

REASONED OPINION

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

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SUMMARY

Amitrole was included in Annex I to Directive 91/414/EEC on 01 January 2002, which is before the entry into force of Regulation (EC) No 396/2005 on 02 September 2008. EFSA is therefore required to provide a reasoned opinion on the review of the existing MRLs for that active substance in compliance with Article 12(2) of the afore mentioned regulation. In order to collect the relevant pesticide residues data, EFSA asked France, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile). The requested information was submitted to EFSA on 28 October 2008 and, after having considered several comments made by EFSA, the RMS provided on 27 October 2009 a revised PROFile.

Based on the conclusions derived in the framework of Directive 91/414/EEC under the supervision of the European Commission, the MRLs established by the Codex Alimentarius Commission, and the additional information provided by the RMS, EFSA issued on 13 December 2011 a draft reasoned opinion that was circulated to Member States' experts for consultation. Comments received by 24 February were considered for finalisation of this reasoned opinion. The following conclusions are derived.

The toxicological profile of amitrole was already evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI being established at 0.001 mg/kg bw/d. An ARfD was not deemed necessary.

Primary crop metabolism was investigated for the fruit and fruiting vegetables crop grouping following spray application of amitrole to soil in apples. Apples were also studied in model studies (excised apple sprouts and cell suspension cultures). In the study representative of the proposed uses that was conducted at exaggerated use rates, parent amitrole was not detected in the mature fruits, and the major metabolite was triazolylalanine. This metabolite was also present as plant conjugates and is amongst the metabolite products named triazole derivative metabolites (TDMs). The only significant difference in the metabolism of amitrole in plants and animals (rat metabolism) is the occurrence of triazolylalanine in plants. EFSA concluded that the relevant residue for enforcement and risk

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assessment is amitrole only. However, as amitrole, similarly to other active substances belonging to the triazole class, is known to produce TDMs, EFSA is of the opinion that the residue definition may require to be revised pending a separate risk assessment for TDMs following a decision on the risk assessment methodology for all substances of the triazole chemical group. Analytical methods for enforcement of this residue definition are available. However primary validation data are not sufficient, and ILV data and confirmatory methods of analysis are not available for these methods and therefore further data are still required.

Regarding the magnitude of residues in primary crops, a sufficient number of supervised residue trials is available for the GAPs reported by the RMS, which allowed EFSA to estimate the expected residue concentrations in the relevant plant commodities and to derive MRLs. These MRLs are currently regarded as tentative pending the data gaps identified on analytical methodology and since for table olives and olives for oil production (a level of 0.05* mg/kg based on residues being found below the LOQ in the trials), storage stability of residues data are not available for high oil content commodities.

As quantifiable residues of amitrole are not expected in the treated crops, there is no need to investigate the effect of industrial and/or household processing. However some limited studies are available, but since the residues in the raw agricultural commodities were less than the LOQ, robust processing factors could not be derived.

Crops evaluated in the framework of this MRL review are not expected to be grown in rotation. Further investigation of residues in rotational crops is therefore not required.

Studies on nature or magnitude of residues in commodities of animal origin are not available, or required. Following the estimation of the dietary burden arising from the authorised uses of amitrole, MRLs for livestock products are not required because livestock is not expected to be exposed to significant levels of amitrole residues.

Chronic consumer exposure resulting from the MRLs derived in the framework of this review was calculated using revision 2 of the EFSA PRIMo. Considering these crops, the highest chronic exposure represented 20.1% of the ADI (German child). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for amitrole. Additional calculations of the consumer exposure, including these CXLs, were therefore carried out, the highest chronic exposure represented 21.3% of the ADI (German child).

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

- Primary method validation data, ILV data and confirmatory methods for enforcement of residues in all plant commodities;
- a residues storage stability study for high oil content commodities to support the periods of storage of olives in the olives SEU trials data;

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.

EFSA emphasizes that the above assessment does not yet take into consideration triazole derivative metabolites (TDMs). Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their triazole derivative metabolites is available.

Code number	Commodity	Existing EU MRL (mg/kg) ^(a)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition: amitrole					
110000	Citrus fruits	0.01	-	0.01*	Further consideration needed ^(b)
120010	Almonds	0.01	-	0.01*	Further consideration needed ^(b)
120060	Hazelnuts	0.01	-	0.01*	Further consideration needed ^(b)
120110	Walnuts	0.01	-	0.01*	Further consideration needed ^(b)
130010	Pome fruits	0.01	0.01*	0.01*	Further consideration needed ^(c)
140010	Stone fruits	0.01	0.01*	0.01*	Further consideration needed ^(c)
151000	Table and wine grapes	0.01	0.05	0.05	Further consideration needed ^(d)
154030	Currants (red, black and white)	0.01	-	0.01*	Further consideration needed ^(b)
154040	Gooseberries	0.01	-	0.01*	Further consideration needed ^(b)
161030	Table olives	0.05	-	0.05*	Further consideration needed ^(b)
402010	Olives for oil production	0.05	-	0.05*	Further consideration needed ^(b)
-	Other products of plant and animal origin	See App C	-	-	Further consideration needed ^(e)

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

(a): (*) is not stated for the existing MRLs although it is considered that these MRLs were all set at the limit of analytical quantification.

(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 could be identified; no CXL is available (combination E-I in Appendix D).

(c): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers could be identified; existing CXL is covered by the tentative MRL when the EU LOQ is considered (combination E-III in Appendix D).

(d): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; GAP evaluated at EU level, which is also not fully supported by data, would lead to a lower tentative MRL (combination E-V in Appendix D).

(e): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. The specific LOQ (same as the default MRL) of 0.01 mg/kg may be considered (combination A-I in Appendix D).

KEY WORDS

amitrole, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, triazole herbicide, herbicide.

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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(2) of that regulation stipulates that EFSA shall provide by 01 September 2009 a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Directive 91/414/EEC⁵ before 02 September 2008. As amitrole was included in Annex I to the above mentioned directive on 01 January 2002, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2008-488 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 on the pesticide residues data that have been considered for the setting of the existing MRLs, EFSA developed the Pesticide Residue Overview File (PROFile). The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

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

France, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for amitrole. The requested information was submitted to EFSA on 28 October 2008 and subsequently checked for completeness. On 27 October 2009, after having clarified some issues with EFSA, the RMS provided a revised PROFile.

A draft reasoned opinion was issued by EFSA on 13 December 2011 and submitted to Member States (MS) for commenting. All MS comments received by 24 February 2012 were considered by EFSA for finalisation of the reasoned opinion.

⁴ Commission Regulation (EC) No 396/2005 of 23 February 2005. OJ L 70, 16.3.2005, p. 1-16.

⁵ Council Directive 91/414/EEC of 15 July 1991, OJ L 230, 19.8.1991, p. 1-32.

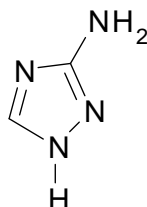
TERMS OF REFERENCE

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

Amitrole is the ISO common name for 1-*H*-1,2,4-triazol-3-amine (IUPAC).



Amitrole (also referred to as aminotriazole) belongs to the group of triazole herbicide compounds. Amitrole is mainly a foliar acting herbicide, with some uptake by roots expected. After absorption amitrole is widely distributed throughout the plant via xylem and phloem transport. The mode of action is considered to be due to the effect of amitrole on a broad range of biochemical processes, such as: biosynthesis of carotenoids and histidine; enzyme production; metabolism of riboflavin and nucleic acids; development of plastids. As such, amitrole is a herbicide for non-selective control of annual and perennial monocotyledonous and dicotyledonous weeds.

Amitrole was evaluated in the framework of Directive 91/414/EEC with France being the designated rapporteur Member State (RMS). The uses supported for the peer review process were the outdoor spray treatment in vineyards, orchards (tree nuts, pome and stone fruits), for intercropping and minimum tillage, and non-crop uses (railroads, roadsides, industrial settings). Following the peer review, which was not carried out by EFSA, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2001/21/EC⁶, entering into force on 01 January 2002. According to Regulation (EU) No 540/2011⁷, amitrole is deemed to have been approved under Regulation (EC) No 1107/2009⁸. This approval is restricted to uses as a herbicide only. As EFSA was not yet involved in the peer review of amitrole, a conclusion of EFSA on this active substance is not available.

The EU MRLs for amitrole are established in Annexes II and IIIB of Regulation (EC) No 396/2005. All existing EU MRLs, which are established for the parent compound amitrole only, are summarized in Appendix C.1 to this document. CXLs for amitrole were also established by the Codex Alimentarius Commission and are reported in Appendix C.2 to this reasoned opinion. Also these CXLs refer to parent compound amitrole only.

⁶ Directive 2001/21/EC of 5 March 2001, OJ L 69, 10.3.2001, p. 17-21.

⁷ Regulation (EU) No 540/2011 of 25 May 2011, OJ L 153, 11.6.2011, p. 1-186.

⁸ Regulation (EC) No 1107/2009 of 21 October 2009, OJ 309, 24.11.2009, p. 1-50.

