European Food Safety Authority

EFSA Journal 2014;12(7):3803

REASONED OPINION

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

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

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 desmedipham. In order to assess the occurrence of desmedipham residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC as well as the European authorisations reported by Member States (incl. the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, some information required by the regulatory framework was found to be missing. Hence, the consumer risk assessment is considered indicative only and all MRL proposals derived by EFSA still require further consideration by risk managers.

KEY WORDS

desmedipham, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, carbanilate, herbicide, EHPC

[1] On request from EFSA, Question No EFSA-Q-2008-524, approved on 24 July 2014.

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

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

Suggested citation: EFSA (European Food Safety Authority), 2014. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for desmedipham according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(7):3803, 35 pp. doi:10.2903/j.efsa.2014.3803

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

SUMMARY

Desmedipham was included in Annex I to Directive 91/414/EEC on 01 March 2005, which is before 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(2) of the aforementioned regulation. In order to collect the relevant pesticide residues data, EFSA asked Finland, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile). The requested information was submitted to EFSA on 25 January 2010 and, after having considered several comments made by EFSA, the RMS provided on 06 September 2011 a revised PROFile.

Based on the conclusions derived in the framework of Directive 91/414/EEC and the additional information provided by the RMS, EFSA issued on 17 February 2014 a draft reasoned opinion that was circulated to Member States' experts for consultation. Comments received by 18 April 2014 were considered in the finalisation of this reasoned opinion. The following conclusions are derived.

The toxicological profile of desmedipham was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI and an ARfD being established at 0.03 mg/kg bw per d and 0.1 mg/kg bw, respectively.

Primary crop metabolism of desmedipham was investigated following foliar application in sugar beet, hereby covering the root and tuber vegetables crop group. However, these studies are not fully reliable and new metabolism data are necessary in order to elucidate the metabolism of desmedipham in root and tuber vegetables. Moreover, the use of desmedipham by foliar application is also authorised on beet leaves, which do not belong to the aforementioned group. In order to cover all crops supported in the framework of this review, an additional metabolism study following foliar application on crops representing leafy vegetables is also required. According to the RMS, a new sugar beet metabolism study will be submitted in the framework of the renewal of the approval of the active substance under Regulation (EC) No 1107/2009 (January 2015). Meanwhile, a tentative residue definition for enforcement and risk assessment in plant commodities is defined as desmedipham only. Validated analytical methods for enforcement of the proposed residue definition are available with an LOQ of 0.01 mg/kg in commodities with high water content.

Regarding the magnitude of residues in primary crops, the available residues data were considered sufficient to derive MRL proposals as well as risk assessment values for sugar beet (root), beetroot and beet leaves (chard). However, as data on plants metabolism are insufficient, only tentative MRLs can be derived. Tentative MRLs were derived for feed crops (fodder beet (root and tops) and sugar beet (tops)) in view of the future need to set MRLs in feed items.

The nature of residues during processing was not investigated. Nevertheless, as quantifiable residues of desmedipham are not expected in the treated crops and the chronic exposure does not exceed 10 % of the ADI, there is no need to investigate the effect of industrial and/or household processing. If robust processing factors were to be required by risk managers, in particular for enforcement purposes, processing studies would be needed.

Occurrence of desmedipham residues in rotational crops was investigated during the peer review. It can be concluded that significant residues in rotational crops are not expected (provided that desmedipham is applied in compliance with the authorised European uses) and that a specific residue definition for rotational crops is not necessary.

Based on the uses reported by the RMS, significant intakes were calculated for dairy ruminants, meat ruminants and pigs. Metabolism studies in lactating ruminants suffered of many deficiencies. Nevertheless, the presence of many metabolites indicates extensive metabolism of parent

desmedipham, involving hydrolysis and conjugation. Based on the extraction profiles, it can be assumed that metabolism fate of desmedipham in ruminants is similar to the one in rat and findings in ruminants can be extrapolated to pigs. As, according to the available metabolism studies, residue levels in ruminant and pig commodities are expected to be negligible, a default residue definition for enforcement and risk assessment in ruminant and pig matrices can be proposed as parent desmedipham only. Validated analytical methods for enforcement of the proposed residue definition are available with an LOQ of 0.05 mg/kg but a confirmatory method is still required. Furthermore, MRLs and risk assessment values for the relevant commodities in ruminants and pigs can be established at the LOQ level. These MRLs can only be tentatively derived but, considering the low residue expected in animal tissue, for the time being new ruminant metabolism studies are desirable only. Nevertheless, EFSA highlights that, if in the future new uses leading to residues above the LOQ in animal commodities will be granted, the proposed formal residue definition will need to be reconsidered and more data on animal metabolism will be required. For poultry matrices, neither a residue definition, nor MRLs or risk assessment values are necessary, as there is no significant exposure of poultry to desmedipham residues.

Chronic and acute consumer exposure resulting from the MRLs derived in the framework of this review was calculated using revision 2 of the EFSA PRIMo. The highest chronic exposure represented 8.2 % of the ADI (British children) and the highest acute exposure amounted to 6.2 % of the ARfD (milk and milk products).

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with the decision tree reported in Appendix D (see summary table). None of the MRL values listed in the table are recommended for inclusion in Annex II to the Regulation as they are not sufficiently supported by data; they therefore require further consideration by risk managers (see summary table footnotes for details). In particular, certain tentative MRLs or existing EU MRLs still need to be confirmed by the following data:

- a confirmatory method for the determination of desmedipham in fat, meat, liver and kidney (a new method will be provided in the framework of the AIR - January 2015);
- a new representative study investigating primary crop metabolism in root and tuber vegetables (a new study will be provided in the framework of the AIR - January 2015);
- a representative study investigating primary crop metabolism in leafy vegetables.

If the above reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

Minor deficiencies were also identified in the assessment but they are not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following data are therefore considered desirable but not essential:

- at least two trials in each zone complying with the northern and southern outdoor GAPs on sugar beet root, fodder beet root and beetroot, where residues are analysed according to the enforcement LOQ (0.01 mg/kg) (new trials will be provided in the framework of the AIR - January 2015);
- at least two trials in each zone complying with the northern and southern outdoor GAPs on sugar beet tops, fodder beet tops and beet leaves (chard), where residues are analysed according to the enforcement LOQ (0.01 mg/kg) (new trials will be provided in the framework of the AIR - January 2015);

- the missing information on the storage conditions of the samples from the concerned residue trials (this information will be provided in the framework of the AIR - January 2015);
- new appropriate ruminant metabolism studies.

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
Enforcement residue definition: desmedipham				
213010	Beetroot	0.05	0.05	Further consideration needed (1)
252030	Beet leaves (chard)	0.05	0.05	Further consideration needed (1)
900010	Sugar beet (root)	0.1	0.05	Further consideration needed (1)
1011010	Swine muscle	-	0.05*	Further consideration needed (1)
1011020	Swine fat (free of lean meat)	-	0.05*	Further consideration needed (1)
1011030	Swine liver	-	0.05*	Further consideration needed (1)
1011040	Swine kidney	-	0.05*	Further consideration needed (1)
1012010	Bovine muscle	-	0.05*	Further consideration needed (1)
1012020	Bovine fat	-	0.05*	Further consideration needed (1)
1012030	Bovine liver	-	0.05*	Further consideration needed (1)
1012040	Bovine kidney	-	0.05*	Further consideration needed (1)
1013010	Sheep muscle	-	0.05*	Further consideration needed (1)
1013020	Sheep fat	-	0.05*	Further consideration needed (1)
1013030	Sheep liver	-	0.0.5*	Further consideration needed (1)
1013040	Sheep kidney	-	0.05*	Further consideration needed (1)
1014010	Goat muscle	-	0.05*	Further consideration needed (1)
1014020	Goat fat	-	0.05*	Further consideration needed (1)
1014030	Goat liver	-	0.0.5*	Further consideration needed (1)
1014040	Goat kidney	-	0.05*	Further consideration needed (1)
1020010	Cattle milk	-	0.05*	Further consideration needed (1)
1020020	Sheep milk	-	0.05*	Further consideration needed (1)
1020030	Goat milk	-	0.05*	Further consideration needed (1)
-	Other products of plant and animal origin	-	-	Further consideration needed (2)

(*): Indicates that the MRL is set at the limit of analytical quantification.
(1): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers could be identified; no CXL is available (combination E-I in Appendix D).
(2): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).

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(2) of that regulation stipulates that EFSA shall provide by 01 September 2009 a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Directive 91/414/EEC[5] before 02 September 2008. As desmedipham was included in Annex I to the above mentioned directive on 01 March 2005, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2008-524 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;
- the analytical methods for enforcement of the proposed MRLs.

Finland, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for desmedipham. The requested information was submitted to EFSA on 25 January 2010 and subsequently checked for completeness. On 06 September 2011, after having clarified some issues with EFSA, the RMS provided a revised PROFile.

A draft reasoned opinion was issued by EFSA on 17 February 2014 and submitted to Member States (MS) for commenting. All MS comments received by 18 April 2014 were considered by EFSA in the 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.

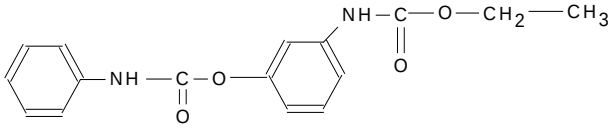
TERMS OF REFERENCE

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

Desmedipham is the ISO common name for ethyl 3-phenylcarbamoyloxycarbanilate (IUPAC).



Desmedipham belongs to the group of carbanilate herbicide compounds. Desmedipham is not a systemic substance. It acts through the foliage of emerged weeds and inhibits the photosynthetic electron transport at the photosystem II receptor site.

Desmedipham was evaluated in the framework of Directive 91/414/EEC with Finland being the designated Rapporteur Member State (RMS). The representative use supported for the peer review process was the outdoor treatment of sugar and fodder beets in both northern and southern Europe. 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 2004/58/EC[6], entering into force on 01 March 2005. According to Regulation (EU) No 540/2011[7], desmedipham is deemed to have been approved under Regulation (EC) No 1107/2009[8]. This approval is restricted to uses as herbicide only. As EFSA was not yet involved in the peer review of desmedipham, a conclusion of EFSA on this active substance is not available.

