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A6-0048/2009

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***II
RECOMMENDATION FOR SECOND READING

on the Council common position for adopting 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, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council
(15079/2/2008 – C6-0005/2009 – 2007/0064(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Avril Doyle

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*.** In the case of amending acts, passages in an existing provision that the Commission has left unchanged, but that Parliament wishes to amend, are highlighted in **bold**. Any deletions that Parliament wishes to make in passages of this kind are indicated thus: [...]. 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). Suggested corrections of this kind are subject to the agreement of the departments concerned.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the Council common position for adopting 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, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council
(15079/2/2008 – C6-0005/2009 – 2007/0064(COD))

(Codecision procedure: second reading)

The European Parliament,

– having regard to the Council common position (15079/2/2008 – C6-0005/2009),

– having regard to its position at first reading[1] on the Commission proposal to Parliament and the Council (COM(2007)0194),

– having regard to Article 251(2) of the EC Treaty,

– having regard to Rule 67 of its Rules of Procedure,

– having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Food Safety (A6-0048/2009),

1. Approves the common position;

2. Notes that the act is adopted in accordance with the common position;

3. Instructs its President to sign the act with the President of the Council pursuant to Article 254(1) of the EC Treaty;

4. Instructs its Secretary-General to sign the act, once it has been verified that all the procedures have been duly completed, and, in agreement with the Secretary-General of the Council, to have it published in the Official Journal of the European Union;

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

[1] Texts adopted, 17.6.2008, P6_TA(2008)0285.

EXPLANATORY STATEMENT

Aim

The aim of the Commission proposal is to limit the exposure of consumers to pharmacologically active substances intended for use in veterinary medicinal products for food producing animals as well as residues thereof in foodstuffs of animal origin. This includes foodstuffs imported from third countries .The intention of new legislation was not to compromise but rather to enhance the availability of veterinary medicinal products in the EU which continues to be a problem for many veterinary practitioners. Finally, and in accordance with the principles of better regulation, the readability and clarity of the existing legislation should be improved.

Procedure

Whereas the European Parliament was able to reach a consensus with relative ease and speed based upon the report adopted in the Environment Committee, Council required considerable internal deliberation under the Portuguese and Slovene Presidencies and was only able to conclude its Common Position under the French Presidency in the second half of 2008.

This was the result of a series of informal trilogues with the Council and the Commission which were concluded in October 2008. The Common Position text approved on the 18 December 2008 by the Council, and announced in the European Parliament on 15 January 2009, fully reflects the compromise achieved through negotiation between the three institutions.

This codecision file can therefore be concluded as an early second reading agreement by a vote on the compromise package, as agreed in the informal trilogue and reflected in the Common Position text, in the Environment Committee and subsequently the Plenary.

Key issues

The key points addressed in the new text are as follows:

- **reference points for action**: this is now defined as the level of a residue of a pharmacologically active substance, established for control reasons in the case of certain substances for which a maximum residue limit has not been laid down in accordance with this Regulation. In addition, Parliament introduced a new Article on implementing reference points for action. The reference points for action shall be reviewed in the light of any new data concerning the protection of human health and the food chain;

- European Food Safety Authority: the risk management recommendations should take into account any relevant scientific findings of the European Food Safety Authority, by way of letters of cooperation;

- scientific risk assessment: the principles of risk assessment pursuant to Articles 4 to 8 shall be applied in order to guarantee a high level of health protection;

- toxicological, as well as pharmacological or microbiological effects in human beings should be considered;

- equidae: a new clause states that veterinary medicinal products which do not have a maximum residue limit for equidae, which are not included in Annex IV of Regulation (EEC) No 2377/90 or in Article 13(2) of this Regulation, and which are used "off-label", as defined in Article 1(16) of Directive 2001/82/EC, and "under the provisions of the cascade" and not administered intra-muscularly or subcutaneously, shall have a nominal withdrawal period of six months. Furthermore, the use of pharmaceuticals containing pharmacologically active ingredients not on "the essential" substances list or the "positive list" for equidae referred to in Article 10(3) of Directive 2001/82/EC and not administered intra-muscularly or subcutaneously, shall have a nominal withdrawal period of six months if deemed of clinical benefit.

