



COUNCIL OF
THE EUROPEAN UNION

Brussels, 14 November 2007

Interinstitutional File:
2007/0064 (COD)

13959/1/07
REV 1

LIMITE

AGRILEG 148
CODEC 1078

REVISED OUTCOME OF PROCEEDINGS

from : Working Party of veterinary experts (Public health)

on : 15 June 2007, 20 July 2007, 19 and 27 September 2007

No. prev. doc. : 11439/07

No. Cion prop. : 8653/07 - COM(2007) 194 final

Subject : 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) N° 2377/90

Further to the meetings of the Working Party of veterinary experts (Public health) on 15 June 2007, 20 July 2007, 19 and 27 September 2007, delegations will find in Annex the draft Regulation annotated with the principal positions of delegations¹, as expressed in the Working Party and in their written contributions.

¹ A large majority of delegations (CZ, DE, ES, FI, FR, IE, PT, SE, UK) that took the floor welcomed the proposal pointing out that it contains many positive elements (basis for extrapolation, procedure for automatic adoption of Codex MRLs, improvements introduced by RPAs compared to LMPRs...). However, many of them stressed the need for further clarifications/amendments on various articles; in view of the Working Party, only these remarks are annotated in the document in Annex. **DK indicated a parliamentary reservation at this stage.**

DRAFT

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**

(Text with EAA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37 and
Article 152(4)(b) thereof,

Having regard to the proposal from the Commission¹,

Having regard to the opinion of the European Economic and Social Committee²,

Having regard to the opinion of the Committee of the Regions³,

Acting in accordance with the procedure referred to in Article 251 of the Treaty⁴,

¹ OJ C , , p. .

² OJ C , , p. .

³ OJ C , , p. .

⁴ OJ C , , p. .

Whereas:

- (1) As a result of scientific and technical progress it is possible to detect the presence of residues of veterinary medicines in foodstuffs at ever lower levels.
- (2) It is necessary to establish maximum residue limits for pharmacologically active substances in respect of various foodstuffs of animal origin, including meat, fish, milk, eggs and honey.
- (3) Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin⁵ introduced Community procedures to evaluate the safety of residues of pharmacologically active substances according to human food safety requirements. A pharmacologically active substance may be used in food-producing animals only if evaluated favourably. Maximum residue limits are established for such a substance if that is considered necessary for the protection of human health.
- (4) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to veterinary medicinal products⁶ provides that veterinary medicinal products may be authorised or used in food-producing animals only if pharmacologically active substances contained therein have been assessed as safe according to Regulation (EEC) No 2377/90. Moreover it contains rules concerning the documentation of use, re-designation ('off label use'), prescription and distribution of veterinary medicinal products intended for use in food-producing animals.

⁵ *OJ L 224, 18.8.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 1831/2006 (OJ L 354, 14.12.2006, p. 5).*

⁶ *OJ L 311, 28.11.2001, p. 1. Directive as last amended by Directive 2004/28/EC (OJ L 136, 30.4.2004, p. 58).*

- (5) In the light of the Commission's public consultation undertaken in 2004 and the Commission's assessment of the experience gained, it has proved necessary to modify the procedures for setting maximum residue limits while maintaining the overall system for setting such limits.
- (6) Maximum residue limits are the points of reference for the establishment, in accordance with Directive 2001/82/EC, of withdrawal periods in marketing authorisations for veterinary medicinal products to be used in food-producing animals as well as for the control of residues in food of animal origin in the Member States and at border inspection posts.
- (7) 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 and repealing Directive 81/602/EEC, 88/146/EEC and 88/229/EEC⁷ prohibits the use of certain substances for specific purposes in food-producing animals. This regulation should apply without prejudice to any Community legislation prohibiting the use in food producing animals of certain substances having a hormonal action.
- (8) Council Regulation (EEC) No 315/93 of the European Parliament and of the Council of 8 February 1993 laying down community procedures for contaminants in food⁸ lays down specific rules for substances not resulting from intentional administration. Those substances should not be subject to the legislation on maximum residue limits.

