

REASONED OPINION

Reasoned opinion on the review of the existing maximum residue levels (MRLs) for metaldehyde according to Article 12 of Regulation (EC) No 396/2005¹

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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 metaldehyde. In order to assess the occurrence of metaldehyde 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 some MRL proposals derived by EFSA still require further consideration by risk managers.

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KEY WORDS

metaldehyde, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, molluscicide

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SUMMARY

Metaldehyde was included in Annex I to Directive 91/414/EEC on 01 June 2011, 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 Austria, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The requested information was submitted to EFSA on 04 January 2012 and, after having considered several comments made by EFSA, the RMS provided on 24 January 2013 a revised PROFile.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EE and the additional information provided by the RMS, EFSA issued on 21 October 2013 a draft reasoned opinion that was circulated to Member States' experts for consultation. Comments received by 20 December 2013 were considered in the finalisation of this reasoned opinion. The following conclusions are derived.

The toxicological profile of metaldehyde was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI and an ARfD being established at 0.02 mg/kg bw per d and 0.3 mg/kg bw, respectively.

Metabolism of metaldehyde was investigated for soil application on fruits and fruiting vegetables, leafy vegetables, root and tuber vegetables, pulses and oilseeds and cereals. These studies demonstrated that parent metaldehyde is extensively degraded with incorporation of its carbon atoms into natural plant constituents. Therefore, the residue definition in all plant commodities for enforcement and risk assessment is proposed as metaldehyde only. Validated analytical methods for enforcement of the proposed residue definition are available.

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 all commodities under evaluation but MRL proposals for roots and tuber vegetables (except swedes), tomatoes, aubergines, leafy brassica and kohlrabi, are only tentative because additional residue trials compliant with GAP are still required.

No study was available to address the effect of processing on the nature of the residue. Based on the structure of metaldehyde, the formation of acetaldehyde cannot be excluded. Also considering that the chronic exposure exceeds 10 % of the ADI, a hydrolysis study investigating the effect of the processing on the nature of metaldehyde is required. This information is mainly needed to support authorisations on potatoes, root and tuber vegetables (except swedes), tomatoes, aubergines, flowering and head brassica, leafy brassica, kohlrabi, lettuce and other salad plants, spinach and similar, fresh legumes, artichoke, leek and pulses, where significant residue levels are found and which may be subject to processing (boiling/brewing/baking). MRLs and risk assessment values for these commodities are therefore considered on a tentative basis only. As no study investigating the magnitude of residues in processed commodities was reported, no processing factors for enforcement or risk assessment could be derived.

According to the soil degradation studies evaluated in the framework of the peer review, DT_{90} values of metaldehyde are expected to range between 8-22 days which is below the trigger value of 100 days, and no relevant soil metabolites were identified. Further investigation of residues in rotational crops is therefore not required and relevant residues in rotational crops are not expected.

Based on the uses reported by the RMS, significant intakes were calculated for all groups of livestock. Metabolism in lactating ruminants was sufficiently investigated. The available study demonstrated that residues of metaldehyde are eliminated as CO_2 or incorporated into natural products. As no compound was identified as a good marker to enforce the presence of metaldehyde residues in animal products,

EFSA proposed a default residue definition for enforcement and risk assessment as metaldehyde. Although it is not expected that metaldehyde has a different route of transformation in poultry and the proposed residue definition can be applied to poultry as well, an additional study on the nature of residues in poultry is desirable. According to the available metabolism study, measurable levels of metaldehyde in edible commodities of animal origin are not expected and no livestock feeding study is needed. Nevertheless, as there are no analytical methods to enforce metaldehyde in food of animal origin, EFSA was not able to derive LOQ and MRL proposals.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For commodities of animal origin, where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure represented 16.4 % of the ADI (French toddler) and the highest acute exposure amounted to 36.7 % of the ARfD (scarole).

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 of the reasoned opinion (see summary table). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see summary table footnotes for details). In particular, some tentative MRLs or existing EU MRLs need to be confirmed by the following data:

- a fully validated analytical method for the determination of metaldehyde in food of animal origin (meat, fat, liver, kidney, milk and eggs);
- a hydrolysis study investigating the effect of sterilisation on the nature of residues, mainly to support authorisations on potatoes, root and tuber vegetables (except swedes), tomatoes, aubergines, flowering and head brassica, leafy brassica, kohlrabi, lettuce and other salad plants, spinach and similar, fresh legumes, artichoke, leek and pulses;
- further clarification of the northern outdoor GAP on carrots, celeriac, horseradish, Jerusalem artichokes, parsnips, parsley root, radishes and salsify as well as 8 residue trials on carrots supporting this GAP;
- 4 residue trials on carrots supporting the southern outdoor GAP on beetroot, turnips, carrots, celeriac, horseradish, Jerusalem artichokes, parsnips, parsley root, radishes and salsify;
- further clarification of the indoor and northern outdoor GAPs on tomatoes and aubergines as well as 8 residue trials supporting each of these GAPs;
- further clarification of the indoor and northern outdoor GAPs on leafy brassica as well as 4 residue trials on kale supporting each of these GAPs;
- further clarification of the indoor and northern outdoor GAPs on kohlrabi as well as 4 residue trials supporting the northern outdoor GAP.

It is highlighted that some of the MRLs derived result from a GAP in one climatic zone only, while other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the following data gaps which are not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

- further clarification of the northern outdoor GAP on tree nuts, pome fruits and stone fruits as well as 4 residue trials on apples and 4 residue trials on stone fruits supporting this GAP;

- further clarification of the indoor GAP on stone fruits as well as 8 residue trials (with a minimum of 4 trials performed on apricots) supporting this GAP;
- 4 residue trials on strawberries and 4 residue trials on either grapes, blackcurrants or other berries, supporting the northern outdoor GAP on table and wine grapes, cane fruits and other small fruits and berries (2 x 0.45 kg a.s./ha);
- 8 residue trials supporting the indoor GAP on strawberries;
- 8 residue trials on cauliflower and 8 residue trials on head cabbage supporting the indoor GAP on flowering and head brassica (2 x 0.45 kg a.s./ha);
- further clarification of the northern outdoor and indoor GAPs on celery as well as 4 residue trials supporting each of these GAPs;
- 4 residue trials supporting the northern outdoor GAP on globe artichoke;
- further clarification of the northern outdoor and indoor GAPs on leek as well as 8 residue trials supporting each of these GAPs;
- 8 residue trials on peas or beans (fresh with pods) and 8 residue trials on peas or beans (fresh without pods), all supporting the indoor GAP on fresh legume vegetables;
- 8 residue trials on maize supporting the northern GAP on maize, millet and sorghum (2 x 0.45 kg a.s./ha);
- 8 residue trials on wheat supporting the northern GAP on small grain cereals (2 x 0.45 kg a.s./ha).

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 these deficiencies are not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following actions and data are therefore considered desirable but not essential:

- an additional study investigating the nature of residues in poultry.

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
Enforcement residue definition: metaldehyde				
110000	Citrus fruits	0.05*	0.05*	Recommended ^(a)
120000	Tree nuts	0.05*	0.05*	Recommended ^(a)
130000	Pome fruits	0.05*	0.05*	Recommended ^(a)
140000	Stone fruits	0.05*	0.05*	Recommended ^(a)
151000	Table and wine grapes	0.05*	0.05*	Recommended ^(a)
152000	Strawberries	0.10	0.05*	Recommended ^(a)
153000	Cane fruits	0.05*	0.05*	Recommended ^(a)

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
154000	Other small fruits and berries	0.05*	0.05*	Recommended ^(a)
211000	Potatoes	0.15	0.15	Further consideration needed ^(b)
213010	Beetroot	2	0.3	Further consideration needed ^(b)
213020	Carrots	2	0.3	Further consideration needed ^(b)
213030	Celeriac	2	0.3	Further consideration needed ^(b)
213040	Horseradish	2	0.3	Further consideration needed ^(b)
213050	Jerusalem artichokes	2	0.3	Further consideration needed ^(b)
213060	Parsnips	2	0.3	Further consideration needed ^(b)
213070	Parsley root	2	0.3	Further consideration needed ^(b)
213080	Radishes	2	0.3	Further consideration needed ^(b)
213090	Salsify	2	0.3	Further consideration needed ^(b)
213100	Swedes	2	0.05*	Recommended ^(a)
213110	Turnips	2	0.3	Further consideration needed ^(b)
231010	Tomatoes	0.05*	0.15	Further consideration needed ^(b)
231030	Aubergines	0.05*	0.15	Further consideration needed ^(b)
241000	Flowering brassica	1	0.4	Further consideration needed ^(b)
242000	Head brassica	1	0.4	Further consideration needed ^(b)
243000	Leafy brassica	1	0.4	Further consideration needed ^(b)
244000	Kohlrabi	0.1	0.15	Further consideration needed ^(b)
251000	Lettuce and other salad plants including Brassicacea	2	2	Further consideration needed ^(b)
252000	Spinach and similar (leaves)	2	2	Further consideration needed ^(b)
256000	Herbs	2	2	Recommended ^(a)
260010	Beans (fresh, with pods)	0.05*	0.4	Further consideration needed ^(b)
260020	Beans (fresh, without pods)	0.05*	0.3	Further consideration needed ^(b)
260030	Peas (fresh, with pods)	0.05*	0.4	Further consideration needed ^(b)
260040	Peas (fresh, without pods)	0.05*	0.3	Further consideration needed ^(b)
270010	Asparagus	1	0.05*	Recommended ^(a)
270030	Celery	1	0.05*	Recommended ^(a)
270040	Fennel	1	0.05*	Recommended ^(a)
270050	Globe artichoke	1	0.07	Further consideration needed ^(b)
270060	Leek	1	0.5	Further consideration needed ^(b)
300000	Pulses (dry)	0.05*	0.2	Further consideration needed ^(b)
401010	Linseed	0.05*	0.60	Recommended ^(a)
401030	Poppy seed	0.05*	0.60	Recommended ^(a)
401040	Sesame seed	0.05*	0.60	Recommended ^(a)
401050	Sunflower seed	0.05*	0.60	Recommended ^(a)

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
401060	Rape seed	0.05*	0.60	Recommended ^(a)
401070	Soya bean	0.05*	0.60	Recommended ^(a)
401080	Mustard seed	0.05*	0.60	Recommended ^(a)
401090	Cotton seed	0.05*	0.60	Recommended ^(a)
401100	Pumpkin seeds	0.05*	0.60	Recommended ^(a)
401110	Safflower	0.05*	0.60	Recommended ^(a)
401120	Borage	0.05*	0.60	Recommended ^(a)
401130	Gold of pleasure	0.05*	0.60	Recommended ^(a)
401140	Hempseed	0.05*	0.60	Recommended ^(a)
500010	Barley grain	0.05*	0.05*	Recommended ^(a)
500030	Maize grain	0.05*	0.05*	Recommended ^(a)
500040	Millet grain	0.05*	0.05*	Recommended ^(a)
500050	Oats grain	0.05*	0.05*	Recommended ^(a)
500070	Rye grain	0.05*	0.05*	Recommended ^(a)
500080	Sorghum grain	0.05*	0.05*	Recommended ^(a)
500090	Wheat grain	0.05*	0.05*	Recommended ^(a)
900010	Sugar beet (root)	0.05*	0.05*	Recommended ^(a)
1011010	Swine meat	0.05*	0.05*	Further consideration needed ^(c)
1011020	Swine fat (free of lean meat)	0.05*	0.05*	Further consideration needed ^(c)
1011030	Swine liver	0.05*	0.05*	Further consideration needed ^(c)
1011040	Swine kidney	0.05*	0.05*	Further consideration needed ^(c)
1012010	Bovine meat	0.05*	0.05*	Further consideration needed ^(c)
1012020	Bovine fat	0.05*	0.05*	Further consideration needed ^(c)
1012030	Bovine liver	0.05*	0.05*	Further consideration needed ^(c)
1012040	Bovine kidney	0.05*	0.05*	Further consideration needed ^(c)
1013010	Sheep meat	0.05*	0.05*	Further consideration needed ^(c)
1013020	Sheep fat	0.05*	0.05*	Further consideration needed ^(c)
1013030	Sheep liver	0.05*	0.05*	Further consideration needed ^(c)
1013040	Sheep kidney	0.05*	0.05*	Further consideration needed ^(c)
1014010	Goat meat	0.05*	0.05*	Further consideration needed ^(c)
1014020	Goat fat	0.05*	0.05*	Further consideration needed ^(c)
1014030	Goat liver	0.05*	0.05*	Further consideration needed ^(c)
1014040	Goat kidney	0.05*	0.05*	Further consideration needed ^(c)
1016010	Poultry meat	0.05*	0.05*	Further consideration needed ^(c)
1016020	Poultry fat	0.05*	0.05*	Further consideration needed ^(c)
1016030	Poultry liver	0.05*	0.05*	Further consideration needed ^(c)

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
1020010	Cattle milk	0.05*	0.05*	Further consideration needed ^(c)
1020020	Sheep milk	0.05*	0.05*	Further consideration needed ^(c)
1020030	Goat milk	0.05*	0.05*	Further consideration needed ^(c)
1030000	Birds' eggs	0.05*	0.05*	Further consideration needed ^(c)
-	Other products of plant and animal origin	See App C	-	Further consideration needed ^(d)

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

(a): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix D).

(b): 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 was identified; no CXL is available (combination E-I in Appendix D).

(c): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL; no CXL is available (combination C-I in Appendix D).

(d): 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).

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BACKGROUND

Regulation (EC) No 396/2005⁴ 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/EEC⁵ a reasoned opinion on the review of the existing MRLs for that active substance. As metaldehyde was included in Annex I to the above mentioned directive on 01 June 2011, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2009-00062 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 Residues Overview File (PROFile). The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

- the nature and magnitude of residues in primary crops;
- the nature and magnitude of residues in processed commodities;
- the nature and magnitude of residues in rotational crops;
- the nature and magnitude of residues in livestock commodities and;
- the analytical methods for enforcement of the proposed MRLs.

Austria, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for metaldehyde and to prepare a supporting evaluation report. The requested information was submitted to EFSA on 04 January 2012 and subsequently checked for completeness. On 24 January 2013, after having clarified some issues with EFSA, the RMS provided a revised PROFile.

A draft reasoned opinion was issued by EFSA on 21 October 2013 and submitted to Member States (MS) for commenting. All MS comments received by 20 December 2013 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.

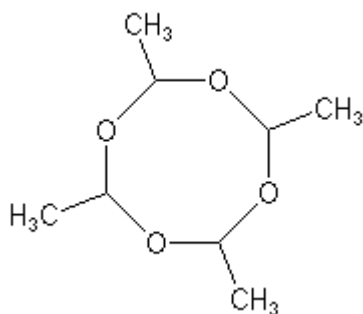
TERMS OF REFERENCE

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

Metaldehyde is the ISO common name for 2,4,6,8-tetramethyl-1,3,5,7-tetraoxacyclooctane (IUPAC).



Metaldehyde is a tetramer of acetaldehyde. It is a molluscicide by contact and stomach action. Metaldehyde poisoned slugs secrete large quantities of slime, desiccate and die. Their mucus cells are irreversibly destroyed.

Metaldehyde was evaluated in the framework of Directive 91/414/EEC with Austria being the designated rapporteur Member State (RMS). The representative uses supported for the peer review process were spreading (manually or with fertiliser spreader) on cereals and oilseed rape to control slugs and snails. Following the Draft Assessment Report (DAR) submission however, all applicants voluntarily withdrew, in accordance with Article 11e of Regulation (EC) No 1490/2002⁶, their support for the inclusion of metaldehyde in Annex I to Directive 91/414/EEC. Consequently, a first decision on non-inclusion of the active substance was published by means of Commission Decision 2008/934/EC⁷, which entered into force on 31 December 2008. In accordance with the provisions laid down in Article 13 of Regulation (EC) No 33/2008⁸, metaldehyde was then subject to a resubmission procedure and a second peer review was carried out by EFSA. Following this second 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 2011/54/EU⁹, which entered into force on 01 June 2011. According to

⁶ Commission Regulation (EC) No 1490/2002 of 14 August 2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000. OJ L 224, 21.8.2002, p.23-48.

⁷ Commission Decision 2008/934/EC of 5 December 2008 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances. OJ L 333, 11.12.2008, p. 11-14.

⁸ Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I. OJ L 15, 18.01.2008, p.5-12.

⁹ Commission Directive 2011/54/EU of 20 April 2011 amending Council Directive 91/414/EEC to include metaldehyde as active substance. OJ L 105, 21.4.2011, p. 28-31.

Regulation (EU) No 540/2011¹⁰, metaldehyde is deemed to have been approved under Regulation (EC) No 1107/2009¹¹. This approval is restricted to uses as molluscicide only.

The EU MRLs for metaldehyde are established in Annexe IIIA of Regulation (EC) No 396/2005. Since the entry into force of that regulation, EFSA recommended the modification of the existing MRLs for various crops (EFSA, 2012) which was legally implemented in Regulation (EU) No 592/2011¹². EFSA also recommended the modification of the existing MRLs for legume vegetables (EFSA, 2014) but this was not yet legally implemented. All existing EU MRLs, which are established for the parent compound only, are summarised in Appendix C to this document. CXLs for metaldehyde are not available.

For the purpose of this MRL review, the critical uses of metaldehyde currently authorised within the EU, have been collected by the RMS and reported in the PROFile. The additional GAPs reported during the consultation of Member States were also considered (see Appendix A). The active substance metaldehyde is authorised in northern and southern Europe for soil application in a large number of crops, both under outdoor and indoor conditions. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

During the consultation of Member States, the Netherlands also reported several GAPs where the product may be applied until harvest of the crop, implying a PHI of 0 days. However such GAPs are not compliant with the outcome of the Standing Committee of the Food Chain and Animal Health that was held on 26-27 February 2007, where it was decided that for GAPs considered in the MRL setting process a minimum PHI of 1 day should be defined. The GAPs reported by the Netherlands were therefore not further considered by EFSA.

¹⁰ 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.

¹¹ 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.

¹² Commission Regulation (EU) No 592/2012 of 4 July 2012 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenazate, captan, cyprodinil, fluopicolide, hexythiazox, isoprothiolane, metaldehyde, oxadixyl and phosmet in or on certain products. OJ L 176, 6.7.2012, p. 1-37.

