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***I
REPORT

on the 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
(COM(2007)0292 – C6-0154/2007 – 2007/0102(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Karin Scheele

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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.

CONTENTS

Page

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the 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 (COM(2007)0292 – C6-0154/2007 – 2007/0102(COD))

(Codecision procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2007)0292),

– having regard to Articles 251(2) and 152(4)(b) of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0154/2007),

– having regard to Rule 51 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinion of the Committee on Agriculture and Rural Development (A6-0067/2008),

1. Approves the Commission proposal as amended;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;

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

Text proposed by the Commission	Amendments by Parliament
Amendment 1 **Recital 6**	
(6) It is therefore appropriate to limit the scope of this Directive only to food producing animals and withdraw the prohibition for pet animals.	(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***.

Justification

The definition of Therapeutic Treatment must also include the possibility to treat navicular disease and laminitis in horses raised for purposes other than meat production. These two relevant diseases cause important suffering in horses and should be adequately treated.

Amendment 2
Recital 8 a (new)

(8a) 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.

Justification

By conducting information campaigns addressed to the relevant groups of citizens, inappropriate or illegal use of substances can partially be avoided.

Amendment 3
Recital 9 a (new)

(9a) The prohibition of the use of oestradiol 17ß in veterinary medicinal products and for oestrus induction in livestock will contribute to a reduction in the oestrogen content of the waste produced by such animals, which, in view of the growing contamination of surface water with pharmaceutical products, including oestrogens, is a significant step towards improving the state of the environment within the Community.

Justification

Zanieczyszczenie wód powierzchniowych hormonami z grupy estrogenów staje się istotnym problemem powodującym niespecyficzne zmiany w zamieszkujących te środowiska organizmach. Nawet bardzo niskie stężenia tych hormonów w wodach powierzchniowych powodują zmiany płci u ryb, czy u płazów.

Estradiol 17-beta, którego dotyczy niniejsza poprawka, jest związkiem o wysokim potencjale estrogennym. Doniesienia naukowe potwierdzają wpływ skażenia środowiska estrogenami nie

tylko na faunę wodną ale także na zdrowie zamieszkujących dane obszary ludzi.

Stąd też, wydaje się, że całkowite wycofanie estradiolu 17-beta z zastosowań dla zwierząt gospodarskich jest także uzasadnione ze względów środowiskowych i przyczyni się do poprawy jakości środowiska naturalnego na terenie Wspólnoty.

Amendment 4
Article 1 - point - 1 (new)
Directive 96/22/EC
Article 1 - paragraph 2 - point (b)

(-1) In Article 1(2), point (b) is 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 [...]*;"*

Justification

While the EU Hormone Ban, as currently formulated, provides for certain exceptional uses of the substances concerned for therapeutic and zootechnical use, these exceptions do not embrace two specific treatments for horses. These relate to use of beta-agonists for treatment of navicular disease and laminitis in horses. These conditions result in degenerative changes to bone in a horse's front feet. The condition can only effectively be treated by a medicine containing a beta-agonist (Isoxuprine hydrochloride) whose mode of action as a peripheral vasodilator improves the flow of blood through the lower parts of the limbs and reduces pain dramatically.

Amendment 5
Article 1 - point 1 a (new)
Directive 96/22/EC
Article 4 - point 2- point (i)

(1a) In Article 4(2), point (i) is replaced by the following:

"(i) allyl trenbolone, administered orally, or beta-agonists to equidae *[...] raised for purposes other than meat production,* provided they are used in accordance with the manufacturer's instructions*;"*

Justification

The reference to pet animals should be removed form Article 4, point 2(i), in accordance with the new scope of the Directive. Furthermore, Member States should be allowed to authorise the use of beta-agonists to treat respiratory problems, navicular disease and laminitis in horses since alternatives are limited.

Amendment 6
Article 1 - point 5 a (new)
Directive 96/22/EC
Article 11 b (new)

(5a) The following Article 11b is 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 17 ß 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."