⁷ OJ L 125, 23.5.1996, p. 3. Directive as last amended by Directive 2003/74/EC of the European Parliament and of the Council (OJ L 262, 14.10.2003, p. 17).

⁸ OJ L 37, 13.2.1993, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

- (9) Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety⁹ lays down the framework for food legislation on a Community level and provides for definitions in that area. It is appropriate that those definitions should apply for the purposes of the legislation on maximum residue limits.
- (10) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules¹⁰ lays down general rules for the control of food in the European Community and provides for definitions in that area. It is appropriate that those definitions should apply for the purposes of the legislation on maximum residue limits.
- (11) Article 57 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency¹¹ entrusts to the European Medicines Agency, hereinafter "the Agency", the task of advising on the maximum limits for residues of veterinary medicinal products which may be accepted in food of animal origin.
- (12) Maximum residue limits should be set for pharmacologically active substances used or intended to be used in veterinary medicinal products placed on the market in the Community.

⁹ *OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 3).*

¹⁰ *OJ L 165, 30.4.2004, p. 1. Regulation as last amended by Regulation (EC) No 854/2004 (OJ L 139, 30.4.2004, p. 206).*

¹¹ *OJ L 136, 30.04.2006, p. 1. Regulation as last amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p. 1).*

- (13) It appears from the public consultation and from the fact that only a small number of veterinary medicinal products for food-producing animals have been authorised in recent years that the obligation to comply with Regulation (EEC) No 2377/90 has meant that such medicinal products have been less readily available.
- (14) In order to ensure animal health and animal welfare, it is necessary that medicinal products are available to treat specific disease conditions. Furthermore, the lack of availability of appropriate veterinary medicinal products for a specific treatment for a specific species may contribute to the misuse or illegal use of substances.
- (15) The system established by Regulation (EEC) No 2377/90 should therefore be modified with a view to increasing the availability of veterinary medicinal products for food-producing animals. In order to serve that objective, provision should be made for the systematic consideration by the Agency of the use of a maximum residue limit established for one species or foodstuff for another species or another foodstuff.
- (16) In order to protect human health, maximum residue limits should be established in accordance with generally recognised principles of safety assessment, taking into account toxicological risks, environmental contamination, as well as unintended microbiological and pharmacological effects of residues.
- (17) It is recognised that, in certain cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based and that other factors relevant to the matter under consideration should legitimately be taken into account including technological aspects of food production and the feasibility of controls; the Agency should therefore provide an opinion on the scientific risk assessment and risk management recommendations on residues of pharmacologically active substances.

- (18) Detailed rules on the format and content of applications for the establishment of maximum residue limits and on methodological principles of risk assessment and risk management recommendations are necessary for the smooth functioning of the overall framework of maximum residue limits.
- (19) Besides veterinary medicines, other products which are not subject to specific legislation on residues are used in animal husbandry, such as disinfectants. Further, veterinary medicinal products not having a marketing authorisation in the Community may be authorised in countries outside the Community. That may be because in other regions different diseases or target species are more prevalent or because companies have chosen not to market a product in the Community. The fact that a product is not authorised in the Community does not necessarily indicate that its use is unsafe. For the pharmacologically active substances of such products, the Commission should be enabled to set a maximum residue limit for food, following an opinion by the Agency in accordance with the principles set for pharmacologically active substances intended for use in veterinary medicinal products.
- (20) The Community contributes in the context of the *Codex Alimentarius* to the development of international standards on maximum residue limits, while ensuring that the high level of human health protection adopted in the Community is not reduced. The Community should therefore take over without a further risk assessment those Codex maximum residue limits it has supported in the relevant Codex Alimentarius Commission meeting. Consistency between international standards and Community legislation on residue limits in food will thereby be further enhanced.