ASSESSMENT

EFSA bases its assessment on the PROFile submitted by the RMS, the evaluation report accompanying the PROFile (Austria, 2011), the Draft Assessment Report (DAR) and its additional report prepared under Council Directive 91/414/EEC (Austria, 2006, 2009), the conclusion on the peer review of the pesticide risk assessment of the active substance metaldehyde (EFSA, 2010), the previous reasoned opinions on metaldehyde (EFSA, 2012, 2014) as well as the evaluation reports submitted during the consultation of Member States (Austria, 2013; France, 2013; Germany, 2014; Italy, 2013; Netherlands, 2014). The assessment is performed in accordance with the legal provisions of the Uniform Principles for Evaluation and Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011¹³ 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 GC-MS, confirmed by GC-MS/MS, and its ILV were evaluated and validated for the determination of metaldehyde in plant matrices with an LOQ of 0.05 mg/kg in high water content, high oil content, acidic and dry commodities (sugar beet, broccoli, rapeseed, orange and wheat grain) (Austria, 2006, 2009).

The multi-residue QuEChERS method in combination with HPLC-MS/MS, as described by CEN (2008), is also available to analyse the parent metaldehyde but validation data were not evaluated in detail because a validated analytical method is reported above.

Hence it is concluded that metaldehyde can be enforced in food of plant origin with an LOQ of 0.05 mg/kg in high water content, high oil content, acidic and dry commodities.

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

During the peer review under Directive 91/414/EEC, no analytical methods are available for the determination of metaldehyde in food of animal origin (Austria, 2006, 2009). Hence there is no evidence that metaldehyde can be enforced in food of animal origin. An analytical method with its ILV and a confirmatory method fully validated for the determination of metaldehyde in food of animal origin (meat, fat, liver, kidney, milk and eggs) are necessary.

2. Mammalian toxicology

The toxicological assessment of metaldehyde was peer reviewed under Directive 91/414/EEC and toxicological reference values were established by EFSA (2010). These toxicological reference values are summarised in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Metaldehyde					
ADI	EFSA	2010	0.02 mg/kg bw per d	2 years – rat	100
ARfD	EFSA	2010	0.3 mg/kg bw	52 weeks – dog (acute neurotoxic effects)	100

¹³ 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.

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

Metabolism of metaldehyde was investigated for soil application (early post-planting or pre-emergence treatments) on fruits and fruiting vegetables (strawberries), leafy vegetables (lettuce), root and tuber vegetables (sugar beet), pulses and oilseeds (rapeseed) and cereals (wheat and rice) using U-¹⁴C-labelled metaldehyde (EFSA, 2010). The characteristics of these studies are summarised in Table 3-1. It is highlighted that the study performed on lettuce is of limited validity and reported for indicative information only.

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

Group	Crop	Label position	Application and sampling details				Remarks
			Method, F or G ^(a)	Rate (kg a.s./ha)	No	Sampling (DAT)	
Fruits and fruiting vegetable	Strawberries	U- ¹⁴ C-metaldehyde	Soil application, F	1.5	1	1, 7, 14, 28, 42, 70, 84, 98	Austria, 2006
Leafy vegetables	Lettuce	U- ¹⁴ C-metaldehyde	Soil application, F	15.4	1	28	Austria, 2006 ^(c)
			Soil application, F	3.6	1 1	4, 6, 8 wks 3, 5 wks	Austria, 2006 ^(d)
Root and tuber vegetables	Sugar beet	U- ¹⁴ C-metaldehyde	Soil application, F	15.4	1	48	Austria, 2006
Pulses and oilseeds	Rapeseed	U- ¹⁴ C-metaldehyde	Soil application, F ^(b)	3.1	2	Forage: 2 Maturity: 58	Austria, 2009
Cereals	Rice	U- ¹⁴ C-metaldehyde	In flooding water, G	5.0	1	114	Austria, 2006
	Wheat	U- ¹⁴ C-metaldehyde	Soil application, F ^(b)	3.5	2	Forage: 1 Hay: 69 Maturity: 69	Austria, 2009

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)

(b): Pre-emergence applications at BBCH 19 and BBCH 29/30.

(c): Study of limited validity because the data on the analytical part of the study are not conclusive

(d): Supplementary study to investigate the uptake of metaldehyde by lettuce from soil; a non-GLP study

In wheat and rapeseed, the proportion of the extractable TRR was higher in the early samplings (forage and hay) than in the late samplings (straw, grain and seed), indicating an increased association of the residues with the samples matrix. The highest TRR was found in forage samples (1 or 2 DAT), amounting to 16.2 mg eq./kg (rape forage) and 9.48 mg eq./kg (wheat). Residues decreased with time representing 4.73 mg eq./kg in wheat hay (21 DAT), 3.94 mg eq./kg in wheat straw (69 DAT) and 1.41 mg eq./kg in wheat grain (69 DAT). It only represented 0.27 mg eq./kg in rapeseed (58 DAT).

The metabolism studies on wheat and rapeseed indicate that the parent compound is the only identified compound in crops. In wheat, it was the major component of the TRR in forage (79.4 % TRR), hay (46.7 % TRR) and straw (20.9 % TRR) while it only represents a small part of the radioactivity in grain (5.9 % TRR; 0.08 mg/kg). It was the same in rapeseed where parent compound accounted for 98.7 % of the TRR in forage but only 1.5 % (0.004 mg/kg) in seeds. Further characterisations of the remaining extractable radioactivity were carried out by means of successive solvent and sequential extractions. This revealed the presence of polar component in wheat and rapeseed, of which acetic acid and higher molecular weight natural products were the major ones, together representing 32 % of the TRR (0.45 mg/kg) in wheat grain. Other unknown compounds were isolated but none of them accounted for more than 8 % of the TRR in wheat and rapeseed. No acetaldehyde was identified. Finally, the non-extractable residues remaining after solvent and sequential extractions was characterised by means of an alternative method involving fractionation into natural products. In rapeseed, wheat straw and wheat grain, 63 to 74.3 % of the remaining radioactivity was associated with a wide range of naturally occurring products in grain (protein, pectin, lignin, starch and lipid).

Although investigations were less advanced, findings were basically the same in rice grain, sugar beet root and strawberries. In these crops, the radioactivity respectively accounted for 0.59 mg eq./kg, 0.61 mg eq./kg and 0.015 mg eq./kg. All studies demonstrated that translocation from soil to plant occurred. In rice grain, most part of the residues was non-extractable (92 % TRR) and was shown to be mainly incorporated into natural constituents such as proteins and starch (69 % TRR). In sugar beet root, 48 % of the radioactivity was extractable but no further attempt was done to characterise or analyse this fraction. The study performed on strawberries did not give further information on the nature of the residue in crops but analyses of soil samples collected at the end of the study showed that about 50 % of the administered radioactivity was lost due to volatilisation, probably as $^{14}\text{CO}_2$.

Consequently, no metabolites were identified in significant amounts and a similar metabolic pathway is expected in all crops. The metabolism studies demonstrated that parent metaldehyde is extensively degraded with incorporation of its carbon atoms in natural products such as proteins, pectin, lignin, starch, lipids, polysaccharides, hemicelluloses and cellulose.

Based on the above finding, EFSA already concluded that the residue definition for enforcement and risk assessment in all plant commodities is metaldehyde only (EFSA, 2010). 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 metaldehyde is authorised in northern and southern Europe for soil application in a large number of crops, both under outdoor and indoor conditions (see Appendix A). To assess the magnitude of metaldehyde residues resulting from these GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Austria, 2011), including residue trials evaluated in the framework of the peer review (EFSA, 2010) or in the framework of previous MRL applications (EFSA, 2012, 2014), and additional data submitted during the consultation of Member States (Austria, 2013; France, 2013; Germany, 2014; Italy, 2013; Netherlands, 2014). All available residue trials that comply with the authorised GAPs are summarised in Table 3-2.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (EC, 2011). A sufficient number of trials complying with the GAP was reported by the RMS for all crops under assessment, except in the following cases:

- General consideration: it is highlighted that several critical GAPs are authorised with 2 applications at a rate of 0.45 kg a.s./ha per application, hereby resulting in a total rate of 0.90 kg a.s./ha per season while some residue trials were performed with 3 applications at lower rates per application (0.20-0.25 kg a.s./ha). Since metaldehyde is authorised for soil

application only and applications are performed early in the growing season for most of the reported crops (*i.e.* before apparition of the consumable part), the compliance of the available residue trials was assessed on the basis of the seasonal rate (*i.e.* number of application x individual application rate). It is also noted however that for several GAPs, all the supporting residue trials were under-dosed (seasonal rate of 0.70 g a.s./ha instead of 0.90 g a.s./ha). In such a case, although the total application rate can be within the 25 % tolerance, EFSA considered that additional residue trials compliant with GAPs should still be required.

- Tree nuts, pome fruits and stone fruits: The critical GAP authorised in the northern zone is not properly reported as no growth stage and/or PHI values are defined. This GAP should therefore be clarified. Moreover, no residue trials are available to support this use and, considering the current extrapolation rules, 4 residue trials on apples and 4 residue trials on stone fruits compliant with the northern GAP are required. For stone fruits, an indoor GAP is also authorised but no residue trials are available to support this GAP, and as for the northern outdoor GAP, this GAP should be further clarified regarding the growth stage and/or PHI (Netherlands, 2014). 8 residue trials (with a minimum of 4 trials performed on apricots) compliant with this GAP for stone fruits are therefore still required. Meanwhile, appropriate MRL and risk assessment values can be derived from the southern data.
- Table and wine grapes, cane fruits and other small fruits & berries: The residue trials supporting the northern uses are not compliant with the reported GAP. While the reported GAP includes a seasonal rate of 0.90 kg a.s./ha, all the trials were carried out with a seasonal rate of 0.70 kg a.s./ha (see also general consideration above). Moreover, an indoor GAP is also authorised for these crops but it is not supported by any residue trial (The Netherlands, 2014). Consequently, although appropriate MRL and risk assessment values can be derived from the southern data, 4 trials on strawberries and 4 trials on either grapes, blackcurrants or other berries, compliant with the northern GAP are still required. The same data set compliant with the indoor GAP is also required.
- Strawberries: The GAP reported by the Netherlands (2014) with a PHI of 0 day was not considered by EFSA (see also the active substance and its use pattern). Therefore, the present assessment is based on the Austrian outdoor and indoor GAPs but no residue trials complying with the indoor GAP are available (Austria, 2013). Although appropriate MRL and risk assessment values can be derived from the northern outdoor data, 8 residue trials compliant with indoor GAP are still required.
- Beetroot, turnips, carrots, celeriac, horseradish, Jerusalem artichokes, parsnips, parsley root, radishes and salsify: The number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements for these crops (4 trials instead of 8). Although tentative MRL and risk assessment values can be derived from these data, 4 additional trials compliant with the southern GAP are still required. Moreover, for carrots, celeriac, horseradish, Jerusalem artichokes, parsnips, parsley root, radishes and salsify, the critical GAP authorised in the northern zone is not properly reported as no growth stage and/or PHI values are defined; residue trials supporting this GAP are also not available. This GAP should therefore be further clarified and 8 residue trials on carrots compliant with this GAP are required.
- Tomatoes and aubergines: The critical GAPs authorised (northern outdoor and indoor) are not properly reported as no growth stage and/or PHI values is defined. These GAPs should therefore be clarified. Moreover, no residue trials compliant with GAP are available to support these uses. In fact, while the reported GAP in northern Europe includes a seasonal rate of 0.90 kg a.s./ha, all the outdoor trials were carried out with a seasonal rate of 3.5 kg a.s./ha. Therefore, these trials are reported on a tentative basis to derive MRL and risk assessment values. However, considering that tomatoes is a major crop in Europe, 8 residue trials compliant with the northern outdoor GAP and 8 residue trials compliant with the indoor GAP are required.

- Broccoli, cauliflower, Brussels sprouts and head cabbage: No residue trials compliant with the indoor GAP are available. In fact, only trials supporting a direct soil application were reported by the RMS (Austria, 2011) but these trials are not acceptable to support the critical GAP by broadcast application. Consequently, although appropriate MRL and risk assessment values can be derived from the outdoor data, 8 trials on cauliflower and 8 trials on head cabbage compliant with the indoor GAP (broadcast application) are still required.
- Leafy brassica: The critical GAPs authorised (northern outdoor and indoor) are not properly reported as no growth stage and/or PHI values are defined. These GAPs should therefore be clarified. Moreover, no residue trials are available to support the indoor GAP and the northern residue trials were performed by soil application instead of broadcast application (as defined by the German GAP). Nevertheless, plants came into (accidental) contact with some granules in the available trials and significant residues were found in three samples out of four (Germany, 2014). These trials were therefore considered on a tentative basis to derive MRL and risk assessment values for the northern outdoor GAP but, considering that leafy brassica are minor crops in Europe, 4 residue trials on kale compliant with the northern outdoor GAP and 4 residue trials on kale compliant with the indoor GAP are still required.
- Kohlrabi: The critical GAPs authorised (northern outdoor and indoor) are not properly reported as no growth stage and/or PHI values are defined. These GAPs should therefore be clarified. Moreover, the northern residue trials were performed by soil application instead of broadcast application (as defined by the German GAP). Nevertheless, plants came into (accidental) contact with some granules in the available trials and significant residues were found in one sample out of four (Germany, 2014). The indoor residue trials, although performed by broadcast application, lead to lower risk assessment values than the northern ones. Hence the northern outdoor trials are considered on a tentative basis to derive MRL and risk assessment values but, considering that kohlrabi is a minor crop in Europe, 4 residue trials compliant with the northern outdoor GAP are still required.
- Lettuce and other salad plants including Brassicacea, fresh herbs: The number of residue trials supporting the indoor GAP is not compliant with the data requirements for these crops (4 trials instead of 8). However, considering that the outdoor GAPs (northern and southern) are fully supported by data, appropriate MRL and risk assessment values can be derived. As the indoor GAP is less critical than the outdoor GAP, additional indoor data are not expected to change the outcome of the assessment. Therefore, such data are not deemed necessary in this case.
- Peas and beans (fresh, with and without pods): No residue trials compliant with the indoor GAP are available. Although appropriate MRL and risk assessment values can be derived from the outdoor data, 8 residue trials on fresh peas or beans with pods and 8 residue trials on fresh peas or beans without pods, all compliant with the indoor GAP, are still required.
- Celery: The critical GAPs authorised (northern outdoor and indoor) are not properly reported as no growth stage and/or PHI values are defined. These GAPs should therefore be clarified. Moreover, no residue trials are available to support these uses. Considering that it is a minor crop in Europe, 4 residue trials compliant with the northern outdoor GAP and 4 residue trials compliant with the indoor GAP are required. Meanwhile, appropriate MRL and risk assessment values can be derived from the southern data.
- Globe artichoke: No residue trials compliant with the northern outdoor GAP are available. Although appropriate MRL and risk assessment values can be derived from the southern data, 4 trials compliant with the northern GAP are still required.

- **Leek:** The critical GAPs authorised (northern outdoor and indoor) are not properly reported as no growth stage and/or PHI values are defined. These GAPs should therefore be clarified. Moreover, no residue trials are available to support these uses. Considering that it is a major crop in northern Europe, 8 residue trials compliant with the northern outdoor GAP and 8 residue trials compliant with the indoor GAP are required. Meanwhile, appropriate MRL and risk assessment values can be derived from the southern data.
- **Small grain cereals (grain and straw):** The residue trials supporting the northern use are not compliant with the reported GAP. While the reported GAP includes a seasonal rate of 0.90 kg a.s./ha, all the trials were carried out with a seasonal rate of 0.70 kg a.s./ha (see also general consideration above). Although appropriate MRL and risk assessment values can be derived from the southern data, 8 trials on wheat compliant with the northern GAP are still required.
- **Maize, millet, sorghum:** The residue trials supporting the northern use are not compliant with the reported GAP. While the reported GAP includes a seasonal rate of 0.90 kg a.s./ha, all the trials were carried out with a seasonal rate of 0.70 kg a.s./ha (see also general consideration above). Although appropriate MRL and risk assessment values can be derived from the southern data, 8 trials on maize compliant with the northern GAP are still required.

The potential degradation of residues during storage of the residue trials samples was also assessed. In the framework of the peer review, storage stability of metaldehyde was demonstrated for a period of 24 months at -20°C in commodities with high water content (Brussels sprouts), for a period of 24 months at -18°C in commodities with high oil content (rape seed) and for a period of 18 months at -18°C in dry commodities (wheat grain) (Austria, 2009). In the current framework, the RMS Austria also evaluated a study demonstrating the stability of metaldehyde for a period of 12 months at -20°C in commodities with high acid content (strawberries). According to the RMS, all residue trial samples reported in the PROFile were stored in compliance with the storage conditions reported above. Degradation of residues during storage of the trial samples is therefore not expected.

Consequently, the available residues data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation but MRL proposals for root and tuber vegetables (except swedes), tomatoes, aubergines, leafy brassica and kohlrabi, are only tentative because additional residue trials compliant with GAP are still required (see also Table 3-2). Where several uses are authorised for one commodity, the final MRL proposal was derived from the most critical use and indicated in bold in Table 3-2. Tentative MRLs were also derived for cereal straw, sugar beet tops and grass in view of the future need to set MRLs in feed items.

Table 3-2: Overview of the available residue 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 (metaldehyde)	Risk assessment (metaldehyde)					
Citrus fruits Tree nuts Pome fruits Stone fruits	NEU	Outdoor	-	-	-	-	-	-	No residue trial submitted. Clarification of the GAP is needed (BBCH and/or PHI). No authorised use on citrus fruits in NEU.
	SEU	Outdoor	8x <0.05	8x <0.05	0.05	0.05	0.05*	1.00	Combined data set of trials performed on oranges/lemons (4) and apples (4) compliant with GAPs on all orchards (Austria, 2011).
	EU	Indoor	-	-	-	-	-	-	No residue trial submitted. Clarification of the GAP is needed (BBCH and/or PHI). Indoor use only authorised for stone fruits (Netherlands, 2014).
Table & wine grapes Cane fruits and other small fruits & berries	NEU	Outdoor	<u>Strawberries:</u> 4x<0.05 <u>Grapes:</u> 4x<0.05	<u>Strawberries:</u> 4x<0.05 <u>Grapes:</u> 4x<0.05	0.05	0.05	0.05* (tentative)	1.00	All trials are performed with under-dosed rate (Austria, 2011); see also body text.
	SEU	Outdoor	<u>Strawberries:</u> 4x <0.05 <u>Grapes:</u> 4x<0.05	<u>Strawberries:</u> 4x <0.05 <u>Grapes:</u> 4x<0.05	0.05	0.05	0.05*	1.00	Trials on strawberries (4) and grapevines (4) compliant with GAP (Austria, 2011).
	EU	Indoor	-	-	-	-	-	-	No residue trial submitted.

