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Committee on Agriculture and Rural Development

PROVISIONAL
2007/0064(COD)

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OPINION

of the Committee on Agriculture and Rural Development

for the Committee on the Environment, Public Health and Food Safety

on the 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
(COM(2007)0194 – C6-0113/2007 – 2007/0064(COD))

Draftsman: Friedrich-Wilhelm Graefe zu Baringdorf

SHORT JUSTIFICATION

The rapporteur welcomes in principle the objectives of the regulation, to simplify legislation improving how maximum residue limits (MRLs) of pharmacologically active substances in foodstuffs of animal origin are set. It is important at the same time to make consumer and animal protection more effective, to simplify procedures and to take due account of the urgent needs that arise repeatedly in practice.

In particular, the rapporteur clarifies the conditions for transferring scientifically identified MRLs to other species (extrapolation), as this could contribute to lowering the cost of authorising veterinary medicinal products, especially for minor areas of application (sheep, goats, horses). Further measures should be taken to increase the quality and availability of veterinary medicinal products for minor use.

The rapporteur has a number of objections as regards incorporating internationally agreed MRLs (Codex Alimentarius). International agreements in this area are of great importance for Europe, which is not only a major importer but also a major exporter. The EU must continue to be able to take specific measures to maintain consumer protection.

As with other proposed simplifications, it must always be taken into consideration that health protection is an overriding Community objective. Due account should therefore be taken of this objective when any decisions are made. As Codex values prejudge the establishment of MRLs in the Community, the Commission must involve the Council and the European Parliament before agreement is reached. Automatically incorporating decisions in which the public, Member States and the European Parliament were not formally involved via the codecision procedure should be avoided, not least in the light of previous experience.

As regards general issues related to assessment, account should be taken of the fact that, essentially, MRLs are of relevance to food legislation. Therefore, when it comes to the risk assessment, the same aspects as in other areas of food legislation must be taken into account. Particular consideration should be given to protecting vulnerable categories of people and the possibility of cumulative effects.

In the interests of improving the manageability and transparency of rules for inspectors, it would appear sensible to set MRLs for substances not used in veterinary medicinal products but that have a similar effect and for substances used mainly abroad that are placed on the market here via animal products. Trade aspects and easing the administrative burden should, however, always be secondary to health protection.

The rapporteur also proposes rules on how to treat pharmacologically active substances for which no limits have been set. Essentially, the proposals correspond to the earlier rules laid down in Regulation (ECC) No 315/93.

The European Parliament's right to be involved when rules on assessment are set must therefore be more widely applied than is proposed by the Commission proposal.

AMENDMENTS

The Committee on Agriculture and Rural Development calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission	Amendments by Parliament

Amendment 1
Article 1, paragraph 1, point (a)

(a) the maximum concentration of a residue of a pharmacologically active substance which may be permitted in food of animal origin (“maximum residue limit”);	(a) the maximum concentration of a residue of a pharmacologically active substance ***contained in a veterinary product*** which may be permitted in food of animal origin (“maximum residue limit”);

Justification

The substances affected by this regulation constitute a large group, all of them being pharmacologically active in a specific fashion. However, the procedures defined later in this text differentiate clearly between those contained in veterinary medicines and those intended for other uses. These two types should therefore be defined as distinct entities from the outset.

Amendment 2
Article 1, paragraph 1, point (a a) (new)

	(aa) the maximum concentration of a residue of an active substance contained in biocidal products used in stockbreeding which are permitted in foodstuffs of animal origin;

Justification

This regulation affects a large group of substances, all of them pharmacologically active in a specific fashion. It is therefore desirable to delimit those substances not included in veterinary medicines which are affected by it. For these, it is preferable to refer to 'active substances', reserving the term 'pharmacologically active' for those intended for the preparation of medicines, in line with the Community legislation on pharmaceuticals.