- (21) Foodstuffs are subject to controls on residues of pharmacologically active substances in accordance with Regulation (EC) No 882/2004. Even if residue limits are not set for such substances pursuant to this Regulation, residues of such substances might occur due to environmental contamination or occurrence of a natural metabolite in the animal. Laboratory methods are capable of finding such residues at ever lower levels. Such residues have caused different control practices in Member States.
- (22) It is therefore appropriate for the Community to provide for procedures to set reference points for control action at concentrations of the residues for which scientific advice indicates that consumer exposure is negligible and laboratory analysis is technically feasible in order to facilitate intra-Community trade and imports.
- (23) The legislation on maximum residue limits should be simplified by placing together in one single Commission Regulation all decisions classifying pharmacologically active substances as regards residues, and setting reference points for action.
- (24) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission¹².

¹² *OJ L 184, 17.7.1999, p. 23. Decision as amended by Council Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).*

- (25) In particular, power should be conferred on the Commission to adopt rules on the conditions for extrapolation and on the establishment of reference points for action. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, and to supplement this Regulation by the addition of new non-essential elements, they should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.
- (26) Since the objectives of the action to be taken, namely to protect human health as well as animal health, and to ensure the availability of appropriate veterinary medicinal products, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale and effects of the action, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (27) For the sake of clarity, it is therefore necessary to replace Regulation (EEC) No 2377/90 with a new Regulation.
- (28) A transitional period should be provided for in order to allow the Commission to prepare and adopt a regulation which contains all applicable decisions pursuant to Regulation 2377/90 and implementing provisions for this new regulation,

HAVE ADOPTED THIS REGULATION:

TITLE I

GENERAL PROVISIONS

Article 1

Subject matter and scope

1. This Regulation lays down rules and procedures in order to establish the following¹³:
 - 1) the maximum concentration of a residue of a pharmacologically active substance¹⁴ which may be permitted in food of animal origin ("maximum residue limit¹⁵");
 - 2) the tolerance level of a residue of a pharmacologically active substance below which human exposure to that residue through food containing the substance is considered negligible ("reference point for action")¹⁶.
2. This Regulation shall not apply to the following:
 - (a) active principles of biological origin intended to produce active or passive immunity or to diagnose a state of immunity, used in immunological veterinary medicinal products;

¹³ *Some delegations (ES, UK, DE) requested a clear reference to the objective of protection of food safety (DE) added that the regulation defines more than rules and procedures of establishment of MRL and RPA.*

¹⁴ *Several delegations (FR, FI, ES, IT, UK) requested clarification as regards substances covered. **FR asked for a clear reference to Directive 98/8/EC in the whereas if biocidal products were to be included.***

¹⁵ *One delegation (FI) suggested to replace 'limit' by 'concentration'.*

¹⁶ *Some delegations (SE, FR, UK) found the definition unclear. One (SE) suggested to refer to 'consumer' instead of 'human' and to specify that the tolerance level would be expressed in mg/kg or µg/kg on a fresh weight basis. Several delegations (FI, FR, UK, DE, IT, ES, CZ, DK, IT) requested a clear reference to a negligible risk for human health. Two delegations (UK, IT) questioned the use of the words 'tolerance level' and suggested (UK) to define the criteria by which levels will be tolerated.*

(b) substances falling within the scope of Regulation (ECC) No 315/93¹⁷;

3. This regulation shall apply without prejudice to Community legislation prohibiting the use in food producing animals of certain substances having a hormonal action¹⁸ as provided by Directive 96/22/EC.

Article 2

Definitions

In addition to the definitions laid down in Article 1 of Directive 2001/82/EC, Article 2 of Regulation (EC) No 882/2004 and Articles 2 and 3 of Regulation (EC) No 178/2002, the following definitions shall apply for the purposes of this Regulation:

- 1) 'residues of pharmacologically active substances' means all pharmacologically active substances, expressed in mg/kg or µg/kg on a fresh weight basis, whether active substances, excipients or degradation products, and their metabolites which remain in food obtained from animals;

¹⁷ *Several delegation (FI, UK, FR, ES, DE) requested to clarify the issue of dual use substances. Some (ES, FR) pointed out the need to exclude explicitly substances used in feed additives. FR requested recommendations for controls regarding the LMR to use as reference when 2 different LMR exist.*

¹⁸ *One delegation (UK) suggested being consistent with 96/22 and recital 7 to include also 'thyrostats and B agonists' in paragraph 3.*

- 2) “food-producing animals” means animals bred, raised, kept, slaughtered or harvested specifically for the purpose of producing food¹⁹.

