REASONED OPINION

Reasoned opinion on the review of the existing maximum residue levels (MRLs) for dodemorph according to Article 12 of Regulation (EC) No 396/2005[1]

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

*This scientific output, published on 22 July 2014, replaces the earlier version published on 6 May 2014**

ABSTRACT

According to Article 12 of Regulation (EC) No 396/2005, the European Food Safety Authority (EFSA) has reviewed the Maximum Residue Levels (MRLs) currently established at European level for the pesticide active substance dodemorph. Considering that this active substance is not authorised for use on edible crops within the European Union, that no MRLs are established by the Codex Alimentarius Commission, and that no import tolerances were notified to EFSA, residues of dodemorph are not expected to occur in any plant or animal commodity. Available data were also not sufficient to derive a residue definition or an LOQ for enforcement against potential illegal uses.

KEY WORDS

dodemorph, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, morpholine, fungicide

[1] On request from EFSA, Question No EFSA-Q-2009-00161, approved on 30 April 2014.

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

[3] Acknowledgement: EFSA wishes to thank the rapporteur Member State the Netherlands for the preparatory work on this scientific output.

* An editorial amendment was carried out that does not materially affect the contents or outcome of this Reasoned Opinion. To avoid confusion, the original version has been removed from the EFSA Journal, but is available on request, as is a version showing all the changes made.

Suggested citation: EFSA (European Food Safety Authority), 2014. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for dodemorph according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(5):3683, 11 pp. doi:10.2903/j.efsa.2014.3683

Available online: www.efsa.europa.eu/efsajournal

SUMMARY

Dodemorph was included in Annex I to Directive 91/414/EEC on 01 September 2009, which is after the entry into force of Regulation (EC) No 396/2005 on 02 September 2008. EFSA is therefore required to provide a reasoned opinion on the review of the existing MRLs for that active substance in compliance with Article 12(1) of the aforementioned regulation. In order to collect the relevant pesticide residues data, EFSA asked The Netherlands, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. A document was submitted on 18 June 2010 confirming that the pesticide use of dodemorph is only intended on non-consumable crops within the European Union (ornamentals) and that no import tolerances for this active substance were notified to the RMS. Submission of a PROFile or an evaluation report was therefore not considered relevant and EFSA based its assessment mainly on the conclusions derived by The Netherlands in the framework of Directive 91/414/EEC.

On 13 January 2014, EFSA issued a draft reasoned opinion that was circulated to Member States' experts for consultation. Comments received by 14 March 2014 were considered in the finalisation of this reasoned opinion. The following conclusions are derived.

The toxicological profile of dodemorph was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI and an ARfD being established at 0.082 mg/kg bw per d and 0.33 mg/kg bw, respectively.

Considering that the use of dodemorph is restricted to non-consumable crops within the European Union, that no CXLs are available for this active substance and that no uses authorised in third countries were notified to the RMS, residues of dodemorph are not expected to occur in any plant or animal commodity. However, this conclusion is only valid if Member States impose adequate restrictions to avoid the use of treated rose petals as human food and to avoid the conversion of treated ornamental fields to edible crop production. Furthermore, since metabolism of dodemorph was not investigated in plants or livestock, EFSA is not able to propose a relevant residue definition for enforcement against a potential illegal use of this compound. Validated analytical methods for enforcement of dodemorph are also not available.

A risk assessment is in principle not required considering that dodemorph residues are not expected to occur in food but the default MRL of 0.01 mg/kg, as defined by Regulation (EC) No 396/2005, provides a satisfactory level of protection for the European consumer.

Considering that the enforcement against the potential illegal use of dodemorph falls under the remit of risk managers, EFSA is not in a position to recommend whether the default MRL of 0.01 mg/kg, as defined by regulation (EC) No 396/2005, should apply or whether the setting of a specific LOQ is necessary. However, dodemorph is in any case not recommended for inclusion in Annex IV to the above regulation and data for deriving a specific LOQ are not available. Although the default MRL of 0.01 mg/kg, as defined by Regulation (EC) No 396/2005, provides a satisfactory level of protection for the European consumer, it cannot be ascertained by EFSA that dodemorph is a valid indicator compound for enforcement against a potential illegal use and that this LOQ level can be achieved through routine enforcement.

