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***II
RECOMMENDATION FOR SECOND READING

on the Council common position for adopting a European Parliament and Council directive 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
(14502/1/2002 – C5-0079/2003 – 2000/0132(COD))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Karl Erik Olsson

Symbols for procedures

*	Consultation procedure *majority of the votes cast*
**I	Cooperation procedure (first reading) *majority of the votes cast*
**II	Cooperation procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***	Assent procedure *majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty*
***I	Codecision procedure (first reading) *majority of the votes cast*
***II	Codecision procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***III	Codecision procedure (third reading) *majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

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PROCEDURAL PAGE

At the sitting of 1 February 2001 Parliament adopted its position at first reading on the proposal for a European Parliament and Council directive 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 (COM(2000) 320 – 2000/0132 (COD)).

At the sitting of 13 March 2003 the President of Parliament announced that the common position had been received and referred to the Committee on the Environment, Public Health and Consumer Policy (14502/1/2002 – C5-0079/2003).

The committee had appointed Karl Erik Olsson rapporteur at its meeting of 12 July 2000.

It considered the common position and draft recommendation for second reading at its meetings of 23 April and 22 May 2003.

At the last meeting it adopted the draft legislative resolution unanimously.

The following were present for the vote: Caroline F. Jackson, chairman; Guido Sacconi, vice-chairman; Karl Erik Olsson, rapporteur; María del Pilar Ayuso González, Hans Blokland, David Robert Bowe, Philip Bushill-Matthews (for John Bowis), Raffaele Costa, Avril Doyle, Cristina García-Orcoyen Tormo, Françoise Grossetête, Marie-Thérèse Hermange (for Martin Callanan), Dieter-Lebrecht Koch (for Marialiese Flemming, pursuant to Rule 153(2)), Eija-Riitta Anneli Korhola, Bernd Lange, Paul A.A.J.G. Lannoye (for Marie Anne Isler Béguin), Peter Liese, Torben Lund, Patricia McKenna, Erik Meijer (for Jonas Sjöstedt), Rosemarie Müller, Riitta Myller, Ria G.H.C. Oomen-Ruijten, Dagmar Roth-Behrendt, Yvonne Sandberg-Fries, Karin Scheele, Ursula Schleicher (for Christa Klaß), Inger Schörling, María Sornosa Martínez, Bart Staes (for Hiltrud Breyer), Catherine Stihler, Kathleen Van Brempt and Phillip Whitehead

The recommendation for second reading was tabled on 23 May 2003.

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the Council common position for adopting a European Parliament and Council directive 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 (14502/1/2002 – C5-0079/2003 – 2000/0132(COD))

(Codecision procedure: second reading)

The European Parliament,

– having regard to the Council common position (14502/1/2002– C5-0079/2003),

– having regard to its position at first reading[1] on the Commission proposal to Parliament and the Council (COM(2000) 320[2]),

– having regard to the amended proposal (COM(2001) 131[3]),

– having regard to Article 251(2) of the EC Treaty,

– having regard to Rule 80 of its Rules of Procedure,

– having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Consumer Policy (A5-0201/2003),

1. Amends the common position as follows;

2. Instructs its President to forward its position to the Council and Commission.

[1] OJ C 267, 21.9.2001, p. 20 and 53-56.
[2] OJ C 337 E, 28.11.2000, p. 163-166.
[3] OJ C 180 E, 26.6.2001, p. 190-196.

Council common position	Amendments by Parliament
Amendment 1 Recital 6	
(6) As regards, in particular, the use of oestradiol 17β, ***with the aim of promoting growth,*** the SCVPH assessment is that a substantial body of recent evidence suggests that it has to be considered as a complete carcinogen, as it exerts both tumour initiating and tumour promoting effects and that the data currently available does not make it possible to give a quantitative estimate of the risk.	(6) As regards, in particular, the use of oestradiol 17β, the SCVPH assessment is that a substantial body of recent evidence suggests that it has to be considered as a complete carcinogen, as it exerts both tumour initiating and tumour promoting effects and that the data currently available does not make it possible to give a quantitative estimate of the risk

Justification

In making a risk assessment, the purpose for which a substance has been used is of no interest; it is the effects to which it gives rise that should be the focus of the assessment. Regardless of the intended aim of using oestradiol 17β, it is carcinogenic.