Commodity	Residue region ^(a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue _(b) (mg/kg)	Highest residue _(c) (mg/kg)	MRL proposal (mg/kg)	Median CF ^(d)	Comments
			Enforcement (metaldehyde)	Risk assessment (metaldehyde)					
Strawberries	NEU	Outdoor	8x<0.05	8x<0.05	0.05	0.05	0.05*	1.00	Trials are compliant with GAP on strawberries which is different from GAP on grapes, cane fruits and all other small fruits and berries (Austria, 2013); see also body text.
	EU	Indoor	-	-	-	-	-	-	No residue trial compliant with GAP (Austria, 2013).
Potatoes	NEU	Outdoor	5x <0.01; 0.02; 0.04; 4x < 0.05; 0.07	5x <0.01; 0.02; 0.04; 4x < 0.05; 0.07	0.03	0.07	0.15	1.00	Combined data set compliant with GAPs: banded between rows & broadcast (EFSA, 2012). Rber = 0.10 Rmax = 0.09 OECD = 0.12
	SEU	Outdoor	6x < 0.01; 0.01; 0.02	6x < 0.01; 0.01; 0.02	0.01	0.02	0.05*	1.00	Trials compliant with GAP (EFSA, 2012). Rber = 0.02 Rmax = 0.02 OECD = 0.03
Beetroot Turnips	NEU	Outdoor	8x<0.05	8x<0.05	0.05	0.05	0.05*	1.00	Direct extrapolation from sugar beet (root) is possible (Austria, 2011); see below.
	SEU	Outdoor	<0.01; <0.01; 0.03; 0.13	<0.01; <0.01; 0.03; 0.13	0.02	0.13	0.3 (tentative)	1.00	Direct extrapolation from carrots is possible on a tentative basis only (Italy, 2013); see below.

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 (metaldehyde)	Risk assessment (metaldehyde)					
Carrots Celeriac Horseradish Jerusalem artichokes Parsnips Parsley root Radishes Salsify	NEU	Outdoor	-	-	-	-	-	-	No residue trial submitted. Clarification of the GAP is needed (BBCH and/or PHI).
	SEU	Outdoor	<0.01; <0.01; 0.03; 0.13	<0.01; <0.01; 0.03; 0.13	0.02	0.13	0.3 (tentative)	1.00	Residue trials on carrots compliant with GAP (Italy, 2013). Rber = 0.21 Rmax = 0.34 OECD = 0.27
Swedes	NEU	Outdoor	8x<0.05	8x<0.05	0.05	0.05	0.05*	1.00	Direct extrapolation from sugar beet (root) is possible (Austria, 2011); see below.
	SEU	Outdoor	10x< 0.01; 2x0.05	10x< 0.01; 2x0.05	0.01	0.05	0.05*	1.00	
Tomatoes Aubergines	NEU	Outdoor	14x<0.05; 0.07; 0.10	14x<0.05; 0.07; 0.10	0.05	0.10	0.15 (tentative)	1.00	Overdosed trials compared to the authorised GAP (Netherlands, 2014); see also body text. Rber = 0.10 Rmax = 0.09 OECD = 0.11
	EU	Indoor	-	-	-	-	-	-	No residue trial submitted. Clarification of the GAP is needed (BBCH and/or PHI).

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 (metaldehyde)	Risk assessment (metaldehyde)					
Flowering & head brassica	NEU	Outdoor	<u>Cauliflower:</u> 3x <0.01; 2x0.03; 2x0.04; 8x<0.05; 0.07 <u>Broccoli:</u> 3 x <0.05; 0.06; 0.08; 0.14 <u>Head cabbage:</u> 3x <0.01; 4x0.02; 2x0.04; 7x<0.05; 0.10 <u>Brussels sprouts:</u> 4x<0.01; 0.01; 3x0.02; 2x<0.05	<u>Cauliflower:</u> 3x <0.01; 2x0.03; 2x0.04; 8x<0.05; 0.07 <u>Broccoli:</u> 3 x <0.05; 0.06; 0.08; 0.14 <u>Head cabbage:</u> 3x <0.01; 4x0.02; 2x0.04; 7x<0.05; 0.10 <u>Brussels sprouts:</u> 4x<0.01; 0.01; 3x0.02; 2x<0.05	0.05	0.14	0.15	1.00	Combined data set compliant with GAPs: banded between rows & broadcast (Austria, 2011, 2013; France, 2013). Rber = 0. 10 Rmax = 0. 09 OECD = 0.14
	SEU	Outdoor	<u>Cauliflower:</u> 3x< 0.01; 0.02; 4x<0.05 <u>Broccoli:</u> <0.05 <u>Head cabbage:</u> < 0.01; <0.05; 0.02; 0.05; 0.06; 0.06; 0.07; 0.36	<u>Cauliflower:</u> 3x< 0.01; 0.02; 4x<0.05 <u>Broccoli:</u> <0.05 <u>Head cabbage:</u> < 0.01; <0.05; 0.02; 0.05; 0.06; 0.06; 0.07; 0.36	0.05	0.36	0.40	1.00	Combined data set compliant with GAP: application directly to the soil for all flowering and head brassica (Austria, 2011; France, 2014). Rber = 0. 11 Rmax = 0. 26 OECD = 0.38
	EU	Indoor	=	=	-	-	-	1.00	No residue trials compliant with GAP (broadcast application) are available; see also body text.

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 (metaldehyde)	Risk assessment (metaldehyde)					
Leafy brassica	NEU	Outdoor	<0.05; 0.06; 0.12; 0.15	<0.05; 0.06; 0.12; 0.15	0.09	0.15	0.40 (tentative)	1.00	Clarification of the GAP is needed (BBCH and/or PHI). Trials performed with direct soil application instead of broadcast (Germany, 2014); see also body text. Rber = 0.29 Rmax = 0.34 OECD = 0.29
	EU	Indoor	-	-	-	-	-	-	No trials submitted. Clarification of the GAP is needed (BBCH and/or PHI).
Kohlrabi	NEU	Outdoor	3x<0.05; 0.08	3x<0.05; 0.08	0.05	0.08	0.15 (tentative)	1.00	Clarification of the GAP is needed (BBCH and/or PHI). Trials performed with direct soil application instead of broadcast (Germany, 2014); see also body text. Rber = 0.15 Rmax = 0.13 OECD = 0.12
	EU	Indoor	2x<0.02; 0.04; 0.05	2x<0.02; 0.04; 0.05	0.03	0.05	0.15	1.00	Clarification of the GAP is needed (BBCH and/or PHI). Trials performed with broadcast application (Germany, 2014). Rber = 0.10 Rmax = 0.11 OECD = 0.09

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 (metaldehyde)	Risk assessment (metaldehyde)					
Lettuce and other salad plants including Brassicacea Spinach and similar Fresh herbs	NEU	Outdoor	2x<0.05; 0.06; 0.09; 0.11; 0.14; 0.15; 0.87	2x<0.05; 0.06; 0.09; 0.11; 0.14; 0.15; 0.87	0.10	0.87	1.5	1.00	Trials on lettuce compliant with the NEU GAP on lettuce and other salad plants (Germany, 2014). Rber = 0.30 Rmax = 1.07 OECD = 1.30
	NEU	Outdoor	3x<0.05; 0.13; 0.13; 0.2; 0.28; 0.53	3x<0.05; 0.13; 0.13; 0.2; 0.28; 0.53	0.13	0.53	0.90	1.00	Trials on lettuce compliant with the NEU GAP on spinach and similar, and fresh herbs (EFSA, 2012). Rber = 0.52 Rmax = 0.70 OECD = 0.83
	SEU	Outdoor	0.05; 0.29; 0.41; 0.42; 0.53; 0.56; 0.57; 1.26	0.05; 0.29; 0.41; 0.42; 0.53; 0.56; 0.57; 1.26	0.48	1.26	2.00	1.00	Trials compliant with GAP (EFSA, 2012); extrapolation to other leafy vegetables possible. Rber = 1.14 Rmax = 1.62 OECD = 1.90
	EU	Indoor	0.10; 0.17; 0.24; 0.29	0.10; 0.17; 0.24; 0.29	0.21	0.29	0.6 (tentative)	1.00	Trials compliant with GAP (Italy, 2014); extrapolation to other leafy vegetables possible. Rber = 0.56 Rmax = 0.63 OECD = 0.60

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 (metaldehyde)	Risk assessment (metaldehyde)					
Peas & Beans (fresh, with pods)	NEU	Outdoor	<u>Peas:</u> 4x<0.01; 0.01; 0.04; 0.09 <u>Beans:</u> 2x<0.01	<u>Peas:</u> 4x<0.01; 0.01; 0.04; 0.09 <u>Beans:</u> 2x<0.01	0.01	0.09	0.15	1.00	Trials compliant with GAP (EFSA, 2014). Rber = 0.05 Rmax = 0.10 OECD = 0.13
	SEU	Outdoor	<u>Peas:</u> 3x<0.01; 2x0.01; 0.06; 0.28 <u>Beans:</u> <0.01; 0.08	<u>Peas:</u> 3x<0.01; 2x0.01; 0.06; 0.28 <u>Beans:</u> <0.01; 0.08	0.01	0.28	0.4	1.00	Trials compliant with GAP (EFSA, 2014). Rber = 0.14 Rmax = 0.32 OECD = 0.41
	EU	Indoor	-	-	-	-	-	-	-
Peas & Beans (fresh, without pods)	NEU	Outdoor	<u>Peas:</u> 6x<0.01; 0.05 <u>Beans:</u> <0.01	<u>Peas:</u> 6x<0.01; 0.05 <u>Beans:</u> <0.01	0.01	0.05	0.08	1.00	Trials compliant with GAP (EFSA, 2014). Rber = 0.02 Rmax = 0.06 OECD = 0.07
	SEU	Outdoor	<u>Peas:</u> 3x<0.01; 0.01; 0.02; 0.09; 0.14 <u>Beans:</u> <0.01	<u>Peas:</u> 3x<0.01; 0.01; 0.02; 0.09; 0.14 <u>Beans:</u> <0.01	0.01	0.14	0.3	1.00	Trials compliant with GAP (EFSA, 2014). Rber = 0.15 Rmax = 0.20 OECD = 0.24
	EU	Indoor	-	-	-	-	-	-	-

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 (metaldehyde)	Risk assessment (metaldehyde)					
Pulses (dry)	NEU	Outdoor	5x<0.01; 0.02; 0.03; 0.06	5x<0.01; 0.02; 0.03; 0.06	0.01	0.06	0.09	1.00	Trials performed on dry beans compliant with GAP (EFSA, 2014). Rber = 0.06 Rmax = 0.08 OECD = 0.09
	SEU	Outdoor	4x<0.01; 0.01; 0.04; 0.06; 0.10	4x<0.01; 0.01; 0.04; 0.06; 0.10	0.01	0.10	0.20	1.00	Trials performed on dry beans compliant with GAP (EFSA, 2014). Rber = 0.11 Rmax = 0.14 OECD = 0.17
Asparagus	SEU	Outdoor	3x<0.01; 0.02	3x<0.01; 0.02	0.01	0.02	0.05*	1.00	Trials compliant with GAP (Italy, 2013). Rber = 0.04 Rmax = 0.04 OECD = 0.03
Celery Fennel	NEU	Outdoor	-	-	-	-	-	-	Only authorised on celery in northern zone. No residue trial submitted. Clarification of the GAP is needed (BBCH and/or PHI).
	SEU	Outdoor	4x<0.01	4x<0.01	0.01	0.01	0.05*	1.00	Trials performed on celery compliant with GAP on celery and fennel (Italy, 2013).
	EU	Indoor	-	-	-	-	-	-	Only authorised on celery under indoor conditions. No residue trial submitted. Clarification of the GAP is needed (BBCH and/or PHI).

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 (metaldehyde)	Risk assessment (metaldehyde)					
Globe artichoke	NEU	Outdoor	-	-	-	-	-	-	No trials available.
	SEU	Outdoor	<0.01; 0.01; 0.02; 0.03	<0.01; 0.01; 0.02; 0.03	0.02	0.03	0.07	1.00	Trials compliant with GAP (Italy, 2013). Rber = 0.06 Rmax = 0.07 OECD = 0.06
Leek	NEU	Outdoor	-	-	-	-	-	-	No residue trial submitted. Clarification of the GAP is needed (BBCH and/or PHI).
	SEU	Outdoor	0.08; 0.1; 0.2; 0.23	0.08; 0.1; 0.2; 0.23	0.15	0.23	0.50	1.00	Trials compliant with GAP (Italy, 2013). Rber = 0.45 Rmax = 0.53 OECD = 0.46
	EU	Indoor	-	-	-	-	-	-	No residue trial submitted. Clarification of the GAP is needed (BBCH and/or PHI).

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 (metaldehyde)	Risk assessment (metaldehyde)					
Linseed Poppy seed Sunflower seed Sesame seed Rape seed Soya bean Mustard seed Cotton seed Pumpkin seeds Safflower Borage Gold of pleasure Hempseed	NEU	Outdoor	15x<0.01; 0.03; 2x0.06; 0.14; 0.53	15x<0.01; 0.03; 2x0.06; 0.14; 0.53	0.01	0.53	0.60	1.00	Trials performed on rapeseed compliant with GAPs for all oilseeds (EFSA, 2012). Rber = 0.05 Rmax = 0.33 OECD = 0.53
	SEU	Outdoor	4x<0.05	4x<0.05	0.05	0.05	0.05*	1.00	Trials performed on sunflower seed compliant with GAPs for sunflower, sesame, soya bean, cotton, pumpkins, safflower, borage, gold of pleasure and hempseed (Austria, 2011). No authorised use for linseed, poppy seed, rape seed and mustard seed in southern Europe.
Small grain cereals	NEU	Outdoor	8x<0.01; 7x <0.05	8x<0.01; 7x <0.05	0.01	0.05	0.05* (tentative)	1.00	All trials performed on wheat with under-dosed rate (Austria, 2011); see also body text.
	SEU	Outdoor	8x <0.01; 3x< 0.05	8x <0.01; 3x< 0.05	0.01	0.05	0.05*	1.00	Trials performed on barley compliant with GAP for all small grain cereals (within the 25 % tolerance interval) (Austria, 2011).

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 (metaldehyde)	Risk assessment (metaldehyde)					
Small grain cereal straw	NEU	Outdoor	8x<0.01; 7x <0.05	8x<0.01; 7x <0.05	0.01	0.05	0.05* (tentative)	1.00	All trials performed on wheat with under-dosed rate (Austria, 2011); see also body text.
	SEU	Outdoor	8x<0.01; 3x< 0.05	8x<0.01; 3x< 0.05	0.01	0.05	0.05*	1.00	Trials performed on barley compliant with GAP for all small cereals (within the 25 % tolerance interval) (Austria, 2011).
Maize grain Millet grain Sorghum grain	NEU	Outdoor	8x<0.05	8x<0.05	0.05	0.05	0.05* (tentative)	1.00	All trials performed on maize with under-dosed rate (Austria, 2011); see also body text.
	SEU	Outdoor	4x<0.05	4x<0.05	0.05	0.05	0.05*	1.00	Trials performed on maize compliant with GAP (Austria, 2011); extrapolation to millet and sorghum is possible.
Sugar beet (root)	NEU	Outdoor	8x<0.05	8x<0.05	0.05	0.05	0.05*	1.00	4 trials compliant with GAP and 4 trials within the 25 % tolerance interval (2x0.35 kg as/ha instead of 2x0.45 kg as/ha) (Austria, 2011).
	SEU	Outdoor	10x< 0.01; 2x0.05	10x< 0.01; 2x0.05	0.01	0.05	0.05	1.00	Trials compliant with GAP (Austria, 2011).

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 (metaldehyde)	Risk assessment (metaldehyde)					
Sugar beet (tops)	NEU	Outdoor	8x<0.05	8x<0.05	0.05	0.05	0.05*	1.00	4 trials compliant with GAP and 4 trials within the 25 % tolerance interval (2x0.35 kg as/ha instead of 2x0.45 kg as/ha) (Austria, 2011).
	SEU	Outdoor	10x< 0.01; 2x<0.05	10x< 0.01; 2x<0.05	0.01	0.05	0.05*	1.00	Trials compliant with GAP (Austria, 2011).
Grass	NEU	Outdoor	4x <0.05	4x <0.05	0.05	0.05	0.05*	1.00	Trials compliant with GAP (Austria, 2011).
	SEU	Outdoor	5x<0.05; 0.17; 0.76	5x<0.05; 0.17; 0.76	0.05	0.76	1.50	1.00	Trials compliant with GAP (Austria, 2011). Rber = 0.34 Rmax = 1.07 OECD = 1.23

(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.

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

3.1.1.3. Effect of industrial processing and/or household preparation

No study was available to address the effect of processing on the nature of the residue. Based on the structure of metaldehyde the formation of acetaldehyde, which is also the major metabolite in soil, cannot be excluded. Moreover, acetaldehyde was defined as a relevant impurity of the active substance and is also known as a potential carcinogen (WHO, 1999). Also considering that the chronic exposure exceeds 10 % of the ADI, the necessity to conclude on its possible presence in processed products is a crucial point in the present assessment, and a hydrolysis study investigating the effect of the processing on the nature of metaldehyde is required. This information is mainly needed to support authorisations on potatoes, root and tuber vegetables (except swedes), tomatoes, aubergines, flowering and head brassica, leafy brassica, kohlrabi, lettuce and other salad plants, spinach and similar, fresh legumes, artichoke, leek and pulses, where significant residue levels are found and which may be subject to processing (boiling/brewing/baking). In the absence of any conclusion on the nature of residues during processing, MRLs and risk assessment values for these commodities should be considered on a tentative basis only.

