European Food Safety Authority

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## REASONED OPINION

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

**European Food Safety Authority**[2, 3]

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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 acibenzolar-S-methyl. In order to assess the occurrence of acibenzolar-S-methyl 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 import tolerances and 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.



## KEY WORDS

acibenzolar-S-methyl, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, benzothiadiazole, plant growth regulator.

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## SUMMARY

Acibenzolar-S-methyl was included in Annex I to Directive 91/414/EEC on 01 November 2001, which is before the entry into force of Regulation (EC) No 396/2005 on 02 September 2008. EFSA is therefore required to provide a reasoned opinion on the review of the existing MRLs for that active substance in compliance with Article 12(2) of the aforementioned regulation. In order to collect the relevant pesticide residues data, EFSA asked France, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile). The requested information was submitted to EFSA on 14 April 2009 and, after having considered several comments made by EFSA, the RMS provided on 15 December 2009 a revised PROFile.

Based on the conclusions derived in the framework of Directive 91/414/EEC and the additional information provided by the RMS, EFSA issued on 29 May 2012 a draft reasoned opinion that was circulated to Member States' experts for consultation. Comments received by 03 August 2012 were discussed in a meeting of experts, which took place on 23 November 2012, and the outcome of that meeting was considered for finalisation of this reasoned opinion. The following conclusions are derived.

The toxicological profile of acibenzolar-S-methyl was evaluated in the framework of Directive 91/414/EEC which resulted in an ADI of 0.1 mg/kg bw per d. An ARfD was not deemed necessary.

Primary crop metabolism of acibenzolar-S-methyl was investigated on three different crops using foliar application treatment. These crops are representative of cereals (wheat), fruits and fruiting vegetables (tomatoes) and leafy vegetables (tobacco, lettuce). During the consultation of member states it was agreed that a general residue definition for enforcement and risk assessment should be set as the sum of acibenzolar-S-methyl and acibenzolar-acid (free and conjugated), expressed as acibenzolar-S-methyl. Analytical methods for enforcement of this residue definition in plants are available with a LOQ of 0.01 mg/kg in high water, dry and high oil content commodities. In future, further information on the occurrence of free acid in plant commodities would be desirable in order to simplify the residue definition for enforcement to acibenzolar acid only.

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 adequate MRLs, except for apples and pears where further clarification on the discrepancies observed in the apple and pear residue trials is required, and for mangoes where further residues trials are still needed to support the MRL proposal.

The nature of residues in processed commodities was considered following the inclusion of acibenzolar-S-methyl in Annex I and it was concluded that the same residue definition as for primary crops can be applied to processed commodities. Studies investigating the magnitude of residues in processed commodities of tomatoes were reported in the PROFile submitted by the RMS. Robust processing factors for enforcement and risk assessment could be derived for peeled tomatoes (0.65) and tomato paste (1.88). Further processing studies are not required as they are not expected to affect the outcome of the risk assessment. However, if more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

The fate of acibenzolar-S-methyl residues in rotational crops of lettuce, radish, winter wheat and maize was investigated during the peer review. All residue levels in the crops were found to be equal or below 0.001 mg/kg. Consequently, residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that acibenzolar-S-methyl is applied in compliance with the GAPs reported in Appendix A.

The nature of acibenzolar-S-methyl residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC. Reported metabolism studies include one study in lactating goat and one study in laying hen. However, it was agreed during the consultation of Member States that no

residue definition or MRLs would be required for products of animal origin based on the following observations; the calculated dietary burden for meat ruminants was the only one to slightly exceed the trigger value of 0.1 mg/kg, low absolute levels in the animal metabolism studies were observed and in the available feeding studies all residues in products of animal origin were below the LOQ, despite the exaggerated 10N dose rate. An analytical method for enforcement of residues in food of animal origin is not necessary.

Chronic consumer exposure resulting from the authorisations reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure was calculated for WHO cluster B representing 0.7 % 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 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 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, certain tentative or existing EU MRLs still need to be confirmed by the following data:

- 2 additional trials supporting the GAP on mangos;
- further clarification on the discrepancies observed in the apple and pear residue trials.

Minor deficiencies were 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 data are therefore considered desirable but not essential:

- further information on the occurrence of free acid in plant commodities in order to simplify the residue definition for enforcement to acibenzolar acid only;
- 1 additional trial on tomato complying with the indoor GAP;
- 4 trials on apricots compliant with the southern outdoor GAP on peaches and apricots (data gap resulting from a new extrapolation rule).

**SUMMARY TABLE**

| Code number | Commodity | Existing EU MRL (mg/kg) | Outcome of the review | |
|---|---|---|---|---|
| | | | MRL (mg/kg) | Comment |
| **Enforcement residue definition (existing):** sum of acibenzolar-S-methyl and acibenzolar acid (CGA 210007) expressed as acibenzolar-S-methyl<br>**Enforcement residue definition (proposed):** sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-S-methyl | | | | |
| 120060 | Hazelnuts | 0.1 | 0.1 | Recommended [(a)] |
| 130010 | Apples | 0.01* | 0.1 | Further consideration needed [(b)] |
| 130020 | Pears | 0.02* | 0.1 | Further consideration needed [(b)] |
| 140010 | Apricots | 0.02* | 0.2 | Recommended [(a)] |

| Code number | Commodity | Existing EU MRL (mg/kg) | Outcome of the review | |
|---|---|---|---|---|
| | | | MRL (mg/kg) | Comment |
| 140030 | Peaches | 0.02* | 0.2 | Recommended [(a)] |
| 163020 | Bananas | 0.1 | 0.08 | Recommended [(a)] |
| 163030 | Mangoes | 0.5 | 0.6 | Further consideration needed [(b)] |
| 231010 | Tomatoes | 1 | 0.9 | Recommended [(a)] |
| 251000 | Lettuce and other salad plants including *Brassicacea* | 0.3 | 0.3 | Recommended [(a)] |
| 252010 | Spinach | 0.3 | 0.3 | Recommended [(a)] |
| 256000 | Herbs | 0.02* | 0.3 | Recommended [(a)] |
| 500010 | Barley grain | 0.05* | 0.05 | Recommended [(a)] |
| 500090 | Wheat grain | 0.05* | 0.05 | Recommended [(a)] |
| - | Other products of plant and/or animal origin | See appendix C | - | Further consideration needed [(c)] |

(*): 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 could be identified; no CXL is available (combination E-I in Appendix D).
(c): 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 396/2005[4] establishes the rules governing the setting and the review of pesticide MRLs at European level. Article 12(2) of that regulation stipulates that EFSA shall provide by 01 September 2009 a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Directive 91/414/EEC[5] before 02 September 2008. As acibenzolar-S-methyl was included in Annex I to the above mentioned directive on 01 November 2001, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2008-486 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 acibenzolar-S-methyl. The requested information was submitted to EFSA on 14 April 2009 and subsequently checked for completeness. On 15 December 2009, after having clarified some issues with EFSA, the RMS provided a revised PROFile.

A draft reasoned opinion was issued by EFSA on 29 May 2012 and submitted to Member States (MS) for commenting. All MS comments received by 03 August 2012 were evaluated by EFSA. As further discussion on some unresolved issues was required, a meeting with MS experts took place on 23 November 2012. The conclusions of this meeting 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.

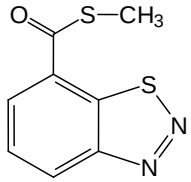
## TERMS OF REFERENCE

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

Acibenzolar-S-methyl is the ISO common name for S-methyl benzo[1,2,3]thiadiazole-7-carbothioate (IUPAC).




Acibenzolar-S-methyl belongs to the group of benzothiadiazole compounds which are used to stimulate the natural, inherent defence mechanisms of plants to prevent plant diseases. The naturally occurring phenomenon of this defence response is called Systemic Activated Resistance (SAR), also known as systemic acquired resistance or systemic induced resistance. SAR is a broad physiological immunization in plants that occurs in nature. Acibenzolar-S-methyl imitates the natural biological SAR induction by activating the same biochemical changes in plants as after a biological induction. Through this activation, control of *Ersiphe graminis* (powdery mildew of cereals), *Peonospora tabacina* (blue mould of tobacco), and Black Sigatoka of banana is achieved. It has been shown that the substance as such does not have an intrinsic fungicidal activity.

Acibenzolar-S-methyl was evaluated in the framework of Directive 91/414/EEC with France being the designated rapporteur Member State (RMS). The representative uses supported for the peer review process were foliar spray applications on cereals, tobacco and banana (EU-Import tolerance). Following the peer review, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2001/87/EC[6], entering into force on 01 November 2001. According to Regulation (EU) No 540/2011[7], acibenzolar-S-methyl is deemed to have been approved under Regulation (EC) No 1107/2009[8]. This approval is restricted to uses as a growth regulator only. As EFSA was not yet involved in the peer review of acibenzolar-S-methyl, a conclusion of EFSA on this active substance is not available.

The EU MRLs for acibenzolar-S-methyl are established in Annex II of Regulation (EC) No 396/2005. Since the entry into force of that regulation, EFSA recommended the modification of the existing MRLs for apricot and peaches (EFSA, 2009), which was legally implemented in Regulation (EC) No 750/2010/EC[9], and lettuce and other salad plants including *Brassicaceae* (EFSA, 2012) which was

[6] Directive 2001/87/EC of 12 October 2001, OJ L 276, 19.10.2001, p. 17–20.
[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.
[9] Regulation (EC) No 750/2010 of 7 July 2010, OJ 220, 21.08.2010, p. 1-56.

legally implemented in Regulation (EU) No 987/2012[10] . For the latter application, the extrapolation from lettuce to other salad plants including *Brassicaceae* was agreed on a provisional basis only and residue trials for open leaf varieties are requested. All existing EU MRLs, which are established for the sum of acibenzolar-S-methyl and acibenzolar acid expressed as acibenzolar-S-methyl, are summarized in Appendix C to this document. CXLs for acibenzolar-S-methyl are not available.

For the purpose of this MRL review, the critical uses of acibenzolar-S-methyl currently authorized within the EU as well as uses authorised in third countries that might have a significant impact on international trade, 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). Several outdoor and indoor uses are authorised on a range of crops with 1-7 applications at rates up to 0.45 kg a.s./ha and PHI ranging between 3-28 days.

## ASSESSMENT

EFSA bases its assessment on the PROFile submitted by the RMS, the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (France, 1998), the review report on acibenzolar-S-methyl (EC, 2002), the previous reasoned opinions on acibenzolar-S-methyl (EFSA 2009, 2012) as well as the evaluation reports submitted during the consultation of Member States (Spain, 2012; Italy, 2012; France, 2012). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation of the Authorization of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[11] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011).

## 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 HPLC-HPLC-UVD was validated for the determination of acibenzolar-S-methyl and acibenzolar acid[12], determined by hydrolysis as the common moiety acibenzolar acid in plant matrices with a LOQ of 0.02 mg/kg in high water (bananas, tomatoes, cucumbers) and dry commodities (cereals) (France, 1998). The method was not sufficiently supported by confirmatory data and therefore it was not considered as being fully validated.

Following the consultation of Member States, EFSA evaluated an LC-MS/MS method and its ILV. The method was validated for the determination of acibenzolar-S-methyl and acibenzolar acid (free and conjugated) with a LOQ of 0.01 mg/kg in high water content commodities (tomatoes, apples, bananas, spinach and peaches), dry commodities (dry tobacco leaves) and high oil content commodities (hazelnuts) (Spain, 2012). This method includes a hydrolysis step during extraction, and therefore determined residues of parent acibenzolar-S-methyl and acibenzolar acid (free and conjugated). The extraction procedure used in both the LC-MS/MS method and in the primary metabolism studies was considered to be sufficiently similar (0.1 M NaOH) and therefore further information on the efficiency of hydrolysis was not deemed necessary.

The multi-residue QuEChERS method in combination with HPLC-MS/MS is also available to analyse acibenzolar-S-methyl and acibenzolar acid separately in high water commodities (EURL, 2012) but this is not considered adequate as the relative standard deviation (RSD) for acibenzolar acid exceeded 20 % and recoveries were approximately 50 % in water containing matrices.

[10] Regulation (EU) No 897/2012 of 01 October 2012, OJ L 266, 2.10.2012, p. 1-31.
[11] Regulation (EU) No 546/2011 of 10 June 2011. OJ L 155, 11.06.2011, p. 127-175.
[12] 1,2,3-benzothiadiazole-7-carboxylic acid: See Appendix E.

Hence it is concluded that the sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated) can be enforced in food of plant origin with a combined LOQ of 0.01 mg/kg in high water content, high oil content and dry commodities.

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

During the peer review under Directive 91/414/EEC, an analytical method using HPLC-UVD was evaluated and validated for the determination of acibenzolar-S-methyl and acibenzolar acid (free and conjugated), determined by hydrolysis as the common moiety acibenzolar acid, in food of animal origin with a LOQ of 0.02 mg/kg in meat and eggs and 0.005 mg/L in milk. No ILV was reported (France, 1998).

However, it was agreed during the consultation of Member States that no residue definition or MRLs would be required for products of animal origin based on the low absolute residue levels in the metabolism studies. In addition the trigger value for the livestock dietary burden was only slightly exceeded for meat ruminants. Therefore an analytical method for enforcement of residues in food of animal origin is not necessary.

## 2. Mammalian toxicology

The toxicological assessment of acibenzolar-S-methyl was peer reviewed under Directive 91/414/EEC and toxicological reference values were established by the European Commission (2002). 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 |
|---|---|---|---|---|---|
| **Acibenzolar-S-methyl** | | | | | |
| ADI | EC | 2002 | 0.1 mg/kg bw per d | 90 d and 12 month dog study | 100 |
| ARfD | EC | 2002 | Not necessary | | |

## 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 acibenzolar-S-methyl was investigated for foliar application on cereals (wheat), fruiting vegetables (tomatoes) and leafy crops (tobacco) using [$^{14}$C-U-phenyl]-acibenzolar-S-methyl (France, 1998). A metabolism study on lettuce, which was not evaluated in the peer review, was presented in the application for the modification of the existing MRLs for acibenzolar-S-methyl in peaches and apricots. The characteristics of all studies are summarized in Table 3-1.

