

REASONED OPINION

Reasoned opinion on the modification of the existing MRL for acibenzolar-S-methyl in lettuce and other salad plants including *Brassicaceae*¹

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SUMMARY

According to Article 6 of Regulation (EC) No 396/2005, France received an application from Syngenta Agro S.A.S. to modify the existing MRLs for acibenzolar-S-methyl in lettuce and other salad plants including *Brassicaceae*. In order to accommodate for the intended use of acibenzolar-S-methyl in France under outdoor and indoor conditions, France proposed to raise the existing MRL in lettuce and other salad plants including *Brassicaceae* from 0.02* mg/kg to 0.3 mg/kg. France drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 11 July 2011.

EFSA derived the following conclusions based on the above mentioned evaluation report, the Draft Assessment Report (DAR) prepared by France under Directive 91/414/EEC, the review report and a previous EFSA reasoned opinion on the modification of the existing MRLs for acibenzolar-S-methyl in peaches and apricots.

The toxicological profile for acibenzolar-S-methyl was investigated in the peer review and data were sufficient to conclude on an ADI value of 0.1 mg/kg bw/day. No ARfD was established because of the low acute toxicity of the active substance.

Metabolism of acibenzolar-S-methyl in primary plants was investigated in the framework of the peer review on cereals (wheat), fruiting vegetables (tomatoes) and leafy vegetables (tobacco). An additional metabolism study on lettuce was evaluated and reported in the evaluation report prepared by France in support of a previous MRL application. The residue definition derived for risk assessment and enforcement for all categories of crops is *acibenzolar-S-methyl* (sum of *acibenzolar-S-methyl* and *acibenzolar acid* (CGA 210007), expressed as *acibenzolar-S-methyl*). The same residue definition for enforcement purposes has been established under Regulation (EC) No 396/2005.

In support to this MRL application, the applicant submitted eight residue trials performed on lettuce (*Lactuca sativa*) carried out under indoor conditions (three of the trials were performed on open leave varieties) as well as six and seven outdoor residue trials were conducted in Northern and Southern Europe, respectively. The residue trials on lettuce grown under indoor conditions generally showed

¹ On request from the European Commission, Question No EFSA-Q-2011-00888, approved on 20 March 2012.

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higher residue levels than the outdoor trials. The residue concentrations on open leaf varieties seem to be in the same range as the residue concentrations on head forming varieties. However, EFSA is of the opinion that a data set of three and five trials for open leaf lettuce and head forming lettuce, respectively, is not sufficiently robust to conclude that the two sets of data represent the same population. Thus, an extrapolation to the whole crop group of lettuce and other salad plants including *Brassicaceae* is not recommended by EFSA. According to the current guidelines five additional trials on open leaf varieties would be required for this extrapolation.

Acibenzolar-S-methyl is hydrolytically stable under the processing conditions representative of pasteurisation and baking/boiling/brewing while a significant degradation was observed under sterilisation processing conditions. Since the major degradation product acibenzolar acid (CGA 210007) was identified as a major plant metabolite, the same residue definition as for raw agricultural commodities (RAC) can be applied for the processed commodities.

Specific studies to assess the magnitude of acibenzolar-S-methyl residues during the processing of crops under consideration are not necessary as the total theoretical maximum daily intake (TMDI) accounted for less than 10 % of the ADI and thermal treatment is not considered as a relevant processing type for lettuce.

The possible occurrence of acibenzolar-S-methyl residues in rotational and/or succeeding crops was investigated; the residue levels in the edible parts of the rotational crops are not expected to exceed the trigger value of 0.01 mg/kg provided that the active substance is applied according to the proposed GAP.

Lettuce and other salad plants including *Brassicaceae* or any of their by-products are not part of the livestock diet. Therefore no further considerations are needed regarding residues in feed and their transfer into food of animal origin.

The chronic consumer risk assessment was performed with revision 2 of the EFSA PRIMo. For the calculation of the chronic exposure, EFSA used the median residue values as derived from the residue trials on lettuce as well as the median residue values for peaches and apricots from the previous EFSA reasoned opinion and also the median residue values for hazelnuts, bananas, mangoes, tomatoes and spinach from the residue database reported in the Pesticide Residue Overview File (PROFile) in order to refine the intake calculations. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annexes II and IIIB of Regulation (EC) No 396/2005 were used as input values.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values ranged from 0.3% to 1.9% of the ADI (WHO cluster diet B). The contribution of residues in lettuce to the total long-term exposure was insignificant (0.04% of the ADI).

An acute dietary risk assessment is not necessary because of the low acute toxicity of the active substance for which no ARfD has been considered as necessary.

EFSA concludes that the intended use of acibenzolar-S-methyl in lettuce only is acceptable with regard to the consumer exposure and the following MRL is recommended to be included in Annex II of Regulation (EC) No 396/2005:

| Code number ^a | Commodity | Existing EC MRL (mg/kg) | Proposed EC MRL (mg/kg) | Justification for the proposal |
|--------------------------|-----------|-------------------------|-------------------------|--------------------------------|
| | | | | |

| Code number ^a | Commodity | Existing EC MRL (mg/kg) | Proposed EC MRL (mg/kg) | Justification for the proposal |
|--|---|-------------------------|-------------------------|--|
| Acibenzolar-S-methyl (sum of acibenzolar-S-methyl and acibenzolar acid (CGA 210007) expressed as acibenzolar-S-methyl) | | | | |
| 0251020 | Lettuce | 0.02* | 0.3 | The proposed MRL on lettuce is sufficiently supported by residue trials reflecting indoor conditions. No risk for consumers was identified for the proposed MRL |
| 0251990 | Others (e.g. lamb's lettuce, scarole, cress, land cress, rocket, rucola, red mustard, leaves and sprouts of <i>Brassica</i> spp, including turnip greens) | 0.02* | no proposal | An extrapolation from lettuce to other lettuce plants included in the crop group is not acceptable since the number of residue trials is not sufficient. 5 additional trials on open leave varieties of lettuce would be required. |

