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 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).