For the purpose of this MRL review, the critical uses of amitrole currently authorized within the EU, have been collected by the RMS and reported in the PROFile. Additional GAPs reported during the Member State consultation were also considered (see Appendix A). According to the reported edible crop GAPs amitrole is applied as a spray treatment to soil in citrus, pome and stone fruits, tree nuts, vineyards, currants, gooseberries and olives in northern and/or southern Europe. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

ASSESSMENT

EFSA bases its assessment on the PROFile submitted by the RMS, the Draft Assessment Report (DAR) and its addendum prepared under Council Directive 91/414/EEC (France, 1996, 2000), the Review Report on amitrole (EC, 2001), as well as the JMPR Evaluation reports (FAO, 1974, 1993, 1998). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation of the Authorization of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011⁹ and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2004, 2010, 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 gas chromatography with nitrogen-phosphorus detection was evaluated and for the determination of amitrole in plant matrices in high water content (apples, pears and cherries) (France, 1996). Further validation data for grapes (high acid) and wine were considered prior to Annex I inclusion (France, 2000). However, as the number of samples for each fortification level was low, the extent of the primary method validation data is limited and no ILV was available, as reported by the RMS in the PROFile submission.

Additionally a further analytical method using high performance liquid chromatography with fluorescence detection was evaluated by the RMS after Annex I inclusion and reported in the PROFile. The method was developed and validated in olives (high fat content commodities) for the determination of amitrole in plant matrices, however the RMS has noted that the extraction of amitrole in this matrix is problematic due its tendency for conjugation with natural plant constituents. As such the method cannot be regarded as sufficiently validated in this matrix.

The multi-residue QuEChERS method in combination with HPLC-MS/MS analyzing for amitrole only was considered, however the data were not sufficient as the validation data were for only one laboratory and showed low recoveries (EURL, 2012).

Hence it is concluded, that parent amitrole cannot be enforced in food of plant origin. Primary method validation data, ILV data and suitable confirmatory methods are data gaps that have been identified indicating that further data should be generated.

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

No methods for analyses for food of animal origin were evaluated in the peer review under Directive 91/414/EEC. After the peer review, the RMS evaluated an additional study, which was also reported

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

in the PROFile. This analytical method used high performance liquid chromatography with circular dichroism detection was developed and was validated in ruminant milk, meat, fat, liver and kidney for the determination of amitrole in animal matrices with a LOQ of 0.01 mg/kg.

However, considering that there is no significant intake of residues by livestock, no residue definition and no MRLs are proposed for commodities of animal origin (section 3.2). Therefore, an analytical method for enforcement of residues in food of animal origin is not necessary. The above method is reported for information only because, without any residues studies investigating the nature and levels of residues in animal products, the residue definition is not established.

2. Mammalian toxicology

The toxicological assessment of amitrole was peer reviewed under Directive 91/414/EEC and toxicological reference values were established by the European Commission (2001). These toxicological reference values are summarized in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Amitrole					
ADI	EC	2001	0.001 mg/kg bw/d	Rat 90 day multigeneration study ^(a)	100
ARfD	EC	2001	Not necessary		

(a): multigeneration study as stated in the critical end-points and the associated ECCO 19 report.

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 amitrole was investigated following soil application on fruits and fruiting vegetables (soil treatment in apple trees) using 3,5-¹⁴C labelled amitrole (France, 1996). Additionally, metabolism of amitrole was investigated after application of 3,5-¹⁴C labelled amitrole to excised sprouts from apple trees and to cell suspension cultures (France, 1996). The characteristics of these studies are summarized in Table 3-1.

Mature fruits from outdoor soil treatment experiments contained at most 0.05 mg/kg TRR. The highest portion of the TRR was identified as triazolylalanine¹⁰ (at most 0.012 mg eq./kg, 22-24%), which occurred in the free form and as conjugates. Parent amitrole itself was not detectable. Of the TRR about 75 % was soluble and 25 % was bound to insoluble material. About 50 % of the radioactivity was reassimilated ¹⁴C incorporated into natural plant constituents. A part of the reassimilated ¹⁴C was present within the insoluble residues and characterised after treatment with cellulase and pectinase. Other metabolites were not cited as found for the outdoor treatment involving soil treatment in apple trees. In contrast to the outdoor field study, the major metabolite in model

¹⁰ triazolylalanine : 3-(1,2,4-triazole-1-yl)-2-aminopropionic acid. See Appendix E

studies (excised apple sprouts and cell suspension cultures) was aminotriazolylalanine¹¹. In cell suspension cultures at high concentrations of amitrole, dihydroxy-1,2,4-triazole¹² was mainly found.

In apple plants, amitrole appears to be metabolised to triazolylalanine presumably via the formation of aminotriazolylalanine from amitrole. There is evidence in apples of formation of conjugates involving triazolylalanine. In contrast, in the mammalian (rat) metabolism, little metabolic transformation occurs with unchanged amitrole being found in tissues and as the majority of radioactivity in urine of rats. Other metabolites identified in the urine of rats were 3-amino-12,4-triazolyl-5-mercaptopuric acid¹³ and 3-amino-5-mercapto-1,2,4-triazole¹⁴. The only significant difference in the metabolism of amitrole in plants and animals (rat metabolism) is the occurrence of triazolylalanine in plants.

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

Group	Crop	Label position	Application and sampling details				
			Method, F or G ^(a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks
Fruits and fruiting vegetable	apple	3,5- ¹⁴ C labelled amitrole	Soil treatment, F	8	1	Not stated (also growth stage at time of treatment not stated)	Soil treatment in apple trees
Fruits and fruiting vegetable	apple	3,5- ¹⁴ C labelled amitrole	Application to excised sprouts, F	-	-	-	In tubs. No further details on application rate and timing stated in the DAR.
Fruits and fruiting vegetable	apple	3,5- ¹⁴ C labelled amitrole	Cell suspension cultures, G	-	-	-	No further details on application rate and timing stated in the DAR.

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

The peer review concluded that the metabolism of amitrole was sufficiently elucidated in primary crops and supported the residue definition for enforcement and risk assessment in fruits and fruiting vegetables following application to the soil is defined as amitrole only (France, 1996). Taking account of the exaggerated rate of the apple metabolism study, EFSA concludes that the metabolic pathway in crops under consideration (fruits and fruiting vegetables) is sufficiently addressed. However, the need to include additional metabolites in a separate residue definition (e.g. triazolylalanine) should be considered when specific data addressing the toxicology of the triazole derivative metabolites (TDMs) has been evaluated (see below). Also, this residue definition is limited to the evaluated uses, i.e. soil application to fruiting crops, since the metabolism has only been investigated as described here in apples. As amitrole is currently not authorized for other types of application further metabolism studies are not needed. The residue definition derived is also in line with those one derived by the JMPR (FAO, 1998).

¹¹ aminotriazolylalanine : 3-(3-amino-1,2,4-triazole-1-yl)-2-aminopropionic acid. See Appendix E

¹² dihydroxy-1,2,4-triazole : 3,5-dihydroxy-1,2,4-triazole. See Appendix E

¹³ 3-amino-12,4-triazolyl-5-mercaptopuric acid. See Appendix E

¹⁴ 3-amino-5-mercapto-1,2,4-triazole. See Appendix E

Validated analytical methods for enforcement of the proposed residue definition are not available (see also section 1.1) because primary validation data, ILV data and confirmatory analytical methods for enforcement of the proposed residue definition are still required.

EFSA emphasizes that the above residue definition does not yet take into consideration triazole derivative metabolites (TDMs). Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their triazole derivative metabolites is available.

3.1.1.2. Magnitude of residues

According to the RMS, the active substance amitrole is authorised in northern and/or southern Europe for spray treatment to soil in citrus, pome and stone fruits, tree nuts, vineyards, currants, gooseberries and olives (see Appendix A). To assess the magnitude of amitrole residues resulting from these GAPs, EFSA considered all residues trials reported in the PROFile including residues trials evaluated in the framework of the peer review (France, 1996). All available residues trials that, according to the RMS, comply with the authorised GAPs, are summarized in Table 3-2.

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

The potential degradation of residues during storage of the residues trials samples was not considered during the peer review under Directive 91/414/EEC. After the peer review, the RMS evaluated an additional study, which was also reported in the PROFile. In this study, storage stability of amitrole was demonstrated for a period of 16 months at an unspecified frozen temperature in commodities with high water content (apple, according to EC, 2010b). Considering that all residues trials samples were stored in compliance with the above reported storage conditions and that apples were previously assumed to have a high acid content (EC, 2004), decline of residues during storage of residues trials samples of fruit crops is not expected. However, it is also noted that storage stability has not been investigated in commodities with high oil content. This information is required in order to confirm the validity of the residues trials reported for olives. For tree nuts (also high oil content), the residues trials data are extrapolated from other fruit trees and storage stability data are therefore not relevant to tree nuts.

Consequently, the available residues data are considered sufficient to derive tentative MRL proposals as well as risk assessment values for all commodities under evaluation (see also Table 3-2). The MRLs are regarded as tentative since primary method validation data, ILV data and confirmatory methods data are outstanding for all commodities and since storage stability data for high oil content commodities (required for olives) are not available.

Table 3-2: Overview of the available residues trials data

Commodity	Residue region ^(a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) ^(b)	Highest residue (mg/kg) ^(c)	MRL proposal (mg/kg)	Median CF ^(d)	Comments
			Enforcement (amitrole)	Risk assessment (amitrole)					
Citrus fruits Almonds Hazelnuts Walnuts Pome fruits Stone fruits	NEU	Outdoor	8 x <0.01	8 x <0.01	0.01	0.01	0.01* ^(e) (tentative)	1.0	Dataset on apples supporting the NEU GAP (1 or 2 applications at 1.2N rate, 4 to 171 days PHI); extrapolation to pears, quinces, cherries and plums is possible; not authorised for other orchard trees in NEU. 12 confirmatory trials on apples and pears with a higher LOQ of 0.02 mg/kg.
	SEU	Outdoor	13 x <0.01	13 x <0.01	0.01	0.01	0.01* ^(e) (tentative)	1.0	Combined dataset on apples (8), pears (1) and peaches (4) in support of the SEU GAP (1 application 1.2N (6 trials on apples) and 1.5N rate (7 trials on apples, pears and peaches), 34 to 172 day PHI); extrapolation to other orchard trees is possible.