The EU MRLs for desmedipham are established in Annexes II and IIIB of Regulation (EC) No 396/2005. All existing EU MRLs, which are established for the parent compound only, are summarized in Appendix C to this document. CXLs for desmedipham are not available.

For the purpose of this MRL review, the critical uses of desmedipham currently authorized within the EU, have been collected by the RMS and reported in the PROFile (see Appendix A). They include early foliar treatments on sugar beet and beetroot, at the maximum rate of 480 g as/ha, both in northern and southern Europe. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

[6] Directive 2004/58/EC of 23 April 2004, amending Council Directive 91/414/EEC to include alpha-cypermethrin, benalaxyl, bromoxynil, desmedipham, ioxynil and phenmedipham as active substances. OJ L 120, 24.4.2004, p. 26-29.

[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.

ASSESSMENT

EFSA bases its assessment on the PROFile submitted by the RMS, the evaluation report accompanying the PROFile (Finland, 2010), the Draft Assessment Report (DAR) and its addenda prepared under Council Directive 91/414/EEC (Finland, 2000, 2002, 2003), and the Review Report on desmedipham (EC, 2004). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation of the Authorization of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[9] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a-g, 2000, 2010a,b, 2011 and OECD, 2011).

1. Methods of analysis

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

During the peer review under Directive 91/414/EEC, an analytical method using LC-MS/MS was evaluated and validated for the determination of desmedipham and its metabolite EHPC[10] in plant matrices with an LOQ of 0.05 mg/kg for each compound in high water content commodities (sugar beet leaves and roots) (Finland, 2000). However, this method is validated for only one mass transition and cannot be considered highly specific according to current guidance document (EC, 2010a). Moreover data about linearity and specificity were not reported and no ILV was available.

A multi-residue DFG S19 method using GC-MS was also evaluated but not validated for the determination of desmedipham in plant matrices (sugar beet root) as data about linearity and specificity were not reported and the number of tested samples was not sufficient (Finland, 2000). Its ILV was evaluated and validated for the determination of desmedipham with an LOQ of 0.03 mg/kg in high water content commodities (sugar beet root) (Finland, 2002). However, this method is not validated on three ion fragments and therefore cannot be considered highly specific according to the current guidance document on analytical methods (EC, 2010a).

In addition, after Annex I inclusion, the RMS also evaluated a multi-residue DFG S19 method using LC-MS/MS and its ILV, which were validated for the determination of desmedipham, and its metabolite EHPC with an LOQ of 0.01 mg/kg for each compound in high water content (sugar beet root), high fat content (oil seed rape), acidic (orange) and dry commodities (wheat grain) (Finland, 2010). However, this method is validated for only one mass transition and cannot be considered highly specific according to the current guidance document on analytical methods (EC, 2010a). Validation data concerning the second mass transition is missing but, according to the RMS, should be submitted in the framework of the renewal of the approval of the active substance under Regulation (EC) No 1107/2009 (January 2015).

The multi-residue QuEChERS method in combination with HPLC-MS/MS, as described by CEN (2008) is also reported for analysis of the desmedipham only with an LOQ of 0.01mg/kg in high water content commodities (Table 1-1). This method can be used as a confirmatory method for the determination of desmedipham in high water content matrices.

[9] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.06.2011, p. 127-175.

[10] EHPC: ethyl (3-hydroxyphenyl)carbamate, see appendix E

Table 1-1: Recovery data for the analysis of desmedipham in different crop groups using the QuEChERS method in combination with LC-MS/MS (EURL, 2014)

Commodity group	Spiking levels (mg/kg)	Recoveries			No of labs
		Mean (%)	RSD (%)	n	
High water content	0.01 0.1	86.8 85.5	3.3 5.5	6 6	1

Hence it is concluded that desmedipham can be enforced in food of plant origin with an LOQ of 0.01 mg/kg in high water content commodities.

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

During the peer review under Directive 91/414/EEC, an analytical method using LC-MS/MS and its ILV were evaluated and validated for the determination of desmedipham and its metabolite EHPC in food of animal origin with an LOQ of 0.05 mg/kg for each compound in milk, meat, fat, liver, kidney and eggs (Finland, 2003). This method can be confirmed by HPLC/UVD method validated for the determination of desmedipham and its metabolite EHPC with LOQ for each compound of 0.02 mg/kg in milk (Finland, 2000). However, a confirmatory method is missing for the determination of desmedipham and its metabolite EHPC in fat, meat, liver and kidney and it is required.

According to the RMS, an analytical method for the determination of desmedipham residue in food of animal matrices will be submitted in the framework of the renewal of the approval of the active substance under Regulation (EC) No 1107/2009 (January 2015).

Hence it is concluded, that desmedipham can be enforced in food of animal origin with an LOQ of 0.05 mg/kg in milk, meat, fat, liver and kidney. However, a confirmatory method is missing for the determination of desmedipham in fat, meat, liver and kidney and it is therefore required.

2. Mammalian toxicology

The toxicological assessment of desmedipham was peer reviewed under Directive 91/414/EEC and toxicological reference values were established by the European Commission (2004). 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
Desmedipham					
ADI	EC	2004	0.03 mg/kg bw per d	2 year, rat	100
ARfD	EC	2004	0.1 mg/kg bw	80-day study in dog Developmental toxicity in rat	100

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 desmedipham was investigated for foliar application on root and tuber vegetables (sugar beet), using m-aminophenol moiety ring- or phenoxy ring-labelled desmedipham (Finland, 2000). The characteristics of these studies are summarized in Table 3-1.

Table 3-1: Summary of available metabolism studies in plants

Group	Crop	Label position	Application and sampling details				
			Method, F or G [(a)]	Rate	No	Sampling (DAT)	Remarks
Root and tuber vegetables	Sugar beet	EPC[(b)] ring	Foliar by microsyringe[(d)], G	0.5 g/plant	1	0, 5, 10, 15, 30, 60, and 90	-
		EPC or PC[(c)] ring	Foliar spraying, G	1 kg a.s./ha	1	0, and 7, 28 and ca 120	-
				5 kg a.s./ha			

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G).
(b): EPC = ethyl 3-[U-^{14}C] phenylcarbomoyloxyphenylcarbamate.
(c): PC = ethyl 3-phenylcarbomoyloxy-[U-^{14}C] phenylcarbamate.
(d): Treatment was performed at the 4-leaf stage.

In the first study, the highest TRR was identified in leaf (64.1 % AR at final harvest). In root, the radioactivity was low but increased continuously throughout the study, reaching a maximum of 3.8 % of the AR 60 days after application (DAT). Compounds were only identified in leaf rinse. At final harvest (90 DAT), the main component of the residue was the metabolite EHPC (49.4 % TRR) while parent desmedipham and m-aminophenol[11]accounted for 27.1 % and for 11.5 % of the TRR, respectively. Some other components were identified, but they remained below 10 % of the TRR. From the second study, no relevant results can be reported since metabolites were only quantified but not identified. It can be highlighted that, in root and shoot at harvest, some metabolites represented more than 10 % of the TRR (up to 17.4 % TRR). Moreover, no information was given on the TRR ratio in each crop part.

The decreasing levels of parent desmedipham during the course of the studies suggest a slow degradation of desmedipham, through cleavage, resulting in the formation of polar components. In particular, metabolite EHPC (also encountered in rat metabolism) was found at high levels in sugar beet leaves. EHPC can be conjugated with sugars. Direct conjugation of parent compound can also occur.

[11] m-aminophenol: 3-aminophenol, see appendix E.

EFSA is of the opinion that both studies showed several deficiencies. Indeed, the first study, dated 1972, was not performed according to the GLP principles. Moreover, from the reported application method ("by microsyringe") and dose rate (in g/plant), it is not possible to ensure that the authorised European uses on beets and beet leaves are covered. In addition, no relevant results could be reported from the second study. Despite the poor quality of the first study, it is likely that residues in roots would be negligible. In leaves, metabolite EHPC was found at higher rates than parent compound and increased from the application to the harvest. This observation does not correspond to the results of the residue trials on sugar beet reported in the monograph (Finland, 2002), where residue levels of metabolite EHPC in leaves and roots were lower than the parent compound at 0 day PHI and both compounds were undetectable at harvest.

Therefore, EFSA concluded that a robust residue definition cannot be established on the basis of the available metabolism studies. Consequently, new metabolism data covering the currently authorised European uses, representative for root and tuber vegetables and leafy vegetables metabolism groups, are required. According to the RMS, a new sugar beet metabolism study will be submitted in the framework of the renewal of the approval of the active substance under Regulation (EC) No 1107/2009 (January 2015). Meanwhile, a tentative residue definition for enforcement and risk assessment in plant commodities is defined as desmedipham only. Validated analytical methods for enforcement of the proposed residue definition are available (see also Section 1.1).

3.1.1.2. Magnitude of residues

According to the RMS, the active substance desmedipham is authorised in northern and southern Europe for foliar application in different crops, only under outdoor conditions (see Appendix A). To assess the magnitude of desmedipham residues resulting from these GAPs, EFSA considered all residue trials reported in the PROFile, including residue trials evaluated in the framework of the peer review (Finland, 2000, 2002, 2003). All available residues trials that, according to the RMS, comply with the authorised GAPs, are summarized in Table 3-2.

The number of residues trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (EC, 2011). For the reported GAPs, sufficient trials are available to derive tentative MRLs and risk assessment values. The following considerations were made by EFSA:

- For sugar beet root, fodder beet root and beetroot, the number of residue trials supporting the outdoor GAPs is not compliant with the data requirements for these crops. However, the reduced number of residues trials is considered acceptable for deriving MRL proposals in this case because results were all below the LOQ and a no residue situation is expected (see also Section 3.1.1.1). Nevertheless, at least two trials for each zone where residues are analysed according to the enforcement LOQ (0.01 mg/kg) would be desirable. According to the RMS, these studies will be submitted in the framework of the renewal of the approval of the active substance under Regulation (EC) No 1107/2009 (January 2015).

