REASONED OPINION

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Review of the existing maximum residue levels for denathonium benzoate according to Article 12 of Regulation (EC) No 396/2005

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Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance denathonium benzoate. Considering that this active substance is not authorised for use on edible crops within the EU, that no MRLs are established by the Codex Alimentarius Commission (codex maximum residue limits), and that no import tolerances were notified to EFSA, residues of denathonium benzoate are not expected to occur in any plant or animal commodity. Available data were not sufficient to derive any enforcement measure against potential illegal uses.

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Summary

Denathonium benzoate was included in Annex I to Directive 91/414/EEC on 1 September 2009 by Commission Directive 2008/127/EC, and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. As the active substance was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, the European Food Safety Authority (EFSA) is required to provide a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance in compliance with Article 12(1) of the aforementioned regulation.

As the basis for the MRL review, on 16 May 2017, EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit their national Good Agricultural Practices (GAPs) by 16 June 2017, in a standardised way, in the format of specific GAP forms allowing the rapporteur Member State (RMS), Portugal, to identify the critical GAPs, in the format of specific GAP overview file. According to the information provided in the GAP forms, only forestry uses are currently authorised within the European Union (EU). The RMS did not report any uses authorised in third countries that might have a significant impact on international trade.

On the basis of all the data submitted by Member States, EFSA, according to the process, should ask Portugal as the designated RMS, to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. Since only uses on forestry (not edible crops) are authorised, the GAP overview file and a PROFile were not considered relevant.

The evaluation report was provided by the RMS to EFSA on 18 September 2017. Following a completeness check undertaken by EFSA, a request for further clarifications was addressed to the RMS on 6 October 2017 and a revised evaluation report received on 19 December 2017. After having considered all the information provided, EFSA finalised the completeness check report which was made available to Member States on 26 January 2018.

Based on the information provided by the RMS and Member States and taking into account the conclusions derived by EFSA in the framework of Directive 91/414/EEC, EFSA prepared in January 2018 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 16 February 2018 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

Residues of denathonium benzoate are not expected to occur in any plant commodity or in any animal product because the use of denathonium benzoate is not intended for direct application on any food or feed crop. No codex maximum residue limits (CXLs) are available for this active substance and no uses authorised in third countries were notified to the RMS. A risk assessment is therefore in principle not required.

According to the EURLs, an limit of quantification (LOQ) of 0.01 mg/kg is achievable for the enforcement of denathonium (sum of denathonium and its salts, expressed as denathonium benzoate) in the four main plant matrices. Due to the lack of data regarding mammalian toxicology, plant and livestock metabolism, EFSA is however not in a position to recommend any enforcement measure against the potential illegal use of denathonium benzoate. It is also not possible to verify whether the (default) MRL of 0.01 mg/kg, as defined by Regulation (EC) No 396/2005, provides sufficient consumer protection in case of misuse.

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Background

Regulation (EC) No 396/2005[1] (hereinafter referred to as 'the Regulation') establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that Regulation stipulates that 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[2] a reasoned opinion on the review of the existing MRLs for that active substance. As denathonium benzoate was included in Annex I to Council Directive 91/414/EEC on 1 September 2009 by means of Commission Directive 2008/127/EC[3], and has been deemed to be approved under Regulation (EC) No 1107/2009[4], in accordance with Commission Implementing Regulation (EU) No 540/2011[5], as amended by Commission Implementing Regulation (EU) No 541/2011[6], EFSA initiated the review of all existing MRLs for that active substance.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC. It should be noted, however, that, in the framework of Directive 91/414/EEC, only a few representative uses are evaluated, whereas MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the European Union (EU), and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Directive 91/414/EEC is therefore insufficient for the assessment of all existing MRLs for a given active substance.

To gain an overview of the pesticide residues data that have been considered for the setting of the existing MRLs, EFSA developed the Pesticide Residues Overview File (PROFile). The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

- the nature and magnitude of residues in primary crops;
- the nature and magnitude of residues in processed commodities;
- the nature and magnitude of residues in rotational crops;
- the nature and magnitude of residues in livestock commodities;

the analytical methods for enforcement of the proposed MRLs.