Justification

By conducting information campaigns addressed to the relevant groups of citizens, inappropriate or illegal use of substances can partially be avoided.

Amendment 7
Article 1 - point 5 b (new)
Directive 96/22/EC
Article 14 b (new)

(5b) The following Article 14b is inserted:

	"Article 14b
	Member States shall communicate regularly to the Commission which administrative and judicial measures they have taken to ensure compliance with this Directive.
	The Commission shall submit a report on the implementation of this Directive to the European Parliament and the Council every five years, with the first report being submitted on 1 January 2009. The report shall contain a complete overview on how the Member States implement this Directive on an administrative and judicial level and shall evaluate in particular the result of residue testing in the Member States, the controls undertaken on farm and in the veterinary sector and the steps taken in order to prevent illegal use of hormones authorised for pets.
	It shall, where appropriate, contain proposals designed to further improve the implementation of the Directive."

Justification

It seems justified to exempt pets from the scope of the Regulation. However, Member States have to undertake the necessary steps to prevent any misuse and report to the Commission on these measures. The legislator needs to be regularly informed about the implementation of the Directive in the Member States.

Amendment 8
Article 2 - paragraph 1

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.	Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [***1 July 2008***] 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.

Justification

2008 seems to be a realistic date for the entry into force of the modifications.

Amendment 9
Annex
Directive 96/22/EC
Annex II

List of prohibited substances:	List of prohibited substances:
List A:	List A: ***prohibited substances***
- Thyrostatic substances,	- Thyrostatic substances,
- Stilbenes, stilbene derivatives, their salts and esters,	- Stilbenes, stilbene derivatives, their salts and esters,
- Oestradiol 17β and its ester-like derivatives.	- Oestradiol 17β and its ester-like derivatives.
List B:	List B: ***prohibited substances with derogations***
- Beta-agonists	- Beta-agonists

Justification

It is important to clarify that beta-agonist, although prohibited in general, may be used in certain specific cases.

EXPLANATORY STATEMENT

Introduction:

- In Directive 96/22/EC the use of thyrostatic substances, stilbenes, stilbene derivatives, their salts and esters which are on list A of Annex II is prohibited for "animals of all species", meaning for both animals or animal products used for human consumption as well as pets.

- The two products on list B in Annex II can be used under certain conditions:

  - for oestradiol 17 ß and its ester-like derivatives these conditions are set out in Article 5a
  - beta agonists can only be used in the cases mentioned in Art 4,par 2

2. The proposed modification**.**

The Commission proposes:

- to exclude pet animals from the scope of this directive, which means that prohibitions for the use of certain substances simply do not apply anymore to them;

- the hormone oestradiol 17 ß which was temporarily allowed to be used for farm animals for the treatment of foetus maceration or mummification or for pyrometer (Art 5, a) will now be banned completely. The fourth application for oestrus induction in cattle, horses, sheep or goats had been granted only until October 2006 and had already expired.

The reasons behind these proposed modifications are the following:

- pet animals suffering f. ex. from hyperthyroidism could not be treated because of the general ban on thyrostatic substances .There might be other examples of diseases affecting pets and which could not be treated because of a general ban of one of these substances. Taking out pet animals from the scope of this directive will allow them to be treated properly and will enhance animal welfare.
- for the use of oestradiol 17 ß ,which as recent evidence suggests, is now to be considered as a complete carcinogen, alternatives now exist on the market so that the use of this hormone is redundant and can be banned completely.

3. Some considerations:

There could be an illegal use of some substances which are used and authorised for pets but not for farm animals. As the Commission points out experience with such category of substances do not form a major problem for the quality of the products of farm animals because the presentation (in very small packages) and the price for such medicines is such as to make illegal use unlikely and very unattractive .

The existence of alternatives for the use of oestradiol 17 ß, namely prostaglandin, is not always sufficiently known amongst primarily the generation of elder veterinarians.
An information campaign would be appropriate now when legislation changes and becomes more compulsory, in order to prevent or reduce unnecessary misuse of substances.

