

REASONED OPINION

Reasoned opinion on the modification of the existing MRL for dodine in pome fruit, apricots and olives¹

European Food Safety Authority²

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, Portugal, herewith referred to as the evaluating Member State (EMS), received an application from the company Agriphar to lower the existing MRL for dodine in apricots to reflect a less critical European use. The applicant also submitted additional residue trials on apples and a new freezer storage stability study in high oil content matrices to confirm the MRLs derived for pome fruit and olives in the previously issued EFSA reasoned opinion. The lowering of the MRL for apricots is justified as for the existing MRL acute consumer intake concerns cannot be excluded. According to EFSA, the submitted data are sufficient to confirm the MRL proposal of 0.9 mg/kg for pome fruits as derived in the previous EFSA reasoned opinion. The MRL proposal of 0.09 mg/kg for apricots has been derived, in accordance with the provisions of the EU guidance document on extrapolation from residue trials on peaches and apples. Although the data are compliant with the data requirements, EFSA recommends performing additional trials on apricots to confirm that the MRL is sufficient to cover the use on apricots. The new freezer storage stability study submitted for dodine in high oil content matrices confirms the validity of the residue trials on olives. Thus, the data gap identified in the previous opinion with regard to the MRL for olives (20 mg/kg) is sufficiently addressed. Based on the risk assessment results, EFSA concludes that the new intended less critical uses on pome fruit and apricots which result in lower MRL proposals compared to the existing MRLs, will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a public health concern.

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KEY WORDS

Dodine, various crops, MRL application, lowering of MRLs, Regulation (EC) No 396/2005, consumer risk assessment, guanidine fungicide.

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² Correspondence: pesticides.mrl@efsa.europa.eu

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005³, Portugal, herewith referred to as the evaluating Member State (EMS), received an application from the company Agriphar to lower the existing MRL for dodine in apricots to reflect a less critical European use. The applicant also submitted additional residue trials on apples and a new freezer storage stability study in high oil content matrices to confirm the MRLs derived for pome fruit and olives in the previously issued EFSA reasoned opinion. The lowering of the MRL for apricots is justified as for the existing MRL acute consumer intake concerns cannot be excluded. The EMS drafted an updated evaluation report according to Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 29 January 2013.

EFSA bases its assessment on the revised evaluation report submitted by the EMS, the Draft Assessment Report (DAR) and the Additional Report prepared by the Rapporteur Member State (RMS) Portugal under Council Directive 91/414/EEC⁴, and the EFSA conclusion on the peer review of the pesticide risk assessment of the active substance dodine.

The toxicological profile of dodine was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.1 mg/kg bw per day and an ARfD of 0.1 mg/kg bw.

The metabolism of dodine in primary crops was investigated in fruits. According to the conclusions of the peer review, the metabolism in all crops was seen to be similar and the residue definition for monitoring and risk assessment was proposed as dodine. For the uses on the crops under consideration EFSA concludes that the metabolism of dodine is sufficiently addressed and the residue definitions agreed in the peer review are applicable.

EFSA concludes that the submitted supervised residue trials are sufficient to confirm the MRL proposal of 0.9 mg/kg for pome fruits as derived in the previous EFSA reasoned opinion. The MRL proposal of 0.09 mg/kg for apricots has been derived, in accordance with the provisions of the EU guidance document on extrapolation from residue trials on peaches and apples. Although the data are compliant with the data requirements, EFSA recommends performing additional trials on apricots to confirm that the MRL is sufficient to cover the use on apricots. The new freezer storage stability study submitted for dodine in high oil content matrices confirms the validity of the residue trials on olives. Thus, the data gap identified in the previous opinion with regard to the MRL for olives (20 mg/kg) is sufficiently addressed. Adequate analytical enforcement methods are available to control the residues of dodine in the commodities under consideration.

Dodine is hydrolytically stable under the processing conditions representative for pasteurisation, boiling/cooking and sterilisation and this for processed commodities the same residue definition as for raw agricultural commodities is applicable.

Since the proposed use of dodine is on permanent crops, the investigation of dodine residues in rotational/succeeding crops is of no relevance.

Since pome fruit pomace can be fed to livestock, in principle residues of dodine in food of animal origin should be assessed. However, considering that the existing EU MRL for pome fruit is higher (5 mg/kg) than the MRL proposal derived under the current assessment (0.9 mg/kg) and that all existing MRLs for livestock are set at the limit of quantification, a detailed examination of the residue situation in livestock was considered unnecessary.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticides Residues Intake Model (PRIMO). For the calculation of the chronic exposure, EFSA used the median residue value as

³ Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005. OJ L 70, 16.03.2005, p. 1-16.

⁴ Council Directive 91/414/EEC of 15 July 1991. OJ L 230, 19.08.1991, p. 1-32.

derived from the residue trials on pome fruit and apricots. For banana, peaches, cherries, table olives and olives for oil production the risk assessment values were available from the previously issued EFSA reasoned opinion. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005 were used as input values.

The acute exposure assessment was performed only with regard to pome fruits and apricots, assuming the consumption of a large portion of the food items as reported in the national food surveys containing residues at the highest level (or median level for olives) as observed in supervised field trials.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated exposure accounted for up to 23.5% of the ADI (WHO Cluster diet B). The contribution of the crops under consideration (expressed in % of the ADI) was 2.11% for apples (DE child diet), 0.12% for pears (IE adult diet), 0.018% for apricots (DE child diet), and below 0.01% for quinces, loquats and medlar.

No acute consumer intake concerns were identified with regard to the MRL proposals for the crops under consideration. The individual contribution to the ARfD accounted for 46% for apples, 42.8 % for pears, 6.9% for quinces, 5.7% for medlar and 2.2% for apricots.

EFSA concludes that the new intended less critical uses on pome fruit and apricots which result in lower MRL proposals compared to the existing MRLs, will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a public health concern.

EFSA proposes to amend the existing MRLs as reported in the summary table.

Summary table

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Dodine				
0130010	Apples	5/0.9 (tentative) ^(b)	0.9	The lowering of the existing MRL is proposed based on a revised GAP since a consumer risk was identified for the existing MRL. The new GAP is sufficiently supported by data to derive a MRL proposal; no consumer risk is associated with this MRL proposal.
0130020	Pears		0.9	
0130030	Quinces	5/0.9 ^(b)	0.9	
0130040	Medlar			
0130050	Loquat			
0140010	Apricots	5/0.01 ^{*(b)}	0.09	The proposed MRL has been derived in accordance with the provisions of the EU guidance document by extrapolation from residue trials on peaches and apples. EFSA notes that it would be desirable to get additional residue trials on apricots to ensure that the MRL sufficiently covers the use on apricots. No consumer intake concerns were identified for the intended SEU uses.