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

^a according to Annex I of Regulation (EC) No 396/2005

KEY WORDS

Acibenzolar-S-methyl, lettuce and other salad plants including *Brassicaceae*, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, benzothiadiazoles, acibenzolar acid (CGA 210007)

TABLE OF CONTENTS

| | |
|---|----|
| Summary | 1 |
| Table of contents | 4 |
| Background | 5 |
| Terms of reference | 5 |
| The active substance and its use pattern | 6 |
| Assessment | 8 |
| 1. Methods of analysis | 8 |
| 1.1. Methods for enforcement of residues in food of plant origin | 8 |
| 1.2. Methods for enforcement of residues in food of animal origin | 8 |
| 2. Mammalian toxicology | 9 |
| 3. Residues | 9 |
| 3.1. Nature and magnitude of residues in plant | 9 |
| 3.1.1. Primary crops | 9 |
| 3.1.2. Rotational crops | 14 |
| 3.2. Nature and magnitude of residues in livestock | 15 |
| 4. Consumer risk assessment | 15 |
| Conclusions and recommendations | 17 |
| References | 19 |
| Appendix A. Good Agricultural Practices (GAPs) | 21 |
| Appendix B. Pesticide Residues Intake Model (PRIMo) | 22 |
| Appendix C. Existing EU maximum residue limits (MRLs) | 23 |
| Pesticides - Web Version - EU MRLs (File created on 10/02/2012 13:50) | 23 |
| Appendix D. List of metabolites and related structural formula | 26 |
| Abbreviations | 27 |

BACKGROUND

Regulation (EC) No 396/2005³ establishes the rules governing the setting of pesticide MRLs at Community level. Article 6 of that regulation lays down that a party requesting an authorisation for the use of a plant protection product in accordance with Directive 91/414/EEC⁴, shall submit to a Member State, when appropriate, an application to set or modify an MRL in accordance with the provisions of Article 7 of that regulation.

France, hereafter referred to as the evaluating Member State (EMS), received an application from the company Syngenta Agro S.A.S⁵ to modify the existing MRL for the active substance acibenzolar-S-methyl in lettuce and other salad plants including *Brassicaceae*. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 11 July 2011. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2011-00888 and the following subject:

Acibenzolar-S-methyl - Application to modify the existing MRL in lettuce and other salad plants including Brassicaceae

EFSA then proceeded with the assessment of the application as required by Article 10 of the Regulation.

TERMS OF REFERENCE

According to Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the calculated deadline for providing the reasoned opinion was 11 October 2011.

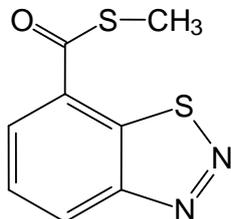
³ Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005. OJ L 70, 16.03.2005, p. 1-16.

⁴ Council Directive 91/414/EEC of 15 July 1991. OJ L 230, 19.08.1991, p. 1-32

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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). In older studies, the development code is used which is CGA 245704.



Molecular weight: 210.3

Acibenzolar-S-methyl belongs to the class of benzothiadiazoles fungicides.

Acibenzolar-S-methyl is 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 activation of the same biochemical changes in plants as after a biological induction. Through this activation, control of *Erysiphe graminis* (powdery mildew of cereals), *Peronospora tabacina* (blue mould of tobacco), and *Mycosphaerella musci* (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 as a new active substance with France acting as the designated Rapporteur Member State (RMS). After having passed successfully the peer review, acibenzolar-S-methyl was included in Annex I of Directive 91/414/EEC by Directive 2001/87/EC⁶ which entered into force on 1 November 2001. The expiry date for approval was extended by Directive 2010/77/EC⁷ to 31 December 2015. The uses evaluated in the peer review were on wheat, spring barley and tobacco.

MRLs for acibenzolar-S-methyl have been established at EU level for the first time in 2003 which were modified in 2008 to accommodate for the new uses authorised in Member States. The MRLs established under the previous European MRL legislation were transferred to Annex II of Regulation (EC) No 396/2005. In 2010, MRLs were modified for peaches and apricots by Regulation (EC) No 750/2010⁸ following recommendations of EFSA (EFSA, 2009). The residue definition for enforcement in plant commodities was established as *acibenzolar-S-methyl (sum of acibenzolar-S-methyl and acibenzolar acid (CGA 210007), expressed as acibenzolar-S-methyl)*. The currently valid MRLs can be found in Appendix C. The Codex Alimentarius Commission did not establish CXLs for this active substance.

The current MRL for lettuce and other salad plants including *Brassicaceae* is set at the LOQ of 0.02* mg/kg. According to the proposal made by the Evaluating Member State it would be necessary to raise this MRL to 0.3 mg/kg.

The GAP for which an authorisation is intended refers to outdoor and indoor foliar applications of acibenzolar-S-methyl on lettuce and other salad plants including *Brassicaceae*. The water dispersible

⁶ Commission Directive No 2001/87/EC of 12 October 2001, OJ L 276 of 19.10.2001, p. 17-20.

⁷ Commission Directive No 2010/77/EC of 10 November 2010, OJ L 293 of 11.11.2010, p. 48-57.

⁸ Commission Regulation No 750/2010/EC of 7 July 2010, OJ L 220 of 21.08.2010, p. 1-56.

granule has to be applied up to three times on the crop with an interval between applications of 10 days at the rate of 14 g a.s./ha for each application and a PHI of 10 days. The intended GAP is summarized in Appendix A.

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (France, 2011), the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (France, 1998), the review report for the active substance (EC, 2002) as well as the previously issued EFSA reasoned opinion on acibenzolar-S-methyl (EFSA, 2009). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation of the Authorization of Plant Protection Products set out in Regulation (EU) No 546/2011⁹ and the currently valid EU guidance documents for consumer risk assessment (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011, EFSA, 2007, OECD, 2011a, 2011b).