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

| Group | Crop | Label position | Application and sampling details | | | | |
|---|---|---|---|---|---|---|---|
| | | | Method, F or G [(a)] | Rate (kg a.s./ha) | No | Sampling (DAT) | Remarks |
| Cereals | Wheat | $^{14}$C-U-phenyl | Foliar, F | 0.05 | 1 | At harvest | Application at the end of tillering |
| | Wheat | $^{14}$C-U-phenyl | Foliar, G | 0.05 | 1 | At harvest | Application at 4 leaf stage |
| Fruits and fruiting vegetables | Tomato | $^{14}$C-U-phenyl | Foliar, G | 0.273[(b)] | 3 | At harvest | - |
| Leafy vegetables | Tobacco | $^{14}$C-U-phenyl | Foliar, G | 0.170[(b)] | 3 | At harvest | - |
| | Lettuce | $^{14}$C-U-phenyl | Foliar, G | 0.42 [(b)] | 4 | At harvest | - |
| | Lettuce | $^{14}$C-U-phenyl | Foliar, G | 0.14 [(b)] | 4 | At harvest | 1$^{st}$ application 7-9 leaf stage |

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

In mature spring wheat grown under field conditions the highest TRR was identified in straw (0.328 mg eq./kg). The TRR in grains and husks were 0.014 mg eq./kg and 0.233 mg eq./kg respectively. Parent was not detected in any of the raw agricultural commodities at harvest.

The non-extractable radioactivity accounted for 59.7% of the TRR (0.0084 mg/kg) in grains, 56.6 % of the TRR (0.13 mg/kg) in the husks and 67.9 % of the TRR (0.22 mg/kg) in the straw. The extractable radioactivity found in grains, husks, straw, ears, stalks and shoots mainly consisted of consisted of acibenzolar acid[13] and 5-OH-acibenzolar acid[14]. After treatment with cellulase or esterase and hydrolysis the relative amounts of the 4 remaining fractions (23 % of the TRR in grains) decreased, in favour of acibenzolar acid. This behaviour indicates that other fractions consisted of the acid in various conjugated forms, mostly as esters of sugars and/or other plant constituents. Characterization of the non-extractable radioactivity in grains showed that 15.8 % of the TRR (0.002 mg/kg) could be hydrolyzed to acibenzolar acid, 5.8 % of the TRR (0.0008 mg/kg) were incorporated into starch and 8.7 % of the TRR (0.0012 mg/kg) were detected in the protein precipitate. In total 39.3 %, 40.9 % and 45.3 % of the radioactivity in grains, husks and straw consisted of or could be converted to acibenzolar acid respectively.

The following absolute TRR levels were indicated at harvest for [$^{14}$C-U-phenyl] acibenzolar-S-methyl in tomatoes (0.312 mg/kg) and foliage (0.719 mg/kg). The non-extractable radioactivity was low accounting for 3.4 % (0.011 mg/kg) in tomatoes and 7.4 % (0.05 mg/kg) in foliage. In tomatoes the main radiolabelled products found were 5-OH acibenzolar acid, 4-OH acibenzolar acid[14] and acibenzolar acid. 5-OH acibenzolar acid accounted for 6.5 % (0.02 mg/kg) and 1.5 % (0.011 mg/kg), 4-OH acibenzolar acid for 0.4 % (0.0012 mg/kg) and 6.1 % (0.04 mg/kg), acibenzolar acid for 8.1 % (0.03 mg/kg) and 19.2 % (0.14 mg/kg) of the TRR in tomatoes and foliage respectively.

Following treatment of the tomato extracts with cellulase, the relative amount of 4-OH acibenzolar acid and acibenzolar acid increased significantly to 8.2 % (0.025 mg/kg) and 34.2 % (0.106 mg/kg) respectively. Complete hydrolysis of the remaining fractions to form acibenzolar acid could be

[13] 1,2,3-benzothiadiazole-7-carboxylic acid. See Appendix E.
[14] 1,2,3-benzothiaziazole-5-hydroxy-7-carboxylic acid. See Appendix E.

achieved following treatment with 0.1N NaOH. After this treatment, acibenzolar acid accounted for 64.3 % (0.20 mg/kg) of the measured residue.

The following absolute TRR levels were indicated at harvest for [$^{14}$C-U-phenyl] acibenzolar-S-methyl in tobacco lower leaves (1.38 mg/kg – uncured), upper leaves (0.434 mg/kg) and stems (0.022 mg/kg). Parent concentration amounted to 0.079 mg/kg, 0.026 mg/kg and 0.002 mg/kg in lower leaves, upper leaves and stems respectively. Curing of the leaves increased the residues about eight fold; lower leaves (11.6 mg/kg) and upper leaves (2.719 mg/kg).

The non-extractable residue accounted for 5.0 % and 9.4 % of the TRR in lower leaves (uncured/cured) and 4.5 % and 7.3 % in upper leaves uncured and cured, respectively. The TLC metabolite pattern of the extracted TRR found in cured and uncured leaves consisted of about 7 metabolite fractions. Three metabolites were characterized as 5-OH acibenzolar acid, 4-OH acibenzolar acid and acibenzolar acid accounting for 1.7% (0.023 mg/kg) and 0.9 % (0.0039 mg/kg), 1.3 % (0.018 mg/kg) and 0.7 % (0.003 mg/kg) and 9.0 % (0.124 mg/kg) and 6.4 % (0.027 mg/kg) of the TRR in uncured lower and upper leaves respectively. After treatment of the crude extracts of leaves with cellulose, the relative amount of the remaining polar metabolite fractions (74 % and 80.8 % of the TRR in lower and upper leaves) decreased to 53.4% and 58.3 % of the TRR. The amount of acibenzolar acid, 5-OH acibenzolar acid and 4-OH acibenzolar acid increased significantly to 22.1 % (0.304 mg/kg) and 21.7 % (0.094 mg/kg), to 4.6% (0.063 mg/kg) and 3.3 % (0.014 mg/kg) and to 7.3 % (0.100 mg/kg) and 5.4 % (0.023 mg/kg) of the total radioactivity respectively both in the lower and upper leaves, respectively. Subsequent hydrolysis nearly completely hydrolyzed the remaining polar metabolite fractions in favour of acibenzolar acid which then accounted then for 70.4 % (0.97 mg/kg) and 73.4 % (0.32 mg/kg) of the TRR in lower and upper leaves respectively.

The following absolute TRR levels at harvest were indicated at harvest for [$^{14}$C-U-phenyl] acibenzolar-S-methyl in lettuce (1.014 mg/kg – low dose rate (1N) and 3.668 mg/kg – high dose rate (3N)). The minor part of the radioactivity was found on the lettuce surface (20.2 % - 2 mg/kg and 23 % - 0.84 mg/kg respectively) whereas the major portion of the total radioactivity penetrated the leaf surface. The surface wash and washed leaves were analyzed separately for characterisation and identification of metabolites. On the surface parent compound was the predominant compound (16.5 %, 0.16 mg/kg of the TRR (1N), 19.3 %, 0.71 mg/kg of the TRR (3N)). The metabolites were in all cases below 1% of the TRR (0.007 mg/kg). In washed leaves, four minor metabolites occurring in concentrations of 0.9 % (0.009 mg/kg) to 4.4 % (0.045 mg/kg) of the TRR (1N). In addition in the trials with the 1N dose rate three unidentified metabolites were detected at non-negligible levels (25 % TRR (0.25 mg/kg), 10.3 % TRR (0.104 mg/kg) and 9.6 % TRR (0.097 mg/kg)) but without any further tentative information. In the 3N trial an additional metabolite was detected in a significant concentration ($I_{1b}$ – 12.6 %). The remaining metabolite fractions consisted mainly of sugar conjugates of 4-OH acibenzolar acid and acibenzolar acid.

In wheat, tomato, tobacco and lettuce the metabolic pathway proceeds via hydrolysis of the parent compound to acibenzolar acid, followed by ester conjugation with sugars in tomato, wheat and leafy vegetables. Subsequent oxidation of the phenyl ring of the acid leads to the formation of further metabolites which finally formed sugar conjugates (O-glycosides). All plant metabolites were also identified in the rat metabolism.

Based on the above findings, it is concluded that acibenzolar-S-methyl and acibenzolar acid (free and conjugated) are the relevant compounds to be considered for risk assessment. During the consultation of Member States, several Member States commented that for enforcement purposes however the residue definition should not include conjugates due to the potential difficulties encountered by laboratories when trying to enforce such a complex residue definition. The issue was discussed in a meeting of experts and it was agreed that the general approach to simplify the enforcement residue definition should be applied where possible. However this was not considered feasible in this case based on the following points;

- The available residues data (see also section 3.1.1.2) are based on the total residue including conjugates and would therefore over-estimate the MRLs (up to 8-fold) compared to the acid alone. Comparison of monitoring results based on acid to the MRLs would therefore have little value for enforcement.

- All available methods reported for enforcement purposes (see section 1.1) involve hydrolysis during the extraction step; there are currently no methods available which analyse for acibenzolar acid and available guidance documents do not allow for rejection of the available methods.

- The use of acibenzolar acid as a marker compound for enforcement purposes is questionable given the low levels observed in the residue trials.

Based on these points, it was accepted by all Member States present that the residue definition for enforcement should be set as the sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated) expressed as acibenzolar-S-methyl. However in future, further information on the occurrence of free acid in plant commodities would be desirable in order to simplify the residue definition for enforcement to acibenzolar acid only.

In conclusion, EFSA proposes that the general residue definition is derived for all crops as the *sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-S-methyl.* This residue definition is applicable for risk assessment and enforcement and covers the crops under consideration. Analytical methods for enforcement of the proposed residue definition are also available (see also section 1.1).

#### 3.1.1.2. Magnitude of residues

According to the RMS, the active substance acibenzolar-S-methyl is authorised in northern and southern Europe for foliar application in a large number of crops, both under outdoor and indoor conditions. Authorisations in South Africa and Central America which might have an impact on international trade were also reported (see Appendix A). To assess the magnitude of acibenzolar-S-methyl 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, 1998) or in the framework of a previous MRL application (EFSA, 2009, 2012), and additional data submitted during the consultation of Member States (Spain, 2012; Italy, 2012; France, 2012). 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 were reported by the RMS for all crops under assessment, except in the following cases:

- Apples and pears: In southern Europe, 6 residue trials on pears and 12 trials on apples were carried out in compliance with the GAP on pears (PHI 14d; France, 2012), while 8 trials on apples were carried out in compliance with the critical GAP on apples (PHI 7d; Italy, 2012). It is not clear to EFSA why the available trials compliant with the GAP on pears result in higher residue levels than the trials compliant with the GAP on apples which is expected to be more critical; further clarifications regarding this discrepancy are therefore still required. Meanwhile, tentative MRL and risk assessment values are derived for both apples and pears on the basis of the most critical data (compliant with the GAP on pears).

- Apricots and peaches: Only residues trials performed on peaches are available while, according to the new extrapolation rules (to be legally implemented on 01 April 2013), at least 4 trials on apricots will be required to support the use on apricot both in northern and southern

Europe (EC, 2011). As the available data are compliant with the former extrapolation rules, appropriate MRL and risk assessment values can be derived. Nevertheless, it would still be desirable to provide 4 trials on apricots compliant with the southern outdoor GAP.

- Mangoes: Six residues trials are reported but four of these were carried out with a lower application rate which may lead to an underestimation of the MRL. Although tentative MRL and risk assessment values can be derived from the available data, 2 additional trials complying with the correct GAP are still required.

- Tomatoes: The number of residues trials supporting the indoor GAP is not compliant with the data requirements for this crop and 1 additional trial complying with the indoor GAP is in principle still required. Considering that this additional trial is not expected to have a significant impact on the MRL setting or on the risk assessment, and that an additional indoor trial is currently being conducted (reported during the consultation of Member States, this additional trial is only considered desirable (minor deficiency); data are sufficient to derive appropriate MRL and risk assessment values.

- Lettuce: Extrapolation from lettuce to other salad plants including *Brassicaceae* was initially not supported by EFSA (2012) due to the lack of residues trials on open leaf varieties. Nevertheless, the extrapolation was accepted on a provisional basis by the Standing Committee on the Food Chain and Animal Health and an outstanding data requirement to provide residue trials on open leaf lettuce varieties was included in Regulation (EU) No 897/2012. During the consultation of Member States organised in the framework of this review, France (2012) clarified that trials initially reported as head forming varieties were actually semi-open leaf varieties. Considering that the residue trials, which were conducted on a variety of open leaf, semi-open leaf and closed (head) lettuce species, gave rise to results in the same range, the proposed extrapolation is now considered acceptable by EFSA.

The potential degradation of residues during storage of the residues trials samples was also assessed. In the framework of the peer review, storage stability of acibenzolar-S-methyl was demonstrated for a period of 24 months at -18°C in dry commodities (wheat grains) (France, 1998). In the framework of the MRL application of acibenzolar-S-methyl on peaches and apricots (EFSA, 2009), storage stability studies were assessed which demonstrated that the residues of acibenzolar-S-methyl and acibenzolar acid are stable for up to 20 months in high water content matrices (tobacco, lettuce, tomato, cabbage, squash and turnips) and dry commodities (wheat) when stored at -20°C. According to the RMS, all residues trial samples reported in the PROFile were stored in compliance with the storage conditions reported above. No storage stability data are available for hazelnuts but this is considered acceptable because samples were stored for not more than one month under freezer conditions. Degradation of residues during storage of the trial samples is therefore not expected.