(a): According to Annex I of Regulation (EC) No 396/2005.

(b): MRL proposals derived in previously issued reasoned opinion (EFSA, 2013).

(*): Indicates that the MRL is set at the limit of analytical quantification.

TABLE OF CONTENTS

Abstract	1
Summary	2
Table of contents	4
Background	5
Terms of reference.....	5
The active substance and its use pattern.....	6
Assessment	7
1. Method of analysis.....	7
1.1. Methods for enforcement of residues in food of plant origin	7
1.2. Methods for enforcement of residues in food of animal origin	7
2. Mammalian toxicology	7
3. Residues.....	8
3.1. Nature and magnitude of residues in plant.....	8
3.1.1. Primary crops.....	8
3.1.2. Rotational crops.....	12
3.2. Nature and magnitude of residues in livestock	12
4. Consumer risk assessment	12
Conclusions and recommendations	14
References	16
Appendices	18
A. Good Agricultural Practice (GAPs).....	18
B. Pesticide Residues Intake Model (PRIMo).....	19
C. Existing EU maximum residue levels (MRLs).....	21
Abbreviations	24

BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at European Union level. Article 6 of that Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC, repealed by Regulation (EC) No 1107/2009, shall submit to a Member State, when appropriate, an application to set or to modify an MRL in accordance with the provisions of Article 7 of that Regulation.

Portugal, hereafter referred to as the evaluating Member State (EMS), received an application from the company Agriphar⁵ to modify the existing MRLs for the active substance dodine in apricots. The applicant also submitted additional residue trials on apples and a new freezer storage stability study in high oil content matrices to confirm the MRLs derived for pome fruit and olives in the previously issued EFSA reasoned opinion (EFSA, 2013). This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation. After completion, the revised evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 29 January 2013.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2013-00092 and the following subject:

Dodine - Application to modify the existing MRLs in various fruits.

The EMS Portugal proposed to lower the existing MRL of 5 mg/kg in apricots to 0.15 mg/kg and confirmed the validity of the MRL of 0.9 mg/kg for pome fruits and 20 mg/kg for table olives and olives for oil production.

EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation.

TERMS OF REFERENCE

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

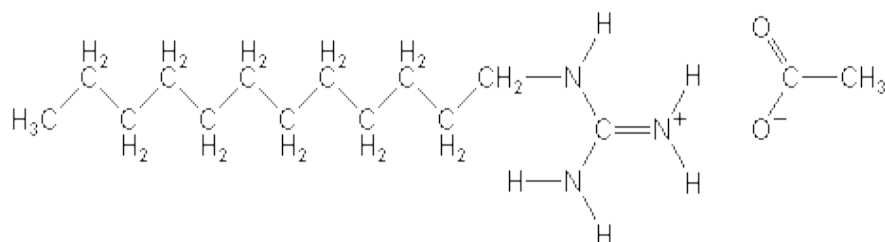
In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the calculated deadline for providing the reasoned opinion is 1 May 2013.

⁵ Agriphar, Rue de Renory 6/1 - Ougrée, 4102, Belgium

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Dodine is the ISO common name for 1-dodecylguanidinium acetate (IUPAC). The chemical structure of the compound is herewith reported:



Molecular weight: 287.4

Dodine is a foliar fungicide with protective and some curative action. It is not systemic but has a translaminar action. It is a multisite inhibitor acting mainly on the fungus membranes. Dodine is used as a foliar spray early in the season mainly against scab on apples and pears, leaf spots diseases on cherries, and leaf curl on peaches.

Dodine was evaluated in the framework of Council Directive 91/414/EEC with Portugal designated as the rapporteur Member State (RMS). Following the Commission Decision 2008/934/EC⁶ concerning the non-inclusion of dodine in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant made a resubmission application for the inclusion of dodine in Annex I of the above mentioned directive. The RMS submitted an evaluation of the additional data in the format of an Additional Report (Portugal, 2009). The representative uses submitted for the peer review refer to foliar application of dodine on fruits (apples, pears, cherries and peaches). The peer review was finalized and an EFSA conclusion was issued in 2010 (EFSA, 2010). According to Commission Directive 2011/9/EU⁷, dodine is included in Annex I of Directive 91/414/EEC for uses as a fungicide only. According to one of the inclusion conditions, the Member States shall pay particular attention to monitor dodine residue levels in pome fruit.

The EU MRLs for dodine are established in Annex IIIA of Regulation (EC) No 396/2005 (Appendix C). The existing EU MRLs for dodine are set at 5 mg/kg in pome fruit and apricots, and at the LOQ of 0.2 mg/kg in table olives and olives for oil production. Codex Alimentarius has established a CXL of 5 mg/kg for pome fruit. EFSA recently issued a reasoned opinion where the lowering of MRLs was proposed for pome fruit (0.9 mg/kg, on a tentative basis), cherries (3 mg/kg), peaches (0.09 mg/kg), apricots (the LOQ of 0.01 mg/kg) and the raising of the MRLs was proposed for banana (0.5 mg/kg), table olives and olives for oil production (20 mg/kg) (EFSA, 2013). EFSA noted that the validity of residue trials data in olives has to be confirmed by submitting an adequate freezer storage stability study (EFSA, 2013).

The applicant now submits a new freezer storage stability of dodine in high oil content matrices as well as additional residue trials on apples to derive a MRL proposal in apricots, to complete the SEU residue data set on pome fruit and to confirm the MRL in olives (Portugal, 2013). The details of the GAPS for dodine are given in Appendix A.

⁶ Commission Decision 2008/934/EC of 5 December 2008, OJ L 333, 11.12.2008, p.11

⁷ Commission Directive 2011/9/EU of 1 February 2011, OJ L 28, 2.2.2011, p.36-39.

ASSESSMENT

EFSA bases its assessment on the updated evaluation report submitted by the EMS (Portugal, 2013), the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (Portugal, 2006), Additional Report prepared under Regulation (EC) No 33/2008⁸ (Portugal, 2009), the conclusion on the peer review of the pesticide risk assessment of the active substance dodine (EFSA, 2010) and the conclusions from the previously issued EFSA reasoned opinion on the modification of existing MRL for dodine (EFSA, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011⁹ and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011; OECD, 2011).

1. Method of analysis

1.1. Methods for enforcement of residues in food of plant origin

Analytical methods for the determination of dodine residues in plant commodities were assessed during the peer review under Directive 91/414/EEC (Portugal 2006, 2009) and in the previously issued EFSA reasoned opinion (EFSA, 2013).

EFSA concludes that sufficiently validated analytical methods are available to control the residues of dodine in high water- and high oil content matrices.

1.2. Methods for enforcement of residues in food of animal origin

The availability of analytical methods for the determination of dodine residues in commodities of animal origin were not investigated in the framework of the peer review since the representative uses assessed did not indicate a need to modify MRLs for animal commodities (EFSA, 2010).