As no study investigating the magnitude of residues in processed commodities was reported, no processing factors for enforcement and risk assessment could be derived.

3.1.2. Rotational crops

All crops under consideration, except permanent crops (orchards and grapes), may be grown in rotation. According to the soil degradation studies evaluated in the framework of the peer review, DT₉₀ values of metaldehyde are expected to range between 8-22 days which is below the trigger value of 100 days (EFSA, 2010). No relevant soil metabolites were identified. According to the European guidelines on rotational crops (EC, 1997b), further investigation of residues in rotational crops is not required and relevant residues in rotational crops are not expected.

3.2. Nature and magnitude of residues in livestock

3.2.1. Dietary burden of livestock

Metaldehyde 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 summarised in Table 3-3. Default processing factors have been included in the calculation in order to consider the potential concentration of residues in some commodities. For rapeseed, linseed and sunflower seed meal, the default processing factor is 2 while for cotton seed and soya bean meal a factor of 1.3 was used. Furthermore, the default processing factor of 4 has been included for grass hay. For pomace and cereal bran however, no default processing factor was applied because metaldehyde is applied early in the growing season and residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected.

Table 3-3: 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: metaldehyde				
Citrus & apple pomace	0.05*	Median residue	0.05*	Median residue
Potatoes	0.03	Median residue	0.07	Highest residue
Turnips	0.05*	Median residue	0.13	Highest residue

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Swedes	0.05*	Median residue	0.05*	Highest residue
Cabbage	0.05	Median residue	0.36	Highest residue
Kale	0.09	Median residue	0.15	Highest residue
Dry pulses	0.01*	Median residue	0.01*	Median residue
Small grain cereal (bran)	0.01*	Median residue	0.01*	Median residue
Small grain cereal straw	0.01*	Median residue	0.05*	Highest residue
Maize grain	0.05*	Median residue	0.05*	Median residue
Cotton seed Soya bean	0.05*	Median residue	0.05*	Median residue
Rape seed meal Linseed meal	0.02	Median residue x 2	0.02	Median residue x 2
Sunflower seed meal	0.10	Median residue x 2	0.10	Median residue x 2
Cotton seed meal Soya bean meal	0.07	Median residue x 1.3	0.07	Median residue x 1.3
Sugar beet (roots)	0.05*	Median residue	0.05*	Highest residue
Sugar beet (leaves)	0.05*	Median residue	0.05*	Highest residue
Grass (fresh)	0.05*	Median residue	0.76	Highest residue
Grass silage	0.05*	Median residue	0.76	Highest residue
Grass hay	0.20	Median residue x 4	3.04	Highest residue x 4

The results of the calculations are reported in Table 3-4. The calculated dietary burdens for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Further investigation of residues is therefore required in all commodities of animal origin.

Table 3-4: 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: metaldehyde					
Dairy ruminants	0.015	0.138	Grass (fresh)	3.84	Y
Meat ruminants	0.023	0.163	Grass (fresh)	3.79	Y
Poultry	0.011	0.028	Turnips	0.44	Y
Pigs	0.017	0.055	Turnips	1.38	Y

3.2.2. Nature of residues

The nature of metaldehyde residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (EFSA, 2010). One metabolism study in lactating goats is available where U-¹⁴C-labelled metaldehyde was administered at two different dose rates. The characteristics of this study are summarised in Table 3-5.

Table 3-5: Summary of available metabolism studies in livestock

Group	Species	Label position	No of animal	Application details		Sample details	
				Rate (mg/kg bw per d)	Duration (days)	Commodity	Time
Lactating ruminants	Goat	U- ¹⁴ C-metaldehyde	1+1	Low dose: 0.038 High dose : 0.315	5	Milk	Daily
						Urine and faeces	Daily
						Expired air	Daily
						Tissues	At sacrifice (6 hours after last dose)

Lactating goats were dosed with 0.038 mg/kg bw per d (low dose) or 0.315 mg/kg bw per d (high dose) of metaldehyde, respectively corresponding to 0.2 and 2 times the exposure of meat ruminant. The study demonstrates that the major part of the radioactivity was exhaled via carbon dioxide (CO₂) (58.1-58.9 % AR). About 3.5-4.4 % of the AR was excreted via urine and faeces. Transfer of residues to milk and tissues occurs but is relatively low, accounting for 6.3-12.1 % of the AR and 2.9-5.7 % of the AR, respectively. In milk, a plateau was reached after 2 days of administration: 0.16 mg/kg (low dose) or 1.6 mg/kg (high dose).

In milk and all tissues, the absence of parent metaldehyde indicated an extensive metabolism. Several extractions and recoveries of the radioactivity showed that the remaining radioactivity is broken down and incorporated into natural products such as fatty acids, amino acids and carbohydrates (EFSA, 2010).

The metabolism study on ruminant shows that residues of metaldehyde are eliminated as CO₂ and incorporated into natural products. As the general metabolic pathways depicted in ruminant and rodents are comparable, these conclusions can be extrapolated to pigs. No information is available for poultry but it is not expected that metaldehyde has a different route of transformation in poultry because metaldehyde is a tetramer of a simple molecular structure (acetaldehyde) which was shown to be completely incorporated into natural constituents in ruminants and rodents. A specific metabolism study for poultry is therefore considered desirable only but not essential. As no compound was identified as a good marker to enforce the presence of metaldehyde residues in animal products, EFSA proposes to define the relevant residue for enforcement and risk assessment in all commodities of animal origin by default as metaldehyde. Nevertheless, no analytical method is available to enforce metaldehyde in food of animal origin. As stated in section 1.2, an analytical method with its ILV and a confirmatory method fully validated for the determination of metaldehyde in food of animal origin (meat, fat, liver, kidney, milk and eggs) are still required.

3.2.3. Magnitude of residues

According to the above mentioned metabolism study, it is concluded that, after exposure to the maximum dietary burden (about 2 times lower than the high dose level of the metabolism study; see also section 3.2.1), significant residues in edible commodities of animal origin are not expected. Therefore, no livestock feeding study is needed.

Nevertheless, as there are no analytical methods to enforce metaldehyde in food of animal origin, EFSA is not in position to derive LOQ and MRL proposals in commodities of animal origin.

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 summarised 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. For commodities of animal origin, where data were insufficient to derive an MRL in section 3, EFSA considered the existing EU MRL for an indicative calculation. 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: metaldehyde				
Citrus fruits	0.05*	Median residue ^(a)	0.05*	Highest residue ^(a)
Tree nuts	0.05*	Median residue ^(a)	0.05*	Highest residue ^(a)
Pome fruits	0.05*	Median residue ^(a)	0.05*	Highest residue ^(a)
Stone fruits	0.05*	Median residue ^(a)	0.05*	Highest residue ^(a)
Table & wine grapes	0.05*	Median residue ^(a)	0.05*	Highest residue ^(a)
Cane fruits	0.05*	Median residue ^(a)	0.05*	Highest residue ^(a)
Other small fruits & berries	0.05*	Median residue ^(a)	0.05*	Highest residue ^(a)
Strawberries	0.05*	Median residue ^(a)	0.05*	Highest residue ^(a)
Potatoes	0.03	Median residue (tentative) ^(b)	0.07	Highest residue (tentative) ^(b)
Beetroot Turnips	0.05*	Median residue (tentative) ^(b)	0.13	Highest residue (tentative) ^(b)
Swedes	0.05*	Median residue ^(a)	0.05*	Highest residue ^(a)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Carrots Celeriac Horseradish Jerusalem artichokes Parsnips Parsley root Radishes Salsify	0.02	Median residue (tentative) ^(b)	0.13	Highest residue (tentative) ^(b)
Tomatoes Aubergines	0.05*	Median residue (tentative) ^(b)	0.10	Highest residue (tentative) ^(b)
Flowering brassica Head brassica	0.05*	Median residue (tentative) ^(b)	0.36	Highest residue (tentative) ^(b)
Leafy brassica	0.09	Median residue (tentative) ^(b)	0.15	Highest residue (tentative) ^(b)
Kohlrabi	0.05*	Median residue (tentative) ^(b)	0.08	Highest residue (tentative) ^(b)
Lettuce and other salad plants including Brassicacea Spinach and similar	0.48	Median residue (tentative) ^(b)	1.26	Highest residue (tentative) ^(b)
Fresh herbs	0.48	Median residue ^(a)	1.26	Highest residue ^(a)
Peas & Beans (fresh, with pods)	0.01*	Median residue (tentative) ^(b)	0.28	Highest residue (tentative) ^(b)
Peas & Beans (fresh, without pods)	0.01*	Median residue (tentative) ^(b)	0.14	Highest residue (tentative) ^(b)
Asparagus	0.01*	Median residue ^(a)	0.02	Highest residue ^(a)
Celery Fennel	0.01*	Median residue ^(a)	0.01*	Highest residue ^(a)
Globe artichoke	0.02	Median residue (tentative) ^(b)	0.03	Highest residue (tentative) ^(b)
Leek	0.15	Median residue (tentative) ^(b)	0.23	Highest residue (tentative) ^(b)
Pulses (dry)	0.01*	Median residue (tentative) ^(b)	0.10	Highest residue (tentative) ^(b)
Sunflower seed Sesame seed Soya bean Cotton seed Pumpkin seeds Safflower Borage Gold of pleasure Hempseed	0.05*	Median residue ^(a)	0.53	Highest residue ^(a)
Rape seed Linseed Poppy seed Mustard seed	0.01*	Median residue ^(a)	0.53	Highest residue ^(a)
Small grain cereals	0.01*	Median residue ^(a)	0.05*	Highest residue ^(a)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Maize grain Millet grain Sorghum grain	0.05*	Median residue ^(a)	0.05*	Highest residue ^(a)
Sugar beet (root)	0.05*	Median residue ^(a)	0.05*	Highest residue ^(a)
Swine meat	0.05*	EU MRL ^(c)	0.05*	EU MRL ^(c)
Swine fat	0.05*	EU MRL ^(c)	0.05*	EU MRL ^(c)
Swine liver	0.05*	EU MRL ^(c)	0.05*	EU MRL ^(c)
Swine kidney	0.05*	EU MRL ^(c)	0.05*	EU MRL ^(c)
Ruminant meat	0.05*	EU MRL ^(c)	0.05*	EU MRL ^(c)
Ruminant fat	0.05*	EU MRL ^(c)	0.05*	EU MRL ^(c)
Ruminant liver	0.05*	EU MRL ^(c)	0.05*	EU MRL ^(c)
Ruminant kidney	0.05*	EU MRL ^(c)	0.05*	EU MRL ^(c)
Poultry meat	0.05*	EU MRL ^(c)	0.05*	EU MRL ^(c)
Poultry fat	0.05*	EU MRL ^(c)	0.05*	EU MRL ^(c)
Poultry liver	0.05*	EU MRL ^(c)	0.05*	EU MRL ^(c)
Birds' eggs	0.05*	EU MRL ^(c)	0.05*	EU MRL ^(c)
Ruminant's milk	0.05*	EU MRL ^(c)	0.05*	EU MRL ^(c)

(*): Indicates that the the input value is proposed at the limit of analytical quantification.

(a): At least one relevant GAP reported by the RMS is fully supported by data for this commodity; the risk assessment values derived in section 3 are used for the exposure calculations.

(b): 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.

(c): Dietary burden relevant to this commodity of animal origin, resulting from the GAPs reported by the RMS, is not supported by data; the existing EU MRL is used for indicative exposure calculations.

The calculated exposures were compared with the toxicological reference values derived for metaldehyde (see Table 2-1); detailed results of the calculations are presented in Appendix B. The highest chronic exposure was calculated for French toddlers, representing 16.4 % of the ADI, and the highest acute exposure was calculated for scarole, representing 36.7 % of the ARfD.

Based on the above calculations, EFSA concludes that the use of metaldehyde on crops fully supported by data (footnotes (a) in Table 4-1), is acceptable with regard to consumer exposure. For the other commodities, major uncertainties remain due to the data gaps identified in section 3, but considering tentative MRLs or existing EU MRLs in the exposure calculation did not indicate a risk to consumers.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of metaldehyde was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI and an ARfD being established at 0.02 mg/kg bw per d and 0.3 mg/kg bw, respectively.

Metabolism of metaldehyde was investigated for soil application on fruits and fruiting vegetables, leafy vegetables, root and tuber vegetables, pulses and oilseeds and cereals. These studies demonstrated that parent metaldehyde is extensively degraded with incorporation of its carbon atoms

into natural plant constituents. Therefore, the residue definition in all plant commodities for enforcement and risk assessment is proposed as metaldehyde only. Validated analytical methods for enforcement of the proposed residue definition are available.

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 all commodities under evaluation but MRL proposals for roots and tuber vegetables (except swedes), tomatoes, aubergines, leafy brassica and kohlrabi, are only tentative because additional residue trials compliant with GAP are still required.

No study was available to address the effect of processing on the nature of the residue. Based on the structure of metaldehyde, the formation of acetaldehyde cannot be excluded. Also considering that the chronic exposure exceeds 10 % of the ADI, a hydrolysis study investigating the effect of the processing on the nature of metaldehyde is required. This information is mainly needed to support authorisations on potatoes, root and tuber vegetables (except swedes), tomatoes, aubergines, flowering and head brassica, leafy brassica, kohlrabi, lettuce and other salad plants, spinach and similar, fresh legumes, artichoke, leek and pulses, where significant residue levels are found and which may be subject to processing (boiling/brewing/baking). MRLs and risk assessment values for these commodities are therefore considered on a tentative basis only. As no study investigating the magnitude of residues in processed commodities was reported, no processing factors for enforcement or risk assessment could be derived.

According to the soil degradation studies evaluated in the framework of the peer review, DT_{90} values of metaldehyde are expected to range between 8-22 days which is below the trigger value of 100 days, and no relevant soil metabolites were identified. Further investigation of residues in rotational crops is therefore not required and relevant residues in rotational crops are not expected.

Based on the uses reported by the RMS, significant intakes were calculated for all groups of livestock. Metabolism in lactating ruminants was sufficiently investigated. The available study demonstrated that residues of metaldehyde are eliminated as CO_2 or incorporated into natural products. As no compound was identified as a good marker to enforce the presence of metaldehyde residues in animal products, EFSA proposed a default residue definition for enforcement and risk assessment as metaldehyde. Although it is not expected that metaldehyde has a different route of transformation in poultry and the proposed residue definition can be applied to poultry as well, an additional study on the nature of residues in poultry is desirable. According to the available metabolism study, measurable levels of metaldehyde in edible commodities of animal origin are not expected and no livestock feeding study is needed. Nevertheless, as there are no analytical methods to enforce metaldehyde in food of animal origin, EFSA was not able to derive LOQ and MRL proposals.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For commodities of animal origin, where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure represented 16.4 % of the ADI (French toddler) and the highest acute exposure amounted to 36.7 % of the ARfD (scarole).

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 of the reasoned opinion (see summary table). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see summary table footnotes for details). In particular, some tentative MRLs or existing EU MRLs need to be confirmed by the following data:

- a fully validated analytical method for the determination of metaldehyde in food of animal origin (meat, fat, liver, kidney, milk and eggs);
- a hydrolysis study investigating the effect of sterilisation on the nature of residues, mainly to support authorisations on potatoes, root and tuber vegetables (except swedes), tomatoes, aubergines, flowering and head brassica, leafy brassica, kohlrabi, lettuce and other salad plants, spinach and similar, fresh legumes, artichoke, leek and pulses;
- further clarification of the northern outdoor GAP on carrots, celeriac, horseradish, Jerusalem artichokes, parsnips, parsley root, radishes and salsify as well as 8 residue trials on carrots supporting this GAP;
- 4 residue trials on carrots supporting the southern outdoor GAP on beetroot, turnips, carrots, celeriac, horseradish, Jerusalem artichokes, parsnips, parsley root, radishes and salsify;
- further clarification of the indoor and northern outdoor GAPs on tomatoes and aubergines as well as 8 residue trials supporting each of these GAPs;
- further clarification of the indoor and northern outdoor GAPs on leafy brassica as well as 4 residue trials on kale supporting each of these GAPs;
- further clarification of the indoor and northern outdoor GAPs on kohlrabi as well as 4 residue trials supporting the northern outdoor GAP.

It is highlighted that some of the MRLs derived result from a GAP in one climatic zone only, while other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the following data gaps which are not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

- further clarification of the northern outdoor GAP on tree nuts, pome fruits and stone fruits as well as 4 residue trials on apples and 4 residue trials on stone fruits supporting this GAP;
- further clarification of the indoor GAP on stone fruits as well as 8 residue trials (with a minimum of 4 trials performed on apricots) supporting this GAP;
- 4 residue trials on strawberries and 4 residue trials on either grapes, blackcurrants or other berries, supporting the northern outdoor GAP on table and wine grapes, cane fruits and other small fruits and berries (2 x 0.45 kg a.s./ha);
- 8 residue trials supporting the indoor GAP on strawberries;
- 8 residue trials on cauliflower and 8 residue trials on head cabbage supporting the indoor GAP on flowering and head brassica (2 x 0.45 kg a.s./ha);
- further clarification of the northern outdoor and indoor GAPs on celery as well as 4 residue trials supporting each of these GAPs;
- 4 residue trials supporting the northern outdoor GAP on globe artichoke;
- further clarification of the northern outdoor and indoor GAPs on leek as well as 8 residue trials supporting each of these GAPs;
- 8 residue trials on peas or beans (fresh with pods) and 8 residue trials on peas or beans (fresh without pods), all supporting the indoor GAP on fresh legume vegetables;

- 8 residue trials on maize supporting the northern GAP on maize, millet and sorghum (2 x 0.45 kg a.s./ha);
- 8 residue trials on wheat supporting the northern GAP on small grain cereals (2 x 0.45 kg a.s./ha).

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 these deficiencies are not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following actions and data are therefore considered desirable but not essential:

- an additional study investigating the nature of residues in poultry.

