COMMISSION REGULATION (EU) 2019/1871

of 7 November 2019

on reference points for action for non-allowed pharmacologically active substances present in food of animal origin and repealing Decision 2005/34/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 Articles 18, 19(3) and 24(4) thereof,

Whereas:

(1) Where necessary for the purpose of official controls of food of animal origin, the Commission may establish reference values ('reference points for action') for residues of pharmacologically active substances in food of animal origin, for which no maximum residue limit has been laid down. Reference points for action should apply to food of animal origin imported from third countries and to food of animal origin produced in the Union.

(2) Following a request from the Commission, the EFSA Panel on Contaminants in the Food Chain (EFSA CONTAM Panel) has adopted guidance on methodological principles and scientific methods to be taken into account when assessing the safety of reference points for action ('EFSA guidance') ([2]). EFSA guidance describes a process for assessing whether the analytical concentration of a pharmacologically active substance, which can be determined by official control laboratories using a validated analytical method, is low enough to adequately protect human health.

(3) EFSA guidance further specifies situations, in which a substance-specific risk assessment should be undertaken by EFSA in accordance with Regulation (EC) No 470/2009. In particular, in order to ensure an adequate level of health protection, substance-specific risk assessments should be performed for pharmacologically active substances, which cause blood dyscrasias (aplastic anaemia) or allergy (excluding skin sensitisation) or which are high potency carcinogens or inorganic substances.

(4) Methodological principles and scientific methods for assessing the safety of reference points for action should therefore be adopted.

(5) Commission Decision 2002/657/EC ([3]) lays down the minimum required performance limits of analytical methods used for detecting a limited number of substances, for which the use is not allowed, or is specifically prohibited in the Union. Those minimum required performance limits correspond to the average limit above which the detection of a substance or its residues can be considered as methodologically meaningful. The minimum required performance limits apply to the matrixes specified in Annex II to that Decision.

([1]) OJ L 152, 16.6.2009, p. 11.
([2]) Updated guidance on methodological principles and scientific methods to be taken into account when establishing Reference Points for Action (RPAs) for non-allowed pharmacologically active substances present in food of animal origin. *EFSA Journal* 2018;16(7):5332.
([3]) Commission Decision 2002/657/EC of 14 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results (OJ L 221, 17.8.2002, p. 8).

(6) Pursuant to Commission Decision 2005/34/EC ([4]), the minimum required performance limits laid down in Decision 2002/657/EC are to be used as reference points for action irrespective of the food matrix tested for food of animal origin, imported from third countries. Food of animal origin, containing residues of a pharmacologically active substance in a concentration at or above the reference point for action, is to be considered not to comply with Union legislation, while food of animal origin containing concentrations below the reference points for action are not to be prohibited from entering the food chain. However, the setting of reference points for action should in no way serve as a pretext for condoning the illegal use of prohibited or non-allowed substances. Therefore any residues of those substances in food of animal origin should be considered undesirable. The reference points for action laid down in Decision 2005/34/EC have been based solely on analytical considerations, taking into account the lowest residue concentration, which can be detected and confirmed with a validated analytical method, without consideration of the toxic potential of the substances in question.

(7) For chloramphenicol, malachite green and nitrofuran metabolites reference points for action have been laid down in Decision 2005/34/EC. For these substances, however, EFSA concluded that following EFSA guidance instead of the standard risk assessment methodology a substance-specific risk assessment was needed. Therefore, following the request of the Commission, the EFSA CONTAM Panel adopted scientific opinions on chloramphenicol in food and feed ([5]), on nitrofurans and their metabolites in food ([6]) and on malachite green in food ([7]).

(8) It is therefore appropriate to lay down reference points for action for these substances, which take into account both the analytical considerations and the toxic potential of these substances. In view of the uncertainties, which EFSA identified in its risk assessments for chloramphenicol and the nitrofuran metabolites, the sensitivity of analytical methods should be improved, in order to enable enforcement of the lowest possible concentrations.

(9) Detection of residues of prohibited or non-allowed substances, even below established reference points for action, could be a signal of misuse of such substances. In such cases Regulation (EC) No 470/2009 requires Member States and, as appropriate, the Commission, to take follow-up measures. To this end, information should be available to the Member States and the Commission through the Rapid Alert System for Food and Feed ([8]).