2. Mammalian toxicology

The toxicological profile of dodine was assessed in the framework of the peer review under Directive 91/414/EEC (EFSA, 2010). The data were sufficient to derive toxicological reference values for dodine which are compiled in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Dodine					
ADI	EFSA	2010	0.1 mg/kg bw per day	Dog, 1 yr and 90 day studies	100
ARfD	EFSA	2010	0.1 mg/kg bw	Rat, developmental study	100

⁸ Commission Regulation of 1 January 2008, OJ L 15, 18.1.2008, p.5

⁹ Commission Regulation (EU) No 546/2011 of 10 June 2011. OJ L 155, 11.06.2011, p. 127-175.

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of dodine in fruits was investigated in the framework of the peer review under Directive 91/414/EEC (Portugal, 2006, 2009; EFSA, 2010). The design and results of metabolism studies are discussed in detail in the previously issued EFSA reasoned opinion (EFSA, 2013). According to the conclusions of the peer review, the metabolism in all crops was seen to be similar, with the major constituent of the residues in apples and strawberries being unchanged dodine. Thus, the residue for monitoring and risk assessment was defined as dodine only (EFSA, 2010). For the uses on the crops under consideration EFSA concludes that the metabolism of dodine is sufficiently addressed and the residue definitions agreed in the peer review are applicable.

3.1.1.2. Magnitude of residues

a. Pome fruit

NEU GAP: 2 x 0.68-0.9 kg a.s./ha; interval 7-10 days; BBCH 01-75; PHI 60 days

In the previously issued EFSA reasoned opinion, a MRL proposal of 0.5 mg/kg was derived for the whole group of pome fruits (apples, pears, quinces, medlar, and loquat) in support of the NEU use, based on eight GAP compliant residue trials (EFSA, 2013). No new data were submitted in the framework of the current application.

SEU GAP: 2 x 0.68-0.9 kg a.s./ha; interval 7-10 days; BBCH 01-75; PHI 60 days

In the previously issued EFSA reasoned opinion, a tentative MRL proposal of 0.9 mg/kg was derived for pome fruit based on six GAP compliant residue trials performed in the SEU (EFSA, 2013). The MRL proposal was considered tentative since according to the EU guidance document at least eight residue trials would be required for pome fruit.

In the framework of the current application the applicant submitted two additional residue trials on apples to complete the residue data set. These two trials which were performed in Greece in 2009 reflect the intended GAP in terms of application rate, number of applications and the PHI; however, a deviation was noticed as regards the growth stage of the last application (BBCH 87-89 while in the GAP it is defined as not later than BBCH 75). Despite this deviation EFSA is of the opinion the trials are appropriate to complete the data package for pome fruit.

Thus, in total 8 residue trials on apples are now available in support of the SEU GAP. According to the EU guidance document on extrapolation rules (EC, 2011), eight residue trials are sufficient to support the extrapolation from apples to the whole group of pome fruit. The tentative MRL proposal of 0.9 mg/kg derived in the previous reasoned opinion of EFSA is confirmed.

b. Apricots

SEU GAP: 2 x 0.9 kg a.s./ha; interval 7-10 days; BBCH 01-69 or after harvest; PHI 75 days

In the previously issued reasoned opinion, the proposal of the EMS to set the MRL at a level of 0.2 mg/kg on the basis of seven residue trials on peaches was not accepted by EFSA because, according to the EU guidance document on extrapolation (EC, 2011), for pesticides used up to or close to harvest (last application after the consumable part of the crop has started to form) an extrapolation from peaches to apricots would not be acceptable. Thus, EFSA proposed the lowering of the existing

EU MRL of 5 mg/kg for which a consumer health concern was identified to the LOQ of 0.01 mg/kg (EFSA, 2013).

Portugal now made the case for re-evaluating the situation, taking into account that according to the intended GAP for dodine on apricots the last application is foreseen at the growth stage BBCH 69 (end of flowering: all petals fallen). This growth stage is considered as a situation where the consumable part of the crop has not yet started to form. According to the EU guidance document under these circumstances wider extrapolation rules would be applicable¹⁰. In addition to the residue trials on peaches, Portugal referred to four additional residue trials on apples reported in the Additional Report (Portugal 2009) which should also be used to complete the residue data package. Thus, according to Portugal sufficient trials are available to derive a MRL proposal of 0.15 mg/kg.

EFSA is of the opinion that the additional residue trials on apples are not fully comparable for the intended GAP on apricots since the PHI of 131-145 days compared to the PHI defined in the intended use on apricots (75 days) is significantly longer. Nevertheless, residue trials on apples reflect residue situation in a crop following an early application (before consumable part of the crop is present) and thus, according to EU guidance document (EC, 2011), could be used in combination with residue trials on stone fruit to extrapolate residue data to apricots.

However, the applicability of the wider extrapolation rules for early applications should be further considered. EFSA notes that the guidance document does not clearly define the growth stage up to which the wider extrapolation rules are acceptable. The use of a pesticide at the end of flowering is probably the boarder line. Under comparable GAPs in terms of application rate and timing of the application, apricots are usually expected to contain higher residues compared to peaches/apples because of their smaller fruit size and because of the shorter vegetation period. Thus, although the guidance document allows the extrapolation from peaches and apples to apricots, there is the risk that the actual residue situation in apricots might be underestimated.

EFSA concludes that in accordance with the EU guidance document (EC, 2011) a MRL proposal of 0.09 mg/kg based on trials on peaches and apples can be derived for apricots. However, it would be desirable to get additional residue trials on apricots reflecting the intended GAP to ensure that the MRL based on the residue trials on peaches is sufficient to cover the use on apricots.

c. Olives (table olives and olives for oil production)

In the previously issued EFSA reasoned opinion, a MRL proposal of 20 mg/kg was derived for table olives and olives for oil production in support of the SEU use (EFSA, 2013). However, EFSA noted a minor data gap regarding the storage stability of dodine residues in high oil content matrices which should be addressed in order to demonstrate the validity of the residue trials supporting the MRL for olives.

In the framework of the current application, the applicant submitted new storage stability with an oily matrix (peanuts and peanut oil) (Portugal, 2013). The study demonstrated the stability of dodine residues in a high oil content matrix for 270 days when stored frozen at $\leq 20^{\circ}\text{C}$. The residue trial samples of olives according to the previous application were stored deep frozen for a period not exceeding 6 months, thus for a period for which integrity of the samples was now demonstrated. Thus, the data gap identified in the previous reasoned opinion is sufficiently addressed.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Table 3-1.