1. Methods of analysis

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

The single analytical method based on HPLC analysis with UV-detection is available for the determination of acibenzolar-S-methyl and its acid metabolite (CGA 210007¹⁰) in commodities with high water content. Acibenzolar-S-methyl and metabolites containing the CGA 210007 moiety¹¹ are hydrolysed into CGA 210007 by heating the homogenised sample in a sodium hydroxide solution followed by an acidic/alkaline/acidic partition. The final determination of CGA 210007 is performed by a two column HPLC switching system with diode-array detection (detection at 235 nm). The method has been validated for crops with high water content (cucumber and tomatoes) with a LOQ of 0.02 mg/kg for acibenzolar (including acibenzolar-S-methyl and its acid metabolite). The conversion factor for CGA 210007 (molecular weight: 180) to acibenzolar-S-methyl (molecular weight 210.3) is 1.17. An ILV was also conducted. Since the HPLC-UV analytical method is not considered as highly specific a confirmatory method is necessary for enforcement purposes.

The reference to the method CEN 15662 (QUECHER LC-MS/MS) (CEN, 2008) was also reported in the evaluation report. The accuracy of the method was considered as acceptable for acibenzolar-S-methyl for high water content matrices while low recoveries (50%) were observed for acibenzolar acid (CGA 210007).

It is concluded that for the intended use on lettuce and other salad plants including *Brassicaceae* a sufficiently validated analytical method is available to enforce the currently established residue definition for monitoring.

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

Analytical methods for the determination of residues in food of animal origin are not assessed in the current application since the crops under consideration are not fed to livestock.

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

¹⁰CGA 210007: Benzo[1,2,3]thiadiazole-7-carboxylic acid: See Appendix D

¹¹ All the identified metabolites in the plant metabolism studies were structurally related to metabolite CGA 210007. Thus the method can be considered as specific for the residue definition for monitoring purposes.

2. Mammalian toxicology

In the peer review under Directive 91/414/EEC an ADI of 0.1 mg/kg bw/d was derived. Due to the low acute toxicity it was concluded that no ARfD has to be established (EC, 2002).

The summarised toxicological reference values can be found in Table 2-1.

Table 2-1. Overview of the toxicological reference values

| | Source | Year | Value (mg/kg bw/d) | Study relied upon | Safety factor |
|-----------------------------|---------------------|------|--------------------|-------------------------------|---------------|
| Acibenzolar-S-methyl | | | | | |
| ADI | COM (review report) | 2002 | 0.1 | 90 day and 12 month dog study | 100 |
| ARfD | COM (review report) | 2002 | - | Not allocated, not necessary | - |

The only metabolite which was included in the residue definition is the acibenzolar acid (CGA 210007). This metabolite was also observed in the rat metabolism. No further toxicological studies were therefore considered as necessary for this compound.

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

Metabolism studies performed with acibenzolar-S-methyl in primary crops (wheat, tomatoes and tobacco) were reported in the DAR (France, 1998) and have been assessed in the framework of the peer review under Directive 91/41/EEC. An additional metabolism study on lettuce was evaluated and reported in the evaluation report prepared by France in support of a previous MRL application. All metabolism studies were performed using the [phenyl-U-¹⁴C] labelling of acibenzolar-S-methyl.

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

| Group | Crop | Label position | Application details | | | | Remarks |
|--------------------------------|---------|---------------------------|---|-----------------------|----------------------|--------------------|---|
| | | | Method, F, G or P ^(a) | Rate | No/ Interval | Sampling DALA | |
| Cereals | Wheat | Phenyl-U- ¹⁴ C | Foliar spray -F (end of tillering), -G (4 leaf stage) | 50 g a.s./ha | nr | 14 (G) n.r. (F) | - |
| Fruits and fruiting vegetables | Tomato | Phenyl-U- ¹⁴ C | Foliar spray, G | 15.2 g a.s./hL | 3 | n.r. | - |
| Leafy vegetables | Tobacco | Phenyl-U- ¹⁴ C | Foliar spray, G | Total 170 g a.s./ha | 3 | n.r. | - |
| | Lettuce | Phenyl-U- ¹⁴ C | Foliar spray, G | 35 g a.s./ha (3 N) | 4 at 1 week interval | 7 | 1 st application: 7-9 leaf stage |
| | | | | 105 g a.s./ha* (10 N) | 4 | 7 | - |

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

(b): Table footnote

n.r. not reported in the DAR

*: Experiment performed at an exaggerated rate to generate higher residues for isolation and metabolites'identification purposes.

The metabolism study on lettuce was evaluated in the previous EFSA reasoned opinion (EFSA, 2009). This study is representative for the intended uses assessed in this application. The total radioactive residues recovered in lettuce at harvest (one week after the last application) accounted for 1.014 mg eq./kg (3 N) and 3.668 mg eq./kg (10 N). A minor part of the radioactivity remained on the surface (20.2 % and 23 % of TRR for the 2 dose rates, respectively) while the major part of the total radioactivity penetrated the leaves (78.8 % and 59.4 % TRR for the 2 dose rates, respectively). The surface wash and the washed leaves were analysed separately for characterisation and identification of metabolites. Acibenzolar-S-methyl constituted the predominant compound of the total residues in the surface wash fraction (16.5 % of TRR- 0.167 mg/kg) (3 N) and (19.3 % of TRR-0.7 mg/kg) (10 N) whereas the identified metabolites were recovered at a trace level (<1% TRR and <0.01 mg/kg). In the washed head leaves, the parent compound was either not detected or recovered at a trace level (0.4 % TRR-0.043 mg/kg) whilst the levels of the four identified minor metabolites, i.e. CGA 324041¹², CGA 323060¹³, CGA 210007 and CGA 243093¹⁴ ranged between 0.9 % and 4.4 % of the TRR. In addition, further unidentified metabolites were detected at a non negligible level (I2: 25 % TRR, I3: 10.3 % TRR, I4: 9.6 % TRR and I1b: 12.6 % TRR) but without any further tentative identification. All other metabolites characterized in the 3N and 10N dose rate studies in lettuce were below 10% of TRR. In the metabolism study in tomatoes the metabolites CGA 324041, CGA 323060 and CGA 210007 were also identified and occurred at a level of 6.5% TRR, 8% TRR and 34% TRR, respectively. The remaining metabolites'fraction consisted mainly of sugar conjugates of CGA 323060 and CGA 210007. The findings of the lettuce metabolism study confirmed the proposed metabolic pathway in

