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COMMISSION OF THE EUROPEAN COMMUNITIES

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2007/0064 (COD)

**COMMUNICATION FROM THE COMMISSION
TO THE EUROPEAN PARLIAMENT**

pursuant to the second subparagraph of Article 251 (2) of the EC Treaty

concerning the

common position of the Council on the adoption of a proposal for a Regulation of the European Parliament and of the Council laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, and repealing Regulation (EEC) No 2377/90

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1. BACKGROUND

Date of transmission of the proposal to the EP and the Council 17 April 2007
(document COM(2007)194 final – 2007/0064 (COD):

Date of the opinion of the European Economic and Social Committee: 26 September 2007

Date of the opinion of the European Parliament, first reading: 17 June 2008

Scheduled date of adoption of the common position: 18 December 2008

2. OBJECTIVE OF THE COMMISSION PROPOSAL

The proposal's aim is to continue to limit consumer exposure to pharmacologically active substances intended to be used in veterinary medicinal products for food producing animals and residues thereof in foodstuffs of animal origin through Community procedures. Nevertheless the proposal should ensure maintenance of a high level of consumer health protection while not compromising availability of veterinary medicinal products in the Community. At the same time, the proposal should contribute to simplification of legislation by improving the readability and clarity of the Regulation in line with the better regulation strategy of the Commission.

The Commission proposal has four key objectives:

1. To improve availability of veterinary medicinal products for food producing animals in order to ensure animal health and welfare and avoid illegal use of substances;
2. To simplify the existing legislation by enhancing readability of the provisions on established Maximum Residue Limits (MRLs) for the end-users (i.e. animal health professionals, control competent authorities in Member States and third countries);
3. To provide clear references for the control of residues of pharmacologically active substances in foodstuffs to improve consumer health protection and the functioning of the Single Market;
4. To clarify the Community procedures establishing MRLs by ensuring consistency with international standards.

3. COMMENTS ON THE COMMON POSITION

3.1 Overall remarks on the common position

The political agreement found by the European Parliament, the Council and the Commission in Trilogue discussions was endorsed by COREPER in its meeting on 29 October 2008. The adoption of the Common Position is scheduled for 18/19 December 2008. It addresses both amendments and modification proposals in a satisfactory way and in the spirit of the initial proposal. A number of changes to the proposal improve the text while maintaining its initial objectives. Amendments and modification proposals often relate to the same provisions of the proposal. Several amendments and modifications constitute editorial improvements. Modifications proposed by the Council have led to a slight restructuring and renumbering.

Key amendments proposed by the European Parliament in the first reading relating to:

- the availability of veterinary medicinal products,
- the provisions on reference points for action, such as the inclusion of control measures, the clarification relating to the residue levels triggering sanctions by competent authorities and equal treatment of Third country imports and intra-Community trade,
- the clarification of the conditions under which a further scientific assessment by the EMEA is not required when an MRL has been set in the framework of Codex Alimentarius Commission of FAO/WHO,

are addressed in the political agreement. In order to respond to specific availability related amendments, two minor changes to Directive 2001/82/EC on the Community code relating to veterinary medicinal products are included. Furthermore, the Commission has agreed to a Declaration on an assessment of options for a future review of Directive 2001/82/EC.

Amendments aiming at the introduction of the regulatory procedure with scrutiny (PRAC) are not present in the political agreement with the exception of PRAC for the adoption of methodological principles for risk assessment and risk management recommendations.

3.2 European Parliament amendments included in full, in part or in principle in the amended proposal and incorporated in full, in part or in principle in the common position

The following amendments are included in the political agreement either fully, partly or in principle:

2 on the future review of the veterinary pharmaceutical legislation, 3, 4, 6 and 45 on the aim of the regulation, 5 on food control, 8 on reference points for action, 9 and 10 on the subject matter and scope of the regulation, 11, 14, 15 and 16 on the contents of the EMEA opinion in the establishment of an MRL, 17 and 18 on the availability of veterinary medicinal products for horses, 20, 31 and 34 on an accelerated procedure for the establishment of MRLs, 21 on the possibility for the Commission, Member States or an interested party or organisation to request an EMEA opinion on an MRL, 23 on the review of an opinion, 24, 25 and 26 on the implementing measures, 28 and 32 on transparency when accepting MRL set in the framework of Codex Alimentarius, 35 on the analytical methods, 37 and 40 on the methods for establishing reference points for action, 38 on the establishment and review of reference points for action, 39 and 41 on the placing of the market of foodstuffs containing residues of a pharmacologically active substance, 42 on action to be taken in the case of confirmed presence of a prohibited or non-authorised substance, 44 on a report to the European Parliament and the Council.

3.3 European Parliament amendments not included in the amended proposal and not incorporated in the common position

1 on the legal base of the regulation, 25 on the implementing measures as regards to the proposed change to the Standing Committee on the Food Chain and Animal Health, 27 on the classification of pharmacologically active substances, 30 on the prohibition of the administration of a substance to food-producing animals, 33 on the proposed change to PRAC when fixing individual MRLs, 36 on the circulation of foodstuff.

