I

(Acts whose publication is obligatory)

COMMISSION REGULATION (EC) No 2796/95

of 4 December 1995

amending Annex II of Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of 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], as last amended by Commission Regulation (EC) No 1798/95 [2], and in particular Articles 7 and 8 thereof,

Whereas, in accordance with Regulation (EEC) No 2377/90, the maximum residue limits must be established progressively for all pharmacologically active substances which are used within the Community in veterinary medicinal products intended for administration to food-producing animals;

Whereas maximum residue limits should be established only after the examination within the Committee for Veterinary Medicinal Products 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;

Whereas, 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 levels which may be present in each of the relevant meat tissues obtained from the treated animal (target tissue) and the nature of the residue which is relevant for the monitoring of residues (marker residue);

Whereas, 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; whereas, however, the 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;

Whereas, 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;

Whereas, a number of pharmacologically active substances are generally recognized as safe; whereas these substances should be inserted into Annex II of Regulation (EEC) No 2377/90;

Whereas, substances used in homeopathic veterinary medicinal products shall be inserted into Annex II of Regulation (EEC) No 2377/90 provided that their concentration does not exceed one part per 10 000;

Whereas 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 adjustment which may be necessary to the authorizations to place the veterinary medicinal products concerned on the market which have been granted in accordance with Council Directive 81/851/EEC [3], as last amended by Directive 93/40/EEC [4] to take account of the provisions of this Regulation;

Whereas the measures provided for in this Regulation are in accordance with the opinion of the Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector,

[1] OJ No L 224, 18. 8. 1990, p. 1.
[2] OJ No L 174, 27. 7. 1995, p. 20.
[3] OJ No L 317, 6. 11. 1981, p. 1.
[4] OJ No L 214, 24. 8. 1993, p. 31.

HAS ADOPTED THIS REGULATION:

Article 1

Annex II of 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 60th day following its publication in the *Official Journal of the European Communities.*

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

Done at Brussels, 4 December 1995.

For the Commission

Martin BANGEMANN

Member of the Commission

ANNEX

Annex II is modified as follows

'3. Substances generally recognized as safe

Pharmacologically active substances	Animal species	Other provisions
3.1. Absinthium extract	All food producing species	
3.2. Acetylmethionine	All food producing species	
3.3. Aluminium hydroxide	All food producing species	
3.4. Aluminium monostearate	All food producing species	
3.5. Ammonium sulfate	All food producing species	
3.6. Benzoyl benzoate	All food producing species	
3.7. Benzyl p-hydroxybenzoate	All food producing species	
3.8. Calcium borogluconate	All food producing species	
3.9. Calcium citrate	All food producing species	
3.10. Camphor	All food producing species	External use only
3.11. Cardamon extract	All food producing species	
3.12. Diethyl sebacate	All food producing species	
3.13. Dimethicone	All food producing species	
3.14. Dimethyl acetamide	All food producing species	
3.15. Dimethyl sulphoxide	All food producing species	
3.16. Ethylenediaminetetraacetic acid and salts	All food producing species	
3.17. Eucalyptol	All food producing species	
3.18. Epinephrine	All food producing species	
3.19. Ethyl oleate	All food producing species	
3.20. Formaldehyde	All food producing species	
3.21. Formic acid	All food producing species	
3.22. Follicle stimulating hormone (natural FSH from all species and their synthetic analogues)	All food producing species	
3.23. Glutaraldehyde	All food producing species	
3.24. Guaiacol	All food producing species	
3.25. Heparin and its salts	All food producing species	
3.26. Human chorionic gonadotropin (natural HCG and its synthetic analogues)	All food producing species	
3.27. Iron ammonium citrate	All food producing species	
3.28. Iron dextran	All food producing species	
3.29. Iron glucoheptonate	All food producing species	
3.30. Isopropanol	All food producing species	
3.31. Lanolin	All food producing species	
3.32. Luteinizing hormone (natural LH from all species and their synthetic analogues)	All food producing species	
3.33. Magnesium chloride	All food producing species	
3.34. Magnesium gluconate	All food producing species	
3.35. Magnesium hypophosphite	All food producing species	
3.36. Mannitol	All food producing species	
3.37. Montanide	All food producing species	
3.38. Methylbenzoate	All food producing species	
3.39. Monothioglycerol	All food producing species	
3.40. Myglyol	All food producing species	
3.41. Orgotein	All food producing species	
3.42. Poloxalene	All food producing species	
3.43. Poloxamer	All food producing species	
3.44. Polyethylene glycol 200	All food producing species	
3.45. Polyethylene glycol 400	All food producing species	
3.46. Polyethylene glycol 600	All food producing species	

Pharmacologically active substances	Animal species	Other provisions
3.47. Polyethylene glycol 3500	All food producing species	
3.48. Polysorbate 80	All food producing species	
3.49. Serotonin	All food producing species	
3.50. Sodium chloride	All food producing species	
3.51. Sodium cromoglycate	All food producing species	
3.52. Sodium dioctylsulphosuccinate	All food producing species	
3.53. Sodium formaldehydesulphoxylate	All food producing species	
3.54. Sodium lauryl sulphate	All food producing species	
3.55. Sodium pyrosulphite	All food producing species	
3.56. Sodium stearate	All food producing species	
3.57. Sodium thiosulphate	All food producing species	
3.58. Tragacanth	All food producing species	
3.59. Urea	All food producing species	
3.60. Zinc sulphate	All food producing species	
3.61. Zinc oxide	All food producing species	

4. Substances used in homeopathic veterinary medicinal products

Pharmacologically active substance(s)	Animal species	Other provisions
4.1. Any substance used in veterinary homeopathic medicinal products provided that its concentration in the product does not exceed one part per 10 000	All food producing species '	