- For sugar beet tops, fodder beet tops and beet leaves (chard), the number of residue trials supporting the outdoor GAPs is compliant with the data requirements for these crops, as they are either feed items or minor crops. Nevertheless, at least two trials for each zone where residues are analysed according to the enforcement LOQ (0.01 mg/kg) would be desirable. According to the RMS, these studies will be submitted in the framework of the renewal of the approval of the active substance under Regulation (EC) No 1107/2009 (January 2015).

The potential degradation of residues during storage of the residues trial samples was also assessed. In a study evaluated by the RMS after the peer review process, storage stability of desmedipham and its metabolite EHPC was demonstrated for a period of 24 months at -18 °C in commodities with high

water content (sugar beet root). It should be noted that, in sugar beet leaves, desmedipham was also stable for 24 months but its metabolite EHPC, for 1 month only (Finland, 2010). The storage conditions were reported by the RMS only for some of the available residues trials: samples were stored frozen for 51 to 471 days (ca. up to 16 months) which is less than the demonstrated storage stability period. As all residue results were below the LOQ, information on the storage conditions of the samples from the other trials is desirable only. According to the RMS, this information will be available in the data submitted in the framework of the renewal of the approval of the active substance under Regulation (EC) No 1107/2009 (January 2015).

Consequently, the available residues data are considered sufficient to derive MRL proposals as well as risk assessment values for sugar beet (root), beetroot and beet leaves (chard). However, as data on plants metabolism are insufficient, only tentative MRLs can be derived. Tentative MRLs were also derived for feed crops (fodder beet (root and tops), sugar beet (tops)) in view of the future need to set MRLs in feed items.

Table 3-2: 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
			Enforcement (Desmedipham)	Risk assessment (Desmedipham)					
Sugar beet (root) Beetroot Fodder beet (root)	NEU	Outdoor	6 × <0.05	6 × <0.05	0.05	0.05	0.05 [e] (tentative)	1.0	Trials on sugar beet compliant with GAP. Extrapolation to beetroot and fodder beet possible.
	SEU	Outdoor	5 × <0.05	5 × <0.05	0.05	0.05	0.05 [e] (tentative)	1.0	Trials on sugar beet compliant with GAP. Extrapolation to beetroot and fodder beet possible.
Sugar beet (tops) Fodder beet (tops) Beet leaves (chard)	NEU	Outdoor	6 × <0.05	6 × <0.05	0.05	0.05	0.05 [e] (tentative)	1.0	Trials on sugar beet compliant with GAP. Extrapolation to fodder beet and beet leaves (chard) possible.
	SEU	Outdoor	5 × <0.05	5 × <0.05	0.05	0.05	0.05 [e] (tentative)	1.0	Trials on sugar beet compliant with GAP. Extrapolation to fodder beet possible. Use on beet leaves not authorised.

(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 residues trial.
(e): These MRLs can only be tentatively derived due to the data gaps for plant metabolism highlighted in Section 3.1.1.1.

3.1.1.3. Effect of industrial processing and/or household preparation

As quantifiable residues of desmedipham are not expected in the treated crops and the chronic exposure does not exceed 10 % of the ADI (see also Section 4), there is no need to investigate the effect of industrial and/or household processing. If robust processing factors were to be required by risk managers, in particular for enforcement purposes, processing studies would be needed.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

All crops under consideration may be grown in rotation. According to the soil degradation studies evaluated in the framework of the peer review, $DT_{90field}$ value of desmedipham ranges between 18.5 - 40 days which is below the trigger value of 100 days. However, it should be noted that DT_{90lab} value of desmedipham ranges between 18 - 714 days (EC, 2004). Furthermore, DT_{90} value of the major soil metabolite EHPC was not investigated. According to the European guidelines on rotational crops (EC, 1997c) and in absence of sufficient information on the degradation rate of desmedipham and its main soil metabolites in soil, further investigation of residues in rotational crops are required.

3.1.2.2. Nature and magnitude of residues

The metabolism of desmedipham in rotational crops – lettuce, radish and wheat – has been evaluated in the framework of the peer review (Finland, 2000). Three confined rotational crop studies investigating the nature of residues following different plant-back intervals are available. The characteristics of these studies are summarised in Table 3-3.

Table 3-3: Summary of available metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details				
			Method, F or G [(a)]	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals	Remarks
Leafy vegetables	Lettuce	EPC[(b)] or PC[(c)] ring	G	2.5	30, 120, 365	Immature Mature	
Root and tuber vegetables	Radish	EPC[(b)] or PC[(c)] ring	G	2.5	30, 120, 365	Immature Mature	
Cereals	Wheat	EPC[(b)] or PC[(c)] ring	G	2.5	30, 120, 365	Immature Mature	

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G).
(b): EPC = ethyl 3-[U-^{14}C] phenylcarbomoyloxyphenylcarbamate.
(c): PC = ethyl 3-phenylcarbomoyloxy-[U-^{14}C] phenylcarbamate.

In the analysed commodities, maximum residues at mature stages were 0.23 mg eq./kg in the 30 day plot (wheat forage), 0.09 mg eq./kg in the 120 day plot (wheat straw) and 0.04 mg eq./kg in the 365 day plot (wheat straw). Residues in all other raw commodities were 0.04 mg eq./kg or below in the 120 day plot and 0.02 mg eq./kg or below in the 365 day plot. Uptake of residues into rotational crops was low at all sampling times, declining rapidly as the planting interval increased. This was due to both a decrease in the total residue in soil with time and a rapid decline in the extractability of the remaining residues.

Considering the overdosing factor of the above study (around 5 times the dose level of the authorised European GAPs) and that desmedipham was applied on bare soil (interception of desmedipham by plants is expected in practice), it can be concluded that desmedipham residue levels in rotational commodities are not expected to exceed 0.01 mg/kg (provided that desmedipham is applied in compliance with the GAPs reported in Appendix A) and that a specific residue definition for rotational crops is not necessary.

3.2. Nature and magnitude of residues in livestock

3.2.1. Dietary burden of livestock

Desmedipham is authorised for use on several crops that might be fed to livestock. The median and maximum dietary burdens were therefore calculated for different groups of livestock using the agreed European methodology (EC, 1996). The input values for all relevant commodities have been selected according to the recommendations of JMPR (FAO, 2009) and are summarized in Table 3-4.

Table 3-4: Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: desmedipham				
Sugar beet leaves	0.05	Median residue	0.05	Highest residue
Fodder beet leaves	0.05	Median residue	0.05	Highest residue
Sugar beets	0.05	Median residue	0.05	Highest residue
Fodder beets	0.05	Median residue	0.05	Highest residue

The results of the calculations are reported in Table 3-5. The calculated dietary burdens were found to exceed the trigger value of 0.1 mg/kg DM for all groups of livestock except poultry. Further investigation of residues is therefore required in these groups of livestock.

Table 3-5: Results of the dietary burden calculation

	Median dietary burden (mg/kg bw per d)	Maximum dietary burden (mg/kg bw per d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: desmedipham					
Dairy ruminants	0.0061	0.0061	Sugar beet leaves	0.17	Y
Meat ruminants	0.0104	0.0104	Sugar beets	0.24	Y
Poultry	0.0032	0.0032	Sugar beets	0.05	N
Pigs	0.0091	0.0091	Sugar beets	0.23	Y

3.2.2. Nature and magnitude of residues

The nature of desmedipham residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (Finland, 2000, 2002, 2003). Reported metabolism studies include two studies in lactating goats and two studies in laying hens (although not required) using m-aminophenol moiety ring- or phenoxy ring- labelled desmedipham. The characteristics of these studies are summarized in Table 3-6.

Table 3-6: Summary of available metabolism studies in livestock

Group	Species	Label position	No of animal	Application details		Sample details	
				Rate	Duration (days)	Commodity	Time
Lactating ruminants	Cow	EPC[(a)] ring	1	0.4 mg/kg bw per d	4	Milk	Twice daily
						Urine and faeces	Once, after final dose prior to sacrifice
						Blood	Prior dosing, and 0.5, 1, 2, 3, 4, 6, 8, 12 and 24 h after initial dose and prior to sacrifice
						Tissues	At sacrifice
		PC[(b)] ring	1	0.35 mg/kg bw per d	7	Milk	Twice daily
						Excreta	Daily
						Tissues	At sacrifice
Laying poultry	Hens	EPC[(a)] ring	6	1.5 mg/hen/d	10	Eggs	Daily
						Excreta	Daily
						Tissues	At sacrifice
		PC[(b)] ring	5	1.5 mg/hen/d	14	Egg	Twice daily
						Excreta	Daily
						Blood	At sacrifice
						Tissues	At sacrifice

(a): EPC = ethyl 3-[U-^{14}C] phenylcarbomoyloxyphenylcarbamate.
(b): PC = ethyl 3-phenylcarbomoyloxy-[U-^{14}C] phenylcarbamate.

Lactating cows were dosed with 0.4 mg/kg bw per d of EPC-labelled desmedipham and 0.35 mg/kg bw per d of PC-labelled desmedipham, corresponding to 35 - 40 times the exposure of meat ruminants. Studies demonstrate that transfer of residues to milk and tissues is significant.

In both studies, radioactivity was extensively excreted via urine (81 % AR in the study with PC-labelled desmedipham). In the study performed with EPC-labelled desmedipham, the highest residue levels were found in kidney (0.307 mg eq./kg) and milk (0.187 mg eq./kg, 5h after the last dose); in muscle, residues were undetectable and in the other matrices they ranged from 0.019 mg eq./kg (omental fat) to 0.040 mg eq./kg (liver). Following administration of PC-labelled desmedipham, the highest residue levels were observed in liver (1.181 mg eq./kg) and kidney

(0.634 mg eq./kg); in the other matrices, they ranged from 0.037 mg eq./kg (omental fat) to 0.157 mg eq./kg (milk, 80h after the 1st dose). It can be observed that the residue levels were about 2 to 30 times higher in internal organs, fat, blood and plasma in the cow treated with PC-labelled desmedipham than in the cow treated with EPC-labelled desmedipham. Residue levels in milk were comparable in both studies.