TABLE OF CONTENTS

BACKGROUND

Regulation (EC) No 396/2005[4] establishes the rules governing the setting and the review of pesticide MRLs at European level. Article 12(1) of that regulation stipulates that 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[5] a reasoned opinion on the review of the existing MRLs for that active substance. As dodemorph was included in Annex I to the above mentioned directive on 01 September 2009, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2009-00161 was included in the EFSA Register of Questions.

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, while MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the 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.

In order to gain an overview of the pesticide residues data that have been considered for the setting of the existing MRLs, EFSA developed the Pesticide Residue 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 and;
- the analytical methods for enforcement of the proposed MRLs.

The Netherlands, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for dodemorph and to prepare a supporting evaluation report. A document was submitted on 18 June 2010 confirming that the pesticide use of dodemorph is only intended on non-consumable crops within the European Union (ornamentals) and that no import tolerances for this active substance were notified to the RMS. Submission of a PROFile or an evaluation report was therefore not considered relevant.

A draft reasoned opinion was issued by EFSA on 13 January 2014 and submitted to Member States (MS) for commenting. All MS comments received by 14 March 2014 were considered by EFSA for finalisation of the reasoned opinion.

[4] 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.

[5] 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.

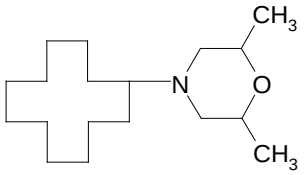
TERMS OF REFERENCE

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

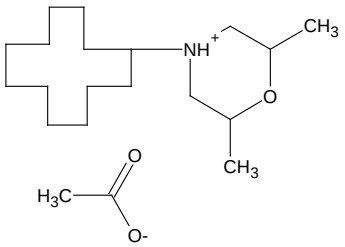
- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;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

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Dodemorph is the ISO common name for 4-cyclododecyl-2,6-dimethylmorpholine (IUPAC) but the variant included in the formulated product evaluated under the peer review was dodemorph acetate.



dodemorph



dodemorph acetate

Dodemorph belongs to the group of morpholine compounds which are used as fungicide for use on protected crops in horticulture (roses) after foliar application (spraying). Dodemorph acts primarily through contact action. After foliar application, dodemorph is absorbed by the plant tissue and translocated acropetally and basipetally. Dodemorph inhibits two enzymes in the sterol biosynthesis pathway of fungi: the enzyme sterol Δ14-reductase and the enzyme sterol Δ8-7-isomerase.

Dodemorph was evaluated in the framework of Directive 91/414/EEC with The Netherlands being the designated rapporteur Member State (RMS). The representative use supported for the peer review process was the outdoor treatment of horticultural crops (roses) at a rate of 10 x 2 kg a.s./ha with a 7 days interval between applications, both in northern and southern Europe. Following the peer review, which was carried out by EFSA, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2008/125/EC[6], which entered into force on 01 September 2009. According to Regulation (EU) No 540/2011[7], dodemorph is deemed to have been approved under Regulation (EC) No 1107/2009[8]. This approval is restricted to uses as fungicide on ornamentals in glasshouse only.

No MRLs are currently set for dodemorph; hence the default MRL of 0.01 mg/kg applies (according to art. 18, 1, b of Regulation (EC) No 396/2005). CXLs for dodemorph are not available.

[6] Directive 2008/125/EC of 19 December 2008 amending Council Directive 91/414/EEC to include aluminium phosphide, calcium phosphide, magnesium phosphide, cymoxanil, dodemorph, 2,5-dichlorobenzoic acid methylester, metamitron, sulcotrione, tebuconazole and triadimenol as active substances. OJ L 344, 20.12.2008, p. 78-88.