The storage stability of dodine in primary crops was investigated in the framework of the peer review of Directive 91/414/EEC (Portugal, 2009). Residues of dodine were found to be stable at $\leq -18^{\circ}\text{C}$ for

¹⁰ According to the EU guidance document (EC, 2011), at least 4 residue trials on apples and either citrus fruit or stone fruit (4 trials) are required to extrapolate to citrus fruit, tree nuts, pome fruit and stone fruit groups.

up to 18 months in matrices with high water content. The residue trial samples of the crops under consideration prior to analysis were stored under conditions for which integrity of the samples was demonstrated and it is thus concluded that the residue data are valid with regard to storage stability.

According to the EMS, the analytical methods used to analyse the supervised residue trial samples have been sufficiently validated and were proven to be fit for purpose (Portugal, 2012, 2013).

Table 3-1: Overview of the available residues trials data

Commodity	Residue region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) ^(b)	Highest residue (mg/kg) ^(c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
			Enforcement (Dodine)	Risk assessment (Dodine)					
Apples → pears, quinces, medlar, loquats	NEU	Outdoor	0.066; 0.115; 0.118; 0.163; 0.187; 0.192; 0.208; 0.217	0.066; 0.115; 0.118; 0.163; 0.187; 0.192; 0.208; 0.217	0.175	0.217	0.5	1.0	R _{ber} = 0.41 R _{max} = 0.33 MRL _{OECD} = 0.49/0.5 See EFSA reasoned opinion (EFSA, 2013).
	SEU	Outdoor	0.031; 0.125; 0.135; 0.296; 0.355; 0.474; 0.125 ^f ; 0.0573 ^f	0.031; 0.125; 0.135; 0.296; 0.355; 0.474; 0.125 ^f ; 0.0573 ^f	0.13	0.47	0.9	1.0	R _{ber} =0.68 R _{max} =0.70 MRL _{OECD} = 0.83/0.9
Peaches, apples → apricots	SEU	Outdoor	Peaches: 5 x <0.05; 0.053; 0.073	Peaches: 5 x <0.05; 0.053; 0.073	0.05	0.07	0.09	1.0	R _{ber} =0.10 R _{max} =0.07 MRL _{OECD} = 0.082/0.09
			Apples: 4 x <0.05 (<0.005; <0.005; 0.008; 0.0057)	Apples: 4 x <0.05 (<0.005; <0.005; 0.008; 0.0057)					

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (*i.e.* outdoor use) or Import (country code) (EC, 2011).

(b): Median value of the individual trial results according to the enforcement residue definition.

(c): Highest value of the individual trial results according to the enforcement residue definition.

(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residue trial.

(e): Statistical estimation of MRLs according to the EU methodology (R_{ber}, R_{max}; EC, 1997g) and unrounded/rounded values according to the OECD methodology (OECD, 2011).

(f): Residue trials compliant with terms of the PHI interval but the last treatment done at a later growth stage than indicated in the intended GAP.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of dodine was investigated in the framework of the peer review (Portugal, 2009). Dodine is hydrolytically stable under the representative processing conditions. Thus, for processed commodities the same residue definition as for raw agricultural commodities is applicable (EFSA, 2010).

In the framework of the previously issued EFSA reasoned opinion a processing factor of 0.009 was derived for raw olive oil and proposed for the inclusion in Annex VI of Regulation (EC) No 396/2005 (EFSA, 2013).

3.1.2. Rotational crops

Since the proposed use of dodine is on permanent crops, the investigation of dodine residues in rotational/succeeding crops is of no relevance.

3.2. Nature and magnitude of residues in livestock

Since pome fruit pomace can be fed to livestock, the nature and magnitude of dodine residues in livestock should be assessed (EC, 1996). However, considering that the existing EU MRL for pome fruit is higher (5 mg/kg) than the MRL proposal derived under the current assessment (0.9 mg/kg) and that all existing MRLs for livestock are set at the limit of quantification, EFSA proposes to perform a comprehensive re-evaluation of the residue situation for livestock in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005. Thus, the nature and magnitude of dodine residues in food of animal origin is not further investigated in the framework of the current application.

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population¹¹ (EFSA, 2007). For the calculation of the chronic exposure, EFSA used the median residue value as derived from the residue trials on apples and peaches (see Table 3-1). The median residue derived from the combined residue data set on apples and peaches was used as an input value for apricots. For banana, peaches, cherries, table olives and olives for oil production the risk assessment values were available from the previously issued EFSA reasoned opinion (EFSA, 2013). For the remaining commodities of plant and animal origin, the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005 were used as input values.

The model assumptions for the long-term exposure assessment are considered to be sufficiently conservative for a first tier exposure assessment, assuming that all food items consumed have been treated with the active substance under consideration. In reality, it is not likely that all food consumed will contain residues at the MRL or at levels of the median residue values identified in supervised field trials. However, if this first tier exposure assessment does not exceed the toxicological reference value for long-term exposure (*i.e.* the ADI), a consumer health risk can be excluded with a high probability.

The acute exposure assessment was performed only with regard to pome fruits and apricots, assuming the consumption of a large portion of the food items as reported in the national food surveys containing residues at the highest level as observed in supervised field trials (Table 3-1). A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation, when required (EFSA, 2007).

The input values used for the dietary exposure calculation are summarised in Table 4-1.

¹¹ The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMO is given in its reference section (EFSA, 2007).

Table 4-1: Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Dodine				
Pome fruit	0.175	Median residue (NEU use) (Table 3-1)	0.47	Highest residue (SEU use) (Table 3-1)
Apricots	0.05	Median residue (peaches and apples) (Table 3-1)	0.07	Highest residue (peaches and apples) (Table 3-1)
Table olives, olives for oil production	6.5	Median residue (EFSA, 2013)	Acute risk assessment was undertaken only with regard to the crops under consideration.	
Peaches	0.05	Median residue (EFSA, 2013)		
Cherries	0.46	Median residue (EFSA, 2013)		
Bananas	0.01	Median residue*peeling factor (EFSA, 2013)		
Other commodities of plant and animal origin	MRL	See Appendix C		

The estimated exposure was then compared with the toxicological reference values derived for dodine (see Table 2-1). The results of the intake calculation are presented in Appendix B to this reasoned opinion.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated exposure accounted for up to 23.5% of the ADI (WHO Cluster diet B). The contribution of the crops under consideration (expressed in % of the ADI) was 2.11% for apples (DE child diet), 0.12% for pears (IE adult diet), 0.018% for apricots (DE child diet), and below 0.01% for quinces, loquats and medlar.

No acute consumer intake concerns were identified with regard to the MRL proposals for the crops under consideration. The individual contribution to the ARfD accounted for 46% for apples, 42.8 % for pears, 6.9% for quinces, 5.7% for medlar and 2.2% for apricots.

