EUROPEAN
COMMISSION

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COMMISSION REGULATION (EU) …/…

of XXX

laying down 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 and a maximum residue limit established for a pharmacologically active substance in one or more species for other species, in accordance with Regulation (EC) No 470/2009

(Text with EEA relevance)

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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 the Council[1], and in particular Article 13(2)(b) thereof,

Whereas:

(1) Pharmacologically active substances are classified on the basis of opinions on MRLs issued by the European Medicines Agency (EMA). Those opinions consist of a scientific risk assessment and risk management considerations.

(2) When carrying out scientific risk assessments and drawing up risk management recommendations, EMA is required to consider using MRLs established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species or MRLs established in one or more species for other species in extrapolation, in order to increase the availability of authorised veterinary medicinal products for conditions affecting food producing animals.

(3) Extrapolation of MRLs involves the process by which residue levels in tissues or food commodities of a food producing species for which MRLs exist are used to estimate residue levels and establish MRLs in a tissue or a food commodity of another species or another tissue or food commodity of the same species for which no, or no complete, conventional residue data is available. For proper application of Regulation (EU) No 470/2009 principles and minimum criteria for extrapolation should be established.

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

[1] OJ L 152, 16.6.2009, p. 11.

HAS ADOPTED THIS REGULATION:

Article 1
Subject matter and scope

This Regulation establishes principles and minimum criteria for using maximum residue limits (MRLs) established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species and MRLs established in one or more species for other species ('extrapolation').

Article 2
Definitions

For the purposes of this Regulation, the following definitions shall apply:

(1) ‘reference species/food commodity/tissue’ means a species/food commodity/tissue in which MRLs based on appropriate and complete data has been established;

(2) ‘concerned species/food commodity/tissue’ means a species/food commodity/tissue for which extrapolation is considered;

(3) ‘major species’ means cattle, sheep for meat, pigs, chicken including eggs, and Salmonidae;

(4) ‘minor species’ means any species other than major species;

(5) ‘related species’ means species belonging to the same category of food producing species of ruminants, monogastrics, mammals, birds or fish*;*

(6) ‘unrelated species’ means species belonging to different categories of food producing species.

Article 3
Principles for extrapolation

The EMA shall consider the extrapolation of MRLs where there is MRL or "No MRL required" status established for the pharmacologically active substance and one of the following circumstances applies to the concerned species:

(1) It is related to a major reference species for which MRLs have been established or a ‘No MRL required’ status exists for the concerned tissue/food commodity;

(2) It is related to a minor reference species for which MRLs have been established or a ‘No MRL required’ status exists for the concerned tissue/food commodity;

(3) It is unrelated to the reference species for which MRLs have been established or a ‘No MRL required’ status exists for the concerned tissue/food commodity;

(4) MRL has been established for the concerned species but not for the concerned tissue/food commodity.

Article 4
Minimum criteria for extrapolation

The EMA may undertake extrapolation only when all of the following conditions are fulfilled:

(a) a full set of residue data for the reference species is available to the EMA;

(b) the degree to which the pharmacologically active substance is metabolised in the reference species is established;

(c) a suitably validated analytical method is available for the reference species;

(d) when considering extrapolation between unrelated species, the similarity of the metabolic profiles in the reference and concerned species is established;

(e) the extrapolated MRLs result in the Theoretical Maximum Daily Intake (TMDI) not exceeding the Acceptable Daily Intake (ADI);

(f) for substances where the marker residue does not include parent compound, it is confirmed that the marker residue is present in the concerned species/food commodity;

(g) in case of extrapolations between different food commodities, an unused portion of the ADI is available to accommodate the additional food item .

Article 5

Extrapolation from major to related minor species

When considering the extrapolation of MRLs from major reference species to minor concerned species within the related species category, the EMA shall apply the following criteria:

(a) extrapolation of the reference species MRLs to the concerned species on a one to one basis is possible where the parent substance is the marker residue in the reference species;

(b) where the parent substance is not the marker residue in the reference species, then confirmation that the marker residue is present in the concerned tissues/food commodities may be required from the applicant;

(c) the established MRLs shall be extrapolated in accordance with the pattern set out in the Annex;

(d) the tissue/food commodity of the major and minor species shall be the same;

(e) a 'No MRL required' status may be directly extrapolated to the concerned species.

Article 6

Extrapolation between unrelated species and from a minor reference species to a major concerned species

When considering the extrapolation of MRLs between unrelated species and from a minor reference species to a major concerned species, the EMA shall apply the following criteria:

(a) extrapolation on a one to one basis from minor to major species may be justified only in cases where it is clear that metabolism in the reference and concerned species are similar;

(b) where extrapolation is considered between unrelated species (including minor species), supportive substance-specific information regarding the similarity of metabolism between the reference and concerned species may be required from the applicant;

(c) where MRLs have been established for more than one unrelated species, the set of MRLs leading to the lowest consumer intake shall be extrapolated to the concerned species on a one to one basis;

(d) the use of other specific safety factors on a case-by-case basis may be considered by the EMA to account for specific uncertainties in the data;

(e) 'no MRL required' status may be extrapolated to the concerned species if the metabolism is similar;

(f) extrapolation of MRLs from terrestrial species to fish with muscle and skin in natural proportions is directly possible where the parent compound is the marker residue and MRL has been established in muscle of the reference species;

(g) extrapolation from fish to mammals/avian species shall not be carried out.

Article 7

Extrapolation across food commodities

When considering the extrapolation across food commodities, the EMA shall apply the following criteria:

(a) for extrapolation across food commodities, the lowest established MRL in the species shall be selected as the point of departure for derivation of the MRL in the concerned food commodity;

(b) use of the remaining portion of the ADI as the point of departure and direct calculation of the MRL may also be possible;

(c) in addition, for the estimation of exposure, a conservative estimate of the ratio of marker to total residues to calculate the TMDI shall be used;

(d) extrapolation between commodities may require adjustment of the MRL values to account for differences in consumption figures;

(e) when extrapolating MRL from other tissues to milk within the same species, consideration shall be given to the physicochemical characteristics of the active substance and how these characteristics may influence accumulation in milk. Use of the lowest ratio of marker to total residues in tissues may be an acceptable point of departure from which to determine the ratio to use for milk;

(f) extrapolation of MRLs from poultry tissues to poultry eggs shall not be carried out;

(g) in the case of extrapolation of MRLs to honey the following points shall be considered:

(i) physico-chemical and biological data on the stability of the marker residue and likely (major) degradation products and their possible formation may be required from the applicant;

(ii) taking into account that "zero days" withdrawal period is desired for honey, residue data shall be needed to demonstrate that the intended use of the substance in bees leads to safe residue levels in honey, without applying a withdrawal period. Such data may also be used for deriving the MRL;

(iii) MRLs may only be extrapolated to honey when information is available to confirm the toxicological relevance of the major residues (including degradation products) in honey and when it is clear that honey from treated bees contains residues below the MRL even without application of a withdrawal period.

Article 8
Entry into force

This Regulation shall enter into force on the twentieth day following that of 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.

Done at Brussels,

For the Commission
The President
Jean-Claude Juncker