Consequently, the available residues data are considered sufficient to derive adequate MRL proposals as well as risk assessment values for all commodities under evaluation, except for apples and pears where further clarification on the discrepancies observed in the apple and pear residue trials is required and for mangoes where further residues trials are still needed to support the MRL proposal (see also Table 3-2). In a case 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.

**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 (Sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated) expressed as acibenzolar-S-methyl) | Risk assessment (Sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated) expressed as acibenzolar-S-methyl) | | | | | |
| Hazelnuts | SEU | Outdoor | 0.035; 0.06; 0.03; 0.04 | 0.035; 0.06; 0.03; 0.04 | 0.04 | 0.06 | 0.1 | 1.00 | Trials compliant with the GAP.<br>$R_{ber}$ = 0.11<br>$R_{max}$ = 0.11 |
| Apples<br>Pears | SEU | Outdoor | Apples (6 x 0.1 kg a.s./ha; PHI 14d): 7 x <0.01; 0.01; 0.058; 0.082; 0.086; 0.09<br><br>Pears (6 x 0.1 kg a.s./ha; PHI 14d): 6 x <0.02<br><br>Apples (6 x 0.1 kg a.s./ha; PHI 7d): 5 x <0.01; 3 x 0.01 | Apples (6 x 0.1 kg a.s./ha; PHI 14d): 7 x <0.01; 0.01; 0.058; 0.082; 0.086; 0.09<br><br>Pears (6 x 0.1 kg a.s./ha; PHI 14d): 6 x <0.02<br><br>Apples (6 x 0.1 kg a.s./ha; PHI 7d): 5 x <0.01; 3 x 0.01 | 0.02 | 0.09 | 0.1[(i)] (tentative) | 1.00 | It is not clear why the trials performed in compliance with the GAP on apples (PHI 7d) lead to lower residues than the trials compliant with the GAP on pears (PHI 14d); further clarification is required (see also body text). Meanwhile, the MRLs are derived from the trials compliant with the GAP on pears.<br>$R_{ber}$ = 0.06<br>$R_{max}$ = 0.10 |
| Peaches<br>Apricots | SEU | Outdoor | 4 x 0.02; 0.048; 0.049; 0.05; 0.09 | 4 x 0.02; 0.048; 0.049; 0.05; 0.09 | 0.03 | 0.09 | 0.2 | 1.00 | Trials on peaches compliant with the GAP for both peaches and apricots.<br>$R_{ber}$ = 0.10<br>$R_{max}$ = 0.12 |

| 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 (Sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated) expressed as acibenzolar-S-methyl) | Risk assessment (Sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated) expressed as acibenzolar-S-methyl) | | | | | |
| Banana | Import (Central America) | Outdoor | 9 x < 0.02; 0.02; 0.03; 0.04; 0.06; 0.08 | 9 x <0.02; 0.02; 0.03; 0.04; 0.06; 0.08 | 0.02 | 0.08 | 0.08 | 1.00 | Trials compliant with the GAP. Residues are slightly overestimated as results are reported for the peel of unbagged bananas but considered acceptable as residues are close to the LOQ.<br>$R_{ber}$ = 0.07<br>$R_{max}$ = 0.08 |
| Mango | Import (ZA) | Outdoor | 0.45 kg as/ha:<br>0.20; 0.26;<br><br>0.15-0.26 kg as/ha;<br>0.075; 0.135; 0.21; 0.36 | 0.45 kg as/ha:<br>0.20; 0.26;<br><br>0.15-0.26 kg as/ha;<br>0.075; 0.135; 0.21; 0.36 | 0.21 | 0.36 | 0.6 [(h)] (tentative) | 1.00 | 2 trials compliant with GAP and 4 trials with lower application rates can only be considered on a tentative basis<br>$R_{ber}$ = 0.57<br>$R_{max}$ = 0.57 |

| 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 (Sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated) expressed as acibenzolar-S-methyl) | Risk assessment (Sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated) expressed as acibenzolar-S-methyl) | | | | | |
| Tomato | NEU | Outdoor | 0.03; 2 x 0.05; 0.06; 0.065 | 0.03; 2 x 0.05; 0.06; 0.065 | 0.05 | 0.07 | 0.2 | 1.00 | Trials compliant with the GAP.<br>$R_{ber}$ = 0.13<br>$R_{max}$ = 0.11 |
| | SEU | Outdoor | 4 x 0.05; 2 x 0.07; 0.08; 2 x 0.10; 0.11; | 4 x 0.05; 2 x 0.07; 0.08; 2 x 0.10; 0.11; | 0.07 | 0.11 | 0.2 | 1.00 | Trials compliant with the GAP.<br>$R_{ber}$ = 0.20<br>$R_{max}$ = 0.14 |
| | EU | Indoor | 0.06; 0.10; 0.29; 0.12; 0.18; 0.62; 0.13 | 0.06; 0.10; 0.29; 0.12; 0.18; 0.62; 0.13 | **0.13** | **0.62** | **0.9** | 1.00 | Trials compliant with the GAP (Spain, 2012).<br>$R_{ber}$ = 0.58<br>$R_{max}$ = 0.87 |
| Lettuce and other salad plants including *Brassicaceae* | NEU | Outdoor | 5 x < 0.02[g]; 0.02[g] | 5 x < 0.02[g]; 0.02[g] | 0.02 | 0.03 | 0.04 | 1.00 | Trials on lettuce are in compliance with the GAP. Pooled data from NEU & SEU. Extrapolation to other salad plants is possible (see body text).<br>$R_{ber}$ = 0.04<br>$R_{max}$ = 0.03 |
| | SEU | Outdoor | 3 x <0.02 [f]; 2 x <0.02 [g]; 0.02 [g]; 0.03 [g] | 3 x <0.02 [f]; 2 x <0.02 [g]; 0.02 [g]; 0.03 [g] | | | | | |
| | EU | Indoor | 0.04[g]; 0.07[g]; 0.08 [e]; 0.1[g]; 0.11[e]; 0.11 [g]; 0.15[g]; 0.15[e] | 0.04[g]; 0.07[g]; 0.08 [e]; 0.1[g]; 0.11[e]; 0.11 [g]; 0.15[g]; 0.15[e] | **0.11** | **0.15** | **0.3** | **1.00** | Trials on lettuce are in compliance with the GAP. Extrapolation to other salad plants is possible (see body text).<br>$R_{ber}$ = 0.28<br>$R_{max}$ = 0.22 |

| 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 (Sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated) expressed as acibenzolar-S-methyl) | Risk assessment (Sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated) expressed as acibenzolar-S-methyl) | | | | | |
| Spinach<br>Herbs | NEU | Outdoor | 0.04; 2 x 0.06; 0.07 | 0.04; 2 x 0.06; 0.07 | 0.06 | 0.07 | 0.2 | 1.00 | Trials on spinach compliant with GAP; extrapolation to herbs is possible.<br>$R_{ber}$ = 0.14<br>$R_{max}$ = 0.12 |
| | SEU | Outdoor | 0.18; 0.11; 0.12; 0.16 | 0.18; 0.11; 0.12; 0.16 | **0.14** | **0.18** | **0.3** | **1.00** | Trials on spinach compliant with GAP; extrapolation to herbs is possible.<br>$R_{ber}$ = 0.35<br>$R_{max}$ = 0.31 |
| Wheat grain<br>Barley grain | NEU | Outdoor | 53 x < 0.02; 0.028 | 53 x < 0.02; 0.028 | **0.02** | **0.03** | **0.05** | 1.00 | Combined data set on barley (11) and wheat (43) supporting the cGAP for small grain cereals.<br>$R_{ber}$ = 0.04<br>$R_{max}$ = 0.02 |
| | SEU | Outdoor | 16 x < 0.02 | 16 x < 0.02 | 0.02 | 0.02 | 0.02 | 1.00 | Trials on wheat compliant with GAP. Not authorised for use on barley in SEU.<br>$R_{ber}$ = 0.04<br>$R_{max}$ = 0.02 |

| 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 (Sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated) expressed as acibenzolar-S-methyl) | Risk assessment (Sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated) expressed as acibenzolar-S-methyl) | | | | | |
| Barley straw<br>Wheat straw | NEU | Outdoor | 2 x <0.02; 2 x <0.047; 16 x <0.05; 7 x <0.1; 7 x 0.05; 5 x 0.07; 0.12; 0.135; 2 x <0.019; 0.047; 0.065; 0.067; 2 x 0.08; 0.086; 0.1 | 2 x <0.02; 2 x <0.047; 16 x <0.05; 7 x <0.1; 7 x 0.05; 5 x 0.07; 0.12; 0.135; 2 x <0.019; 0.047; 0.065; 0.067; 2 x 0.08; 0.086; 0.1 | **0.05** | **0.14** | **0.2** | 1.00 | Combined dataset on barley (11) and wheat (39) supporting the critical GAPs for small grain cereals.<br>$R_{ber}$ = 0.16<br>$R_{max}$ = 0.12 |
| | SEU | Outdoor | <0.02; <0.047; <0.047; 5 x <0.05; 4 x 0.05; 0.065; 0.07 | <0.02; <0.047; <0.047; 5 x <0.05; 4 x 0.05; 0.065; 0.07 | 0.05 | 0.07 | 0.1 | 1.00 | Trials on wheat compliant with GAP. Not authorised for use on barley in SEU.<br>$R_{ber}$ = 0.10<br>$R_{max}$ = 0.08 |

(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): Residues trials performed on leafy (open) lettuce varieties.
(f): Residues trials performed on head forming (closed) lettuce varieties.
(g): Residue trials performed on head forming (semi-open) lettuce varieties
(h): Based on an inadequate number of residue trials performed at the correct GAP.
(i): Based on the discrepancies observed in the apple and pear residue trials.
(*): Indicates that the MRL is set at the limit of analytical quantification.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of acibenzolar-S-methyl was not investigated in the framework of the peer review. A study investigating the residue levels of acibenzolar-S-methyl in tobacco leaves (France, 1998) subjected to curing and pyrolysis was conducted. In addition, the effect of processing on the nature of acibenzolar-S-methyl was investigated in studies performed at three test conditions representing pasteurisation, baking/brewing/boiling and sterilisation (20 minutes at 90°C, pH 4; 60 minutes at 100°C, pH 5; 20 minutes at 120°C, pH 6) was investigated under the framework of a previous reasoned opinion (EFSA, 2012). EFSA concluded that the compound is hydrolytically stable under processing conditions representative of pasteurisation and baking/boiling/brewing while a significant degradation of the parent compound into acibenzolar acid accounting for 50.5 % of the applied radioactivity was observed under sterilisation conditions. The same residue definition as for primary crops can therefore be applied to processed commodities.

Studies investigating the magnitude of residues in any processed commodities were not reported in the framework of the peer review (France, 1998) or in any previous reasoned opinion of EFSA. Processing studies on tomatoes were nevertheless presented in the PROFile. An overview of all available processing studies is available in Table 3-3. Robust processing factors for enforcement and risk assessment were derived for peeled tomatoes and tomato paste but no robust processing factors for enforcement or risk assessment could be derived for ketchup and tomato juice as they were not sufficiently supported by studies; a minimum of 3 processing studies is normally required. The processing factors for tomato ketchup and tomato juice reported in Table 3-3 should therefore be considered as indicative only.

Further processing studies are not required as they are not expected to affect the outcome of the risk assessment. However, if more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

**Table 3-3:** Overview of the available processing studies

| Processed commodity | Number of studies | Median PF [(a)] | Median CF [(b)] | Comments |
|---|---|---|---|---|
| Tomatoes, peeled and canned | 4 | 0.65 | 1.00 | - |
| Tomatoes, paste | 4 | 1.88 | 1.00 | - |
| Tomatoes, ketchup | 2 | 1.88 | 1.00 | - |
| Tomatoes, juice | 2 | 0.78 | 1.00 | - |

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
(b): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

### 3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

All crops under consideration, except permanent crops (apples, pears, bananas, mangos and hazelnuts), may be grown in rotation. According to the laboratory soil degradation studies evaluated in the framework of the peer review, $DT_{90}$ values of acibenzolar-S-methyl are expected to range between 0.7-3.3 days which is below the trigger value of 100 days. $DT_{90}$ values of the major soil metabolite acibenzolar acid are expected to range between 43.9 and 354 days which is higher than the trigger value of 100 days (France, 1998). According to the European guidelines on rotational crops (EC,

1997b), further investigation of residues in rotational crops is not required for acibenzolar-S-methyl however for the acibenzolar acid further consideration is needed.

3.1.2.2. Nature and magnitude of residues

The metabolism of acibenzolar-S-methyl in rotational crops – lettuce, radish, winter wheat and maize – after application of [$^{14}$C-U-phenyl]-acibenzolar-S-methyl has been evaluated (France, 1998). A confined rotational crop study investigating the nature of residues following different plant-back intervals is available. The characteristics of these studies are summarised in Table 3-4.

**Table 3-4:** Summary of available metabolism studies in rotational crops

| Crop group | Crop | Label position | Application and sampling details | | | | |
|---|---|---|---|---|---|---|---|
| | | | Method, F or G [(a)] | Rate (kg a.s./ha) | Sowing intervals (DAT) | Harvest Intervals (DAT) | Remarks |
| Leafy vegetables | Lettuce | $^{14}$C-U-phenyl | Soil spraying, F | 0.05 | 30, 113, 141, 337 | At harvest | - |
| Root and tuber vegetables | Radish | $^{14}$C-U-phenyl | Soil spraying, F | 0.05 | 30, 113, 141, 337 | At harvest | - |
| Cereals | Wheat | $^{14}$C-U-phenyl | Soil spraying, F | 0.05 | 30, 113, 141, 337 | At harvest | - |
| | Maize | $^{14}$C-U-phenyl | Soil spraying, F | 0.05 | 30, 113, 141, 337 | At harvest | - |

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

The fate of [$^{14}$C-U-phenyl]-acibenzolar-S-methyl residues in rotational crops were tested in lettuce, radish, winter wheat and maize in a bare ground soil application at a rate of 50 g a.s./ha. Rotational crops, lettuce, radish winter wheat and maize were planted at 30, 113, 141 and 337 days after soil treatment. All TRR levels in the crops were found to be equal to or below 0.001 mg/kg which was too low for further identification

Since no residue analysis in rotational crops was performed, the study does not allow comparing the metabolic patterns in rotational and primary crops. However from the levels observed in the rotational crops study it can be concluded that the uptake of residues from soil will not be significant in rotational crops, provided that acibenzolar-S-methyl is applied in compliance with the GAPs reported in Appendix A.