The extraction yields from the EPC-labelled desmedipham study were not reported, while, for the PC-labelled desmedipham study, they were acceptable, ranging from 69.4 % TRR (renal fat) to 95.5 % TRR (milk). In the EPC-labelled desmedipham study, metabolite EHPC constituted the most important component of the residue in every matrix where residues were sufficiently high to be identified (75.1 % TRR in milk, 76.7 % TRR, in kidney and 13.6 % TRR in liver). Metabolite 3-acetamidophenol[12] was detected at low levels in all tissues. In the PC-labelled desmedipham study, 4-acetamidophenol[13] was the main identified metabolite in all samples analysed (64.3 % TRR, 0.1 mg eq./kg in milk, 24.4 % TRR, 0.16 mg eq./kg in kidney, 23.7 % TRR, 0.02 mg eq./kg in muscle, 23.1 % TRR, 0.27 mg eq./kg in liver, 22 % TRR, 0.01 mg eq./kg in renal fat, 20.2 % TRR, <0.01 mg eq./kg in omental fat). 4-aminophenol[14] was also detected in all tissues, being above 10 % TRR in kidney (15.6 % TRR, 0.01 mg eq./kg) and omental fat (14.3 % TRR, <0.01 mg eq./kg). Several unknown components were also detected in tissues, amounting up to 25.8 % TRR or 0.3 mg eq./kg (liver). Indeed, complete identification of the radioactive residues was not performed in this study as only two reference compounds were used: 4-acetamidophenol and 4-aminophenol. In particular, samples were not analysed for N-(phenyl)methyl carbamate[15], one of the main PC-ring pathway metabolites in rat. Nevertheless, based on the extraction profiles, it can be assumed that the unidentified components are probably conjugates and reaction products with endogenous material.

Laying hens were dosed with approximately 1 mg/kg bw per d of desmedipham in both studies, which is about 300 times the exposure of poultry. Studies demonstrate that transfer of residues to eggs and tissues is significant.

Considering the two studies, highest residue levels were found in egg yolk (0.654 mg/kg), liver (0.402 mg/kg) and skin (0.399 mg/kg). As in the studies in cow, the levels of PC labelled residues were significantly higher than with the EPC labelled.

From the EPC-labelled desmedipham study, tissue residues were very low (<0.008 mg/kg). This can be explained by the fast elimination of the radioactivity observed: at least 85 % of each daily dose was excreted during the subsequent 24h. The highest TRR was identified in egg yolk (0.05 - 0.06 mg/kg), where metabolites 3-aminophenol and EHPC were the major components representing 47.5 % and 26.5 % of total residue, respectively. From the PC-labelled desmedipham study, highly polar radioactive compounds were the major components in most tissues. Other metabolites were identified but were all present in very small amounts (<0.011 % of the administrated dose).

In the metabolism studies on both ruminant and poultry, the presence of many metabolites indicates extensive metabolism involving hydrolysis and conjugation of parent desmedipham. The general metabolic pathways in rodents and ruminants seem to be comparable although the deficiencies identified in the studies; the findings in ruminants can therefore be extrapolated to pigs.

Based on the above findings and according to the authorised European uses, neither a residue definition, nor MRLs or risk assessment values are necessary for poultry matrices.

[12] 3-acetamidophenol: *N*-(3-hydroxyphenyl)acetamide, see appendix E.
[13] 4-acetamidophenol: *N*-(4-hydroxyphenyl)acetamide, see appendix E.
[14] 4-aminophenol, see appendix E.
[15] N-(phenyl)methyl carbamate: methyl phenylcarbamate, see appendix E.

For ruminants, despite the deficiencies of the available studies, metabolites EHPC and 4-acetamidophenol seem to be the major components of the residue in animal tissues. Nevertheless, as 4-acetamidophenol is a common metabolite formed from pendimethalin, EHPC is considered as a representative marker of the residue in products of animal origin. However, according to the available metabolism studies, after exposure to the maximum dietary burden (about 40 times lower than the application dose rate of the metabolism studies; see also Section 3.2.1), residue levels in ruminant and pig commodities are expected to remain below the enforcement LOQ of 0.05 mg/kg. Therefore, a default residue definition for enforcement and risk assessment in ruminant and pig matrices can be proposed as parent desmedipham only. Validated analytical methods for enforcement of the proposed residue definition are available but a confirmatory method is still required (see also Section 1.1). Furthermore, no livestock feeding study is needed and MRLs and risk assessment values for the relevant commodities in ruminants and pigs can be established at the LOQ level. These MRLs can only be tentatively derived, due to the data gaps identified in Section 1.2 and 3.1.1.

Considering that no residues are expected in ruminant matrices with regards to the currently authorized European uses, new ruminant metabolism studies are desirable only. Nevertheless, EFSA highlights that, if new uses leading to residues above the LOQ in animal commodities will be granted in the future, the proposed formal residue definition will need to be reconsidered and more data on animal metabolism will be required.

Log P_{ow} of desmedipham (3.39) is higher than 3 (Finland, 2000). Nevertheless, according to the results of the livestock metabolism studies (desmedipham was never found in any tissues), EFSA concludes that the residue in commodities of animal origin is not fat soluble.

4. Consumer risk assessment

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo) (EFSA, 2007). Input values for the exposure calculations were derived in compliance with Appendix D and are summarized in Table 4-1. The tentative median and highest residue values selected for chronic and acute intake calculations are based on the residue levels in the raw agricultural commodities reported in Section 3. The contributions of other commodities, for which no GAP was reported in the framework of this review, were not included in the calculation.

Table 4-1: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: desmedipham				
Beetroot	0.05	Median residue (tentative) [a]	0.05	Highest residue (tentative) [a]
Beet leaves (chards)	0.05	Median residue (tentative) [a]	0.05	Highest residue (tentative) [a]
Sugar beet (root)	0.05	Median residue (tentative) [a]	0.05	Highest residue (tentative) [a]
Swine meat	0.05*	Median residue (tentative) [b]	0.05*	Highest residue (tentative) [b]
Swine fat (free of lean meat)	0.05*	Median residue (tentative) [b]	0.05*	Highest residue (tentative) [b]
Swine liver	0.05*	Median residue (tentative) [b]	0.05*	Highest residue (tentative) [b]
Swine kidney	0.05*	Median residue (tentative) [b]	0.05*	Highest residue (tentative) [b]
Ruminant meat	0.05*	Median residue (tentative) [b]	0.05*	Highest residue (tentative) [b]
Ruminant fat	0.05*	Median residue (tentative) [b]	0.05*	Highest residue (tentative) [b]
Ruminant liver	0.05*	Median residue (tentative) [b]	0.05*	Highest residue (tentative) [b]
Ruminant kidney	0.05*	Median residue (tentative) [b]	0.05*	Highest residue (tentative) [b]
Ruminant milk	0.05*	Median residue (tentative) [b]	0.05*	Highest residue (tentative) [b]

(*): Indicates that the input value is proposed at the limit of analytical quantification.
(a): Use reported by the RMS is not fully supported by data but the risk assessment values derived in Section 3 are used for indicative exposure calculations.
(b): Dietary burden relevant to this commodity of animal origin, resulting from the GAPs reported by the RMS, is not fully supported by data; the risk assessment values derived in Section 3 are used for indicative exposure calculations.

The calculated exposures were compared to the toxicological reference values derived for desmedipham (see Table 2-1); detailed results of the calculations are presented in Appendix B. The highest chronic exposure was calculated for British children, representing 8.2 % of the ADI, and the highest acute exposure was calculated for milk and milk products, representing 6.2 % of the ARfD.

Based on the above calculations, for all crops authorised, major uncertainties remain due to the data gaps identified in Section 3, in particular with regard to the residue definition in plant commodities, but considering tentative MRLs in the exposure calculation did not indicate a risk to consumers.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of desmedipham was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI and an ARfD being established at 0.03 mg/kg bw per d and 0.1 mg/kg bw, respectively.

Primary crop metabolism of desmedipham was investigated following foliar application in sugar beet, hereby covering the root and tuber vegetables crop group. However, these studies are not fully reliable and new metabolism data are necessary in order to elucidate the metabolism of desmedipham in root and tuber vegetables. Moreover, the use of desmedipham by foliar application is also authorised on beet leaves, which do not belong to the aforementioned group. In order to cover all crops supported in the framework of this review, an additional metabolism study following foliar application on crops representing leafy vegetables is also required. According to the RMS, a new sugar beet metabolism study will be submitted in the framework of the renewal of the approval of the active substance under Regulation (EC) No 1107/2009 (January 2015). Meanwhile, a tentative residue definition for enforcement and risk assessment in plant commodities is defined as desmedipham only. Validated analytical methods for enforcement of the proposed residue definition are available with an LOQ of 0.01 mg/kg in commodities with high water content.

Regarding the magnitude of residues in primary crops, the available residues data were considered sufficient to derive MRL proposals as well as risk assessment values for sugar beet (root), beetroot and beet leaves (chard). However, as data on plants metabolism are insufficient, only tentative MRLs can be derived. Tentative MRLs were derived for feed crops (fodder beet (root and tops) and sugar beet (tops)) in view of the future need to set MRLs in feed items.

The nature of residues during processing was not investigated. Nevertheless, as quantifiable residues of desmedipham are not expected in the treated crops and the chronic exposure does not exceed 10 % of the ADI, there is no need to investigate the effect of industrial and/or household processing. If robust processing factors were to be required by risk managers, in particular for enforcement purposes, processing studies would be needed.

Occurrence of desmedipham residues in rotational crops was investigated during the peer review. It can be concluded that significant residues in rotational crops are not expected (provided that desmedipham is applied in compliance with the authorised European uses) and that a specific residue definition for rotational crops is not necessary.

