Modification of the existing maximum residue level for acibenzolar-S-methyl in hazelnuts

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Syngenta France SAS submitted a request to the competent national authority in France to modify the existing maximum residue level (MRL) for the active substance acibenzolar-S-methyl in hazelnuts. The data submitted in support of the request were found to be sufficient to derive an MRL proposal for hazelnuts/cobnuts. Adequate analytical methods for enforcement are available to control residues of acibenzolar-S-methyl in the plant matrix under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of acibenzolar-S-methyl according to the reported agricultural practice is unlikely to present a risk to consumer health.

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In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta France SAS submitted an application to the competent national authority in France (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance acibenzolar-S-methyl in hazelnuts. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 12 December 2018. To accommodate for the intended use of acibenzolar-S-methyl, the EMS proposed to raise the existing MRL from 0.1 to 0.2 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. Based on the conclusions derived by EFSA in the framework of the European Union (EU) pesticides peer review under Regulation (EC) No 1107/2009, the data evaluated under previous MRL assessments, and the data provided by the EMS in the framework of the present MRL application, the following conclusions are derived.

The metabolism of acibenzolar-S-methyl following foliar application was investigated in crops belonging to the groups of fruit crops, leafy crops and cereals. Studies investigating the effect of processing on the nature of acibenzolar-S-methyl (hydrolysis studies) demonstrated that the active substance is stable under conditions that simulate pasteurisation and baking, brewing and boiling process but is likely to degrade to acibenzolar acid under sterilisation conditions; the residue pattern in processed commodities is qualitatively comparable to the residue pattern in raw commodities.

As the proposed use of acibenzolar-S-methyl is on a permanent crop, investigations of residues in rotational crops are not required.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites and degradation products, the residue definitions for plant products were proposed for enforcement and risk assessment as: 'sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-S-methyl’ (limited to fruit crops, cereals and tobacco). These residue definitions are applicable to primary crops and processed products.

EFSA concluded that for the crop assessed in this application, metabolism of acibenzolar-S-methyl in primary crops, and the possible degradation in processed products has been sufficiently addressed and that the previously derived residue definitions are applicable.

Sufficiently validated analytical methods based on high performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) are available to quantify residues in the crop assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg in the crop assessed (limit of quantification (LOQ)).

The available residue trials are sufficient to derive an MRL proposal of 0.2 mg/kg for hazelnuts/cobnuts.

Specific studies investigating the magnitude of acibenzolar-S-methyl residues in processed commodities are not required as the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the acceptable daily intake (ADI).

Residues of acibenzolar-S-methyl in commodities of animal origin were not assessed since the crop under consideration in this MRL application is normally not fed to livestock.

The toxicological profile of acibenzolar-S-methyl was assessed in the framework of the EU pesticides peer review under Regulation (EC) No 1107/2009 and the data were sufficient to derive an ADI of 0.03 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.03 mg/kg bw. The metabolite acibenzolar acid, included in the residue definition, is of similar toxicity as the parent active substance.

The consumer risk assessment was performed with revision 3 of the EFSA Pesticide Residues Intake Model (PRIMo). The short-term exposure assessment was performed only with regard to the commodity assessed in this application, in accordance with the internationally agreed methodology based on the highest residue (HR) value derived from supervised field trials. The estimated maximum exposure in percentage of the ARfD accounted for 0.8%. The comprehensive long-term exposure assessment performed in the framework of the MRL review was updated with the supervised trials median residue (STMR) value for hazelnuts derived from the residue trials submitted in support of this MRL application, and the relevant STMR values derived in EFSA opinions published after the MRL review, and the relevant STMR values derived in Codex MRL assessments for the acceptable Codex Maximum Residue Limits (CXLs). The highest estimated long-term dietary intake was 3% of the ADI.
(GEMS/Food G06 diet). The contribution of residues expected in hazelnuts assessed in this application to the overall long-term exposure was up to 0.02% of ADI (DE child).

EFSA concluded that the proposed use of acibenzolar-S-methyl on hazelnuts will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

EFSA proposes to amend the existing MRL as reported in the summary table below.

