Establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin


(Codecision procedure: first reading)

The European Parliament,

— having regard to the Commission proposal to the European Parliament and the Council (COM(2007)0194),
— having regard to Article 251(2) and Articles 37 and 152(4)(b) of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0113/2007),
— having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,
— having regard to Rules 51 and 35 of its Rules of Procedure,
— having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinion of the Committee on Agriculture and Rural Development (A6-0190/2008),

1. Approves the Commission proposal as amended;
2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;
3. Instructs its President to forward its position to the Council and Commission.

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission,
Having regard to the opinion of the European Economic and Social Committee (1),

Having regard to the opinion of the Committee of the Regions (2),

Acting in accordance with the procedure referred to in Article 251 of the Treaty (3),

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) Despite the existence of the procedure laid down in Articles 10 and 11 of 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 (4) (the ‘cascade’ procedure) to enable the treatment of animals where there is no suitable veterinary medicine authorised, there remain many unmet therapeutic needs for veterinary medicinal products in the European Union. There is an urgent need to address this challenge through a fundamental review of the legislation governing the authorisation of veterinary medicines. Such a review should balance innovation and the competitiveness of the animal health industry with the regulatory requirements. Special attention needs to be paid to the authorisation of generic veterinary medicines where data exclusivity waivers from the safety and efficacy standards do not apply to the requirements for the environmental impact studies. Particular care must also be taken to cater for the specificities of the animal health sector in the EU, as it is a multi-species, complex, and often limited market which is nonetheless vital to the realisation of the potential of the agriculture, apiculture, aquaculture and bloodstock sectors and to the security of the EU food supplies.

(3) In order to protect public 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. Other scientific assessments of the safety of substances concerned which may have been undertaken by international organisations or scientific committees established within the Community should also be taken into account.

(4) 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.

(5) 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.

(6) Directive 2001/82/EC (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.

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(2) OJ C ...
(7) In the light of the European Parliament’s resolution of 3 May 2001 (1) on the availability of veterinary medicinal products, 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.

(8) 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.

(9) Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists (2) 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.

(10) Council Regulation (EEC) No 315/93 (3) of 8 February 1993 laying down community procedures for contaminants in food (4) lays down specific rules for substances not resulting from intentional administration. Those substances should not be subject to the legislation on maximum residue limits.

(11) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 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 (5) 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.

(12) 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 (6) 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. Priority should be given to the detection of the use of prohibited substances and part of the samples should be selected according to risk analysis principles.

(13) 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 (7) 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.

(14) 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.

(15) 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.

(2) OJ L 125, 23.5.1996, p. 3.
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.

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. In this respect, the adequacy of the safety factors already inherent in the system should be taken into account in order to ensure that animal welfare is not compromised.

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.

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.

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.

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 maintained 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.

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.
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 serve as a pretext for condoning the illegal use of non-authorised substances to treat food-producing animals. Therefore, any residues of those substances in food must be considered undesirable.

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.

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 (1).

In particular, the Commission should be empowered 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, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Since the objectives of this Regulation, 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.

For the sake of clarity, it is therefore necessary to replace Regulation (EEC) No 2377/90 with a new regulation.

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 (EEC) No 2377/90 and implementing provisions for this new regulation,

HAVE ADOPTED THIS REGULATION:

TITLE I
GENERAL PROVISIONS

Article 1

Subject matter and scope

1. For the purpose of ensuring food safety, 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 level of a residue of a pharmacologically active substance, established for control reasons in the case of certain substances for which a maximum residue limit has not been laid down in accordance with this Regulation (reference points 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 (EEC) 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
1. 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’).

2. 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. Such recommendations shall take into account any relevant scientific findings of the European Food Safety Authority, by way of letters of cooperation.

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 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 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

1. The risk management recommendations shall be based on the scientific risk assessment performed in accordance with Article 6 and shall consist of 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 animal feed production, the feasibility of controls, conditions of use and application of the substances in veterinary medicinal products, compliance with good veterinary practice and the likelihood of misuse or illegal use; misuse includes the prophylactic use of veterinary medicinal products when diseases can be managed by making proportionate and reasonable changes to the conditions in which animals are kept;

(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) 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.