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 (amitrole)	Risk assessment (amitrole)					
Grapes (table and wine) Currants (red, black and white) Gooseberries	NEU	Outdoor	5 x <0.01	5 x <0.01	0.01	0.01	0.01* ^(e) (tentative)	1.0	Trials on table grapes at 1N application rate; PHI ranged from 28 – 120 days; extrapolation to currants and gooseberries is possible. 11 confirmatory trials on grapes with LOQ of 0.02 mg/kg.
	SEU	Outdoor	4 x <0.01	4 x <0.01	0.01	0.01	0.01* ^(e) (tentative)	1.0	Trials on table grapes at 1.2N application rate; PHI ranged from 15-189 days; not authorised for use on currants and gooseberries in SEU. 12 confirmatory trials on grapes with LOQ of 0.02 mg/kg (8) and 0.025 mg/kg (4).
Olives (table and for oil production)	SEU	Outdoor	8 x <0.04	8 x <0.04	0.04	0.04	0.05* ^(f) (tentative)	1.0	Trials were conducted on table olives with a 1.3N exaggerated rate; PHI ranges from 0 to 35 days.

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

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

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

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

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

(e): Tentative MRL proposal as sufficient primary method validation data, ILV data and confirmatory methods data are not available for all commodities.

(f): Tentative MRL proposal as sufficient primary method validation data, ILV data and confirmatory methods data are not available for all commodities and storage stability data are not available for commodities with high oil content.

3.1.1.3. Effect of industrial processing and/or household preparation

As quantifiable residues of amitrole are not expected in the treated crops, there is no need to investigate the effect of industrial and/or household processing. Although not required, studies investigating the magnitude of residues in processed commodities of amitrole were briefly reported in the framework of the peer review (France, 1996) but no robust processing factors for enforcement and risk assessment could be derived as the residue definition for the processing situation is not confirmed and residues were below the LOQ in both the raw and the processed commodity.

Nevertheless, further processing studies are not required in this case, as the studies submitted were not strictly necessary.

3.1.2. Rotational crops

Crops evaluated in the framework of this MRL review are not expected to be grown in rotation. Further investigation of residues in rotational crops is therefore not required.

3.2. Nature and magnitude of residues in livestock

Amitrole is authorised for use on citrus and apple that might be fed to livestock. The median and maximum dietary burdens were therefore calculated for different groups of livestock using the agreed European methodology (EC, 1996). The input values for all relevant commodities have been selected according to the recommendations of JMPR (FAO, 2009) and are summarized in Table 3-4. Residues of amitrole in trials were below the LOQ (<0.01 mg/kg) and in the apple metabolism study amitrole was not detected in mature fruits. Concentration of residues in processed commodities thereof is therefore not expected. On this basis, default processing factors for apple and citrus pomace have not been included in the calculation.

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 - amitrole				
orange, pomace	0.01	Median residue	0.01	Median residue
lemon, pomace	0.01	Median residue	0.01	Median residue
grapefruit, pomace	0.01	Median residue	0.01	Median residue
lime, pomace	0.01	Median residue	0.01	Median residue
mandarin, pomace	0.01	Median residue	0.01	Median residue
apple, pomace	0.01	Median residue	0.01	Median residue

The results of the calculations are reported in Table 3-5. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg DM, further investigation of residues as well as the setting of MRLs in commodities of animal origin is not necessary.

Table 3-4: Results of the dietary burden calculation

	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition - amitrole					
Dairy ruminants	0.0002	0.0002	Orange pomace	0.0043	No
Meat ruminants	0.0006	0.0006	Orange pomace	0.0130	No
Poultry	-	-	Not relevant ^(a)	-	No
Pigs	-	-	Not relevant ^(a)	-	No

(a): Not relevant as fruit pomace is not a significant part of the diet for poultry or pigs (EC, 1996)

4. Consumer risk assessment

In the framework of this review, only the uses of amitrole reported by the RMS in Appendix A were considered, however the use of amitrole was previously also assessed by the JMPR (FAO, 1974, 1993, 1998). The CXLs, resulting from these assessments by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. In order to facilitate consideration of these CXLs by risk managers, the consumer exposure was calculated both with and without consideration of the existing CXLs (see Appendix C.2).

4.1. Consumer risk assessment without consideration of the existing CXLs

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

Table 4-1: Input values for the consumer risk assessment (without consideration of CXLs)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition - amitrole		
Citrus fruits	0.01	Median residue (=LOQ, tentative) ^(a)
Pome fruits	0.01	Median residue (=LOQ, tentative) ^(a)
Stone fruits	0.01	Median residue (=LOQ, tentative) ^(a)
Tree nuts (almonds, hazelnuts, walnuts)	0.01	Median residue (=LOQ, tentative) ^(a)
Currants (red, black and white)	0.01	Median residue (=LOQ, tentative) ^(a)
Gooseberries	0.01	Median residue (=LOQ, tentative) ^(a)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Table and wine grapes	0.01	Median residue (=LOQ, tentative) ^(a)
Table olives and olives for oil production	0.04	Median residue (=LOQ, tentative) ^(a)

(a): Use reported by the RMS is not fully supported by data but the risk assessment values derived in section 3 are used for indicative exposure calculations.

The calculated exposures were compared with the toxicological reference value derived for amitrole (see Table 2-1); detailed results of the calculations are presented as the EU scenario in Appendix B.1. The highest chronic exposure was calculated for German child, representing 20.1% of the ADI.

Based on the above calculations, EFSA concludes that for the use of amitrole on all crops uncertainties remain due to the data gaps identified in section 3 but considering tentative MRLs in the exposure calculation did not indicate a risk to consumers.

EFSA emphasizes that the above assessment does not yet take into consideration triazole derivative metabolites (TDMs). Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their triazole derivative metabolites is available.

4.2. Consumer risk assessment with consideration of the existing CXLs

In order to include the CXLs in the calculations of the consumer exposure, all data relevant to the consumer exposure assessment have been collected from JMPR evaluations and reported in Appendix C.2 to this document. These CXLs were compared with the EU MRL proposals in compliance with Appendix D and input values resulting from this comparison are summarized in Table 4-2. It is noted however that CXLs are not considered to be sufficiently supported by data because the assessment of data at European level has indicated that adequate analytical methods for enforcement of these CXLs are currently not available. Moreover, the CXLs for pome fruits and stone fruits (at 0.05*mg/kg) are higher than the tentative median residue values reported in section 3. Since these data represent an LOQ situation, the CXL is considered to be covered for these crops when the EU proposed LOQ of 0.01 mg/kg is used in the consumer risk assessment.

Table 4-2: Input values for the consumer risk assessment (with consideration of CXLs)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition - amitrole		
Citrus fruits	0.01	Median residue (=LOQ, tentative) ^(a)
Pome fruits	0.01	Median residue (=LOQ, tentative) ^(a)
Stone fruits	0.01	Median residue (=LOQ, tentative) ^(a)
Tree nuts (almonds, hazelnuts, walnuts)	0.01	Median residue (=LOQ, tentative) ^(a)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Currants (red, black and white)	0.01	Median residue (=LOQ, tentative) ^(a)
Gooseberries	0.01	Median residue (=LOQ, tentative) ^(a)
Table and wine grapes	0.02	Median residue (CXL, tentative) ^(b)
Table olives and olives for oil production	0.04	Median residue (=LOQ, tentative) ^(a)

(a): Use reported by the RMS is not fully supported by data but the risk assessment values derived in section 3 are used for indicative exposure calculations.

(b): CXL is not sufficiently supported by data but the corresponding risk assessment value (median for grapes from trials according to French and Australian GAP, see Appendix C.2) is used for indicative exposure calculations.

Chronic exposure calculations were also performed using revision 2 of the EFSA PRIMo and calculated exposures were compared with the toxicological reference value derived for amitrole (see Table 2-1); detailed results of the calculations are presented as the EU/Codex scenario in Appendix B.2. The highest chronic exposure was calculated for German child, representing 21.3% of the ADI. Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Based on the above calculations, EFSA concludes that uncertainties remain for the CXL in grapes as it is not well supported by data. Nevertheless, inclusion of this CXL in the exposure calculation did not indicate any risk to European consumers.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of amitrole was already evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI being established at 0.001 mg/kg bw/d. An ARfD was not deemed necessary.

Primary crop metabolism was investigated for the fruit and fruiting vegetables crop grouping following spray application of amitrole to soil in apples. Apples were also studied in model studies (excised apple sprouts and cell suspension cultures). In the study representative of the proposed uses that was conducted at exaggerated use rates, parent amitrole was not detected in the mature fruits, and the major metabolite was triazolylalanine. This metabolite was also present as plant conjugates and is amongst the metabolite products named triazole derivative metabolites (TDMs). The only significant difference in the metabolism of amitrole in plants and animals (rat metabolism) is the occurrence of triazolylalanine in plants. EFSA concluded that the relevant residue for enforcement and risk assessment is amitrole only. However, as amitrole, similarly to other active substances belonging to the triazole class, is known to produce TDMs, EFSA is of the opinion that the residue definition may require to be revised pending a separate risk assessment for TDMs following a decision on the risk assessment methodology for all substances of the triazole chemical group. Analytical methods for enforcement of this residue definition are available. However primary validation data are not sufficient, and ILV data and confirmatory methods of analysis are not available for these methods and therefore further data are still required.