As the basis for the MRL review, on 16 May 2017, EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit their national Good Agricultural Practices (GAPs) that are authorised in different Member States by 16 June 2017, in a standardised way in the format of specific GAP forms. In the framework of this consultation, four Member States provided feedback on their national authorisations of denathonium benzoate. According to the information provided, only forestry uses are currently authorised within the EU. The RMS did not report any uses authorised in third countries that might have a significant impact on international trade.

On the basis of all the data submitted by Member States, EFSA, according to the process, should ask Portugal as the designated RMS, to complete the PROFile and to prepare a supporting evaluation report.

The evaluation report was initially provided by the RMS to EFSA on 18 September 2017. Since only uses on forestry (not edible crops) are authorised, the GAP overview file and a PROFile were not considered relevant in this case and were not submitted. Following a completeness check undertaken by EFSA, a request for further clarifications was addressed to the RMS on 6 October 2017 and a revised evaluation report received on 19 December 2017. After having considered all the information provided, EFSA finalised the completeness check report which was made available to Member States on 26 January 2018.

[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] Commission Directive 2008/127/EC of 18 December 2008 amending Council Directive 91/414/EEC to include several active substances. OJ No L 344, 20.12.2008, p. 89–111.

[4] 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.

[5] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.

[6] Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 187–188.

Based on the information provided by the RMS and Member States and taking into account the conclusions derived by EFSA in the framework of Directive 91/414/EEC, EFSA prepared in January 2018 a draft reasoned opinion, which was submitted to Member States for commenting via a written procedure. All comments received by 16 February 2018 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Portugal, 2017) is considered as supporting document to this reasoned opinion and, thus, is made publicly available.

In addition, key supporting documents to this reasoned opinion are the completeness check report (EFSA, 2018a) and the Member States consultation report (EFSA, 2018b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion.

Terms of Reference

According to Article 12 of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

The active substance and its use pattern

Denathonium benzoate is a common name for *N*-benzyl-2-[(2,6-dimethylphenyl)amino]-*N*,*N*-diethyl-2-oxoethanaminium benzoate or benzyldiethyl[[2,6-xylylcarbamoyl]methyl]ammonium benzoate (IUPAC).

Denathonium benzoate is used as a repellent, by a combination of optical and bitter taste effects.

The chemical structure of denathonium benzoate is reported in Appendix B.

Denathonium benzoate was evaluated in the framework of Directive 91/414/EEC with Portugal designated as RMS. The representative use supported for the peer review process was as repellent in forestry. Following the peer review, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2008/127/EC, which entered into force on 1 September 2009. According to Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011, denathonium benzoate is deemed to have been approved under Regulation (EC) No 1107/2009. This approval is restricted to uses as repellent in forest trees only.

The EU MRLs for denathonium benzoate are set to default (0.01 mg/kg) according to Article 18(1) (b) of Regulation (EC) No 396/2005 and codex maximum residue limits (CXLs) for this active substance are not available. For the purpose of this MRL review, only uses on forestry were reported. These uses comprise applications by spraying the undiluted product or by coating with brush or dip on deciduous/coniferous forest trees, as a repellent against game browsing damage. The RMS did not report any uses authorised in third countries that might have a significant impact on international trade.

Assessment

Considering that the use of denathonium benzoate is only authorised within the EU on forestry (non-consumable crops), that no CXLs are available for this active substance and that no uses authorised in third countries were notified to the RMS, European consumers are not expected to be exposed to residues of this active substance and a consumer risk assessment is, in principle, not required. Risk managers might have interest, however, to enforce against the potential illegal use of denathonium benzoate within the EU as well as the presence of illegitimate residue levels in imported products.

In order to assist risk managers in applying the most appropriate enforcement measures, EFSA assessed the available data with particular attention for the analytical methods, the toxicological reference values and the nature of residues in plants and livestock.

EFSA has based its assessment on the evaluation report submitted by the RMS (Portugal, 2017), the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC (Portugal, 2007, 2011) and the conclusion on the peer review of the pesticide risk assessment of the active substance denathonium benzoate (EFSA, 2012). The evaluation report submitted by the RMS in the framework of this review (Portugal, 2017) was considered as additional supporting information.

The toxicological assessment of denathonium benzoate was peer reviewed under Directive 91/414/EEC but no toxicological reference values have been proposed due to the lack of information. Further information was not considered necessary as direct application on crops is not intended (EFSA, 2012).