Based on the uses reported by the RMS, significant intakes were calculated for dairy ruminants, meat ruminants and pigs. Metabolism studies in lactating ruminants suffered of many deficiencies. Nevertheless, the presence of many metabolites indicates extensive metabolism of parent desmedipham, involving hydrolysis and conjugation. Based on the extraction profiles, it can be assumed that metabolism fate of desmedipham in ruminants is similar to the one in rat and findings in ruminants can be extrapolated to pigs. As, according to the available metabolism studies, residue

levels in ruminant and pig commodities are expected to be negligible, a default residue definition for enforcement and risk assessment in ruminant and pig matrices can be proposed as parent desmedipham only. Validated analytical methods for enforcement of the proposed residue definition are available with an LOQ of 0.05 mg/kg but a confirmatory method is still required. Furthermore, MRLs and risk assessment values for the relevant commodities in ruminants and pigs can be established at the LOQ level. These MRLs can only be tentatively derived but, considering the low residue expected in animal tissue, for the time being new ruminant metabolism studies are desirable only. Nevertheless, EFSA highlights that, if in the future new uses leading to residues above the LOQ in animal commodities will be granted, the proposed formal residue definition will need to be reconsidered and more data on animal metabolism will be required. For poultry matrices, neither a residue definition, nor MRLs or risk assessment values are necessary, as there is no significant exposure of poultry to desmedipham residues.

Chronic and acute consumer exposure resulting from the MRLs derived in the framework of this review was calculated using revision 2 of the EFSA PRIMo. The highest chronic exposure represented 8.2 % of the ADI (British children) and the highest acute exposure amounted to 6.2 % of the ARfD (milk and milk products).

RECOMMENDATIONS

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with the decision tree reported in Appendix D (see summary table). None of the MRL values listed in the table are recommended for inclusion in Annex II to the Regulation as they are not sufficiently supported by data; they therefore require further consideration by risk managers (see summary table footnotes for details). In particular, certain tentative MRLs or existing EU MRLs still need to be confirmed by the following data:

- a confirmatory method for the determination of desmedipham in fat, meat, liver and kidney (a new method will be provided in the framework of the AIR - January 2015);
- a new representative study investigating primary crop metabolism in root and tuber vegetables (a new study will be provided in the framework of the AIR - January 2015);
- a representative study investigating primary crop metabolism in leafy vegetables.

If the above reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

Minor deficiencies were also identified in the assessment but they are not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following data are therefore considered desirable but not essential:

- at least two trials in each zone complying with the northern and southern outdoor GAPs on sugar beet root, fodder beet root and beetroot, where residues are analysed according to the enforcement LOQ (0.01 mg/kg) (new trials will be provided in the framework of the AIR - January 2015);
- at least two trials in each zone complying with the northern and southern outdoor GAPs on sugar beet tops, fodder beet tops and beet leaves (chard), where residues are analysed according to the enforcement LOQ (0.01 mg/kg) (new trials will be provided in the framework of the AIR - January 2015);

- the missing information on the storage conditions of the samples from the concerned residue trials (this information will be provided in the framework of the AIR - January 2015);

- new appropriate ruminant metabolism studies.

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
Enforcement residue definition: desmedipham				
213010	Beetroot	0.05	0.05	Further consideration needed (1)
252030	Beet leaves (chard)	0.05	0.05	Further consideration needed (1)
900010	Sugar beet (root)	0.1	0.05	Further consideration needed (1)
1011010	Swine muscle	-	0.05*	Further consideration needed (1)
1011020	Swine fat (free of lean meat)	-	0.05*	Further consideration needed (1)
1011030	Swine liver	-	0.05*	Further consideration needed (1)
1011040	Swine kidney	-	0.05*	Further consideration needed (1)
1012010	Bovine muscle	-	0.05*	Further consideration needed (1)
1012020	Bovine fat	-	0.05*	Further consideration needed (1)
1012030	Bovine liver	-	0.05*	Further consideration needed (1)
1012040	Bovine kidney	-	0.05*	Further consideration needed (1)
1013010	Sheep muscle	-	0.05*	Further consideration needed (1)
1013020	Sheep fat	-	0.05*	Further consideration needed (1)
1013030	Sheep liver	-	0.0.5*	Further consideration needed (1)
1013040	Sheep kidney	-	0.05*	Further consideration needed (1)
1014010	Goat muscle	-	0.05*	Further consideration needed (1)
1014020	Goat fat	-	0.05*	Further consideration needed (1)
1014030	Goat liver	-	0.0.5*	Further consideration needed (1)
1014040	Goat kidney	-	0.05*	Further consideration needed (1)
1020010	Cattle milk	-	0.05*	Further consideration needed (1)
1020020	Sheep milk	-	0.05*	Further consideration needed (1)
1020030	Goat milk	-	0.05*	Further consideration needed (1)
-	Other products of plant and animal origin	-	-	Further consideration needed (2)

(*): Indicates that the MRL is set at the limit of analytical quantification.
(1): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers could be identified; no CXL is available (combination E-I in Appendix D).
(2): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).

DOCUMENTATION PROVIDED TO EFSA

1. Pesticide Residues Overview File (PROFile) on desmedipham prepared by the rapporteur Member State Finland in the framework of Article 12 of Regulation (EC) No 396/2005. Submitted to EFSA on 25 January 2010. Last updated on 06 September 2011.

REFERENCES

CEN (European Committee for Standardization), 2008. Foods of plant origin - Determination of pesticide residues using GC-MS and/or LC-MS/MS following acetonitrile extraction/partitioning and clean-up by dispersive SPE. QuEChERS-method. EN 15662, November 2008.

EC (European Commission), 1996. Appendix G. Livestock Feeding Studies. 7031/VI/95 rev.4

EC (European Commission), 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev.3.

EC (European Commission), 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev.6.

EC (European Commission), 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev.2.

EC (European Commission), 1997d. Appendix E. Processing studies. 7035/VI/95-rev.5.

EC (European Commission), 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev.3.

EC (European Commission), 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev.5.

EC (European Commission), 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010.

EC (European Commission), 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414. SANCO/3029/99-rev.4.

EC (European Commission), 2004. Review report for the active substance desmedipham. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 13 February 2004 in view of the inclusion of desmedipham in Annex I of Council Directive 91/414/EEC. SANCO/4061/2001-Final, 13 February 2004.

EC (European Commission), 2010a. Residue analytical methods. For post-registration control. SANCO/825/00-rev.8.1.

EC (European Commission), 2010b. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010 Rev. 0, finalized in the Standing Committee on the Food Chain and Animal Health at its meeting of 23-24 March 2010.

EC (European Commission), 2011. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.9.

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

EURL (European Union Reference Laboratories for Pesticide Residues), 2014. Data pool on method validation for pesticide residues. Status on 30 January 2014. Available online: www.eurl-pesticides-datapool.eu

FAO (Food and Agriculture Organization of the United Nations), 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed**.** Pesticide Residues. 2nd Ed. FAO Plant Production and Protection Paper 197, 264 pp.

Finland, 2000. Draft assessment report on the active substance desmedipham prepared by the rapporteur Member State Finland in the framework of Council Directive 91/414/EEC, April 2000.

Finland, 2002. Addendum to the draft assessment report on the active substance desmedipham prepared by the rapporteur Member State Finland in the framework of Council Directive 91/414/EEC, October 2002.

Finland, 2003. Addendum to the draft assessment report on the active substance desmedipham prepared by the rapporteur Member State Finland in the framework of Council Directive 91/414/EEC, October 2003.

Finland, 2010. Evaluation report on the review of the existing EU MRLs for desmedipham prepared by the rapporteur Member State Finland in the framework of Article 12 of Regulation (EC) No 396/2005, January 2010.

OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL Calculator: User Guide. In: Series on Pesticides No 56. ENV/JM/MONO(2011)2, 01 March 2011.

Appendix A – Good Agricultural Practices (GAPs)

Critical Outdoor GAPs for Northern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Beetroot	*Beta vulgaris subsp. Vulgaris*	NEU	Outdoor	PL, UK	Grassy and dicot weed species	EC	160,0	g/L	Foliar treatment - spraying	10	18	1	3				160,00	g a.i./ha	n.a.	Max application rate of desmedipham is 0.48 kg as/ha per season.
Beet leaves (chard)	*Beta vulgaris*	NEU	Outdoor	UK	Grassy and dicot weed species	EC	160,0	g/L	Foliar treatment - spraying	10	18	1	3				160,00	g a.i./ha	n.a.	Max application rate of desmedipham is 0.48 kg as/ha per season.
Sugar beet	*Beta vulgaris*	NEU	Outdoor	CZ, HU, PL, SK, UK	Grassy and dicot weed species	EC	160,0	g/L	Foliar treatment - spraying	10	18	1	3				160,00	g a.i./ha	n.a.	Max application rate of desmedipham is 0.48 kg as/ha per season.
Fodder beet	*Beta vulgaris*	NEU	Outdoor	CZ, PL, SK, UK	Grassy and dicot weed species	EC	160,0	g/L	Foliar treatment - spraying	10	18	1	3				160,00	g a.i./ha	n.a.	Max application rate of desmedipham is 0.48 kg as/ha per season.

n.a.: not applicable

Critical Outdoor GAPs for Southern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Beetroot	*Beta vulgaris subsp. Vulgaris*	SEU	Outdoor	ES	Grassy and dicot weed species	EC	160,0	g/L	Foliar treatment - spraying	10	18	1	3				160,00	g a.i./ha	n.a.	Max application rate of desmedipham is 0.48 kg as/ha per season. The following alternatives are authorised in Spain: -1 x 0,48 kg as/ha -2x0,24 kg as/ha -3x0,16 kg as/ha
Sugar beet	*Beta vulgaris*	SEU	Outdoor	EL, ES, SL	Grassy and dicot weed species	EC	160,0	g/L	Foliar treatment - spraying	10	18	1	3				160,00	g a.i./ha	n.a.	Max application rate of desmedipham is 0.48 kg as/ha per season. The following alternatives are authorised in Spain: -1 x 0,48 kg as/ha -2x0,24 kg as/ha -3x0,16 kg as/ha
Fodder beet	*Beta vulgaris*	SEU	Outdoor	ES, SL	Grassy and dicot weed species	EC	160,0	g/L	Foliar treatment - spraying	10	18	1	3				160,00	g a.i./ha	n.a.	Max application rate of desmedipham is 0.48 kg as/ha per season. The following alternatives are authorised in Spain: -1 x 0,48 kg as/ha -2x0,24 kg as/ha -3x0,16 kg as/ha

n.a.: not applicable

Appendix B – Pesticide Residues Intake Model (PRIMo)

