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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

{SEC(2007)484}
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(presented by the Commission)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

- **Grounds for and objectives of the proposal**

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

In order to achieve the aim pursued, the following specific objectives have to be born in mind:

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

- **General context**

The current legal framework for MRLs has lead to particular problems:

(a) Availability of veterinary medicines has decreased to an extent that creates adverse effects for public and animal health and animal welfare.

(b) International standards supported by the EU cannot be included in Community legislation without a new scientific assessment by the European Medicines Agency.

(c) Control services of Member States have no points of reference in particular for substances detected in food from third countries.

(d) The current legislation is difficult to understand.

In the absence of a change of existing legislation, a further deterioration of the availability of veterinary medicinal products can be expected with a negative impact on human health, animal health and animal welfare. Furthermore, the negative impact on the animal health industry and food industry would be increased over time.

- **Existing provisions in the area of the proposal**

Regulation (EEC) No 2377/90

The main changes proposed are the following:

- make the assessment of possibilities for extrapolation a compulsory part of the overall scientific assessment and create a legal basis for the Commission to lay down the principles for applying extrapolation;
- introduce an obligation to adapt Community legislation to include MRLs set by Codex with the support of the EU;
- create a specific legal framework to set maximum residue limits for pharmacologically active substances not intended to be authorised as veterinary medicines in particular for control purposes and for imported food;

- **Consistency with the other policies and objectives of the Union**

Not applicable.

2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

- **Consultation of interested parties**

Consultation methods, main sectors targeted and general profile of respondents

The Commission published a Reflection Paper in December 2003 requesting comments on the various points raised for the reconsideration and modification of the Community legislation concerning residues of veterinary medicinal products. This paper analysed the reasons for the difficulties encountered in the application of the existing legislation and sought to propose alternative ways to achieve a high level of consumer protection coupled with continued availability and development of veterinary medicinal products for the European market and good functioning of the intra- and extra Community trade in food of animal origin. Comments on ten main questions were solicited in the Reflection Paper.

The Reflection Paper was published on the websites of Directorate General Enterprises and Industry and Directorate General Health and Consumer Protection of the European Commission.

Two Member States meetings took place on 13 December 2004 and 11 July 2005. At the meeting on 13 December 2004 on the follow-up of the Reflection Paper on residues in food conceptual ideas for legislative amendments were discussed and it was agreed to continue the discussion in six expert Working Groups during spring 2005.

At the meeting with the Member States on 11 July 2005, proposals for changes in the legislation on residues of pharmacologically active substances used in food producing animals identified by the six Working Groups were presented in a Discussion Paper for discussion with Member States representatives.

European bodies which sent comments on the Reflection Paper on residues in food were invited to a meeting on 18th July 2005. Twenty one European organizations attended the meeting. Proposals for changes in the legislation on residues of pharmacologically active substances used in food producing animals identified by six Working Group of Member States' experts were presented in the same Discussion Paper than the one presented to the Member States representatives.

In order to assess the impact of the different possible options, the Commission consulted stakeholders with questionnaires. They were requested to complete a specific questionnaire ranking the different potential solutions identified by the six expert working Groups. The questionnaire was sent to the working groups' experts and to professional organizations' representatives. They were asked to provide their assessment on the key areas of interest.

The impacts were evaluated with a distinction between a positive or a negative impact. A semi-quantitative assessment was provided.

Summary of responses and how they have been taken into account

Public consultation on the Reflection Paper closed end of March 2003. Comments were received from over 40 sources including 12 Member States, the European Medicines Agency, one European association for the veterinary profession, the pharmaceutical animal health industry and its European asssociation, the organisations of primary producers of foodstuff of animal origin, umbrella organisations of the European food industry as well as European organisations for particular types of food production (dairy, meat and sausages, fish, honey, dried fruit, nuts and spices), two countries outside the EU and a few individual persons.

The meetings with Member States' experts and stakeholders on the Discussion Paper resulted in important guidance for the Commission on major items. The main ideas of this consultation were taken on board by the Commission in the drafting of the legal proposal. The semi-quantitative assessment based on stakelholders interviews was used for the impact assessment.

An open consultation was conducted over the internet from 18/12/2003 to 20/03/2004. The Commission received 40 response(s). The results are available on http://europa.eu.int/common/entreprise/pharmaceuticals/pharmacos/archives 2004.htm.

