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

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) 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;

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(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 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:

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Article 1

1 For the purposes of this Directive, the definitions of meat and meat products given in Directives 64/433/EEC[7], 71/118/EEC[8], 77/99/EEC[9], and 91/495/EEC[10], the definitions of aquaculture products given in Directive 91/493/EEC[11] and the definitions of veterinary medicinal products given in Directives 81/851/EEC[12] and 81/852/EEC[13] 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;

[F1 b ‘therapeutic treatment’ shall mean the administering — under Article 4 of this Directive — to an individual farm animal of an authorised 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 as well as to treat respiratory problems, navicular disease and laminitis and to induce tocolysis in equidae;**]**

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.

Textual Amendments

F1 Substituted by Directive 2008/97/EC of the European Parliament and of the Council of 19 November 2008 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists (Text with EEA relevance).

[F2[F1 Article 2

Member States shall prohibit the placing on the market of the substances listed in Annex II for administering to any animals, the meat and products of which are intended for human consumption, for purposes other than those provided for in point 2 of Article 4.**]**

Textual Amendments

F1 Substituted by Directive 2008/97/EC of the European Parliament and of the Council of 19 November 2008 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists (Text with EEA relevance).

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F2 Substituted by Directive 2003/74/EC of the European Parliament and of the Council of 22 September 2003 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists.

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**[**F3 or **][**F3 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;

(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).**]**

Textual Amendments

F2 Substituted by Directive 2003/74/EC of the European Parliament and of the Council of 22 September 2003 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists.

F3 Deleted by Directive 2008/97/EC of the European Parliament and of the Council of 19 November 2008 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists (Text with EEA relevance).

Article 4

Notwithstanding Articles 2 and 3, Member States may authorize:

1. the administering to farm animals, for therapeutic purposes, of **[**F4oestradiol 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,

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— 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) **[**[F1]allyl trenbolone, administered orally, or beta-agonists to equidae, 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.

Textual Amendments

F1 Substituted by Directive 2008/97/EC of the European Parliament and of the Council of 19 November 2008 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists (Text with EEA relevance).

F4 Deleted by Directive 2003/74/EC of the European Parliament and of the Council of 22 September 2003 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists.

Article 5

[[F2]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[(14)].**]** 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