Full details of all endpoints and the consumer risk assessment can be found in Appendices B–D.

| Code(a) | Commodity        | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                      |
|---------|------------------|-------------------------|-------------------------|-------------------------------------------|
| 120060  | Hazelnuts/cobnuts| 0.1                     | **0.2**                 | The submitted data are sufficient to derive an MRL proposal for the SEU use. Risk for consumers unlikely |

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
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Assessment

The detailed description of the intended use of acibenzolar-S-methyl in hazelnuts, which is the basis for the current maximum residue level (MRL) application, is reported in Appendix A. Acibenzolar-S-methyl is the ISO common name for S-methyl benzo[1,2,3]thiadiazole-7-carbothioate (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Acibenzolar-S-methyl has been evaluated for renewal of approval in the framework of Regulation (EC) No 1107/2009 according to Commission Regulation (EU) No 1141/2010\(^1\), as amended by Commission Implementing Regulation (EU) No 380/2013\(^2\), with France as designated rapporteur Member State (RMS); the representative uses assessed were foliar spraying on pome fruit, tomato and tobacco. The renewal assessment report (RAR) prepared by the RMS has been peer reviewed by European Food Safety Authority (EFSA) (EFSA, 2014). The decision to renew the approval of acibenzolar-S-methyl for the use as a plant activator was taken on 1 April 2016.\(^3\)

The European Union (EU) MRLs for acibenzolar-S-methyl are established in Annex II of Regulation (EC) No 396/2005\(^4\). The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2013) and the proposed modifications have been implemented in the MRL legislation.\(^5\) After completion of the MRL review, EFSA has issued several reasoned opinions on the modification of MRLs for acibenzolar-S-methyl. The proposals from these reasoned opinions have been considered in the MRL legislation.\(^6\) Certain Codex Maximum Residue Limits (CXLs) for acibenzolar-S-methyl, for which the EU expressed its support during the Codex Committee on Pesticide Residues (CCPR) meeting, have been transposed into EU legislation by Commission Regulation (EU) 2018/687.\(^7\)

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta France SAS submitted an application to the competent national authority in France (evaluating Member State, EMS) to modify the existing MRL for the active substance acibenzolar-S-methyl in hazelnuts. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 12 December 2018. To accommodate for the intended use of acibenzolar-S-methyl, the EMS proposed to raise the existing MRL from 0.1 to 0.2 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation.

EFSA based its assessment on the evaluation report submitted by the EMS (France, 2018), the RAR (and its final addendum) prepared under Regulation (EC) No 1107/2009 (France, 2013, 2014), the European Commission review report on acibenzolar-S-methyl (European Commission, 2016), the conclusion on the peer review of the pesticide risk assessment of the active substance acibenzolar-S-methyl (EFSA, 2014), as well as the conclusions from previous EFSA opinions on acibenzolar-S-methyl (EFSA, 2017, 2018b), including the review of the existing MRLs for acibenzolar-S-methyl according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2013).

\(^{1}\) Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances. OJ L 322, 8.12.2010, p. 10–19.

\(^{2}\) Commission Implementing Regulation (EU) No 380/2013 of 25 April 2013 amending Regulation (EU) No 1141/2010 as regards the submission of the supplementary complete dossier to the Authority, the other Member States and the Commission. OJ L 116, 26.4.2013, p. 4–4.

\(^{3}\) Commission Implementing Regulation (EU) 2016/389 of 17 March 2016 renewing the approval of the active substance acibenzolar-S-methyl in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 73, 18.3.2016, p. 77–80.

\(^{4}\) Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1–16.

\(^{5}\) Commission Regulation (EU) No 703/2014 of 19 June 2014 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acibenzolar-S-methyl, ethoxyquin, flusilazole, isoxaflutole, molinate, propoxycarbazone, pyraflufen-ethyl, quinoclamine and warfarin in or on certain products. OJ L 186, 26.6.2014, p. 1–48.

\(^{6}\) For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN

\(^{7}\) Commission Regulation (EU) 2018/687 of 4 May 2018 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acibenzolar-S-methyl, benzovindiflupy, bifenthrin, bixafen, chlorantraniliprole, deltamethrin, flonicamid, fluaifop-P, isofetamid, mefenacetone, pendimethalin and teflubenzuron in or on certain products. OJ L 121/63, 16.5.2018, p. 63–104.
For this application, the data requirements established in Regulation (EU) No 544/2011\textsuperscript{8} and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a,b,c,d,e,f,g, 2000, 2010a,b, 2017; OECD, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011\textsuperscript{9}.

