Commission Regulation (EU) No 1119/2014 of 16 October 2014 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 1119/2014

of 16 October 2014

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/EEC[(1)], 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 Council[(2)]. 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products for use on ornamental crops, but all authorisations for plant protection products containing DDAC have been revoked following the withdrawal of the approval[(3)]. 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.

(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

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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 data[4]. 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 MRLs[5]. 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)[6][7] 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,

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.

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Done at Brussels, 16 October 2014.

For the Commission

The President

José Manuel BARROSO

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ANNEX

Annex III to Regulation (EC) No 396/2005 is amended as follows:

In part A, the following columns for benzalkonium chloride and didecyldimethylammonium chloride are added:

PESTICIDE RESIDUES AND MAXIMUM RESIDUE LEVELS (MG/KG)

Code number	**Groups and examples of individual products to which the MRLs apply**[a]	**Benzalkonium chloride (mixture of alkylbenzyldimethylammonium chlorides with alkyl chain lengths of C_8, C_{10}, C_{12}, C_{14}, C_{16} and C_{18})**	**Didecyldimethylammonium chloride (mixture of alkyl-quaternary ammonium salts with alkyl chain lengths of C_8, C_{10} and C_{12})**
0100000	1. **FRUIT FRESH OR FROZEN NUTS**	0,1 (+)	0,1 (+)
0110000	(i) **Citrus fruit**		
0110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo (except mineola), ugli and other hybrids)		
0110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)		
0110030	Lemons (Citron, lemon, Buddha's hand (*Citrus medica* var. *sarcodactylis*))		
0110040	Limes		
0110050	Mandarins (Clementine, tangerine, mineola and other hybrids tangor (*Citrus reticulata* × *sinensis*))		
0110990	Others		
0120000	(ii) **Tree nuts**		
0120010	Almonds		
0120020	Brazil nuts		

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0120030	Cashew nuts		
0120040	Chestnuts		
0120050	Coconuts		
0120060	Hazelnuts (Filbert)		
0120070	Macadamia		
0120080	Pecans		
0120090	Pine nuts		
0120100	Pistachios		
0120110	Walnuts		
0120990	Others		
0130000	(iii) **Pome fruit**		
0130010	Apples (Crab apple)		
0130020	Pears (Oriental pear)		
0130030	Quinces		
0130040	Medlar		
0130050	Loquat		
0130990	Others		
0140000	(iv) **Stone fruit**		
0140010	Apricots		
0140020	Cherries (Sweet cherries, sour cherries)		
0140030	Peaches (Nectarines and similar hybrids)		
0140040	Plums (Damson, greengage, mirabelle, sloe, red date/Chinese date/Chinese jujube (*Ziziphus zizyphus*))		
0140990	Others		
0150000	(v) **Berries & small fruit**		
0151000	(a) *Table and wine grapes*		
0151010	Table grapes		
0151020	Wine grapes		