A specific residue definition for rotational crops is not deemed necessary due to the very low residue levels expected.

## 3.2. Nature and magnitude of residues in livestock

### 3.2.1. Dietary burden of livestock

Acibenzolar-S-methyl is authorised for use on or 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 3-5. For apple pomace and cereal bran, default processing factors of 2.5 and 8, respectively, have been

included in the calculation in order to consider potential concentration of residues in these commodities.

**Table 3-5:** Input values for the dietary burden calculation

| Commodity | Median dietary burden | | Maximum dietary burden | |
|---|---|---|---|---|
| | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Apple pomace | 0.05 | Median residue x 2.5 | 0.05 | Median residue x 2.5 |
| Wheat grain | 0.02 | Median residue | 0.02 | Median residue |
| Wheat straw | 0.05 | Median residue | 0.14 | Highest residue |
| Barley grain | 0.02 | Median residue | 0.02 | Median residue |
| Barley straw | 0.05 | Median residue | 0.14 | Highest residue |
| Wheat bran | 0.16 | Median residue x 8 | 0.16 | Median residue x 8 |

The results of the calculations are reported in Table 3-6. The calculated dietary burden for meat ruminants was found to exceed the trigger value of 0.1 mg/kg DM.

**Table 3-6:** 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) |
|---|---|---|---|---|---|
| Dairy ruminants | 0.0025 | 0.0032 | Wheat bran | 0.09 | N |
| Meat ruminants | 0.0056 | 0.0077 | Apple pomace | 0.18 | Y |
| Poultry | 0.0017 | 0.0017 | Wheat bran | 0.03 | N |
| Pigs | 0.0014 | 0.0014 | Wheat bran | 0.04 | N |

### 3.2.2. Nature and magnitude of residues

The nature of acibenzolar-S-methyl residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (France, 1998). Reported metabolism studies include one study in lactating goats and one study in laying hens using [$^{14}$C-U-phenyl] labelled acibenzolar-S-methyl. The characteristics of these studies are summarised in Table 3-7.

**Table 3-7:** 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 | $^{14}$C-U-phenyl | 2 | 10.36 | 4 | Milk | Twice daily |
| | | | | | | Urine and faeces | Daily |
| | | | | | | Tissues | At sacrifice |
| Laying poultry | Hens | $^{14}$C-U-phenyl | 5 | 11.41 | 4 | Tissues | At sacrifice |
| | | | | | | Eggs | Daily |
| | | | | | | Excreta | Daily |

Lactating goats were dosed with 10.36 mg/kg bw per d of acibenzolar-S-methyl, corresponding to approximately 2000 times the maximum exposure of meat ruminant. Studies demonstrate that transfer of residues to milk and tissues is not significant given the high dose rate. The highest residue levels were found in faeces (7.56 mg/kg) and urine (1.385 mg/kg). Levels in kidney (0.283 mg/kg), liver (0.041 mg/kg), fat (0.002 mg/kg), muscle (0.003 mg/kg) and milk (0.012 mg/kg) were lower.

Laying hens were dosed with 11.41 mg/kg bw per d of acibenzolar-S-methyl, corresponding to approximately 7000 times the maximum exposure of poultry. Studies demonstrate that transfer of residues to eggs and tissues is relatively low at this high dose. The highest residue levels were found in excreta (16.7 mg/kg). Levels in liver (0.332 mg/kg), skin and fat (0.038 mg/kg), lean meat (0.013 mg/kg) and egg white (0.001 mg/kg) were lower.

The metabolism studies in ruminant show that the hydrolysis product acibenzolar acid (68.9 % - 5.2 mg/kg, 68.9 % - 0.95 mg/kg, 89.8 % - 0.25 mg/kg, 77.9 % - 0.031 mg/kg, 64.6 % - 0.0019 mg/kg and 70.4 % - 0.0084 mg/kg TRR in faeces, urine, kidney, liver, muscle and milk respectively) is the main component of the residue in tissues and milk. Parent acibenzolar-S-methyl was eliminated via faeces. The glycine conjugate of acibenzolar acid was not detectable in goat urine but was found in goat milk (22.1 % - 0.026 mg/kg TRR). The characterisation of the metabolites in goat fat was not attempted. The remaining radioactivity in tissues was composed of diverse minor fractions which could be quantitatively hydrolysed to acibenzolar acid.

The metabolism study in laying poultry show that the hydrolysis product acibenzolar acid (18.7 % - 3.12 mg/kg, 77.2 % - 0.256 mg/kg, 76.8 % - 0.03 mg/kg, 73.2 % - 0.0095 mg/kg and 50 % TRR – 0.0005 mg/kg in excreta, liver, skin and fat, lean meat and egg white respectively) is the main component of the residue in tissues and eggs. As in goats, parent acibenzolar-S-methyl was present only in excreta (1.6 % TRR). The remaining radioactivity in tissues was composed of diverse minor fractions which could be quantitatively hydrolysed to acibenzolar acid.

In both goats and hens, the presence of acibenzolar acid and the low levels of parent acibenzolar-S-methyl indicate extensive metabolism involving the hydrolysis of the carbothioate group. The general metabolic pathway in rodents and ruminants were found to be comparable; the findings in ruminants can therefore be extrapolated to pigs.

Nevertheless, considering that:

- the calculated dietary burden for meat ruminants was the only one to slightly exceed the trigger value of 0.1 mg/kg;
- low absolute levels in the animal metabolism studies were observed;
- in the feeding studies considered in the DAR all residues in products of animal origin were below the LOQ, despite the exaggerated 10 N dose rate (France, 1998);

EFSA concludes that there is no need to define a residue in commodities of animal origin and that MRLs are not required.

## 4. Consumer risk assessment

Chronic exposure calculations for all crops authorised 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 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

| Commodity | Chronic risk assessment | |
|---|---|---|
| | **Input value (mg/kg)** | **Comment** |
| **Risk assessment residue definition:** sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-S-methyl | | |
| Hazelnuts | 0.04 | Median residue [(a)] |
| Apples | 0.02 | Median residue (tentative) [(b)] |
| Pears | 0.02 | Median residue (tentative) [(b)] |
| Apricots | 0.03 | Median residue [(a)] |
| Peaches | 0.03 | Median residue [(a)] |
| Bananas | 0.02 | Median residue [(a)] |
| Mangos | 0.21 | Median residue (tentative) [(b)] |
| Tomatoes | 0.13 | Median residue [(a)] |
| Lettuce and other salad plants including *Brassicacea* | 0.11 | Median residue [(a)] |
| Spinach | 0.14 | Median residue [(a)] |
| Herbs | 0.14 | Median residue [(a)] |
| Barley grain | 0.02 | Median residue [(a)] |
| Wheat grain | 0.02 | Median residue [(a)] |

(a): At least one relevant GAP reported by the RMS is fully supported by data for this commodity; the risk assessment value derived in section 3 is used for the exposure calculations.
(b): Use reported by the RMS is not fully supported by data but the risk assessment value derived in section 3 is used for indicative exposure calculations.

The calculated exposures were compared with the toxicological reference value derived for acibenzolar-S-methyl (see Table 2-1); detailed results of the calculations are presented in Appendix B. The highest chronic exposure was calculated for (WHO Cluster diet B), representing 0.7 % of the ADI.

Based on the above calculations, EFSA concludes that the use of acibenzolar-S-methyl on crops fully supported by data (footnote a in Table 4-1), is acceptable with regard to consumer exposure. For the other 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.

## CONCLUSIONS AND RECOMMENDATIONS

### CONCLUSIONS

The toxicological profile of acibenzolar-S-methyl was evaluated in the framework of Directive 91/414/EEC which resulted in an ADI of 0.1 mg/kg bw per d. An ARfD was not deemed necessary.

Primary crop metabolism of acibenzolar-S-methyl was investigated on three different crops using foliar application treatment. These crops are representative of cereals (wheat), fruits and fruiting vegetables (tomatoes) and leafy vegetables (tobacco, lettuce). During the consultation of member states it was agreed that a general residue definition for enforcement and risk assessment should be set as the sum of acibenzolar-S-methyl and acibenzolar-acid (free and conjugated), expressed as acibenzolar-S-methyl. Analytical methods for enforcement of this residue definition in plants are available with a LOQ of 0.01 mg/kg in high water, dry and high oil content commodities. In future, further information on the occurrence of free acid in plant commodities would be desirable in order to simplify the residue definition for enforcement to acibenzolar acid only.

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 adequate MRLs, except for apples and pears where further clarification on the discrepancies observed in the apple and pear residue trials is required, and for mangoes where further residues trials are still needed to support the MRL proposal.

The nature of residues in processed commodities was considered following the inclusion of acibenzolar-S-methyl in Annex I and it was concluded that the same residue definition as for primary crops can be applied to processed commodities. Studies investigating the magnitude of residues in processed commodities of tomatoes were reported in the PROFile submitted by the RMS. Robust processing factors for enforcement and risk assessment could be derived for peeled tomatoes (0.65) and tomato paste (1.88). Further processing studies are not required as they are not expected to affect the outcome of the risk assessment. However, if more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

The fate of acibenzolar-S-methyl residues in rotational crops of lettuce, radish, winter wheat and maize was investigated during the peer review. All residue levels in the crops were found to be equal or below 0.001 mg/kg. Consequently, residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that acibenzolar-S-methyl is applied in compliance with the GAPs reported in Appendix A.

The nature of acibenzolar-S-methyl residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC. Reported metabolism studies include one study in lactating goat and one study in laying hen. However, it was agreed during the consultation of Member States that no residue definition or MRLs would be required for products of animal origin based on the following observations; the calculated dietary burden for meat ruminants was the only one to slightly exceed the trigger value of 0.1 mg/kg, low absolute levels in the animal metabolism studies were observed and in the available feeding studies all residues in products of animal origin were below the LOQ, despite the

exaggerated 10N dose rate. An analytical method for enforcement of residues in food of animal origin is not necessary.

Chronic consumer exposure resulting from the authorisations reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure was calculated for WHO cluster B representing 0.7 % of the ADI. Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

## 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 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, certain tentative or existing EU MRLs still need to be confirmed by the following data:

- 2 additional trials supporting the GAP on mangos;
- further clarification on the discrepancies observed in the apple and pear residue trials.

Minor deficiencies were 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 data are therefore considered desirable but not essential:

- further information on the occurrence of free acid in plant commodities in order to simplify the residue definition for enforcement to acibenzolar acid only;
- 1 additional trial on tomato complying with the indoor GAP;
- 4 trials on apricots compliant with the southern outdoor GAP on peaches and apricots (data gap resulting from a new extrapolation rule).

## SUMMARY TABLE

| Code number | Commodity | Existing EU MRL (mg/kg) | Outcome of the review | |
|---|---|---|---|---|
| | | | MRL (mg/kg) | Comment |
| **Enforcement residue definition (existing):** sum of acibenzolar-S-methyl and acibenzolar acid (CGA 210007) expressed as acibenzolar-S-methyl<br>**Enforcement residue definition (proposed):** sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-S-methyl | | | | |
| 120060 | Hazelnuts | 0.1 | 0.1 | Recommended [(a)] |
| 130010 | Apples | 0.01* | 0.1 | Further consideration needed [(b)] |
| 130020 | Pears | 0.02* | 0.1 | Further consideration needed [(b)] |
| 140010 | Apricots | 0.02* | 0.2 | Recommended [(a)] |
| 140030 | Peaches | 0.02* | 0.2 | Recommended [(a)] |
| 163020 | Bananas | 0.1 | 0.08 | Recommended [(a)] |

| Code number | Commodity | Existing EU MRL (mg/kg) | Outcome of the review | |
|---|---|---|---|---|
| | | | MRL (mg/kg) | Comment |
| 163030 | Mangoes | 0.5 | 0.6 | Further consideration needed [(b)] |
| 231010 | Tomatoes | 1 | 0.9 | Recommended [(a)] |
| 251000 | Lettuce and other salad plants including *Brassicacea* | 0.3 | 0.3 | Recommended [(a)] |
| 252010 | Spinach | 0.3 | 0.3 | Recommended [(a)] |
| 256000 | Herbs | 0.02* | 0.3 | Recommended [(a)] |
| 500010 | Barley grain | 0.05* | 0.05 | Recommended [(a)] |
| 500090 | Wheat grain | 0.05* | 0.05 | Recommended [(a)] |
| - | Other products of plant and/or animal origin | See appendix C | - | Further consideration needed [(c)] |