Regarding the magnitude of residues in primary crops, a sufficient number of supervised residue trials is available for the GAPs reported by the RMS, which allowed EFSA to estimate the expected residue concentrations in the relevant plant commodities and to derive MRLs. These MRLs are currently

regarded as tentative pending the data gaps identified on analytical methodology and since for table olives and olives for oil production (a level of 0.05* mg/kg based on residues being found below the LOQ in the trials), storage stability of residues data are not available for high oil content commodities.

As quantifiable residues of amitrole are not expected in the treated crops, there is no need to investigate the effect of industrial and/or household processing. However some limited studies are available, but since the residues in the raw agricultural commodities were less than the LOQ, robust processing factors could not be derived.

Crops evaluated in the framework of this MRL review are not expected to be grown in rotation. Further investigation of residues in rotational crops is therefore not required.

Studies on nature or magnitude of residues in commodities of animal origin are not available, or required. Following the estimation of the dietary burden arising from the authorised uses of amitrole, MRLs for livestock products are not required because livestock is not expected to be exposed to significant levels of amitrole residues.

Chronic consumer exposure resulting from the MRLs derived in the framework of this review was calculated using revision 2 of the EFSA PRIMo. Considering these crops, the highest chronic exposure represented 20.1% of the ADI (German child). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for amitrole. Additional calculations of the consumer exposure, including these CXLs, were therefore carried out, the highest chronic exposure represented 21.3% of the ADI (German child).

RECOMMENDATIONS

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

- Primary method validation data, ILV data and confirmatory methods for enforcement of residues in all plant commodities;
- a residues storage stability study for high oil content commodities to support the periods of storage of olives in the olives SEU trials data;

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.

EFSA emphasizes that the above assessment does not yet take into consideration triazole derivative metabolites (TDMs). Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their triazole derivative metabolites is available.

Code number	Commodity	Existing EU MRL (mg/kg) ^(a)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition: amitrole					
110000	Citrus fruits	0.01	-	0.01*	Further consideration needed ^(b)
120010	Almonds	0.01	-	0.01*	Further consideration needed ^(b)
120060	Hazelnuts	0.01	-	0.01*	Further consideration needed ^(b)
120110	Walnuts	0.01	-	0.01*	Further consideration needed ^(b)
130010	Pome fruits	0.01	0.01*	0.01*	Further consideration needed ^(c)
140010	Stone fruits	0.01	0.01*	0.01*	Further consideration needed ^(c)
151000	Table and wine grapes	0.01	0.05	0.05	Further consideration needed ^(d)
154030	Currants (red, black and white)	0.01	-	0.01*	Further consideration needed ^(b)
154040	Gooseberries	0.01	-	0.01*	Further consideration needed ^(b)
161030	Table olives	0.05	-	0.05*	Further consideration needed ^(b)
402010	Olives for oil production	0.05	-	0.05*	Further consideration needed ^(b)
-	Other products of plant and animal origin	See App C	-	-	Further consideration needed ^(e)

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

(a): (*) is not stated for the existing MRLs although it is considered that these MRLs were all set at the limit of analytical quantification.

(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 could be identified; no CXL is available (combination E-I in Appendix D).

(c): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers could be identified; existing CXL is covered by the tentative MRL when the EU LOQ is considered (combination E-III in Appendix D).

(d): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; GAP evaluated at EU level, which is also not fully supported by data, would lead to a lower tentative MRL (combination E-V in Appendix D).

(e): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. The specific LOQ (same as 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 amitrole prepared by the rapporteur Member State France in the framework of Article 12 of Regulation (EC) No 396/2005. Submitted to EFSA on 28 October 2008. Last updated on 27 October 2009.

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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			Application							Application rate			PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Apples	<i>Malus domestica</i>	NEU	Outdoor	FR	WEEDS	SG	86.0	% (w/w)	Soil treatment - spraying			1	2	60		1.20	4.00	kg a.i./ha	35	Band application (on row) or spot treatment - Application from Autumn to Spring
Pears	<i>Pyrus communis</i>	NEU	Outdoor	FR	WEEDS	SG	86.0	% (w/w)	Soil treatment - spraying			1	2	60		1.20	4.00	kg a.i./ha	35	Band application (on row) or spot treatment - Application from Autumn to Spring
Quinces	<i>Cydonia oblonga</i>	NEU	Outdoor	FR	WEEDS	SG	86.0	% (w/w)	Soil treatment - spraying			1	2	60		1.20	4.00	kg a.i./ha	35	Band application (on row) or spot treatment - Application from Autumn to Spring
Cherries	<i>Prunus cerasus</i> , <i>Prunus avium</i>	NEU	Outdoor	FR	WEEDS	SG	86.0	% (w/w)	Soil treatment - spraying			1	2	60		1.20	4.00	kg a.i./ha	35	Band application (on row) or spot treatment - Application from Autumn to Spring
Plums	<i>Prunus domestica</i>	NEU	Outdoor	FR	WEEDS	SG	86.0	% (w/w)	Soil treatment - spraying			1	2	60		1.20	4.00	kg a.i./ha	35	Band application (on row) or spot treatment - Application from Autumn to Spring
Wine grapes	<i>Vitis euvitis</i>	NEU	Outdoor	FR	WEEDS	SG	86.0	% (w/w)	Soil treatment - spraying			1	3	60		1.20	4.00	kg a.i./ha	28	Band application (on row) or spot treatment - Application from Autumn to Spring
Currants (red, black and white)	<i>Ribes nigrum</i> , <i>rubrum</i>	NEU	Outdoor	NL	WEEDS	SC	250.0	g/L	Soil treatment - spraying	0	0		1			3.00	4.00	kg a.i./ha		Spraying of aerial parts of weeds under currant bushes - Application after harvest , no later than 1 November - not within 3 months of planting
Gooseberries	<i>Ribes uva-crispa</i>	NEU	Outdoor	NL	WEEDS	SC	250.0	g/L	Soil treatment - spraying	0	0		1			3.00	4.00	kg a.i./ha		Spraying of aerial parts of weeds under gooseberries bushes - Application after harvest , no later than 1 November - not within 3 months of planting