2. Veterinary medicinal products which do not have a maximum residue limit for equidae, which are not included in Annex IV of Regulation (EEC) No 2377/90 or in Article 13(2) of this Regulation, and which are used ‘off-label’, as defined in Article 1(16) of Directive 2001/82/EC, and under the provisions of Articles 10 and 11 in Directive 2001/82/EC and not administered intra-muscularly or subcutaneously, shall have a nominal withdrawal period of six months.

3. The use of pharmaceuticals containing pharmacologically active ingredients not on the list of substances essential for the treatment of equidae referred to in Article 10(3) of Directive 2001/82/EC and not administered intra-muscularly or subcutaneously, shall have a nominal withdrawal period of six months.

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.

5. In specific cases where urgent authorisation is required to ensure the protection of human health and animal health and welfare, the Commission may, in accordance with the regulatory procedure with scrutiny referred to in Article 23(3), establish a provisional maximum residue limit for a period not exceeding five years.
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. The Commission, Member States or a third party pursuing legitimate interests may forward to the Agency requests for an opinion on maximum residue limits for pharmacologically active substances in any of the following circumstances:

(a) the substance in question is authorised for use in a veterinary medicinal product in a third country and no application in respect of that substance has been submitted pursuant to Article 3, or

(b) the substance in question is included in a medicinal product intended to be used pursuant to Article 11 of Directive 2001/82/EC and no application in respect of that substance has been submitted pursuant to Article 3 of this Regulation, or

(c) the substance in question is included in a biocidal product used in animal-rearing and a maximum residue limit must be established pursuant to Article 10(2)(ii)(b) of Directive 98/8/EC of the European Parliament and of the Council (1), or

(d) the substance in question can be used to treat animals effectively, in the case of minor species or minor uses, where no specific medicines yet exist.

2. In the circumstances of paragraph 1(d), where minor species or uses are concerned, the request may be forwarded to the Agency by an interested party or organisation.

3. Articles 4 to 7 shall apply.

4. The applications for an opinion which are referred to in paragraph 1 shall comply with the format and content requirements laid down by the Commission pursuant to Article 12(1).

5. 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.

6. 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, any person who has submitted an application for an opinion pursuant to 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) to (4) or Article 9(5) and (6) 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. The Commission shall, in consultation with the Agency, adopt rules on:
   
   (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.

The rules referred to in point (a) shall be adopted in accordance with the regulatory procedure referred to in Article 23(2) and, in the case of point (b), in accordance with the regulatory procedure with scrutiny referred to in Article 23(3).

2. The Commission shall, in consultation with the Agency and interested parties, 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 23(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 presence of a substance or residues thereof in a product of animal origin.
3. A maximum residue limit shall be laid down where it appears necessary for the protection of human health:

(a) pursuant to an opinion of the Agency in accordance with Articles 4, 9 or 10; or

(b) pursuant to a vote by the Community Delegation at the Codex Alimentarius in favour of the establishment of a maximum residue limit for a pharmacologically active substance intended for use in a veterinary medicinal product, provided that the scientific data taken into consideration have been made available to the Community representative in Codex Alimentarius prior to the vote in the Codex Alimentarius Commission. In this 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 risk 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 presence of a substance or residues thereof in a product of animal origin shall be prohibited, pursuant to an opinion in accordance with Articles 4, 9 or 10, in either of the following circumstances:

(a) where any presence of a pharmacologically active substance or residues thereof in foods of animal origin constitutes a risk to human health;

(b) where no final conclusion concerning the effect on human health of 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
Accelerated procedure for an Agency opinion

1. In specific cases where a veterinary medicinal product or a biocidal product needs to be authorised as a matter of urgency for reasons relating to the protection of public health or of animal health or welfare, the Commission, any person who has requested an opinion pursuant to Article 3 or a Member State may ask the Agency to carry out an accelerated procedure for the assessment of the maximum residue limit of a pharmacologically active substance contained in those products.