(10) In order to allow official laboratories to adapt their methods to the updated reference points for action for chloramphenicol, malachite green and nitrofuran metabolites, a period of three years should be allowed to elapse before these lowered reference points for action become applicable.

(11) As this Regulation takes over the provisions of Decision 2005/34/EC, updates and further expands them, for reasons of legal certainty Decision 2005/34/EC should be repealed.

(12) 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

Scope

This Regulation lays down:

(a) rules for the establishment of reference points for action for residues of pharmacologically actives substances, for which no maximum residue limit has been laid down in accordance with Regulation (EC) No 470/2009;

([4]) Commission Decision 2005/34/EC of 11 January 2005 laying down harmonised standards for the testing for certain residues in products of animal origin imported from third countries (OJ L 16, 20.1.2005, p. 61).

([5]) EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2014. Scientific Opinion on Chloramphenicol in food and feed. *EFSA Journal* 2014;12(11):3907, 145 pp. doi:10.2903/j.efsa.2014.3907.

([6]) EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2015. Scientific Opinion on nitrofurans and their metabolites in food. *EFSA Journal* 2015;13(6):4140, 217 pp. doi:10.2903/j.efsa.2015.4140.

([7]) EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2016. Scientific Opinion on malachite green in food. *EFSA Journal* 2016;14(7):4530, 80 pp. doi:10.2903/j.efsa.2016.4530.

([8]) Commission Regulation (EU) No 16/2011 of 10 January 2011, laying down implementing measures for the Rapid alert system for food and feed (OJ L 6, 11.1.2011, p. 7).

(b) methodological principles and scientific methods for the risk assessment of the safety of reference points for action;

(c) reference points for action for residues from certain pharmacologically active substances for which no maximum residue limit has been laid down in accordance with Regulation (EC) No 470/2009;

(d) specific rules on action to be taken in the case of a confirmed presence of a residue of a prohibited or non-allowed substance at levels above, equal to or below the reference point for action.

Article 2

Rules for the establishment of reference points for action

Reference points for action shall be set at the lowest level which can analytically be achieved by the official control laboratories, designated in accordance with Article 37 of Regulation (EU) 2017/625 of the European Parliament and of the Council ([9]).

Reference points for action shall be regularly reviewed to ensure that they correspond to the lowest levels, which are achievable, taking into account the most recent scientific developments.

When setting or reviewing reference points for action, the Commission shall consult the relevant European Reference Laboratories on the analytical capabilities of National Reference Laboratories and official laboratories, as regards the lowest residue concentration, which can be identified with an analytical method, validated in accordance with the requirements of Decision 2002/657/EC.

Article 3

Methodological principles and scientific methods of risk assessment

1. The risk assessment applied for the assessment of the safety of reference points for action shall take into account:

(a) the toxic potential and pharmacological activity of the substance;

(b) intake of the residue via food.

2. For the purpose of determining the toxic potential and pharmacological activity of the substance, the following toxicological screening values shall be applied:

(a) for Group I substances, corresponding to non-allowed pharmacologically active substances for which there is direct evidence of genotoxicity or for which there is an alert for genotoxicity (from structure activity relationships or read across) or for which there is a lack of information on genotoxicity, and hence genotoxicity cannot be excluded 0,0025 µg/kg body weight (b.w.) per day;

(b) for Group II substances, corresponding to non-allowed pharmacologically active substances with pharmacological activity on the nervous system or the reproductive system, or that are corticoids 0,0042 µg/kg b.w. per day;

(c) for Group III substances, corresponding to non-allowed pharmacologically active substances with anti-infectious, anti-inflammatory and antiparasitic effect and other pharmacologically active agents 0,22 µg/kg b.w. per day.

3. The relevant food intake shall be determined based on food consumption figures, food consumption patterns and the occurrence of the substance in different food commodities.

([9]) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

4. The safety of reference points for action shall be assessed, by verifying whether the toxicological screening value, divided by the relevant food intake, is higher than or equal to the analytical capability of the official control laboratories, in which case the safety of the reference point for action at the analytical capability level is guaranteed.

Article 4

Substance-specific risk assessment

1. A request shall be addressed to EFSA for a substance-specific risk assessment as to whether reference points for action are adequate to protect human health, in particular for substances:

(a) that cause blood dyscrasias or allergy (excluding skin sensitisation);

(b) that are high potency carcinogens;

(c) for which genotoxicity cannot be excluded, if there is experimental or other evidence that the use of the toxicological screening value of 0,0025 µg/kg b.w. per day may not be adequately health protective.