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			Growth stage	From BBCH	Until BBCH	Number		Interval (days)				Min. rate	Max. rate	Rate Unit
							Conc.	Unit					Min.	Max.	Min.	Max.					
Grapefruit	<i>Citrus paradisi</i>	SEU	Outdoor	ES	WEEDS	SL	240.0	g/L	Soil treatment - spraying			1	3	60		1.20	3.60	kg a.i./ha	35	Application : all year around except during fruit ripening - Broadcast spraying between crop plants with tractor mounted boom - preparation include ammonium thiocyanate at 215g/L	
Oranges	<i>Citrus sinensis</i>	SEU	Outdoor	ES	WEEDS	SL	240.0	g/L	Soil treatment - spraying			1	3	60		1.20	3.60	kg a.i./ha	35	Application : all year around except during fruit ripening - Broadcast spraying between crop plants with tractor mounted boom - preparation include ammonium thiocyanate at 215g/L	
Lemons	<i>Citrus limon</i>	SEU	Outdoor	ES	WEEDS	SL	240.0	g/L	Soil treatment - spraying			1	3	60		1.20	3.60	kg a.i./ha	35	Application : all year around except during fruit ripening - Broadcast spraying between crop plants with tractor mounted boom - preparation include ammonium thiocyanate at 215g/L	
Limes	<i>Citrus aurantifolia</i>	SEU	Outdoor	ES	WEEDS	SL	240.0	g/L	Soil treatment - spraying			1	3	60		1.20	3.60	kg a.i./ha	35	Application : all year around except during fruit ripening - Broadcast spraying between crop plants with tractor mounted boom - preparation include ammonium thiocyanate at 215g/L	
Mandarins	<i>Citrus reticulata</i>	SEU	Outdoor	ES	WEEDS	SL	240.0	g/L	Soil treatment - spraying			1	3	60		1.20	3.60	kg a.i./ha	35	Application : all year around except during fruit ripening - Broadcast spraying between crop plants with tractor mounted boom - preparation include ammonium thiocyanate at 215g/L	
Almonds	<i>Prunus dulcis</i>	SEU	Outdoor	FR	WEEDS	SG	86.0	% (w/w)	Soil treatment - spraying			1	2	60		1.20	4.00	kg a.i./ha	35	Band application (on row) or spot treatment - Application from Autumn to Spring	
Hazelnuts	<i>Corylus avellana</i>	SEU	Outdoor	FR	WEEDS	SG	86.0	% (w/w)	Soil treatment - spraying			1	2	60		1.20	4.00	kg a.i./ha	35	Band application (on row) or spot treatment - Application from Autumn to Spring	
Walnuts	<i>Juglans regia</i>	SEU	Outdoor	FR	WEEDS	SG	86.0	% (w/w)	Soil treatment - spraying			1	2	60		1.20	4.00	kg a.i./ha	35	Band application (on row) or spot treatment - Application from Autumn to Spring	
Apples	<i>Malus domestica</i>	SEU	Outdoor	FR	WEEDS	SG	86.0	% (w/w)	Soil treatment - spraying			1	2	60		1.20	4.00	kg a.i./ha	35	Band application (on row) or spot treatment - Application from Autumn to Spring	
Pears	<i>Pyrus communis</i>	SEU	Outdoor	FR	WEEDS	SG	86.0	% (w/w)	Soil treatment - spraying			1	2	60		1.20	4.00	kg a.i./ha	35	Band application (on row) or spot treatment - Application from Autumn to Spring	
Quinces	<i>Cydonia oblonga</i>	SEU	Outdoor	FR	WEEDS	SG	86.0	% (w/w)	Soil treatment - spraying			1	2	60		1.20	4.00	kg a.i./ha	35	Band application (on row) or spot treatment - Application from Autumn to Spring	
Medlar	<i>Mespilus germanica</i>	SEU	Outdoor	ES	WEEDS	SG	86.0	% (w/w)	Soil treatment - spraying			1	2	60		1.20	4.00	kg a.i./ha	35	Band application (on row) or spot treatment - Application from Autumn to Spring	
Loquat	<i>Eriobotrya japonica</i>	SEU	Outdoor	ES	WEEDS	SG	86.0	% (w/w)	Soil treatment - spraying			1	2	60		1.20	4.00	kg a.i./ha	35	Band application (on row) or spot treatment - Application from Autumn to Spring	
Apricots	<i>Prunus ameniaca</i>	SEU	Outdoor	FR	WEEDS	SG	86.0	% (w/w)	Soil treatment - spraying			1	2	60		1.20	4.00	kg a.i./ha	35	Band application (on row) or spot treatment - Application from Autumn to Spring	
Cherries	<i>Prunus cerasus</i> , <i>Prunus avium</i>	SEU	Outdoor	FR	WEEDS	SG	86.0	% (w/w)	Soil treatment - spraying			1	2	60		1.20	4.00	kg a.i./ha	35	Band application (on row) or spot treatment - Application from Autumn to Spring	
Peaches	<i>Prunus persica</i>	SEU	Outdoor	FR	WEEDS	SG	86.0	% (w/w)	Soil treatment - spraying			1	2	60		1.20	4.00	kg a.i./ha	35	Band application (on row) or spot treatment - Application from Autumn to Spring	
Plums	<i>Prunus domestica</i>	SEU	Outdoor	FR	WEEDS	SG	86.0	% (w/w)	Soil treatment - spraying			1	2	60		1.20	4.00	kg a.i./ha	35	Band application (on row) or spot treatment - Application from Autumn to Spring	
Table grapes	<i>Vitis euvtis</i>	SEU	Outdoor	FR	WEEDS	SG	86.0	% (w/w)	Soil treatment - spraying			1	3	60		1.20	4.00	kg a.i./ha	28	Band application (on row) or spot treatment - Application from Autumn to Spring	
Wine grapes	<i>Vitis euvtis</i>	SEU	Outdoor	FR	WEEDS	SG	86.0	% (w/w)	Soil treatment - spraying			1	3	60		1.20	4.00	kg a.i./ha	28	Band application (on row) or spot treatment - Application from Autumn to Spring	
Table olives	<i>Olea europaea</i>	SEU	Outdoor	PT	WEEDS	SC	240.0	g/L	Soil treatment - spraying			1				0.96	2.58	kg a.i./ha		In olives tree, do not apply after the falling of the fruit - In France use on olive is currently evaluated with 2.29g/ha and 90 days PHI (preparation also contain oxyfluorfen 100g/l and ammonium thiocyanate 458.9 g/L)	
Olives for oil production	<i>Olea europaea</i>	SEU	Outdoor	PT	WEEDS	SC	240.0	g/L	Soil treatment - spraying			1				0.96	2.58	kg a.i./ha		In olives tree, do not apply after the falling of the fruit - In France use on olive is currently evaluated with 2.29g/ha and 90 days PHI (preparation also contain oxyfluorfen 100g/l and ammonium thiocyanate 458.9 g/L)	

n.a.: not applicable

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Appendix B.1 – EU scenario 1 including all EU MRL proposals resulting from the GAPs reported by the RMS

Appendix B.2 – EU/Codex scenario 1 including demonstrated safe EU MRL proposals and all CXLs

APPENDIX B.1 – EU SCENARIO 1 INCLUDING ALL EU MRL PROPOSALS RESULTING FROM THE GAPS REPORTED BY THE RMS

				amitrole				Prepare workbook for refined calculations			
				Status of the active substance: Included		Code no.:					
				LOQ (mg/kg bw):		proposed LOQ:					
				Toxicological end points				Undo refined calculations			
				ADI (mg/kg bw/day): 0.001		ARfD (mg/kg bw): n.n.					
				Source of ADI: COM		Source of ARfD: COM					
				Year of evaluation: 2001		Year of evaluation: 2001					
Chronic risk assessment - refined calculations											
				TMDI (range) in % of ADI minimum - maximum							
				2 20							
				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)	
	20.1	DE child		12.1	Apples	3.8	Oranges	1.3	Table grapes		
	14.1	WHO Cluster diet B		7.7	Olives for oil production	1.8	Wine grapes	1.0	Apples		
	12.3	NL child		6.3	Apples	3.1	Oranges	0.8	Table grapes		
	7.5	ES child		2.9	Olives for oil production	2.2	Oranges	1.1	Apples		
	7.2	IE adult		1.3	Wine grapes	1.0	Oranges	0.8	Apples		
	6.6	PT General population		2.5	Wine grapes	1.1	Apples	1.0	Olives for oil production		
	6.5	FR all population		4.0	Wine grapes	0.8	Olives for oil production	0.5	Apples		
	5.6	FR toddler		2.6	Apples	2.0	Oranges	0.3	Mandarins		
	5.2	ES adult		1.7	Olives for oil production	1.3	Oranges	0.8	Apples		
	4.8	WHO cluster diet E		1.6	Wine grapes	0.8	Apples	0.7	Olives for oil production		
	4.8	UK Toddler		2.0	Oranges	1.7	Apples	0.3	Mandarins		
	4.3	NL general		1.5	Oranges	1.2	Apples	0.6	Wine grapes		
	4.1	FR infant		2.5	Apples	0.9	Oranges	0.3	Pears		
	3.7	DK child		2.3	Apples	0.7	Pears	0.2	Table grapes		
	3.5	UK Infant		1.6	Apples	1.3	Oranges	0.3	Pears		
	3.3	SE general population 90th percentile		1.1	Apples	0.7	Oranges	0.4	Mandarins		
	3.2	PL general population		2.0	Apples	0.3	Table grapes	0.3	Pears		
	3.1	WHO regional European diet		0.7	Apples	0.5	Olives for oil production	0.5	Oranges		
	2.9	WHO Cluster diet F		0.9	Oranges	0.7	Apples	0.6	Wine grapes		
	2.8	DK adult		1.4	Wine grapes	0.8	Apples	0.2	Pears		
	2.8	UK vegetarian		0.9	Oranges	0.8	Wine grapes	0.6	Apples		
	2.7	IT kids/toddler		0.9	Apples	0.5	Oranges	0.3	Peaches		
	2.4	IT adult		0.8	Apples	0.4	Peaches	0.4	Oranges		
	2.4	UK Adult		1.1	Wine grapes	0.6	Oranges	0.4	Apples		
	2.2	WHO cluster diet D		0.7	Apples	0.4	Wine grapes	0.2	Oranges		
	2.2	LT adult		1.9	Apples	0.2	Pears	0.1	Oranges		
	2.0	FI adult		1.0	Oranges	0.4	Apples	0.3	Wine grapes		
Conclusion:											
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.											
A long-term intake of residues of amitrole is unlikely to present a public health concern.											

APPENDIX B.2 – EU/CODEX SCENARIO 1 INCLUDING DEMONSTRATED SAFE EU MRL PROPOSALS AND ALL CXLs

				<div>amitrole</div>				<div>Prepare workbook for refined calculations</div>			
				Status of the active substance: Included		Code no.					
				LOQ (mg/kg bw):		proposed LOQ:					
				Toxicological end points							
				ADI (mg/kg bw/day): 0.001		ARID (mg/kg bw): n.n.		<div>Undo refined calculations</div>			
				Source of ADI: COM		Source of ARID: COM					
				Year of evaluation: 2001		Year of evaluation: 2001					
Chronic risk assessment - refined calculations											
				TMDI (range) in % of ADI minimum - maximum							
				2 21							
				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	pTMRs at LOQ (in % of ADI)	
	21.3	DE child		12.1	Apples	3.8	Oranges	2.5	Table grapes		
	16.3	WHO Cluster diet B		7.7	Olives for oil production	3.6	Wine grapes	1.0	Apples		
	13.0	NL child		6.3	Apples	3.1	Oranges	1.5	Table grapes		
	10.6	FR all population		8.0	Wine grapes	0.8	Olives for oil production	0.5	Apples		
	9.4	PT General population		5.0	Wine grapes	1.1	Apples	1.0	Olives for oil production		
	8.7	IE adult		2.5	Wine grapes	1.0	Oranges	0.8	Apples		
	7.5	ES child		2.9	Olives for oil production	2.2	Oranges	1.1	Apples		
	6.6	WHO cluster diet E		3.2	Wine grapes	0.8	Apples	0.7	Olives for oil production		
	5.8	FR toddler		2.6	Apples	2.0	Oranges	0.4	Table grapes		
	5.7	ES adult		1.7	Olives for oil production	1.3	Oranges	0.8	Wine grapes		
	5.2	NL general		1.5	Oranges	1.3	Wine grapes	1.2	Apples		
	5.0	UK Toddler		2.0	Oranges	1.7	Apples	0.5	Table grapes		
	4.3	DK adult		2.8	Wine grapes	0.8	Apples	0.2	Pears		
	4.2	FR infant		2.5	Apples	0.9	Oranges	0.3	Pears		
	3.9	DK child		2.3	Apples	0.7	Pears	0.4	Table grapes		
	3.7	UK vegetarian		1.6	Wine grapes	0.9	Oranges	0.6	Apples		
	3.6	UK Infant		1.6	Apples	1.3	Oranges	0.3	Pears		
	3.6	WHO Cluster diet F		1.2	Wine grapes	0.9	Oranges	0.7	Apples		
	3.5	UK Adult		2.2	Wine grapes	0.6	Oranges	0.4	Apples		
	3.5	WHO regional European diet		0.7	Apples	0.5	Olives for oil production	0.5	Oranges		
	3.5	PL general population		2.0	Apples	0.6	Table grapes	0.3	Pears		
	3.3	SE general population 90th percentile		1.1	Apples	0.7	Oranges	0.4	Mandarins		
	2.8	IT kids/toddler		0.9	Apples	0.5	Oranges	0.3	Peaches		
	2.8	WHO cluster diet D		0.7	Wine grapes	0.7	Apples	0.4	Table grapes		
	2.6	IT adult		0.8	Apples	0.4	Peaches	0.4	Oranges		
	2.4	FI adult		1.0	Oranges	0.6	Wine grapes	0.4	Apples		
	2.2	LT adult		1.9	Apples	0.2	Pears	0.1	Oranges		
Conclusion:											
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs were below the ADI. A long-term intake of residues of amitrole is unlikely to present a public health concern.											