18.12.2007

OPINION OF THE COMMITTEE ON AGRICULTURE AND RURAL DEVELOPMENT

for the Committee on the Environment, Public Health and Food Safety

on the 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
(COM(2007)0292 – C6-0154/2007 – 2007/0102(COD))

Draftsman: Duarte Freitas

SHORT JUSTIFICATION

European Commission proposal

The Commission proposes to remove pet animals from the scope of the Council Directive 96/22/EC which would enable the treatment of these kinds of animals with substances having a thyrostatic action and of beta-agonists. The ban on these substances will, however, continue for food-producing animals.

Furthermore the Commission proposes to prohibit entirely the use of oestradiol 17ß and its ester-like derivates in food-producing animals, putting an end to the various derogations that still exist today.

The Commission intends to simplify and to improve the comprehensibility of Community legislation and to maintain and improve the provisions regarding food security considering that these substances may cause important health problems to human beings.

Position of the draftsman

The draftsman envisages achieving a balance between consumer protection, animal welfare and scientific assessment.

Underlining the need to ensure health and welfare of animals by making veterinary medicinal products available, the draftsman welcomes the Commission's proposal to take pet animals out of the scope of the existing legislation on substances having a thyrostatic action and of beta-agonists.

The draftsman notes that a comparison of prices and presentations of products with e.g. a thyrostatic action intended for use on pet animals, shows that it is economically unattractive to

use pet products e.g. on cattle. Furthermore, these substances could strongly contribute to improving the well-being of pet animals that suffer from diseases like hyperthyroidism.

The draftsman welcomes the entire prohibition of the use of oestradiol 17ß and its ester like derivates in food producing animals. The draftsman pleads for a rapid adoption of the new provisions, explaining that the changes in relation to the banning of use of oestradiol 17ß and its ester-like derivatives are in line with the conclusions of the Commission report[1] presented in 2005.

The draftsman proposes to take advantage of these changes to Directive 96/22/EC to amend the definition of therapeutic treatment used therein in order to allow the use of beta-agonists to treat navicular disease and laminitis in *equidae* raised for purposes other than meat production.

AMENDMENTS

The Committee on Agriculture and Rural Development calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission	Amendments by Parliament
Amendment 1 RECITAL 6	
(6) It is therefore appropriate to limit the scope of this Directive only to food producing animals and withdraw the prohibition for pet animals.	(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***.
Justification	
The definition of Therapeutic Treatment must also include the possibility to treat navicular disease and laminitis in horses raised for purposes other than meat production. These two relevant diseases cause important suffering in horses and should be adequately treated.	

[1] "*Report concerning the availability of alternative veterinary medicinal products to those containing oestradiol 17β or its ester-like derivatives for the treatment of fetal maceration or mummification in cattle, and for the treatment of pyometra*".

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

(-1) In Article 1, paragraph 2, point (b) is replaced by the following:

"(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 raised for purposes other than meat production;"

Justification

The definition of Therapeutic Treatment must also include the possibility to treat navicular disease and laminitis in horses raised for purposes other than meat production. These two relevant diseases cause important suffering in horses and should be adequately treated.

Amendment 3
ARTICLE 1, POINT 1 A (new)
Article 4, paragraph 2, point (i) (Directive 96/22/EC)

(1a) In Article 4, paragraph 2, point (i) is replaced by the following:

"(i) allyl trenbolone, administered orally, or beta-agonists to equidae raised for purposes other than meat production, provided they are used in accordance with the manufacturer's instructions;"

Justification

The reference to pet animals should be removed form Article 4, point 2(i), in accordance with the new scope of the Directive. Furthermore, Member States should be allowed to authorise the use of beta-agonists to treat respiratory problems, navicular disease and laminitis in

horses since alternatives are limited.