2. The Commission shall, where appropriate, submit a request to EFSA for a substance-specific risk assessment as to whether a reference point for action is adequate to protect human health, where application of the method laid down in Article 3(4) indicates that the toxicological screening value, divided by the relevant food intake, is lower than the analytical capability of the official control laboratories, and that there is little or no possibility of significant improvement in the analytical capability within a short to medium time frame.

3. Where the substance specific risk assessment is inconclusive, due to uncertainties regarding certain aspects of the toxicological or exposure assessment, and no guarantees are available on whether the lowest analytically achievable concentration is sufficiently safe for consumers, the European and National Reference Laboratories shall endeavour to improve the sensitivity of analytical methods in order to be able to enforce lower concentrations and the reference points for action shall be set at levels which are low enough to stimulate improvement of the lowest achievable levels.

Article 5

Enforcement of reference points for action

For the purpose of control in food of animal origin of some residues of substances, whose use is prohibited or not allowed in the Union, the reference points for action, laid down in the Annex, shall apply irrespective of the food matrix tested.

Food of animal origin, containing residues of a pharmacologically active substance in a concentration at or above the reference point for action, shall be considered not to comply with Union legislation and shall not enter the food chain. Food of animal origin containing residues of a pharmacologically active substance in a concentration at a level below the reference point for action shall not be prohibited from entering the food chain.

Article 6

Information exchange and investigations in case of confirmed presence of a prohibited or non-allowed substance

Where the results of official controls, including analytical tests, identify residues of prohibited or non-allowed substances at levels above, equal to or below the reference points for action, the competent authority shall carry out the investigations referred to in Articles 137(2) or (3) of Regulation (EU) 2017/625 and Articles 13, 16(2), 17 and 22 to 24 of Directive 96/23/EC ([10]), to determine whether there has been illegal treatment with a prohibited or non-allowed pharmacologically active substance.

([10]) Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10).

In the event of established non-compliance, the competent authority shall take one or more actions referred to in Article 138 of Regulation (EU) 2017/625 and Articles 15(3), 17 and 23 to 25 of Directive 96/23/EC.

The competent authority shall retain a record of the findings. Where the results of official controls, including analytical tests on foods of animal origin from the same operator, show a recurrent pattern pointing to suspicion of non-compliance related to one or several prohibited or non-allowed substances from a particular origin, the competent authority shall inform the Commission and the other Member States in the Standing Committee on Plants, Animals, Food and Feed.

Where the recurrent pattern concerns imported food, the Commission shall bring this to the attention of the competent authority of the country or countries of origin.

Member States shall report the results of official controls, including analytical tests, showing confirmed presence of a prohibited or non-allowed substance at levels above or equal to the reference points for action through the Rapid Alert System for Food and Feed.

Article 7

Repeal of Decision 2005/34/EC

Decision 2005/34/EC is repealed.

Article 8

Application of the reference points for action

The reference points for action, set out in the Annex to this Regulation shall apply from 28 November 2022.

Until the date laid down in the first paragraph the minimum required performance limits for chloramphenicol, nitrofuran metabolites and the sum of malachite green and leucomalachite green, included in Annex II to Decision 2002/657/EC, shall apply as reference points for action for food of animal origin imported from third countries and for food of animal origin produced in the Union.

Article 9

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, 7 November 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Reference points for action (RPA)

Substance	RPA (µg/kg)	Other provisions
Chloramphenicol	0,15	
Malachite green	0,5	0,5 µg/kg for the sum of malachite green and leucomalachite green
Nitrofurans and their metabolites	0,5 ([1])	0,5 µg/kg for each of the metabolites of furazolidone (AOZ or 3-amino-2-oxazolidinone), furaltadone (AMOZ or 3-amino-5-methylmorpholino-2-oxazolidinone), nitrofurantoin (AHD or 1-aminohydantoin), nitrofurazone (SEM or semicarbazide) and nifursol (DNSH or 3,5-dinitrosalicylic acid hydrazide)

([1]) Due to the natural occurrence of SEM in crayfish at levels above the RPA, only levels of AOZ, AMOZ, AHD and DNSH above the RPA are a clear indication of the illegal use of nitrofurans and their metabolites. The RPA of 0,5 µg/kg for SEM in crayfish shall only be applied, when the illegal use of nitrofurazone on crayfish has been established.