APPENDIX C – EXISTING EU MAXIMUM RESIDUE LIMITS (MRLs) AND CODEX LIMITS (CXLs)

Appendix C.1 – Existing EU MRLs

Appendix C.2 – Existing CXLs

APPENDIX C.1 – EXISTING EU MRLs

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

Code number	Groups and examples of individual products to which the MRLs apply (a)	Amitrole
100000	1. FRUIT FRESH OR FROZEN; NUTS	0.01
110000	(i) Citrus fruit	0.01
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0.01
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0.01
110030	Lemons (Citron, lemon)	0.01
110040	Limes	0.01
110050	Mandarins (Clementine, tangerine and other hybrids)	0.01
110990	Others	0.01
120000	(ii) Tree nuts (shelled or unshelled)	0.01
120010	Almonds	0.01
120020	Brazil nuts	0.01
120030	Cashew nuts	0.01
120040	Chestnuts	0.01
120050	Coconuts	0.01
120060	Hazelnuts (Filbert)	0.01
120070	Macadamia	0.01
120080	Pecans	0.01
120090	Pine nuts	0.01
120100	Pistachios	0.01
120110	Walnuts	0.01
120990	Others	0.01
130000	(iii) Pome fruit	0.01
130010	Apples (Crab apple)	0.01
130020	Pears (Oriental pear)	0.01
130030	Quinces	0.01
130040	Medlar	0.01
130050	Loquat	0.01
130990	Others	0.01
140000	(iv) Stone fruit	0.01
140010	Apricots	0.01
140020	Cherries (sweet cherries, sour cherries)	0.01
140030	Peaches (Nectarines and similar hybrids)	0.01
140040	Plums (Damson, greengage, mirabelle)	0.01

Code number	Groups and examples of individual products to which the MRLs apply (a)	Amitrole
140990	Others	0.01
150000	(v) Berries & small fruit	0.01
151000	(a) Table and wine grapes	0.01
151010	Table grapes	0.01
151020	Wine grapes	0.01
152000	(b) Strawberries	0.01
153000	(c) Cane fruit	0.01
153010	Blackberries	0.01
153020	Dewberries (Loganberries, Boysenberries, and cloudberrries)	0.01
153030	Raspberries (Wineberries)	0.01
153990	Others	0.01
154000	(d) Other small fruit & berries	0.01
154010	Blueberries (Bilberries cowberries (red bilberries))	0.01
154020	Cranberries	0.01
154030	Currants (red, black and white)	0.01
154040	Gooseberries (Including hybrids with other ribes species)	0.01
154050	Rose hips	0.01
154060	Mulberries (arbutus berry)	0.01
154070	Azarole (mediteranean medlar)	0.01
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea salallowthorn), hawthorn, service berries, and other treeberries)	0.01
154990	Others	0.01
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	
161010	Dates	0.01
161020	Figs	0.01
161030	Table olives	0.01
161040	Kumquats (Marumi kumquats, nagami kumquats)	0.01
161050	Carambola (Bilimbi)	0.01
161060	Persimmon	0.01
161070	Jambolan (java plum) (Java apple (water apple), pomereac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0.01

Code number	Groups and examples of individual products to which the MRLs apply (a)	Amitrole
161990	Others	0.01
162000	(b) Inedible peel, small	0.01
162010	Kiwi	0.01
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0.01
162030	Passion fruit	0.01
162040	Prickly pear (cactus fruit)	0.01
162050	Star apple	0.01
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammy sapote)	0.01
162990	Others	0.01
163000	(c) Inedible peel, large	0.01
163010	Avocados	0.01
163020	Bananas (Dwarf banana, plantain, apple banana)	0.01
163030	Mangoes	0.01
163040	Papaya	0.01
163050	Pomegranate	0.01
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0.01
163070	Guava	0.01
163080	Pineapples	0.01
163090	Bread fruit (Jackfruit)	0.01
163100	Durian	0.01
163110	Soursop (guanabana)	0.01
163990	Others	0.01
200000	2. VEGETABLES FRESH OR FROZEN	0.01
210000	(i) Root and tuber vegetables	0.01
211000	(a) Potatoes	0.01
212000	(b) Tropical root and tuber vegetables	0.01
212010	Cassava (Dasheen, eddloe (Japanese taro), tannia)	0.01
212020	Sweet potatoes	0.01
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0.01
212040	Arrowroot	0.01
212990	Others	0.01

Code number	Groups and examples of individual products to which the MRLs apply (a)	Amitrole
213000	(c) Other root and tuber vegetables except sugar beet	0.01
213010	Beetroot	0.01
213020	Carrots	0.01
213030	Celeriac	0.01
213040	Horseradish	0.01
213050	Jerusalem artichokes	0.01
213060	Parsnips	0.01
213070	Parsley root	0.01
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0.01
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0.01
213100	Swedes	0.01
213110	Turnips	0.01
213990	Others	0.01
220000	(ii) Bulb vegetables	0.01
220010	Garlic	0.01
220020	Onions (Silverskin onions)	0.01
220030	Shallots	0.01
220040	Spring onions (Welsh onion and similar varieties)	0.01
220990	Others	0.01
230000	(iii) Fruiting vegetables	0.01
231000	(a) Solanacea	0.01
231010	Tomatoes (Cherry tomatoes,)	0.01
231020	Peppers (Chilli peppers)	0.01
231030	Aubergines (egg plants) (Pepino)	0.01
231040	Okra, lady's fingers	0.01
231990	Others	0.01
232000	(b) Cucurbits - edible peel	0.01
232010	Cucumbers	0.01
232020	Gherkins	0.01
232030	Courgettes (Summer squash, marrow (patisson))	0.01
232990	Others	0.01
233000	(c) Cucurbits-inedible peel	0.01
233010	Melons (Kiwano)	0.01
233020	Pumpkins (Winter squash)	0.01
233030	Watermelons	0.01
233990	Others	0.01

Code number	Groups and examples of individual products to which the MRLs apply (a)	Amitrole
234000	(d) Sweet corn	0.01
239000	(e) Other fruiting vegetables	0.01
240000	(iv) Brassica vegetables	0.01
241000	(a) Flowering brassica	0.01
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0.01
241020	Cauliflower	0.01
241990	Others	0.01
242000	(b) Head brassica	0.01
242010	Brussels sprouts	0.01
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0.01
242990	Others	0.01
243000	(c) Leafy brassica	0.01
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0.01
243020	Kale (Borecole (curly kale), collards)	0.01
243990	Others	0.01
244000	(d) Kohlrabi	0.01
250000	(v) Leaf vegetables & fresh herbs	0.01
251000	(a) Lettuce and other salad plants including Brassicaceae	0.01
251010	Lamb's lettuce (Italian cornsalad)	0.01
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0.01
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leaf endive, sugar loaf)	0.01
251040	Cress	0.01
251050	Land cress	0.01
251060	Rocket, Rucola (Wild rocket)	0.01
251070	Red mustard	0.01
251080	Leaves and sprouts of Brassica spp (Mizuna)	0.01
251990	Others	0.01
252000	(b) Spinach & similar (leaves)	0.01
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0.01
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0.01