- **Collection and use of expertise**

There was no need for external expertise.

- **Impact assessment**

- Option 1 - To maintain the current legal framework. Maintaining the current legal framework would mean that existing availability problems would be unresolved. The existing practice of only limited use of extrapolation one residue limit to different tissues and species would continue. Consistency with international standards could not be promoted as the current legislation requires new scientific assessment. Moreover, the lack of harmonisation in the area of control would persist with different control levels of Member States without a clear scientific basis. The general lack of clarity of the legislation would not be overcome and risks of erroneous application would continue.

- Option 2 - To review the existing regulation by incorporating specific legal provisions and amending existing rules to address the specific objectives. A review provides the chance to overcome the existing shortage of veterinary medicines in the medium and long term by establishing a clear legal basis for extended use of one residue limit for other tissues and species. International standards supported by the European Union could directly be incorporated in European Union legislation. Furthermore, the food industry and third countries would be provided with a clear science-based European Union reference for residues of substances not intended for use in veterinary medicines in the Community. Finally, improved clarity could be achieved with the review of the legislation, in particular by creating one consolidated list of substances with their different classifications. This should result in improved compliance. Overall the administrative burden would be reduced.

- Option 3 - To replace the existing legislation by guidelines. The option of replacing the existing legislation by guidelines would create public health risks Deregulation of the internal market and different levels of food safety could lead to crisis in consumer confidence with major economic losses. Self-regulation would result in a reduced administrative burden, but this effect would be offset by enforcement mechanisms to be created under such system.

3. LEGAL ELEMENTS OF THE PROPOSAL

- **Summary of the proposed action**

The legal proposal addresses the shortcomings of the current situation by amending on substance the existing legal framework on maximum residue limits while leaving the overall system of setting maximum residue limits based on scientific assessment intact. The main changes proposed are the following:

- make the assessment of possibilies for extrapolation a compulsory part of the overall scientific assessment and create a legal basis for the Commission to lay down the principles for applying extrapolation;

- introduce an obligation to adapt Community legislation to include MRLs set by Codex with the support of the EU;

- create a specific legal framework to set maximum residue limits for pharmacologically active substances not intended to be authorised as veterinary medicines in particular for control purposes and for imported food;

- rearrange the sequence of articles in order to create a logical structure, differentiating in particular risk assessment and risk management provisions;

- integrate in a separate Commission regulation the rules (MRLs, conditions of use, prohibitions) relating to individual substances, which are currently in 4 annexes of the current basic act.

- **Legal basis**

Article 37, Article 152 (4) (b) of the Treaty

- **Subsidiarity principle**

The proposal falls under the exclusive competence of the Community. The subsidiarity principle therefore does not apply.

- **Proportionality principle**

The proposal complies with the proportionality principle for the following reason(s).

The setting of residue limits is an integral part of the Community system of authorisations for veterinary medicinal product and of food controls in the EU. While controls are carried out by Member States, there is no choice than fixing the same residue limits for the benefit of the free circulation of goods in the EU.

The objective is to reduce the administrative burden for economic operators compared with the burden caused by the existing legal framework.

The administrative burden would be reduced by three factors:

– the absence of the need for a separate scientific assessment of active substances which have been assessed by Codex. The reduction would result on the one hand from the non-delivery of a full file including all requested data and on the other hand from the speeding-up of the process of authorising the veterinary medicine in question.

– the reduction of scientific data to be provided, if the scientific committee extends the application of extrapolation. Actually, as the new regulation would require the committee to consider extrapolation and to balance their decision on setting maximum residue limits with the need to ensure availability of medicines, broader use of extrapolation can be expected.

– The harmonisation of control standards for certain residues in food. Industry currently faces an unjustified burden by divergent control reference points in different Member States. The benefits of the common market can not be fully realised for this reason and also imports from third countries face unnecessary obstacles. Refusal of consignments or even destruction of goods cause drastic economic consequences for producers and traders, which could be avoided to a large extent with one single transparent reference point applied by competent authorities in all Member States.

- **Choice of instruments**

Proposed instruments: regulation.

Other means would not be adequate for the following reason(s).

Self regulation would result in the total deregulation of the single market and most probably major discrepancies in veterinary medicinal products availability as well as discrepancies in level of safety of food of animal origin within the Community. Consumer confidence on meat and meat products is currently built on a single harmonised set of rules applied under the strict supervision of competent authorities. Self regulation could not assure a comparable level of harmonisation and enforcement. Clearly, risks for consumer health would increase as a result of self regulation because there would be no comparable enforcement mechanism available ensuring the respect of adequate residue limits.