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
Enforcement residue definition: metaldehyde				
110000	Citrus fruits	0.05*	0.05*	Recommended ^(a)
120000	Tree nuts	0.05*	0.05*	Recommended ^(a)
130000	Pome fruits	0.05*	0.05*	Recommended ^(a)
140000	Stone fruits	0.05*	0.05*	Recommended ^(a)
151000	Table and wine grapes	0.05*	0.05*	Recommended ^(a)
152000	Strawberries	0.10	0.05*	Recommended ^(a)
153000	Cane fruits	0.05*	0.05*	Recommended ^(a)
154000	Other small fruits and berries	0.05*	0.05*	Recommended ^(a)
211000	Potatoes	0.15	0.15	Further consideration needed ^(b)
213010	Beetroot	2	0.3	Further consideration needed ^(b)
213020	Carrots	2	0.3	Further consideration needed ^(b)
213030	Celeriac	2	0.3	Further consideration needed ^(b)
213040	Horseradish	2	0.3	Further consideration needed ^(b)
213050	Jerusalem artichokes	2	0.3	Further consideration needed ^(b)
213060	Parsnips	2	0.3	Further consideration needed ^(b)
213070	Parsley root	2	0.3	Further consideration needed ^(b)
213080	Radishes	2	0.3	Further consideration needed ^(b)
213090	Salsify	2	0.3	Further consideration needed ^(b)
213100	Swedes	2	0.05*	Recommended ^(a)
213110	Turnips	2	0.3	Further consideration needed ^(b)
231010	Tomatoes	0.05*	0.15	Further consideration needed ^(b)
231030	Aubergines	0.05*	0.15	Further consideration needed ^(b)
241000	Flowering brassica	1	0.4	Further consideration needed ^(b)

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
242000	Head brassica	1	0.4	Further consideration needed ^(b)
243000	Leafy brassica	1	0.4	Further consideration needed ^(b)
244000	Kohlrabi	0.1	0.15	Further consideration needed ^(b)
251000	Lettuce and other salad plants including Brassicacea	2	2	Further consideration needed ^(b)
252000	Spinach and similar (leaves)	2	2	Further consideration needed ^(b)
256000	Herbs	2	2	Recommended ^(a)
260010	Beans (fresh, with pods)	0.05*	0.4	Further consideration needed ^(b)
260020	Beans (fresh, without pods)	0.05*	0.3	Further consideration needed ^(b)
260030	Peas (fresh, with pods)	0.05*	0.4	Further consideration needed ^(b)
260040	Peas (fresh, without pods)	0.05*	0.3	Further consideration needed ^(b)
270010	Asparagus	1	0.05*	Recommended ^(a)
270030	Celery	1	0.05*	Recommended ^(a)
270040	Fennel	1	0.05*	Recommended ^(a)
270050	Globe artichoke	1	0.07	Further consideration needed ^(b)
270060	Leek	1	0.5	Further consideration needed ^(b)
300000	Pulses (dry)	0.05*	0.2	Further consideration needed ^(b)
401010	Linseed	0.05*	0.60	Recommended ^(a)
401030	Poppy seed	0.05*	0.60	Recommended ^(a)
401040	Sesame seed	0.05*	0.60	Recommended ^(a)
401050	Sunflower seed	0.05*	0.60	Recommended ^(a)
401060	Rape seed	0.05*	0.60	Recommended ^(a)
401070	Soya bean	0.05*	0.60	Recommended ^(a)
401080	Mustard seed	0.05*	0.60	Recommended ^(a)
401090	Cotton seed	0.05*	0.60	Recommended ^(a)
401100	Pumpkin seeds	0.05*	0.60	Recommended ^(a)
401110	Safflower	0.05*	0.60	Recommended ^(a)
401120	Borage	0.05*	0.60	Recommended ^(a)
401130	Gold of pleasure	0.05*	0.60	Recommended ^(a)
401140	Hempseed	0.05*	0.60	Recommended ^(a)
500010	Barley grain	0.05*	0.05*	Recommended ^(a)
500030	Maize grain	0.05*	0.05*	Recommended ^(a)
500040	Millet grain	0.05*	0.05*	Recommended ^(a)
500050	Oats grain	0.05*	0.05*	Recommended ^(a)
500070	Rye grain	0.05*	0.05*	Recommended ^(a)
500080	Sorghum grain	0.05*	0.05*	Recommended ^(a)
500090	Wheat grain	0.05*	0.05*	Recommended ^(a)

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
900010	Sugar beet (root)	0.05*	0.05*	Recommended ^(a)
1011010	Swine meat	0.05*	0.05*	Further consideration needed ^(c)
1011020	Swine fat (free of lean meat)	0.05*	0.05*	Further consideration needed ^(c)
1011030	Swine liver	0.05*	0.05*	Further consideration needed ^(c)
1011040	Swine kidney	0.05*	0.05*	Further consideration needed ^(c)
1012010	Bovine meat	0.05*	0.05*	Further consideration needed ^(c)
1012020	Bovine fat	0.05*	0.05*	Further consideration needed ^(c)
1012030	Bovine liver	0.05*	0.05*	Further consideration needed ^(c)
1012040	Bovine kidney	0.05*	0.05*	Further consideration needed ^(c)
1013010	Sheep meat	0.05*	0.05*	Further consideration needed ^(c)
1013020	Sheep fat	0.05*	0.05*	Further consideration needed ^(c)
1013030	Sheep liver	0.05*	0.05*	Further consideration needed ^(c)
1013040	Sheep kidney	0.05*	0.05*	Further consideration needed ^(c)
1014010	Goat meat	0.05*	0.05*	Further consideration needed ^(c)
1014020	Goat fat	0.05*	0.05*	Further consideration needed ^(c)
1014030	Goat liver	0.05*	0.05*	Further consideration needed ^(c)
1014040	Goat kidney	0.05*	0.05*	Further consideration needed ^(c)
1016010	Poultry meat	0.05*	0.05*	Further consideration needed ^(c)
1016020	Poultry fat	0.05*	0.05*	Further consideration needed ^(c)
1016030	Poultry liver	0.05*	0.05*	Further consideration needed ^(c)
1020010	Cattle milk	0.05*	0.05*	Further consideration needed ^(c)
1020020	Sheep milk	0.05*	0.05*	Further consideration needed ^(c)
1020030	Goat milk	0.05*	0.05*	Further consideration needed ^(c)
1030000	Birds' eggs	0.05*	0.05*	Further consideration needed ^(c)
-	Other products of plant and animal origin	See App C	-	Further consideration needed ^(d)

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

(a): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix D).

(b): 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 was identified; no CXL is available (combination E-I in Appendix D).

(c): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL; no CXL is available (combination C-I in Appendix D).

(d): 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 metaldehyde prepared by the rapporteur Member State Austria in the framework of Article 12 of Regulation (EC) No 396/2005. Submitted to EFSA on 04 January 2012. Last updated on 25 January 2013.

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APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

Critical Outdoor GAPs for Northern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Method	Application				Application rate			PHI or waiting period (days)	Comments (max. 250 characters)		
Common name	Scientific name					Type	Content			Growth stage	Number		Interval (days)		Min. rate	Max. rate			Rate Unit	
							Conc.	Unit			From BBCH	Until BBCH	Min.	Max.						Min.
Almonds	<i>Prunus dulcis</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Brazil nuts	<i>Bertholletia excelsa</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Cashew nuts	<i>Anacardium occidentale</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Chestnuts	<i>Castanea sativa</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Coconuts	<i>Cocos nucifera</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Hazelnuts	<i>Corylus avellana</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Macadamia	<i>Macadamia ternifolia</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Pecans	<i>Carya illinoensis</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Pine nuts	<i>Pinus pinea</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Pistachios	<i>Pistachia vera</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Walnuts	<i>Juglans regia</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Apples	<i>Malus domestica</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Pears	<i>Pyrus communis</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Quinces	<i>Cydonia oblonga</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Medlar	<i>Mespilus germanica</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Loquat	<i>Eriobotrya japonica</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Apricots	<i>Prunus armeniaca</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Cherries	<i>Prunus cerasus, Prunus avium</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Peaches	<i>Prunus persica</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Plums	<i>Prunus domestica</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Table grapes	<i>Vitis vulpitis</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	69	2	7	14		0,45	kg a.i./ha	n.a. Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Wine grapes	<i>Vitis vulpitis</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	69	2	7	14		0,45	kg a.i./ha	n.a. Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Strawberries	<i>Fragaria x ananassa</i>	NEU	Outdoor	AT	slugs, snails	GR	64,0	g/kg	Soil treatment - granules in row	60	89	2	14			0,21	kg a.i./ha	n.a. application directly to the soil; max. total dose= 0.42 kg as/ha (NL GAP with PHI of 0 day was disregarded)		
Blackberries	<i>Rubus fruticosus</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	69	2	7	14		0,45	kg a.i./ha	n.a. Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Dewberries	<i>Rubus cerasius</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	69	2	7	14		0,45	kg a.i./ha	n.a. Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Raspberries	<i>Rubus idaeus</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	69	2	7	14		0,45	kg a.i./ha	n.a. Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Blueberries	<i>Vaccinium corymbosum</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	69	2	7	14		0,45	kg a.i./ha	n.a. Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Cranberries	<i>Vaccinium macrocarpon</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	69	2	7	14		0,45	kg a.i./ha	n.a. Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Currants (red, black and white)	<i>Ribes nigrum, rubrum</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	69	2	7	14		0,45	kg a.i./ha	n.a. Scattering at attack (broadcast ap.) only from 1 March to 1 September.		

Critical Outdoor GAPS for Northern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Method	Application				Application rate			PHI or waiting period (days)	Comments (max. 250 characters)		
Common name	Scientific name					Type	Content			From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min. rate			Max. rate	Rate Unit
							Conc.	Unit												
Gooseberries	<i>Ribes uva-crispa</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	69		2	7	14		0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.
Rose hips	<i>Rosa carina</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	69		2	7	14		0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.
Mulberries	<i>Morus spp.</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	69		2	7	14		0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.
Azarole (mediterranean medlar)	<i>Crataegus azarolus</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	69		2	7	14		0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.
Elderberries	<i>Sambucus nigra</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	69		2	7	14		0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.
Potatoes	<i>Tuber form Solanum Spp</i>	NEU	Outdoor	NEU	slugs, snails	GB	30,0	g/kg	Soil treatment - granules overall	0	45		3		14		0,21	kg a.i./ha	n.a.	Broadcast app. limited to BBCH 45 (EFSA Journal 2012; 10(1):2515). Other authorised GAP: Soil application with 2 applic. At 0.35 kg as/ha).
Beetroot	<i>Beta vulgaris subsp. Vulgaris</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall				2	7	14	0,42	0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.
Carrots	<i>Daucus carota</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall				2	7	14	0,42	0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.
Celeriac	<i>Apium graveolens var. rapaceum</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall				2	7	14	0,42	0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.
Horseradish	<i>Ammoracia rusticana</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall				2	7	14	0,42	0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.
Jerusalem artichokes	<i>Helianthus tuberosus</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall				2	7	14	0,42	0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.
Parsnips	<i>Pastinaca sativa</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall				2	7	14	0,42	0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.
Parsley root	<i>Petroselinum crispum</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall				2	7	14	0,42	0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.
Radishes	<i>Raphanus sativus var. sativus</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall				2	7	14	0,42	0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.
Salsify	<i>Tragopogon porrifolius</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall				2	7	14	0,42	0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.
Swedes	<i>Brassica napus var. napobrassica</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall				2	7	14	0,42	0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.
Turnips	<i>Brassica rapa</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall				2	7	14	0,42	0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.
Tomatoes	<i>Lycopersicon esculentum</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall				2	7	14	0,42	0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.
Aubergines (egg plants)	<i>Solanum melongena</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall				2	7	14	0,42	0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.
Broccoli	<i>Brassica oleracea var. italica</i>	NEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	40		4	5		0,10	0,20	kg a.i./ha	n.a.	Broadcast app. limited to BBCH 40 (max 0,7 kg ai/ha per season). Other authorised GAP: Banded between rows with 3 x 0,2 kg as/ha (until BBCH 49; PHI 1 d).
Cauliflower	<i>Brassica oleracea var. botrytis</i>	NEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	40		4	5		0,10	0,20	kg a.i./ha	n.a.	Broadcast app. limited to BBCH 40 (max 0,7 kg ai/ha per season). Other authorised GAP: Banded between rows with 3 x 0,2 kg as/ha (until BBCH 49; PHI 1 d).
Brussels sprouts	<i>Brassica oleracea var. gemmifera</i>	NEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	40		4	5		0,10	0,20	kg a.i./ha	n.a.	Broadcast app. limited to BBCH 40 (max 0,7 kg ai/ha per season). Other authorised GAP: Banded between rows with 3 x 0,2 kg as/ha (until BBCH 49; PHI 1 d).
Head cabbage	<i>Brassica oleracea convar capitata</i>	NEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	40		4	5		0,10	0,20	kg a.i./ha	n.a.	Broadcast app. limited to BBCH 40 (max 0,7 kg ai/ha per season). Other authorised GAP: Banded between rows with 3 x 0,2 kg as/ha (until BBCH 49; PHI 1 d).

Critical Outdoor GAPS for Northern Europe																			
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Method	Application				Application rate			PHI or waiting period (days)	Comments (max. 250 characters)	
Common name	Scientific name					Content		Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit			
						Conc.	Unit	From BBCH		Until BBCH	Min.	Max.	Min.						Max.
Chinese cabbage	<i>Brassica pekinensis</i>	NEU	Outdoor	DE	slugs, snails	GB	50,0	g/kg	Soil treatment - granules overall			2	14			0,35	kg a.i./ha		spreading at beginning of infestation; PHI still to be clarified.
Kale	<i>Brassica oleracea</i> convar. <i>Acephalea</i>	NEU	Outdoor	DE	slugs, snails	GB	50,0	g/kg	Soil treatment - granules overall			2	14			0,35	kg a.i./ha		spreading at beginning of infestation; PHI still to be clarified.
Kohlrabi	<i>Brassica oleracea</i> convar. <i>acephala</i> , var. <i>gongylodes</i>	NEU	Outdoor	DE	slugs, snails	GB	50,0	g/kg	Soil treatment - granules overall			2	14			0,35	kg a.i./ha		spreading at beginning of infestation; PHI still to be clarified.
Lamb's lettuce	<i>Valerianella locusta</i>	NEU	Outdoor	DE	slugs, snails	GB	50,0	g/kg	Soil treatment - granules overall			2	14			0,35	kg a.i./ha	3	PHI not specified by DE was derived from the available trials.
Lettuce	<i>Lactuca sativa</i>	NEU	Outdoor	DE	slugs, snails	GB	50,0	g/kg	Soil treatment - granules overall			2	14			0,35	kg a.i./ha	3	PHI not specified by DE was derived from the available trials.
Scarole (broad-leaf endive)	<i>Cichorium endivia</i>	NEU	Outdoor	DE	slugs, snails	GB	50,0	g/kg	Soil treatment - granules overall			2	14			0,35	kg a.i./ha	3	PHI not specified by DE was derived from the available trials.
Cress	<i>Lepidium sativum</i>	NEU	Outdoor	DE	slugs, snails	GB	50,0	g/kg	Soil treatment - granules overall			2	14			0,35	kg a.i./ha	3	PHI not specified by DE was derived from the available trials.
Land cress	<i>Barbarea verna</i>	NEU	Outdoor	DE	slugs, snails	GB	50,0	g/kg	Soil treatment - granules overall			2	14			0,35	kg a.i./ha	3	PHI not specified by DE was derived from the available trials.
Rocket, Rucola	<i>Eruca sativa</i> (<i>Diplotaxis spec.</i>)	NEU	Outdoor	DE	slugs, snails	GB	50,0	g/kg	Soil treatment - granules overall			2	14			0,35	kg a.i./ha	3	PHI not specified by DE was derived from the available trials.
Red mustard	<i>Brassica juncea</i> var. <i>rugosa</i>	NEU	Outdoor	DE	slugs, snails	GB	50,0	g/kg	Soil treatment - granules overall			2	14			0,35	kg a.i./ha	3	PHI not specified by DE was derived from the available trials.
Leaves and sprouts of Brassica spp	<i>Brassica spp</i>	NEU	Outdoor	DE	slugs, snails	GB	50,0	g/kg	Soil treatment - granules overall			2	14			0,35	kg a.i./ha	3	PHI not specified by DE was derived from the available trials.
Spinach	<i>Spinacia oleracea</i>	NEU	Outdoor	NL	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41	4		5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.
Purslane	<i>Portulaca oleracea</i>	NEU	Outdoor	NL	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41	4		5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.
Beet leaves (chard)	<i>Beta vulgaris</i>	NEU	Outdoor	NL	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41	4		5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.
Chervil	<i>Anthriscus cerefolium</i>	NEU	Outdoor	NL	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41	4		5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.
Chives	<i>Allium schoenoprasum</i>	NEU	Outdoor	NL	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41	4		5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.
Celery leaves	<i>Apium graveolens</i> var. <i>seccalinum</i>	NEU	Outdoor	NL	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41	4		5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.
Parsley	<i>Petroselinum crispum</i>	NEU	Outdoor	NL	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41	4		5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.
Sage	<i>Salvia officinalis</i>	NEU	Outdoor	NL	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41	4		5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.
Rosemary	<i>Rosmarinus officinalis</i>	NEU	Outdoor	NL	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41	4		5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.
Thyme	<i>Thymus spp.</i>	NEU	Outdoor	NL	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41	4		5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.