TITLE II

MAXIMUM RESIDUE LIMITS

CHAPTER 1 RISK ASSESSMENT AND RISK MANAGEMENT

Section 1 Pharmacologically active substances intended for use in veterinary medicinal products

Article 3

Application for an opinion of the Agency

Any pharmacologically active substance intended for use in veterinary medicinal products for administration to food-producing animals shall be subject to an opinion²⁰ of the European Medicines Agency ("the Agency") on the maximum residue limit, formulated by the Committee for Medicinal Products for Veterinary Use (‘the Committee’).

¹⁹ *Some delegations (ES, FI) questioned the use of the term 'animals' instead of 'species' preferring the term 'species' (FI). On the contrary, DK welcomed a reference to 'animals' and not to 'species'. Several delegations (FI, FR, SE, DE) proposed to delete the word 'specifically'. Some delegations (FI, CZ) pointed out the problem of game and hunted animals. ES requested to delete the term 'harvested' in particular if substances other than those used in VMP are part of the scope. CZ requested a reference to fishing and to food. DE preferred to exclude wild animals from the scope.*

²⁰ *One delegation (DK) pointed out the need to reword this sentence as in the case of Codex MRL supported by the Community there will be no opinion from the Agency.*

To that end, the holder of a marketing authorisation for a veterinary medicinal product in which such a substance is used, the applicant for such a marketing authorisation or a person intending to apply for such a marketing authorisation, shall submit an application to the Agency²¹.

Article 4

Opinion of the Agency

- 1) The opinion of the Agency shall consist in a scientific risk assessment and risk management recommendations.

- 2) The scientific risk assessment and the risk management recommendations shall aim to ensure a high level of human health protection, whilst also ensuring that human health, animal health and animal welfare are not negatively affected by the lack of availability of appropriate veterinary medicinal products.

²¹ *Some delegations (ES, FI) requested that this procedure is also opened to Member States and to Commission (ES). One delegation (CZ) requested that it is explicitly indicated that an applicant for a marketing authorisation of a VMP including a substance having already an MRL established needs not to introduce an application for an MRL. DE questioned the use of the word 'holder' as a holder should already have an application for an opinion on MRL.*

Article 5
Extrapolation

With a view to ensuring the availability of authorised veterinary medicinal products for conditions affecting food-producing species, 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^{22 23 24 25}.

Article 6
Scientific risk assessment

- 1) The scientific risk assessment²⁶ 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 appreciable²⁷ 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).

²² *Several delegations requested clear rules on when and how extrapolation should be carried out (FI, UK, ES, IT, NL, DE, DK). One delegation (ES) proposed that extrapolation is carried also on request from MS.*

²³ *Some delegations (DK, FR) questioned the tissue to tissue extrapolation as scientific and technical development should be awaited before introducing it.*

²⁴ *Several delegations (SE, DK, UK, IT) indicated the need to maintain a high level of consumer safety.*

²⁵ *Some delegations (ES, FR) requested that extrapolation is made available for new substances and also substances already evaluated. Others (FI) insisted on the fact that resources were limited and would not allow extrapolation in all cases. UK pointed out a potential conflict between directive 2001/110 requiring the honey to be pure and the use of VMP in bees following extrapolation.*

²⁶ *Several delegations (FI, UK, ES) asked for a better separation between risk evaluation and risk management.*

²⁷ *UK suggested referring to 'insignificant' health risk here.*

- 2) The scientific risk assessment shall concern the following:
- a. the type and amount of residue considered not to present a safety concern for human health;
 - b. the risk of unintended²⁸ pharmacological or microbiological effects in human beings;
 - c. residues that occur in food of plant origin or come from the environment²⁹.
- 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 data³⁰.