Amendment 2 Recital 8	
(8) Subsequent to the opinion of the SCVPH of 30 April 1999, new and more recent scientific information under consideration on some of the six hormones was made available to the Commission from the United Kingdom's Veterinary Products Committee, in October 1999, the Committee on Veterinary Medicinal Products of the European Community (CVM), in December 1999, and the Joint FAO/WHO Expert Committee on Food Additives (JECFA), in February 2000. ***The CVM has noted in particular that oestradiol 17β has a carcinogenic effect only after prolonged exposure and at levels which are considerably higher than those needed for a physiological (oestrogenic) response.*** All this latest scientific information was brought to the attention of the SCVPH, which reviewed it	(8) Subsequent to the opinion of the SCVPH of 30 April 1999, new and more recent scientific information under consideration on some of the six hormones was made available to the Commission from the United Kingdom's Veterinary Products Committee, in October 1999, the Committee on Veterinary Medicinal Products of the European Community (CVM), in December 1999, and the Joint FAO/WHO Expert Committee on Food Additives (JECFA), in February 2000. All this latest scientific information was brought to the attention of the SCVPH, which reviewed it and, on 3 May 2000, concluded that it did not provide convincing data and arguments requiring revision of the conclusions

and, on 3 May 2000, concluded that it did not provide convincing data and arguments requiring revision of the conclusions drawn in its opinion of 30 April 1999. The SCVPH confirmed in its opinion of 10 April 2002 its previous opinion's validity, after revising it in the light of the most recent scientific data.	drawn in its opinion of 30 April 1999. The SCVPH confirmed in its opinion of 10 April 2002 its previous opinion's validity, after revising it in the light of the most recent scientific data.

Justification

The SCVPH has taken note of the most recent data but has seen no reason to change its conclusions.

Amendment 3
Recital 11

(11) ***However, the*** use of certain of the above substances***, where this is necessary,*** for therapeutic purposes or zootechnical treatment may continue to be authorised ***as it is not likely to constitute a hazard for public health due to the nature and the limited duration of the treatments, the limited quantities administered and*** the strict conditions laid down in Directive 96/22/EC in order to prevent any ***possible*** misuse***.***	(11) ***The*** use of certain of the above substances for therapeutic purposes or zootechnical treatment may***, however,*** continue to be authorised ***under the*** strict conditions laid down in Directive 96/22/EC in order to prevent any misuse***, save as regards oestradiol 17β and its ester-like derivatives whose administration may only be authorised for therapeutic treatment to non-farm animals, in view of the results of the risk assessment.***

Justification

Scientific data show that oestradiol 17β is carcinogenic. It exerts both tumour initiating and tumour promoting effects. It is important that the cautionary principle is applied where there is uncertainty about the danger of a substance. Since there are effective alternatives to oestradiol 17β, there are no grounds for authorising it.

Amendment 4
Recital 12

(12) ***However, in the light of the existing information it is appropriate to limit as far as reasonably achievable the exposure to oestradiol 17β and only authorise those treatments for which no viable effective alternatives exist and which are not likely to present an unacceptable risk to public health.*** In general, there are alternative treatments or strategies available to replace most of the uses of oestradiol 17β for therapeutic or zootechnical purposes. ***Nonetheless, studies appear to show that at present no viable effective alternatives exist in all the Member States for certain treatments which are currently authorised (foetus maceration or mummification, pyometra in cattle and oestrus induction in cattle, horses, sheep or goats). The use of oestradiol 17β for such treatments does not seem to pose an unacceptable risk if appropriate measures are taken to avoid any abusive use. It therefore appears necessary to maintain the possibility of authorising the treatments mentioned above under strict and verifiable conditions so as to prevent any possible misuse and any unacceptable risk for public health. It is necessary to review within a given time the provisions concerning treatments of farm animals with oestradiol 17β***.	(12) In general, there are alternative treatments or strategies available to replace the use of oestradiol 17β for therapeutic or zootechnical purposes; ***the real need for oestradiol 17β for the treatment of specific limited conditions in individual animals will be identified by the Commission in association with competent authorities, with a view to developing appropriate alternative solutions before the entry into force of this Directive.***

Justification

Self-explanatory.

Amendment 5

ARTICLE 1, POINT 1
Article 2, introductory statement (Directive 96/22/EC)

Member States shall prohibit:	Member States shall ***strictly*** prohibit:

(Reinstates Amendment 5 (first part) from first reading)

Justification

The importance of this prohibition in the case of animals for human consumption must be emphasised.