According to the information provided by the EURLs, an limit of quantification (LOQ) of 0.01 mg/kg is achievable for the enforcement of denathonium (sum of denathonium and its salts, expressed as denathonium benzoate) in high water, high acid, dry and high oil content matrices by using the QuEChERS or the QuOil methods (EFSA, 2018b). Nevertheless, under the peer review of Directive 91/414/EEC, no analytical methods for enforcement of denathonium benzoate in commodities of plant and animal origin were available and no residue data were provided because direct application on any food or feed crop is not intended. Consequently, EFSA is not in a position to recommend any enforcement measure against the potential illegal uses of denathonium benzoate.

Due to lack of data on toxicology of the compound, it is also not possible to assess whether the (default) MRL of 0.01 mg/kg, as defined by Regulation (EC) No 396/2005, would provide adequate consumer protection in case of misuse. However, considering the mode of action of denathonium benzoate as taste repellent and its physical and chemical properties (permanent coating, white colour) any misuse is expected to be easily identified.

Conclusions and recommendations

Residues of denathonium benzoate are not expected to occur in any plant commodity or in any animal product because the use of denathonium benzoate is not intended for direct application on any food or feed crop. No CXLs are available for this active substance and no uses authorised in third countries were notified to the RMS. A risk assessment is therefore in principle not required. Due to the lack of data regarding mammalian toxicology, plant and livestock metabolism, EFSA is however not in a position to recommend any enforcement measure against the potential illegal use of denathonium benzoate. It is also not possible to verify whether the (default) MRL of 0.01 mg/kg, as defined by Regulation (EC) No 396/2005, provides sufficient consumer protection in case of misuse.

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Abbreviations

a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	codex maximum residue limit
DAR	draft assessment report
EURLs	European Union Reference Laboratories for Pesticide Residues (former CRLs)
GAP	Good Agricultural Practice
ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification

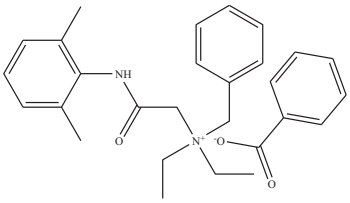
MRL	maximum residue level
MS	Member States
NEU	northern European Union
PROFile	(EFSA) Pesticide Residues Overview File
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RMS	rapporteur Member State
SEU	southern European Union
SMILES	simplified molecular-input line-entry system
TAR	total applied radioactivity
WHO	World Health Organization

Appendix A – Summary of authorised uses considered for the review of MRLs

Crop and/or situation[a]	MS Country	NEU SEUG	Product name	F G or I[b]	Pests or Group of pests controlled[c]	Preparation		Application				Application rate per treatment			PHI (days)[m]	Remarks
						Type[d–f]	Conc. a.s.[i]	Method kind[f–h]	Growth Stages & season[j]	Number min–max[k]	Interval between application min–max	g a.s /hL min-max[l]	Water L/ha min–max	g a.s./ ha min–max[l]		
Deciduous/ coniferous forest trees	SE	NEU	Arbinol B/(ASU 90 820 P) SIT11010D	F	Roe deer (*Capreolus capreolus*) Red deer (*Cervus elaphus*)	AL	0.11 g/L	Brush-on, dip, spray	Against gnawing during winter	1	–	0.66 L/ 1,000 trees	Undiluted application	–	n.a.	

MRL: maximum residue level; MS: Member State; NEU: northern European Union; SEU: southern European Union; a.s.: active substance
(a): For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure).
(b): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(c): e.g. biting and sucking insects, soil born insects, foliar fungi, weeds.
(d): e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR), other liquids to be used undiluted (AL).
(e): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(f): All abbreviations used must be explained.
(g): Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench.
(h): Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant type of equipment used must be indicated.
(i): g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application.
(k): Indicate the minimum and maximum number of applications possible under practical conditions of use.
(l): The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha.
(m): PHI: minimum pre-harvest interval.

Appendix B – Used compound codes

Code/trivial name	Chemical name/SMILES notation	Structural formula
Denathonium benzoate	*N*-benzyl-2-[(2,6-dimethylphenyl)amino]-*N*,*N*-diethyl-2-oxoethanaminium benzoate or benzyldiethyl[[2,6-xylylcarbamoyl]methyl]ammonium benzoate	

SMILES: simplified molecular-input line-entry system.