STATEMENT

APPROVED: 14 December 2021

doi: 10.2903/j.efsa.2022.7061

Pesticide active substances that do not require a review of the existing maximum residue levels under Article 12 of Regulation (EC) No 396/2005

European Food Safety Authority (EFSA)

Abstract

Regulation (EC) No 396/2005 establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. According to Article 12(1) of Regulation (EC) No 396/2005, EFSA shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC a reasoned opinion on the review of the existing MRLs for that active substance. Article 12(2) of that Regulation stipulates that EFSA shall provide by 1 September 2009 a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Directive 91/414/EEC before 2 September 2008. Among the active substances that need to be reviewed under Article 12(1) or Article 12(2) of Regulation (EC) No 396/2005, EFSA identified 6 active substances for which a review of MRLs is no longer considered necessary. EFSA prepared a statement explaining the reasons why a review of MRLs for these substances became obsolete. The relevant question numbers are considered addressed by this statement.

Keywords: Regulation (EC) No 396/2005, MRLs, peer review, active substance

Requestor: European Commission

Question numbers: EFSA-Q-2008-527, EFSA-Q-2008-535, EFSA-Q-2008-588, EFSA-Q-2009-00027, EFSA-Q-2010-00185, EFSA-Q-2010-00193

Correspondence: pesticides.mrl@efsa.europa.eu

Declarations of interest: The declarations of interest of all scientific experts active in EFSA's work are available at https://ess.efsa.europa.eu/doi/doiweb/doisearch.

Suggested citation: EFSA (European Food Safety Authority), 2022. Statement on pesticide active substances that do not require a review of the existing maximum residue levels under Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2022;20(1):7061, 9 pp. https://doi.org/10.2903/j.efsa.2022.7061

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.

Summary

Regulation (EC) No 396/2005 establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. According to Article 12(1) of Regulation (EC) No 396/2005, the European Food Safety Authority (EFSA) shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC a reasoned opinion on the review of the existing MRLs for that active substance. Article 12(2) of that Regulation stipulates that EFSA shall provide by 1 September 2009 a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Directive 91/414/EEC before 2 September 2008.

According to the legal provisions, EFSA shall base its reasoned opinion on the relevant assessment report prepared under Directive 91/414/EEC or Regulation (EC) No 1107/2009. The reasoned opinion should cover all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance, including analytical methods and limit of determination (LOD) for enforcement of the proposed MRLs. All proposed MRLs should accommodate uses authorised within the European Union (EU), and uses authorised in third countries that have a significant impact on international trade. Among the active substances that need to be reviewed under Article 12(1) and 12(2) of Regulation (EC) No 396/2005, EFSA identified six active substances for which a review of MRLs is no longer considered necessary.

EFSA prepared a statement explaining the reasons why a review of MRLs for these substances became obsolete. The corresponding question numbers are considered addressed by this statement. Furthermore, for three active substances, the existing uses were assessed in the framework of the renewal (combined assessment). The list of active substances for which the MRL review was addressed during the renewal in the course of 2021 is also reported as an Annex to this statement.

The statement was circulated to Member States for consultation via a written procedure before finalisation.

Table of contents

1. Introduction

Regulation (EC) No 396/2005[1] establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. According to Article 12(1) of Regulation (EC) No 396/2005, EFSA shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC[2] a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance. Article 12(2) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide by 1 September 2009 a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Directive 91/414/EEC before 2 September 2008. According to the legal provisions, EFSA shall base its reasoned opinion on the relevant assessment report prepared under Directive 91/414/EEC or Regulation (EC) No 1107/2009[3]. The reasoned opinion should cover all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance, including analytical methods and limit of determination (LOD) for enforcement of the proposed MRLs. All proposed MRLs should accommodate uses authorised within the European Union (EU), and uses authorised in third countries that have a significant impact on international trade.

Among the active substances that need to be reviewed under Article 12(1) and Article 12(2) of Regulation (EC) No 396/2005, EFSA identified six active substances for which a review of MRLs is no longer considered necessary. EFSA prepared a statement explaining the reasons why a review of MRLs for these substances became obsolete. Furthermore, for three active substances, the existing uses were assessed in the framework of the renewal (combined assessment). The list of active substances for which the MRL review was addressed during the renewal in the course of 2021 and until the adoption of this statement, is also reported in an Annex to this statement.