(*): 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 could be identified; no CXL is available (combination E-I in Appendix D).
(c): 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 acibenzolar-S-methyl prepared by France in the framework of Article 12 of Regulation (EC) No 396/2005. Submitted to EFSA on 14 April 2009. Last updated on 15 December 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 charachters) |
| Common name | Scientific name | | | | | Type | Content | | Method | Growth stage | | Number | | Interval (days) | | Min. rate | Max. rate | Rate Unit | | |
| | | | | | | | Conc. | Unit | | From BBCH | Until BBCH | Min. | Max. | Min. | Max. | | | | | |
| Tomatoes | *Lycopersicum esculentum* | NEU | Outdoor | EU | | WG | | | Foliar treatment - spraying | 16 | 79 | | 6 | 7 | 10 | 0.01 | 0.03 | kg a.i./ha | 3 | |
| Lamb's lettuce | *Valerianella locusta* | NEU | Outdoor | FR | | WG | 40.0 | g/kg | foliar treatment - spraying | 18 | 43 | | 3 | | 10 | | 0.01 | kg a.i./ha | 10 | 0.35 kg product/ha *1 to 3 applications maximum per cycle (3 under high infestation of downy mildew), with a total of 6 applications max per year on the same site. |
| Lettuce | *Lactuca sativa* | NEU | Outdoor | FR | | WG | 40.0 | g/kg | foliar treatment - spraying | 18 | 43 | | 3 | | 10 | | 0.01 | kg a.i./ha | 10 | 0.35 kg product/ha *1 to 3 applications maximum per cycle (3 under high infestation of downy mildew), with a total of 6 applications max per year on the same site. |
| Scarole (broad-leaf endive) | *Cichorium endiva* | NEU | Outdoor | FR | | WG | 40.0 | g/kg | foliar treatment - spraying | 18 | 43 | | 3 | | 10 | | 0.01 | kg a.i./ha | 10 | 0.35 kg product/ha *1 to 3 applications maximum per cycle (3 under high infestation of downy mildew), with a total of 6 applications max per year on the same site. |
| Cress | *Lepidium sativum* | NEU | Outdoor | FR | | WG | 40.0 | g/kg | foliar treatment - spraying | 18 | 43 | | 3 | | 10 | | 0.01 | kg a.i./ha | 10 | 0.35 kg product/ha *1 to 3 applications maximum per cycle (3 under high infestation of downy mildew), with a total of 6 applications max per year on the same site. |
| Land cress | *Barbarea verna* | NEU | Outdoor | FR | | WG | 40.0 | g/kg | foliar treatment - spraying | 18 | 43 | | 3 | | 10 | | 0.01 | kg a.i./ha | 10 | 0.35 kg product/ha *1 to 3 applications maximum per cycle (3 under high infestation of downy mildew), with a total of 6 applications max per year on the same site. |
| Rocket, Rucola | *Eruca sativa (Diplotaxis spec.)* | NEU | Outdoor | FR | | WG | 40.0 | g/kg | foliar treatment - spraying | 18 | 43 | | 3 | | 10 | | 0.01 | kg a.i./ha | 10 | 0.35 kg product/ha *1 to 3 applications maximum per cycle (3 under high infestation of downy mildew), with a total of 6 applications max per year on the same site. |
| Red mustard | *Brassica juncea var. rugosa* | NEU | Outdoor | FR | | WG | 40.0 | g/kg | foliar treatment - spraying | 18 | 43 | | 3 | | 10 | | 0.01 | kg a.i./ha | 10 | 0.35 kg product/ha *1 to 3 applications maximum per cycle (3 under high infestation of downy mildew), with a total of 6 applications max per year on the same site. |
| Leaves and sprouts of Brassica spp | *Brassica spp* | NEU | Outdoor | FR | | WG | 40.0 | g/kg | foliar treatment - spraying | 18 | 43 | | 3 | | 10 | | 0.01 | kg a.i./ha | 10 | 0.35 kg product/ha *1 to 3 applications maximum per cycle (3 under high infestation of downy mildew), with a total of 6 applications max per year on the same site. |
| Spinach | *Spinacia oleracea* | NEU | Outdoor | FR | | WG | | | Foliar treatment - spraying | 10 | 49 | | 3 | 7 | 10 | | 0.01 | kg a.i./ha | 10 | |
| Chervil | *Anthriscus cerefolium* | NEU | Outdoor | FR | | WG | | | Foliar treatment - spraying | 10 | 49 | | 3 | 7 | 10 | | 0.01 | kg a.i./ha | 10 | |
| Chives | *Allium schoenoprasum* | NEU | Outdoor | FR | | WG | | | Foliar treatment - spraying | 10 | 49 | | 3 | 7 | 10 | | 0.01 | kg a.i./ha | 10 | |
| Celery leaves | *Apium graveolens var. seccalinum* | NEU | Outdoor | FR | | WG | | | Foliar treatment - spraying | 10 | 49 | | 3 | 7 | 10 | | 0.01 | kg a.i./ha | 10 | |
| Parsley | *Petroselinum crispum* | NEU | Outdoor | FR | | WG | | | Foliar treatment - spraying | 10 | 49 | | 3 | 7 | 10 | | 0.01 | kg a.i./ha | 10 | |
| Sage | *Salvia officinalis* | NEU | Outdoor | FR | | WG | | | Foliar treatment - spraying | 10 | 49 | | 3 | 7 | 10 | | 0.01 | kg a.i./ha | 10 | |
| Rosemary | *Rosmarinus officinalis* | NEU | Outdoor | FR | | WG | | | Foliar treatment - spraying | 10 | 49 | | 3 | 7 | 10 | | 0.01 | kg a.i./ha | 10 | |
| Thyme | *Thymus spp.* | NEU | Outdoor | FR | | WG | | | Foliar treatment - spraying | 10 | 49 | | 3 | 7 | 10 | | 0.01 | kg a.i./ha | 10 | |
| Basil | *Ocimum basilicum* | NEU | Outdoor | FR | | WG | | | Foliar treatment - spraying | 10 | 49 | | 3 | 7 | 10 | | 0.01 | kg a.i./ha | 10 | |
| Bay leaves (laurel) | *Laurus nobilis* | NEU | Outdoor | FR | | WG | | | Foliar treatment - spraying | 10 | 49 | | 3 | 7 | 10 | | 0.01 | kg a.i./ha | 10 | |
| Tarragon | *Artemisia dracunculus* | NEU | Outdoor | FR | | WG | | | Foliar treatment - spraying | 10 | 49 | | 3 | 7 | 10 | | 0.01 | kg a.i./ha | 10 | |
| Barley | *Hordeum spp.* | NEU | Outdoor | EU | | WG | | | Foliar treatment - spraying | | 32 | | 1 | | | | 0.03 | kg a.i./ha | n.a. | |
| Wheat | *Triticum aestivum* | NEU | Outdoor | FR | | WG | | | Foliar treatment - spraying | | 32 | | 1 | | | | 0.03 | kg a.i./ha | 60 | |

n.a.: not applicable

| Critical Outdoor GAPs for Southern Europe | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Crop | | Region | Outdoor/ Indoor | Member state or Country | Pests controlled | Formulation | | | Application | | | | | | | Application rate | | | PHI or waiting period (days) | Comments (max. 250 charachters) |
| Common name | Scientific name | | | | | Type | Content | | Method | Growth stage | | Number | | Interval (days) | | Min. rate | Max. rate | Rate Unit | | |
| | | | | | | | Conc. | Unit | | From BBCH | Until BBCH | Min. | Max. | Min. | Max. | | | | | |
| Hazelnuts | *Corylus avellana* | SEU | Outdoor | IT | | WG | | | Foliar treatment - spraying | | | 1 | 5 | 21 | 28 | | 0.03 | kg a.i./ha | 28 | |
| Apples | *Malus domesticus* | SEU | Outdoor | IT | | WG | | | Foliar treatment - spraying | 59 | 60 | 1 | 6 | 5 | 7 | 0.08 | 0.10 | kg a.i./ha | 7 | |
| Pears | *Pyrus communis* | SEU | Outdoor | IT | | WG | | | Foliar treatment - spraying | 59 | 87 | 1 | 6 | 5 | 7 | 0.08 | 0.10 | kg a.i./ha | 14 | |
| Apricots | *Prunus armeniaca* | SEU | Outdoor | FR | | WG | 500.0 | g/kg | Foliar treatment - spraying | | | | 5 | 10 | 14 | | 0.08 | kg a.i./ha | 7 | |
| Peaches | *Prunus persica* | SEU | Outdoor | FR | | WG | 500.0 | g/kg | Foliar treatment - spraying | | | | 5 | 10 | 14 | | 0.08 | kg a.i./ha | 7 | |
| Tomatoes | *Lycopersicum esculentum* | SEU | Outdoor | EU | | WG | | | Foliar treatment - spraying | 16 | 79 | | 6 | 7 | 10 | 0.01 | 0.03 | kg a.i./ha | 3 | |
| Lamb's lettuce | *Valerianella locusta* | SEU | Outdoor | FR | | WG | 40.0 | g/kg | foliar treatment - spraying | 18 | 43 | | 3 | | 10 | | 0.01 | kg a.i./ha | 10 | 0.35 kg product/ha *1 to 3 applications maximum per cycle (3 under high infestation of downy mildew), with a total of 6 applications max per year on the same site. |
| Lettuce | *Lactuca sativa* | SEU | Outdoor | FR | | WG | 40.0 | g/kg | foliar treatment - spraying | 18 | 43 | | 3 | | 10 | | 0.01 | kg a.i./ha | 10 | 0.35 kg product/ha *1 to 3 applications maximum per cycle (3 under high infestation of downy mildew), with a total of 6 applications max per year on the same site. |
| Scarole (broad-leaf endive) | *Cichorium endiva* | SEU | Outdoor | FR | | WG | 40.0 | g/kg | foliar treatment - spraying | 18 | 43 | | 3 | | 10 | | 0.01 | kg a.i./ha | 10 | 0.35 kg product/ha *1 to 3 applications maximum per cycle (3 under high infestation of downy mildew), with a total of 6 applications max per year on the same site. |
| Cress | *Lepidium sativum* | SEU | Outdoor | FR | | WG | 40.0 | g/kg | foliar treatment - spraying | 18 | 43 | | 3 | | 10 | | 0.01 | kg a.i./ha | 10 | 0.35 kg product/ha *1 to 3 applications maximum per cycle (3 under high infestation of downy mildew), with a total of 6 applications max per year on the same site. |
| Land cress | *Barbarea verna* | SEU | Outdoor | FR | | WG | 40.0 | g/kg | foliar treatment - spraying | 18 | 43 | | 3 | | 10 | | 0.01 | kg a.i./ha | 10 | 0.35 kg product/ha *1 to 3 applications maximum per cycle (3 under high infestation of downy mildew), with a total of 6 applications max per year on the same site. |
| Rocket, Rucola | *Eruca sativa (Diplotaxis spec.)* | SEU | Outdoor | FR | | WG | 40.0 | g/kg | foliar treatment - spraying | 18 | 43 | | 3 | | 10 | | 0.01 | kg a.i./ha | 10 | 0.35 kg product/ha *1 to 3 applications maximum per cycle (3 under high infestation of downy mildew), with a total of 6 applications max per year on the same site. |
| Red mustard | *Brassica juncea var. rugosa* | SEU | Outdoor | FR | | WG | 40.0 | g/kg | foliar treatment - spraying | 18 | 43 | | 3 | | 10 | | 0.01 | kg a.i./ha | 10 | 0.35 kg product/ha *1 to 3 applications maximum per cycle (3 under high infestation of downy mildew), with a total of 6 applications max per year on the same site. |
| Leaves and sprouts of Brassica spp | *Brassica spp* | SEU | Outdoor | FR | | WG | 40.0 | g/kg | foliar treatment - spraying | 18 | 43 | | 3 | | 10 | | 0.01 | kg a.i./ha | 10 | 0.35 kg product/ha *1 to 3 applications maximum per cycle (3 under high infestation of downy mildew), with a total of 6 applications max per year on the same site. |
| Spinach | *Spinacia oleracea* | SEU | Outdoor | FR | | WG | | | Foliar treatment - spraying | 10 | 49 | | 3 | 7 | 10 | | 0.01 | kg a.i./ha | 10 | |
| Chervil | *Anthriscus cerefolium* | SEU | Outdoor | FR | | WG | | | Foliar treatment - spraying | 10 | 49 | | 3 | 7 | 10 | | 0.01 | kg a.i./ha | 10 | |
| Chives | *Allium schoenoprasum* | SEU | Outdoor | FR | | WG | | | Foliar treatment - spraying | 10 | 49 | | 3 | 7 | 10 | | 0.01 | kg a.i./ha | 10 | |
| Celery leaves | *Apium graveolens var. seccalinum* | SEU | Outdoor | FR | | WG | | | Foliar treatment - spraying | 10 | 49 | | 3 | 7 | 10 | | 0.01 | kg a.i./ha | 10 | |
| Parsley | *Petroselinum crispum* | SEU | Outdoor | FR | | WG | | | Foliar treatment - spraying | 10 | 49 | | 3 | 7 | 10 | | 0.01 | kg a.i./ha | 10 | |
| Sage | *Salvia officinalis* | SEU | Outdoor | FR | | WG | | | Foliar treatment - spraying | 10 | 49 | | 3 | 7 | 10 | | 0.01 | kg a.i./ha | 10 | |
| Rosemary | *Rosmarinus officinalis* | SEU | Outdoor | FR | | WG | | | Foliar treatment - spraying | 10 | 49 | | 3 | 7 | 10 | | 0.01 | kg a.i./ha | 10 | |
| Thyme | *Thymus spp.* | SEU | Outdoor | FR | | WG | | | Foliar treatment - spraying | 10 | 49 | | 3 | 7 | 10 | | 0.01 | kg a.i./ha | 10 | |
| Basil | *Ocimum basilicum* | SEU | Outdoor | FR | | WG | | | Foliar treatment - spraying | 10 | 49 | | 3 | 7 | 10 | | 0.01 | kg a.i./ha | 10 | |
| Bay leaves (laurel) | *Laurus nobilis* | SEU | Outdoor | FR | | WG | | | Foliar treatment - spraying | 10 | 49 | | 3 | 7 | 10 | | 0.01 | kg a.i./ha | 10 | |
| Tarragon | *Artemisia dracunculus* | SEU | Outdoor | FR | | WG | | | Foliar treatment - spraying | 10 | 49 | | 3 | 7 | 10 | | 0.01 | kg a.i./ha | 10 | |
| Wheat | *Triticum aestivum* | SEU | Outdoor | FR | | WG | | | Foliar treatment - spraying | | 32 | | 1 | | | | 0.03 | kg a.i./ha | 60 | |