[7] 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.

[8] 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 309, 24.11.2009, p. 1–50.

Dodemorph is only registered for use on non-consumable crops within the European Union (ornamentals) and the RMS did not report any use authorised in third countries that might have a significant impact on international trade.

ASSESSMENT

Considering that the use of dodemorph is only authorised on non-consumable crops within the EU (ornamentals), 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 the interest, however, to enforce against the potential illegal use of dodemorph within the EU and against 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. The assessment of EFSA is mainly based on the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (Netherlands, 2007) and the conclusion on the peer review of the pesticide risk assessment of the active substance dodemorph (EFSA, 2008).

1. Methods of analysis

No validated analytical methods for enforcement of dodemorph residues in commodities of plant or animal origin are available.

EURLs commented during the MS consultation that analytical methods are available for the determination of dodemorph in the 4 main commodity groups of plant origin as well as all commodities of animal origin with an LOQ of 0.01mg/kg, except for cocoa beans. However, detailed information was not available and the validity of these methods according to the current guideline could not be verified by EFSA.

2. Mammalian toxicology

The toxicological assessment of dodemorph was peer reviewed under Directive 91/414/EEC and toxicological reference values were established by EFSA (2008), both for dodemorph and dodemorph acetate, a variant of dodemorph used in formulated products. These toxicological reference values are summarized in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Dodemorph					
ADI	EFSA	2008	0.082 mg/kg bw per d	1 year dog	100
ARfD	EFSA	2008	0.33 mg/kg bw	Developmental study rabbit	100
Dodemorph acetate					
ADI	EFSA	2008	0.1 mg/kg bw per d	1 year dog	100
ARfD	EFSA	2008	0.4 mg/kg bw	Developmental study rabbit	100

3. Residues

Under Directive 91/414/EEC, no residue data were provided because the representative uses supported for the peer review process only included non-edible crops (roses). Also in the framework of this review, such data are not required because no other uses are registered within the EU or in third countries that might have a significant impact on international trade.

Since metabolism of dodemorph was not investigated in plants or livestock, EFSA is not able to propose a relevant residue definition for enforcement against a potential illegal use of this compound.

EFSA highlights that the uptake of dodemorph residue in the potential following crops has not been investigated although the conversion of ornamental fields to edible crop production cannot be excluded. Member States should therefore impose adequate restrictions on the conversion of treated ornamental fields to edible crop production.

4. Consumer risk assessment

A risk assessment is in principle not required considering that dodemorph is only registered for use on non-consumable crops provided that Member States impose adequate restrictions to avoid the use of treated rose petals as human food and to avoid the conversion of treated ornamental fields to edible crop production. In order to assess whether the default MRL of 0.01 mg/kg is sufficiently protective for European consumers, acute and chronic intake calculations were performed using revision 2 of the EFSA PRIMo (EFSA, 2007), and compared with the toxicological reference values derived for dodemorph (see Table 2-1)

Detailed results of the chronic and acute intake calculations are presented in Appendix A to this document. The highest chronic exposure was calculated for French toddlers, representing 0.9 % of the ADI, and the highest acute exposure was calculated for potatoes and melons, representing 0.5 % of the ARfD. EFSA highlights that the above calculation does not reflect real exposure of consumers to dodemorph residues; it is a theoretical calculation indicating that the default MRL of 0.01 mg/kg provides a satisfactory level of protection for the European consumer.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of dodemorph was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI and an ARfD being established at 0.082 mg/kg bw per d and 0.33 mg/kg bw, respectively.

Considering that the use of dodemorph is restricted to non-consumable crops within the European Union, that no CXLs are available for this active substance and that no uses authorised in third countries were notified to the RMS, residues of dodemorph are not expected to occur in any plant or animal commodity. However, this conclusion is only valid if Member States impose adequate restrictions to avoid the use of treated rose petals as human food and to avoid the conversion of treated ornamental fields to edible crop production. Furthermore, since metabolism of dodemorph was not investigated in plants or livestock, EFSA is not able to propose a relevant residue definition for enforcement against a potential illegal use of this compound. Validated analytical methods for enforcement of dodemorph are also not available.