Amendment 3
Article 5

With a view to ensuring the availability of authorised veterinary medicinal products for conditions affecting food-producing species,	***In line with the objective of ensuring a high level of health protection and with the principles laid down in Article 6, the***

the Committee shall, when carrying out scientific risk assessments and when drawing up risk management recommendations, consider using maximum residue limits established ***for a pharmacologically active substance in*** a particular foodstuff for another foodstuff derived from the same species, ***or in*** one or more species for other species.	***Committee shall,*** with a view to ensuring the availability of authorised veterinary medicinal products for conditions affecting food-producing species, when carrying out scientific risk assessments and when drawing up risk management recommendations, consider using***:***
	(a) maximum residue limits established ***in relation to*** a particular foodstuff for another foodstuff derived from the same species,
	(b) maximum residue limits established in relation to one or more species for other species.
	In the event of extrapolation between different animal species, a safety factor should be applied when setting maximum residue limits.

Justification

This article lays down the general conditions for extrapolation. The rapporteur supports the objective set out in the Commission proposal of improving test procedures by making greater use of extrapolation (i.e. applying results to other foodstuffs or animal species) during risk assessment. This objective will contribute to increasing the availability of active substances, particularly for smaller groups of animals (goats, sheep etc.). The changes proposed here simply serve to ensure that, even when extrapolation is applied, there must be an appropriate reduction in authorised residue levels. It should also be made clear that extrapolation needs to occur in 'two dimensions' - between species, between tissues and between tissues of different species. The proposed wording is more explicit in this sense.

Amendment 4
Article 6, paragraph 1

1. The scientific risk assessment shall consider the metabolism and depletion of pharmacologically active substances in ***relevant*** animal species and the type of residues, and the amount thereof, that may be ingested by human beings over a lifetime without an appreciable health risk expressed in terms of acceptable daily ***intake*** (ADI). Alternative approaches to ADI may be used, if they have been laid down by the Commission as provided for in Article 12(1).	1. The scientific risk assessment shall consider the metabolism and depletion of pharmacologically active substances in ***different*** animal species and the type of residues, and the amount thereof, that may be ingested by human beings over a lifetime without an appreciable health risk expressed in terms of acceptable daily ***ingestion*** (ADI). Alternative approaches to ADI may be used, if they have been laid down by the Commission as provided for in Article 12(1).

Justification

The use of 'ingestion' rather than 'intake' is more consistent with the terminology used in this field. It is preferable to refer to 'different' rather than 'relevant' animal species since this is broader and the soundness of the generalisation implied by extrapolation will be the greater the larger the number of species taken into account.

Amendment 5
Article 6, paragraph 2, point (b)

(b) the risk of ***unintended*** pharmacological or microbiological effects in human beings;	(b) the risk of pharmacological or microbiological effects in human beings;

Justification

The presence of residues of medicines (or other substances governed by this legislation) in foodstuffs is accidental and unintended. There is therefore no reason to make a distinction between intended and unintended effects, as all will be unintended.

Amendment 6
Article 6, paragraph 3

3. If the metabolism and depletion of the substance cannot be assessed ***and the use of the substance is designed to promote animal health and welfare***, the scientific risk assessment may take into account monitoring data or exposure data.	3. If the metabolism and depletion of the substance cannot be assessed, the scientific risk assessment may take into account monitoring data or exposure data.

Justification

The words 'and the use of the substance is designed to promote animal health and welfare' are redundant, since all the substances concerned are intended for at least one of those purposes.

Amendment 7
Article 7, point (c)

(c) whether or not a maximum residue limit or a provisional maximum residue limit should be established for a pharmacologically active substance in veterinary medicinal products, ***residues of which have been found in a particular foodstuff of animal origin, the level of that maximum residue limit*** and, where appropriate, any conditions or restrictions for the use of the substance concerned;	(c) whether or not a maximum residue limit or a provisional maximum residue limit should be established for a pharmacologically active substance in veterinary medicinal products, and, where appropriate, any conditions or restrictions for the use of the substance concerned;

Justification

[The first part of this amendment does not affect the English version]. This amendment deletes an unnecessary specification, since the presence of residues and the fixing of a tolerance threshold constitute the raison d'être as such of the MRLs.