A selected list of end points of the studies assessed by EFSA in the framework of this MRL application including the end points of relevant studies assessed previously is presented in Appendix B.

The evaluation report submitted by the EMS (France, 2018) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of acibenzolar-S-methyl in primary crops belonging to the group of fruiting vegetables (tomato), leafy crops (tobacco, lettuce) and cereals (wheat) has been investigated in the framework of the EU pesticides peer review and during the MRL review (EFSA, 2013, 2014). The metabolic pathway of acibenzolar-S-methyl proceeds via hydrolysis of the parent compound to acibenzolar acid followed by ester conjugation with sugars (EFSA, 2013). The metabolite 4-OH acibenzolar acid was observed in leafy crops, and in the peer review process, it was recommended that this metabolite should be considered for inclusion in the residue definition for risk assessment for crop groups other than fruit crops and cereals (EFSA, 2014).

1.1.2. Nature of residues in rotational crops

As the proposed use of acibenzolar-S-methyl is on a permanent crop, investigations of residues in rotational crops are not required.

1.1.3. Nature of residues in processed commodities

Standard hydrolysis studies investigating the nature of residues in processed commodities were assessed previously (EFSA, 2013, 2014). Residues were considered to be stable under conditions that simulate pasteurisation and baking, brewing and boiling. Under conditions that simulate sterilisation, significant degradation into acibenzolar acid occurs; based on this characterisation, the residue pattern in processed commodities is expected to be qualitatively comparable to the residue pattern in raw commodities.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of residues of acibenzolar-S-methyl were submitted with the current MRL application (France, 2018). The methods are sufficiently validated in the crop under consideration for residues of acibenzolar-S-methyl and acibenzolar acid and its conjugates, expressed as acibenzolar-S-methyl. The methods allow quantifying residues at or above the LOQ of 0.01 mg/kg for the total residue (sum of acibenzolar-S-methyl and acibenzolar acid, free and conjugates) in crops belonging to the groups of high-oil content and high-water content commodities, and in dry tobacco leaves. An independent laboratory validation (ILV) is available and a confirmatory method was not required due to the method specificity.

1.1.5. Stability of residues in plants

Information on the stability of acibenzolar-S-methyl and acibenzolar acid in frozen samples of hazelnuts (high oil content matrix) was submitted with the current application. It was demonstrated

\textsuperscript{8} Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.

\textsuperscript{9} Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
that residues in samples of hazelnuts were stable for at least 197 days when stored at –20°C (France, 2018). The applicant indicated that the study is to continue up to 12 months.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and degradation products, the following residue definitions were proposed in the framework of the MRL Review (EFSA, 2013):

- Residue definition for enforcement: sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-S-methyl;
- Residue definition for risk assessment: sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-S-methyl (limited to fruit crops, cereals and tobacco).

Subsequently, during the renewal of approval in the framework of Regulation (EC) No 1107/2009, EFSA proposed that the residue definition for risk assessment should be limited to cereals, fruits and fruiting vegetables and tobacco (EFSA, 2014). Further consideration would be required for other crop groups, e.g. whether inclusion of the metabolite 4-OH acibenzolar acid would be appropriate in the residue definition for risk assessment.

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition. Taking into account the proposed use in hazelnut assessed in this application, EFSA concluded that these residue definitions are appropriate, and no modification is required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, six residue trials conducted in hazelnuts were submitted. Four residue trials performed in Italy in 1999 (25 g a.s./ha, five applications, BBCH 73-81, 14-day interval, 28-day preharvest interval (PHI)) were not fully compliant with the Good Agricultural Practice (GAP), which foresees a maximum of four applications. However, considering that the number of applications was 25% higher than the GAP and the relatively long interval from the additional application to harvest (84 days), the trials were judged to be sufficiently representative of the GAP to use for the derivation of MRL and risk assessment values. Trials conducted at the same experimental site were not sufficiently independent and the highest residue value was selected (different experimental conditions). The mean residue value was used where experimental replicates were sampled. From the residue trials performed in 1999, two residue trials were sufficiently independent and acceptable. Two GAP compliant residue trials were performed in southern France and Italy in 2017 (25 g a.s./ha, four applications at BBCH 73-86, 14-day interval, 28-day PHI). In total, four residue trials were acceptable and sufficiently representative of the intended use GAP on hazelnuts (France, 2018).

