Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (Text with EEA relevance)

TITLE II

MAXIMUM RESIDUE LIMITS

CHAPTER I

Risk assessment and risk management

Section 1

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

Article 3

Application for an opinion of the Agency

Except in cases where the Codex Alimentarius procedure referred to in Article 14(3) of this Regulation applies, any pharmacologically active substance intended for use in the Community in veterinary medicinal products which are to be administered to food-producing animals shall be subject to an opinion of the European Medicines Agency (the Agency) established by Article 55 of Regulation (EC) No 726/2004 on the maximum residue limit, formulated by the Committee for Medicinal Products for Veterinary Use (the Committee) established by Article 30 of that Regulation.

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

Article 4

Opinion of the Agency

1 The opinion of the Agency shall consist of 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. The opinion shall take account of any relevant scientific findings of the European Food Safety Authority (EFSA) established by Article 22 of Regulation (EC) No 178/2002.

Article 5

Extrapolation

With a view to ensuring the availability of authorised veterinary medicinal products for conditions affecting food-producing animals, the Agency, while ensuring a high level of protection of human health, 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 maximum residue limits established for a pharmacologically active substance 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, 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 13(2).

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 that come from the environment.

3 If the metabolism and depletion of the substance cannot be assessed, the scientific risk assessment may take into account monitoring data or exposure data.

Article 7

Risk management recommendations

The risk management recommendations shall be based on the scientific risk assessment performed in accordance with Article 6 and shall consist 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 feed production, the feasibility of controls, conditions of use and application of the substances in veterinary medicinal products, good practice in the use of veterinary medicinal and biocidal products and the likelihood of misuse or illegal use;

(c) whether or not a maximum residue limit or a provisional maximum residue limit should be established for a pharmacologically active substance in veterinary medicinal products, the level of that maximum residue limit and, where appropriate, any conditions or restrictions for the use of the substance concerned;

(d) whether the data provided are not sufficient to allow a safe limit to be identified, or whether a final conclusion concerning human health with regard to residues of a substance cannot be established given the lack of scientific information. In either case, no maximum residue limit may be recommended.

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 13(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 of receipt of a valid application in accordance with Article 3 and paragraph 1 of this Article. This time limit shall be suspended where the Agency requests the submission of supplementary information on the given substance within a specific time period, and shall remain suspended until such time as the requested supplementary information 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 submit the detailed grounds for his request to the Agency within 60 days of receipt of the opinion.

Within 60 days of receipt of the applicant's grounds for a re-examination request, the Committee shall consider whether its opinion should be revised and adopt the final opinion. The reasons for the conclusion reached on the request shall be annexed to the final opinion.

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

Section 2

Other pharmacologically active substances for which an opinion of the Agency may be requested

Article 9

Opinion of the Agency requested by the Commission or a Member State

1 The Commission or a Member State may submit to the Agency a request for an opinion on maximum residue limits in either of the following circumstances:

a where the substance in question is authorised for use in a veterinary medicinal product in a third country and no application for the establishment of a maximum residue limit for that substance in respect of the foodstuff or species concerned has been submitted pursuant to Article 3;

b where 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 for the establishment of a maximum residue limit for that substance in respect of the foodstuff or species concerned has been submitted pursuant to Article 3 of this Regulation.

In the circumstances of point (b) of the first subparagraph, where minor species or minor uses are concerned, the request may be submitted to the Agency by an interested party or organisation.

Articles 4 to 7 shall apply.

A request for an opinion referred to in the first subparagraph of this paragraph shall comply with the format and content requirements laid down by the Commission pursuant to Article 13(1).

2 The Agency shall ensure that the opinion of the Committee is given within 210 days of receipt of the request by the Commission, a Member State or an interested party or organisation. This time limit shall be suspended if the Agency requests the submission of supplementary information on the given substance within a specific time period and until such time as the requested supplementary information has been provided.

3 Within 15 days of the adoption of the final opinion, the Agency shall forward it to the Commission and, as applicable, to the Member State or the interested party or organisation which made the request, stating the grounds for its conclusions.

Article 10

Pharmacologically active substances contained in biocidal products used in animal husbandry

1 For the purposes of Article 10(2)(ii) of Directive 98/8/EC, for pharmacologically active substances intended to be used in a biocidal product used in animal husbandry, the maximum residue limit shall be established:

a following the procedure referred to in Article 9 of this Regulation for:

(i) active substances/product type combinations included in the 10-year programme of work referred to in Article 16(2) of Directive 98/8/EC;

(ii) active substances/product type combinations to be included in Annexes I, IA or IB to Directive 98/8/EC for which a dossier has been accepted by the competent authority as referred to in Article 11(1)(b) of that Directive before 6 July 2009;

b following the procedure referred to in Article 8 of this Regulation and on the basis of an application submitted in accordance with Article 3 of this Regulation for all other active substances/product type combinations to be included in Annexes I, IA or IB to Directive 98/8/EC for which the establishment of a maximum residue limit is deemed necessary by the Member States or the Commission.

2 The Commission shall classify the pharmacologically active substances referred to in paragraph 1 in accordance with Article 14. For the purposes of classification, a regulation as referred to in Article 17(1) shall be adopted by the Commission.