²⁸ *Some delegations (ES, DE) proposed to delete the word 'unintended' and to add 'toxicological' effects under a). UK requested a clear reference to 'toxicological' risks under b).*

²⁹ *One delegation (CZ) requested a clarification to specify that this does not relate to the assessment of residues introduced in the environment or in food from treated animals. ES requested the use of existing wording in Regulation 2377/90.*

³⁰ *One delegation (FI) requested a definition of 'exposure and monitoring data'. Some delegations (SE, IT) questioned the relevance of these data as there will probably not be available. Some delegations (DK, SE, IT) considered that risk can not properly be evaluated if metabolism and depletion are not assessed. ES proposed to delete from 'and the use' to 'welfare'. UK proposed to clarify the meaning of 'if the metabolism and depletion of the substance cannot be assessed'. On the contrary, FR, UK and NL were in favour of the introduction of alternative approaches to ADI as well as to the use of monitoring and exposure data when necessary/appropriate.*

Article 7

Risk management recommendations

The risk management³¹ recommendations shall be based on the scientific risk assessment performed in accordance with Article 6 and shall consist in an assessment of the following:

1. the availability of alternative substances for the treatment of the relevant species or the necessity of the substance evaluated in order to avoid unnecessary suffering for animals or to ensure the safety of those treating them;
2. other legitimate factors such as the technological aspects of food³² production, the feasibility of controls, conditions of use and application of the substances in veterinary medicinal products and the likelihood of misuse or illegal use;
3. 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 origin³³, the level of that maximum residue limit and, where appropriate, any conditions or restrictions for the use of the substance concerned;

³¹ *UK questioned whether it was appropriate that the EMEA has a risk management role.*

³² *One delegation (ES) requested to introduce a reference to 'feed' production.*

³³ *One delegation (ES) proposed to delete the part of the sentence from 'residues' to 'origin'.*

4. whether it is feasible to establish a maximum residue limit when the data provided do not allow a safe limit to be identified, or when no final conclusion concerning human health with regard to residues of a substance can be drawn owing to the lack of scientific information³⁴.

Article 8

Applications and procedures

- 1) The application referred to in Article 3 shall comply with the format and content laid down by the Commission as provided for in Article 12(1) and shall be accompanied by the fee payable to the Agency.

- 2) The Agency shall ensure that the opinion of the Committee is given within 210 days following the receipt of a valid application in accordance with Article 3 and paragraph 1 of this Article. This time limit shall be suspended when the Agency requests the submission of supplementary information on the given substance within a specific time period, and until such time as the supplementary information requested has been provided.

³⁴ *Several delegations (FR, FI, DK, UK) pointed out it should not be possible to establish MRL in the absence of scientific data. UK pointed out a possible contradiction between 7 d) and 13 6). One delegation (ES) proposed to introduce after d) a new e) relating to recommendations on the establishment of withdrawal periods when 'cascade' is used.*

- 3) The Agency shall forward the opinion referred to in Article 4 to the applicant. Within 15 days of receipt of the opinion, the applicant may provide written notice to the Agency that he wishes to request a re-examination of the opinion. In that case the applicant shall forward the detailed grounds for his request to the Agency within 60 days of receipt of the opinion.

Within 60 days of the receipt of the grounds for the request, the Committee shall consider whether its opinion should be revised. The reasons for the conclusion reached on the request shall be annexed to the final opinion referred to in paragraph 4.

- 4) Within 15 days of the adoption of the final opinion, the Agency shall forward it both to the Commission and to the applicant, stating the grounds for its conclusions³⁵.

³⁵ *Several delegations (ES, FR, NL, FI, UK) were in favour of the introduction of an urgent procedure for establishment of MRL in case there is a need for in order to protect animal health. On the opposite, one delegation (DK) did not consider it necessary.*

Section 2 Pharmacologically active substances not intended for use in veterinary medicinal products

Article 9

Agency's opinion requested by the Commission or the Member States

- 1) For substances³⁶ not intended for use in veterinary medicinal products to be placed on the market in the Community³⁷ 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 limits³⁸.

Articles 4 to 8³⁹ shall apply.