The draft statement was circulated to Member States (MSs) for consultation via a written procedure. Comments received by 19 November 2021 were considered during the finalisation of this statement. The collation of comments received on the draft statement is considered as a background document to this statement and is made publicly available (EFSA, 2021).

2. Assessment

The following substances have been assessed by EFSA in this statement.

The active substances **chlorates (incl. Mg, Na, K chlorates)** were not included in Annex I to Council Directive 91/414/EEC in accordance with Commission Decision 2008/865/EC[4]. An EFSA conclusion on the peer review of the pesticide risk assessment is not available for this substance. No codex maximum residue limits (CXLs) are established by the Codex Alimentarius Commission and no import tolerances are currently in place for chlorates. 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. Since these uses lead to detectable residues of chlorate in food, temporary MRLs were recently legally implemented by Commission Regulation (EU) 2020/749[5]. Therefore, based on all the considerations reported above, the review of MRLs for chlorates becomes obsolete.

The active substance **didecyldimethylammonium chloride (DDAC)** was initially included in Annex I to Council Directive 91/414/EEC in accordance with Commission Directive 2009/70/EC[6]. An EFSA conclusion on the peer review for the pesticide risk assessment is available for this active substance (EFSA, 2009a). Since the notifier failed to provide the confirmatory information specified in

[1] 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. OJ L 70, 16.3.2005, p. 1–16.

[2] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32. Repealed by Regulation (EC) No 1107/2009.

[3] 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. 1–50.

[4] 2008/865/EC: Commission Decision 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 (notified under document number C(2008) 6587). OJ L 307, 18.11.2008, p. 7–8.

[5] Commission Regulation (EU) 2020/749 of 4 June 2020 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. OJ L 178, 8.6.2020, p. 7–20.

[6] Commission Directive 2009/70/EC of 25 June 2009 amending Council Directive 91/414/EEC to include difenacoum, didecyldimethylammonium chloride and sulphur as active substances. OJ L 164, 26.6.2009, p. 59–63.

Commission Directive 2009/70/EC, the approval for DDAC was withdrawn by Commission Implementing Regulation (EU) No 175/2013[7]. No CXLs are established by the Codex Alimentarius Commission and no import tolerances are currently in place for this active substance. Apart from its former use in plant protection products, DDAC is also a substance used in biocidal products. In the framework of quality controls performed by food business operators, unavoidable residues of DDAC were identified which exceeded the limit of 0.01 mg/kg (default MRL established in Article 18(1)(b) of Regulation (E)C No 396/2005). Based on the results of the monitoring data generated by EU Member States, European Commission proposed to set a temporary MRL at the level of 0.1 mg/kg in all commodities and requested EFSA to perform a dietary exposure assessment for the proposed temporary MRLs for DDAC. In its reasoned opinion (EFSA, 2014), EFSA concluded that although risk assessment was affected by a high degree of uncertainties due to the limited information available, the proposed temporary MRLs were expected to sufficiently protect consumers. Consequently, these temporary MRLs were legally implemented by Commission Regulation (EU) No 1119/2014[8]. Therefore, based on all the considerations reported above, the review of MRLs under Article 12 of Regulation (EC) No 396/2005 is considered obsolete for this active substance.

The active substance **dimethoate** was initially included in Annex I to Council Directive 91/414/EEC by Commission Directive 2007/25/EC[9]. Following the EFSA peer review of the pesticide risk assessment (EFSA, 2018c), dimethoate was not renewed by Commission Implementing Regulation (EU) 2019/1090[10]. After the decision of non-renewal, the active substance was moved to Annex V of Regulation (EC) No 396/2005 with specific MRLs at limit of quantification (LOQ) by Commission Regulation (EU) 2021/155[11]. Therefore, the review of MRLs for this substance becomes obsolete.