A risk assessment is in principle not required considering that dodemorph residues are not expected to occur in food but the default MRL of 0.01 mg/kg, as defined by Regulation (EC) No 396/2005, provides a satisfactory level of protection for the European consumer.

Considering that the enforcement against the potential illegal use of dodemorph falls under the remit of risk managers, EFSA is not in a position to recommend whether the default MRL of 0.01 mg/kg, as defined by regulation (EC) No 396/2005, should apply or whether the setting of a specific LOQ is necessary. However, dodemorph is in any case not recommended for inclusion in Annex IV to the above regulation and data for deriving a specific LOQ are not available. Although the default MRL of 0.01 mg/kg, as defined by Regulation (EC) No 396/2005, provides a satisfactory level of protection for the European consumer, it cannot be ascertained by EFSA that dodemorph is a valid indicator compound for enforcement against a potential illegal use and that this LOQ level can be achieved through routine enforcement.

REFERENCES

EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers' health arising from proposed temporary EU MRLs according to Regulation (EC) No 396/2005 on Maximum Residue Levels of Pesticides in Food and Feed of Plant and Animal Origin. 15 March 2007. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2008. Conclusion on the peer review of the pesticide risk assessment of the active substance dodemorph. The EFSA Journal 2008, 170r, 1-60.

The Netherlands, 2007. Draft assessment report on the active substance dodemorph prepared by the rapporteur Member State the Netherlands in the framework of Council Directive 91/414/EEC, January 2007.

APPENDIX A – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Dodemorph			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,082**	ARfD (mg/kg bw):	**0,33**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2008**	Year of evaluation:	**2008**