A directive would not be adequate, because the residue limits are directly applicable. Furthermore, uniform administrative or scientific procedures have to apply for the applications for setting residue limits to the European Medicines Agency (EMEA), scientific assessments by the EMEA and the scientific opinions issued by the EMEA.

4. BUDGETARY IMPLICATION

The proposal has no implication for the Community budget.

5. ADDITIONAL INFORMATION

- **Simplification**

The proposal provides for simplification of legislation.

The proposal intends

- to rearrange the sequence of articles in order to create a logical structure, differentiating in particular risk assessment and risk management provisions;

- integrate in one single annex of a separate Commission regulation the rules (MRLs, conditions of use, prohibitions) relating to individual substances, which are currently in 4 different annexes.

- the public authorities profit from the improved readibility of the residue legislation. In particular the consolidation in one single regulation of all residue limits makes the work of enforcement by control authorities easier.

- timelines for procedural management would be clearly fixed for all parties involved. International standards supported by the Community would be automatically recognised without the need to submit any specific application at Community level, and thus avoiding duplication of work. The development time and cost for new products should be accordingly reduced. Animal health and welfare and consumer health shall benefit significantly by making legislation clearer and thus potentially improving compliance with legislative requirements.

- furthermore, the review of the MRL Regulation would also introduce more transparency for all end users. The compilation of all substances and their MRL related provisions in one Commission regulation replacing the existing four annexes would improve the readability and comprehension, in particular if sorted to the alphabet. Veterinarians should have access to a unique document collating all the necessary information on all substances evaluated as they are allowed to use in exceptional circumstances products for a food producing species without an explicit authorisation of this product (article 11 of Directive 2001/82/EC). Thereby simplification would help to improve availability of veterinary medicine for certain animal species or conditions. Equally third countries exporting foodstuffs of animal origin in the Community would benefit from that simplification and clarification of the Community requirements as compliance should get easier.

- The proposal is included in the Commission's rolling programme for up-date and simplification of the acquis communautaire.

- **Repeal of existing legislation**

The adoption of the proposal will lead to the repeal of existing legislation.

- **Recasting**

The proposal involves recasting.

- **European Economic Area**

The proposed act concerns an EEA matter and should therefore extend to the European Economic Area.

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(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 Commission[1],

Having regard to the opinion of the European Economic and Social Committee[2],

Having regard to the opinion of the Committee of the Regions[3],

Acting in accordance with the procedure referred to in Article 251 of the Treaty[4],

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 origin[5] 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.

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1 OJ C , , p. .
2 OJ C , , p. .
3 OJ C , , p. .
4 OJ C , , p. .
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).

(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 products[6] 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) 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/EEC[7] 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 food[8] lays down specific rules for substances not resulting from intentional administration. Those substances should not be subject to the legislation on maximum residue limits.

(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 safety[9] 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 rules[10] lays down general rules

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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).

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 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).

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 Agency[11] 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.

(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.

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[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).

(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 Commission[12].

(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.

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[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).

(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 following:

   (a) the maximum concentration of a residue of a pharmacologically active substance which may be permitted in food of animal origin ("maximum residue limit");

   (b) 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").

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 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:

(a) '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;

(b) "food-producing animals": means animals bred, raised, kept, slaughtered or harvested specifically 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

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 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').

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 Agency.

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.

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.

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 unintended 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 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.

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 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, 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;

(d) 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 information.

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 not intended for use in veterinary medicinal products

Article 9
Agency's opinion requested by the Commission or the Member States

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.

Articles 4 to 8 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.

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 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 9, 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.

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.

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 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 favour 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.* 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 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 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).

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 differences.

2. 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).

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 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 16
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 where the provisions of this Regulation and its implementing measures have been complied with.

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 substances which are not subject to a classification in accordance with Article 13(2)(a), (b) or (c).

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).

The reference points for action shall be reviewed regularly in the light of technological progress.

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 methods.

2. The Commission may 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 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.

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

1. 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	*For the Council*
The President	*The President*

LEGISLATIVE FINANCIAL STATEMENT

TITLE OF ACTION: 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, repealing Regulation (EEC) No 2377/90

Policy area(s): Internal Market (Article 95 TEC).

