in Annex III, the Commission shall seek additional information, taking into account recent scientific data from all possible sources, and keep the measures applied under regular review with a view to timely presentation to the European Parliament and to the Council of any necessary proposals.

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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.

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[1] 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).

[2] 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).

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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 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.

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Article 14a

Notwithstanding Articles 3 and 5a, and without prejudice to Article 2, farm animals for which it can be certified that they have been administered oestradiol 17β or its ester-like derivatives for therapeutic or zootechnical purposes prior to 14 October 2004 shall be subject to the same provisions as those laid down for the substances authorised in accordance with Article 4(1) as regards therapeutic use and Article 5 as regards zootechnical use.

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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.

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ANNEX I

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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	—	

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This Directive	Directives 81/602/EEC, 88/146/EEC and 88/299/EEC
Article 16	—
Annex	—

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ANNEX II

List of prohibited substances:

List A:

— thyrostatic substances
— stilbenes, stilbene derivatives, their salts and esters

List B:

— oestradiol 17β and its ester-like derivatives
— beta-agonists

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ANNEX III

List of provisionally prohibited substances:

substances having oestrogenic (other than oestradiol 17β and its ester-like derivatives), androgenic or gestagenic action.