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 | | | Application | | | | | | | Application rate | | | PHI or wiaiting period (days) | Comments (max. 250 charachters) |
| Common name | Scientific name | | | | | Type | Content | | Method | Growth stage | | Number | | Interval (days) | | Min. rate | Max. rate | Rate Unit | | |
| | | | | | | | Conc. | Unit | | From BBCH | Until BBCH | Min. | Max. | Min. | Max. | | | | | |
| Tomatoes | *Lycopersicum esculentum* | NEU/SEU | Indoor | EU | | | | | Foliar treatment - spraying | 16 | 79 | | 6 | 7 | 10 | 0.01 | 0.03 | kg a.i./ha | 3 | |
| Lamb's lettuce | *Valerianella locusta* | NEU/SEU | Indoor | FR | | WG | 40.0 | g/kg | foliar treatment - spraying | 18 | 43 | | 3 | | 10 | | 0.01 | kg a.i./ha | 10 | 0.35 kg product/ha *1 to 3 applications maximum per cycle (3 under high infestation of downy mildew), with a total of 6 applications max per year on the same site. |
| Lettuce | *Lactuca sativa* | NEU/SEU | Indoor | FR | | WG | 40.0 | g/kg | foliar treatment - spraying | 18 | 43 | | 3 | | 10 | | 0.01 | kg a.i./ha | 10 | 0.35 kg product/ha *1 to 3 applications maximum per cycle (3 under high infestation of downy mildew), with a total of 6 applications max per year on the same site. |
| Scarole (broad-leaf endive) | *Cichorium endiva* | NEU/SEU | Indoor | FR | | WG | 40.0 | g/kg | foliar treatment - spraying | 18 | 43 | | 3 | | 10 | | 0.01 | kg a.i./ha | 10 | 0.35 kg product/ha *1 to 3 applications maximum per cycle (3 under high infestation of downy mildew), with a total of 6 applications max per year on the same site. |
| Cress | *Lepidium sativum* | NEU/SEU | Indoor | FR | | WG | 40.0 | g/kg | foliar treatment - spraying | 18 | 43 | | 3 | | 10 | | 0.01 | kg a.i./ha | 10 | 0.35 kg product/ha *1 to 3 applications maximum per cycle (3 under high infestation of downy mildew), with a total of 6 applications max per year on the same site. |
| Land cress | *Barbarea verna* | NEU/SEU | Indoor | FR | | WG | 40.0 | g/kg | foliar treatment - spraying | 18 | 43 | | 3 | | 10 | | 0.01 | kg a.i./ha | 10 | 0.35 kg product/ha *1 to 3 applications maximum per cycle (3 under high infestation of downy mildew), with a total of 6 applications max per year on the same site. |
| Rocket, Rucola | *Eruca sativa (Diplotaxis spec.)* | NEU/SEU | Indoor | FR | | WG | 40.0 | g/kg | foliar treatment - spraying | 18 | 43 | | 3 | | 10 | | 0.01 | kg a.i./ha | 10 | 0.35 kg product/ha *1 to 3 applications maximum per cycle (3 under high infestation of downy mildew), with a total of 6 applications max per year on the same site. |
| Red mustard | *Brassica juncea var. rugosa* | NEU/SEU | Indoor | FR | | WG | 40.0 | g/kg | foliar treatment - spraying | 18 | 43 | | 3 | | 10 | | 0.01 | kg a.i./ha | 10 | 0.35 kg product/ha *1 to 3 applications maximum per cycle (3 under high infestation of downy mildew), with a total of 6 applications max per year on the same site. |
| Leaves and sprouts of Brassica spp | *Brassica spp* | NEU/SEU | Indoor | FR | | WG | 40.0 | g/kg | foliar treatment - spraying | 18 | 43 | | 3 | | 10 | | 0.01 | kg a.i./ha | 10 | 0.35 kg product/ha *1 to 3 applications maximum per cycle (3 under high infestation of downy mildew), with a total of 6 applications max per year on the same site. |

n.a.: not applicable

| Critical GAPs for Import Tolerances (non-European indoor, outdoor or post-harvest treatments) | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Crop | | Region | Outdoor/ Indoor | Member state or Country | Pests controlled | Formulation | | | Application | | | | | | | Application rate | | | PHI or wiaiting period (days) | Comments (max. 250 charachters) |
| Common name | Scientific name | | | | | Type | Content | | Method | Growth stage | | Number | | Interval (days) | | Min. rate | Max. rate | Rate Unit | | |
| | | | | | | | Conc. | Unit | | From BBCH | Until BBCH | Min. | Max. | Min. | Max. | | | | | |
| Bananas | *Musa x paradisica* | non-EU | Outdoor | Central america | | | | | Foliar treatment - spraying | | | 5 | 7 | | | | 0.05 | kg a.i./ha | 0 | |
| Mangoes | *Mangifera indica* | non-EU | Outdoor | south african | | | | | Foliar treatment - spraying | | | | 6 | | | | 0.45 | kg a.i./ha | 21 | |

n.a.: not applicable

## APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

| acibenzolar-s-methyl | | | |
|---|---|---|---|
| Status of the active substance: | **Included** | Code no. | |
| LOQ (mg/kg bw): | | proposed LOQ: | |
| **Toxicological end points** | | | |
| ADI (mg/kg bw/day): | **0.1** | ARfD (mg/kg bw): | **n.n.** |
| Source of ADI: | **COM** | Source of ARfD: | **COM** |
| Year of evaluation: | **2001** | Year of evaluation: | **2001** |

**Prepare workbook for refined calculations**

**Undo refined calculations**

### Chronic risk assessment - refined calculations

| | TMDI (range) in % of ADI minimum - maximum |
|---|---|
| | 0 – 1 |
| **No of diets exceeding ADI:** | --- |

| Highest calculated TMDI values in % of ADI | MS Diet | Highest contributor to MS diet (in % of ADI) | Commodity / group of commodities | 2nd contributor to MS diet (in % of ADI) | Commodity / group of commodities | 3rd contributor to MS diet (in % of ADI) | Commodity / group of commodities | pTMRLs at LOQ (in % of ADI) |
|---|---|---|---|---|---|---|---|---|
| 0.7 | WHO Cluster diet B | 0.4 | Tomatoes | 0.2 | Wheat | 0.0 | Lettuce | |
| 0.6 | DE child | 0.2 | Apples | 0.1 | Tomatoes | 0.1 | Wheat | |
| 0.5 | NL child | 0.1 | Apples | 0.1 | Wheat | 0.1 | Tomatoes | |
| 0.4 | IT kids/toddler | 0.2 | Tomatoes | 0.1 | Wheat | 0.0 | Lettuce | |
| 0.3 | FR toddler | 0.1 | Tomatoes | 0.1 | Spinach | 0.1 | Apples | |
| 0.3 | IT adult | 0.2 | Tomatoes | 0.1 | Wheat | 0.0 | Lettuce | |
| 0.3 | ES child | 0.1 | Tomatoes | 0.1 | Wheat | 0.0 | Lettuce | |
| 0.3 | WHO cluster diet D | 0.1 | Tomatoes | 0.1 | Wheat | 0.0 | Apples | |
| 0.3 | WHO regional European diet | 0.1 | Tomatoes | 0.1 | Wheat | 0.0 | Lettuce | |
| 0.3 | DK child | 0.1 | Wheat | 0.1 | Tomatoes | 0.0 | Apples | |
| 0.3 | ES adult | 0.1 | Tomatoes | 0.1 | Lettuce | 0.0 | Wheat | |
| 0.3 | IE adult | 0.1 | Tomatoes | 0.0 | Wheat | 0.0 | Mangoes | |
| 0.2 | SE general population 90th percentile | 0.1 | Tomatoes | 0.1 | Wheat | 0.0 | Bananas | |
| 0.2 | PT General population | 0.1 | Tomatoes | 0.1 | Wheat | 0.0 | Apples | |
| 0.2 | WHO Cluster diet F | 0.1 | Tomatoes | 0.1 | Wheat | 0.0 | Lettuce | |
| 0.2 | WHO cluster diet E | 0.1 | Wheat | 0.1 | Tomatoes | 0.0 | Apples | |
| 0.2 | UK Toddler | 0.1 | Wheat | 0.1 | Tomatoes | 0.0 | Apples | |
| 0.2 | NL general | 0.1 | Tomatoes | 0.0 | Wheat | 0.0 | Apples | |
| 0.2 | UK Infant | 0.1 | Wheat | 0.0 | Tomatoes | 0.0 | Apples | |
| 0.2 | FR infant | 0.1 | Spinach | 0.1 | Apples | 0.0 | Tomatoes | |
| 0.2 | PL general population | 0.1 | Tomatoes | 0.0 | Apples | 0.0 | Pears | |
| 0.2 | UK vegetarian | 0.1 | Tomatoes | 0.0 | Wheat | 0.0 | Lettuce | |
| 0.2 | FR all population | 0.1 | Wheat | 0.1 | Tomatoes | 0.0 | Lettuce | |
| 0.2 | LT adult | 0.1 | Tomatoes | 0.0 | Apples | 0.0 | Wheat | |
| 0.1 | DK adult | 0.1 | Tomatoes | 0.0 | Wheat | 0.0 | Apples | |
| 0.1 | UK Adult | 0.1 | Tomatoes | 0.0 | Wheat | 0.0 | Lettuce | |
| 0.1 | FI adult | 0.1 | Tomatoes | 0.0 | Wheat | 0.0 | Lettuce | |

**Conclusion:**

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.

A long-term intake of residues of acibenzolar-s-methyl is unlikely to present a public health concern.

# APPENDIX C – EXISTING EU MAXIMUM RESIDUE LIMITS (MRLS)

(Pesticides - Web Version - EU MRLs (File created on 14/02/2013 11:00)

| Code number | Groups and examples of individual products to which the MRLs apply (a) | Acibenzolar-S-methyl (sum of acybenzolar-S-methyl and acibenzolar acid (CGA 210007) expressed as acybenzolar-S-methyl) |
|---|---|---|
| 100000 | 1. FRUIT FRESH OR FROZEN; NUTS | |
| 110000 | (i) Citrus fruit | 0,02* |
| 110010 | Grapefruit (Shaddocks, pomelos, sweeties, tangelo **(except mineola)**, ugli and other hybrids) | 0,02* |
| 110020 | Oranges (Bergamot, bitter orange, chinotto and other hybrids) | 0,02* |
| 110030 | Lemons (Citron, lemon) | 0,02* |
| 110040 | Limes | 0,02* |
| 110050 | Mandarins (Clementine, tangerine, **mineola** and other hybrids) | 0,02* |
| 110990 | Others | 0,02* |
| 120000 | (ii) Tree nuts (shelled or unshelled) | |
| 120010 | Almonds | 0,02* |
| 120020 | Brazil nuts | 0,02* |
| 120030 | Cashew nuts | 0,02* |
| 120040 | Chestnuts | 0,02* |
| 120050 | Coconuts | 0,02* |
| 120060 | Hazelnuts (Filbert) | 0,1 |
| 120070 | Macadamia | 0,02* |
| 120080 | Pecans | 0,02* |
| 120090 | Pine nuts | 0,02* |
| 120100 | Pistachios | 0,02* |
| 120110 | Walnuts | 0,02* |
| 120990 | Others | 0,02* |
| 130000 | (iii) Pome fruit | 0,02* |
| 130010 | Apples (Crab apple) | 0,02* |
| 130020 | Pears (Oriental pear) | 0,02* |
| 130030 | Quinces | 0,02* |
| 130040 | Medlar | 0,02* |
| 130050 | Loquat | 0,02* |
| 130990 | Others | 0,02* |
| 140000 | (iv) Stone fruit | |
| 140010 | Apricots | 0,2 |
| 140020 | Cherries (sweet cherries, sour cherries ) | 0,02* |
| 140030 | Peaches (Nectarines and similar hybrids) | 0,2 |
| 140040 | Plums (Damson, greengage, mirabelle, **sloe**) | 0,02* |
| 140990 | Others | 0,02* |
| 150000 | (v) Berries & small fruit | 0,02* |
| 151000 | (a) Table and wine grapes | 0,02* |
| 151010 | Table grapes | 0,02* |
| 151020 | Wine grapes | 0,02* |
| 152000 | (b) Strawberries | 0,02* |
| 153000 | (c) Cane fruit | 0,02* |
| 153010 | Blackberries | 0,02* |
| 153020 | Dewberries (Loganberries, boysenberries, and cloudberries) | 0,02* |
| 153030 | Raspberries (Wineberries, **arctic bramble/raspberry, (*Rubus arcticus*), nectar raspberries (*Rubus arcticus x idaeus)***) | 0,02* |
| 153990 | Others | 0,02* |
| 154000 | (d) Other small fruit & berries | 0,02* |
| 154010 | Blueberries (Bilberries ) | 0,02* |
| 154020 | Cranberries (**Cowberries (red bilberries)**) | 0,02* |
| 154030 | Currants (red, black and white) | 0,02* |
| 154040 | Gooseberries (Including hybrids with other ribes species) | 0,02* |
| 154050 | Rose hips | 0,02* |
| 154060 | Mulberries (arbutus berry) | 0,02* |
| 154070 | Azarole (mediteranean medlar) (Kiwiberry *(Actinidia arguta)*) | 0,02* |
| 154080 | Elderberries (Black chokeberry (appleberry), mountain ash, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries) | 0,02* |
| 154990 | Others | 0,02* |
| 160000 | (vi) Miscellaneous fruit | |
| 161000 | (a) Edible peel | 0,02* |
| 161010 | Dates | 0,02* |
| 161020 | Figs | 0,02* |
| 161030 | Table olives | 0,02* |
| 161040 | Kumquats (Marumi kumquats, nagami kumquats, **limequats** (*Citrus aurantifolia x Fortunella spp.*)) | 0,02* |
| 161050 | Carambola (Bilimbi) | 0,02* |
| 161060 | Persimmon | 0,02* |
| 161070 | Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry Surinam cherry (grumichama *Eugenia uniflora*), ) | 0,02* |
| 161990 | Others | 0,02* |
| 162000 | (b) Inedible peel, small | 0,02* |
| 162010 | Kiwi | 0,02* |
| 162020 | Lychee (Litchi) (Pulasan, rambutan (hairy litchi), **mangosteen**) | 0,02* |
| 162030 | Passion fruit | 0,02* |
| 162040 | Prickly pear (cactus fruit) | 0,02* |
| 162050 | Star apple | 0,02* |
| 162060 | American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote) | 0,02* |
| 162990 | Others | 0,02* |
| 163000 | (c) Inedible peel, large | |
| 163010 | Avocados | 0,02* |
| 163020 | Bananas (Dwarf | 0,1 |