Activit(y/ies): The following policies are concerned by the proposal:

– Review of the Community pharmaceutical acquis as regards residues of veterinary medicinal products

– Public health

– Internal market

1. BUDGET LINE(S) + HEADING(S)

02.030201 – European Medicines Agency — Subsidy under Titles 1 and 2

02.030202 – European Medicines Agency — Subsidy under Title 3

2. OVERALL FIGURES

2.1. Total allocation for action (Part B): 0€ million for commitment

Revenues: The proposed regulation's financial impact on revenues is uncertain. An increase in applications for authorisations of veterinary medicinal products could lead to an increase of fee revenues for the EMEA.

Expenditure: The proposed review will not change the principle, that the system of residue limits is operated by the European Medicines Agency (EMEA) and the Commission. Additional scientific assessments will be required for residue limits for control purposes while less assessments will result from the taking over of limits set by Codex alimentarius and from extrapolation requirements. In overall terms the review will thus have a very limited impact on resources which can not be quantified.

2.2. Period of application:

The assumption is that the proposed regulation would apply from the end of 2009.

2.3. Overall multiannual estimate of expenditure:

Costs for the Commission: None.

Costs for the European Medicines Agency (EMEA): Negligible or none.

2.4. Compatibility with financial programming and financial perspective

[X] Proposal is compatible with existing financial programming.

2.5. Financial impact on revenue:

[X] Proposal has a negligible financial impact

3. BUDGET CHARACTERISTICS

Type of expenditure		New	EFTA contribution	Contributions form applicant countries	Heading in financial perspective

4. LEGAL BASIS

– Treaty establishing the European Community – Articles 37, and 152 (4) (b)

5. DESCRIPTION AND GROUNDS

5.1. Need for Community intervention

The need for the review stems from the experience with the existing legal framework for residue limits which has lead to very complex legal provisions difficult to read and understand and to a lack of veterinary medicines for food producing animals. Consequently the specific objectives of the proposal are:

- To improve availability of veterinary medicinal products for food producing animals;
- To simplify the existing legislation;
- To provide clear references for the control of pharmacologically active substances in food;
- To ensure consistency with international standards.

5.2. Action envisaged and budget intervention arrangements

Expected results with a budgetary implication can be measured in terms of:

– The number of marketing authorisations for veterinary medicinal products.

5.3. Methods of implementation

Centralised Management, directly by the Commission and indirectly by delegation to a body set up by the Communities as referred to in Article 185 of the Financial Regulation (EMEA). The proposed regulation confirms the two step procedure for the setting of residue limits: a first step (stage of scientific assessment) conducted by the EMEA and a second step (decision-making stage) conducted by the Commission.

6. FINANCIAL IMPACT

See section 2.

7. IMPACT ON STAFF AND ADMINISTRATIVE EXPENDITURE

See section 2.

8. FOLLOW-UP AND EVALUATION

8.1. Follow-up arrangements

Articles 67 to 70 of Regulation (EC) No 726/2004 lay down financial provisions for the annual preparation, execution, monitoring and reporting of the EMEA budget, including costs resulting from the evaluation, supervision and post-authorisation vigilance of medicinal products. Consequently, adequate monitoring data regarding the fee revenues under the proposed regulation will be collected in the context of the implementation of these Articles.

8.2. Arrangements and schedule for the planned evaluation

After 4 years after entry into force, the Commission should evaluate the experience acquired as a result of the operation of the review of the system establishing maximum residue limits, and this will include details set up under its implementing provisions.

9. ANTI-FRAUD MEASURES

The European Medicines Agency has specific budgetary control mechanisms and procedures. The Management Board, which comprises representatives of the Member States, the Commission and the European Parliament, adopts the budget (Article 66(f) of Regulation (EC) No 726/2004), as well as the internal financial provisions (Article 66(g)). The European Court of Auditors examines the execution of the budget each year (Article 68.3).

Regarding fraud, corruption and other unlawful activities, the provisions of Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF) apply to the EMEA without restriction. Besides, a decision concerning co-operation with the OLAF was already adopted on 1 June 1999 (EMEA/D/15007/99).

Finally, the Quality Management System applied by the Agency supports a continuous review, whose objective is to ensure that the correct procedures are followed and that these procedures and policies are pertinent and efficient. Several internal audits are undertaken each year as part of this process.