The active substance **ethoprophos** was initially included in Annex I to Council Directive 91/414/EEC by Commission Directive 2007/52/EC[12]. Following the EFSA peer review of the pesticide risk assessment (EFSA, 2018a), ethoprophos was not renewed by Commission Implementing Regulation (EU) 2019/344[13]. After the decision of non-renewal, the active substance was moved to Annex V of Regulation (EC) No 396/2005 with specific MRLs at LOQ by Commission Regulation (EU) 2021/155. Therefore, the review of MRLs for this substance becomes obsolete.

The active substance **methiocarb** was initially included in Annex I to Council Directive 91/414/EEC by Commission Directive 2007/5/EC[14]. Following the EFSA peer review of the pesticide risk assessment (EFSA, 2018b), methiocarb was not renewed by Commission Implementing Regulation (EU) 2019/1606[15]. After the decision of non-renewal, the active substance was moved to Annex V of Regulation (EC) No 396/2005 with specific MRLs at LOQ by Commission Regulation (EU) 2021/155. Therefore, the review of MRLs for this substance becomes obsolete.

[7] 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. 4–5.

[8] 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. OJ L 304, 23.10.2014, p. 43–74.

[9] Commission Directive 2007/25/EC of 23 April 2007 amending Council Directive 91/414/EEC to include dimethoate, dimethomorph, glufosinate, metribuzin, phosmet and propamocarb as active substances. OJ L 106, 24.4.2007, p. 34–42.

[10] Commission Implementing Regulation (EU) 2019/1090 of 26 June 2019 concerning the non-renewal of approval of the active substance dimethoate, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 173, 27.6.2019, p. 39–41.

[11] Commission Regulation (EU) 2021/155 of 9 February 2021 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for carbon tetrachloride, chlorothalonil, chlorpropham, dimethoate, ethoprophos, fenamidone, methiocarb, omethoate, propiconazole and pymetrozine in or on certain products. OJ L 46, 10.2.2021, p. 5–33.

[12] Commission Directive 2007/52/EC of 16 August 2007 amending Council Directive 91/414/EEC to include ethoprophos, pirimiphos-methyl and fipronil as active substances. OJ L 214, 17.8.2007, p. 3–8.

[13] Commission Implementing Regulation (EU) 2019/344 of 28 February 2019 concerning the non-renewal of approval of the active substance ethoprophos, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 62, 1.3.2019, p. 7–9.

[14] Commission Directive 2007/5/EC of 7 February 2007 amending Council Directive 91/414/EEC to include captan, folpet, formetanate and methiocarb as active substances. OJ L 35, 8.2.2007, p. 11–17.

[15] Commission Implementing Regulation (EU) 2019/1606 of 27 September 2019 concerning the non-renewal of the approval of the active substance methiocarb, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 250, 30.9.2019, p. 53–55.

The active substance **nicotine** was not included in Annex I to Council Directive 91/414/EEC by Commission Decision 2009/9/EC[16]. An EFSA conclusion on the peer review of the pesticide risk assessment is not available for this substance. No CXLs are established by the Codex Alimentarius Commission and no import tolerances are currently in place for nicotine. In the framework of quality controls performed by food business operators, residues of nicotine were identified in wild fungi, tea, herbal infusions, spices, rose hips and fresh herbs, which exceeded the limit of 0.01 mg/kg (default MRL established in Article 18(1)(b) of Regulation (E)C No 396/2005). Consequently, EFSA was asked to give an opinion on public health risks of nicotine residues in wild fungi and on the setting of temporary MRLs for nicotine in tea, herbal infusions, spices, rose hips and fresh herbs. Based on the assessments performed by EFSA (2009b, 2011) and the monitoring data generated by Member States, food business operators and Chinese government, temporary MRLs were established for wild fungi by Commission Regulation (EU) No 765/2010[17] and for tea, herbal infusions, spices, rose hips and fresh herbs by Commission Regulation (EU) No 812/2011[18]. Considering most recent monitoring data and pending the submission and evaluation of new data and information on the natural occurrence or formation of nicotine in the concerned products, the validity of these temporary MRLs has been extended by Commission Regulation (EU) No 2017/978[19]. Therefore, based on all the considerations reported above, the review of MRLs for this substance becomes obsolete.