| Code number | Groups and examples of individual products to which the MRLs apply (a) | Acibenzolar-S-methyl (sum of acybenzolar-S-methyl and acibenzolar acid (CGA 210007) expressed as acybenzolar-S-methyl) |
|---|---|---|
| | banana, plantain, apple banana) | |
| 163030 | Mangoes | 0,5 |
| 163040 | Papaya | 0,02* |
| 163050 | Pomegranate | 0,02* |
| 163060 | Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae) | 0,02* |
| 163070 | Guava (**Red pitaya or dragon fruit (*Hylocereus undatus)***) | 0,02* |
| 163080 | Pineapples | 0,02* |
| 163090 | Bread fruit (Jackfruit) | 0,02* |
| 163100 | Durian | 0,02* |
| 163110 | Soursop (guanabana) | 0,02* |
| 163990 | Others | 0,02* |
| 200000 | 2. VEGETABLES FRESH OR FROZEN | |
| 210000 | (i) Root and tuber vegetables | 0,02* |
| 211000 | (a) Potatoes | 0,02* |
| 212000 | (b) Tropical root and tuber vegetables | 0,02* |
| 212010 | Cassava (Dasheen, eddoe (Japanese taro), tannia) | 0,02* |
| 212020 | Sweet potatoes | 0,02* |
| 212030 | Yams (Potato bean (yam bean), Mexican yam bean) | 0,02* |
| 212040 | Arrowroot | 0,02* |
| 212990 | Others | 0,02* |
| 213000 | (c) Other root and tuber vegetables except sugar beet | 0,02* |
| 213010 | Beetroot | 0,02* |
| 213020 | Carrots | 0,02* |
| 213030 | Celeriac | 0,02* |
| 213040 | Horseradish (**Angelica roots, lovage roots, gentiana roots,** ) | 0,02* |
| 213050 | Jerusalem artichokes | 0,02* |
| 213060 | Parsnips | 0,02* |
| 213070 | Parsley root | 0,02* |
| 213080 | Radishes (Black radish, Japanese radish, small radish and similar varieties, **tiger nut (*Cyperus esculentus)***) | 0,02* |
| 213090 | Salsify (Scorzonera, Spanish salsify (Spanish oysterplant)) | 0,02* |
| 213100 | Swedes | 0,02* |
| 213110 | Turnips | 0,02* |
| 213990 | Others | 0,02* |
| 220000 | (ii) Bulb vegetables | 0,02* |
| 220010 | Garlic | 0,02* |
| 220020 | Onions (Silverskin onions) | 0,02* |
| 220030 | Shallots | 0,02* |
| 220040 | Spring onions (Welsh onion and similar varieties) | 0,02* |
| 220990 | Others | 0,02* |
| 230000 | (iii) Fruiting vegetables | |
| 231000 | (a) Solanacea | |
| 231010 | Tomatoes (Cherry tomatoes**, tree tomato, *Physalis*, gojiberry, wolfberry (*Lycium barbarum and L. chinense*)**) | 1 |
| 231020 | Peppers (Chilli peppers) | 0,02* |
| 231030 | Aubergines (egg plants) (Pepino) | 0,02* |
| 231040 | Okra, lady's fingers | 0,02* |
| 231990 | Others | 0,02* |
| 232000 | (b) Cucurbits - edible peel | 0,02* |
| 232010 | Cucumbers | 0,02* |
| 232020 | Gherkins | 0,02* |
| 232030 | Courgettes (Summer squash, marrow (patisson)) | 0,02* |
| 232990 | Others | 0,02* |
| 233000 | (c) Cucurbits-inedible peel | 0,02* |
| 233010 | Melons (Kiwano ) | 0,02* |
| 233020 | Pumpkins (Winter squash) | 0,02* |
| 233030 | Watermelons | 0,02* |
| 233990 | Others | 0,02* |
| 234000 | (d) Sweet corn | 0,02* |
| 239000 | (e) Other fruiting vegetables | 0,02* |
| 240000 | (iv) Brassica vegetables | 0,02* |
| 241000 | (a) Flowering brassica | 0,02* |
| 241010 | Broccoli (Calabrese, Chinese broccoli, broccoli raab ) | 0,02* |
| 241020 | Cauliflower | 0,02* |
| 241990 | Others | 0,02* |
| 242000 | (b) Head brassica | 0,02* |
| 242010 | Brussels sprouts | 0,02* |
| 242020 | Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage) | 0,02* |
| 242990 | Others | 0,02* |
| 243000 | (c) Leafy brassica | 0,02* |
| 243010 | Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), choi sum, peking cabbage (pe-tsai), ) | |
| 243020 | Kale (Borecole (curly kale), collards, **Portuguese Kale, Portuguese cabbage,** cow cabbage) | 0,02* |
| 243990 | Others | 0,02* |
| 244000 | (d) Kohlrabi | 0,02* |
| 250000 | (v) Leaf vegetables & fresh herbs | |
| 251000 | (a) Lettuce and other salad plants including Brassicacea | 0,3 (ft) |
| 251010 | Lamb´s lettuce (Italian cornsalad) | 0,3 (ft) |
| 251020 | Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce) | 0,3 (ft) |
| 251030 | Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf) | 0,3 (ft) |
| 251040 | Cress | 0,3 (ft) |
| 251050 | Land cress | 0,3 (ft) |
| 251060 | Rocket, Rucola (Wild rocket) | 0,3 (ft) |
| 251070 | Red mustard | 0,3 (ft) |
| 251080 | Leaves and sprouts of Brassica spp (Mizuna, **leaves of peas and radish and other babyleaf brassica crops (crops harvested up to 8 true leaf stage)**) | 0,3 (ft) |
| 251990 | Others | 0,3 (ft) |

| Code number | Groups and examples of individual products to which the MRLs apply (a) | Acibenzolar-S-methyl (sum of acybenzolar-S-methyl and acibenzolar acid (CGA 210007) expressed as acybenzolar-S-methyl) |
|---|---|---|
| 252000 | (b) Spinach & similar (leaves) | |
| 252010 | Spinach (New Zealand spinach, **amaranthus spinach**) | 0,3 |
| 252020 | Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth, **Agretti (*Salsola soda*)**) | 0,02* |
| 252030 | Beet leaves (chard) (Leaves of beetroot) | 0,02* |
| 252990 | Others | 0,02* |
| 253000 | (c) Vine leaves (grape leaves) | 0,02* |
| 254000 | (d) Water cress | 0,02* |
| 255000 | (e) Witloof | 0,02* |
| 256000 | (f) Herbs | 0,3 |
| 256010 | Chervil | 0,3 |
| 256020 | Chives | 0,3 |
| 256030 | Celery leaves (Fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other *Apiacea* leaves) | 0,3 |
| 256040 | Parsley | 0,3 |
| 256050 | Sage (Winter savory, summer savory, ) | 0,3 |
| 256060 | Rosemary | 0,3 |
| 256070 | Thyme (Marjoram, oregano) | 0,3 |
| 256080 | Basil (Balm leaves, mint, peppermint) | 0,3 |
| 256090 | Bay leaves (laurel) | 0,3 |
| 256100 | Tarragon (Hyssop) | 0,3 |
| 256990 | Others (**Edible flowers** ) | 0,3 |
| 260000 | (vi) Legume vegetables (fresh) | 0,02* |
| 260010 | Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans) | 0,02* |
| 260020 | Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea) | 0,02* |
| 260030 | Peas (with pods) (Mangetout (sugar peas, snow peas)) | 0,02* |
| 260040 | Peas (without pods) (Garden pea, green pea, chickpea) | 0,02* |
| 260050 | Lentils | 0,02* |
| 260990 | Others | 0,02* |
| 270000 | (vii) Stem vegetables (fresh) | 0,02* |
| 270010 | Asparagus | 0,02* |
| 270020 | Cardoons | 0,02* |
| 270030 | Celery | 0,02* |
| 270040 | Fennel | 0,02* |
| 270050 | Globe artichokes | 0,02* |
| 270060 | Leek | 0,02* |
| 270070 | Rhubarb | 0,02* |
| 270080 | Bamboo shoots | 0,02* |
| 270090 | Palm hearts | 0,02* |
| 270990 | Others | 0,02* |
| 280000 | (viii) Fungi | 0,02* |
| 280010 | Cultivated (Common mushroom, Oyster mushroom, Shi-take) | 0,02* |
| 280020 | Wild (Chanterelle, Truffle, Morel, Cep) | 0,02* |
| 280990 | Others | 0,02* |
| 290000 | (ix) Sea weeds | 0,02* |
| 300000 | 3. PULSES, DRY | 0,02* |
| 300010 | Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas) | 0,02* |
| 300020 | Lentils | 0,02* |
| 300030 | Peas (Chickpeas, field peas, chickling vetch) | 0,02* |
| 300040 | Lupins | 0,02* |
| 300990 | Others | 0,02* |
| 400000 | 4. OILSEEDS AND OILFRUITS | |
| 401000 | (i) Oilseeds | 0,05* |
| 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) | 0,05* |
| 401070 | Soya bean | 0,05* |
| 401080 | Mustard seed | 0,05* |
| 401090 | Cotton seed | 0,05* |
| 401100 | Pumpkin seeds (**Other seeds of *cucurbitacea***) | 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* |
| 402000 | (ii) Oilfruits | |
| 402010 | Olives for oil production | 0,02* |
| 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 (**Amaranthus, quinoa**) | 0,05* |
| 500030 | Maize | 0,05* |
| 500040 | Millet (Foxtail millet, teff) | 0,05* |
| 500050 | Oats | 0,05* |
| 500060 | Rice | 0,05* |
| 500070 | Rye | 0,05* |
| 500080 | Sorghum | 0,05* |
| 500090 | Wheat (Spelt, triticale ) | 0,05* |
| 500990 | Others | 0,05* |
| 600000 | 6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA | 0,05* |
| 610000 | (i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis) | 0,05* |
| 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 (**Elderflowers *(Sambucus nigra)*** ) | 0,05* |
| 631050 | Lime (linden) | 0,05* |
| 631990 | Others | 0,05* |
| 632000 | (b) Leaves | 0,05* |
| 632010 | Strawberry leaves | 0,05* |
| 632020 | Rooibos leaves (**Ginkgo 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* |

| Code number | Groups and examples of individual products to which the MRLs apply (a) | Acibenzolar-S-methyl (sum of acybenzolar-S-methyl and acibenzolar acid (CGA 210007) expressed as acybenzolar-S-methyl) |
|---|---|---|
| 633990 | Others | 0,05* |
| 639000 | (d) Other herbal infusions | 0,05* |
| 640000 | (iv) Cocoa (fermented beans) | 0,05* |
| 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* |
| 870000 | (vii) Aril | 0,05* |
| 870010 | Mace | 0,05* |
| 870990 | Others | 0,05* |
| 900000 | 9. SUGAR PLANTS | 0,02* |
| 900010 | Sugar beet (root) | 0,02* |
| 900020 | Sugar cane | 0,02* |
| 900030 | Chicory roots | 0,02* |
| 900990 | Others | 0,02* |
| 1000000 | 10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS | 0,02* |
| 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 | 0,02* |
| 1011000 | (a) Swine | 0,02* |
| 1011010 | Meat | 0,02* |
| 1011020 | Fat free of lean meat | 0,02* |
| 1011030 | Liver | 0,02* |
| 1011040 | Kidney | 0,02* |
| 1011050 | Edible offal | 0,02* |
| 1011990 | Others | 0,02* |
| 1012000 | (b) Bovine | 0,02* |
| 1012010 | Meat | 0,02* |
| 1012020 | Fat | 0,02* |
| 1012030 | Liver | 0,02* |
| 1012040 | Kidney | 0,02* |
| 1012050 | Edible offal | 0,02* |
| 1012990 | Others | 0,02* |
| 1013000 | (c) Sheep | 0,02* |
| 1013010 | Meat | 0,02* |
| 1013020 | Fat | 0,02* |
| 1013030 | Liver | 0,02* |
| 1013040 | Kidney | 0,02* |
| 1013050 | Edible offal | 0,02* |
| 1013990 | Others | 0,02* |
| 1014000 | (d) Goat | 0,02* |
| 1014010 | Meat | 0,02* |
| 1014020 | Fat | 0,02* |
| 1014030 | Liver | 0,02* |
| 1014040 | Kidney | 0,02* |
| 1014050 | Edible offal | 0,02* |
| 1014990 | Others | 0,02* |
| 1015000 | (e) Horses, asses, mules or hinnies | 0,02* |
| 1015010 | Meat | 0,02* |
| 1015020 | Fat | 0,02* |
| 1015030 | Liver | 0,02* |
| 1015040 | Kidney | 0,02* |
| 1015050 | Edible offal | 0,02* |
| 1015990 | Others | 0,02* |
| 1016000 | (f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon | 0,02* |
| 1016010 | Meat | 0,02* |
| 1016020 | Fat | 0,02* |
| 1016030 | Liver | 0,02* |
| 1016040 | Kidney | 0,02* |
| 1016050 | Edible offal | 0,02* |
| 1016990 | Others | 0,02* |
| 1017000 | (g) Other farm animals (Rabbit, Kangaroo) | 0,02* |
| 1017010 | Meat | 0,02* |
| 1017020 | Fat | 0,02* |
| 1017030 | Liver | 0,02* |
| 1017040 | Kidney | 0,02* |
| 1017050 | Edible offal | 0,02* |
| 1017990 | Others | 0,02* |
| 1020000 | (ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd | 0,02* |
| 1020010 | Cattle | 0,02* |
| 1020020 | Sheep | 0,02* |
| 1020030 | Goat | 0,02* |
| 1020040 | Horse | 0,02* |
| 1020990 | Others | 0,02* |
| 1030000 | (iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter | 0,02* |
| 1030010 | Chicken | 0,02* |
| 1030020 | Duck | 0,02* |
| 1030030 | Goose | 0,02* |
| 1030040 | Quail | 0,02* |
| 1030990 | Others | 0,02* |
| 1040000 | (iv) Honey (Royal jelly, pollen) | 0,02* |
| 1050000 | (v) Amphibians and | 0,02* |

