DIRECTIVES

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)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(b) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee ([1]),

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ([2]),

Whereas:

(1) Article 2 of Directive 96/22/EC ([3]) prohibits, *inter alia*, the placing on the market of stilbenes, stilbene derivatives, their salts and esters and thyrostatic substances for administering to animals of all species.

(2) The reason for that absolute prohibition was that potential abuse or misuse would be more difficult if there were no product authorised for any animal species whatsoever on the market.

(3) However, experience gained in particular with national residue plans submitted under Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products ([4]) has shown that the misuse of product presentations intended for pet animals does not play a role as a source of abuse or misuse. That is partly because it is economically unattractive to use presentations intended for pet animals for growth promotion in food-producing animals.

(4) Moreover, the prohibition of thyrostatic substances has harmful consequences for the welfare of pet animals (dogs and cats) due to the lack of an alternative treatment for hyperthyroidism in those animals.

(5) The Protocol on protection and welfare of animals annexed to the Treaty provides that the Community and the Member States are to pay full regard to the welfare requirements of animals in the implementation of Community policies, in particular with regard to the internal market.

(6) It is therefore appropriate to limit the scope of Directive 96/22/EC only to food-producing animals and withdraw the prohibition for pet animals, as well as to adjust the definition of therapeutic treatment.

(7) The Opinion of the Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) of 30 April 1999 on the potential risks to human health from hormone residues in bovine meat and meat products (which was reviewed on 3 May 2000 and confirmed on 10 April 2002) concluded that there is a substantial body of recent evidence suggesting that oestradiol 17ß has to be considered as a complete carcinogen, as it exerts both tumour-initiating and tumour-promoting effects, and that the data currently available do not make it possible to give a quantitative estimate of the risk to human health. As a result, Directive 96/22/EC was amended by Directive 2003/74/EC so as to, *inter alia*, prohibit permanently the use of oestradiol 17β as a growth promoter and reduce substantively all other circumstances in which it can be administered to all farm animals for therapeutic or zootechnical purposes pending further examination of the factual and scientific situation and the veterinary practices in the Member States.

([1]) OJ C 10, 15.1.2008, p. 57.
([2]) Opinion of the European Parliament of 5 June 2008 (not yet published in the Official Journal) and Council Decision of 20 October 2008.
([3]) OJ L 125, 23.5.1996, p. 3.
([4]) OJ L 125, 23.5.1996, p. 10.

(8) Article 11a of Directive 96/22/EC required the Commission to present a report by 14 October 2005 concerning the availability of alternative veterinary medicinal products to those containing oestradiol 17β for food-producing animals for therapeutic purposes. The Commission sought expert advice and established the relevant scientific report, which was forwarded to the European Parliament and the Council on 11 October 2005. That Report concludes that oestradiol 17β is not essential in the production of food-producing animals because the use of the available alternatives (especially prostaglandins) by practising veterinarians is already quite common in the Member States and that the complete prohibition of the use of oestradiol 17β for food-producing animals would have no, or only a negligible, impact on farming and animal welfare.

(9) Proper compliance with the relevant legislation and the elimination of inappropriate use of unauthorised substances can be enhanced by means of objective information and awareness campaigns.

(10) A temporary exemption was provided for the use of oestradiol 17β for oestrus induction in cattle, horses, sheep or goats until 14 October 2006. Since effective alternative products exist and are already used, and in order to ensure the high level of health protection chosen in the Community, that exemption should not be renewed.

(11) Directive 96/22/EC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 96/22/EC is hereby amended as follows:

1. In Article 1(2), point (b) shall be replaced by the following:

'(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;'.

2. Article 2 shall be replaced by the following:

'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.'.

3. In Article 4, point 2(i) shall be replaced by the following:

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

4. Article 5a shall be deleted.

5. In Articles 3, 6, 7, 8, 11 and 14 a, the references to Article 5a shall be deleted.

6. In Article 11, paragraph 1 shall be replaced by the following:

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

7. Article 11a shall be replaced by the following:

'Article 11a

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 the timely presentation to the European Parliament and to the Council of any necessary proposals.'.

8. The following Article shall be inserted:

'Article 11b

The Commission, in collaboration with the Member States, shall set up an information and awareness campaign on the complete ban on the use of oestradiol 17β in food-producing animals, aimed at farmers and veterinary organisations in the EU as well as the relevant organisations outside the EU which are directly or indirectly involved in the export to the EU of food of animal origin falling within the scope of this Directive.'.

9. Annex II shall be replaced by the text appearing in the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 January 2009. They shall forthwith communicate to the Commission the text of such laws, regulations and administrative provisions together with a table showing the correlation between them and this Directive.

When they are adopted by Member States, these measures 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 provisions of national law which they adopt in the field covered by this Directive.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Strasbourg, 19 November 2008.

For the European Parliament	*For the Council*
The President	*The President*
H.-G. PÖTTERING	J.-P. JOUYET

ANNEX

'ANNEX II

List of prohibited substances:

List A: prohibited substances

— Thyrostatic substances,

— Stilbenes, stilbene derivatives, their salts and esters,

— Oestradiol 17β and its ester-like derivatives.

List B: prohibited substances with derogations

— Beta-agonists'