Amendment 6
ARTICLE 1, POINT 1
Article 2, paragraph (b) (Directive 96/22/EC)

b) the placing on the market of the substances listed in Annex II, List B of this Directive 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***.	(b) the placing on the market of the substances listed in Annex II, List B of this Directive 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.***

Justification

Technical adaptation related to deletion of new article 5a.

Amendment 7
ARTICLE 1, POINT 1
Article 3, paragraph (b) (Directive 96/22/EC)

b) the holding, except under official control, of animals referred to in point (a) on a farm, the placing on the market or 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***;	(b) the holding, except under official control, of animals referred to in point (a) on a farm, the placing on the market or 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 and 5;***

Justification

Technical adaptation related to deletion of new article 5a.

Amendment 8ARTICLE 1, POINT 2
Article 4, 2a (new) (Directive 96/22/EC)

	2(a) The following paragraph is added: Member States shall prohibit oestradiol 17β and its ester-like derivatives for use in growth promotion, for therapeutic purposes and zootechnical treatment except for therapeutic treatment under veterinary supervision of non-farm animals.

Justification

Exceptions can be made for the treatment of non-farm animals, i.e. for animals not used for food production. In other cases, the use of oestradiol 17ß should be replaced by other methods of treatment.

Amendment 9
ARTICLE 1, POINT 4
Article 5a, paragraph 1 (Directive 96/22/EC)

4. The following article shall be added: "Article 5a ***1. 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:*** ***– the treatment of foetus maceration or mummification in cattle,*** ***– the treatment of pyometra in cattle,***	***Delete***

or

– ***oestrus induction in cattle, horses, sheep or goats,***

in accordance with Directive 2001/82/EC.

The treatment must be carried out by the veterinarian himself 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:

– ***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."

Justification

In view of the dangerousness of the substance it is important to safeguard consumers' health and to apply the cautionary principle. There are a number of alternative drugs within the Community to achieve the same effects and they should be used instead.

Amendment 10
ARTICLE 1, POINT 5
Article 6(1), paragraph 1 (Directive 96/22/EC)

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

Justification

Technical adaptation related to deletion of new article 5a.

Amendment 11
ARTICLE 1, POINT 6
Article 7(1), paragraph 1 (Directive 96/22/EC)

"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."	"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 or 5*** and may authorise the affixing of the Community stamp to meat from such animals where the conditions laid down in Articles ***4 or 5*** and the withdrawal periods provided for in the authorisation to place on the market are complied with."

Justification

Technical adaptation related to deletion of new article 5a.

Amendment 12
ARTICLE 1, POINT 7
Article 8, paragraph (c) (Directive 96/22/EC)

(c) in point 2(d), the words "in Articles 4 and 5" shall be replaced by "in Articles 4, 5 and 5a".	***Delete***

Justification

Technical adaptation related to deletion of new article 5a.

Amendment 13
ARTICLE 1, POINT 8
Article 11(2)(a), paragraph (b), subparagraph ii (Directive 96/22/EC)

"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;"	"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 and 7*** and the withdrawal periods allowed in international recommendations have been observed;"

Justification

Technical adaptation related to deletion of new article 5a.

Amendment 14
ARTICLE 1, POINT 9
Article 11a (Directive 96/22/EC)

"Article 11a ***The Commission shall present within two years from * to the European Parliament and the Council a report on the availability of alternative veterinary medicinal products to those containing oestradiol 17β or its ester-like derivatives and present to them the following year any necessary proposals intending to replace in due time these substances. Likewise, with regard to the substances listed in Annex III, the Commission shall seek additional information, taking into***	***Delete***

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 the Council of any necessary proposals."

Justification

Alternatives to oestradiol 17ß are already available.

Amendment 15
ARTICLE 1, POINT 10
Article 14a, paragraph 1 (Directive 96/22/EC)

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 ..... 2002 * 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."	Notwithstanding ***Article 3*** 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 ..... 2002 * 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.

Justification

Technical adaptation related to deletion of new article 5a.

Amendment 16
Annex 2

List of prohibited substances: List A:	List of prohibited substances: List A:

– Thyrostatic substances – Stilbenes, stilben derivatives, their salt and esters	– Thyrostatic substances – Stilbenes, stilben derivatives, their salt and esters ***– Oestradiol 17β and its ester-like derivatives***
List B: ***– Oestradiol 17β and its ester-like derivatives,*** – β-agonists	***List B:*** – β-agonists

Justification

Technical adaptation related to deletion of new article 5a.

