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ADDENDUM TO THE "I/A" ITEM NOTE

from : the Working Party of Agricultural Counsellors/Attachés
on 29 October 2007
to : Permanent Representatives Committee (Part 1) / Council

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Subject : Proposal for a Directive of the European Parliament and of the Council amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyreostatic action and of beta agonists

Delegations will find in Annex the compromise text of the Presidency¹.

¹ The changes in comparison to the initial proposal are presented in **bold** letters.

DRAFT

**DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming
of certain substances having a hormonal or thyreostatic 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 Commission¹,

Having regard to the opinion of the Economic and Social Committee²,

Having regard to the opinion of the Committee of the Regions³,

Acting in accordance with the procedure laid down in Article 251 of the Treaty;

Whereas:

- (1) Article 2 of Council Directive 96/22/EC⁴ prohibits inter alia the placing on the market of thyrostatic substances, stilbenes, stilbene derivatives, their salts and esters for administering to animals of all species.

¹ OJ C ...

² OJ C ...

³ OJ C ...

⁴ OJ L 125, 23.5.1996, p. 3. Directive as amended by Directive 2003/74/EC of the European Parliament and of the Council (OJ L 262, 14.10.2003, p. 17).

- (2) The reason for that absolute prohibition was that potential abuse or misuse would be more difficult if there was on the market no product authorised for any animal species whatsoever.
- (3) However, experience gained in particular with national residue plans submitted under 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/EEC¹ 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 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 establishing the European Community 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 this Directive only to food producing animals and withdraw the prohibition for pet animals **as well as to adjust the definition of therapeutic treatment.**

¹ OJ L 125, 23.5.1996, p. 10. Directive as last amended by Regulation (EC) No 882/2004 of the European Parliament and of the Council (OJ L 165, 30.4.2004, p. 1).

- (7) The Opinion of the Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) of 30 April 1999 on potential adverse effects 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 17 β 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 which inter alia prohibited permanently the use of oestradiol 17 β as a growth promoter and reduced 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 called for the presentation of a report on the necessity of the use of the hormone oestradiol 17 β in animals (food producing animals) for therapeutic purposes by 14 October 2005. The European Commission has sought expert advice and established the relevant scientific report, which has been forwarded to the European Parliament and the Council on 11 October 2005¹. That Report concludes that oestradiol 17 β is not essential in food animal production, 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 17 β for food-producing animals would have no or only a negligible impact on farming and animal welfare.
- (9) A temporary exemption was provided for the use of oestradiol 17 β 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.

¹ See the *"Report concerning the availability of alternative veterinary medicinal products to those containing oestradiol 17 β or its ester-like derivatives for the treatment of fetal maceration or mummification in cattle, and for the treatment of pyometra"*, available at : http://ec.europa.eu/food/animal/resources/comm_staff_work_doc11102005_en.pdf.

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, paragraph 2 (b) is replaced by the following:

"2. (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 as well as to treat respiratory problems, navicular disease and laminitis and to induce tocolysis in equidae ;"

2. Article 2 is 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) of the first paragraph is replaced by the following:

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

4. Article 5a is deleted.
5. In Articles 3, 6, 7, 8, 11 and 14 a, the references to Article 5a are deleted.
6. In Article 11, paragraph 1 is replaced by the following :

“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 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 authorized to import farm or aquaculture animals or meat or products obtained from such animals.”

7. Article 11a is 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 timely presentation to the European Parliament and to the Council of any necessary proposals.”

8. Annex II is replaced by the text in the Annex to this Directive.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [1 July 2007] at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication.
Member States shall determine how such reference is to be made.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament For the Council

The President

The President

ANNEX

“ANNEX II

List of prohibited substances :

List A : prohibited substances

- Thyrostatic substances,
- Stilbenes, stilbene derivatives, their salts and esters,
- Oestradiol 17 β and its ester-like derivatives.

List B : prohibited substances with derogations

- Beta-agonists”

