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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	13 February 2018
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	D054961/02
Subject:	COMMISSION REGULATION (EU) …/… of XXX establishing the methodological principles for the risk assessment and risk management recommendations referred to in Regulation (EC) No 470/2009

Delegations will find attached document D054961/02.

Encl.: D054961/02

EUROPEAN
COMMISSION

Brussels, XXX
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[…](2017) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

establishing the methodological principles for the risk assessment and risk management recommendations referred to in Regulation (EC) No 470/2009

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

of XXX

establishing the methodological principles for the risk assessment and risk management recommendations referred to in Regulation (EC) No 470/2009

(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 13(2)(a) thereof,

Whereas:

(1) Regulation (EC) No 470/2009 provides that, except in cases where the Codex Alimentarius procedure applies, any pharmacologically active substance intended for use in the Union in veterinary medicinal products which are to be administered to food-producing animals shall be subject to an opinion of the European Medicines Agency ('Agency') on the maximum residue limits ('MRLs') of pharmacologically active substances used or intended to be used in veterinary medicinal products. The Agency's opinion should consist of a scientific risk assessment and risk management recommendations.

(2) Regulation (EC) No 470/2009 empowers the Commission to adopt measures establishing the methodological principles for the risk assessment and risk management recommendations regarding the establishment of the MRLs of pharmacologically active substances.

(3) In order to provide legal certainty, clarity and predictability with regard to the process of the establishment of MRLs, it is appropriate that the criteria against which the Agency appraise the applications are provided for in this Regulation.

(4) The methodological principles for the risk assessment and risk management recommendations should aim to ensure a high level of human health protection, whilst also ensuring that human health, animal health and animal welfare are not negatively affected by the lack of availability of appropriate veterinary medicinal products.

(5) Taking into account the requirements set out in Article 6 of Regulation (EC) No 470/2009, the detailed rules on the methodological principles for the scientific risk assessment part of the Agency's opinion should be laid down in this Regulation.

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

(6) Taking into account the requirements set out in Article 7 of Regulation (EC) No 470/2009, the detailed rules on the methodological principles for the risk management recommendations part of Agency's opinion should be laid down in this Regulation. In the risk management recommendations, the Agency is also required to consider the availability of alternative substances and other legitimate factors, such as the technological aspects of food and feed production or the feasibility of controls. Therefore it is appropriate to lay down rules on that requirement.

(7) 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
Subject matter

1. This Regulation sets out the methodological principles for the scientific risk assessment and risk management recommendations referred to in Articles 6 and 7 of Regulation (EC) No 470/2009 that shall be applied by the Agency when preparing opinions on the MRLs of pharmacologically active substances which may be permitted in food of animal origin under that Regulation.

2. The methodological principles for the scientific risk assessment are set out in Annex I.

3. The methodological principles for the risk management recommendations are set out in Annex II.

Article 2
Definitions

For the purposes of this Regulation, in addition to the definitions set out in Regulation (EC) No 470/2009, the following definitions shall apply:

– 'major metabolites' means metabolites comprising ≥100 µg/kg or ≥10% of the total residue in a sample collected from the target animal species in the metabolism study;

– 'marker residue' means a residue whose concentration is in a known relationship to the concentration of total residue in an edible tissue;

– 'dairy starter cultures' means prepared cultures of microorganism employed in the manufacture of a variety of dairy products including butter, cheese, yoghurt and cultured milk.

Article 3
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