Based on the above explanation, the following question numbers are considered addressed (Table 1).

Table 1: List of active substances that do not require MRL review

No.	Question number (MRL review)	Active substance	RMS	Status under Reg (EU) No 1107/2009	Assessment made by EFSA	MRL Regulation
1.	EFSA-Q-2009-00027	Chlorates	FR	Not approved	EFSA CONTAM Panel (2015)	Reg. (EU) 2020/749
2.	EFSA-Q-2010-00185	Didecyldimethylammonium chloride	NL	Not approved	EFSA (2009a)	Reg. (EU) 1119/2014
3.	EFSA-Q-2008-527	Dimethoate	IT	Not approved	EFSA (2018c)	Reg. (EU) 2021/155
4.	EFSA-Q-2008-535	Ethoprophos	IT	Not approved	EFSA (2018a)	Reg. (EU) 2021/155
5.	EFSA-Q-2008-588	Methiocarb (aka mercaptodimethur)	DE	Not approved	EFSA (2018b)	Reg. (EU) 2021/155
6.	EFSA-Q-2010-00193	Nicotine	FR	Not approved	EFSA (2009b, 2011)	Reg. EU) 2017/978

RMS: rapporteur Member State; MRL: maximum residue level.

3. Conclusions

Among the active substances that need to be reviewed under Article 12 of Regulation (EC) No 396/2005, EFSA identified 6 active substances for which a review of MRLs is not needed. EFSA therefore

[16] Commission Decision 2009/9/EC of 8 December 2008 concerning the non-inclusion of nicotine in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance. OJ L 5, 9.1.2009, p.7–8.

[17] Commission Regulation (EU) No 765/2010 of 25 August 2010 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorothalonil clothianidin, difenoconazole, fenhexamid, flubendiamide, nicotine, spirotetramat, thiacloprid and thiamethoxam in or on certain products. OJ L 226, 28.8.2010, p. 1–37. OJ L 208, 13.8.2011, p. 1–22.

[18] Commission Regulation (EU) No 812/2011 of 10 August 2011 amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for dimethomorph, fluopicolide, mandipropamid, metrafenone, nicotine and spirotetramat in or on certain products.

[19] Commission Regulation (EU) 2017/978 of 9 June 2017 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fluopyram; hexachlorocyclohexane (HCH), alpha-isomer; hexachlorocyclohexane (HCH), beta-isomer; hexachlorocyclohexane (HCH), sum of isomers, except the gamma isomer; lindane (hexachlorocyclohexane (HCH), gamma-isomer); nicotine and profenofos in or on certain products. OJ L 151, 14.6.2017, p. 1–37.

prepared a statement explaining the reasons why a review of MRLs is no longer necessary for these active substances. The corresponding question numbers are considered addressed by this statement.

References

EFSA (European Food Safety Authority), 2009a. Conclusion on pesticide peer review of the pesticide risk assessment of the active substance incorrectly named didecyldimethylammonium chloride. EFSA Journal 2008;214r, 54 pp. https://doi.org/10.2903/j.efsa.2009.214r

EFSA (European Food Safety Authority), 2009b. Potential risks for public health due to the presence of nicotine in wild mushrooms. EFSA Journal 2009;7(5):RN-286, 47 pp. https://doi.org/10.2903/j.efsa.2009.286r

EFSA (European Food Safety Authority), 2011. Reasoned opinion on the setting of temporary MRLs for nicotine in tea, herbal infusions, spices, rose hips and fresh herbs. EFSA Journal 2011;9(3):2098, 50 pp. https://doi.org/10.2903/j.efsa.2011.2098

EFSA (European Food Safety Authority), 2014. 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. https://doi.org/10.2903/j.efsa.2014.3675