Amendment 8
Article 7, point (d a) (new)

(da) the feasibility of submitting recommendations aimed at contributing to establishing withdrawal periods for other food-producing species where it is necessary to use the cascade system.

Justification
[not translated: over-length - see instructions from Planning on Fdr]

Amendment 9
Article 8, paragraph 4 a (new)

4a. 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 referred to in Article 21(3), establish a provisional maximum residue limit for a period not exceeding five years.

Justification
It may in some cases be necessary to proceed to an urgent authorisation for the use of medicines or other products for combating animal diseases or ensuring animal welfare (e.g. when fighting carriers of newly appeared infectious diseases or in the pharmacological treatment of certain epidemics). Where the seriousness of the situation calls for it and in order to avert major damage to animal health and welfare, an emergency procedure should be available for setting a provisional MRL.

Amendment 10
Title II, Chapter 1, Section 2, title

Pharmacologically active substances not intended for use in veterinary medicinal products	Pharmacologically active substances not intended for use in veterinary medicinal products ***and other active substances not included in Section 1***

Justification

The title is changed in line with other amendments tabled.

Amendment 11
Article 9, paragraph 1, subparagraph 1

1. 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 in accordance with Article 3, the Commission ***or*** Member States may forward to the Agency requests for an opinion on maximum residue limits.	1. 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 in accordance with Article 3, the Commission***,*** Member States ***or a third party pursuing legitimate interests*** may forward to the Agency requests for an opinion on maximum residue limits.

Justification

Paragraph 3 suggests that third parties may also forward requests, although this possibility is not included in paragraph 1. Systematic clarification.

Amendment 12
Article 13, title

Classification of ***pharmacologically*** active substances	Classification of active substances

Justification

This is in line with the amendments on Article 1.

Amendment 13
Article 13, paragraph 1

1. The Commission shall classify the ***pharmacologically*** active substances subject to an opinion of the Agency on the maximum residue limit in accordance with Articles 4, 9 or 10.	The Commission shall classify the active substances subject to an opinion of the Agency on the maximum residue limit in accordance with Articles 4, 9 or 10. *(This amendment applies to the entire article. Its adoption will require technical modifications throughout the article.)*

Justification

To ensure consistency with the amendment tabled to Article 1(1) adding a new point (aa), and to make it clear that this article should apply to all the substances cited in that Article 1, it is

desirable to delete 'pharmacologically'.

Amendment 14
Article 13, paragraph 4

4. A provisional maximum residue limit may be established for ***a pharmacologically*** active substance in cases where scientific data are incomplete, provided that there are no grounds for supposing that residues of the substance concerned at the level proposed present a ***hazard for*** human health.	4. A provisional maximum residue limit may be established for ***an*** active substance in cases where scientific data are incomplete, provided that there are no grounds for supposing that residues of the substance concerned at the level proposed present a ***risk to*** human health. ***The decision on risk must be based on the principles referred to in Article 6 and the rules laid down in Article 12.***
The provisional maximum residue limit shall apply for a defined period of time, which shall not exceed ***five years***. That period may be extended once for a period not exceeding two years where it is demonstrated that such an extension would allow scientific studies in progress to be completed.	The provisional maximum residue limit shall apply for a defined period of time, which shall not exceed ***three years***. That period may be extended once for a period not exceeding two years where it is demonstrated that such an extension would allow scientific studies in progress to be completed.

Justification

The maximum period of five years for provisional authorisation would appear too long. As a rule, the substances involved have undergone an authorisation or other test procedure, meaning that the required results would have to be available within three years. This is a longer time period than for setting limits under the normal procedure.