2. The format and the content of the application shall be laid down by the Commission pursuant to the provisions of Article 12(1).

3. Notwithstanding the provisions of Articles 8(2) and 9(2), the Agency shall ensure that the Committee is able to issue its opinion within 150 days following receipt of the application.
Article 15

Normal 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 Delegation at the Codex Alimentarius in favour of the establishment of a maximum residue limit 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 90 days after the end of the regulatory procedure with scrutiny referred to in Article 23(3).

3. In the case of the accelerated procedure referred to in Article 14, the Commission shall adopt the Regulation referred to in paragraph 1 of this Article within 15 days of the end of the regulatory procedure referred to in Article 23(2).

Article 16

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 harmonised sampling for detecting residues of pharmacologically active substances for which maximum residue limits have been determined in accordance with Article 13 of this Regulation. The Agency shall provide the Community reference laboratories and national reference laboratories designated in accordance with Regulation (EC) No 882/2004 with information concerning those methods.

Article 17

Circulation of foodstuff

Member States shall prohibit the import and placing on the market of food of animal origin containing residues resulting from the illegal administration of pharmacologically active substances which are not subject to a classification in accordance with Article 13(2)(a), (b) or (c).

Accordingly, imports from third countries of food containing residues resulting from the illegal administration of substances whose use is use is banned within the European Union shall be prohibited in the interests of public health.

TITLE III

REFERENCE POINTS FOR ACTION

Article 18

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).
The principles of risk assessment pursuant to Articles 4 to 8 shall be applied in order to guarantee a high level of health protection.

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 23(3).

2. The reference points for action shall be reviewed in the light of any new data concerning the protection of human health and the food chain.

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

Article 19
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 including scientific methods 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 23(3).

Article 20
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.

Article 21
Placing on the market
If the maximum residue limits or reference quantities established under this Regulation are exceeded, the product shall not be placed on the market as a foodstuff, transformed into foodstuffs or mixed with foodstuffs.
Article 22

Implementing reference points for action

1. Where checks are carried out on food of animal origin and the results of analytical tests confirm the presence of a pharmacologically active substance which is not subject to a classification in accordance with Article 13(2)(a), (b) or (c) at a level equal to or higher than its reference point for action, the relevant batch shall be deemed not to comply with Community legislation.

2. Where the results of analytical tests carried out on food of animal origin are below the reference points for action, the product’s entry into the food chain shall be authorised. The competent authority shall retain a record of the findings in case of recurrence. Where the results of analytical tests on products of the same origin show a recurrent pattern indicating a potential problem, the competent authority shall inform the Commission and the other Member States in the Standing Committee on the Food Chain and Animal Health. The Commission shall bring the matter to the attention of the competent authority of the country or countries of origin and shall submit appropriate proposals.

3. Detailed rules shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(3).

TITLE IV

FINAL PROVISIONS

Article 23

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 24

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 25

Classification of pharmacologically active substances under Regulation (EEC) No 2377/90

By … (*), the Commission shall adopt, in accordance with the regulatory procedure with scrutiny referred to in Article 23(3), a Regulation containing the pharmacologically active substances and their classification regarding maximum residues limits in accordance with Annexes I to IV of Regulation (EEC) No 2377/90.

Article 26

Report to the European Parliament and the Council

The Commission shall, by … (**), submit a report to the European Parliament and the Council. The report shall, in particular, review the experience gained from the application of this Regulation. The report shall, if appropriate, be accompanied by relevant proposals.

Article 27

Repeal

1. Regulation (EEC) No 2377/90 is repealed.

2. Annexes I to IV to the repealed Regulation shall continue to apply until the entry into force of the Regulation referred to in Article 25. Annex V to the repealed Regulation shall continue to apply until the entry into force of the measures referred to in Article 12(1).

3. References to the repealed Regulation shall be construed as references to this Regulation and to the Regulation referred to in Article 25.

Article 28

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 …, on …

For the European Parliament       For the Council
The President                     The President

(*) 90 days after the entry into force of this Regulation.
(**) Five years after the entry into force of this Regulation.