

# Procedure file

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

| Key players                   |  |                                       |            |
|-------------------------------|--|---------------------------------------|------------|
| European Parliament           | Committee responsible                                  | Rapporteur                            | Appointed  |
|                               | <b>ENVI</b> Environment, Public Health and Food Safety |                                       | 10/09/2007 |
|                               |  | PSE <a href="#">SCHEELE Karin</a>     |            |
|                               | Committee for opinion                                  | Rapporteur for opinion                | Appointed  |
|                               | <b>AGRI</b> Agriculture and Rural Development          |                                       | 04/07/2007 |
|                               |  | PPE-DE <a href="#">FREITAS Duarte</a> |            |
| Council of the European Union | Council configuration                                  | Meeting                               | Date       |
|                               | <a href="#">Environment</a>                            | <a href="#">2898</a>                  | 20/10/2008 |
|                               | <a href="#">Agriculture and Fisheries</a>              | <a href="#">2841</a>                  | 17/12/2007 |
| European Commission           | Commission DG  | Commissioner                          |            |
|                               | <a href="#">Health and Food Safety</a>                 | VASSILIOU Androulla                   |            |

| Key events |   |   |         |
|------------|---|---|---------|
| 04/06/2007 | Legislative proposal published                          | <a href="#">COM(2007)0292</a>   | Summary |
| 07/06/2007 | Committee referral announced in Parliament, 1st reading |   |         |
| 17/12/2007 | Debate in Council                                       | <a href="#">2841</a>  | Summary |
| 26/02/2008 | Vote in committee, 1st reading                          |   | Summary |
| 06/03/2008 | Committee report tabled for plenary, 1st reading        | <a href="#">A6-0067/2008</a>  |         |
| 05/06/2008 | Results of vote in Parliament                           |  |         |
| 05/06/2008 | Decision by Parliament, 1st reading                     | <a href="#">T6-0251/2008</a>  | Summary |
| 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  |
|                            | Amending Directive 96/22/EC <a href="#">1993/1036(CNS)</a>     |
| Legal basis                | EC Treaty (after Amsterdam) EC 152-p4b                         |
| Stage reached in procedure | Procedure completed  |
| Committee dossier          | ENVI/6/50175   |

### Documentation gateway

|   |      |                                |            |     |         |
|---|------|--------------------------------|------------|-----|---------|
| Legislative proposal  |      | <a href="#">COM(2007)0292</a>  | 04/06/2007 | EC  | Summary |
| Document attached to the procedure                              |      | <a href="#">SEC(2007)0733</a>  | 04/06/2007 | EC  |         |
| Economic and Social Committee: opinion, report                  |      | <a href="#">CES1253/2007</a>   | 26/09/2007 | ESC |         |
| Committee opinion   | AGRI | <a href="#">PE392.346</a>      | 18/12/2007 | EP  |         |
| Committee draft report  |      | <a href="#">PE400.330</a>      | 09/01/2008 | EP  |         |
| Amendments tabled in committee                                  |      | <a href="#">PE400.625</a>      | 01/02/2008 | EP  |         |
| Committee report tabled for plenary, 1st reading/single reading |      | <a href="#">A6-0067/2008</a>   | 06/03/2008 | EP  |         |
| Text adopted by Parliament, 1st reading/single reading          |      | <a href="#">T6-0251/2008</a>   | 05/06/2008 | EP  | Summary |
| Commission response to text adopted in plenary                  |      | <a href="#">SP(2008)4439</a>   | 16/07/2008 | EC  |         |
| Draft final act   |      | <a href="#">03667/2008/LEX</a> | 19/11/2008 | CSL |         |

### Additional information

|                      |                         |
|----------------------|-------------------------|
| National parliaments | <a href="#">IPEX</a>    |
| European Commission  | <a href="#">EUR-Lex</a> |

### Final act

[Directive 2008/97](#)  
[OJ L 318 28.11.2008, p. 0009](#) Summary

## beta-agonists

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**PURPOSE:** to amend Council Directive 96/22/EC concerning the prohibition on the use in stock farming of certain substances having a hormonal or thyrostatic 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 17 $\beta$  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 17 $\beta$  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 17 $\beta$  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 17 $\beta$  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 thyrostatic action and of beta-agonists

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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 17 $\beta$  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 thyrostatic action and of beta-agonists

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The Committee on the Environment, Public Health and Food Safety adopted a report drafted by Karin SCHEELE (PES, AT), and amended, in the first reading of the codecision procedure, 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 thyrostatic action and of beta-agonists.

The main amendments 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  $\beta$  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;
- 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 the 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;
- 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 July 2008 (rather than 1 July 2007).

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

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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 codecision 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  $\beta$  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

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**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 17? 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.