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from : General Secretariat

to : Council

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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) No 2377/90
- Progress report

Delegations will find enclosed the draft Regulation as suggested by the Presidency.

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 origin¹ 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 products² 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.

¹ 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).

² 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/EEC¹ 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 food² lays down specific rules for substances not resulting from intentional administration. Those substances should not be subject to the legislation on maximum residue limits.

¹ 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).

² 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 safety¹ 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 rules² 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 Agency³ 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.

¹ *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).*

² *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).*

³ *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, such as disinfectants are used in animal husbandry. These products are biocidal products as defined in Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market. 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 laboratory analysis is technically feasible in order to facilitate intra-Community trade and imports, without undermining a high level of human health protection in the Community. However, the setting of reference points for control action should in no way precondone the illegal use of non authorized substances to treat food producing animals. Therefore, any residues of those substances in food are in fact undesirable.
- (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 Commission¹.

¹ 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, with a view to ensuring food safety, rules and procedures in order to establish the following:
 - (a) the maximum concentration of a residue of a pharmacologically active substance contained in veterinary medicinal products or in biocidal products used in animal husbandry which may be permitted in food of animal origin ("maximum residue limit");
 - (b) the level of a residue of a pharmacologically active substance established for control purposes in the case of certain substances for which maximum residue limit has not been set pursuant to this regulation ("reference point for action").

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;
 - (b) substances falling within the scope of Regulation (ECC) No 315/93;

3. This regulation shall apply without prejudice to Community legislation prohibiting the use in food producing animals of certain substances having a hormonal action or thyrostatic action and of beta-agonists 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;
- 2) “food-producing animals”: means animals bred, raised, kept, slaughtered or harvested for the purpose of producing food.

TITLE II

MAXIMUM RESIDUE LIMITS

CHAPTER 1 RISK ASSESSMENT AND RISK MANAGEMENT

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

Article 3

Application for an opinion of the Agency

Except in cases where the *Codex Alimentarius* procedure referred to in Article 13 (3) applies, any pharmacologically active substance intended for use in veterinary medicinal products in the Community for administration to food-producing animals shall be subject to an opinion of the European Medicines Agency ("the Agency") on the maximum residue limit, formulated by the Committee for Medicinal Products for Veterinary Use ('the Committee') established respectively by articles 55 and 30 of Regulation (EC) No 726/2004.

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

Article 4
Opinion of the Agency

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

- 1) 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.

Article 5
Extrapolation

- 1) With a view to ensuring the availability of authorised veterinary medicinal products for conditions affecting food-producing species, the Agency, whilst bearing in mind the need to ensure a high level of human health protection, shall, when carrying out scientific risk assessments and when drawing up risk management recommendations, consider:
 - (a) using maximum residue limits established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species, or

 - (b) using maximum residue limits established for a pharmacologically active substance in one or more species for other species, or

 - (c) using maximum residue limits established for a pharmacologically active substance in a particular foodstuff derived from one species for another foodstuff derived from other species.

- 2) The Commission shall, in consultation with the Agency, adopt rules on the use of a maximum residue limit of a particular foodstuff for another foodstuff of the same species, or of one or more species for other species. 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.

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).

Article 6

Scientific risk assessment

- 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).
- 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 toxicological, pharmacological or microbiological effects in human beings;
 - c. residues that occur in food of plant origin or come from the environment.

- 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.

Article 7

Risk management recommendations

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

- a) 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;
- b) other legitimate factors such as the technological aspects of food and feed 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;
- 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, the level of that maximum residue limit and, where appropriate, any conditions or restrictions for the use of the substance concerned;

- d) 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 information, that it is not possible to establish a maximum residue limit.

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.

- 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 conclusions.

Section 2 Pharmacologically active substances contained in veterinary medicinal products used outside the Community or in biocidal products used in animal husbandry

Article 9

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

- 1) The Commission or Member States may forward to the Agency requests for an opinion on maximum residue limits for pharmacologically active substances in one of the following circumstances:
 - (a) the substance concerned is authorised for use in a veterinary medicinal product in a third country and no application in accordance with Article 3 has been made for that substance or,
 - (b) the substance concerned is included in a medicinal product intended to be used in accordance with Article 11 of Directive 2001/82/EC but no application in accordance with Article 3 has been made for that substance or,
 - (c) the substance concerned is included in a biocidal product used in animal husbandry, and a maximum residue limit should be established pursuant to Article 10 (2) (ii) of Directive 98/8.

2) Articles 4 to 7 shall apply.

Requests for an opinion referred to in paragraph 1 shall comply with the format and content laid down by the Commission as provided for in Article 12(1).

The Agency shall ensure that the opinion of the Committee is given within 210 days following the receipt of the request by the Commission or Member State. 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.

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 which made the request, stating the grounds for its conclusions.

Section 3 Common provisions

Article 10

Review of an opinion

Where the Commission, any person having applied for an opinion under Article 3, or a Member State, 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) to (4) or Article 9(2) and (3) respectively shall apply to the new opinion.

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) In accordance with the regulatory procedure with scrutiny referred to in Article 20(3), the Commission shall, in consultation with the Agency, adopt rules designed to amend non-essential elements of this Regulation by supplementing it as referred to in Article 5 (2).

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 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 and subsequently reviewed 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 the adoption at the *Codex Alimentarius* Commission, without objection from the Community, of a maximum residue limit for a pharmacologically active substance intended for use in a veterinary medicinal product. 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.

- 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 circumstances:

- 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.

Article 13 bis

Accelerated procedure for Agency's opinion

In specific cases, where urgent authorisation of a veterinary medicinal product or a biocidal product is needed to protect human health, animal health or animal welfare, the Commission, any person applying for an opinion under Article 3, or a Member State may request an accelerated evaluation procedure of the Agency on the maximum residue limit of the pharmacologically active substance included in such products.

The format and content of the request shall be laid down by the Commission as provided for in Article 12(1).

By way of derogation to Articles 9 (2) and 8 (2), the Agency shall ensure that the opinion of the Committee is given within [150 days] following the receipt of the request.

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 Regulation within 30 days after receipt of the result of an adoption by the *Codex Alimentarius* Commission, without objection from the Community, of a maximum residue limit as referred to in Article 13(3).
- 2) Where the opinion of the Agency is required and the draft Regulation is not in accordance with this opinion, the Commission shall provide a detailed explanation of the reasons for the differences.
- 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).
- 4) In case of accelerated procedure as referred to in Article 13 bis the Commission shall adopt the Regulation referred to in paragraph 1 in accordance with, and within [15] days after the end of the regulatory procedure referred to in Article 20(2).

TITLE III

REFERENCE POINTS FOR ACTION

Article 15

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 substances 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 technical and scientific progress.

Article 16

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 methods.

- 2) If the basic scientific data on the substance in question is available, the Commission shall 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.

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).

Article 17

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 18

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 appropriate 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 19
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 limits or reference points for action where the provisions of this Regulation and its implementing measures have been complied with.

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.

- 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)

- 1) 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.
- 2) For any substance referred to in paragraph 1, for which a maximum residue limit was established under Regulation (EEC) 2377/90, the Commission or Member States may also forward to the Agency requests for an opinion on extrapolation to other species or tissues in accordance with Article 5.

The procedure of Article 14 shall apply.

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