The residue trials samples were analysed for acibenzolar-S-methyl and acibenzolar acid and its conjugates, expressed as acibenzolar-S-methyl, in accordance with in the residue definition for enforcement and risk assessment. According to the assessment of the EMS, the methods of analysis were sufficiently validated and fit for purpose with LOQs of either 0.02 mg/kg (1999 trials) or 0.01 mg/kg (2017 trials). The samples were stored under conditions for which integrity of the residues has been demonstrated, except for one trial where samples were stored for 7.2 months before analysis whereas storage stability has been demonstrated for up to 6.5 months, which was judged to be a minor deviation (storage stability study ongoing up to 12 months).

The number and quality of the trials is sufficient to derive an MRL proposal of 0.2 mg/kg for hazelnuts/cobnuts on the basis of the intended southern Europe (SEU) GAP.

1.2.2. Magnitude of residues in rotational crops

As the proposed use of acibenzolar-S-methyl is on a permanent crop, investigations of residues in rotational crops are not required.

1.2.3. Magnitude of residues in processed commodities

Specific processing studies for the crop under assessment are not available. Processing studies are not required considering that the TMDI is less than 10% of the acceptable daily intake (ADI).
1.2.4. Proposed MRLs

The available data are considered sufficient to derive an MRL proposal as well as risk assessment values for the commodity under evaluation (see Appendix B.1.2.1). In Section 3, EFSA assessed whether residues on this crop resulting from the intended use are likely to pose a consumer health risk.

2. Residues in livestock

Residues in livestock are not relevant as hazelnuts are not normally used for feed purposes.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3 of the EFSA PRIMo (EFSA, 2018a). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference values for acibenzolar-S-methyl used in the risk assessment (i.e. ADI and ARfD values) were derived in the framework of the EU pesticides peer review (EFSA, 2014). The metabolite acibenzolar acid, which is included in the residue definition, was shown to share the toxicity potential of the parent acibenzolar-S-methyl, and therefore, the reference values of the parent are applicable to this metabolite (EFSA, 2014).

3.1. Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed only with regard to the commodity assessed in this application in accordance with the internationally agreed methodology (EFSA, 2018a). The calculations were based on the HR derived from supervised field trials and the complete list of input values can be found in Appendix D.2.

The short-term exposure did not exceed the ARfD for the crop assessed in this application. The estimated maximum exposure in percentage of the ARfD accounted for 0.8% (see Appendix B.3).

3.2. Long-term (chronic) dietary risk assessment

A comprehensive long-term exposure assessment was performed in the framework of the MRL review, taking into account the existing uses at EU level. EFSA updated the calculation with the STMR value for hazelnuts derived from the residue trials submitted in support of this MRL application, and the relevant STMR values derived in EFSA opinions published after the MRL review (EFSA, 2013, 2014, 2017, 2018b), and the relevant STMR values derived in Codex MRL assessments for the CXLs taken over in the EU MRL legislation (FAO, 2016). The input values used in the exposure calculations are summarised in Appendix D.2.

The highest estimated long-term dietary intake was 3% of the ADI (GEMS/Food G06 diet). The contribution of residues expected in hazelnuts assessed in this application to the overall long-term exposure was up to 0.02% of ADI (DE child). The results of the long-term dietary risk assessment are presented in Appendix B.3.