Code number	Groups and examples of individual products to which the MRLs apply (a)	Amitrole
252030	Beet leaves (chard) (Leaves of beetroot)	0.01
252990	Others	0.01
253000	(c) Vine leaves (grape leaves)	0.01
254000	(d) Water cress	0.01
255000	(e) Witloof	0.01
256000	(f) Herbs	0.01
256010	Chervil	0.01
256020	Chives	0.01
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	0.01
256040	Parsley	0.01
256050	Sage (Winter savory, summer savory,)	0.01
256060	Rosemary	0.01
256070	Thyme (marjoram, oregano)	0.01
256080	Basil (Balm leaves, mint, peppermint)	0.01
256090	Bay leaves (laurel)	0.01
256100	Taragon (Hyssop)	0.01
256990	Others	0.01
260000	(vi) Legume vegetables (fresh)	0.01
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0.01
260020	Beans (without pods) (Broad beans, Flageolet, jack bean, lima bean, cowpea)	0.01
260030	Peas (with pods) (Mangetout (sugar peas))	0.01
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0.01
260050	Lentils	0.01
260990	Others	0.01
270000	(vii) Stem vegetables (fresh)	0.01
270010	Asparagus	0.01
270020	Cardoons	0.01
270030	Celery	0.01
270040	Fennel	0.01
270050	Globe artichokes	0.01
270060	Leek	0.01
270070	Rhubarb	0.01
270080	Bamboo shoots	0.01
270090	Palm hearts	0.01
270990	Others	0.01
280000	(viii) Fungi	0.01

Code number	Groups and examples of individual products to which the MRLs apply (a)	Amitrole
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0.01
280020	Wild (Chanterelle, Truffle, Morel)	0.01
280990	Others	0.01
290000	(ix) Sea weeds	0.01
300000	3. PULSES, DRY	0.01
300010	Beans (Broad beans, navy beans, flageolet, jack beans, lima beans, field beans, cowpeas)	0.01
300020	Lentils	0.01
300030	Peas (Chickpeas, field peas, chickling vetch)	0.01
300040	Lupins	0.01
300990	Others	0.01
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	0.02
401010	Linseed	0.02
401020	Peanuts	0.02
401030	Poppy seed	0.02
401040	Sesame seed	0.02
401050	Sunflower seed	0.02
401060	Rape seed (Bird rapeseed, turnip rape)	0.02
401070	Soya bean	0.02
401080	Mustard seed	0.02
401090	Cotton seed	0.02
401100	Pumpkin seeds	0.02
401110	Safflower	0.02
401120	Borage	0.02
401130	Gold of pleasure	0.02
401140	Hempseed	0.02
401150	Castor bean	0.02
401990	Others	0.02
402000	(ii) Oilfruits	
402010	Olives for oil production	0.05
402020	Palm nuts (palmoil kernels)	0.02
402030	Palmfruit	0.02
402040	Kapok	0.02
402990	Others	0.02
500000	5. CEREALS	0.01
500010	Barley	0.01
500020	Buckwheat	0.01
500030	Maize	0.01
500040	Millet (Foxtail millet, teff)	0.01
500050	Oats	0.01
500060	Rice	0.01

Code number	Groups and examples of individual products to which the MRLs apply (a)	Amitrole
500070	Rye	0.01
500080	Sorghum	0.01
500090	Wheat (Spelt Triticale)	0.01
500990	Others	0.01
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0.02
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0.02
620000	(ii) Coffee beans	0.02
630000	(iii) Herbal infusions (dried)	0.02
631000	(a) Flowers	0.02
631010	Camomille flowers	0.02
631020	Hybiscus flowers	0.02
631030	Rose petals	0.02
631040	Jasmine flowers	0.02
631050	Lime (linden)	0.02
631990	Others	0.02
632000	(b) Leaves	0.02
632010	Strawberry leaves	0.02
632020	Rooibos leaves	0.02
632030	Maté	0.02
632990	Others	0.02
633000	(c) Roots	0.02
633010	Valerian root	0.02
633020	Ginseng root	0.02
633990	Others	0.02
639000	(d) Other herbal infusions	0.02
640000	(iv) Cocoa (fermented beans)	0.02
650000	(v) Carob (st johns bread)	0.02
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0.02
800000	8. SPICES	0.02
810000	(i) Seeds	0.02
810010	Anise	0.02
810020	Black caraway	0.02
810030	Celery seed (Lovage seed)	0.02
810040	Coriander seed	0.02
810050	Cumin seed	0.02
810060	Dill seed	0.02
810070	Fennel seed	0.02
810080	Fenugreek	0.02
810090	Nutmeg	0.02
810990	Others	0.02
820000	(ii) Fruits and berries	0.02
820010	Allspice	0.02
820020	Anise pepper (Japan pepper)	0.02

Code number	Groups and examples of individual products to which the MRLs apply (a)	Amitrole
820030	Caraway	0.02
820040	Cardamom	0.02
820050	Juniper berries	0.02
820060	Pepper, black and white (Long pepper, pink pepper)	0.02
820070	Vanilla pods	0.02
820080	Tamarind	0.02
820990	Others	0.02
830000	(iii) Bark	0.02
830010	Cinnamon (Cassia)	0.02
830990	Others	0.02
840000	(iv) Roots or rhizome	0.02
840010	Liquorice	0.02
840020	Ginger	0.02
840030	Tumeric (Curcuma)	0.02
840040	Horseradish	0.02
840990	Others	0.02
850000	(v) Buds	0.02
850010	Cloves	0.02
850020	Capers	0.02
850990	Others	0.02
860000	(vi) Flower stigma	0.02
860010	Saffron	0.02
860990	Others	0.02
870000	(vii) Aril	0.02
870010	Mace	0.02
870990	Others	0.02
900000	9. SUGAR PLANTS	0.01
900010	Sugar beet (root)	0.01
900020	Sugar cane	0.01
900030	Chicory roots	0.01
900990	Others	0.01

Code number	Groups and examples of individual products to which the MRLs apply (a)	Amitrole
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	
1011000	(a) Swine	
1011010	Meat	
1011020	Fat free of lean meat	
1011030	Liver	
1011040	Kidney	
1011050	Edible offal	
1011990	Others	
1012000	(b) Bovine	
1012010	Meat	
1012020	Fat	
1012030	Liver	
1012040	Kidney	
1012050	Edible offal	
1012990	Others	
1013000	(c) Sheep	
1013010	Meat	
1013020	Fat	
1013030	Liver	
1013040	Kidney	
1013050	Edible offal	
1013990	Others	
1014000	(d) Goat	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Amitrole
1014010	Meat	
1014020	Fat	
1014030	Liver	
1014040	Kidney	
1014050	Edible offal	
1014990	Others	
1015000	(e) Horses, asses, mules or hinnies	
1015010	Meat	
1015020	Fat	
1015030	Liver	
1015040	Kidney	
1015050	Edible offal	
1015990	Others	
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	
1016010	Meat	
1016020	Fat	
1016030	Liver	
1016040	Kidney	
1016050	Edible offal	
1016990	Others	
1017000	(g) Other farm animals (Rabbit, Kangaroo)	
1017010	Meat	
1017020	Fat	
1017030	Liver	
1017040	Kidney	
1017050	Edible offal	
1017990	Others	
1020000	(ii) Milk and cream, not concentrated, nor containing	

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

(*) Indicates lower limit of analytical determination

(a): Table footnote

APPENDIX C.2 – EXISTING CXLS

Summary of CXLs for amitrole in plant commodities															
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation		
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
130010	Apples	amitrole	0.01 *	amitrole	0	n.c.	1	n.c.	0.01	0.01	n.a.	1	1998	No	Trials were carried out in the EU on apples, pears and peaches (stone removed) according to the French GAP, however these also covered an Australian GAP. CXL set at 0.05* as this was found to be a practical LOD. All residues were <LOQ of 0.01 or 0.02 mg/kg - EFSA HR therefore stated as highest LOQ.
130020	Pears	amitrole	0.01 *	amitrole	0	n.c.	1	n.c.	0.01	0.01	n.a.	1	1998	No	
130030	Quinces	amitrole	0.01 *	amitrole	0	n.c.	1	n.c.	0.01	0.01	n.a.	1	1998	No	
130040	Medlar	amitrole	0.01 *	amitrole	0	n.c.	1	n.c.	0.01	0.01	n.a.	1	1998	No	
130050	Loquat	amitrole	0.01 *	amitrole	0	n.c.	1	n.c.	0.01	0.01	n.a.	1	1998	No	
140010	Apricots	amitrole	0.01 *	amitrole	0	n.c.	1	n.c.	0.01	0.01	n.a.	1	1998	No	
140020	Cherries	amitrole	0.01 *	amitrole	0	n.c.	1	n.c.	0.01	0.01	n.a.	1	1998	No	
140030	Peaches	amitrole	0.01 *	amitrole	0	n.c.	1	n.c.	0.01	0.01	n.a.	1	1998	No	Trials were carried out in the EU according to the French GAP, however these trials also covered an Australian GAP. CXL set at 0.05 as the HR of 0.087 mg/kg may have resulted from contamination, the next highest residue was 0.03
140040	Plums	amitrole	0.01 *	amitrole	0	n.c.	1	n.c.	0.01	0.01	n.a.	1	1998	No	
151010	Table grapes	amitrole	0.05	amitrole	0.02	n.c.	1	n.c.	0.02	0.03	n.a.	1	1998	No	
151020	Wine grapes	amitrole	0.05	amitrole	0.02	n.c.	1	n.c.	0.02	0.03	n.a.	1	1998	No	