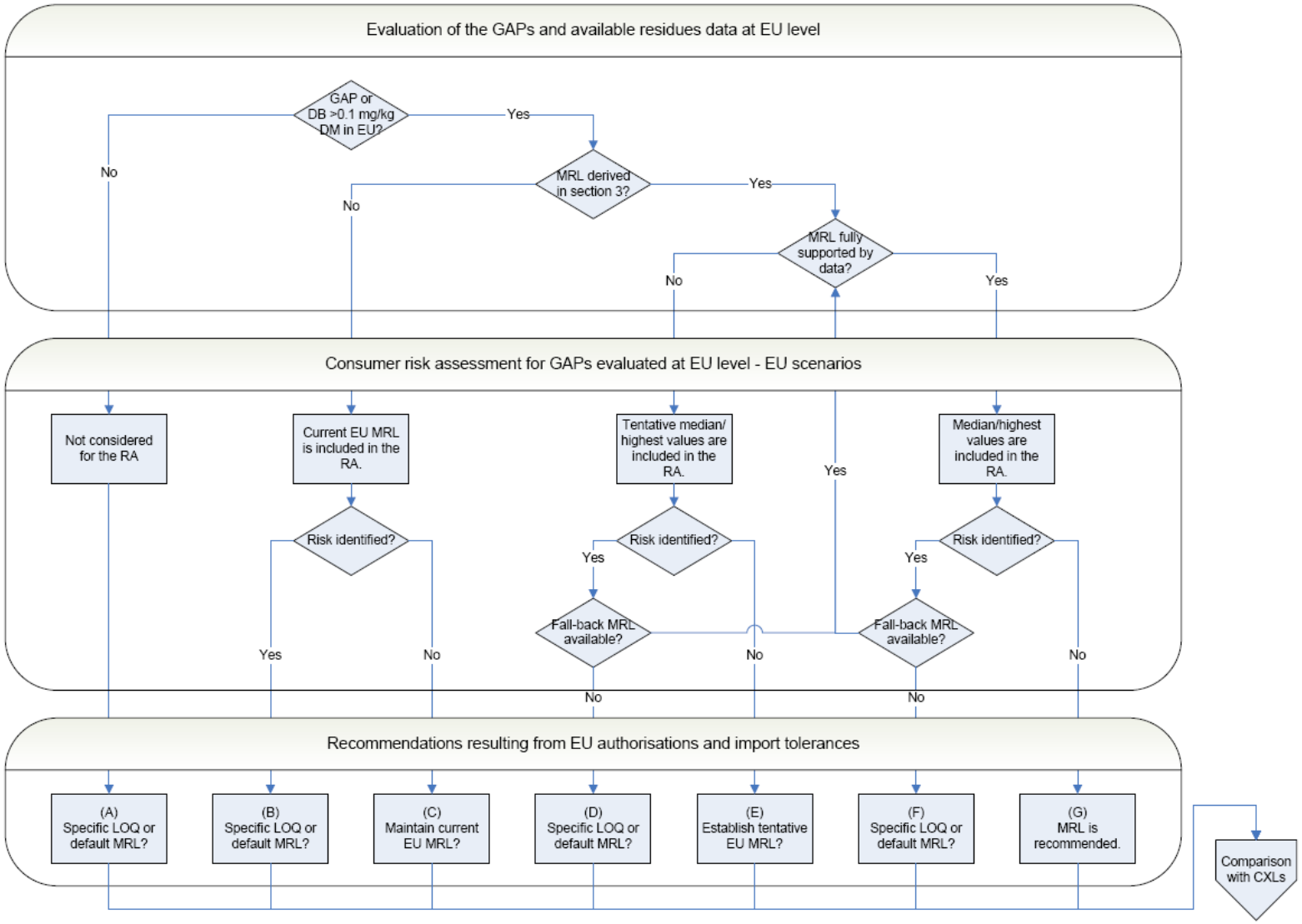
| | | |
|---|---|---|
| | reptiles (Frog legs, crocodiles) | |
| 1060000 | (vi) Snails | 0,02* |
| 1070000 | (vii) Other terrestrial | 0,02* |

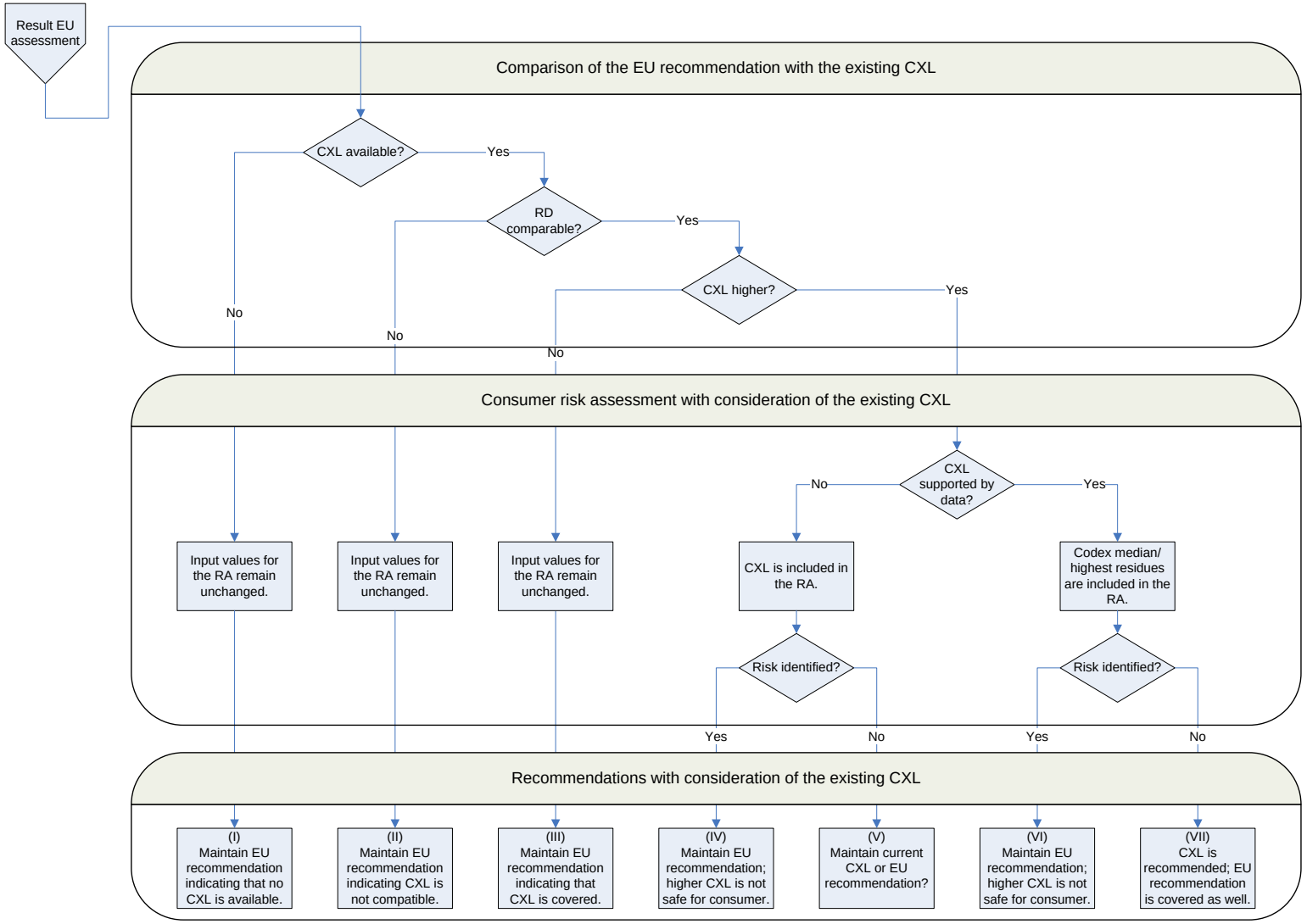
| | | |
|---|---|---|
| | animal products | |

(*) Indicates lower limit of analytical determination

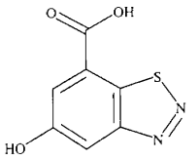
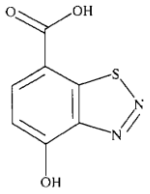
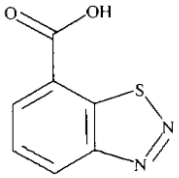
0251000(a) **Lettuce and other salad plants including Brassicacea**: Residue trials of open leaf lettuce varieties to be submitted to the evaluating Member State, the Authority and the European Commission by 1 October 2014 at the latest. Reassessment of data may lead to modification of the MRL.
025101 **Lamb's Lettuce (Italian cornsalad)**: Residue trials of open leaf lettuce varieties to be submitted to the evaluating Member State, the Authority and the European Commission by 1 October 2014 at the latest. Reassessment of data may lead to modification of the MRL.
0251020 **Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)**: Residue trials of open leaf lettuce varieties to be submitted to the evaluating Member State, the Authority and the European Commission by 1 October 2014 at the latest. Reassessment of data may lead to modification of the MRL.
0251030 **Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf**: Residue trials of open leaf lettuce varieties to be submitted to the evaluating Member State, the Authority and the European Commission by 1 October 2014 at the latest. Reassessment of data may lead to modification of the MRL.
0251040 **Cress**: Residue trials of open leaf lettuce varieties to be submitted to the evaluating Member State, the Authority and the European Commission by 1 October 2014 at the latest. Reassessment of data may lead to modification of the MRL.
0251050 **Land Cress**: Residue trials of open leaf lettuce varieties to be submitted to the evaluating Member State, the Authority and the European Commission by 1 October 2014 at the latest. Reassessment of data may lead to modification of the MRL.
0251060 **Rocket, Rucola (Wild Rocket)**: Residue trials of open leaf lettuce varieties to be submitted to the evaluating Member State, the Authority and the European Commission by 1 October 2014 at the latest. Reassessment of data may lead to modification of the MRL.
0251070 **Red mustard**: Residue trials of open leaf lettuce varieties to be submitted to the evaluating Member State, the Authority and the European Commission by 1 October 2014 at the latest. Reassessment of data may lead to modification of the MRL.
0251080 **Leaves and sprouts of Brassica spp (Mizuna, leaves of peas and radish and other babyleaf brassica crops (crops harvested up to 8 true leaf stage)**: trials of open leaf lettuce varieties to be submitted to the evaluating Member State, the Authority and the European Commission by 1 October 2014 at the latest. Reassessment of data may lead to modification of the MRL.
0251990 **Others**: Residue trials of open leaf lettuce varieties to be submitted to the evaluating Member State, the Authority and the European Commission by 1 October 2014 at the latest. Reassessment of data may lead to modification of the MRL.

## APPENDIX D – DECISION TREE FOR DERIVING MRL RECOMMENDATIONS




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

## APPENDIX E – LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

| Common name | IUPAC name | Structural formula |
|---|---|---|
| 5-OH acibenzolar acid | 1,2,3-benzothiadiazole-5-hydroxy-7-carboxylic acid |  |
| 4-OH acibenzolar acid | 1,2,3-benzothiadiazole-4-hydroxy-7-carboxylic acid |  |
| acibenzolar acid | 1,2,3-benzothiadiazole-7-carboxylic acid |  |

## ABBREVIATIONS

| | |
|---|---|
| a.s. | active substance |
| ADI | acceptable daily intake |
| ARfD | acute reference dose |
| 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 Organisation of the United Nations |
| GAP | good agricultural practice |
| ha | hectare |
| HPLC-MS/MS | high performance liquid chromatography with tandem mass spectrometry |
| HPLC- HPLC-UVD | high performance liquid chromatography with column switching and ultra-violet detector |
| ILV | independent laboratory validation |

| | |
|---|---|
| ISO | International Organisation for Standardization |
| IUPAC | International Union of Pure and Applied Chemistry |
| L | litre |
| LC-MS/MS | liquid chromatography with tandem mass spectrometry |
| LOQ | limit of quantification |
| MRL | maximum residue limit |
| MS | Member States |
| NEU | northern European Union |
| PF | processing factor |
| PHI | pre-harvest interval |
| PROFile | (EFSA) Pesticide Residue Overview File |
| PRIMo | (EFSA) Pesticide Residues Intake Model |
| $R_{ber}$ | statistical calculation of the MRL by using a non-parametric method |
| $R_{max}$ | statistical calculation of the MRL by using a parametric method |
| RMS | rapporteur Member State |
| SAR | Systemic Activated Resistance |
| SEU | Southern European Union |
| TLC | thin layer chromatography |
| TRR | total radioactive residue |
| WHO | World Health Organisation |