EFSA concluded that the long-term intake of residues of acibenzolar-S-methyl resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

4. Conclusion and recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for hazelnuts.

EFSA concluded that the proposed use of acibenzolar-S-methyl on hazelnuts will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

The MRL recommendations are summarised in Appendix B.4.
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Abbreviations

a.s. active substance
ADI acceptable daily intake
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CCPR Codex Committee on Pesticide Residues
CF conversion factor for enforcement to risk assessment residue definition
CXL Codex maximum residue limit
DAT days after treatment
EMS evaluating Member State
EU European Union
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
HPLC-MS/MS high performance liquid chromatography with tandem mass spectrometry
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
ILV independent laboratory validation
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
LOQ limit of quantification
MRL maximum residue level
NEU northern Europe
OECD Organisation for Economic Co-operation and Development
PBI plant back interval
PHI preharvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
RA risk assessment
RD residue definition
RMS rapporteur Member State
SANCO Directorate-General for Health and Consumers
SEU southern Europe
STMR supervised trials median residue
TMDI theoretical maximum daily intake
TRR total radioactive residue
UV ultraviolet (detector)
WG water-dispersible granule
Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F G or I (a) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | Remarks |
|-----------------------|-------------------------|-------------|-----------------------------------|-------------|-------------|-------------------------------|---------|
|                       |                         |             |                                   | Type (b)    | Conc. a.s.  | Method Kind                    | Unit    |
|                       |                         |             |                                   |             |            | Range of growth stages & season (c) | PHI (days) (d) | |
|                       |                         |             |                                   |             |            | Number min–max                  | g a.s./hL | |
|                       |                         |             |                                   |             |            | Interval between application (min) | Water L/ha | |
|                       |                         |             |                                   |             |            |                                | Rate     | |
| Hazelnuts/cobnuts     | SEU (Italy, Portugal)   | F           | Pseudomonas avellanae             | WG 500 g/kg | Foliar treatment - broadcast spraying | BBCH 31–87 | 1–4                       | Max 1,000 | 25 g a.s./ha   | 28 |

NEU: northern European Union; SEU: southern European Union; MS: Member State.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide formulation types and international coding system.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.
## Appendix B – List of end points

### B.1. Residues in plants

#### B.1.1. Nature of residues and methods of analysis in plants

#### B.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/source |
|-----------------------------------|-------------|---------|----------------|----------------|----------------|
| Fruit crops                       | Tomato      | Foliar, G | 3 × 0.273 kg a.s./ha | 1 h to 30 DAT | $^{14}$C-U-phenyl]-acibenzolar-S-methyl (France, 1998; EFSA, 2013) |
| Leafy crops                       | Tobacco     | Foliar, G | 3 × 0.170 kg a.s./ha | 1 h after the 1st application; 21 days after the 2nd application and 17, 27, 35, 45, 52 DAT |
|                                  | Lettuce     | Foliar, G | 4 × 0.42 kg a.s./ha | 1 h after 1st application, 7 DAT |
|                                  | Lettuce     | Foliar, G | 4 × 0.14 kg a.s./ha (1st application 7–9 leaf stage) | 7 DAT |
| Cereals/grass                     | Wheat       | Foliar, F | 1 × 0.05 kg a.s./ha (application at the end of tillering) | 1 h, 14, 28, 75 DAT |
|                                  | Wheat       | Foliar, G | 1 × 0.05 kg a.s./ha (application at 4 leaf stage) | 0, 1, 3, 7, 14 DAT |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/source |
|--------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                     | Radish      | Bare soil application, F, 0.05 kg a.s./ha | 30, 113, 141, 337 | Radiolabelled active substance: $^{14}$C-U-phenyl]-acibenzolar-S-methyl (France, 1998; EFSA, 2013) |
| Leafy crops                          | Lettuce     | Bare soil application, F, 0.05 kg a.s./ha | 30, 113, 141, 337 |
| Cereal (small grain) (grain)         | Wheat       | Bare soil application, F, 0.05 kg a.s./ha | 30, 113, 141, 337 |
|                                     | Maize       | Bare soil application, F, 0.05 Kg a.s./ha | 30, 113, 141, 337 |
## Processed Commodities (Hydrolysis Study)

| Conditions                        | Stable? | Comment/source                                      |
|-----------------------------------|---------|-----------------------------------------------------|
| Pasteurisation (20 min, 90°C, pH 4) | Yes     | EFSA (2014)                                         |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes     | EFSA (2014)                                         |
| Sterilisation (20 min, 120°C, pH 6) | No      | Significant degradation into acibenzolar acid under sterilisation conditions (EFSA, 2014) |
| Other processing conditions       | –       | –                                                   |

DAT: days after treatment; PBI: plant-back interval.