Desmedipham			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.03**	ARfD (mg/kg bw):	**0.1**
Source of ADI:	**COM**	Source of ARfD:	**COM**
Year of evaluation:	**2004**	Year of evaluation:	**2004**

Prepare workbook for refined calculations

Undo refined calculations

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum

No of diets exceeding ADI: --- 8

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)
8.2	UK Infant	6.5	Milk and cream,	1.7	Sugar beet (root)	0.0	Bovine: Liver	
7.3	UK Toddler	3.8	Sugar beet (root)	3.4	Milk and cream,	0.0	Bovine: Liver	
6.9	FR toddler	6.6	Milk and cream,	0.2	Bovine: Meat	0.1	Swine: Meat	
5.4	NL child	4.9	Milk and cream,	0.3	Swine: Meat	0.2	Bovine: Meat	
4.4	FR infant	4.3	Milk and cream,	0.1	Bovine: Meat	0.0	Swine: Meat	
2.6	ES child	2.1	Milk and cream,	0.2	Bovine: Meat	0.2	Swine: Meat	
2.5	DE child	2.4	Milk and cream,	0.1	Swine: Meat	0.1	Bovine: Meat	
2.1	DK child	2.1	Milk and cream,	0.0	Bovine: Liver	0.0	Beetroot	
2.1	SE general population 90th percentile	2.1	Milk and cream,	0.0	Beetroot	0.0	Beet leaves (chard)	
1.4	NL general	1.1	Milk and cream,	0.2	Swine: Meat	0.1	Bovine: Meat	
1.3	WHO regional European diet	0.8	Milk and cream,	0.2	Swine: Meat	0.2	Bovine: Meat	
1.2	UK vegetarian	0.6	Sugar beet (root)	0.5	Milk and cream,	0.0	Beetroot	
1.2	UK Adult	0.7	Sugar beet (root)	0.5	Milk and cream,	0.0	Bovine: Liver	
1.1	ES adult	0.8	Milk and cream,	0.1	Bovine: Meat	0.1	Swine: Meat	
1.1	WHO Cluster diet B	0.5	Milk and cream,	0.1	Bovine: Meat	0.1	Swine: Meat	
1.0	WHO Cluster diet F	0.7	Milk and cream,	0.2	Swine: Meat	0.1	Bovine: Meat	
1.0	WHO cluster diet D	0.8	Milk and cream,	0.1	Bovine: Meat	0.0	Swine: Meat	
1.0	DK adult	0.9	Milk and cream,	0.1	Bovine: Meat	0.0	Bovine: Liver	
1.0	FI adult	0.9	Milk and cream,	0.0	Beetroot		FRUIT (FRESH OR FROZEN)	
0.9	LT adult	0.7	Milk and cream,	0.2	Swine: Meat	0.0	Bovine: Meat	
0.8	WHO cluster diet E	0.5	Milk and cream,	0.1	Bovine: Meat	0.1	Swine: Meat	
0.7	IE adult	0.5	Milk and cream,	0.1	Bovine: Meat	0.1	Swine: Meat	
0.6	FR all population	0.4	Milk and cream,	0.1	Bovine: Meat	0.0	Swine: Meat	
0.0	PL general population	0.0	Beetroot	0.0	Beet leaves (chard)		FRUIT (FRESH OR FROZEN)	
0.0	IT adult	0.0	Beet leaves (chard)	0.0	Beetroot		FRUIT (FRESH OR FROZEN)	
0.0	IT kids/toddler	0.0	Beet leaves (chard)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	PT General population		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Desmedipham 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 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)
	6.2	Milk and milk	0.05 / -	6.2	Milk and milk	0.05 / -	1.3	Sugar beet (root)	0.05 / -	1.3	Sugar beet (root)	0.05 / -
	3.2	Sugar beet (root)	0.05 / -	3.2	Sugar beet (root)	0.05 / -	0.9	Milk and milk	0.05 / -	0.9	Milk and milk products: Cattle	0.05 / -
	2.2	Beetroot	0.05 / -	1.6	Beetroot	0.05 / -	0.7	Beetroot	0.05 / -	0.5	Beetroot	0.05 / -
	1.2	Milk and milk	0.05 / -	1.2	Milk and milk	0.05 / -	0.4	Beet leaves (chard)	0.05 / -	0.3	Milk and milk products: Goat	0.05 / -
	0.9	Beet leaves (chard)	0.05 / -	0.7	Beet leaves	0.05 / -	0.3	Milk and milk	0.05 / -	0.3	Beet leaves (chard)	0.05 / -
	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)			
	*) 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 Desmedipham 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.											

Appendix C – Existing EU maximum residue limits (MRLs)

(Pesticides - Web Version - EU MRLs (File created on 24/10/2011 11:12)

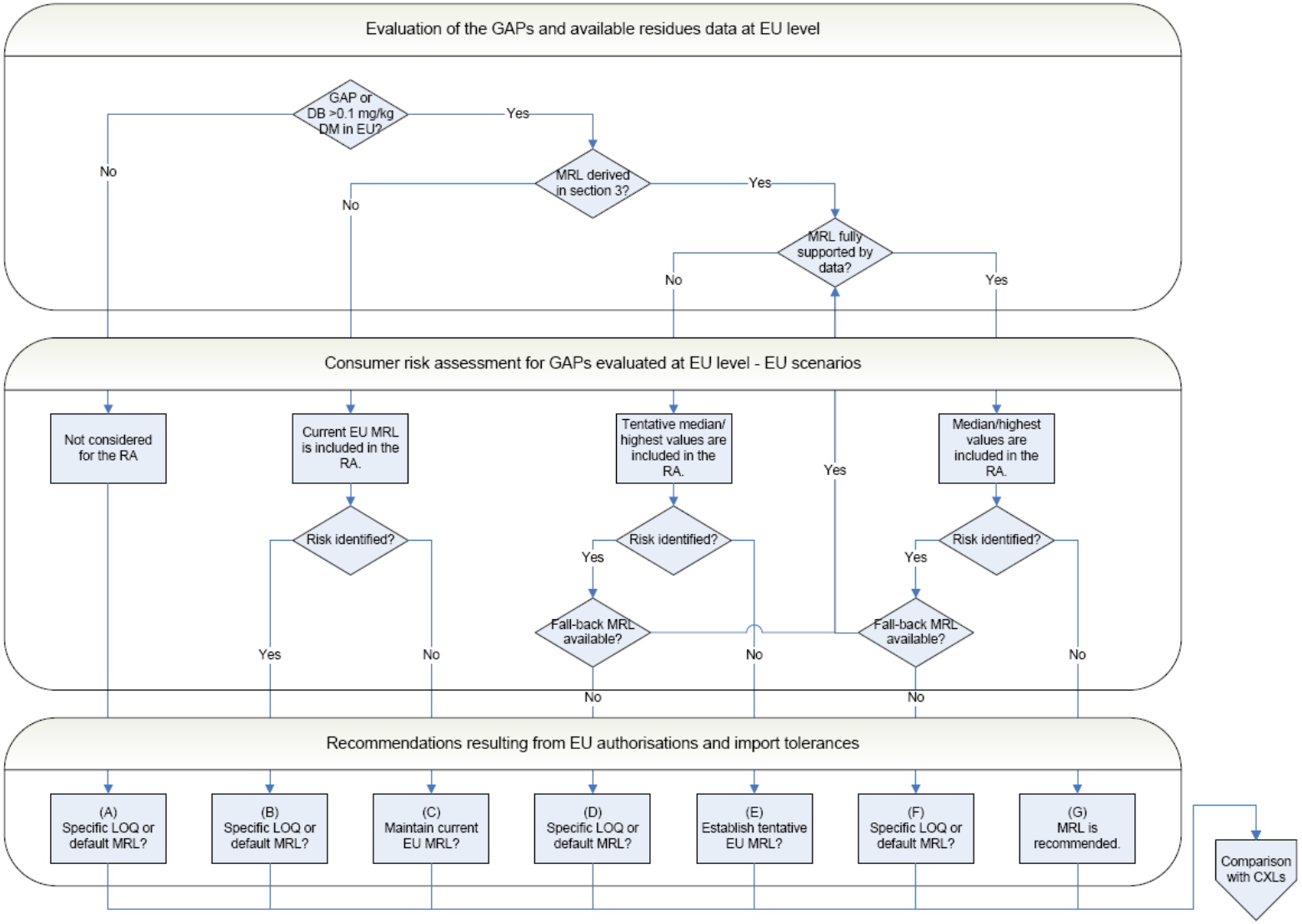
Code number	Groups and examples of individual products to which the MRLs apply (a)	desmedipham
100000	1. FRUIT FRESH OR FROZEN; NUTS	0,05*
110000	(i) Citrus fruit	0,05*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,05*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,05*
110030	Lemons (Citron, lemon)	0,05*
110040	Limes	0,05*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,05*
110990	Others	0,05*
120000	(ii) Tree nuts (shelled or unshelled)	0,05*
120010	Almonds	0,05*
120020	Brazil nuts	0,05*
120030	Cashew nuts	0,05*
120040	Chestnuts	0,05*
120050	Coconuts	0,05*
120060	Hazelnuts (Filbert)	0,05*
120070	Macadamia	0,05*
120080	Pecans	0,05*
120090	Pine nuts	0,05*
120100	Pistachios	0,05*
120110	Walnuts	0,05*
120990	Others	0,05*
130000	(iii) Pome fruit	0,05*
130010	Apples (Crab apple)	0,05*
130020	Pears (Oriental pear)	0,05*
130030	Quinces	0,05*
130040	Medlar	0,05*
130050	Loquat	0,05*
130990	Others	0,05*
140000	(iv) Stone fruit	0,05*
140010	Apricots	0,05*
140020	Cherries (sweet cherries, sour cherries)	0,05*
140030	Peaches (Nectarines and similar hybrids)	0,05*
140040	Plums (Damson, greengage, mirabelle)	0,05*
140990	Others	0,05*
150000	(v) Berries & small fruit	0,05*
151000	(a) Table and wine grapes	0,05*
151010	Table grapes	0,05*
151020	Wine grapes	0,05*
152000	(b) Strawberries	0,05*
153000	(c) Cane fruit	0,05*
153010	Blackberries	0,05*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,05*
153030	Raspberries (Wineberries)	0,05*
153990	Others	0,05*
154000	(d) Other small fruit & berries	0,05*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,05*
154020	Cranberries	0,05*
154030	Currants (red, black and white)	0,05*
154040	Gooseberries (Including hybrids with other ribes species)	0,05*
154050	Rose hips	0,05*
154060	Mulberries (arbutus berry)	0,05*
154070	Azarole (mediteranean medlar)	0,05*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,05*
154990	Others	0,05*
160000	(vi) Miscellaneous fruit	0,05*
161000	(a) Edible peel	0,05*
161010	Dates	0,05*
161020	Figs	0,05*
161030	Table olives	0,05*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,05*
161050	Carambola (Bilimbi)	0,05*
161060	Persimmon	0,05*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0,05*
161990	Others	0,05*
162000	(b) Inedible peel, small	0,05*
162010	Kiwi	0,05*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,05*
162030	Passion fruit	0,05*
162040	Prickly pear (cactus fruit)	0,05*
162050	Star apple	0,05*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,05*
162990	Others	0,05*
163000	(c) Inedible peel, large	0,05*
163010	Avocados	0,05*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,05*
163030	Mangoes	0,05*
163040	Papaya	0,05*
163050	Pomegranate	0,05*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,05*
163070	Guava	0,05*
163080	Pineapples	0,05*
163090	Bread fruit (Jackfruit)	0,05*
163100	Durian	0,05*
163110	Soursop (guanabana)	0,05*
163990	Others	0,05*
200000	2. VEGETABLES FRESH OR FROZEN	0,05*
210000	(i) Root and tuber vegetables	0,05*
211000	(a) Potatoes	0,05*
212000	(b) Tropical root and tuber vegetables	0,05*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,05*
212020	Sweet potatoes	0,05*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,05*
212040	Arrowroot	0,05*
212990	Others	0,05*
213000	(c) Other root and tuber vegetables except sugar beet	0,05*
213010	Beetroot	0,05*
213020	Carrots	0,05*
213030	Celeriac	0,05*
213040	Horseradish	0,05*
213050	Jerusalem artichokes	0,05*
213060	Parsnips	0,05*
213070	Parsley root	0,05*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,05*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,05*
213100	Swedes	0,05*
213110	Turnips	0,05*
213990	Others	0,05*
220000	(ii) Bulb vegetables	0,05*
220010	Garlic	0,05*
220020	Onions (Silverskin onions)	0,05*
220030	Shallots	0,05*
220040	Spring onions (Welsh onion and similar varieties)	0,05*
220990	Others	0,05*
230000	(iii) Fruiting vegetables	0,05*
231000	(a) Solanacea	0,05*
231010	Tomatoes (Cherry tomatoes,)	0,05*
231020	Peppers (Chilli peppers)	0,05*
231030	Aubergines (egg plants) (Pepino)	0,05*
231040	Okra, lady's fingers	0,05*
231990	Others	0,05*
232000	(b) Cucurbits - edible peel	0,05*
232010	Cucumbers	0,05*
232020	Gherkins	0,05*
232030	Courgettes (Summer squash, marrow (patisson))	0,05*
232990	Others	0,05*
233000	(c) Cucurbits-inedible peel	0,05*