- 2) The Agency shall ensure that the opinion of the Committee is given within 210 days following the receipt of the request by the Commission. This time limit shall be suspended when the Agency requests submission of supplementary information on the given substance within a specific time period, and until such time as the supplementary information requested has been provided.

³⁶ *Several delegations (FI, FR, ES, UK) pointed out the need to clarify which substances would be eligible for the procedure of this article. In addition **FR** requested a clarification on the relationship between this article and some other articles of the regulation (in particular Article 17) as well as other regulations.*

One (FR) indicated that it should be clear that forbidden substances in the EU are not eligible for this procedure.

³⁷ *Some delegations (FI, SE, ES) requested the part of the sentence 'not intended for use in veterinary medicinal products to be placed on the market in the Community' is deleted.*

³⁸ *Some delegations (ES, UK) questioned the financing and the data requirements for the procedure of article 9 as well as the workload for the Agency (UK).*

³⁹ *Some delegations (UK, ES) questioned whether 9 2) and 3) were needed if articles 4 to 8 are to apply.*

- 3) Within 15 days of the adoption of the final opinion, the Agency shall forward it to the Commission and, as the case may be, to the Member State or party ⁴⁰ which made the request, stating the grounds for its conclusions.

Section 3 Common provisions

Article 10

Review of an opinion

Where the Commission, the applicant under Article 3, or a Member State under Article 9⁴¹, as a result of new information, considers that a review of an opinion is necessary in order to protect human or animal health, it may request the Agency to issue a new opinion on the substances in question.

That request shall be accompanied by information explaining the issue to be addressed. Article 8(2) and (4) or Article 9(2) and (3) respectively shall apply to the new opinion.

⁴⁰ *One delegation (FI) questioned the meaning of the word 'party'.*

⁴¹ *One delegation (ES) proposed that the possibilities to ask for a review should be more open to MS, Commission and applicant without any reference to articles 3 or 9. UK recalled the problem of workload/resources for the Agency.*

Article 11
Publication of opinions

The Agency shall publish the opinions referred to in Articles 4, 9 and 10, after deleting any information of a commercially confidential nature.

Article 12
Implementing Measures

- 1) In accordance with the regulatory procedure referred to in Article 20(2), the Commission shall, in consultation with the Agency, adopt the following:
 - a. the form in which applications referred to in Article 3 and requests referred to in Article 9 are to be presented, and the content of these applications;
 - b. the methodological principles of the risk assessment and risk management recommendations referred to in Articles 6 and 7, including technical requirements in accordance with internationally agreed standards.

- 2) The Commission shall, in consultation with the Agency, adopt rules on the use of a maximum residue level of a particular foodstuff for another foodstuff of the same species, or of one or more species for other species as referred to in Article 5. Those rules shall specify how and under what circumstances scientific data on residues in a particular foodstuff or in a species or more species may be used for setting a maximum residue limit in other foodstuffs, or other species.

- 3) Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).

CHAPTER II CLASSIFICATION

Article 13

Classification of pharmacologically active substances

- 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.
- 2) The classification shall include a list of pharmacologically active substances and the therapeutic classes to which they belong. The classification shall also entail the establishment, in relation to each such substance, of one of the following:
- (a) a maximum residue limit;
 - (b) a provisional maximum residue limit;
 - (c) the absence of a maximum residue limit⁴²;

⁴² *Several delegations (ES, FI, UK, FR, DE) pointed out the need to clarify the substances covered and proposed to refer to 'the absence of need to establish a maximum residue limit'.*

(d) a prohibition on the administration of a substance.

- 3) A maximum residue limit shall be laid down where it appears necessary for the protection of human health pursuant to an opinion of the Agency in accordance with Articles 4, 9 or 10 or pursuant to a vote by the Community in favour⁴³ of the establishment of a maximum residue limit for a pharmacologically active substance intended for use in a veterinary medicinal product in the *Codex Alimentarius*⁴⁴. In the latter case an additional assessment by the Agency is not required.
- 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.

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.