¹² CGA 324041: 5-hydroxy-benzo[1,2,3]thiadiazole-7-carboxylic acid: See Appendix D

¹³ CGA 323060: 4-Hydroxy-benzo[1,2,3]thiadiazole-7-carboxylic acid: See Appendix D

¹⁴CGA 243093 (16a): Benzo[1,2,3]thiadiazole-7-yl-methanol: See Appendix D

all categories of crops derived in the peer review from the metabolism studies in wheat, tomato and tobacco.

EFSA concludes that the nature of the residues resulting from the use of acibenzolar-S-methyl is sufficiently elucidated and is similar for all the categories of crops. The metabolic pathway of acibenzolar-S-methyl proceeds via hydrolysis of the parent compound to acibenzolar acid (CGA 210007), followed by ester glycoside conjugation. Subsequent oxidation of the phenyl ring of the acid metabolite CGA 210007 led to metabolites CGA 324041 and CGA 323060 (except for wheat) followed by sugar conjugation as O-Glycosides. In lettuce, an additional minor metabolic route of degradation consisted of the reduction of the carboxyl group of CGA 210007 giving the metabolite CGA 243093 with further ester conjugation with sugars.

In conclusion, the general residue definition derived for all crops was set as the *acibenzolar-S-methyl (sum of acibenzolar-S-methyl and acibenzolar acid (CGA 210007), expressed as acibenzolar-S-methyl)*. This residue definition is applicable for risk assessment and monitoring and covers the crops under consideration.

3.1.1.2. Magnitude of residues

In support to this MRL application, the applicant submitted eight residue trials carried out under indoor conditions while six and seven outdoor residue trials were conducted on head lettuce in Northern and Southern Europe, respectively. The trials were performed between 1998 and 2000.

Since lettuce is a major crop, a minimum of eight trials would be required (EC, 2011) for the Northern and Southern EU zone respectively and for the indoor conditions. Although the number of available trials is not sufficient for the outdoor GAPs according to the data requirements defined in the guidance document, EFSA derived a MRL proposal from the pooled data since the residue concentrations were all in the same range. However, it is noted that this MRL proposal is based on trials performed in head forming varieties only. It is therefore expected that on open leaf varieties higher residues may occur, taking into account that the same amount of active substance per hectare is applied and that the yield for head forming lettuces compared to open leaf varieties is expected to be significantly higher. Thus, the MRL proposal is affected by uncertainties and might underestimate the actual residue levels expected under realistic conditions in open leaf varieties.

The eight residue trials on lettuce grown under indoor conditions generally showed higher residue levels than the outdoor trials. Three of the trials submitted in support of the indoor GAP were performed with open leaf varieties of lettuce. The residue concentrations on open leaf varieties seem to be in the same range as the residue concentrations on head forming varieties. However, EFSA is of the opinion that a data set of three and five trials for open leaf lettuce and head forming lettuce, respectively, is not sufficiently robust to conclude that the two sets of data represent the same population. Thus, an extrapolation to the whole crop group of lettuce and other salad plants including *Brassicaceae* is not recommended by EFSA. According to the current guidelines (EC, 2011), five additional trials on open leaf varieties would be required for this extrapolation.

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 its acid metabolite (CGA 210007) 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. The maximum storage interval of the supervised residue trials samples on lettuce prior to analysis was covered by the storage stability data on acibenzolar-S-methyl and its acid metabolite (CGA 210007).

According to the EMS, the analytical method used to analyse the supervised residue trial samples (a method based on LC-MS/MS) has been sufficiently validated and was proven to be fit for enforcement purposes (France, 2011).

EFSA concludes that the data reflecting indoor conditions are sufficient to derive a MRL proposal of 0.3 mg/kg which would be appropriate for the intended use of acibenzolar-S-methyl on lettuce (*Lactuca sativa*). An extrapolation to other salad plants included in the crop group (i.e. lamb's lettuce, scarole, cress, land cress, rocket, rucola, red mustard, leaves and sprouts of *Brassica* spp.) is not recommended since the number of trials on open leaf varieties is not sufficient.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposal are summarized in Table 3-2.

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

| Commodity | 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 | Risk assessment | | | | | |
| Enforcement and risk assessment residue definition: Sum of acibenzolar-S-methyl and acibenzolar acid (CGA 210007) expressed as acibenzolar-S-methyl | | | | | | | | | |
| Lettuce (<i>Lactuca sativa</i>) | EU | Indoor | 0.04 ⁽¹⁾ ; 0.07 ⁽¹⁾ ; 0.08 ⁽²⁾ ; 0.1 ⁽¹⁾ ; 0.11 ⁽¹⁾ ; 0.11 ⁽²⁾ ; 0.15 ⁽¹⁾ ; 0.15 ⁽²⁾ | 0.04 ⁽¹⁾ ; 0.07 ⁽¹⁾ ; 0.08 ⁽²⁾ ; 0.1 ⁽¹⁾ ; 0.11 ⁽¹⁾ ; 0.11 ⁽²⁾ ; 0.15 ⁽¹⁾ ; 0.15 ⁽²⁾ | 0.11 | 0.15 | 0.3 | 1 | R _{ber} =0.28 R _{max} =0.22 OECD MRL ^x =0.3 Extrapolation to the whole group of salad plants was requested. Number of trials on open leave varieties is not sufficient for this extrapolation. |
| | NEU | Outdoor | 5x<0.02 ⁽¹⁾ ; 0.02 ⁽¹⁾ | 5x<0.02 ⁽¹⁾ ; 0.02 ⁽¹⁾ | 0.02 | 0.03 | 0.04 | 1 | Pooled data from NEU & SEU R _{ber} =0.04 R _{max} =0.03 OECD MRL ^x =0.04 |
| | SEU | Outdoor | 5x<0.02 ⁽¹⁾ ; 0.02 ⁽¹⁾ ; 0.03 ⁽¹⁾ | 5x<0.02 ⁽¹⁾ ; 0.02 ⁽¹⁾ ; 0.03 ⁽¹⁾ | | | | | |