However, any specific provisions relating to the conditions of use of the substances classified in accordance with the first subparagraph of this paragraph shall be laid down pursuant to Article 10(2) of Directive 98/8/EC.

3 The costs of evaluations carried out by the Agency following a request made in accordance with paragraph 1(a) of this Article shall be covered by the budget of the Agency as referred to in Article 67 of Regulation (EC) No 726/2004. However, this shall not apply to the evaluation costs of a rapporteur designated, in accordance with Article 62(1) of that Regulation, for the establishment of a maximum residue limit where that rapporteur has been appointed by a Member State that has already received a fee for that evaluation on the basis of Article 25 of Directive 98/8/EC.

The amount of the fees for evaluations carried out by the Agency and the rapporteur following an application made in accordance with paragraph 1(b) of this Article shall be established in accordance with Article 70 of Regulation (EC) No 726/2004. Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products[(1)] shall apply.

Section 3

Common provisions

Article 11

Review of an opinion

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

Where a maximum residue limit has been established in accordance with this Regulation for specific foodstuffs or species, Articles 3 and 9 shall apply for the establishment of a maximum residue limit for that substance for other foodstuffs or species.

The request referred to in the first subparagraph shall be accompanied by information explaining the issue to be addressed. Article 8(2) to (4) or Article 9(2) and (3), as appropriate, shall apply to the new opinion.

Article 12

Publication of opinions

The Agency shall publish the opinions referred to in Articles 4, 9 and 11 after deleting any information of a commercially confidential nature.

Article 13

Implementing measures

1 In accordance with the regulatory procedure referred to in Article 25(2), the Commission shall, in consultation with the Agency, adopt measures regarding the form and content of the applications and requests referred to in Articles 3 and 9.

2 The Commission shall, in consultation with the Agency, Member States and interested parties, adopt measures regarding:

a the methodological principles for the risk assessment and risk management recommendations referred to in Articles 6 and 7, including technical requirements in accordance with internationally agreed standards;

b rules on the use of a maximum residue limit established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species, or a maximum residue limit established for a pharmacologically active substance in 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 25(3).

CHAPTER II

Classification

Article 14

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 Article 4, 9 or 11, as appropriate.

2 The classification shall include a list of pharmacologically active substances and the therapeutic classes to which they belong. The classification shall also establish, in relation to each such substance, and, where appropriate, specific foodstuffs or species, one of the following:

a a maximum residue limit;

b a provisional maximum residue limit;

c the absence of the need to establish a maximum residue limit;

d a prohibition on the administration of a substance.

3 A maximum residue limit shall be laid down where it appears necessary for the protection of human health:

a pursuant to an opinion of the Agency in accordance with Article 4, 9 or 11, as appropriate; or

b pursuant to a decision of the Codex Alimentarius Commission, without objection from the Community Delegation, in favour 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 Delegation prior to the decision of the Codex Alimentarius Commission. In this case, an additional assessment by the Agency shall not be required.

4 A provisional maximum residue limit may be established in cases where scientific data are incomplete, provided that there are no grounds for supposing that residues of that substance at the level proposed constitute a hazard to 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 completion of scientific studies in progress.

5 No maximum residue limit shall be established where, pursuant to an opinion in accordance with Article 4, 9 or 11, as appropriate, 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 Article 4, 9 or 11, as appropriate, in either of the following circumstances:

a where any presence of a pharmacologically active substance or residues thereof in foods of animal origin may constitute a hazard 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 15

Accelerated procedure for an opinion of the Agency

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 submitted an application for 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 content of the application referred to in paragraph 1 of this Article shall be laid down by the Commission pursuant to Article 13(1).

3 By way of derogation from the time limits laid down in Article 8(2) and Article 9(2), the Agency shall ensure that the opinion of the Committee is given within 120 days of receipt of the application.

Article 16

Administration of substances to food-producing animals

1 Only pharmacologically active substances which are classified in accordance with Article 14(2)(a), (b) or (c) may be administered to food-producing animals within the Community, provided that such administration is in accordance with Directive 2001/82/EC.

2 Paragraph 1 shall not apply in the case of clinical trials which are accepted by the competent authorities following notification or authorisation in accordance with the legislation in force and which do not cause foodstuffs obtained from livestock participating in such trials to contain residues which constitute a hazard to human health.

Article 17

Procedure

1 For the purposes of the classification provided for in Article 14, the Commission shall prepare a draft regulation within 30 days of receipt of an opinion of the Agency as referred to in Article 4, 9 or 11, as appropriate. The Commission shall also prepare a draft regulation within 30 days of receipt of the decision of the Codex Alimentarius Commission, without objection from the Community Delegation, in favour of the establishment of a maximum residue limit as referred to in Article 14(3).

Where the opinion of the Agency is required and the draft regulation is not in accordance with this opinion, the Commission shall provide a detailed explanation of the reasons for the divergence.

2 The regulation referred to in paragraph 1 of this Article shall be adopted by the Commission in accordance with, and within 30 days of the end of, the regulatory procedure referred to in Article 25(2).

3 In the case of an accelerated procedure as referred to in Article 15, the Commission shall adopt the regulation referred to in paragraph 1 of this Article in accordance with, and within 15 days of the end of, the regulatory procedure referred to in Article 25(2).

(**1**) OJ L 35, 15.2.1995, p. 1.