Amendment 15
Article 13, paragraph 6, point (a)

(a) where any use of ***a pharmacologically*** active substance in food-producing animals constitutes a ***hazard*** to human health;	(a) where any use of ***an*** active substance in food-producing animals constitutes a ***risk*** to human health;

Amendment 16
Article 16

Member States may not prohibit or impede the import and placing on the market of food of animal origin on grounds related to maximum residue limits where the provisions of this Regulation and its implementing measures have been complied with.	Member States may not prohibit or impede the import and placing on the market of food of animal origin on grounds related to maximum residue limits ***or reference points for action*** where the provisions of this Regulation and its implementing measures have been complied with.

Justification

This regulation establishes two indices related to the health standards of foodstuffs in the context of the presence of other substances, namely MRLs and reference points for action. Foodstuffs of animal origin which do not exceed the threshold under whichever index supplies shall be considered safe and may move freely, with no obstacles related to residues. Article 16 should deal with freedom of movement in relation to both indices and not just to MRLs.

Amendment 17
Article 18, paragraph 1

1. The reference points for action shall be based on the content of an analyte in a sample, which can be detected and confirmed by a reference control *laboratories* designated in accordance with Regulation (EC) No 882/2004 with an analytical method validated according to Community requirements. In this, the Commission shall be advised by the relevant Community reference laboratory on the performance of analytical methods.	1. The reference points for action shall be based on ***the maximum residue limit for the substance concerned and/or*** the content of an analyte in a sample, which can be detected and confirmed by a reference control *laboratory* designated in accordance with Regulation (EC) No 882/2004 with an analytical method validated according to Community requirements. In this, the Commission shall be advised by the relevant Community reference laboratory on the performance of analytical methods.

Justification

Where the relevant committee considers the determination of a reference point for action, it is possible that there already exists an MRL for certain tissues or species. In these circumstances, there is no doubt that the MRLs already in existence should be taken into account when establishing reference points for action on the same basis as any other available data of a purely analytic nature.

Amendment 18
Article 22

Within [***60***] days after the entry into force of this Regulation, the Commission shall adopt, in accordance with the regulatory procedure referred to in ***Article 20(2)***, a Regulation containing the pharmacologically active substances and their classification regarding maximum residues limits in accordance with Annexes I to IV of Regulation (EEC) No 2377/90.	Within [***90***] days after the entry into force of this Regulation, the Commission shall adopt, in accordance with the regulatory procedure ***with scrutiny*** referred to in ***Article 20(3)***, a Regulation containing the pharmacologically active substances and their classification regarding maximum residues limits in accordance with Annexes I to IV of Regulation (EEC) No 2377/90.

Justification

This relates to the adoption of the annexe to this regulation. The regulatory procedure with

scrutiny should be applied in this case.

PROCEDURE

Title	Establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin
References	COM(2007)0194 - C6-0113/2007 - 2007/0064(COD)
Committee responsible	ENVI
Opinion by Date announced in plenary	AGRI 24.5.2007
Drafts(wo)man Date appointed	Friedrich-Wilhelm Graefe zu Baringdorf 8.5.2007
Discussed in committee	11.9.2007 9.10.2007 21.11.2007
Date adopted	21.11.2007
Result of final vote	+: 27 –: 1 0: 0
Members present for the final vote	Vincenzo Aita, Peter Baco, Bernadette Bourzai, Niels Busk, Luis Manuel Capoulas Santos, Giuseppe Castiglione, Albert Deß, Duarte Freitas, Ioannis Gklavakis, Lutz Goepel, Bogdan Golik, Friedrich-Wilhelm Graefe zu Baringdorf, Elisabeth Jeggle, Heinz Kindermann, Diamanto Manolakou, Mairead McGuinness, Rosa Miguélez Ramos, Neil Parish, Agnes Schierhuber, Willem Schuth, Czesław Adam Siekierski, Petya Stavreva, Csaba Sándor Tabajdi, Donato Tommaso Veraldi
Substitute(s) present for the final vote	Katerina Batzeli, Esther De Lange, Wiesław Stefan Kuc, Zdzisław Zbigniew Podkański