### Can a general residue definition be proposed for primary crops?

| Rotational crop and primary crop metabolism similar? | Comment/source |
|-----------------------------------------------------|----------------|
| No                                                  | EFSA (2014)    |
| Yes                                                 | EFSA (2014)    |

### Residue pattern in processed commodities similar to residue pattern in raw commodities?

| Plant residue definition for monitoring (RD-Mo) | Comment/source |
|-------------------------------------------------|----------------|
| Yes                                             | Sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-S-methyl |

### Plant residue definition for risk assessment (RD-RA)

| Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs) | Comment/source |
|--------------------------------------------------------------------------------------------|----------------|
| Matrices with high water content, high acid content and tobacco: HPLC–MS/MS with an LOQ of 0.01 mg/kg (EFSA, 2014; France, 2016) | |
| Matrices with high water content, high oil content and dry tobacco leaves: HPLC–MS/MS, LOQ 0.01mg/kg. Confirmatory method not required. ILV available. (France, 2018) | |
### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period | Compounds covered | Comment/source |
|-----------------------------------|----------|-----------|--------|----------------|------------------|---------------|
|                                   |          |           |        | Value | Unit                 |               |
| High water content                | Tobacco, lettuce, tomato, cabbage, squash and turnips | –20 | 20 months |  | acibenzolar-S-methyl, acibenzolar acid | EFSA (2013) |
| High water content                | Lettuce  | –20       | 12 months |  | 4-OH acibenzolar acid | France (2018) |
| High oil content                  | Hazelnuts | –20       | 197 days |  | acibenzolar-S-methyl, acibenzolar acid | Study to continue up to 12 months (France, 2018) |
| High oil content                  | Rape seed | –20       | 12 months |  | 4-OH acibenzolar acid | France (2018) |
| High protein content              | Dried beans | –20       | 12 months |  | 4-OH acibenzolar acid | France (2018) |
| Dry/high starch                   | Wheat grain | –18       | 24 months |  | acibenzolar-S-methyl, acibenzolar acid | EFSA (2013) |
| Dry/high starch                   | Wheat grain, potato tuber | –20 | 12 months |  | 4-OH acibenzolar acid | France (2018) |
| High acid content                 | Strawberries | –21       | 10 months |  | acibenzolar-S-methyl, acibenzolar acid | EFSA (2017) |
| High acid content                 | Kiwi fruit | –20       | 12 months |  | 4-OH acibenzolar acid | France (2018) |
| Processed products                | –         | –            | –             | –   | –                | –             |
| Others                            | Wheat straw | –20       | 12 months |  | 4-OH acibenzolar acid | France (2018) |
| Forage                            | –         | –            | –             | –   | –                | –             |
B.1.2. Magnitude of residues in plants

B.1.2.1. Summary of residues data from the supervised residue trials

| Commodity | Region/indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/source | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d) |
|-----------|------------------|---------------------------------------------------------------|-----------------|------------------------|--------------|----------------|-------|
| Hazelnuts | SEU              | 0.04,(e) 0.05, 0.06,(e) 0.07 | Residue trials on hazelnuts sufficiently representative of the intended use GAP (see Section 1.2.1) | **0.2** | **0.07** | **0.06** | – |

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.  
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.  
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.  
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.  
(e): Trial conducted with five applications not fully compliant with the GAP which foresees a maximum four applications but judged to be sufficiently representative of the GAP.
B.1.2.2. Residues in rotational crops

| No | TRR levels were found to be at or below 0.001 mg/kg in all crop parts following an application of 50 g/ha of acibenzolar-S-methyl on bare soil. Further metabolite identification could therefore not be conducted to depict a metabolic pathway in rotational crops (EFSA, 2018b) |
| Not triggered | EFSA (2018b) |

TRR: total radioactive residue.

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL application.

B.2. Residues in livestock

Not relevant to the present MRL application.