Critical Outdoor GAPS for Northern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Method	Application				Application rate			PHI or waiting period (days)	Comments (max. 250 characters)		
Common name	Scientific name					Type	Content			From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min. rate			Max. rate	Rate Unit
							Conc.	Unit												
Basil	<i>Ocimum basilicum</i>	NEU	Outdoor	NL	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41		4	5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.	
Bay leaves (laurel)	<i>Laurus nobilis</i>	NEU	Outdoor	NL	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41		4	5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.	
Tarragon	<i>Artemisia dracunculus</i>	NEU	Outdoor	NL	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41		4	5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.	
Beans (with pods)	<i>Phaseolus vulgaris</i>	NEU	Outdoor	UK	slugs, snails	GB	30,0	g/kg	Soil treatment - granules in row	0	50	1	2	7	14	0,18	0,35	kg a.i./ha	28	GAP reported in EFSA Journal 2014; 12(1):3537
Beans (without pods)	<i>Phaseolus vulgaris</i>	NEU	Outdoor	UK	slugs, snails	GB	30,0	g/kg	Soil treatment - granules in row	0	50	1	2	7	14	0,18	0,35	kg a.i./ha	28	GAP reported in EFSA Journal 2014; 12(1):3537
Peas (with pods)	<i>Pisum sativum</i>	NEU	Outdoor	UK	slugs, snails	GB	30,0	g/kg	Soil treatment - granules in row	0	50	1	2	7	14	0,18	0,35	kg a.i./ha	28	GAP reported in EFSA Journal 2014; 12(1):3537
Peas (without pods)	<i>Pisum sativum</i>	NEU	Outdoor	UK	slugs, snails	GB	30,0	g/kg	Soil treatment - granules in row	0	50	1	2	7	14	0,18	0,35	kg a.i./ha	28	GAP reported in EFSA Journal 2014; 12(1):3537
Celery	<i>Apium graveolens var. dulce</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall				2	7	14	0,42	0,45	kg a.i./ha		Scattering at attack (broadcast ap.) only from 1 March to 1 September.
Globe artichokes	<i>Cynara scolymus</i>	NEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	39		4	5		0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha.	
Leek	<i>Allium porum</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall				2	7	14	0,42	0,45	kg a.i./ha		Scattering at attack (broadcast ap.) only from 1 March to 1 September.
Beans (dry)	<i>Phaseolus vulgaris</i>	NEU	Outdoor	UK	slugs, snails	GB	50,0	g/kg	Soil treatment - granules in row	0	19	1	2	7	14	0,18	0,35	kg a.i./ha	n.a.	GAP reported in EFSA Journal 2014; 12(1):3537 - another GAP with app rate 0,45 kg ai/ha still authorised in NL (no trials).
Lentils (dry)	<i>Lens culinaris syn. L. esculenta</i>	NEU	Outdoor	UK	slugs, snails	GB	50,0	g/kg	Soil treatment - granules in row	0	19	1	2	7	14	0,18	0,35	kg a.i./ha	n.a.	GAP reported in EFSA Journal 2014; 12(1):3537 - another GAP with app rate 0,45 kg ai/ha still authorised in NL (no trials).
Peas (dry)	<i>Pisum sativum</i>	NEU	Outdoor	UK	slugs, snails	GB	50,0	g/kg	Soil treatment - granules in row	0	19	1	2	7	14	0,18	0,35	kg a.i./ha	n.a.	GAP reported in EFSA Journal 2014; 12(1):3537 - another GAP with app rate 0,45 kg ai/ha still authorised in NL (no trials).
Lupins	<i>Lupinus spp.</i>	NEU	Outdoor	UK	slugs, snails	GB	50,0	g/kg	Soil treatment - granules in row	0	19	1	2	7	14	0,18	0,35	kg a.i./ha	n.a.	GAP reported in EFSA Journal 2014; 12(1):3537 - another GAP with app rate 0,45 kg ai/ha still authorised in NL (no trials).
Linseed	<i>Linum usitatissimum</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	29	1	2	14		0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September. EFSA Journal 2012; 10(1): 2515	
Poppy seed	<i>Papaver somniferum</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	29	1	2	14		0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September. EFSA Journal 2012; 10(1): 2515	
Sesame seed	<i>Sesamum indicum syn. S. orientale</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	29	1	2	7	14		0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.
Sunflower seed	<i>Helianthus annuus</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	29	1	2	7	14		0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.
Rape seed	<i>Brassica napus</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	29	1	2	7	14		0,45	kg a.i./ha	n.a.	EFSA Journal 2012; 10(1): 2515. Other GAP: 3x0.21 kg as/ha, PHI not specified"; compliant residue data were combined.
Soya bean	<i>Glycine max</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	29	1	2	7	14		0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.
Mustard seed	<i>Brassica nigra</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	29	1	2	7	14		0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September; EFSA Journal 2012; 10(1): 2515.
Cotton seed	<i>Gossypium spp.</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	29	1	2	7	14		0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.

Critical Outdoor GAPs for Northern Europe																						
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Method	Application						Application rate			PHI or waiting period (days)	Comments (max. 250 characters)		
Common name	Scientific name					Type	Content			From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Min. rate			Max. rate	Rate Unit
							Conc.	Unit														
Pumpkin seeds	<i>Cucurbita pepo var. oleifera</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	29	1	2	7	14		0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Safflower	<i>Carthamus tinctorius</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	29	1	2	7	14		0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Borage	<i>Borago officinalis</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	29	1	2	7	14		0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Gold of pleasure	<i>Camelina sativa</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	29	1	2	7	14		0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Hempseed	<i>Cannabis sativa</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	29	1	2	7	14		0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Barley	<i>Hordeum spp.</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	29		2	7	14	0,42	0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September; winter cereals only allowed in period 1 September - 1 March		
Maize	<i>Zea mays</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	15		2	7	14	0,42	0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September; winter cereals only allowed in period 1 September - 1 March		
Millet	<i>Panicum spp.</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	15		2	7	14	0,42	0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September; winter cereals only allowed in period 1 September - 1 March		
Oats	<i>Avena fatua</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	29		2	7	14	0,42	0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September; winter cereals only allowed in period 1 September - 1 March		
Rye	<i>Secale cereale</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	29		2	7	14	0,42	0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September; winter cereals only allowed in period 1 September - 1 March		
Sorghum	<i>Sorghum bicolor</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	15		2	7	14	0,42	0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September; winter cereals only allowed in period 1 September - 1 March		
Wheat	<i>Triticum aestivum</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	29		2	7	14	0,42	0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September; winter cereals only allowed in period 1 September - 1 March		
Sugar beet	<i>Beta vulgaris</i>	NEU	Outdoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	15		2	7	14	0,42	0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.)		
Grass	<i>not specified</i>	NEU	Outdoor	AT	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	15		4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha			

n.a.: not applicable

Critical Outdoor GAPs for Southern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Method	Application				Application rate			PHI or waiting period (days)	Comments (max. 250 characters)		
Common name	Scientific name					Type	Content			From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min. rate			Max. rate	Rate Unit
							Conc.	Unit												
Grapefruit	<i>Citrus paradisi</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Oranges	<i>Citrus sinensis</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Lemons	<i>Citrus limon</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Limes	<i>Citrus aurantifolia</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Mandarins	<i>Citrus reticulata</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Almonds	<i>Prunus dulcis</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Brazil nuts	<i>Bertholletia excelsa</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Cashew nuts	<i>Anacardium occidentale</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Chestnuts	<i>Castanea sativa</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Coconuts	<i>Cocos nucifera</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Hazelnuts	<i>Corylus avellana</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Macadamia	<i>Macadamia ternifolia</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Pecans	<i>Carya illinoensis</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Pine nuts	<i>Pinus pinea</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Pistachios	<i>Pistachia vera</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Walnuts	<i>Juglans regia</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Apples	<i>Malus domestica</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Pears	<i>Pyrus communis</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Quinces	<i>Cydonia oblonga</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Medlar	<i>Mespilus germanica</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Loquat	<i>Eriobotrya japonica</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Apricots	<i>Prunus armeniaca</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Cherries	<i>Prunus cerasus</i> , <i>Prunus avium</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Peaches	<i>Prunus persica</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Plums	<i>Prunus domestica</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Table grapes	<i>Vitis euveitis</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Wine grapes	<i>Vitis euveitis</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Blackberries	<i>Rubus fruticosus</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Dewberries	<i>Rubus ceasus</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Raspberries	<i>Rubus idaeus</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Blueberries	<i>Vaccinium corymbosum</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Cranberries	<i>Vaccinium macrocarpon</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		
Currants (red, black and white)	<i>Ribes nigrum</i> , <i>rubrum</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69	4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha		

Critical Outdoor GAPs for Southern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Method	Application				Application rate			PHI or waiting period (days)	Comments (max. 250 characters)		
Common name	Scientific name					Type	Content			From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min. rate			Max. rate	Rate Unit
							Conc.	Unit												
Gooseberries	<i>Ribes uva-crispa</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69		4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha	
Rose hips	<i>Rosa canina</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69		4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha	
Mulberries	<i>Morus spp.</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69		4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha	
Azarole (mediterranean medlar)	<i>Crataegus azarolus</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69		4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha	
Elderberries	<i>Sambucus nigra</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	69		4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha	
Potatoes	<i>Tuber form Solanum Spp</i>	SEU	Outdoor	FR	slugs, snails	GB	30,0	g/kg	Soil treatment - granules in row	0	45		3	14		0,21	kg a.i./ha	n.a.	application directly to the soil EFSA Journal 2012; 10(1):2515	
Beetroot	<i>Beta vulgaris subsp. Vulgaris</i>	SEU	Outdoor	IT	slugs, snails	GR	5,0	g/kg	Soil treatment - granules in row	0	49		2			0,35	kg a.i./ha	20	application directly to the soil; max. total dose= 0.7 kg as/ha	
Carrots	<i>Daucus carota</i>	SEU	Outdoor	IT	slugs, snails	GR	5,0	g/kg	Soil treatment - granules in row	0	49		2			0,35	kg a.i./ha	20	application directly to the soil; max. total dose= 0.7 kg as/ha	
Celeriac	<i>Apium graveolens var. rapaceum</i>	SEU	Outdoor	IT	slugs, snails	GR	5,0	g/kg	Soil treatment - granules in row	0	49		2			0,35	kg a.i./ha	20	application directly to the soil; max. total dose= 0.7 kg as/ha	
Horseradish	<i>Ammoracia rusticana</i>	SEU	Outdoor	IT	slugs, snails	GR	5,0	g/kg	Soil treatment - granules in row	0	49		2			0,35	kg a.i./ha	20	application directly to the soil; max. total dose= 0.7 kg as/ha	
Jerusalem artichokes	<i>Helianthus tuberosus</i>	SEU	Outdoor	IT	slugs, snails	GR	5,0	g/kg	Soil treatment - granules in row	0	49		2			0,35	kg a.i./ha	20	application directly to the soil; max. total dose= 0.7 kg as/ha	
Parsnips	<i>Pastinaca sativa</i>	SEU	Outdoor	IT	slugs, snails	GR	5,0	g/kg	Soil treatment - granules in row	0	49		2			0,35	kg a.i./ha	20	application directly to the soil; max. total dose= 0.7 kg as/ha	
Parsley root	<i>Petroselinum crispum</i>	SEU	Outdoor	IT	slugs, snails	GR	5,0	g/kg	Soil treatment - granules in row	0	49		2			0,35	kg a.i./ha	20	application directly to the soil; max. total dose= 0.7 kg as/ha	
Radishes	<i>Raphanus sativus var. sativus</i>	SEU	Outdoor	IT	slugs, snails	GR	5,0	g/kg	Soil treatment - granules in row	0	49		2			0,35	kg a.i./ha	20	application directly to the soil; max. total dose= 0.7 kg as/ha	
Salsify	<i>Tragopogon porifolius</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	15		4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha	
Swedes	<i>Brassica napus var. napobrassica</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	15		4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha	
Turnips	<i>Brassica rapa</i>	SEU	Outdoor	IT	slugs, snails	GR	5,0	g/kg	Soil treatment - granules in row	0	49		2			0,35	kg a.i./ha	20	application directly to the soil; max. total dose= 0.7 kg as/ha	
Broccoli	<i>Brassica oleracea var. italica</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	40		4	5	0,10	0,20	kg a.i./ha	n.a.	Broadcast app. limited to BBCH 40 (max 0,7 kg ai/ha per season). Other authorised GAP: Banded between rows with 3 x 0,2 kg as/ha (until BBCH 49; PHI 1 d).	
Cauliflower	<i>Brassica oleracea var. botrytis</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	40		4	5	0,10	0,20	kg a.i./ha	n.a.	Broadcast app. limited to BBCH 40 (max 0,7 kg ai/ha per season). Other authorised GAP: Banded between rows with 3 x 0,2 kg as/ha (until BBCH 49; PHI 1 d).	
Brussels sprouts	<i>Brassica oleracea var. gemmifera</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	40		4	5	0,10	0,20	kg a.i./ha	n.a.	Broadcast app. limited to BBCH 40 (max 0,7 kg ai/ha per season). Other authorised GAP: Banded between rows with 3 x 0,2 kg as/ha (until BBCH 49; PHI 1 d).	
Head cabbage	<i>Brassica oleracea convar capitata</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	40		4	5	0,10	0,20	kg a.i./ha	n.a.	Broadcast app. limited to BBCH 40 (max 0,7 kg ai/ha per season). Other authorised GAP: Banded between rows with 3 x 0,2 kg as/ha (until BBCH 49; PHI 1 d).	
Lamb's lettuce	<i>Valerianella locusta</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41		4	5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.	
Lettuce	<i>Lactuca sativa</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41		4	5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.	
Scarole (broad-leaf endive)	<i>Cichorium endiva</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41		4	5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.	

Critical Outdoor GAPS for Southern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Method	Application				Application rate			PHI or waiting period (days)	Comments (max. 250 characters)		
Common name	Scientific name					Type	Content			From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min. rate			Max. rate	Rate Unit
							Conc.	Unit												
Cress	<i>Lepidium sativum</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41		4	5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.	
Land cress	<i>Barbarea verna</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41		4	5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.	
Rocket, Rucola	<i>Eruca sativa</i> (<i>Diplotaxis spec.</i>)	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41		4	5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.	
Red mustard	<i>Brassica juncea</i> var. <i>rugosa</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41		4	5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.	
Leaves and sprouts of Brassica spp	<i>Brassica</i> spp	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41		4	5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.	
Spinach	<i>Spinacia oleracea</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41		4	5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.	
Purslane	<i>Portulaca oleracea</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41		4	5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.	
Beet leaves (chard)	<i>Beta vulgaris</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41		4	5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.	
Chervil	<i>Anthriscus cerefolium</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41		4	5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.	
Chives	<i>Allium schoenoprasum</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41		4	5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.	
Celery leaves	<i>Apium graveolens</i> var. <i>seccalinum</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41		4	5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.	
Parsley	<i>Petroselinum crispum</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41		4	5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.	
Sage	<i>Salvia officinalis</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41		4	5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.	
Rosemary	<i>Rosmarinus officinalis</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41		4	5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.	
Thyme	<i>Thymus</i> spp.	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41		4	5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.	
Basil	<i>Ocimum basilicum</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41		4	5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.	

Critical Outdoor GAPs for Southern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Method	Application				Application rate			PHI or waiting period (days)	Comments (max. 250 characters)		
Common name	Scientific name					Type	Content			From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min. rate			Max. rate	Rate Unit
							Conc.	Unit												
Bay leaves (laurel)	<i>Laurus nobilis</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41		4	5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.	
Tarragon	<i>Artemisia dracunculus</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules overall	0	41		4	5	0,10	0,20	kg a.i./ha	n.a.	Max seasonal app. rate 700 g as/ha. Also including seed admixture or in-furrow application, where specified.	
Beans (with pods)	<i>Phaseolus vulgaris</i>	SEU	Outdoor	ES	slugs, snails	GB	30,0	g/kg	Soil treatment - granules in row	0	50	1	2	7	14	0,18	0,35	kg a.i./ha	28	GAP reported in EFSA Journal 2014; 12(1):3537
Beans (without pods)	<i>Phaseolus vulgaris</i>	SEU	Outdoor	ES	slugs, snails	GB	30,0	g/kg	Soil treatment - granules in row	0	50	1	2	7	14	0,18	0,35	kg a.i./ha	28	GAP reported in EFSA Journal 2014; 12(1):3537
Peas (with pods)	<i>Pisum sativum</i>	SEU	Outdoor	ES	slugs, snails	GB	30,0	g/kg	Soil treatment - granules in row	0	50	1	2	7	14	0,18	0,35	kg a.i./ha	28	GAP reported in EFSA Journal 2014; 12(1):3537
Peas (without pods)	<i>Pisum sativum</i>	SEU	Outdoor	ES	slugs, snails	GB	30,0	g/kg	Soil treatment - granules in row	0	50	1	2	7	14	0,18	0,35	kg a.i./ha	28	GAP reported in EFSA Journal 2014; 12(1):3537
Asparagus	<i>Asparagus officinalis</i>	SEU	Outdoor	IT	slugs, snails	GR	5,0	g/kg	Soil treatment - granules in row				2	7	14		0,35	kg a.i./ha	20	application directly to the soil; max. total dose= 0.7 kg as/ha
Celery	<i>Apium graveolens var. dulce</i>	SEU	Outdoor	IT	slugs, snails	GR	5,0	g/kg	Soil treatment - granules in row	0	19		2	7	14		0,35	kg a.i./ha	20	application directly to the soil; max. total dose= 0.7 kg as/ha
Fennel	<i>Foeniculum vulgare</i>	SEU	Outdoor	IT	slugs, snails	GR	5,0	g/kg	Soil treatment - granules in row				2	7	14		0,35	kg a.i./ha	20	application directly to the soil; max. total dose= 0.7 kg as/ha
Globe artichokes	<i>Cynara scolymus</i>	SEU	Outdoor	IT	slugs, snails	GR	5,0	g/kg	Soil treatment - granules in row				2	7	14		0,35	kg a.i./ha	20	application directly to the soil; max. total dose= 0.7 kg as/ha
Leek	<i>Allium porum</i>	SEU	Outdoor	IT	slugs, snails	GR	5,0	g/kg	Soil treatment - granules in row				2	7	14		0,35	kg a.i./ha	20	application directly to the soil; max. total dose= 0.7 kg as/ha
Beans (dry)	<i>Phaseolus vulgaris</i>	SEU	Outdoor	FR	slugs, snails	GB	50,0	g/kg	Soil treatment - granules in row	0	19	1	2	7	14	0,18	0,35	kg a.i./ha	n.a.	GAP reported in EFSA Journal 2014; 12(1):3537 - another GAP with app rate 0,45 kg ai/ha still authorised in NL (no trials).
Lentils (dry)	<i>Lens culinaris syn. L. esculenta</i>	SEU	Outdoor	FR	slugs, snails	GB	50,0	g/kg	Soil treatment - granules in row	0	19	1	2	7	14	0,18	0,35	kg a.i./ha	n.a.	GAP reported in EFSA Journal 2014; 12(1):3537 - another GAP with app rate 0,45 kg ai/ha still authorised in NL (no trials).
Peas (dry)	<i>Pisum sativum</i>	SEU	Outdoor	FR	slugs, snails	GB	50,0	g/kg	Soil treatment - granules in row	0	19	1	2	7	14	0,18	0,35	kg a.i./ha	n.a.	GAP reported in EFSA Journal 2014; 12(1):3537 - another GAP with app rate 0,45 kg ai/ha still authorised in NL (no trials).
Lupins	<i>Lupinus spp.</i>	SEU	Outdoor	FR	slugs, snails	GB	50,0	g/kg	Soil treatment - granules in row	0	19	1	2	7	14	0,18	0,35	kg a.i./ha	n.a.	GAP reported in EFSA Journal 2014; 12(1):3537 - another GAP with app rate 0,45 kg ai/ha still authorised in NL (no trials).
Sesame seed	<i>Sesamum indicum syn. S. orientale</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	17		4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha	
Sunflower seed	<i>Helianthus annuus</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	17		4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha	
Soya bean	<i>Glycine max</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	17		4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha	
Cotton seed	<i>Gossypium spp.</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	17		4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha	
Pumpkin seeds	<i>Cucurbita pepo var. oleifera</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	17		4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha	
Safflower	<i>Carthamus tinctorius</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	17		4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha	
Borage	<i>Borago officinalis</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	17		4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha	
Gold of pleasure	<i>Camelina sativa</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	17		4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha	
Hempseed	<i>Cannabis sativa</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	17		4	5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha	

