Commission Regulation (EC) No 1851/2004 of 25 October 2004 amending Annex I to Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits for veterinary medicinal products in foodstuffs of animal origin (Text with EEA relevance)

COMMISSION REGULATION (EC) No 1851/2004

of 25 October 2004

amending Annex I to Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits for veterinary medicinal products in foodstuffs of animal origin

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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[(1)], and in particular Articles 7 and 8 thereof,

Whereas:

(1) In accordance with Regulation (EEC) No 2377/90, maximum residue limits should be established for all pharmacologically active substances that are used within the Community in veterinary medicinal products intended for administration to food-producing animals.

(2) Maximum residue limits should be established only after the examination within the Committee for Veterinary Medicinal Products (CVMP) of all the relevant information concerning the safety of residues of the substance concerned for the consumer of foodstuffs of animal origin and the impact of residues on the industrial processing of foodstuffs.

(3) In establishing maximum residue limits for residues of veterinary medicinal products in foodstuffs of animal origin, it is necessary to specify the animal species in which residues may be present, the relevant food obtained from the treated animal (‘target tissue’) as well as the nature of the residue that is relevant for the monitoring of residues (‘marker residue’).

(4) For the control of residues, as provided for in appropriate Community legislation, maximum residue limits should usually be established for the target tissues of liver or kidney. However, liver and kidney are frequently removed from carcasses moving in international trade, and maximum residue limits should therefore also always be established for muscle or fat tissues.

(5) In the case of veterinary medicinal products intended for use in laying birds, lactating animals or honey bees, maximum residue limits must also be established for eggs, milk or honey.

(6) Regulation (EEC) No 2377/90 provides that the establishment of maximum residue limits shall in no way prejudice the application of other relevant Community legislation.

(7) Based on an opinion of the CVMP, Annex III of Regulation (EEC) No 2377/90 was amended by Commission Regulation (EC) No 997/1999[(2)] to include provisional maximum residue limits for morantel, in order to allow for the completion of scientific studies, notably concerning the marker residue and the analytical method for the determination of residues of morantel in the target tissues. These maximum residue limits were subsequently extended by Commission Regulation (EC) No 1322/2001[(3)] to allow the applicant further time for completion of the requested studies.

(8) The requested data on the marker residue and the analytical method was evaluated by the CVMP and found to be not completely in accordance with the requirements laid down in Volume 8 of the Rules Governing Medicinal Products in the European Union. The method was nevertheless considered fully validated for muscle and milk and either kidney or liver for the species cattle and sheep. The CVMP subsequently proposed to insert morantel in Annex II of Regulation (EEC) No 2377/90, with the motivation that residues of morantel depleted rapidly and therefore the establishment of maximum residue limits was not necessary for the protection of public health.

(9) As residues of morantel in foodstuff from treated animals may supersede the acceptable daily intake 24 hours after administration, it is considered necessary, for reasons of consumer safety and to allow adequate withdrawal periods to be established for veterinary medicinal products containing morantel, to establish maximum residues limits, taking account of the maximum residue limits previously established.

(10) Morantel is a pharmacologically active anthelmintic substance which has been in use in veterinary medicinal products for food-producing animal species for a considerable time for treatment against roundworms and tapeworms. In view of the possible development of resistance, it is considered that access to multiple choices for treatment should remain possible.

(11) According to Regulation (EC) No 178/2002[(4)], risk management shall take into account the results of risk assessment and other factors legitimate to the matter under consideration, such as detection methods and feasibility of controls for the purpose of avoiding risks from such substances. The relevant Community Reference Laboratory has confirmed that the methods proposed by the applicant can be made applicable for confirmatory analyses of morantel in the target tissues.

(12) The Commission considers that it is appropriate to include morantel in Annex I for cattle and sheep to provide safeguards for the consumer and to allow relevant controls of morantel in foodstuffs of treated animals.

(13) A period of 60 days should be allowed before the entry into force of this Regulation in order to allow Member States to make any adjustments which may be necessary to

the authorisations to place the veterinary medicinal products concerned on the market which have been granted in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products[(5)].

(14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products.

HAS ADOPTED THE FOLLOWING REGULATION:

Article 1

Annex I to Regulation (EEC) No 2377/90 is hereby amended as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on the third day following its publication in the *Official Journal of the European Union*.

It shall apply from the sixtieth day following its publication.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 October 2004.

For the Commission

Olli REHN

Member of the Commission