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.

(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.

(x) : The MRL calculated using the OECD MRL calculator (OECD, 2011b)

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

⁽¹⁾: “Head” lettuce variety

⁽²⁾: “Open leaf” lettuce variety

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of acibenzolar-S-methyl was investigated in studies performed at three test conditions representing pasteurization, baking/brewing/boiling and sterilization (20 minutes at 90°C, pH 4; 60 minutes at 100°C, pH 5; 20 minutes at 120°C, pH 6). The studies were reported under the framework of this application (France, 2011). EMS concluded that the compound is hydrolytically stable under the processing conditions representative of pasteurisation and baking/boiling/brewing while a significant degradation of the parent compound into its acid metabolite (CGA 210007) accounting for 50.5% of the applied radioactivity was observed under the sterilisation conditions.

Thus, for processed commodities the same residue definition as for raw agricultural commodities (RAC) is applicable.

Specific studies to assess the magnitude of acibenzolar-S-methyl residues during the processing of crops under consideration are not necessary as the total theoretical maximum daily intake (TMDI) amounts to less than 10 % of the ADI and thermal treatment is not considered as a relevant processing type for lettuce (EC, 1997d).

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

The crops under consideration may be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed.

The soil degradation studies demonstrated that the degradation rate of acibenzolar-S-methyl is rapid under laboratory conditions (DT_{90lab} : 1.8 days) while the kinetic of degradation for the acid metabolite CGA 210007 was considered as very slow with a DT_{90lab} : 293 days which is above the trigger value of 100 days (EC, 2002). Thus, further studies investigating the nature and magnitude of the acibenzolar-S-methyl residues and their potential uptake in rotational crops are required (EC, 1997c).

3.1.2.2. Nature of residues

The metabolism of acibenzolar-S-methyl in rotational crops was assessed in the DAR prepared under Directive 91/414/EEC (France, 1998).

The fate of [phenyl-(U)-¹⁴C]-acibenzolar-S-methyl residues in rotational crops was investigated after application of the test substance on bare soil at a rate of 50 g a.s./ha. Lettuce, radish, winter wheat and corn were planted at 30, 113, 141 and 337 days plant back intervals. Since the total radioactive residues in the edible parts of the rotated crops were found to be below 0.001 mg/kg, no further investigation of the nature of the residues in rotational crops was attempted.

3.1.2.3. Magnitude of residues

Based on the outcome of the confined rotational crop metabolism study, it was concluded that significant residue levels are unlikely to occur in the edible parts of rotated crops provided that the compound is used on the crops under consideration according to the proposed pattern.

3.2. Nature and magnitude of residues in livestock

Lettuce and other salad plants including *Brassicaceae* or any of their by-products are not part of the livestock diet. Therefore no further consideration is relevant regarding residues in feed and their transfer into food of animal origin.

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population ¹⁵ (EFSA, 2007).

For the calculation of the chronic exposure, EFSA used the median residue values as derived from the residue trials on the crops under consideration (see Table 3-2), and the median residue values in peaches and apricots reported in the previously issued EFSA reasoned opinions (EFSA, 2009). For some commodities, STMR values could be derived from the residue database reported in the Pesticide Residue Overview File (PROFile) which was provided by France in support of the MRL review according to Article 12(2) of Regulation 396/2005 (France, 2009). For the remaining commodities of plant and animal origin, the existing MRLs as established in Annexes II and III B of Regulation (EC) No 396/2005 were used as input values. The model assumptions for the long-term exposure assessment are considered to be rather conservative, assuming that all food items consumed have been treated with the active substance under consideration. In reality, it is not likely that all food consumed will contain residues at the MRL or at levels of the median residue values identified in supervised field trials. However, if this first tier exposure assessment, does not exceed the toxicological reference value for long-term exposure (i.e. the ADI), a consumer health risk can be excluded with a high probability.

No acute risk assessment was performed because an ARfD has not been considered as necessary.

The input values used for the dietary exposure calculation are summarized in Table 4-1.

Table 4-1: Input values for the consumer dietary exposure assessment

| Commodity | Chronic exposure assessment | | Acute exposure assessment | |
|---|-----------------------------|-------------------------------|--|---------|
| | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Risk assessment residue definition: Acibenzolar-S-methyl (sum of acibenzolar-S-methyl and acibenzolar acid (CGA 210007) expressed as acibenzolar-S-methyl) | | | | |
| Lettuce | 0.105 | Median residue | Acute risk assessment was not performed since no ARfD is necessary for acibenzolar-S-methyl. | |
| Hazelnuts | 0.04 | Median residue (France, 2009) | | |
| Apricots | 0.034 | Median residue (EFSA, 2009) | | |
| Peaches | 0.034 | Median residue (EFSA, 2009) | | |

¹⁵ The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

| Commodity | Chronic exposure assessment | | Acute exposure assessment | |
|---|-----------------------------|-------------------------------|---------------------------|---------|
| | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Bananas | 0.02 | Median residue (France, 2009) | | |
| Mangoes | 0.21 | Median residue (France, 2009) | | |
| Tomatoes | 0.19 | Median residue (France, 2009) | | |
| Spinach | 0.14 | Median residue (France, 2009) | | |
| Other commodities of plant or animal origin | EC MRL | See Appendix C | | |

The estimated exposure was then compared with the toxicological reference values derived for acibenzolar-S-methyl (see Table 2-1). The results of the intake calculation are presented in Appendix B to this reasoned opinion.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values ranged from 0.3% to 1.9% of the ADI (WHO cluster diet B). The contribution of residues in lettuce to the total long-term exposure was insignificant (0.04% of the ADI).

