Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (Text with EEA relevance)

COMMISSION REGULATION (EU) No 37/2010

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on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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[(1)], and in particular Article 27(1) thereof,

Whereas:

(1) In order to protect public health, pharmacologically active substances, on the basis of the scientific assessment of the safety of those substances, were classified in four Annexes 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[(2)]. Annex I contained substances for which a maximum residue limit was established, Annex II contained substances for which it was not necessary to establish a maximum residue limit, Annex III contained substances for which a provisional maximum residue limit was established and Annex IV contained substances for which a maximum residue limit could not be established because residues of those substances, at whatever limit, constitute a hazard to human health.

(2) For reasons of simplification, it is necessary to incorporate those pharmacologically active substances and their classification regarding maximum residue limits in a Commission Regulation. As this classification follows the classification system foreseen in Regulation (EC) No 470/2009, the classification should also be taken account of with regard to the possibility to administer those pharmacologically active substances to food-producing animals.

(3) Existing information on the therapeutical classification of pharmacologically active substances contained in the Annexes to Regulation (EEC) No 2377/90 should be incorporated into a column on the therapeutical classification of substances.

***Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) No 37/2010. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(4) For reasons of ease of use, all pharmacologically active substances should be listed in one Annex in alphabetical order. For reasons of clarity, two separate tables should be established: one for allowed substances, listed in Annexes I, II and III of Regulation (EEC) No 2377/90, and one for prohibited substances, listed on Annex IV to that Regulation.

(5) Provisional maximum residue limits for pharmacologically active substances, laid down in Annex III to Regulation (EEC) No 2377/90 for which the period of application has ended, should not be incorporated into this Regulation.

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

HAS ADOPTED THIS REGULATION:

Article 1

Pharmacologically active substances and their classification regarding maximum residue limits are set out in the Annex.

Article 2

This Regulation shall enter into force on the 20th day following 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.

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ANNEX

Pharmacologically active substances and their classification regarding maximum residue limits (MRL)

TABLE 1

Allowed substances

Pharmacologically active Substance	**Marker residue**	**Animal Species**	**MRL**	**Target Tissues**	**Other Provisions (according to *Article 14(7) of Regulation (EC) No 470/2009*)**	**Therapeutic Classification**
Abamectin	Avermectin B1a	Bovine	10 µg/kg 20 µg/kg	Fat Liver	NO ENTRY	Antiparasitic agents/ Agents acting against endo- and ectoparasites
		Ovine	20 µg/kg 50 µg/kg 25 µg/kg 20 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption.	
Absinthium extract	NOT APPLICABLE	All food producing species	No MRL required	NOT APPLICABLE	NO ENTRY	NO ENTRY
Acetyl cysteine	NOT APPLICABLE	All food producing species	No MRL required	NOT APPLICABLE	NO ENTRY	NO ENTRY
Acetylmethionine	NOT APPLICABLE	All food producing species	No MRL required	NOT APPLICABLE	NO ENTRY	NO ENTRY
Acetylsalicylic acid	NOT APPLICABLE	All food producing species except fin fish	No MRL required	NOT APPLICABLE	Not for use in animals from which milk or eggs are produced for human consumption.	NO ENTRY
Acetylsalicylic acid DL-lysine	NOT APPLICABLE	All food producing species except fin fish	No MRL required	NOT APPLICABLE	Not for use in animals from which milk or eggs are produced	NO ENTRY

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					for human consumption.	
Adenosine and its 5'-mono-, 5'-di-and 5' triphosphates	NOT APPLICABLE	All food producing species	No MRL required	NOT APPLICABLE	NO ENTRY	NO ENTRY
Adonis vernalis	NOT APPLICABLE	All food producing species	No MRL required	NOT APPLICABLE	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias, at concentrations in the products not exceeding one part per hundred only.	NO ENTRY
Aesculus hippocastanum	NOT APPLICABLE	All food producing species	No MRL required	NOT APPLICABLE	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations in the products not exceeding one part per ten only.	NO ENTRY
Agnus castus	NOT APPLICABLE	All food producing species	No MRL required	NOT APPLICABLE	For use in homeopathic veterinary medicinal products prepared according	NO ENTRY

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					to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only.	
Ailanthus altissima	NOT APPLICABLE	All food producing species	No MRL required	NOT APPLICABLE	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only.	NO ENTRY
Alanine	NOT APPLICABLE	All food producing species	No MRL required	NOT APPLICABLE	NO ENTRY	NO ENTRY
[F1Alarelin	NOT APPLICABLE	All food-producing species	No MRL required	NOT APPLICABLE	NO ENTRY	Agents acting on the reproductive system]
Albendazole	Sum of albendazole sulphoxide, albendazole sulphone, and albendazole 2-amino sulphone, expressed	All ruminants	100 µg/kg 100 µg/kg 1 000 µg/kg 500 µg/kg 100 µg/kg	Muscle Fat Liver Kidney Milk	NO ENTRY	Antiparasitic agents/ Agents against endoparasites