Amendment 4
ANNEX
Annex II (Directive 96/22/EC)

List of prohibited substances:	List of prohibited substances:
List A:	List A: ***prohibited substances***
- Thyrostatic substances,	- Thyrostatic substances,
- Stilbenes, stilbene derivatives, their salts and esters,	- Stilbenes, stilbene derivatives, their salts and esters,
- Oestradiol 17β and its ester-like derivatives.	- Oestradiol 17β and its ester-like derivatives.
List B:	List B: ***prohibited substances with derogations***
- Beta-agonists”	- Beta-agonists”

Justification

It is important to clarify that beta-agonist, although prohibited in general, may be used in certain specific cases.

PROCEDURE

Title	Prohibition on the use in stockfarming of certain substances having a hormonal or thyreostatic action and of beta agonists
References	COM(2007)0292 - C6-0154/2007 - 2007/0102(COD)
Committee responsible	ENVI
Opinion by Date announced in plenary	AGRI 7.6.2007
Drafts(wo)man Date appointed	Duarte Freitas 4.7.2007
Discussed in committee	20.11.2007 18.12.2007
Date adopted	18.12.2007
Result of final vote	+: 26 –: 1 0: 0
Members present for the final vote	Sergio Berlato, Bernadette Bourzai, Niels Busk, Luis Manuel Capoulas Santos, Giuseppe Castiglione, Albert Deß, Gintaras Didžiokas, Carmen Fraga Estévez, Duarte Freitas, Ioannis Gklavakis, Lutz Goepel, Friedrich-Wilhelm Graefe zu Baringdorf, Esther Herranz García, Lily Jacobs, Elisabeth Jeggle, Heinz Kindermann, Neil Parish, María Isabel Salinas García, Agnes Schierhuber, Willem Schuth, Czesław Adam Siekierski, Alyn Smith, Dimitar Stoyanov, Donato Tommaso Veraldi
Substitute(s) present for the final vote	Pilar Ayuso, Katerina Batzeli, Esther De Lange

PROCEDURE

Title	Prohibition on the use in stockfarming of certain substances having a hormonal or thyreostatic action and of beta agonists
References	COM(2007)0292 – C6-0154/2007 – 2007/0102(COD)
Date submitted to Parliament	4.6.2007
Committee responsible Date announced in plenary	ENVI 7.6.2007
Committee(s) asked for opinion(s) Date announced in plenary	AGRI 7.6.2007
Rapporteur(s) Date appointed	Karin Scheele 10.9.2007
Discussed in committee	28.1.2008
Date adopted	26.2.2008
Result of final vote	+: 56 –: 0 0: 0
Members present for the final vote	Adamos Adamou, Pilar Ayuso, Irena Belohorská, Johannes Blokland, John Bowis, Frieda Brepoels, Magor Imre Csibi, Avril Doyle, Mojca Drčar Murko, Edite Estrela, Jill Evans, Karl-Heinz Florenz, Matthias Groote, Françoise Grossetête, Gyula Hegyi, Jens Holm, Marie Anne Isler Béguin, Caroline Jackson, Dan Jørgensen, Christa Klaß, Eija-Riitta Korhola, Holger Krahmer, Urszula Krupa, Aldis Kušķis, Peter Liese, Jules Maaten, Linda McAvan, Roberto Musacchio, Riitta Myller, Miroslav Ouzký, Vladko Todorov Panayotov, Vittorio Prodi, Frédérique Ries, Dagmar Roth-Behrendt, Guido Sacconi, Karin Scheele, Richard Seeber, María Sornosa Martínez, Antonios Trakatellis, Evangelia Tzampazi, Thomas Ulmer, Marcello Vernola, Anja Weisgerber, Åsa Westlund, Anders Wijkman, Glenis Willmott
Substitute(s) present for the final vote	Inés Ayala Sender, Iles Braghetto, Kathalijne Maria Buitenweg, Genowefa Grabowska, Jutta Haug, Erna Hennicot-Schoepges, Johannes Lebech, Jiří Maštálka, Alojz Peterle, Lambert van Nistelrooij