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)

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.

(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:

(**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.