EFSA (European Food Safety Authority), Arena M, Auteri D, Barmaz S, Brancato A, Brocca D, Bura L, Carrasco Cabrera L, Chiusolo A, Civitella C, Court Marques D, Crivellente F, Ctverackova L, De Lentdecker C, Egsmose M, Erdos Z, Fait G, Ferreira L, Goumenou M, Greco L, Ippolito A, Istace F, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Magrans JO, Medina P, Mineo D, Miron I, Molnar T, Padovani L, Parra Morte JM, Pedersen R, Reich H, Riemenschneider C, Sacchi A, Santos M, Serafimova R, Sharp R, Stanek A, Streissl F, Sturma J, Szentes C, Tarazona J, Terron A, Theobald A, Vagenende B, Van Dijk J and Villamar-Bouza L, 2018a. Conclusion on the peer review of the pesticide risk assessment of the active substance ethoprophos. EFSA Journal 2018;16(10):5290, 26 pp. https://doi.org/10.2903/j.efsa.2018.5290

EFSA (European Food Safety Authority), Arena M, Auteri D, Barmaz S, Brancato A, Brocca D, Bura L, Carrasco Cabrera L, Chiusolo A, Civitella C, Court Marques D, Crivellente F, Ctverackova L, De Lentdecker C, Egsmose M, Erdos Z, Fait G, Ferreira L, Greco L, Ippolito A, Istace F, Jarrah S, Kardassi D, Leuschner R, Lostia A, Lythgo C, Magrans JO, Medina P, Mineo D, Miron I, Molnar T, Padovani L, Parra Morte JM, Pedersen R, Reich H, Sacchi A, Santos M, Serafimova R, Sharp R, Stanek A, Streissl F, Sturma J, Szentes C, Tarazona J, Terron A, Theobald A, Vagenende B, Van Dijk J and Villamar-Bouza L, 2018b. Conclusion on the peer review of the pesticide risk assessment of the active substance methiocarb. EFSA Journal 2018;16(10):5429, 26 pp. https://doi.org/10.2903/j.efsa.2018.5429

EFSA (European Food Safety Authority), Arena M, Auteri D, Barmaz S, Brancato A, Brocca D, Bura L, Carrasco Cabrera L, Chiusolo A, Civitella C, Court Marques D, Crivellente F, Ctverackova L, De Lentdecker C, Egsmose M, Erdos Z, Fait G, Ferreira L, Greco L, Ippolito A, Istace F, Jarrah S, Kardassi D, Leuschner R, Lostia A, Lythgo C, Magrans JO, Medina P, Mineo D, Miron I, Molnar T, Padovani L, Parra Morte JM, Pedersen R, Reich H, Sacchi A, Santos M, Serafimova R, Sharp R, Stanek A, Streissl F, Sturma J, Szentes C, Tarazona J, Terron A, Theobald A, Vagenende B, Van Dijk J and Villamar-Bouza L, 2018c. Conclusion on the peer review of the pesticide risk assessment of the active substance dimethoate. EFSA Journal 2018;16(10):5454, 29 pp. https://doi.org/10.2903/j.efsa.2018.5454

EFSA (European Food Safety Authority), 2021. Member States consultation report on the active substances that do not require a review of the existing maximum residue levels under Article 12 of Regulation (EC) No 396/2005 prepared by EFSA in the framework of Article 12 of Regulation (EC)No 396/2005, 26 November 2021. Available online: www.efsa.europa.eu

EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2015. Scientific Opinion on risks for public health related to the presence of chlorate in food. EFSA Journal 2015;13(6):4135, 103 pp. https://doi.org/10.2903/j.efsa.2015.4135

Abbreviations

CXL	codex maximum residue limit
DDAC	didecyldimethylammonium chloride
LOD	limit of determination
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
RMS	rapporteur Member State

Annex A – Active substances for which the Article 12 review was addressed in 2021 in the framework of the peer review for the renewal until the adoption of this statement

Q-number	Active substance	RMS	Adoption date	Link to EFSA conclusions
EFSA-Q-2009-00156	Calcium carbonate	ES	26/2/2021	https://www.efsa.europa.eu/it/efsajournal/pub/6500
EFSA-Q-2009-00181	Potassium hydrogen carbonate	NL	14/4/2021	https://www.efsa.europa.eu/it/efsajournal/pub/6593
EFSA-Q-2009-00158	Carbon dioxide	FR	30/4/2021	https://www.efsa.europa.eu/en/efsajournal/pub/6605

RMS: rapporteur Member State.