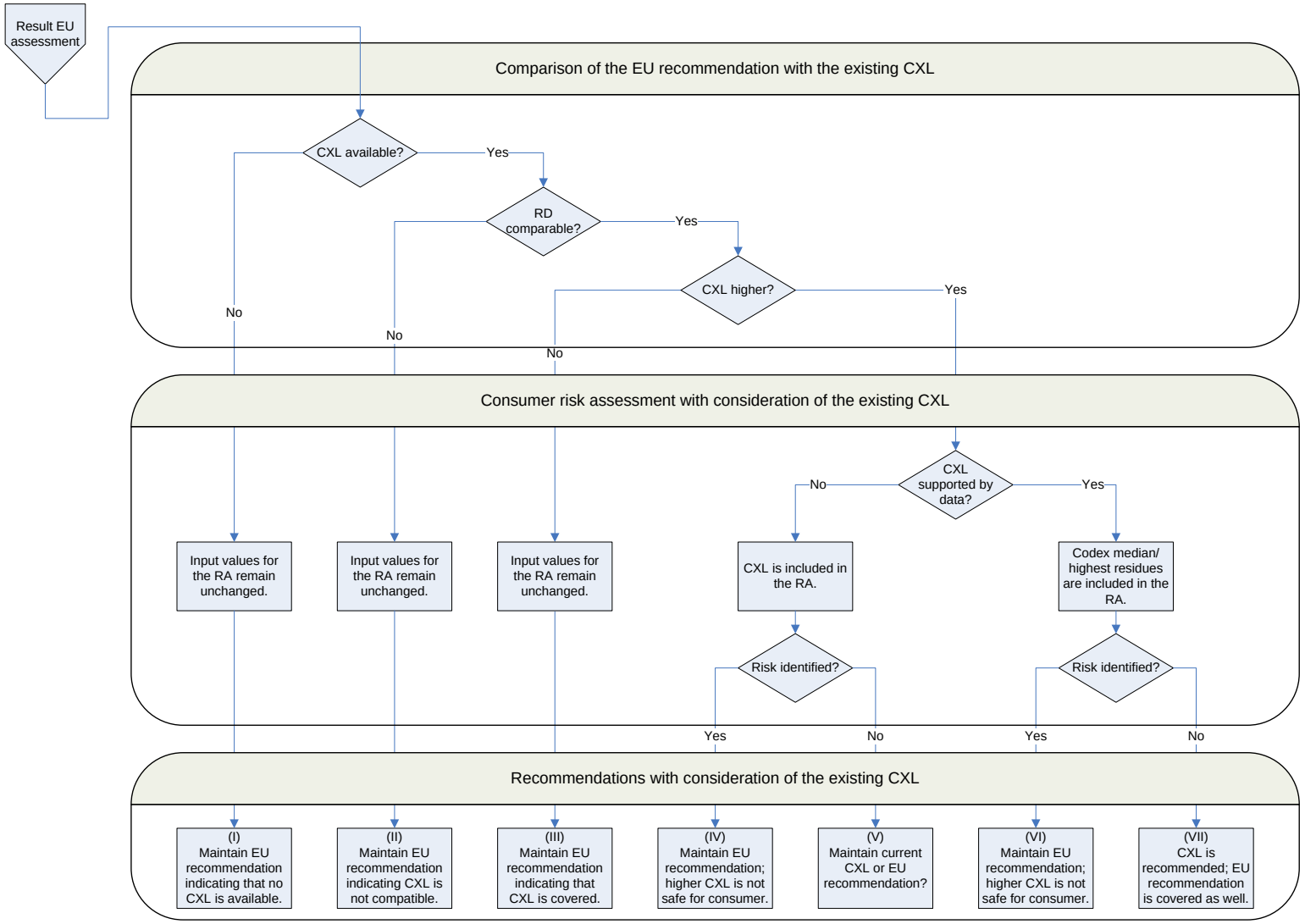
Code number	Groups and examples of individual products to which the MRLs apply (a)	desmedipham
233010	Melons (Kiwano)	0,05*
233020	Pumpkins (Winter squash)	0,05*
233030	Watermelons	0,05*
233990	Others	0,05*
234000	(d) Sweet corn	0,05*
239000	(e) Other fruiting vegetables	0,05*
240000	(iv) Brassica vegetables	0,05*
241000	(a) Flowering brassica	0,05*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,05*
241020	Cauliflower	0,05*
241990	Others	0,05*
242000	(b) Head brassica	0,05*
242010	Brussels sprouts	0,05*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,05*
242990	Others	0,05*
243000	(c) Leafy brassica	0,05*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,05*
243020	Kale (Borecole (curly kale), collards)	0,05*
243990	Others	0,05*
244000	(d) Kohlrabi	0,05*
250000	(v) Leaf vegetables & fresh herbs	0,05*
251000	(a) Lettuce and other salad plants including Brassicacea	0,05*
251010	Lamb´s lettuce (Italian cornsalad)	0,05*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,05*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,05*
251040	Cress	0,05*
251050	Land cress	0,05*
251060	Rocket, Rucola (Wild rocket)	0,05*
251070	Red mustard	0,05*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,05*
251990	Others	0,05*
252000	(b) Spinach & similar (leaves)	0,05*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,05*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth)	0,05*
252030	Beet leaves (chard) (Leaves of beetroot)	0,05*
252990	Others	0,05*
253000	(c) Vine leaves (grape leaves)	0,05*
254000	(d) Water cress	0,05*
255000	(e) Witloof	0,05*
256000	(f) Herbs	0,05*
256010	Chervil	0,05*
256020	Chives	0,05*
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	0,05*
256040	Parsley	0,05*
256050	Sage (Winter savory, summer savory,)	0,05*
256060	Rosemary	0,05*
256070	Thyme (marjoram, oregano)	0,05*
256080	Basil (Balm leaves, mint, peppermint)	0,05*
256090	Bay leaves (laurel)	0,05*
256100	Tarragon (Hyssop)	0,05*
256990	Others	0,05*
260000	(vi) Legume vegetables (fresh)	0,05*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,05*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,05*
260030	Peas (with pods) (Mangetout (sugar peas))	0,05*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,05*
260050	Lentils	0,05*
260990	Others	0,05*
270000	(vii) Stem vegetables (fresh)	0,05*
270010	Asparagus	0,05*
270020	Cardoons	0,05*
270030	Celery	0,05*
270040	Fennel	0,05*
270050	Globe artichokes	0,05*
270060	Leek	0,05*
270070	Rhubarb	0,05*
270080	Bamboo shoots	0,05*
270090	Palm hearts	0,05*
270990	Others	0,05*
280000	(viii) Fungi	0,05*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,05*
280020	Wild (Chanterelle, Truffle, Morel ,)	0,05*
280990	Others	0,05*
290000	(ix) Sea weeds	0,05*
300000	3. PULSES, DRY	0,05*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,05*
300020	Lentils	0,05*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,05*
300040	Lupins	0,05*
300990	Others	0,05*
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	0,1*
401010	Linseed	0,1*
401020	Peanuts	0,1*
401030	Poppy seed	0,1*
401040	Sesame seed	0,1*
401050	Sunflower seed	0,1*
401060	Rape seed (Bird rapeseed, turnip rape)	0,1*
401070	Soya bean	0,1*
401080	Mustard seed	0,1*
401090	Cotton seed	0,1*
401100	Pumpkin seeds	0,1*
401110	Safflower	0,1*
401120	Borage	0,1*
401130	Gold of pleasure	0,1*
401140	Hempseed	0,1*
401150	Castor bean	0,1*
401990	Others	0,1*
402000	(ii) Oilfruits	
402010	Olives for oil production	0,05*
402020	Palm nuts (palmoil kernels)	0,1*
402030	Palmfruit	0,1*
402040	Kapok	0,1*
402990	Others	0,1*
500000	5. CEREALS	0,05*
500010	Barley	0,05*
500020	Buckwheat	0,05*
500030	Maize	0,05*
500040	Millet (Foxtail millet, teff)	0,05*
500050	Oats	0,05*
500060	Rice	0,05*
500070	Rye	0,05*
500080	Sorghum	0,05*
500090	Wheat (Spelt Triticale)	0,05*
500990	Others	0,05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,1*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,1*
620000	(ii) Coffee beans	0,1*
630000	(iii) Herbal infusions (dried)	0,1*
631000	(a) Flowers	0,1*
631010	Camomille flowers	0,1*
631020	Hybiscus flowers	0,1*
631030	Rose petals	0,1*
631040	Jasmine flowers	0,1*
631050	Lime (linden)	0,1*
631990	Others	0,1*
632000	(b) Leaves	0,1*
632010	Strawberry leaves	0,1*
632020	Rooibos leaves	0,1*
632030	Maté	0,1*
632990	Others	0,1*
633000	(c) Roots	0,1*
633010	Valerian root	0,1*
633020	Ginseng root	0,1*
633990	Others	0,1*
639000	(d) Other herbal infusions	0,1*
640000	(iv) Cocoa (fermented beans)	0,1*
650000	(v) Carob (st johns bread)	0,1*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,1*
800000	8. SPICES	0,1*
810000	(i) Seeds	0,1*
810010	Anise	0,1*
810020	Black caraway	0,1*
810030	Celery seed (Lovage seed)	0,1*