EFSA concludes that the new intended less critical uses on pome fruit and apricots which result in lower MRL proposals compared to the existing MRLs, will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a public health concern.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of dodine was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.1 mg/kg bw per day and an ARfD of 0.1 mg/kg bw.

The metabolism of dodine in primary crops was investigated in fruits. According to the conclusions of the peer review, the metabolism in all crops was seen to be similar and the residue definition for monitoring and risk assessment was proposed as dodine. For the uses on the crops under consideration EFSA concludes that the metabolism of dodine is sufficiently addressed and the residue definitions agreed in the peer review are applicable.

EFSA concludes that the submitted supervised residue trials are sufficient to confirm the MRL proposal of 0.9 mg/kg for pome fruits as derived in the previous EFSA reasoned opinion. The MRL proposal of 0.09 mg/kg for apricots has been derived, in accordance with the provisions of the EU guidance document on extrapolation from residue trials on peaches and apples. Although the data are compliant with the data requirements, EFSA recommends performing additional trials on apricots to confirm that the MRL is sufficient to cover the use on apricots. The new freezer storage stability study submitted for dodine in high oil content matrices confirms the validity of the residue trials on olives. Thus, the data gap identified in the previous opinion with regard to the MRL for olives (20 mg/kg) is sufficiently addressed. Adequate analytical enforcement methods are available to control the residues of dodine in the commodities under consideration.

Dodine is hydrolytically stable under the processing conditions representative for pasteurisation, boiling/cooking and sterilisation and this for processed commodities the same residue definition as for raw agricultural commodities is applicable.

Since the proposed use of dodine is on permanent crops, the investigation of dodine residues in rotational/succeeding crops is of no relevance.

Since pome fruit pomace can be fed to livestock, in principle residues of dodine in food of animal origin should be assessed. However, considering that the existing EU MRL for pome fruit is higher (5 mg/kg) than the MRL proposal derived under the current assessment (0.9 mg/kg) and that all existing MRLs for livestock are set at the limit of quantification, a detailed examination of the residue situation in livestock was considered unnecessary.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticides Residues Intake Model (PRIMO). For the calculation of the chronic exposure, EFSA used the median residue value as derived from the residue trials on pome fruit and apricots. For banana, peaches, cherries, table olives and olives for oil production the risk assessment values were available from the previously issued EFSA reasoned opinion. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005 were used as input values.

The acute exposure assessment was performed only with regard to pome fruits and apricots, assuming the consumption of a large portion of the food items as reported in the national food surveys containing residues at the highest level (or median level for olives) as observed in supervised field trials.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated exposure accounted for up to 23.5% of the ADI (WHO Cluster diet B). The contribution of the crops under consideration (expressed in % of the ADI) was 2.11% for apples (DE child diet), 0.12% for pears (IE adult diet), 0.018% for apricots (DE child diet), and below 0.01% for quinces, loquats and medlar.

No acute consumer intake concerns were identified with regard to the MRL proposals for the crops under consideration. The individual contribution to the ARfD accounted for 46% for apples, 42.8 % for pears, 6.9% for quinces, 5.7% for medlar and 2.2% for apricots.

EFSA concludes that the new intended less critical uses on pome fruit and apricots which result in lower MRL proposals compared to the existing MRLs, will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a public health concern.

RECOMMENDATIONS

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Dodine				
0130010	Apples	5/0.9 (tentative) ^(b)	0.9	The lowering of the existing MRL is proposed based on a revised GAP since a consumer risk was identified for the existing MRL. The new GAP is sufficiently supported by data to derive a MRL proposal; no consumer risk is associated with this MRL proposal.
0130020	Pears		0.9	
0130030	Quinces		0.9	
0130040	Medlar			
0130050	Loquat			
0140010	Apricots	5/0.01 ^{*(b)}	0.09	The proposed MRL has been derived in accordance with the provisions of the EU guidance document by extrapolation from residue trials on peaches and apples. EFSA notes that it would be desirable to get additional residue trials on apricots to ensure that the MRL sufficiently covers the use on apricots. No consumer intake concerns were identified for the intended SEU uses.

(a): According to Annex I of Regulation (EC) No 396/2005.

(b): MRL proposals derived in previously issued reasoned opinion (EFSA, 2013).

(*): Indicates that the MRL is set at the limit of analytical quantification.

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APPENDICES

A. GOOD AGRICULTURAL PRACTICE (GAPs)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d - f)	conc. of a.s. (i)	method kind (f - h)	growth stage & season (j)	number min max (k)	interval min max	kg as/hL min max	water L/ha min max	kg a.s./ha min max		
Pome fruits	NEU/SEU	F	Scab (<i>Venturia inaequalis</i> / <i>Venturia piri</i>)	SC	400 g/L	Foliar spray	From bud opening (BBCH 01) till 60 days before harvest (BBCH 75)	2	7-10	0.045-0.45	200-1500	0.68-0.9	60	1.7-2.25 L Syllit/ha
Peaches, apricots, nectarines and similar hybrids	SEU	F	Peach leaf curl (<i>Taphrina deformans</i>)	SC	400 g/L	Foliar spray	From bud swelling (BBCH 01) till petal fall (BBCH 69) or later from 50% leaf falling till after leaf falling (autumn)	2	7-10	0.06-0.18	500-1500	0.9	75	2.25 L Syllit/ha

Remarks:

- (a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), glasshouse 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)
- (e) GCPF Technical Monograph No 2, 4th Ed., 1999 or other codes, e.g. OECD/CIPAC, should be used
- (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 plants - type of equipment used must be indicated
- (i) g/kg or g/l
- (j) Growth stage at last treatment (Growth stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., 2001), including where relevant, information on season at time of application
- (k) The minimum and maximum number of application possible under practical conditions of use must be provided
- (l) PHI - minimum pre-harvest interval
- (m) Remarks may include: Extent of use/economic importance/restrictions (*i.e.* feeding, grazing)

B. PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Dodine									
Status of the active substance:		Included		Code no.		Prepare workbook for refined calculations			
LOQ (mg/kg bw):				proposed LOQ:					
Toxicological end points									
ADI (mg/kg bw/day):		0.1		ARfD (mg/kg bw):		0.1			
Source of ADI:		EFSA		Source of ARfD:		EFSA			
Year of evaluation:		2011		Year of evaluation:		2011			
Chronic risk assessment - refined calculations									
			TMDI (range) in % of ADI minimum - maximum						
			3 23						
			No of diets exceeding ADI:						