3.4 Changes to the original proposal introduced by the Commission in the amended proposal and incorporated in the common position

There was no amended proposal.

3.5 Other modifications introduced by the Council common position compared with the original proposal

In general terms, some modifications to the initial proposal have led to a restructuring of the initial text; thus, Article 15 dealing with analytical methods has been included in Title IV. Furthermore, modifications related to Titles III and IV of the initial proposal have led in parts to a renumbering of these Titles without, however, bringing change to the key elements included in the initial text.

The following specific modifications have been introduced:

Recital 19 is amended to clarify the inclusion of biocidal products used in animal husbandry into the proposal. Furthermore, it is stated that Regulation (EC) No 726/2004 shall be amended to include the advising on MRLs of residues of active substances in biocidal products within the tasks of the EMEA.

A new Recital 19a on the financing modalities of the evaluation related to the establishment of the maximum residue limit for pharmacologically active substances to be used in biocidal products used in animal husbandry is added.

New Recitals 21a, 21b and 22a are added in order to take account of the inclusion of food control management measures in the proposal.

Recital 25 is amended to clarify the conferment of powers to the Commission.

A new Recital 25a is introduced to take account of the inclusion of an urgency procedure in the framework of the comitology procedure for the establishment of reference points for action.

Recital 28 is amended to clarify the incorporation of pharmacologically active substances and their classification regarding MRLs as laid down in the annexes of the current MRL-regulation.

Article 1 paragraph 3 is modified to include a complete reference to Directive 96/22/EC.

In Article 2 (b) the word "specifically" is deleted.

The title of Section 1 in Title II of the initial proposal is amended for reasons of clarity.

The wording of Article 3 is amended for reasons of clarity.

The wording of Article 5 is amended to include a reference to human health protection in the extrapolation process.

For reasons of clarity of the wording, Article 7 point (c) is modified by deleting the passage "..., residues of which have been found in a particular foodstuff of animal origin,..". .

Article 7 point (d) is modified to clarify the situation where no MRL shall be recommended.

The title of Section 2 in Title II of the initial proposal is amended for reasons of clarity.

Article 9 paragraphs 2 and 3 are amended to include Member States and interested parties and organisation as possible requestors for an MRL in the framework of Article 9.

In line with Recital 19 and 19a, a new Article 9a is introduced to clarify the proposal's intention to include biocidal products used in animal husbandry in the proposal. The Commission agrees to this clarification. At the same time the financing modalities of the evaluation of this category of products are laid down.

In Article 10 a new second paragraph relating to the extension of existing MRLs is introduced.

Article 13 paragraph 2 is modified insofar as the classification of pharmacologically active substances shall also mention specific foodstuffs/ species where appropriate.

A slight rewording of Article 13 paragraph 2, point (c) is undertaken for reasons of clarity.

A new Article 13b is introduced, relating to the administration of substances to food producing animals, thus, taking up the contents of Article 14(1) of the current MRL-regulation.

The wording of Article 14 paragraph 1, subparagraph 2 is slightly amended.

The wording of Article 17 paragraph 1, renumbered as Article 15 paragraph 1 in the political agreement, is slightly amended.

The urgency procedure in the framework of the comitology procedure for the establishment of reference points for action has been added to Article 17, renumbered as Article 15 in the political agreement.

Article 18 paragraphs 1 and 2, renumbered as Article 16 paragraphs 1 and 2 in the political agreement have been modified to clarify the procedure for the establishment of the reference points for action.

A new paragraph 4 is added to Article 21, thus, aligning this provision with the introduction of the urgency procedure in the framework of the comitology procedure for the establishment of reference points for action.

A new paragraph 2 is added to Article 22 in order to introduce the possibility for an extrapolation for substances already classified under the current MRL-regulation.

A new Article 23a is added in line with Recital 19, foreseeing an amendment to Regulation (EC) No 726/2004 in order to include the advising on MRLs of residues of active substances in biocidal products within the tasks of the EMEA.

4. CONCLUSION

The Commission fully supports the common position.

5. DECLARATION BY THE COMMISSION

As regards a future revision of Directive 2001/82/EC on the Community code relating to veterinary medicinal products, the Commission proposed to make a declaration, thus, allowing addressing EP amendment 2 proposing a new Recital 1a.

The wording of the proposed Commission Declaration is as follows:

“The Commission is aware of concerns expressed by citizens, veterinarians, Member States and the animal health industry as regards the directive laying down the rules for the authorization of veterinary medicinal products, in particular the importance of addressing existing problems linked to the availability of veterinary medicines and the use of medicinal products in species for which they are not authorized and any disproportionate regulatory burden hampering innovation, whilst ensuring a high level of consumer safety with respect to food of animal origin. The Commission points out that positive steps are being taken in this direction such as the simplification of the rules on variations of veterinary medicinal products and this review of the legislation on maximum residue limits in food.

In addition, in order to address the objectives of consumer safety and animal health protection, competitiveness of the veterinary industry including SMEs and reduction of administrative burden, the Commission will present in 2010 an assessment of the problems in the application of the veterinary medicinal products directive with a view to making, where appropriate, legal proposals.”