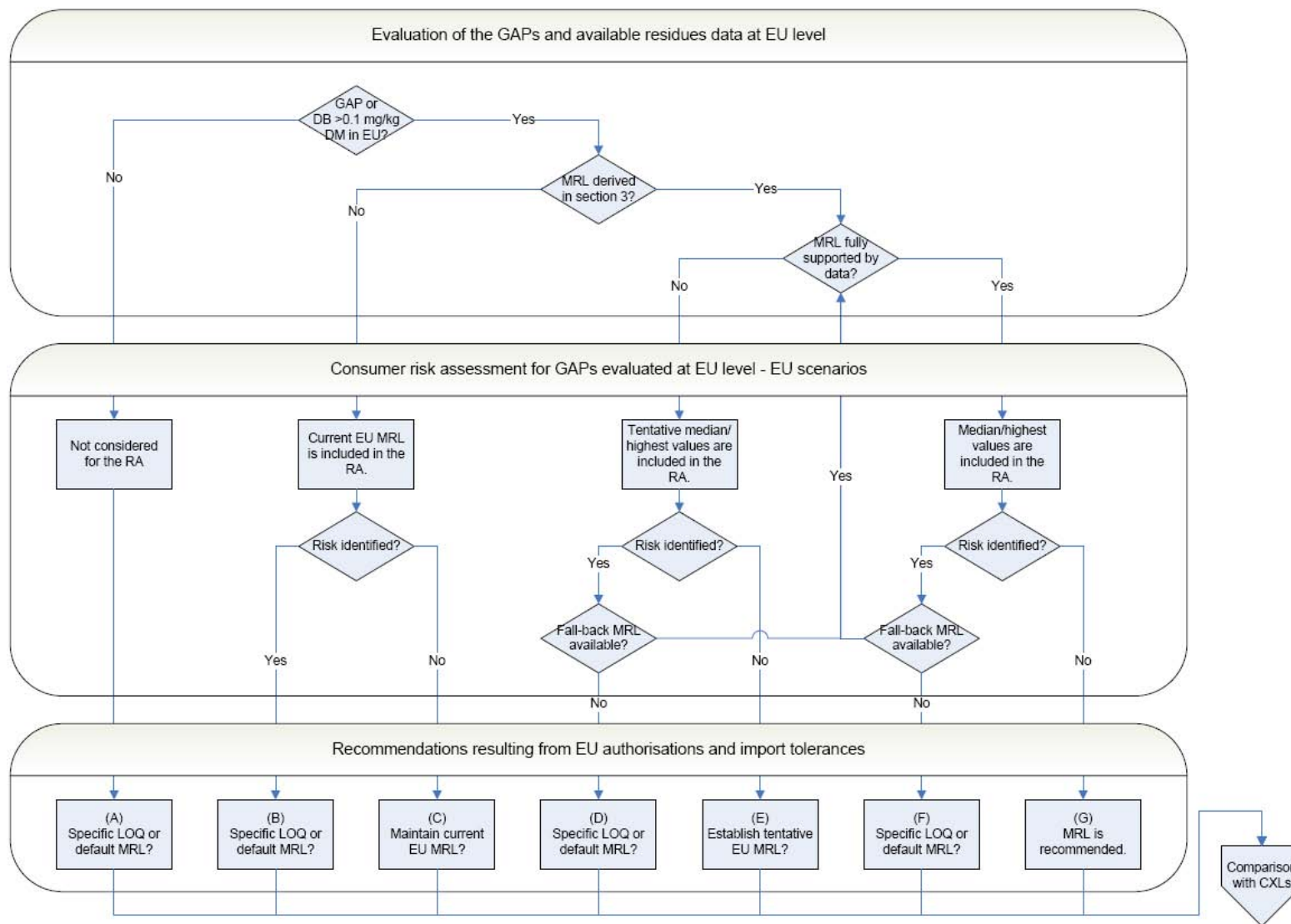
(*) Indicates the lower limit of analytical quantification.

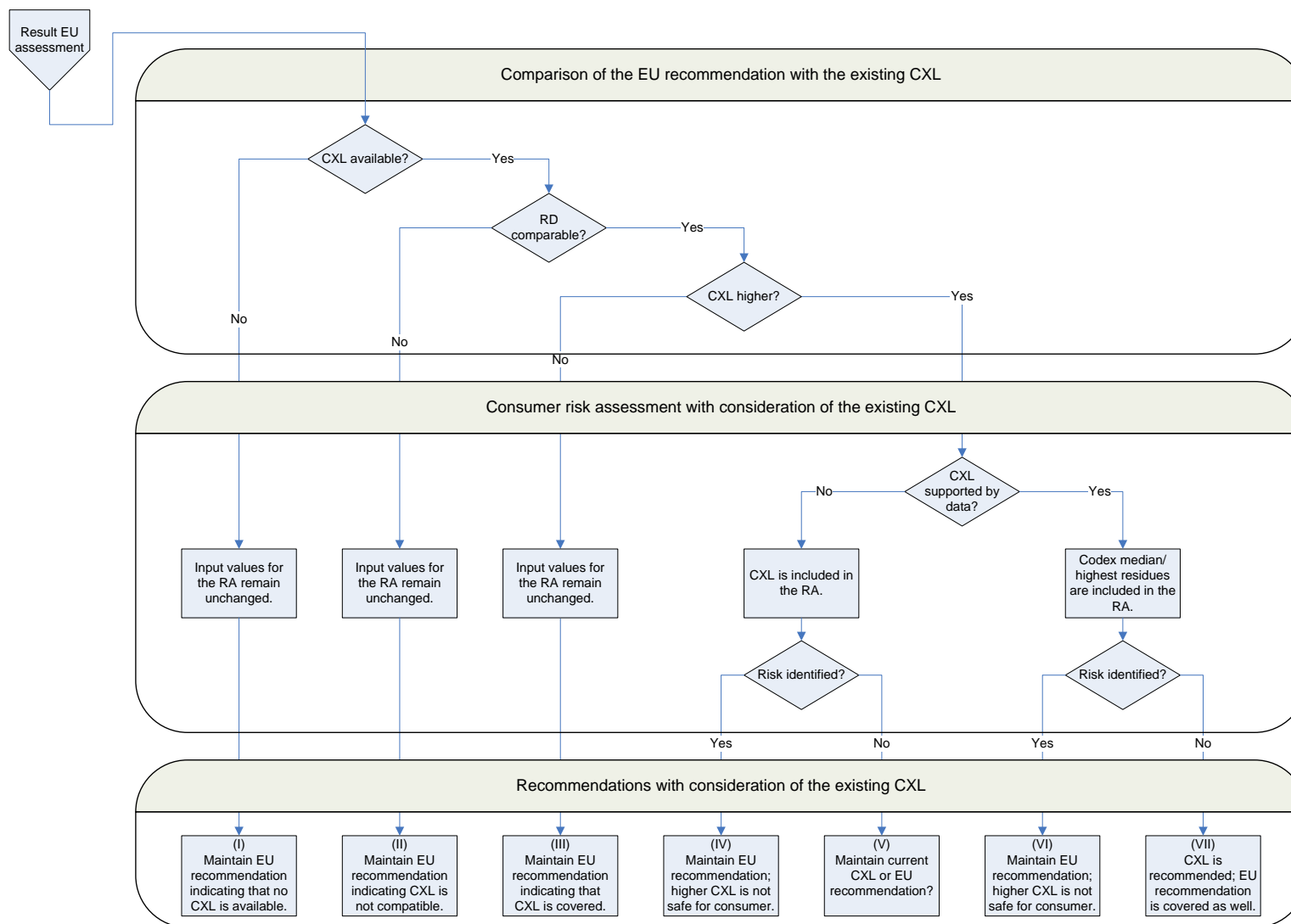
n.a.: not applicable

n.c.: not considered

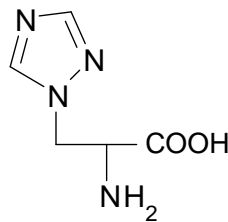
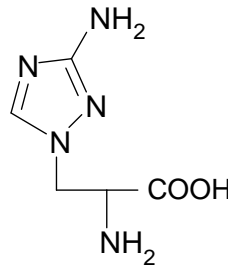
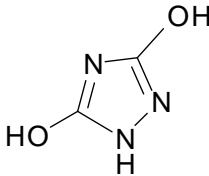
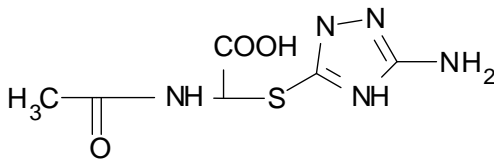
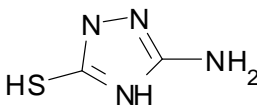
n.k.: not known

APPENDIX D – DECISION TREE FOR DERIVING MRL RECOMMENDATIONS





APPENDIX E – LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

Common name	IUPAC name	Structural formula
triazolylalanine	3-(1,2,4-triazole-1-yl)-2-aminopropionic acid	
aminotriazolylalanine	3-(3-amino-1,2,4-triazole-1-yl)-2-aminopropionic acid	
dihydroxy-1,2,4-triazole	3,5-dihydroxy-1,2,4-triazole	
3-amino-1,2,4-triazolyl-5-mercaptopuric acid	3-amino-1,2,4-triazolyl-5-mercaptopuric acid	
3-amino-5-mercapto-1,2,4-triazole	3-amino-5-mercapto-1,2,4-triazole	

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
CAC	Codex Alimentarius Commission
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DAT	days after treatment
DM	dry matter
EC	European Commission
ECCO	European Community Co-Ordination
EFSA	European Food Safety Authority
eq	residue expressed as a.s. equivalent
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
ha	hectare
ILV	independent laboratory validation
ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States

NEU	northern European Union
PHI	pre-harvest interval
PROFile	(EFSA) Pesticide Residue Overview File
PRIMo	(EFSA) Pesticide Residues Intake Model
RMS	rapporteur Member State
SEU	Southern European Union
TDM	triazole derivative metabolites
TRR	total radioactive residue
WHO	World Health Organisation