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)	
23.5	WHO Cluster diet B	12.5	Olives for oil production	1.7	Wheat	0.8	Spinach		
23.3	FR toddler	7.9	Milk and cream,	7.1	Spinach	3.1	Strawberries		
18.2	NL child	5.9	Milk and cream,	3.7	Spinach	1.2	Potatoes		
15.6	FR infant	5.1	Milk and cream,	4.4	Spinach	2.4	Strawberries		
15.3	DE child	2.9	Milk and cream,	2.4	Strawberries	2.1	Apples		
14.4	UK Infant	7.7	Milk and cream,	2.0	Sugar beet (root)	1.1	Strawberries		
13.8	UK Toddler	4.6	Sugar beet (root)	4.1	Milk and cream,	1.0	Strawberries		
13.0	ES child	4.8	Olives for oil production	2.5	Milk and cream,	0.9	Wheat		
12.2	IE adult	1.6	Plums	1.3	Spinach	1.2	Strawberries		
8.8	WHO cluster diet E	1.1	Olives for oil production	0.8	Wheat	0.8	Potatoes		
8.6	DK child	2.5	Milk and cream,	1.1	Wheat	0.9	Rye		
8.0	SE general population 90th percentile	2.5	Milk and cream,	0.8	Potatoes	0.8	Strawberries		
8.0	ES adult	2.7	Olives for oil production	1.0	Milk and cream,	0.7	Spinach		
7.5	WHO regional European diet	1.0	Milk and cream,	0.8	Olives for oil production	0.8	Potatoes		
6.9	WHO cluster diet D	1.3	Wheat	1.0	Milk and cream,	0.8	Potatoes		
6.4	NL general	1.4	Spinach	1.3	Milk and cream,	0.5	Potatoes		
6.2	PT General population	1.7	Olives for oil production	1.1	Potatoes	0.8	Wheat		
5.8	WHO Cluster diet F	0.8	Milk and cream,	0.7	Wheat	0.7	Potatoes		
5.6	FR all population	1.3	Olives for oil production	0.8	Wine grapes	0.7	Wheat		
4.8	IT kids/toddler	1.3	Wheat	0.6	Strawberries	0.6	Spinach		
4.4	UK vegetarian	0.8	Sugar beet (root)	0.7	Milk and cream,	0.4	Wheat		
4.2	IT adult	1.0	Spinach	0.8	Wheat	0.4	Plums		
3.7	UK Adult	0.8	Sugar beet (root)	0.6	Milk and cream,	0.3	Wheat		
3.6	DK adult	1.1	Milk and cream,	0.4	Wheat	0.3	Potatoes		
3.5	LT adult	0.8	Milk and cream,	0.6	Potatoes	0.3	Apples		
3.3	FI adult	1.1	Milk and cream,	0.4	Strawberries	0.2	Potatoes		
3.0	PL general population	0.9	Plums	0.7	Potatoes	0.4	Apples		
Conclusion:									
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Dodine is unlikely to present a public health concern.									

Acute risk assessment /children - refined calculations						Acute risk assessment / adults / general population - refined calculations						
The acute risk assessment is based on the ARfD.												
For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.												
In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.												
In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.												
Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100 % of the ARfD.												
Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):			No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):		
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	IESTI 1	*)	**)	IESTI 2	*)	**)	IESTI 1	*)	**)	IESTI 2	*)	**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	46.0	Apples	0.47 / -	33.9	Apples	0.47 / -	10.5	Apples	0.47 / -	8.8	Apples	0.47 / -
	42.8	Pears	0.47 / -	30.8	Pears	0.47 / -	10.1	Pears	0.47 / -	7.7	Pears	0.47 / -
	6.9	Quinces	0.47 / -	5.4	Quinces	0.47 / -	3.7	Quinces	0.47 / -	3.0	Quinces	0.47 / -
5.7	Medlar	0.47 / -	4.3	Medlar	0.47 / -	2.8	Medlar	0.47 / -	2.1	Medlar	0.47 / -	
2.2	Apricots	0.07 / -	1.7	Apricots	0.07 / -	0.5	Apricots	0.07 / -	0.4	Apricots	0.07 / -	
No of critical MRLs (IESTI 1)						No of critical MRLs (IESTI 2)						
---						---						
Processed commodities	No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:		
	---			---			---			---		
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.												
**) pTMRL: provisional temporary MRL												
***) pTMRL: provisional temporary MRL for unprocessed commodity												
Conclusion:												
For Dodine IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.												
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.												
For processed commodities, no exceedance of the ARfD/ADI was identified.												

C. EXISTING EU MAXIMUM RESIDUE LEVELS (MRLs)

(Pesticides - Web Version - EU MRLs (File created on 05/12/2012 17:12))

Code number	Groups and examples of individual products to which the MRLs apply	Dodine
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,2*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, uglı and other hybrids)	0,2*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,2*
110030	Lemons (Citron, lemon)	0,2*
110040	Limes	0,2*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,2*
110990	Others	0,2*
120000	(ii) Tree nuts (shelled or unshelled)	
120010	Almonds	0,2*
120020	Brazil nuts	0,2*
120030	Cashew nuts	0,2*
120040	Chestnuts	0,2*
120050	Coconuts	0,2*
120060	Hazelnuts (Filbert)	0,2*
120070	Macadamia	0,2*
120080	Pecans	5
120090	Pine nuts	0,2*
120100	Pistachios	0,2*
120110	Walnuts	5
120990	Others	0,2*
130000	(iii) Pome fruit	
130010	Apples (Crab apple)	5 /0,9 ^(a)
130020	Pears (Oriental pear)	5 /0,9 ^(a)
130030	Quinces	5/0,9 ^(a)
130040	Medlar	5/0,9 ^(a)
130050	Loquat	5/0,9 ^(a)
130990	Others	5/0,9 ^(a)
140000	(iv) Stone fruit	
140010	Apricots	5/0,01* ^(a)
140020	Cherries (sweet cherries, sour cherries)	5/3 ^(a)
140030	Peaches (Nectarines and similar hybrids)	5/0,09 ^(a)
140040	Plums (Damson, greengage, mirabelle)	5
140990	Others	5
150000	(v) Berries & small fruit	

Code number	Groups and examples of individual products to which the MRLs apply	Dodine
151000	(a) Table and wine grapes	0,2*
151010	Table grapes	0,2*
151020	Wine grapes	0,2*
152000	(b) Strawberries	5
153000	(c) Cane fruit	0,2*
153010	Blackberries	0,2*
153020	Dewberries (Loganberries, Boysenberries, and cloudberry)	0,2*
153030	Raspberries (Wineberries)	0,2*
153990	Others	0,2*
154000	(d) Other small fruit & berries	0,2*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,2*
154020	Cranberries	0,2*
154030	Currents (red, black and white)	0,2*
154040	Gooseberries (Including hybrids with other ribes species)	0,2*
154050	Rose hips	0,2*
154060	Mulberries (arbutus berry)	0,2*
154070	Azarole (mediterranean medlar)	0,2*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sawallowthorn), hawthorn, service berries, and other treeberries)	0,2*
154990	Others	0,2*
160000	(vi) Miscellaneous fruit	0,2*
161000	(a) Edible peel	0,2*
161010	Dates	0,2*
161020	Figs	0,2*
161030	Table olives	0,2*/20 ^(a)
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,2*
161050	Carambola (Bilimbi)	0,2*
161060	Persimmon	0,2*
161070	Jambolan (java plum) (Java apple (water apple), pomegranate, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,2*
161990	Others	0,2*
162000	(b) Inedible peel, small	0,2*
162010	Kiwi	0,2*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,2*
162030	Passion fruit	0,2*