Code number	Groups and examples of individual products to which the MRLs apply (a)	desmedipham
810040	Coriander seed	0,1*
810050	Cumin seed	0,1*
810060	Dill seed	0,1*
810070	Fennel seed	0,1*
810080	Fenugreek	0,1*
810090	Nutmeg	0,1*
810990	Others	0,1*
820000	(ii) Fruits and berries	0,1*
820010	Allspice	0,1*
820020	Anise pepper (Japan pepper)	0,1*
820030	Caraway	0,1*
820040	Cardamom	0,1*
820050	Juniper berries	0,1*
820060	Pepper, black and white (Long pepper, pink pepper)	0,1*
820070	Vanilla pods	0,1*
820080	Tamarind	0,1*
820990	Others	0,1*
830000	(iii) Bark	0,1*
830010	Cinnamon (Cassia)	0,1*
830990	Others	0,1*
840000	(iv) Roots or rhizome	0,1*
840010	Liquorice	0,1*
840020	Ginger	0,1*
840030	Turmeric (Curcuma)	0,1*
840040	Horseradish	0,1*
840990	Others	0,1*
850000	(v) Buds	0,1*
850010	Cloves	0,1*
850020	Capers	0,1*
850990	Others	0,1*
860000	(vi) Flower stigma	0,1*
860010	Saffron	0,1*
860990	Others	0,1*
870000	(vii) Aril	0,1*
870010	Mace	0,1*
870990	Others	0,1*
900000	9. SUGAR PLANTS	
900010	Sugar beet (root)	0,1
900020	Sugar cane	0,05*
900030	Chicory roots	0,05*
900990	Others	0,05*
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	
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	
1011000	(a) Swine	
1011010	Meat	
1011020	Fat free of lean meat	
1011030	Liver	
1011040	Kidney	
1011050	Edible offal	
1011990	Others	
1012000	(b) Bovine	
1012010	Meat	
1012020	Fat	
1012030	Liver	
1012040	Kidney	
1012050	Edible offal	
1012990	Others	
1013000	(c) Sheep	
1013010	Meat	
1013020	Fat	
1013030	Liver	
1013040	Kidney	
1013050	Edible offal	
1013990	Others	
1014000	(d) Goat	
1014010	Meat	
1014020	Fat	
1014030	Liver	
1014040	Kidney	
1014050	Edible offal	
1014990	Others	
1015000	(e) Horses, asses, mules or hinnies	
1015010	Meat	
1015020	Fat	
1015030	Liver	
1015040	Kidney	
1015050	Edible offal	
1015990	Others	
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl- , ostrich, pigeon	
1016010	Meat	
1016020	Fat	
1016030	Liver	
1016040	Kidney	
1016050	Edible offal	
1016990	Others	
1017000	(g) Other farm animals (Rabbit, Kangaroo)	
1017010	Meat	
1017020	Fat	
1017030	Liver	
1017040	Kidney	
1017050	Edible offal	
1017990	Others	
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	
1020010	Cattle	
1020020	Sheep	
1020030	Goat	
1020040	Horse	
1020990	Others	
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	
1030010	Chicken	
1030020	Duck	
1030030	Goose	
1030040	Quail	
1030990	Others	
1040000	(iv) Honey (Royal jelly, pollen)	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	

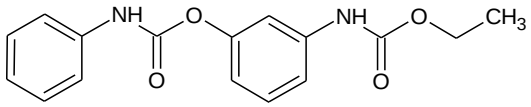
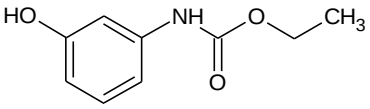
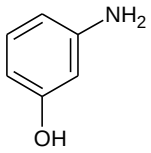
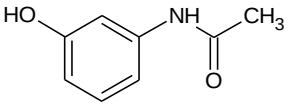
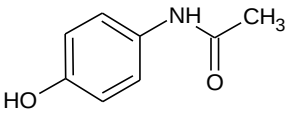
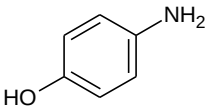
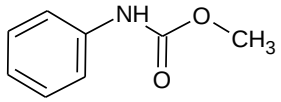
(*) Indicates lower limit of analytical determination
(a): Table footnote

Appendix D – Decision tree for deriving MRL recommendations




Result EU assessment
Comparison of the EU recommendation with the existing CXL
CXL available?
Yes
No
RD comparable?
Yes
No
CXL higher?
Yes
No
Consumer risk assessment with consideration of the existing CXL
CXL supported by data?
No
Yes
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
CXL is included in the RA.
Codex median/ highest residues are included in the RA.
Risk identified?
Risk identified?
Yes
No
Yes
No
Recommendations with consideration of the existing CXL
(I) Maintain EU recommendation indicating that no CXL is available.
(II) Maintain EU recommendation indicating CXL is not compatible.
(III) Maintain EU recommendation indicating that CXL is covered.
(IV) Maintain EU recommendation; higher CXL is not safe for consumer.
(V) Maintain current CXL or EU recommendation?
(VI) Maintain EU recommendation; higher CXL is not safe for consumer.
(VII) CXL is recommended; EU recommendation is covered as well.

Appendix E – List of metabolites and related structural formula

Common name	IUPAC name	Structural formula
desmedipham	ethyl 3-phenylcarbamoyloxycarbanilate	
EHPC	ethyl (3-hydroxyphenyl)carbamate	
m-aminophenol	3-aminophenol	
3-acetamidophenol	*N*-(3-hydroxyphenyl)acetamide	
4-acetamidophenol	*N*-(4-hydroxyphenyl)acetamide	
4-aminophenol	4-aminophenol	
N-(phenyl)methyl carbamate	methyl phenylcarbamate	

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CEN	European Committee for Standardization (Comité Européen de Normalisation)
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DAT	days after treatment
DM	dry matter
DT_{90}	period required for 90 percent dissipation (define method of estimation)
EC	European Commission
EFSA	European Food Safety Authority
EHPC	N-(3-hydroxy phenyl) ethyl carbamate
EPC	ethyl 3-[U-^{14}C] phenylcarbomoyloxyphenylcarbamate
eq	residue expressed as a.s. equivalent
EU	European Union
EURL	EU Reference Laboratories (former CRLs)
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GC-MS	gas chromatography with mass spectrometry
Ha	Hectare
HPLC-UVD	high performance liquid chromatography with ultra-violet detector

ILV	independent laboratory validation
ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC-MS/MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PC	ethyl 3-phenylcarbomoyloxy-[U-^{14}C] phenylcarbamate
PHI	pre-harvest interval
P_{ow}	partition coefficient n-octanol/water
PROFile	(EFSA) Pesticide Residue Overview File
PRIMo	(EFSA) Pesticide Residues Intake Model
RMS	rapporteur Member State
SEU	southern European Union
TRR	total radioactive residue
WHO	World Health Organization