⁴³ *Several delegations (FR, DK, ES, CZ, UK, DE, IT, NL) requested for clarification on this provision: meaning of vote in favour and procedure to be followed to accept and introduce Codex MRL.*

⁴⁴ *Some delegations (ES, FR, DK, UK, IT) asked for clarification on procedures for substances for which an MRL has already been established in the EU. On this issue, some delegations (FR, DK) indicated that it should be restricted to substances for which an MRL has not already been established in the EU. **FR stressed that the adoption of CODEX MRLs even in cases where EU MRLs already exist could have serious consequences as e.g. the need to revise withdrawal periods based on these EU MRLs and subsequently marketing authorisations of VMPs.***

- 5) No maximum residue limit shall be established where, pursuant to an opinion in accordance with Articles 4, 9 or 10, it is not necessary for the protection of human health.
- 6) The administration of a substance to food-producing animals shall be prohibited, pursuant to an opinion in accordance with Articles 4, 9 or 10, in either of the following circumstances⁴⁵:
- a. where any use of a pharmacologically active substance in food-producing animals constitutes a hazard to human health;
 - b. where no final conclusion concerning human health with regard to residues of a substance can be drawn.
- 7) Where it appears necessary for the protection of human health, the classification shall include conditions and restrictions for the use or application of a pharmacologically active substance used in veterinary medicinal products which is subject to a maximum residue limit, or for which no maximum residue limit has been set.

⁴⁵ *Some delegations (DE, UK) requested a clear prohibition of the use of substances not listed in 13 a, b or c in food producing animals to include non evaluated substances. Linked to this issue, some delegations (FR, DE, CZ, IT) questioned about substances not evaluated neither at codex level nor at EU level(how to consider them and where to place them). **SE stressed that the use for food production of animals treated with substances not approved for food producing animals shall be clearly prohibited. FR requested whether - as a consequence of 6 b) - substances which evaluation was not completed would be listed under the list foreseen under 13 2 d).***

Article 14
Procedure

- 1) For the purpose of the classification provided for in Article 13, the Commission shall prepare a draft Regulation within 30 days after receipt of the Agency's opinion referred to in Articles 4, 9(1) or 10. The Commission shall also prepare a draft Regulation⁴⁶ within 30 days after receipt of the result of a vote by the Community in favour of the establishment of a maximum residue limit in the *Codex Alimentarius* as referred to in Article 13(3).

- 2) Where the draft Regulation is not in accordance with the opinion of the Agency, the Commission shall provide a detailed explanation of the reasons for the differences⁴⁷.

- 3) The Regulation referred to in paragraph 1 shall be adopted by the Commission in accordance with, and within 30 days after the end of the regulatory procedure referred to in Article 20(2).

⁴⁶ *One delegation (FR) indicated that other legitimate factors could be used by the Commission to draft the regulation. **Article 14 should be modified accordingly to reflect this possibility.***

⁴⁷ *One delegation (DK) pointed out the need to reword this subparagraph as for codex MRL supported by the EU there will not be any opinion from the Agency. [...].*

Article 15
Analytical methods

The Agency shall consult Community reference laboratories for laboratory analysis of residues designated by the Commission in accordance with Regulation (EC) No 882/2004, on appropriate⁴⁸ analytical methods for detecting residues of pharmacologically active substances for which maximum residue limits have been determined in accordance with Article 13. The Agency shall provide the Community reference laboratories and national reference laboratories designated in accordance with Regulation (EC) No 882/2004 with those methods.

Article 16⁴⁹
Circulation of foodstuff

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 limits⁵⁰ where the provisions of this Regulation and its implementing measures have been complied with.

⁴⁸ *One delegation (UK) suggested the term 'appropriate' to be deleted. UK proposed to use instead wording of Article 23 (3) of Directive 2001/82.*

⁴⁹ *Some delegations (SE, ES) questioned the place of articles 15 and 16 that would be better placed under the final provisions chapter. One delegation (DE) wondered if article 16 was needed here.*

⁵⁰ *Some delegations (ES, DE) requested to introduce a reference to RPA if this article was kept. (UK) wondered if a reference to RPA was needed or not in Article 16.*

TITLE III

REFERENCE POINTS FOR ACTION

Article 17

Establishment and review

- 1) When it is appropriate in order to ensure the functioning of controls of food of animal origin imported or placed on the market, in accordance with Regulation (EC) No 882/2004, the Commission may establish reference points for action for residues from pharmacologically active substances⁵¹ which are not subject to a classification in accordance with Article 13(2) (a), (b) or (c).