Code number	Groups and examples of individual products to which the MRLs apply	Dodine
162040	Prickly pear (cactus fruit)	0,2*
162050	Star apple	0,2*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammy sapote)	0,2*
162990	Others	0,2*
163000	(c) Inedible peel, large	0,2*
163010	Avocados	0,2*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,2*/0,5 ^(a)
163030	Mangoes	0,2*
163040	Papaya	0,2*
163050	Pomegranate	0,2*
163060	Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	0,2*
163070	Guava	0,2*
163080	Pineapples	0,2*
163090	Bread fruit (Jackfruit)	0,2*
163100	Durian	0,2*
163110	Soursop (guanabana)	0,2*
163990	Others	0,2*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	0,2*
211000	(a) Potatoes	0,2*
212000	(b) Tropical root and tuber vegetables	0,2*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,2*
212020	Sweet potatoes	0,2*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,2*
212040	Arrowroot	0,2*
212990	Others	0,2*
213000	(c) Other root and tuber vegetables except sugar beet	0,2*
213010	Beetroot	0,2*
213020	Carrots	0,2*
213030	Celeriac	0,2*
213040	Horseradish	0,2*
213050	Jerusalem artichokes	0,2*
213060	Parsnips	0,2*
213070	Parsley root	0,2*

Code number	Groups and examples of individual products to which the MRLs apply	Dodine
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,2*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,2*
213100	Swedes	0,2*
213110	Turnips	0,2*
213990	Others	0,2*
220000	(ii) Bulb vegetables	
220010	Garlic	0,2*
220020	Onions (Silverskin onions)	0,2*
220030	Shallots	0,2*
220040	Spring onions (Welsh onion and similar varieties)	0,2*
220990	Others	0,2*
230000	(iii) Fruiting vegetables	0,2*
231000	(a) Solanacea	0,2*
231010	Tomatoes (Cherry tomatoes,)	0,2*
231020	Peppers (Chilli peppers)	0,2*
231030	Aubergines (egg plants) (Pepino)	0,2*
231040	Okra, lady's fingers	0,2*
231990	Others	0,2*
232000	(b) Cucurbits - edible peel	0,2*
232010	Cucumbers	0,2*
232020	Gherkins	0,2*
232030	Courgettes (Summer squash, marrow (patisson))	0,2*
232990	Others	0,2*
233000	(c) Cucurbits-inedible peel	0,2*
233010	Melons (Kiwano)	0,2*
233020	Pumpkins (Winter squash)	0,2*
233030	Watermelons	0,2*
233990	Others	0,2*
234000	(d) Sweet corn	0,2*
239000	(e) Other fruiting vegetables	0,2*
240000	(iv) Brassica vegetables	0,2*
241000	(a) Flowering brassica	0,2*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,2*
241020	Cauliflower	0,2*
241990	Others	0,2*
242000	(b) Head brassica	0,2*
242010	Brussels sprouts	0,2*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy	0,2*

Code number	Groups and examples of individual products to which the MRLs apply	Dodine
	cabbage, white cabbage)	
242990	Others	0,2*
243000	(c) Leafy brassica	0,2*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,2*
243020	Kale (Borecole (curly kale), collards)	0,2*
243990	Others	0,2*
244000	(d) Kohlrabi	0,2*
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicacea	0,2*
251010	Lamb's lettuce (Italian comsalad)	0,2*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,2*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leaf endive, sugar loaf)	0,2*
251040	Cress	0,2*
251050	Land cress	0,2*
251060	Rocket, Rucola (Wild rocket)	0,2*
251070	Red mustard	0,2*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,2*
251990	Others	0,2*
252000	(b) Spinach & similar (leaves)	
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	10
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,2*
252030	Beet leaves (chard) (Leaves of beetroot)	0,2*
252990	Others	0,2*
253000	(c) Vine leaves (grape leaves)	0,2*
254000	(d) Water cress	0,2*
255000	(e) Witloof	0,2*
256000	(f) Herbs	0,2*
256010	Chervil	0,2*
256020	Chives	0,2*
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	0,2*

Code number	Groups and examples of individual products to which the MRLs apply	Dodine
256040	Parsley	0,2*
256050	Sage (Winter savory, summer savory,)	0,2*
256060	Rosemary	0,2*
256070	Thyme (marjoram, oregano)	0,2*
256080	Basil (Balm leaves, mint, peppermint)	0,2*
256090	Bay leaves (laurel)	0,2*
256100	Tarragon (Hyssop)	0,2*
256990	Others	0,2*
260000	(vi) Legume vegetables (fresh)	0,2*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,2*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,2*
260030	Peas (with pods) (Mangetout (sugar peas))	0,2*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,2*
260050	Lentils	0,2*
260990	Others	0,2*
270000	(vii) Stem vegetables (fresh)	0,2*
270010	Asparagus	0,2*
270020	Cardoons	0,2*
270030	Celery	0,2*
270040	Fennel	0,2*
270050	Globe artichokes	0,2*
270060	Leek	0,2*
270070	Rhubarb	0,2*
270080	Bamboo shoots	0,2*
270090	Palm hearts	0,2*
270990	Others	0,2*
280000	(viii) Fungi	0,2*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,2*
280020	Wild (Chanterelle, Truffle, Morel)	0,2*
280990	Others	0,2*
290000	(ix) Sea weeds	0,2*
300000	3. PULSES, DRY	0,2*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,2*
300020	Lentils	0,2*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,2*
300040	Lupins	0,2*

