Commission Implementing Regulation (EU) 2018/470 of 21 March 2018 on detailed rules on the maximum residue limit to be considered for control purposes for foodstuffs derived from animals which have been treated in the EU under Article 11 of Directive 2001/82/EC (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/470

of 21 March 2018

on detailed rules on the maximum residue limit to be considered for control purposes for foodstuffs derived from animals which have been treated in the EU under Article 11 of Directive 2001/82/EC

(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 23 thereof,

Whereas:

(1) Regulation (EC) No 470/2009 provides for the establishment of maximum residue limits ('MRLs') for pharmacologically active substances intended for use in the Union in veterinary medicinal products administered to food-producing animals and in biocidal products used in animal husbandry.

(2) Table 1 of the Annex to Commission Regulation (EU) No 37/2010[(2)] ('Table 1') sets out the pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin. In relation to some substances, different MRLs are set out for different species or groups of species and for different target tissues of those species or groups of species.

(3) Article 11 of Directive 2001/82/EC of the European Parliament and of the Council[(3)] lays down rules regarding the treatment of food-producing animals affected by a condition for which no veterinary medicinal product is authorised in a Member State. In particular, paragraph 2 of that Article, read together with Article 29 of Regulation (EC) No 470/2009, provides that such animals may be treated with medicinal products containing pharmacologically active substances only if those substances are included in Table 1 of the Annex to Regulation (EU) No 37/2010.

(4) The Commission is required to adopt detailed rules on the MRLs to be considered for control purposes for foodstuffs derived from animals treated under Article 11 of

Directive 2001/82/EC. For specific target tissues of animal species treated in the EU under Article 11 of Directive 2001/82/EC, no MRLs may be included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010. In order to ensure a high level of consumer protection, specific rules are needed to specify which MRLs apply in those cases. The rules should take into account the MRLs established under Regulation (EC) No 470/2009 for different animal species and different target tissues, for which a risk assessment has demonstrated their safety to consumers. Applying the existing MRLs to tissue-species combinations for which no MRL has been set, in combination with the application of the appropriate withdrawal periods or the default minimum withdrawal periods according to Article 11, provides sufficient guarantees for consumer safety.

(5) For treatments under Article 11 of Directive 2001/82/EC it is most appropriate to refer to MRLs, which are established in Table 1 for species that have a similar anatomy and metabolism, in order to define MRLs, for residues of veterinary medicinal products in animal species not listed in Table 1. Therefore food-producing animal species should be placed into groups and related to each other according to the different anatomical and metabolic relationships between them.

(6) Preferentially MRLs listed in Table 1 for the same target tissue in a related or more closely related species are considered and as a last resort the lowest MRL for any target tissue in any species.

(7) In case in Table 1 restrictions are defined regarding the application of the MRL for certain uses, these restrictions apply also to possible uses on other animal species and/or target tissues.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

This Regulation lays down the maximum residue limit to be considered for control purposes for foodstuffs derived from animals which have been treated in the EU under Article 11 of Directive 2001/82/EC.

Article 2

1 For the purposes of this Regulation, food-producing animals shall be grouped as follows:

a ruminants;
b monogastric mammals;
c poultry and ratites;
d fin fish;
e bees;
f crustaceans;
g molluscs.

2 For the purposes of this Regulation, animal species shall be considered to be ‘related’ or ‘more closely related’ to each other as follows:

a animal species belonging, according to paragraph 1, to the same group shall be considered to be 'related' species;

b within the ruminants group, ovine and caprine species shall be considered to be 'more closely related' to each other than to bovine species and bovine species shall be considered to be 'more closely related' to each other than to either ovine or caprine species;

c *Equidae* and rabbits shall be considered to be equally related to monogastric mammals and ruminants. However, ruminants shall not be considered to be related to either *Equidae* or rabbits.

3 For the purposes of this Regulation, different target tissues shall be equated as follows:

a the target tissue 'skin and fat' in porcine and poultry species shall be equated to the target tissue 'fat' in other animal species, and vice versa;

b the target tissue 'skin and muscle' in fin fish shall be equated to the target tissue 'muscle' in other animal species, and vice versa;

c the edible parts of crustaceans and molluscs shall be equated to the target tissue 'muscle' in other animal species.

Article 3

For pharmacologically active substances included in Table 1 of the Annex to Regulation (EU) No 37/2010 ('Table 1') for which at least one MRL or provisional MRL has been established, the MRL to be considered for control purposes for a target tissue derived from an animal species treated in the EU under Article 11 of Directive 2001/82/EC ('the treated species') shall be as follows:

(a) if at least one MRL is established in Table 1 for that target tissue in any species related to the treated species:

(1) the MRL to be considered for control purposes shall be the lowest of all the MRLs established in Table 1 for that target tissue in species related to the treated species;

(2) if, however, the treated species is a species referred to in Article 2(2)(b) of this Regulation and MRLs are established in Table 1 for that target tissue in species that are more closely related to the treated species, the MRL to be considered for control purposes shall be the lowest of the MRLs established for that target tissue in those more closely related species;

(b) if point (a) does not apply, the MRL to be considered for control purposes shall be the lowest of all the MRLs established in Table 1 for that target tissue in species that are not related to the treated species;

(c) if neither point (a) nor point (b) produces the MRL to be considered for control purposes, the MRL to be considered for control purpose shall be the lowest of all the MRLs established in Table 1 for other target tissues in any animal species;

(d) in case in Table 1 restrictions are defined regarding the application of the MRL for certain uses, these restrictions equally apply when considering an MRL under article 3(a), 3(b) and 3(c) for possible uses on other animal species and/or target tissues.

Article 4

For pharmacologically active substances included in Table 1 of the Annex to Regulation (EU) No 37/2010 for which no MRL is required, in accordance with Article 14(5) of Regulation (EC) No 470/2009, there shall be no MRL required for control purposes

for any target tissue derived from animal species treated in the EU under Article 11 of Directive 2001/82/EC, provided that the restrictions established in Table 1 are complied with.

Article 5

The MRLs applicable in Table 1 of the Annex to Regulation (EU) No 37/2010 at the time of placing on the market of foodstuffs of animal origin, shall be applicable to the controlled products.

Article 6

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, 21 March 2018.

For the Commission

The President

Jean-Claude JUNCKER

(**1**) OJ L 152, 16.6.2009, p. 11.

(**2**) 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 (OJ L 15, 20.1.2010, p. 1).

(**3**) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).