Consequently EFSA concludes that the intended use of acibenzolar-S-methyl on lettuce will not result in a consumer exposure exceeding the toxicological reference values and therefore will not pose a public health concern.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile for acibenzolar-S-methyl was investigated in the peer review and data were sufficient to conclude on an ADI value of 0.1 mg/kg bw/day. No ARfD was established because of the low acute toxicity of the active substance.

Metabolism of acibenzolar-S-methyl in primary plants was investigated in the framework of the peer review on cereals (wheat), fruiting vegetables (tomatoes) and leafy vegetables (tobacco). An additional metabolism study on lettuce was evaluated and reported in the evaluation report prepared by France in support of a previous MRL application. The residue definition derived for risk assessment and enforcement for all categories of crops is *acibenzolar-S-methyl* (sum of *acibenzolar-S-methyl* and *acibenzolar acid* (CGA 210007), expressed as *acibenzolar-S-methyl*). The same residue definition for enforcement purposes has been established under Regulation (EC) No 396/2005.

In support to this MRL application, the applicant submitted eight residue trials performed on lettuce (*Lactuca sativa*) carried out under indoor conditions (three of the trials were performed on open leaf varieties) as well as six and seven outdoor residue trials were conducted in Northern and Southern Europe, respectively. The residue trials on lettuce grown under indoor conditions generally showed higher residue levels than the outdoor trials. The residue concentrations on open leaf varieties seem to be in the same range as the residue concentrations on head forming varieties. However, EFSA is of the opinion that a data set of three and five trials for open leaf lettuce and head forming lettuce, respectively, is not sufficiently robust to conclude that the two sets of data represent the same population. Thus, an extrapolation to the whole crop group of lettuce and other salad plants including *Brassicaceae* is not recommended by EFSA. According to the current guidelines five additional trials on open leaf varieties would be required for this extrapolation.

Acibenzolar-S-methyl is hydrolytically stable under the processing conditions representative of pasteurisation and baking/boiling/brewing while a significant degradation was observed under sterilisation processing conditions. Since the major degradation product acibenzolar acid (CGA 210007) was identified as a major plant metabolite, the same residue definition as for raw agricultural commodities (RAC) can be applied for the processed commodities.

Specific studies to assess the magnitude of acibenzolar-S-methyl residues during the processing of crops under consideration are not necessary as the total theoretical maximum daily intake (TMDI) accounted for less than 10 % of the ADI and thermal treatment is not considered as a relevant processing type for lettuce.

The possible occurrence of acibenzolar-S-methyl residues in rotational and/or succeeding crops was investigated; the residue levels in the edible parts of the rotational crops are not expected to exceed the trigger value of 0.01 mg/kg provided that the active substance is applied according to the proposed GAP.

Lettuce and other salad plants including *Brassicaceae* or any of their by-products are not part of the livestock diet. Therefore no further considerations are needed regarding residues in feed and their transfer into food of animal origin.

The chronic consumer risk assessment was performed with revision 2 of the EFSA PRIMo. For the calculation of the chronic exposure, EFSA used the median residue values as derived from the residue trials on lettuce as well as the median residue values for peaches and apricots from the previous EFSA reasoned opinion and also the median residue values for hazelnuts, bananas, mangoes, tomatoes and spinach from the residue database reported in the Pesticide Residue Overview File (PROFile) in order

to refine the intake calculations. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annexes II and IIIB of Regulation (EC) No 396/2005 were used as input values.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values ranged from 0.3% to 1.9% of the ADI (WHO cluster diet B). The contribution of residues in lettuce to the total long-term exposure was insignificant (0.04% of the ADI).

An acute dietary risk assessment is not necessary because of the low acute toxicity of the active substance for which no ARfD has been considered as necessary.

EFSA concludes that the intended use of acibenzolar-S-methyl in lettuce is acceptable with regard to the consumer exposure.

RECOMMENDATIONS

| Code number ^a | Commodity | Existing EC MRL (mg/kg) | Proposed EC MRL (mg/kg) | Justification for the proposal |
|--|---|-------------------------|-------------------------|--|
| Acibenzolar-S-methyl (sum of acibenzolar-S-methyl and acibenzolar acid (CGA 210007) expressed as acibenzolar-S-methyl) | | | | |
| 0251020 | Lettuce | 0.02* | 0.3 | The proposed MRL on lettuce is sufficiently supported by residue trials reflecting indoor conditions. No risk for consumers was identified for the proposed MRL |
| 0251990 | Others (e.g. lamb's lettuce, scarole, cress, land cress, rocket, rucola, red mustard, leaves and sprouts of <i>Brassica</i> spp, including turnip greens) | 0.02* | no proposal | An extrapolation from lettuce to other lettuce plants included in the crop group is not acceptable since the number of residue trials is not sufficient. 5 additional trials on open leave varieties of lettuce would be required. |