Code number	Groups and examples of individual products to which the MRLs apply	Dodine
300990	Others	0,2*
400000	4. OILSEEDS AND OILFRUITS	0,2*
401000	(i) Oilseeds	0,2*
401010	Linseed	0,2*
401020	Peanuts	0,2*
401030	Poppy seed	0,2*
401040	Sesame seed	0,2*
401050	Sunflower seed	0,2*
401060	Rape seed (Bird rapeseed, turnip rape)	0,2*
401070	Soya bean	0,2*
401080	Mustard seed	0,2*
401090	Cotton seed	0,2*
401100	Pumpkin seeds	0,2*
401110	Safflower	0,2*
401120	Borage	0,2*
401130	Gold of pleasure	0,2*
401140	Hempseed	0,2*
401150	Castor bean	0,2*
401990	Others	0,2*
402000	(ii) Oilfruits	0,2*
402010	Olives for oil production	0,2*/20 ^(a)
402020	Palm nuts (palmoil kernels)	0,2*
402030	Palmfruit	0,2*
402040	Kapok	0,2*
402990	Others	0,2*
500000	5. CEREALS	0,2*
500010	Barley	0,2*
500020	Buckwheat	0,2*
500030	Maize	0,2*
500040	Millet (Foxtail millet, teff)	0,2*
500050	Oats	0,2*
500060	Rice	0,2*
500070	Rye	0,2*
500080	Sorghum	0,2*
500090	Wheat (Spelt Triticale)	0,2*
500990	Others	0,2*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,2*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,2*
620000	(ii) Coffee beans	0,2*
630000	(iii) Herbal infusions (dried)	0,2*
631000	(a) Flowers	0,2*
631010	Camomille flowers	0,2*
631020	Hybiscus flowers	0,2*
631030	Rose petals	0,2*
631040	Jasmine flowers	0,2*

Code number	Groups and examples of individual products to which the MRLs apply	Dodine
631050	Lime (linden)	0,2*
631990	Others	0,2*
632000	(b) Leaves	0,2*
632010	Strawberry leaves	0,2*
632020	Rooibos leaves	0,2*
632030	Maté	0,2*
632990	Others	0,2*
633000	(c) Roots	0,2*
633010	Valerian root	0,2*
633020	Ginseng root	0,2*
633990	Others	0,2*
639000	(d) Other herbal infusions	0,2*
640000	(iv) Cocoa (fermented beans)	0,2*
650000	(v) Carob (st johns bread)	0,2*
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	0,2*
800000	8. SPICES	0,2*
810000	(i) Seeds	0,2*
810010	Anise	0,2*
810020	Black caraway	0,2*
810030	Celery seed (Lovage seed)	0,2*
810040	Coriander seed	0,2*
810050	Cumin seed	0,2*
810060	Dill seed	0,2*
810070	Fennel seed	0,2*
810080	Fenugreek	0,2*
810090	Nutmeg	0,2*
810990	Others	0,2*
820000	(ii) Fruits and berries	0,2*
820010	Allspice	0,2*
820020	Anise pepper (Japan pepper)	0,2*
820030	Caraway	0,2*
820040	Cardamom	0,2*
820050	Juniper berries	0,2*
820060	Pepper, black and white (Long pepper, pink pepper)	0,2*
820070	Vanilla pods	0,2*
820080	Tamarind	0,2*
820990	Others	0,2*
830000	(iii) Bark	0,2*
830010	Cinnamon (Cassia)	0,2*
830990	Others	0,2*
840000	(iv) Roots or rhizome	0,2*
840010	Liquorice	0,2*
840020	Ginger	0,2*
840030	Turmeric (Curcuma)	0,2*
840040	Horseradish	0,2*
840990	Others	0,2*

Code number	Groups and examples of individual products to which the MRLs apply	Dodine
850000	(v) Buds	0,2*
850010	Cloves	0,2*
850020	Capers	0,2*
850990	Others	0,2*
860000	(vi) Flower stigma	0,2*
860010	Saffron	0,2*
860990	Others	0,2*
870000	(vii) Aril	0,2*
870010	Mace	0,2*
870990	Others	0,2*
900000	9. SUGAR PLANTS	0,2*
900010	Sugar beet (root)	0,2*
900020	Sugar cane	0,2*
900030	Chicory roots	0,2*
900990	Others	0,2*
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	0,2*
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	0,2*
1011000	(a) Swine	0,2*
1011010	Meat	0,2*
1011020	Fat free of lean meat	0,2*

Code number	Groups and examples of individual products to which the MRLs apply	Dodine
1011030	Liver	0,2*
1011040	Kidney	0,2*
1011050	Edible offal	0,2*
1011990	Others	0,2*
1012000	(b) Bovine	0,2*
1012010	Meat	0,2*
1012020	Fat	0,2*
1012030	Liver	0,2*
1012040	Kidney	0,2*
1012050	Edible offal	0,2*
1012990	Others	0,2*
1013000	(c) Sheep	0,2*
1013010	Meat	0,2*
1013020	Fat	0,2*
1013030	Liver	0,2*
1013040	Kidney	0,2*
1013050	Edible offal	0,2*
1013990	Others	0,2*
1014000	(d) Goat	0,2*
1014010	Meat	0,2*
1014020	Fat	0,2*
1014030	Liver	0,2*
1014040	Kidney	0,2*
1014050	Edible offal	0,2*
1014990	Others	0,2*
1015000	(e) Horses, asses, mules or hinnies	0,2*

Code number	Groups and examples of individual products to which the MRLs apply	Dodine
1015010	Meat	0,2*
1015020	Fat	0,2*
1015030	Liver	0,2*
1015040	Kidney	0,2*
1015050	Edible offal	0,2*
1015990	Others	0,2*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,2*
1016010	Meat	0,2*
1016020	Fat	0,2*
1016030	Liver	0,2*
1016040	Kidney	0,2*
1016050	Edible offal	0,2*
1016990	Others	0,2*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,2*
1017010	Meat	0,2*
1017020	Fat	0,2*
1017030	Liver	0,2*
1017040	Kidney	0,2*
1017050	Edible offal	0,2*
1017990	Others	0,2*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and	0,2*

Code number	Groups and examples of individual products to which the MRLs apply	Dodine
	curd	
1020010	Cattle	0,2*
1020020	Sheep	0,2*
1020030	Goat	0,2*
1020040	Horse	0,2*
1020990	Others	0,2*
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,2*
1030010	Chicken	0,2*
1030020	Duck	0,2*
1030030	Goose	0,2*
1030040	Quail	0,2*
1030990	Others	0,2*
1040000	(iv) Honey (Royal jelly, pollen)	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	

(*) Indicates lower limit of analytical determination

(a) MRL proposals (EFSA, 2013)

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DALA	days after last application
DAR	Draft Assessment Report
DAT	days after treatment
DE	Germany
EC	European Community
EFSA	European Food Safety Authority
EMS	evaluating Member State
ES	Spain
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation
GLP	Good Laboratory Practice
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
IE	Ireland
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
kg	kilogram
L	litre

LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS/MS	tandem mass spectrometry
MSD	mass spectrometry detector
NEU	northern European Union
MW	molecular weight
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
R_{ber}	statistical calculation of the MRL by using a non-parametric method
R_{max}	statistical calculation of the MRL by using a parametric method
RAC	raw agricultural commodity
RD	residue definition
RMS	rappporteur Member State
SE	Sweden
SC	suspension concentrate
SEU	Southern European Union
TRR	total radioactive residue
WHO	World Health Organisation
wk	week
yr	year