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COMMISSION STAFF WORKING DOCUMENT

Accompanying document 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**

IMPACT ASSESSMENT

**The impact of the proposal on business with special reference to small and medium-
sized enterprises (SMEs)**

{COM(2007)292 final}

IMPACT ASSESSMENT

The impact of the proposal on business with special reference to small and medium-sized enterprises (SMEs)

1. TITLE OF PROPOSAL

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

2. DOCUMENT REFERENCE NUMBER

SANCO/2006/3368

3. THE PROPOSAL

The proposal intends to:

1. Take pet animals out of the scope of the legislation.
2. Prohibit the use of oestradiol 17 β in food producing animals entirely.
3. Simplification of legislation.

4. PROBLEM DEFINITION

As regards pet animals, Council Directive 96/22/EC, Article 2 (a) specifically prohibits the placing on the market of substances listed in Annex II A for administering to animals of "all species". The rationale 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. Comparison of the prices and presentations of products substances with e.g. thyreostatic action intended for use in pet animals, however, shows that is economically unattractive to use pet products e.g. in cattle. Moreover, reports of the Member States related to the implementation of the national residue plans to be established according to Directive 96/23/EC¹ show that illegal use can rather be linked to illegal production or import of substances.

Moreover, as regards thyreostatic substances, it is necessary to revoke this prohibition in particular in order to avoid unnecessary suffering of dogs and cats due to hyperthyroidism which cannot be treated without the changes to legislation proposed because the necessary veterinary medicinal product may not be authorized in the Community.

¹ OJ C 125, 23.5.1996, p. 10.

As regards oestradiol 17 β , the risk assessment of oestradiol 17 β by the Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) of 1999 on the potential adverse effects to human health from hormone residues in bovine meat and meat products (which has been reviewed and confirmed in 2000 and 2002) concluded that there is a substantial body of recent evidence suggesting 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 do not make it possible to give a quantitative estimate of the risk.

Council Directive 2003/74/EC amended Council Directive 96/22/EC to reduce the circumstances under which oestradiol 17 β may be administered for purposes other than growth promotion. Only three uses remained permissible on a transitional basis and under strict veterinary control: treatment of foetus maceration/mummification, pyometra in cattle (for animal welfare reasons) and oestrus induction in cattle, horses, sheep and goats (Article 5a). The latter use has to be phased out by until 14 October 2006 and for the rest of the uses the Commission was to present a report in October 2005.

Article 11 a of Council Directive 96/22/EC as amended by Council Directive 2003/74/EC requires the presentation of a report on the necessity of the use of the hormone oestradiol 17 β in food animal production. A *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 prepared* (later addressed as the Report) by an independent scientist has been presented by the Commission in October 2006². The Report concludes that oestradiol 17 β is not essential in food animal production.

Simplification and improvement of consistency are key to promotion of Better Regulation for Growth and Jobs in the European Union³ which is one of the main overarching objectives of the Commission.

5. POLICY OBJECTIVES

The general objective is to maintain a high level of consumer protection by prohibiting the use of certain substances in food producing animals.

At the same time the following specific objectives have to be considered:

- To ensure health and welfare of animals by making veterinary medicinal products available.
- Consistency with the other Community policies such as subsidiarity and proportionality.
- The intention to simplify and to improve the readability of Community legislation.

² SEC(2005)1303 of 11.10.2005.

³ COM(2005) 97 and COM(2005) 535 final.

6. POLICY OPTIONS AND IMPLICATIONS

In order to address these issues in this proposal, the following options have been identified:

1. Not to propose any changes to the current legislation.

This would mean ignoring the needs of animal welfare and the advice provided by the Scientific Committee on Veterinary Measures relating to Public Health (concluding that there is a substantial body of recent evidence suggesting that oestradiol 17 β has to be considered as a complete carcinogen) as well as the advice provided by the expert report on the necessity of the use of oestradiol 17 β in animal production.

2. Revoke and replace the existing Directive by another instrument and merging it with Regulation (EEC) No 2377/90 which also contains restriction of use of substances having a hormonal or thyrostatic action and of beta-agonists with the objective of simplification.

This solution has been intensively considered. The idea of merging Directive 96/22/EC with Regulation (EEC) No 2377/90 has been rejected for legal as well as procedural and organisational reasons. The option to revoke and replace Directive 96/22/EC by another instrument seems, considering the limited changes proposed, disproportionate and unnecessary.

3. Prohibit oestradiol 17 β completely by deleting Article 5a and to introduce an exemption for the use of thyrostatic substances in pet animals in Article 2. This solution would add undue complexity and thus defies the call for more simple legislation. It also does not take into account the reports from Member States concerning the sources of illegal use.

4. Prohibit oestradiol 17 β completely but limit the scope of the legislations to food producing animals.

This solution would best address the three objectives: complete prohibition of oestradiol 17 β for use in food producing animals, ensuring the availability of treatments for pet animals and the general call for a more simple legislation under the precondition that the existing legal framework is maintained.

As stated above, comparison of the prices and presentations of products substances with e.g. thyreostatic action intended for use in pet animals shows that is economically unattractive to use pet products e.g. in cattle. Moreover, reports of the Member States related to the implementation of the national residue plans to be established according to Directive 96/23/EC⁴ show that illegal use can rather be linked to illegal production or import of substances. This is emphasised by the growing importance of the Internet and the increasing international trade. The same reports show that no illegal uses of stilbenes, stilbene derivates, their salts and esters could be discovered in more than five years past.

⁴ OJ C 125, 23.5.1996, p. 10.