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

^a according to Annex I of Regulation (EC) No 396/2005

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Appendix A. GOOD AGRICULTURAL PRACTICES (GAPS)

| Crop and/or situation (a) | Member State or Country | F G or I (b) | Pest or group of pests controlled (c) | Formulation | | Application | | | | Application rate per treatment | | | PHI (days) (l) | Remarks (m) | |
|--|-------------------------|-----------------|--|-----------------|----------------------|------------------------|--|--------------------------------|------------------|--------------------------------|--------------------|--------------------|-------------------|----------------|--|
| | | | | type (d - f) | conc. of a.s. (i) | method kind (f - h) | growth stage & season (j) | number min max (k) | interval min max | kg as/hL min max | water L/ha min max | kg a.s./ha min max | | | |
| Lettuce and other salad plants including <i>Brassicaceae</i> | FR | F and G/I | Downy mildew (<i>Bremia lactucae</i>) | WG | 40 g/kg | foliar spray | Preventative application BBCH GS 18-43 | 1 – 3* (10 day spray interval) | | | | 500-1000 | 0.014 | 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. |

- Remarks:
- (a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
 - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 - (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
 - (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 - (e) GCPF Technical Monograph No 2, 4th Ed., 1999 or other codes, e.g.
 - (f) OECD/CIPAC, should be used
 - (g) All abbreviations used must be explained
 - (h) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
 - (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
 - (i) g/kg or g/l
 - (j) Growth stage at last treatment (Growth stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., 2001), including where relevant, information on season at time of application
 - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
 - (l) PHI - minimum pre-harvest interval
 - (m) Remarks may include: Extent of use/economic importance/restrictions (i.e. feeding, grazing)

Appendix C. EXISTING EU MAXIMUM RESIDUE LIMITS (MRLs)

PESTICIDES - WEB VERSION - EU MRLs (FILE CREATED ON 10/02/2012 13:50)

| Code number | Groups and examples of individual products to which the MRLs apply (a) | Acibenzolar-S-methyl (see residue definition) |
|-------------|---|---|
| 100000 | 1. FRUIT FRESH OR FROZEN; NUTS | |
| 110000 | (i) Citrus fruit | 0,02* |
| 110010 | Grapefruit (Shaddock, pomelos, sweets, tangelo, 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 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* |

| Code number | Groups and examples of individual products to which the MRLs apply (a) | Acibenzolar-S-methyl (see residue definition) |
|-------------|--|---|
| 140000 | (iv) Stone fruit | 0,02* |
| 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) | 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) | 0,02* |
| 153990 | Others | 0,02* |
| 154000 | (d) Other small fruit & berries | 0,02* |
| 154010 | Blueberries (Bilberries cowberries (red bilberries)) | 0,02* |
| 154020 | Cranberries | 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) | 0,02* |
| 154080 | Elderberries (Black chokeberry (appleberry), mountain ash, azarole, 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) | 0,02* |
| 161050 | Carambola (Bilimbi) | 0,02* |
| 161060 | Persimmon | 0,02* |
| 161070 | Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilian cherry) | 0,02* |

| Code number | Groups and examples of individual products to which the MRLs apply (a) | Acibenzolar-S-methyl (see residue definition) |
|-------------|---|---|
| | (gumichama), Surinam cherry) | |
| 161990 | Others | 0,02* |
| 162000 | (b) Inedible peel, small | 0,02* |
| 162010 | Kiwi | 0,02* |
| 162020 | Lychee (Litchi) (Pulasan, rambutan (hairy litchi)) | 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 mammy sapote) | 0,02* |
| 162990 | Others | 0,02* |
| 163000 | (c) Inedible peel, large | |
| 163010 | Avocados | 0,02* |
| 163020 | Bananas (Dwarf banana, plantain, apple banana) | 0,1 |
| 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 | 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 | (j) 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* |

| Code number | Groups and examples of individual products to which the MRLs apply (a) | Acibenzolar-S-methyl (see residue definition) |
|-------------|--|---|
| 213030 | Celeriac | 0,02* |
| 213040 | Horseradish | 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) | 0,02* |
| 213090 | Salsify (Scorzonera, Spanish salsify (Spanish oysterplant)) | 0,02* |
| 213100 | Swedes | 0,02* |
| 213110 | Tumips | 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) Solanaceae | |
| 231010 | Tomatoes (Cherry tomatoes,) | 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* |

| Code number | Groups and examples of individual products to which the MRLs apply (a) | Acibenzolar-S-methyl (see residue definition) |
|-------------|--|---|
| 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), peking cabbage (pe-tsai), cow cabbage) | 0,02* |
| 243020 | Kale (Borecole (curly kale), collards) | 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 Brassicaceae | 0,02* |
| 251010 | Lamb's lettuce (Italian comsalad) | 0,02* |
| 251020 | Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce) | 0,02* |
| 251030 | Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf) | 0,02* |
| 251040 | Cress | 0,02* |
| 251050 | Land cress | 0,02* |
| 251060 | Rocket, Rucola (Wild rocket) | 0,02* |
| 251070 | Red mustard | 0,02* |
| 251080 | Leaves and sprouts of Brassica spp (Mizuna) | 0,02* |
| 251990 | Others | 0,02* |
| 252000 | (b) Spinach & similar (leaves) | |
| 252010 | Spinach (New Zealand spinach, turnip greens (turnip tops)) | 0,3 |
| 252020 | Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort) | 0,3 |
| 252030 | Beet leaves (chard) (Leaves of beetroot) | 0,3 |
| 252990 | Others | 0,3 |
| 253000 | (c) Vine leaves (grape leaves) | 0,3 |
| 254000 | (d) Water cress | 0,3 |
| 255000 | (e) Witloof | 0,3 |
| 256000 | (f) Herbs | 0,3 |
| 256010 | Chervil | 0,3 |

| Code number | Groups and examples of individual products to which the MRLs apply (a) | Acibenzolar-S-methyl (see residue definition) |
|-------------|--|---|
| 256020 | Chives | 0,3 |
| 256030 | Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea) | 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 | Tamagon (Hyssop) | 0,3 |
| 256990 | Others | 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)) | 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) | 0,02* |
| 280990 | Others | 0,02* |
| 290000 | (ix) Sea weeds | |