Chronic risk assessment

	TMDI (range) in % of ADI minimum - maximum
	0 1
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)
0,9	FR toddler	0,5	PRODUCTS OF ANIMAL ORIGIN	0,2	VEGETABLES	0,1	FRUIT (FRESH OR FROZEN)	
0,9	UK Infant	0,5	PRODUCTS OF ANIMAL ORIGIN	0,1	SUGAR PLANTS	0,1	VEGETABLES	
0,8	UK Toddler	0,3	PRODUCTS OF ANIMAL ORIGIN	0,3	SUGAR PLANTS	0,1	FRUIT (FRESH OR FROZEN)	
0,8	NL child	0,4	PRODUCTS OF ANIMAL ORIGIN	0,2	FRUIT (FRESH OR FROZEN)	0,1	VEGETABLES	
0,8	FR infant	0,3	PRODUCTS OF ANIMAL ORIGIN	0,3	VEGETABLES	0,2	FRUIT (FRESH OR FROZEN)	
0,7	DE child	0,3	PRODUCTS OF ANIMAL ORIGIN	0,3	FRUIT (FRESH OR FROZEN)	0,1	VEGETABLES	
0,6	WHO Cluster diet B	0,2	VEGETABLES	0,1	CEREALS	0,1	FRUIT (FRESH OR FROZEN)	
0,5	DK child	0,3	PRODUCTS OF ANIMAL ORIGIN	0,1	CEREALS	0,1	VEGETABLES	
0,5	SE general population 90th percentile	0,2	PRODUCTS OF ANIMAL ORIGIN	0,1	VEGETABLES	0,1	FRUIT (FRESH OR FROZEN)	
0,4	ES child	0,2	PRODUCTS OF ANIMAL ORIGIN	0,1	FRUIT (FRESH OR FROZEN)	0,1	CEREALS	
0,4	IE adult	0,1	FRUIT (FRESH OR FROZEN)	0,1	VEGETABLES	0,1	CEREALS	
0,4	WHO cluster diet E	0,1	VEGETABLES	0,1	PRODUCTS OF ANIMAL ORIGIN	0,1	CEREALS	
0,3	WHO cluster diet D	0,1	VEGETABLES	0,1	CEREALS	0,1	PRODUCTS OF ANIMAL ORIGIN	
0,3	WHO regional European diet	0,1	PRODUCTS OF ANIMAL ORIGIN	0,1	VEGETABLES	0,0	CEREALS	
0,3	WHO Cluster diet F	0,1	PRODUCTS OF ANIMAL ORIGIN	0,1	VEGETABLES	0,1	CEREALS	
0,3	NL general	0,1	PRODUCTS OF ANIMAL ORIGIN	0,1	VEGETABLES	0,1	FRUIT (FRESH OR FROZEN)	
0,2	ES adult	0,1	PRODUCTS OF ANIMAL ORIGIN	0,0	FRUIT (FRESH OR FROZEN)	0,0	VEGETABLES	
0,2	UK vegetarian	0,0	SUGAR PLANTS	0,0	VEGETABLES	0,0	PRODUCTS OF ANIMAL ORIGIN	
0,2	FR all population	0,1	FRUIT (FRESH OR FROZEN)	0,1	PRODUCTS OF ANIMAL ORIGIN	0,0	VEGETABLES	
0,2	PT General population	0,1	FRUIT (FRESH OR FROZEN)	0,1	VEGETABLES	0,1	CEREALS	
0,2	UK Adult	0,1	PRODUCTS OF ANIMAL ORIGIN	0,0	SUGAR PLANTS	0,0	VEGETABLES	
0,2	DK adult	0,1	PRODUCTS OF ANIMAL ORIGIN	0,0	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	
0,2	IT kids/toddler	0,1	CEREALS	0,1	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	
0,2	LT adult	0,1	PRODUCTS OF ANIMAL ORIGIN	0,1	VEGETABLES	0,0	CEREALS	
0,2	FI adult	0,1	PRODUCTS OF ANIMAL ORIGIN	0,0	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	
0,1	IT adult	0,1	CEREALS	0,0	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	
0,1	PL general population	0,1	VEGETABLES	0,0	FRUIT (FRESH OR FROZEN)	0,0	PULSES, DRY	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Dodemorph is unlikely to present a public health concern.

Acute risk assessment /children	Acute risk assessment / adults / general population

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 variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads 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):**		---
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)
0,5	Potatoes	0,01 / -	0,5	Melons	0,01 / -	0,2	Pumpkins	0,01 / -	0,2	Pumpkins	0,01 / -
0,5	Melons	0,01 / -	0,4	Milk and milk	0,01 / -	0,1	Watermelons	0,01 / -	0,1	Watermelons	0,01 / -
0,4	Oranges	0,01 / -	0,4	Watermelons	0,01 / -	0,1	Melons	0,01 / -	0,1	Melons	0,01 / -
0,4	Milk and milk	0,01 / -	0,3	Potatoes	0,01 / -	0,1	Chinese cabbage	0,01 / -	0,1	Chinese cabbage	0,01 / -
0,4	Watermelons	0,01 / -	0,3	Pineapples	0,01 / -	0,1	Cauliflower	0,01 / -	0,1	Cauliflower	0,01 / -
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:**		---			
		*****)**						*****)**			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
0,2	Apple juice	0,01 / -				0,0	Orange juice	0,01 / -			
0,2	Orange juice	0,01 / -				0,0	Apple juice	0,01 / -			
0,1	Carrot, juice	0,01 / -				0,0	Bread/pizza	0,01 / -			
0,1	Grape juice	0,01 / -				0,0	Wine	0,01 / -			
0,1	Peach juice	0,01 / -				0,0	Pineapples preserved	0,01 / -			

*) 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 Dodemorph 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.

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
EURLs	EU Reference Laboratories (former CRLs)
ha	hectare
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residue Overview File
RMS	Rapporteur Member State