Comparison of the prices and presentations of products substances with thyrostatic action intended for use in dogs and cats, shows that it is economically unattractive to use dog and cat products in cattle for meat production. For example, the administration of the active substance methimazole at 600 mg/day to cattle for 35 to 56 days, results according to a study by Burroughs and others⁵ in 0.181 kg live-weight gain per animal per day compared to control animals. If methimazole was given via the 5 mg pet tablets, a farmer would require 120 tablets/head/day. If the net purchase price would be around a realistic € 0.25 per tablet, this would equate € 30 /head/day. Over 56 days, would amount to € 1680 per head. The resulting weight gain of only 10.1 kg would cost the farmer approximately € 166 per kg live-weight. If the current price for a cattle carcass is € 400 per 100 kg or € 4 per kg, 10.1 kg would equal € 40.40 and thus equal approximately one fortieth of the investment in the medical treatment.

Option 4 would allow the authorisation of veterinary medicinal products containing of stilbenes, stilbene derivates, their salts and esters. There is currently no demand for the authorisation of these products. New authorisations would, however, have to consider potential misuse. Presentations that are likely to be misused can therefore be rejected as not designed for use in pet animals only.

The subject of the proposal falls under the exclusive competence of the Community since 1981. There is a long standing consensus that the subject is to be regulated at Community level. The subsidiarity principle therefore does not apply.

7. THE IMPACT ON BUSINESS

Animal owners, practicing veterinarians, the veterinary pharmaceutical industry and Member States competent authorities for authorisation of veterinary medicinal products will be affected by this proposal.

As concerns thyrostatic substances this proposal allows the pharmaceutical industry to successfully apply for the authorisation of products containing thyrostatic substances for use in pet animals. It also keeps products containing oestradiol 17 β intended for pet animals on the market. Products for pet animals are a growing market because the numbers of pet animals kept is raising and the animals are kept until old age. Hyperthyroidism is more frequent in old animals.

Thus legislation allowing the authorisation of veterinary medicinal products for pet animals will have positive effect for their owners, practicing veterinarians and the veterinary pharmaceutical industry.

As regards oestradiol 17 β , the Report (page 5) concludes that "*non-availability of oestradiol would have minimal effect on farm/industry economics, farmer decisions,*

⁵ Burroughs, W. Raun, A. Trenkle, A. Raun, N. (1960) Further observations upon the effects of methimazole upon feedlot performance and carcass characteristics of fattening beef cattle *Journal of Animal Science* 19:465-9.

and animal welfare". The withdrawal of products containing oestradiol 17 β will consequently have no or only a negligible negative effect on farmers, practicing veterinarians and the veterinary pharmaceutical industry. This should not imply higher treatment prices. Some veterinarians and farmers will have to accustom themselves to new products for the treatment of reproductive disorders. Member States competent authorities for authorisation of veterinary medicinal products will have to inform the few pharmaceutical companies that have marketing authorisations for veterinary medicinal products containing oestradiol 17 β that those respective marketing authorisation are to be withdrawn. This falls under their routine activities.

The changes proposed will contribute to achieving a high level of human health protection.

Considering the above, it is unlikely that the proposal will have measurable effects on employment, on investment and the creation of new businesses or on the competitiveness of businesses. If at all measurable the effect will most likely be positive due to the increased business with pet animals. Accordingly the proposal does not have to contain measures to take account of the specific situation of small and medium-sized firms.

The proposal has no particular geographical focus nor has it a particular effect for small industries.

8. CONSULTATION

The Report is based on the consultation of:

- evidence from the scientific literature,
- input provided by Regulatory Authorities,
- a survey completed by over 80 practising veterinarians,
- information from specialist veterinarians and
- the author's (Prof Hilary Dobson of the University of Liverpool) experience.

Council discussions of the Report in July 2006⁶ had the following outcome: Member States thanked the Commission services for its comprehensive and well presented report. Concerning the impact of non availability of oestradiol 17 β on "the food chain animal industry" the conclusion that the non availability of oestradiol-17 β would have minimal economic effects with regard to animal species entering the food chain was shared by a wide majority of delegations⁷. However, Member States asked the Commission to ensure the availability of oestradiol 17 β and thyrostatic substances for animals not intended to enter the food chain.

⁶ Council Document 11303/06 AGRILEG 122 of 05/07/2006.

⁷ MT, NL and P delegations were not represented and E delegation had a scrutiny reservation.

9. SUMMARY:

The proposal intends to:

1. Take pet animals out of the scope of the legislation.
2. Prohibit the use of oestradiol 17 β in food producing animals entirely.
3. Simplification of legislation.

The policy options considered in the impact assessment are:

1. Not to propose any changes to the current legislation.
2. Revoke and replace the existing Directive by another instrument and merging it with Regulation (EEC) No 2377/90 which also contains restriction of use of substances having a hormonal or thyrostatic action and of beta-agonists with the objective of simplification.
3. Prohibit oestradiol 17 β completely by deleting Article 5a and to introduce an exemption for the use of thyrostatic substances in pet animals in Article 2. This solution would add undue complexity and thus defies the call for more simple legislation. It also does not take into account the reports from Member States concerning the sources of illegal use.
4. Prohibit oestradiol 17 β completely but limit the scope of the legislations to food producing animals.

After the assessment of the option it is concluded that option 4 addresses the three specific objectives prohibition of oestradiol 17 β , availability of treatments for pet animals and the general call for a more simple legislation best. It continues to contribute to the achievement of a high level of human health protection.