Basic information

2007/0102(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Directive	Procedure completed
Stockfarming: prohibition of certain substances having a hormonal or thyreostatic action and of beta-agonists Amending Directive 96/22/EC 1993/1036(CNS) **Subject** 3.10.08 Animal health requirements, veterinary legislation and pharmacy 4.60.04.04 Food safety	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	SCHEELE Karin (PSE)	10/09/2007

Committee for opinion	Rapporteur for opinion	Appointed
AGRI Agriculture and Rural Development	FREITAS Duarte (PPE-DE)	04/07/2007

Council of the European Union

Council configuration	Meetings	Date
Agriculture and Fisheries	2841	2007-12-17
Environment	2898	2008-10-20

European Commission

Commission DG	Commissioner
Health and Food Safety	VASSILIOU Androulla

Key events

Date	Event	Reference	Summary
04/06/2007	Legislative proposal published	COM(2007)0292	Summary
07/06/2007	Committee referral announced in Parliament, 1st reading		
17/12/2007	Debate in Council		Summary
26/02/2008	Vote in committee, 1st reading		Summary

06/03/2008	Committee report tabled for plenary, 1st reading	A6-0067/2008	
05/06/2008	Decision by Parliament, 1st reading	T6-0251/2008	Summary
05/06/2008	Results of vote in Parliament		
20/10/2008	Act adopted by Council after Parliament's 1st reading		
19/11/2008	Final act signed		
19/11/2008	End of procedure in Parliament		
28/11/2008	Final act published in Official Journal		

Technical information

Procedure reference	2007/0102(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
Amendments and repeals	Amending Directive 96/22/EC 1993/1036(CNS)
Legal basis	EC Treaty (after Amsterdam) EC 152-p4b
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/6/50175

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee opinion	AGRI	PE392.346	18/12/2007	
Committee draft report		PE400.330	09/01/2008	
Amendments tabled in committee		PE400.625	01/02/2008	
Committee report tabled for plenary, 1st reading/single reading		A6-0067/2008	06/03/2008	
Text adopted by Parliament, 1st reading/single reading		T6-0251/2008	05/06/2008	Summary

Council of the EU

Document type	Reference	Date	Summary
Draft final act	03667/2008/LEX	19/11/2008	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2007)0292	04/06/2007	Summary

Document attached to the procedure	SEC(2007)0733	04/06/2007	
Commission response to text adopted in plenary	SP(2008)4439	16/07/2008	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES1253/2007	26/09/2007	

Additional information

Source	Document	Date
National parliaments	IPEX	
European Commission	EUR-Lex	

Final act

Directive 2008/0097
OJ L 318 28.11.2008, p. 0009 Summary

Stockfarming: prohibition of certain substances having a hormonal or thyreostatic action and of beta-agonists

2007/0102(COD) - 05/06/2008 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted, by 692 votes to 2 with 11 abstentions, a legislative resolution making some amendments to 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. The report had been tabled for consideration in plenary by Karin **SCHEELE** (PES, AT) on behalf of the Committee on the Environment, Public Health and Food Safety.

The main amendments – adopted under the 1st reading of the codecsion procedure – are as follows:

-the definition of 'therapeutic treatment' has been amended;

-Member States should be allowed to authorise the use of beta-agonists to treat respiratory problems, navicular disease and laminitis in horse raised for purposes other than meat production since alternatives are limited;

-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;

-Annex II is amended to clarify that beta-agonist, although prohibited in general, may be used in certain specific cases;

-lastly, transposition of the Directive should be by 1 January 2009 (rather than 1 July 2007).

Stockfarming: prohibition of certain substances having a hormonal or thyreostatic action and of beta-agonists

2007/0102(COD) - 17/12/2007

The Council reached a general approach on a proposal for a 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.

The agreed text will serve as a basis for informal trilogue discussions with the European Parliament in view of a first reading agreement.

The proposal is aimed at taking pet animals out of the scope of the legislation and prohibiting the use of oestradiol 17ß in food producing animals entirely. In addition, the definition of therapeutic treatment was adjusted, in particular with regard to the use of beta-agonists.

Stockfarming: prohibition of certain substances having a hormonal or thyreostatic action and of beta-agonists

2007/0102(COD) - 04/06/2007 - Legislative proposal

PURPOSE: to amend Council Directive 96/22/EC concerning the prohibition on the use in stock farming of certain substances having a hormonal or thyreostatic action and of beta-agonists.

PROPOSED ACT: Directive of the European Parliament and of the Council.

CONTENT: this proposal aims to:

- take pet animals out of the scope of the legislation;
- prohibit the use of oestradiol 17ß in food producing animals entirely.

Article 2 (a) of Council Directive 96/22/EC specifically prohibits the placing on the market of substances listed in Annex II for administering to animals of "all species". The motive behind the prohibition of substances for all species is that misuse would be more difficult if no product authorised for whatever species were on the market.

Several Member States and the veterinary pharmaceutical industry complained to the Commission services that marketing authorisations cannot be granted for products containing substances to treat hyperthyroidism in pet animals due to the restrictions of Directive 96/22/EC. They appealed to the Commission to mitigate the situation.

As regards Oestradiol 17ß and its ester like derivates, it appears that the use of the alternative substances such as prostaglandins is already common. Veterinarians predict an insignificant impact of future unavailability of oestradiol 17ß and its ester like derivates on farmers and on animal welfare. It is also observed that the unavailability of oestradiol and its ester like derivates would have minimal economic effect. This is because the incidence of fetal mummification and fetal maceration is low, and although the incidence of pyometra is higher, methods of prevention not involving use of oestradiol do exist and would be preferable.

Member States and the veterinary pharmaceutical industry provided their opinion on thyrostatic substances. The Member States have also confirmed in a Council meeting on 11 October 2005 in July 2006 that if oestradiol 17ß and its ester like derivates were to be prohibited for food producing animals, the substance should remain available for pet animals.

Stockfarming: prohibition of certain substances having a hormonal or thyreostatic action and of beta-agonists

2007/0102(COD) - 19/11/2008 - Final act

PURPOSE: to amend current legislation on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists.

LEGISLATIVE ACT: Directive 2008/97/EC 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 thyrostatic action and of beta-agonists.

CONTENT: having reached agreement with the European Parliament at first reading, the Directive definitively prohibits the administration of oestradiol 17 B to any animal in order to guarantee the highest level of health protection and authorises the use of stilbenes, stilbene derivatives, their salts and esters or of thyrostatic substances for pet animals on animal welfare grounds. Member States shall be allowed to authorise the use of beta-agonists to treat horses raised for purposes other than meat production, provided they are used in accordance with the manufacturer’s instructions.

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 the Directive.

ENTRY INTO FORCE: 18/12/2008.

TRANSPOSITION: 01/01/2009.