- 2) Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 21(3).

- 3) The reference points for action shall be reviewed regularly in the light of technological progress⁵².

⁵¹ *Several delegations (FI, FR, ES, UK, BE, DE) requested for a clarification on the substances covered and also procedures (UK, ES). Some (FI,FR,DE) indicated that RPA should not be established for substances for which an MRL exists already even if not for all species or tissues. FR added that there shouldn't be any RPA established for a substance eligible to one of the procedures in Articles 3 or 9. On the contrary, ES considered that RPA should be fixed also for substances having an MRL, when extrapolation is not possible to all tissues and species.*

⁵² *Some delegations (FR, UK) requested that a review is carried out also in the light of scientific progress and monitoring and surveillance data (FR). UK recommended to keep RPA fixed for a certain period of time unless based on available data it appears that a new limit has to be set.*

Article 18

Methods for establishing reference points for action

- 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 methods⁵³.

- 2) The Commission may⁵⁴ forward a request to the European Food Safety Authority for a risk assessment as to whether the reference points for action are adequate to protect human health. In those cases the European Food Safety Authority shall ensure that the opinion is given to the Commission within 210 days after receipt of the request.

- 3) The risk assessment shall take account of rules to be adopted by the Commission in consultation with the European Food Safety Authority.

⁵³ *Some delegations (FI, SE) suggested to keep referring to analytical performance limit leading to further actions in controls and not to food safety, as these RPA are not scientifically based. One delegation (DK) indicated the need to use all available knowledge to set RPA.*

⁵⁴ *Several delegations (FR, DE, UK, ES, FI, DK) insisted on the need for a systematic scientific evaluation by EFSA, if necessary together with EMEA, before setting an RPA. Similarly, CZ indicated the need to verify that the content does not present a safety concern for consumer health. UK suggested introducing a new whereas specifying that 'RPA in no way condones the illegal use of non authorized substances to treat food producing animals and that any residues of that substance in food are undesirable'. In addition, UK questioned about future of MRPL and Directive 34/2005 and UK and SE wondered if MRPL are becoming RPA. If yes, UK suggested bringing here some text from 34/2005. BE and DE also asked for management measures to be introduced here. **FR requested that such measures are at least discussed in parallel. UK and FR questioned whether EFSA had been consulted on this proposal on RPAs. FR requested EFSA specifies conditions for the evaluation of RPAs.***

Those rules, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 21(3)⁵⁵.

Article 19

Community contribution to the support measures for reference points for action

If the application of this Title requires the Community to finance measures in support of the establishment and functioning of the reference points for action, Article 66(1)(c) of Regulation (EC) No 882/2004 shall apply.

TITLE IV

FINAL PROVISIONS

Article 20

Standing Committee on Veterinary Medicinal Products

- 1) The Commission shall be assisted by the Standing Committee on Veterinary Medicinal Products.

- 2) Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at one month.

⁵⁵ *The Presidency questioned on the reasons for differences on Comitology procedures for RPA and LMR.*

- 3) Where reference is made to this paragraph, Article 5a (1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 21

Standing Committee on the Food Chain and Animal Health

- 1) The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.
- 2) Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at one month.

- 3) Where reference is made to this paragraph, Article 5a (1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 22

Classification of pharmacologically active substances under Regulation 2377/90(EEC)

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.

Article 23

Repeal

Regulation (EEC) N° 2377/90 is repealed.

Annexes I to IV to the repealed Regulation shall continue to apply until the entry into force of the Regulation referred to in Article 22. Annex V to the repealed Regulation shall continue to apply until the entry into force of the measures referred to in Article 12(1).

References to the repealed Regulation shall be construed as references to this Regulation and to the Regulation referred to in Article 22.

Article 24

Entry into Force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament

The President

For the Council

The President