- urgent authorisation: in specific cases where urgent authorisation is required to ensure the protection of human health and animal health and welfare, the Commission may, in accordance with the regulatory procedure with scrutiny, establish a provisional maximum residue limit for a period not exceeding five years;

- requests for an opinion on maximum residue limits: the proposal had stated that the Commission or Member States may forward to the Agency requests for an opinion for substances not intended for use in veterinary medicinal products to be placed on the market in the Community and where no application for such substances has been made. Parliament introduced wording which states that the Commission, Member States or a third party pursuing legitimate interests may forward to the Agency requests for an opinion on MRLs for pharmacologically active substances in certain circumstances which are prescribed in the text;

- comitology: defining the methodology of the risk assessment and of risk management will be done in accordance with the regulatory procedure with scrutiny. Moreover, Parliament altered the time limits for the adoption of decisions;

- accelerated procedure for an Agency opinion: a new clause states that, in specific cases where a veterinary medicinal product or a biocidal product needs to be authorised as a matter of urgency for reasons relating to the protection of public health or of animal health or welfare, the Commission, any person who has requested an opinion, or a Member State may ask the Agency to carry out an accelerated procedure for the assessment of the maximum residue limit of a pharmacologically active substance contained in those products. The Agency shall ensure that the Committee is able to issue its opinion within 150 days following receipt of the application;

- placing on the market: a new Article states that if the maximum residue limits or reference quantities established under this Regulation are exceeded, the product shall not be placed on the market as a foodstuff, transformed into foodstuffs or mixed with foodstuffs.

  Foodstuffs of animal origin containing pharmacologically active substances for which no maximum residue limits have been set may not be placed on the market;

- import: Member States shall prohibit the import and placing on the market of food of animal origin containing residues resulting from the illegal administration of

pharmacologically active substances which are not subject to a classification in accordance with the text. Accordingly, imports from third countries of food containing residues resulting from the illegal administration of substances whose use is use is banned within the European Union shall be prohibited in the interests of public health;

- report: the Commission shall, not later than five years after the entry into force of the Regulation, submit a report which will, in particular, review the experience gained from the application of the Regulation, and, if appropriate, be accompanied by proposals.

Rapporteur's recommendation

The rapporteur, Avril Doyle (EPP-ED, IE), recommends the adoption *en bloc* of the Common Position by the Environment Committee and the Plenary without modification or amendment as it reflects in its entirety the agreement reached with Council and the Commission.

PROCEDURE

Title	Establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin
References	15079/2/2008 – C6-0005/2009 – 2007/0064(COD)
Date of Parliament's first reading – P number	17.6.2008 T6-0285/2008
Commission proposal	COM(2007)0194 - C6-0113/2007
Date receipt of common position announced in plenary	15.1.2009
Committee responsible Date announced in plenary	ENVI 15.1.2009
Rapporteur(s) Date appointed	Avril Doyle 12.6.2007
Date adopted	10.2.2009
Result of final vote	+: 37 –: 4 0: 1
Members present for the final vote	Adamos Adamou, Georgs Andrejevs, Pilar Ayuso, Irena Belohorská, Maria Berger, Johannes Blokland, John Bowis, Martin Callanan, Magor Imre Csibi, Avril Doyle, Mojca Drčar Murko, Elisabetta Gardini, Matthias Groote, Françoise Grossetête, Satu Hassi, Gyula Hegyi, Marie Anne Isler Béguin, Holger Krahmer, Urszula Krupa, Linda McAvan, Péter Olajos, Miroslav Ouzký, Vladko Todorov Panayotov, Vittorio Prodi, Frédérique Ries, Dagmar Roth-Behrendt, Guido Sacconi, Amalia Sartori, Carl Schlyter, Horst Schnellhardt, Richard Seeber, María Sornosa Martínez, Andres Tarand, Antonios Trakatellis, Thomas Ulmer, Åsa Westlund
Substitute(s) present for the final vote	Iles Braghetto, Milan Gaľa, Jutta Haug, Justas Vincas Paleckis, Bart Staes
Substitute(s) under Rule 178(2) present for the final vote	Emanuel Jardim Fernandes