



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/10684/2015 Rev. 3
[...] (2018) **XXX** draft

COMMISSION REGULATION (EU) .../...

of XXX

amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorate in or on certain products

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION REGULATION (EU) .../...

of **XXX**

amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorate in or on certain products

(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 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC¹, and in particular Article 14(1)(a) and Article 16(1)(a) thereof,

Whereas:

- (1) According to Commission Decision 2008/865/EC² all authorisations for plant protection products containing chlorate have been revoked following the non-inclusion of chlorate in Annex I to Council Directive 91/414/EEC³.
- (2) No specific maximum residue levels (MRLs) have been set for chlorate and, as this substance has not been included in Annex IV to Regulation (EC) No 396/2005, currently the default MRL of 0.01 mg/kg applies to all food and feed commodities included in Annex I to Regulation (EC) No 396/2005.
- (3) Apart from its former use in plant protection products, chlorate is also a substance that is formed as by-product resulting from the use of chlorine disinfectants in food and drinking water processing. These uses lead to detectable residues of chlorate in food.
- (4) The European Food Safety Authority ('the Authority') collected between 2014 and 2018 monitoring data to investigate the presence of residues of chlorate in food and drinking water. Those data indicated that chlorate residues are present at levels that frequently exceed the default MRL of 0.01 mg/kg and that the levels vary depending on the source and the product. It follows from those findings that even if good hygiene practices are used, in order to ensure an adequate hygiene of food products, it is currently not possible to achieve levels of chlorate residues compliant with the current MRL of 0.01 mg/kg.
- (5) The Authority adopted a scientific opinion concerning the risks for public health related to the presence of chlorate in food.⁴ In that opinion the Authority established a

¹ OJ L 70, 16.3.2005, p. 1.

² Commission Decision 2008/865/EC of 10 November 2008 concerning the non-inclusion of chlorate in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance (OJ L 307, 18.11.2008, p. 7).

³ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.08.1991, p. 1).

⁴ EFSA (European Food Safety Authority), 2015. Scientific opinion on the risks for public health related to the presence of chlorate in food. EFSA Journal 2015;13(6):4135, 103 pp.

tolerable daily intake (TDI) of 3 µg/kg body weight per day and an acute reference dose (ARfD) of 36 µg/kg body weight.

- (6) The Authority concluded that based on the data collected in 2014 the acute dietary exposure to chlorate does not exceed the ARfD. The mean dietary exposures to chlorate in European countries are close to or slightly exceeding the TDI. Certain subgroups of the population such as infants and children may exceed the TDI about twofold. Therefore the exposure of the population to chlorate should be reduced.
- (7) The evolution of the chlorate levels in food between 2014 and 2018 shows a general trend towards decreasing levels, suggesting that manufacturing practices have already improved. However, the default level of 0.01 mg/kg can currently not be achieved even with current best practices and a temporary solution is needed.
- (8) It is therefore appropriate to set temporary MRLs for chlorate according to the ALARA principle ('as low as reasonably achievable') at the level corresponding to the 95th percentile of the occurrence data reflecting levels that are realistically achievable when good manufacturing practices are used. The temporary MRLs should be reviewed within five years of publication of this Regulation in the light of further progress made by food business operators to bring chlorate levels down, or whenever new information and data become available that would warrant an earlier review.
- (9) The Commission consulted the European Union reference laboratories on appropriate limits of determination (LODs) for chlorate residues in certain specific commodities.
- (10) Based on the scientific opinion of the Authority and taking into account the factors relevant to the matter under consideration, the proposed MRLs fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.
- (11) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (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

Annex III to Regulation (EC) No 396/2005 is amended in accordance with the Annex to this Regulation.

Article 2

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