EXPLANATORY STATEMENT

Background

Council Directive 96/22/EG prohibits the use in stockfarming of certain substances having a hormonal or thyrostatic action and of ß-agonists. With certain exceptions, the Directive also prohibits imports from third countries of farm animals and aquaculture animals to which the prohibited substances have been administered.

The ban resulted in a dispute being brought before the World Trade Organisation (WTO) as to whether this was consistent with current trade agreements. In 1998, the Commission began a supplementary risk assessment on the basis of the recommendations made by the WTO's dispute settlement body.

In 1999, the Scientific Committee on Veterinary measures relating to Public Health (SCVPH) presented its assessment of potential adverse effects on public health of hormone residues (oestradiol 17ß, testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate) in meat and meat products. The conclusions were:

— excess intake of hormone residues and their metabolites constitutes a risk to consumers' health but the levels of conclusive evidence for the six hormones assessed were different;
— the hormones could have endocrine, developmental, immunological, neurobiological, immunotoxic, genotoxic and carcinogenic effects. The biggest risk is to prepubertal children;
— it is not possible to define any thresholds or approve any daily intake for any of the hormones.

The SCVHP made the assessment that the use of oestradiol 17ß in particular must be considered to be carcinogenic. The substance can initiate tumours and promote the growth of existing tumours.

The SCVPH's report is not the only report on the subject by the EU's committees of experts, however. In December 1999, the EC's Committee on Veterinary Medicinal Products (CVMP) delivered its opinion on the use of the six hormones [1]. This committee makes different assessments of the risks to consumers than the SCVPH, in particular with regard to oestradiol 17ß. According to the CVMP, the risk of oestradiol 17ß having genotoxic and carcinogenic properties is so small that no limit values are required. According to the committee, these properties can only emerge after prolonged exposure and at far higher doses than are required for any physiological (oestrogenic) response. The CVMP also states that these substances are used almost exclusively for clinical, therapeutic and zootechnical purposes in the EU and that their use is not particularly widespread. As regards the properties of the hormones, the UK Veterinary Products Committee and the FAO/WHO Expert Committee on Food Additives (JEFCA) make similar judgements.

The differing interpretations of the available scientific data are probably due to diverging views of the concept of risk and of how risks should be assessed. Those who argue that the dangers of administering these hormones are being exaggerated stress in particular that they are used in small quantities and most often not specifically for growth promotion purposes,

[1] EMEA/CVMPH/885/99.

and also that their use in the Member States, for clinical, therapeutic and zootechnical purposes - is strictly regulated and regularly subject to veterinary supervision. In response to these views, one could just as well argue, on the basis of the precautionary principle, that there is no actual need to use the hormones for such purposes, especially as a number of alternative treatments and methods are available in the Community that produce the same effects.

It is unfortunate that, in the new article 5a, the Council has chosen to authorise the administering to farm animals of veterinary medicinal products containing oestradiol 17ß, even though its use is restricted to certain treatments. In view of the dangerousness of the substance it is important to apply the precautionary principle to safeguard consumers' health. In April 2002, following a review of the most recent scientific data, the SCVHP noted that no new facts had come to light which altered the criteria on which the previous opinion had been based.

Conclusions
There are many well-founded reasons for applying the precautionary principle with regard to the use of the hormones in question:

– on public health grounds, as the hormones can in particular have carcinogenic and genotoxic effects,

– on consumer protection grounds, as hormone use entails some health risk and, in the cases under consideration, there are no obvious benefits to the consumer in treating animals to increase their natural hormone levels,

– on environmental grounds, partly owing to the fact that in the USA, increased levels of hormones have been found in the environment close to 'feed lots' where animals are gathered together for a final hormone-enriched feed,

– on animal welfare grounds, as the question must be asked as to whether hormone treatment, and the resulting abnormal rate of growth, do not cause some suffering to animals owing to the stress such treatment causes,

– on ethical grounds, which are becoming increasingly significant as scientific advances are made in areas such as medicine, veterinary medicine and biotechnology. Whilst mankind needs to exploit available know-how, such needs must always be balanced against an ethically based consideration of whether we have a right to substantially alter the conditions which govern the life of human beings and other creatures.

It is important that the European Union should, through its own research programmes and by supporting various research projects, help to supplement, consolidate and broaden knowledge of the use of natural and synthetic hormones. It is also important, even before the Directive enters into force, that the Commission put into practice its plans for joining with the competent authorities to develop and provide information on suitable alternatives to the use of oestradiol 17ß for the treatment of individual animals.