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Subject:	COMMISSION REGULATION (EU) No .../.. 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 benzalkonium chloride and didecyldimethylammonium chloride in or on certain products (Text with EEA relevance)

Delegations will find attached document D033900/02.

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COMMISSION REGULATION (EU) No .../..

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 benzalkonium chloride and didecyldimethylammonium chloride in or on certain products

(Text with EEA relevance)

COMMISSION REGULATION (EU) No .../..

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 benzalkonium chloride and didecyldimethylammonium chloride 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) Up to now, no specific maximum residue levels (MRLs) have been set for benzalkonium chloride (BAC) and didecyldimethylammonium chloride (DDAC) and those substances have not been included in Annex IV to Regulation (EC) No 396/2005.
- (2) BAC is not an approved active substance in plant protection products under Regulation (EC) No 1107/2009 of the European Parliament and of the Council². DDAC was approved as an active substance in plant protection products for use on ornamental crops, but all authorisations for plant protection products containing DDAC have been revoked following the withdrawal of the approval³. Both substances are used as biocides for disinfection. That use may lead to detectable residues in food.
- (3) The Commission received information from Member States and business operators showing the presence of BAC and DDAC in or on certain products leading to higher residues than the default MRL of 0.01 mg/kg laid down in Regulation (EC) No 396/2005.

¹ OJ L 70, 16.3.2005, p. 1.

² Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

³ Commission Implementing Regulation (EU) No 175/2013 of 27 February 2013 amending Implementing Regulation (EU) No 540/2011 as regards the withdrawal of the approval of the active substance didecyldimethylammonium chloride (OJ L 56, 28.2.2013, p. 4).

- (4) The European Food Safety Authority, hereinafter ‘the Authority’, collected monitoring data in 2012 and 2013 to investigate the presence of residues of BAC and DDAC in food. Those data were generated by Member States and food business operators and showed that those substances are present at levels that vary depending on the source and product, but that the levels frequently exceed the default MRL of 0.01 mg/kg. These findings provide evidence of the unavoidable presence of BAC and DDAC in or on certain products.
- (5) The Authority provided a technical report on the statistical evaluation of the collected data⁴. It assessed whether the temporary MRLs proposed by the Commission services sufficiently protect consumers as regards their possible exposure to residues due to the use in biocidal products and gave a reasoned opinion on the proposed MRLs⁵. It forwarded the report and the opinion to the Commission and the Member States and made them available to the public.
- (6) The Authority concluded in its reasoned opinion that while the risk assessment is affected by a high degree of uncertainties due to the limited information available, the proposed temporary MRLs are expected to sufficiently protect consumers. The Authority took into account the health assessments performed by the German Bundesinstitut für Risikobewertung (BfR)⁶⁷ on BAC and DDAC. Neither the lifetime exposure to the substances via consumption of all food products that may contain them, nor the short term exposure due to extreme consumption of the relevant crops showed that there is a risk that the acceptable daily intake (ADI) or the acute reference dose (ARfD) is exceeded. The Authority proposed to change the residue definition for BAC.
- (7) It is appropriate to set temporary MRLs for BAC and DDAC, based on the available monitoring data and on the reasoned opinion of the Authority. Those temporary MRLs should be reviewed within five years, to evaluate new data and information that will become available.
- (8) Based on the reasoned opinion of the Authority and taking into account the factors relevant to the matter under consideration, the appropriate modifications to the MRLs fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.
- (9) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

⁴ European Food Safety Authority; Evaluation of monitoring data on residues of didecyldimethylammonium chloride (DDAC) and benzalkonium chloride (BAC). EFSA supporting publication 2013:EN-483, 30 pp.

⁵ European Food Safety Authority; Reasoned opinion on the dietary risk assessment for proposed temporary maximum residue levels (MRLs) of didecyldimethylammonium chloride (DDAC) and benzalkonium chloride (BAC). EFSA Journal 2014;12(4):3675, 23 pp.

⁶ Bundesinstitut für Risikobewertung; Gesundheitliche Bewertung der Rückstände von Didecyldimethylammoniumchlorid (DDAC) in Lebensmitteln. BfR opinion No 027/2012, 9 July 2012, as amended on 21 January 2013, 16 pp.

⁷ Bundesinstitut für Risikobewertung; Health assessment of benzalkonium chloride residues in food. BfR opinion No 032/2012, 13 July 2012, 14 pp.

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
José Manuel BARROSO