| Code number | Groups and examples of individual products to which the MRLs apply (a) | Acibenzolar-S-methyl (see residue definition) |
|-------------|---|---|
| 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. OIL SEEDS 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 | 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 | 0,05* |
| 500030 | Maize | 0,05* |
| 500040 | Millet (Foxtail millet, tef) | 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 | 0,05* |

| Code number | Groups and examples of individual products to which the MRLs apply (a) | Acibenzolar-S-methyl (see residue definition) |
|-------------|--|---|
| | INFUSIONS AND COCOA | |
| 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 | 0,05* |
| 631050 | Lime (linden) | 0,05* |
| 631990 | Others | 0,05* |
| 632000 | (b) Leaves | 0,05* |
| 632010 | Strawberry leaves | 0,05* |
| 632020 | Rooibos leaves | 0,05* |
| 632030 | Maté | 0,05* |
| 632990 | Others | 0,05* |
| 633000 | (c) Roots | 0,05* |
| 633010 | Valerian root | 0,05* |
| 633020 | Ginseng root | 0,05* |
| 633990 | Others | 0,05* |
| 639000 | (d) Other herbal infusions | 0,05* |
| 640000 | (iv) Cocoa (fermented 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 | 0,05* |

| Code number | Groups and examples of individual products to which the MRLs apply (a) | Acibenzolar-S-methyl (see residue definition) |
|-------------|--|---|
| | pepper, pink pepper) | |
| 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) Ail | 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 | |

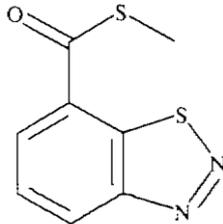
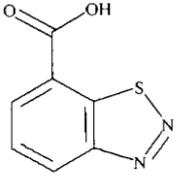
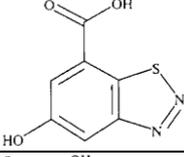
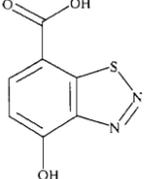
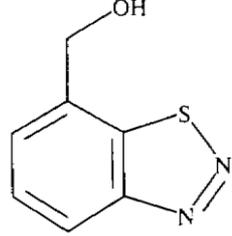
| Code number | Groups and examples of individual products to which the MRLs apply (a) | Acibenzolar-S-methyl (see residue definition) |
|-------------|--|---|
| | ANIMALS | |
| 1010000 | (i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these | 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* |

| Code number | Groups and examples of individual products to which the MRLs apply (a) | Acibenzolar-S-methyl (see residue definition) |
|-------------|---|---|
| 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 | 0,02* |

| Code number | Groups and examples of individual products to which the MRLs apply (a) | Acibenzolar-S-methyl (see residue definition) |
|-------------|---|---|
| | concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd | |
| 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) | |
| 1050000 | (v) Amphibians and reptiles (Frog legs, crocodiles) | |
| 1060000 | (vi) Snails | |
| 1070000 | (vii) Other terrestrial animal products | |

(*) Indicates lower limit of analytical determination

Appendix D. LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

| Common name | IUPAC name | Structure |
|--------------------------------------|---|--|
| CGA 245704 (Acibenzolar-S-methyl) | S-methyl benzo[1,2,3]thiadiazole-7- carbothioate |  |
| CGA 210007 | Benzo[1,2,3]thiadiazole-7- carboxylic acid |  |
| CGA 324041 | 5-hydroxy- benzo[1,2,3]thiadiazole-7- carboxylic acid |  |
| CGA 323060 | 4-Hydroxy- benzo[1,2,3]thiadiazole-7- carboxylic acid |  |
| CGA 243093 | Benzo[1,2,3]thiadiazole-7-yl- methanol |  |

ABBREVIATIONS

| | |
|---------------------|--|
| ADI | acceptable daily intake |
| AR | applied radioactivity |
| ARfD | acute reference dose |
| a.s. | active substance |
| BBCH | growth stages of mono- and dicotyledonous plants |
| bw | body weight |
| CEN | European Committee for Standardization (Comité Européen de Normalisation, <i>French</i>) |
| CF | conversion factor for enforcement residue definition to risk assessment residue definition |
| CXL | Codex Maximum Residue Limit (Codex MRL) |
| d | day |
| DALA | days after last application |
| DAR | Draft Assessment Report (prepared under Council Directive 91/414/EEC) |
| DT _{90lab} | period required for 90% dissipation (laboratory method) |
| EC | European Community |
| EFSA | European Food Safety Authority |
| EMS | evaluating Member State |
| eq | residue expressed as a.s. equivalent |
| EU | European Union |
| FAO | Food and Agriculture Organisation of the United Nations |
| GAP | good agricultural practice |
| GS | growth stage |
| ha | hectare |
| HPLC | high performance liquid chromatography |
| ILV | independent laboratory validation |
| ISO | International Organization for Standardization |
| IUPAC | International Union of Pure and Applied Chemistry |
| kg | kilogram |
| L | litre |
| LC | liquid chromatography |
| LOQ | limit of quantification (determination) |
| MRL | maximum residue limit |
| MS | Member States |

| | |
|-----------|---|
| MS/MS | tandem mass spectrometry |
| NEU | northern European Union |
| OECD | Organization for Economic Co-operation and Development |
| PHI | pre-harvest interval |
| ppm | parts per million (10^{-6}) |
| PRIMo | (EFSA) Pesticide Residues Intake Model |
| QuEChERS | Quick, Easy, Cheap, Effective, Rugged, and Safe (method) |
| 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 |
| RAC | raw agricultural commodity |
| RD | residue definition |
| RMS | rapporteur Member State |
| SEU | Southern European Union |
| TMDI | theoretical maximum daily intake |
| TRR | total radioactive residue |
| UV | ultra-violet (detection or detector) |
| WG | water dispersible granule |