Critical Outdoor GAPs for Southern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Method	Application				Application rate			PHI or waiting period (days)	Comments (max. 250 characters)		
Common name	Scientific name					Type	Content			From BBCH	Until BBCH	Number Min. Max.	Interval (days) Min. Max.	Min. rate	Max. rate	Rate Unit				
							Conc.	Unit												
Barley	<i>Hordeum spp.</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	29		4		5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha
Maize	<i>Zea mays</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	15		4		5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha
Millet	<i>Panicum spp.</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	15		4		5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha
Oats	<i>Avena fatua</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	29		4		5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha
Rye	<i>Secale cereale</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	29		4		5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha
Sorghum	<i>Sorghum bicolor</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	15		4		5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha
Wheat	<i>Triticum aestivum</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	29		4		5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha
Sugar beet	<i>Beta vulgaris</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	15		4		5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha
Grass	<i>not specified</i>	SEU	Outdoor	FR	slugs, snails	GB	40,0	g/kg	Soil treatment - granules in row	0	15		4		5	0,10	0,20	kg a.i./ha	n.a.	application directly to the soil; max. total dose= 0.7 kg as/ha

n.a.: not applicable

Critical Indoor GAPs for Northern and Southern Europe (incl. post-harvest treatments)																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Method	Application				Application rate			PHI or waiting period (days)	Comments (max. 250 characters)		
Common name	Scientific name					Type	Content			Growth stage	Number		Interval (days)		Min. rate	Max. rate			Rate Unit	
							Conc.	Unit			From BBCH	Until BBCH	Min.	Max.						Min.
Apricots	<i>Prunus armeniaca</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Cherries	<i>Prunus cerasus</i> , <i>Prunus avium</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Peaches	<i>Prunus persica</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Plums	<i>Prunus domestica</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Table grapes	<i>Vitis evitis</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	69	2	7	14		0,45	kg a.i./ha	n.a. Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Wine grapes	<i>Vitis evitis</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	69	2	7	14		0,45	kg a.i./ha	n.a. Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Strawberries	<i>Fragaria x ananassa</i>	NEU/SEU	Indoor	AT	slugs, snails	GR	64,0	g/kg	Soil treatment - granules in row	60	89	2	14			0,21	kg a.i./ha	n.a. application directly to the soil; max. total dose= 0.42 kg as/ha (NL GAP with PHI of 0 day was disregarded)		
Blackberries	<i>Rubus fruticosus</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Dewberries	<i>Rubus caesius</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Raspberries	<i>Rubus idaeus</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Blueberries	<i>Vaccinium corymbosum</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Cranberries	<i>Vaccinium macrocarpon</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Currants (red, black and white)	<i>Ribes nigrum</i> , <i>rubrum</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Gooseberries	<i>Ribes uva-crispa</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Rose hips	<i>Rosa canina</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Mulberries	<i>Morus spp.</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Azarole (mediterranean medlar)	<i>Crataegus azarolus</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Elderberries	<i>Sambucus nigra</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14		0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Tomatoes	<i>Lycopersicon esculentum</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14	0,42	0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Aubergines (egg plants)	<i>Solanum melongena</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14	0,42	0,45	kg a.i./ha	Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Broccoli	<i>Brassica oleracea</i> var. <i>italica</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	49	2	7	14	0,42	0,45	kg a.i./ha	n.a. Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Cauliflower	<i>Brassica oleracea</i> var. <i>botrytis</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	49	2	7	14	0,42	0,45	kg a.i./ha	n.a. Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Brussels sprouts	<i>Brassica oleracea</i> var. <i>gemmifera</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	49	2	7	14	0,42	0,45	kg a.i./ha	n.a. Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Head cabbage	<i>Brassica oleracea</i> convar. <i>capitata</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	49	2	7	14	0,42	0,45	kg a.i./ha	n.a. Scattering at attack (broadcast ap.) only from 1 March to 1 September.		
Chinese cabbage	<i>Brassica pekinensis</i>	NEU/SEU	Indoor	DE	slugs, snails	GB	50,0	g/kg	Soil treatment - granules overall			2	14			0,35	kg a.i./ha	spreading at beginning of infestation; PHI still to be clarified.		
Kale	<i>Brassica oleracea</i> convar. <i>Acephala</i>	NEU/SEU	Indoor	DE	slugs, snails	GB	50,0	g/kg	Soil treatment - granules overall			2	14			0,35	kg a.i./ha	spreading at beginning of infestation; PHI still to be clarified.		
Kohlrabi	<i>Brassica oleracea</i> convar. <i>acephala</i> , var. <i>gongylodes</i>	NEU/SEU	Indoor	DE	slugs, snails	GB	50,0	g/kg	Soil treatment - granules overall			2	14			0,35	kg a.i./ha	spreading at beginning of infestation; PHI still to be clarified.		

Critical Indoor GAPs for Northern and Southern Europe (incl. post-harvest treatments)																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Method	Application				Application rate			PHI or waiting period (days)	Comments (max. 250 characters)		
Common name	Scientific name					Type	Content			Growth stage	Number		Interval (days)		Min. rate	Max. rate			Rate Unit	
							Conc.	Unit			From BBCH	Until BBCH	Min.	Max.						Min.
Lamb's lettuce	<i>Valerianella locusta</i>	NEU/SEU	Indoor	IT, DE	slugs, snails	GR	5,0	g/kg	Soil treatment - granules overall	0	19	2	7	14	0,35	kg a.i./ha	20	max rate per season: 0,7 kg ai/ha. Other authorised GAP in NL: 2x0,45 kg ai/ha (broadcast); no PHI		
Lettuce	<i>Lactuca sativa</i>	NEU/SEU	Indoor	IT, DE	slugs, snails	GR	5,0	g/kg	Soil treatment - granules overall	0	19	2	7	14	0,35	kg a.i./ha	20	max rate per season: 0,7 kg ai/ha. Other authorised GAP in NL: 2x0,45 kg ai/ha (broadcast); no PHI		
Scarole (broad-leaf endive)	<i>Cichorium endiva</i>	NEU/SEU	Indoor	IT, DE	slugs, snails	GR	5,0	g/kg	Soil treatment - granules overall	0	19	2	7	14	0,35	kg a.i./ha	20	max rate per season: 0,7 kg ai/ha. Other authorised GAP in NL: 2x0,45 kg ai/ha (broadcast); no PHI		
Cress	<i>Lepidium sativum</i>	NEU/SEU	Indoor	IT, DE	slugs, snails	GR	5,0	g/kg	Soil treatment - granules overall	0	19	2	7	14	0,35	kg a.i./ha	20	max rate per season: 0,7 kg ai/ha. Other authorised GAP in NL: 2x0,45 kg ai/ha (broadcast); no PHI		
Land cress	<i>Barbarea verna</i>	NEU/SEU	Indoor	IT, DE	slugs, snails	GR	5,0	g/kg	Soil treatment - granules overall	0	19	2	7	14	0,35	kg a.i./ha	20	max rate per season: 0,7 kg ai/ha. Other authorised GAP in NL: 2x0,45 kg ai/ha (broadcast); no PHI		
Rocket, Rucola	<i>Eruca sativa (Diplotaxis spec.)</i>	NEU/SEU	Indoor	IT, DE	slugs, snails	GR	5,0	g/kg	Soil treatment - granules overall	0	19	2	7	14	0,35	kg a.i./ha	20	max rate per season: 0,7 kg ai/ha. Other authorised GAP in NL: 2x0,45 kg ai/ha (broadcast); no PHI		
Red mustard	<i>Brassica juncea var. rugosa</i>	NEU/SEU	Indoor	IT, DE	slugs, snails	GR	5,0	g/kg	Soil treatment - granules overall	0	19	2	7	14	0,35	kg a.i./ha	20	max rate per season: 0,7 kg ai/ha. Other authorised GAP in NL: 2x0,45 kg ai/ha (broadcast); no PHI		
Leaves and sprouts of Brassica spp	<i>Brassica spp</i>	NEU/SEU	Indoor	IT, DE	slugs, snails	GR	5,0	g/kg	Soil treatment - granules overall	0	19	2	7	14	0,35	kg a.i./ha	20	max rate per season: 0,7 kg ai/ha. Other authorised GAP in NL: 2x0,45 kg ai/ha (broadcast); no PHI		
Chervil	<i>Anthriscus cerefolium</i>	NEU/SEU	Indoor	IT	slugs, snails	GR	5,0	g/kg	Soil treatment - granules overall	0	19	2	7	14	0,35	kg a.i./ha	20	max rate per season: 0,7 kg ai/ha.		
Chives	<i>Allium schoenoprasum</i>	NEU/SEU	Indoor	IT	slugs, snails	GR	5,0	g/kg	Soil treatment - granules overall	0	19	2	7	14	0,35	kg a.i./ha	20	max rate per season: 0,7 kg ai/ha.		
Celery leaves	<i>Apium graveolens var. seccalinum</i>	NEU/SEU	Indoor	IT	slugs, snails	GR	5,0	g/kg	Soil treatment - granules overall	0	19	2	7	14	0,35	kg a.i./ha	20	max rate per season: 0,7 kg ai/ha.		
Parsley	<i>Petroselinum crispum</i>	NEU/SEU	Indoor	IT	slugs, snails	GR	5,0	g/kg	Soil treatment - granules overall	0	19	2	7	14	0,35	kg a.i./ha	20	max rate per season: 0,7 kg ai/ha.		
Sage	<i>Salvia officinalis</i>	NEU/SEU	Indoor	IT	slugs, snails	GR	5,0	g/kg	Soil treatment - granules overall	0	19	2	7	14	0,35	kg a.i./ha	20	max rate per season: 0,7 kg ai/ha.		
Rosemary	<i>Rosmarinus officinalis</i>	NEU/SEU	Indoor	IT	slugs, snails	GR	5,0	g/kg	Soil treatment - granules overall	0	19	2	7	14	0,35	kg a.i./ha	20	max rate per season: 0,7 kg ai/ha.		
Thyme	<i>Thymus spp.</i>	NEU/SEU	Indoor	IT	slugs, snails	GR	5,0	g/kg	Soil treatment - granules overall	0	19	2	7	14	0,35	kg a.i./ha	20	max rate per season: 0,7 kg ai/ha.		
Basil	<i>Ocimum basilicum</i>	NEU/SEU	Indoor	IT	slugs, snails	GR	5,0	g/kg	Soil treatment - granules overall	0	19	2	7	14	0,35	kg a.i./ha	20	max rate per season: 0,7 kg ai/ha.		
Bay leaves (laurel)	<i>Laurus nobilis</i>	NEU/SEU	Indoor	IT	slugs, snails	GR	5,0	g/kg	Soil treatment - granules overall	0	19	2	7	14	0,35	kg a.i./ha	20	max rate per season: 0,7 kg ai/ha.		
Tarragon	<i>Artemisia dracunculus</i>	NEU/SEU	Indoor	IT	slugs, snails	GR	5,0	g/kg	Soil treatment - granules overall	0	19	2	7	14	0,35	kg a.i./ha	20	max rate per season: 0,7 kg ai/ha.		
Beans (with pods)	<i>Phaseolus vulgaris</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	15	2	7	14	0,42	0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.	
Beans (without pods)	<i>Phaseolus vulgaris</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	15	2	7	14	0,42	0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.	
Peas (with pods)	<i>Pisum sativum</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	15	2	7	14	0,42	0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.	
Peas (without pods)	<i>Pisum sativum</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall	0	15	2	7	14	0,42	0,45	kg a.i./ha	n.a.	Scattering at attack (broadcast ap.) only from 1 March to 1 September.	
Celery	<i>Apium graveolens var. dulce</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14	0,42	0,45	kg a.i./ha		Scattering at attack (broadcast ap.) only from 1 March to 1 September.	
Leek	<i>Allium porum</i>	NEU/SEU	Indoor	NL	slugs, snails	GR	64,0	g/kg	Soil treatment - granules overall			2	7	14	0,42	0,45	kg a.i./ha		Scattering at attack (broadcast ap.) only from 1 March to 1 September.	

n.a.: not applicable

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Metaldehyde			
Status of the active substance:	Included	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0,02	ARfD (mg/kg bw):	0,3
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2010	Year of evaluation:	2010

Chronic risk assessment - refined calculations								
		TMDI (range) in % of ADI minimum - maximum						
		2 16						
		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)
16,4	FR toddler	9,9	Milk and cream,	1,7	Spinach	0,8	Potatoes	
15,3	NL child	7,3	Milk and cream,	1,6	Apples	0,9	Potatoes	
14,9	UK Infant	9,7	Milk and cream,	2,5	Sugar beet (root)	0,5	Potatoes	
13,6	UK Toddler	5,7	Sugar beet (root)	5,2	Milk and cream,	0,5	Potatoes	
11,4	DE child	3,6	Milk and cream,	3,0	Apples	1,0	Oranges	
10,6	FR infant	6,4	Milk and cream,	1,1	Spinach	0,6	Apples	
7,9	WHO Cluster diet B	0,9	Lettuce	0,8	Milk and cream,	0,8	Tomatoes	
7,9	ES child	3,1	Milk and cream,	1,0	Lettuce	0,5	Oranges	
5,9	SE general population 90th percentile	3,1	Milk and cream,	0,6	Potatoes	0,3	Apples	
5,9	IE adult	0,7	Milk and cream,	0,6	Maize	0,3	Potatoes	
5,9	DK child	3,2	Milk and cream,	0,6	Apples	0,4	Potatoes	
5,5	WHO regional European diet	1,2	Milk and cream,	0,9	Lettuce	0,6	Potatoes	
5,3	NL general	1,6	Milk and cream,	0,4	Potatoes	0,4	Oranges	
5,1	ES adult	1,3	Lettuce	1,2	Milk and cream,	0,3	Oranges	
5,0	WHO cluster diet E	0,7	Milk and cream,	0,6	Potatoes	0,4	Wine grapes	
4,8	WHO Cluster diet F	1,0	Milk and cream,	0,7	Lettuce	0,5	Potatoes	
4,5	WHO cluster diet D	1,3	Milk and cream,	0,6	Potatoes	0,3	Wheat	
4,1	FR all population	1,0	Wine grapes	0,7	Milk and cream,	0,5	Other lettuce and other salad	
3,6	UK vegetarian	0,9	Sugar beet (root)	0,8	Milk and cream,	0,3	Lettuce	
3,3	UK Adult	1,0	Sugar beet (root)	0,7	Milk and cream,	0,3	Lettuce	
3,2	IT adult	0,9	Lettuce	0,4	Other lettuce and other salad plants	0,3	Tomatoes	
3,1	LT adult	1,0	Milk and cream,	0,5	Potatoes	0,5	Apples	
3,1	IT kids/toddler	0,7	Lettuce	0,4	Tomatoes	0,3	Wheat	
3,0	PT General population	0,8	Potatoes	0,6	Wine grapes	0,3	Apples	
2,9	DK adult	1,3	Milk and cream,	0,3	Wine grapes	0,2	Potatoes	
2,7	FI adult	1,4	Milk and cream,	0,2	Oranges	0,2	Lettuce	
1,9	PL general population	0,5	Potatoes	0,5	Apples	0,2	Tomatoes	

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

Acute risk assessment /children - refined calculations	Acute risk assessment / adults / general population - refined calculations
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The acute risk assessment is based on the ARfD.

For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100 % of the ARfD.

Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):			No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):		
	---			---			---			---		
	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)
36,7	Scarole (broad-leaf)	1,26 / -	36,7	Scarole (broad-leaf)	1,26 / -	4,6	Lettuce	1,26 / -	3,9	Purslane	1,26 / -	
11,3	Lettuce	1,26 / -	9,5	Spinach	1,26 / -	4,3	Purslane	1,26 / -	3,8	Cauliflower	0,36 / -	
9,5	Spinach	1,26 / -	7,9	Cauliflower	0,36 / -	3,8	Cauliflower	0,36 / -	3,8	Spinach	1,26 / -	
7,9	Cauliflower	0,36 / -	6,8	Lettuce	1,26 / -	3,8	Head cabbage	0,36 / -	3,7	Scarole (broad-leaf endive)	1,26 / -	
7,4	Beet leaves (chard)	1,26 / -	5,6	Beet leaves	1,26 / -	3,8	Spinach	1,26 / -	2,8	Lettuce	1,26 / -	
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:		
	---			---		
	***)	pTMRL/	threshold MRL	***)	pTMRL/	threshold MRL
	Highest % of ARfD/ADI	Processed commodities	(mg/kg)	Highest % of ARfD/ADI	Processed commodities	(mg/kg)
1,9	Carrot, juice	0,13 / -	0,2	Orange juice	0,05 / -	
0,8	Apple juice	0,05 / -	0,1	Apple juice	0,05 / -	
0,8	Orange juice	0,05 / -	0,1	Bread/pizza	0,05 / -	
0,6	Tomato juice	0,1 / -	0,1	Wine	0,05 / -	
0,6	Celeriac juice	0,13 / -	0,1	Tomato (preserved-	0,1 / -	

*) 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 Metaldehyde 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 30/08/2013 10:00)

Code number	Groups and examples of individual products to which the MRLs apply ^(a)	Metaldehyde
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,05*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, uglı 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)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply ^(a)	Metaldehyde
	and similar hybrids)	
140040	Plums (Damson, greengage, mirabelle)	0,05*
140990	Others	0,05*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	0,05*
151010	Table grapes	0,05*
151020	Wine grapes	0,05*
152000	(b) Strawberries	0,1
153000	(c) Cane fruit	0,05*
153010	Blackberries	0,05*
153020	Dewberries (Loganberries, Boysenberries, and cloudberrries)	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 shallowthorn), hawthorn, service berries, and other treeberries)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply ^(a)	Metaldehyde
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, Brazilian 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)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply ^(a)	Metaldehyde
	(sweetsop) , llama and other medium sized Annonaceae)	
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	
210000	(i) Root and tuber vegetables	
211000	(a) Potatoes	0,15
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	2
213010	Beetroot	2
213020	Carrots	2
213030	Celeriac	2
213040	Horseradish	2
213050	Jerusalem artichokes	2
213060	Parsnips	2
213070	Parsley root	2
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	2
213090	Salsify (Scorzoneria, Spanish salsify (Spanish oysterplant))	2
213100	Swedes	2
213110	Turnips	2

Code number	Groups and examples of individual products to which the MRLs apply ^(a)	Metaldehyde
213990	Others	2
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*
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	
241000	(a) Flowering brassica	1
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	1
241020	Cauliflower	1
241990	Others	1
242000	(b) Head brassica	1
242010	Brussels sprouts	1
242020	Head cabbage (Pointed head cabbage, red	1

Code number	Groups and examples of individual products to which the MRLs apply ^(a)	Metaldehyde
	cabbage, savoy cabbage, white cabbage)	
242990	Others	1
243000	(c) Leafy brassica	1
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	1
243020	Kale (Borecole (curly kale), collards)	1
243990	Others	1
244000	(d) Kohlrabi	0,1
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicaceae	2
251010	Lamb's lettuce (Italian cornsalad)	2
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	2
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leaf endive, sugar loaf)	2
251040	Cress	2
251050	Land cress	2
251060	Rocket, Rucola (Wild rocket)	2
251070	Red mustard	2
251080	Leaves and sprouts of Brassica spp (Mizuna)	2
251990	Others	2
252000	(b) Spinach & similar (leaves)	2
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	2
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel,	2

Code number	Groups and examples of individual products to which the MRLs apply ^(a)	Metaldehyde
	glasswort)	
252030	Beet leaves (chard) (Leaves of beetroot)	2
252990	Others	2
253000	(c) Vine leaves (grape leaves)	0,05*
254000	(d) Water cress	0,05*
255000	(e) Witloof	0,05*
256000	(f) Herbs	2
256010	Chervil	2
256020	Chives	2
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	2
256040	Parsley	2
256050	Sage (Winter savory, summer savory,)	2
256060	Rosemary	2
256070	Thyme (marjoram, oregano)	2
256080	Basil (Balm leaves, mint, peppermint)	2
256090	Bay leaves (laurel)	2
256100	Tarragon (Hyssop)	2
256990	Others	2
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	1

Code number	Groups and examples of individual products to which the MRLs apply ^(a)	Metaldehyde
	(fresh)	
270010	Asparagus	1
270020	Cardoons	1
270030	Celery	1
270040	Fennel	1
270050	Globe artichokes	1
270060	Leek	1
270070	Rhubarb	1
270080	Bamboo shoots	1
270090	Palm hearts	1
270990	Others	1
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	
401010	Linseed	0,05*
401020	Peanuts	0,05*
401030	Poppy seed	0,05*
401040	Sesame seed	0,05*
401050	Sunflower seed	0,05*
401060	Rape seed (Bird rapeseed, turnip rape)	0,6
401070	Soya bean	0,05*
401080	Mustard seed	0,05*
401090	Cotton seed	0,05*
401100	Pumpkin seeds	0,05*
401110	Safflower	0,05*
401120	Borage	0,05*
401130	Gold of pleasure	0,05*
401140	Hempseed	0,05*
401150	Castor bean	0,05*
401990	Others	0,05*

Code number	Groups and examples of individual products to which the MRLs apply ^(a)	Metaldehyde
402000	(ii) Oilfruits	0,05*
402010	Olives for oil production	0,05*
402020	Palm nuts (palmoil kernels)	0,05*
402030	Palmfruit	0,05*
402040	Kapok	0,05*
402990	Others	0,05*
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	
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,1
620000	(ii) Coffee beans	0,05*
630000	(iii) Herbal infusions (dried)	0,05*
631000	(a) Flowers	0,05*
631010	Camomille flowers	0,05*
631020	Hybiscus flowers	0,05*
631030	Rose petals	0,05*
631040	Jasmine flowers	0,05*
631050	Lime (linden)	0,05*
631990	Others	0,05*
632000	(b) Leaves	0,05*
632010	Strawberry leaves	0,05*
632020	Rooibos leaves	0,05*
632030	Maté	0,05*
632990	Others	0,05*
633000	(c) Roots	0,05*
633010	Valerian root	0,05*
633020	Ginseng root	0,05*
633990	Others	0,05*
639000	(d) Other herbal infusions	0,05*
640000	(iv) Cocoa (fermented)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply ^(a)	Metaldehyde
	beans)	
650000	(v) Carob (st johns bread)	0,05*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,05*
800000	8. SPICES	0,05*
810000	(i) Seeds	0,05*
810010	Anise	0,05*
810020	Black caraway	0,05*
810030	Celery seed (Lovage seed)	0,05*
810040	Coriander seed	0,05*
810050	Cumin seed	0,05*
810060	Dill seed	0,05*
810070	Fennel seed	0,05*
810080	Fenugreek	0,05*
810090	Nutmeg	0,05*
810990	Others	0,05*
820000	(ii) Fruits and berries	0,05*
820010	Allspice	0,05*
820020	Anise pepper (Japan pepper)	0,05*
820030	Caraway	0,05*
820040	Cardamom	0,05*
820050	Juniper berries	0,05*
820060	Pepper, black and white (Long pepper, pink pepper)	0,05*
820070	Vanilla pods	0,05*
820080	Tamarind	0,05*
820990	Others	0,05*
830000	(iii) Bark	0,05*
830010	Cinnamon (Cassia)	0,05*
830990	Others	0,05*
840000	(iv) Roots or rhizome	0,05*
840010	Liquorice	0,05*
840020	Ginger	0,05*
840030	Turmeric (Curcuma)	0,05*
840040	Horseradish	0,05*
840990	Others	0,05*
850000	(v) Buds	0,05*
850010	Cloves	0,05*
850020	Capers	0,05*
850990	Others	0,05*
860000	(vi) Flower stigma	0,05*
860010	Saffron	0,05*
860990	Others	0,05*

Code number	Groups and examples of individual products to which the MRLs apply ^(a)	Metaldehyde
870000	(vii) Aril	0,05*
870010	Mace	0,05*
870990	Others	0,05*
900000	9. SUGAR PLANTS	0,05*
900010	Sugar beet (root)	0,05*
900020	Sugar cane	0,05*
900030	Chicory roots	0,05*
900990	Others	0,05*
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	0,05*
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	0,05*
1011000	(a) Swine	0,05*
1011010	Meat	0,05*
1011020	Fat free of lean meat	0,05*
1011030	Liver	0,05*
1011040	Kidney	0,05*
1011050	Edible offal	0,05*
1011990	Others	0,05*
1012000	(b) Bovine	0,05*
1012010	Meat	0,05*
1012020	Fat	0,05*
1012030	Liver	0,05*
1012040	Kidney	0,05*
1012050	Edible offal	0,05*
1012990	Others	0,05*
1013000	(c) Sheep	0,05*
1013010	Meat	0,05*
1013020	Fat	0,05*
1013030	Liver	0,05*
1013040	Kidney	0,05*
1013050	Edible offal	0,05*
1013990	Others	0,05*
1014000	(d) Goat	0,05*
1014010	Meat	0,05*
1014020	Fat	0,05*
1014030	Liver	0,05*
1014040	Kidney	0,05*

Code number	Groups and examples of individual products to which the MRLs apply ^(a)	Metaldehyde
1014050	Edible offal	0,05*
1014990	Others	0,05*
1015000	(e) Horses, asses, mules or hinnies	0,05*
1015010	Meat	0,05*
1015020	Fat	0,05*
1015030	Liver	0,05*
1015040	Kidney	0,05*
1015050	Edible offal	0,05*
1015990	Others	0,05*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05*
1016010	Meat	0,05*
1016020	Fat	0,05*
1016030	Liver	0,05*
1016040	Kidney	0,05*
1016050	Edible offal	0,05*
1016990	Others	0,05*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,05*
1017010	Meat	0,05*
1017020	Fat	0,05*
1017030	Liver	0,05*
1017040	Kidney	0,05*
1017050	Edible offal	0,05*
1017990	Others	0,05*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,05*
1020010	Cattle	0,05*
1020020	Sheep	0,05*
1020030	Goat	0,05*
1020040	Horse	0,05*
1020990	Others	0,05*
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	0,05*

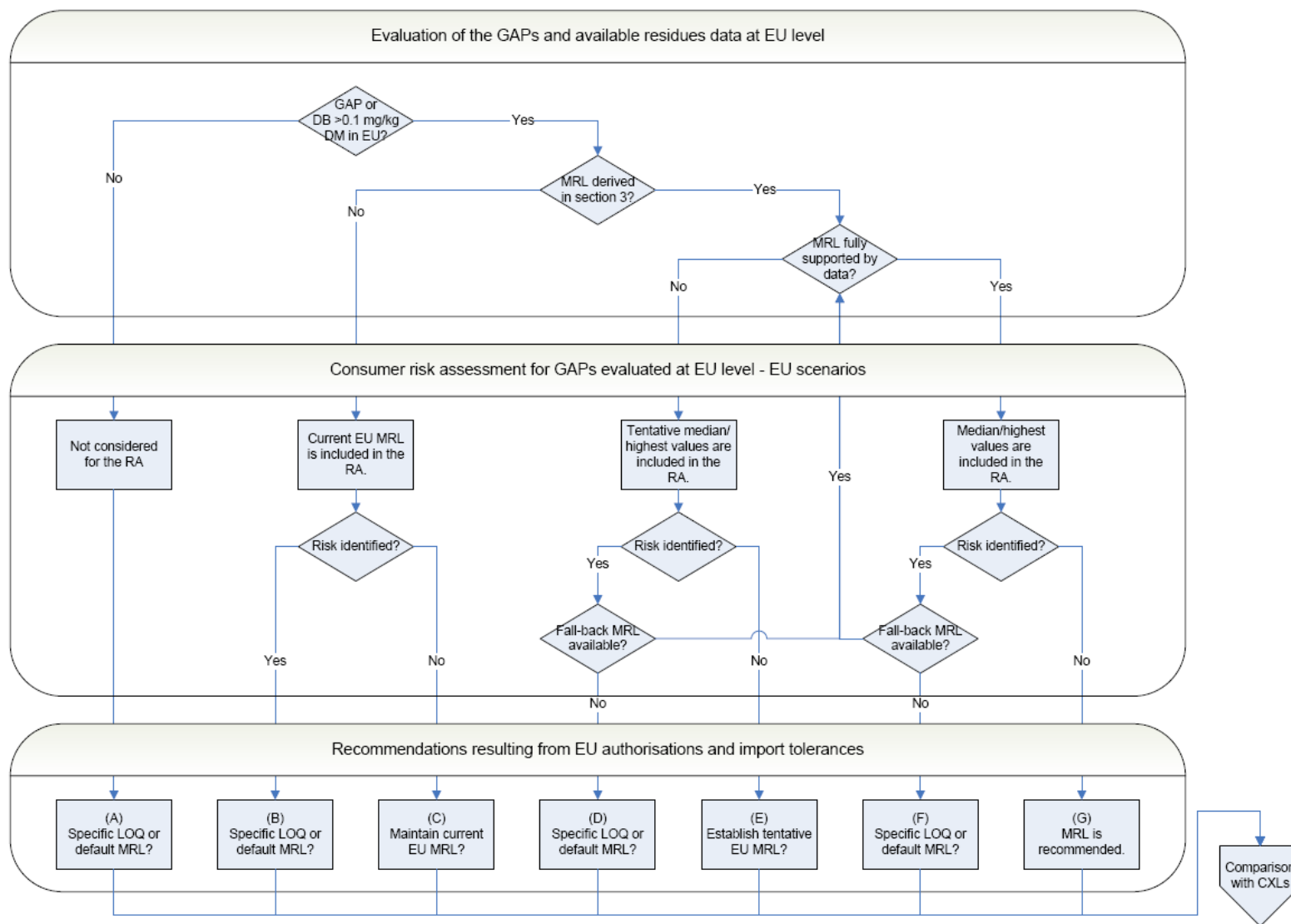
Code number	Groups and examples of individual products to which the MRLs apply ^(a)	Metaldehyde
	containing added sugar or sweetening matter	
1030010	Chicken	0,05*
1030020	Duck	0,05*
1030030	Goose	0,05*
1030040	Quail	0,05*

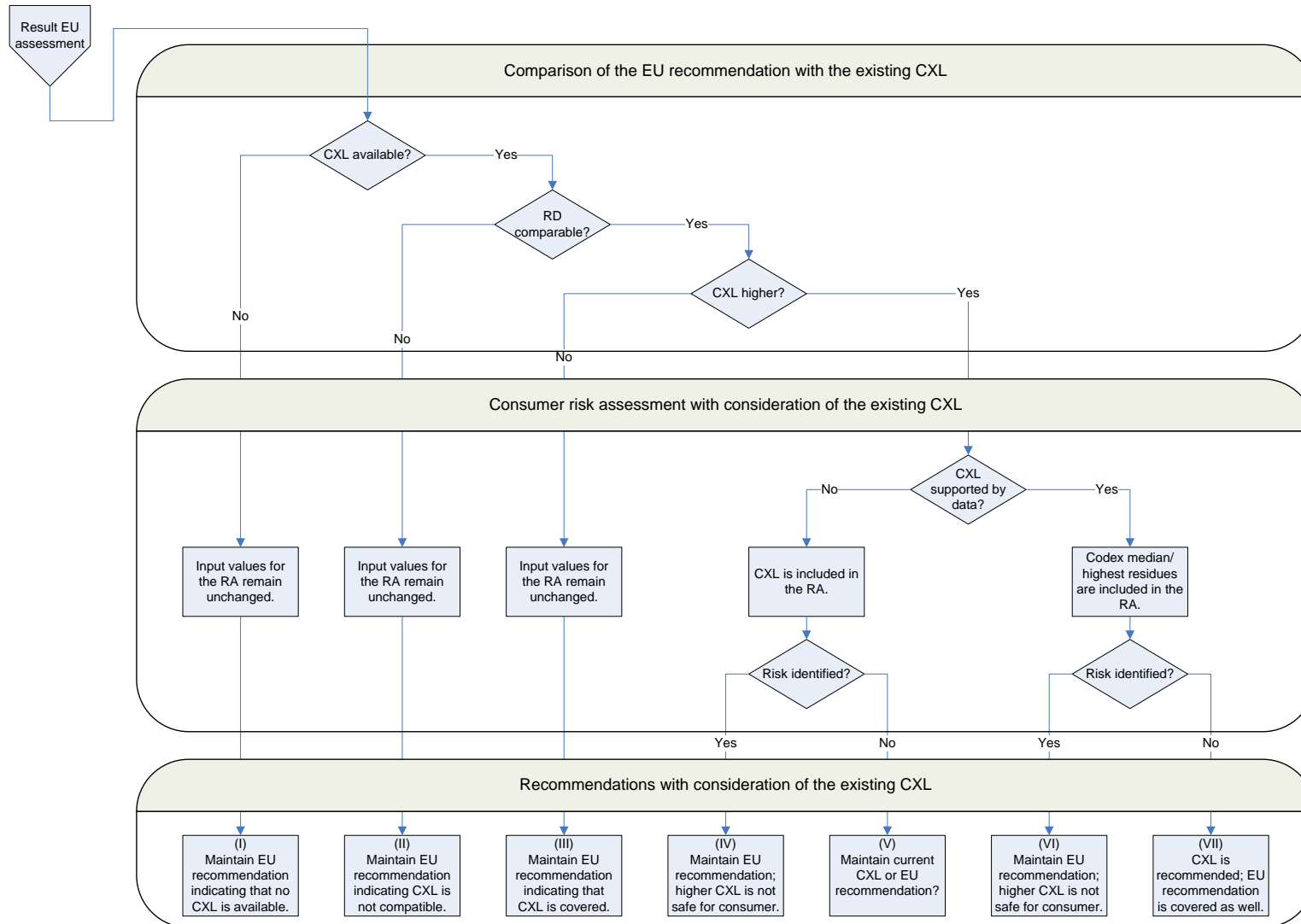
Code number	Groups and examples of individual products to which the MRLs apply ^(a)	Metaldehyde
1030990	Others	0,05*
1040000	(iv) Honey (Royal jelly, pollen)	0,05*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply ^(a)	Metaldehyde
1060000	(vi) Snails	0,05*
1070000	(vii) Other terrestrial animal products	0,05*

(*) Indicates lower limit of analytical determination

APPENDIX D – DECISION TREE FOR DERIVING MRL RECOMMENDATIONS





ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
AR	applied radioactivity
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
DB	dietary burden
DM	dry matter
DT ₉₀	period required for 90 percent dissipation (define method of estimation)
EC	European Commission
EFSA	European Food Safety Authority
eq	residue expressed as a.s. equivalent
EU	European Union
EURLs	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
GC-MS/MS	gas chromatography with tandem mass spectrometry
ha	hectare
ILV	independent laboratory validation

ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	northern European Union
OECD	Organization for Economic Co-operation and Development
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
R_{ber}	statistical calculation of the MRL by using a non-parametric method
R_{max}	statistical calculation of the MRL by using a parametric method
RMS	Rapporteur Member State
SEU	Southern European Union
TRR	total radioactive residue
WHO	World Health Organisation
wks	weeks