B.3. Consumer risk assessment

| ARfD | 0.03 mg/kg bw (EFSA, 2014) |
| Highest IESTI, according to EFSA PRIMo | Hazelnuts: 0.8% of ARfD |
| Assumptions made for the calculations | The calculation is based on the highest residue levels expected in raw agricultural commodities |

| ADI | 0.03 mg/kg bw per day (EFSA, 2014) |
| Highest IEDI, according to EFSA PRIMo | 3% ADI (GEMS/Food G06 diet) |
| Contribution of crop assessed: | Hazelnuts: 0.02% of ADI (DE child) |
| Assumptions made for the calculations | The calculation is based on the median residue levels derived for raw agricultural commodities. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation |

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; GAP: Good Agricultural Practice; MRL: maximum residue level.
### B.4. Recommended MRLs

| Code\(^{(a)}\) | Commodity     | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|--------------|---------------|-------------------------|-------------------------|-----------------------|
| 120060       | Hazelnuts/cobnuts | 0.1                     | 0.2                     | The submitted data are sufficient to derive an MRL proposal for the SEU use. Risk for consumers unlikely |

\(^{(a)}\): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

Enforcement residue definition: Acibenzolar-S-methyl (sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-S-methyl)
### Acibenzolar-S-methyl

#### Toxico logical reference values

| Acute reference value | Chronic reference value |
|-----------------------|-------------------------|
| LOQ (µg/kg) | ADI (mg/kg bw per day) | ARfD (mg/kg bw) |
| 0.01 | 0.03 | 0.03 |
| 0.05 | 0.03 | 0.03 |

Source of ADI and ARfD: EFSA.

#### EFSA PRIMo revision 3.0; 2017/12/11

Year of evaluation: 2014

No of diets exceeding the ADI: ---

#### Calculated exposure (% of ADI) MS Diet

| Commodity/group of commodities | Exposure (% of ADI) MS Diet |
|-------------------------------|---------------------------|
| Cucumbers                     | 3% 0.85                   |
| Apples                        | 3% 0.83                   |
| Wheat                         | 2% 0.62                   |
| Tomatoes                      | 2% 0.47                   |
| Lettuces                      | 2% 0.45                   |
| Tomatoes                      | 2% 0.45                   |
| Onions                        | 1% 0.44                   |
| Wheat                         | 1% 0.43                   |
| Lettuces                      | 1% 0.42                   |
| Tomatoes                      | 1% 0.41                   |
| Spinaches                     | 1% 0.40                   |
| Spinaches                     | 1% 0.39                   |
| Bananas                       | 1% 0.38                   |
| Wheat                         | 1% 0.36                   |
| Lettuces                      | 1% 0.35                   |
| Apples                        | 0.9% 0.28                 |
| Wheat                         | 0.9% 0.27                 |
| Lettuces                      | 0.9% 0.26                 |
| Apples                        | 0.8% 0.25                 |
| Bananas                       | 0.8% 0.24                 |
| Lettuces                      | 0.7% 0.21                 |
| Other lettuce and other salad plants | 0.6% 0.19 |
| Apples                        | 0.5% 0.16                 |
| Bananas                       | 0.5% 0.14                 |
| Lettuces                      | 0.2% 0.05                 |

#### Details – acute risk assessment/children

| Commodity/group of commodities | Exposure (% of ADI) MS Diet |
|--------------------------------|---------------------------|
| Cucumbers                     | 3% 0.85                   |
| Tomatoes                      | 3% 0.83                   |
| Wheat                         | 2% 0.62                   |
| Tomatoes                      | 2% 0.47                   |
| Lettuces                      | 2% 0.45                   |
| Tomatoes                      | 2% 0.45                   |
| Onions                        | 1% 0.44                   |
| Wheat                         | 1% 0.43                   |
| Lettuces                      | 1% 0.42                   |
| Tomatoes                      | 1% 0.41                   |
| Spinaches                     | 1% 0.40                   |
| Spinaches                     | 1% 0.39                   |
| Bananas                       | 1% 0.38                   |
| Wheat                         | 1% 0.36                   |
| Lettuces                      | 1% 0.35                   |
| Apples                        | 0.9% 0.28                 |
| Wheat                         | 0.9% 0.27                 |
| Lettuces                      | 0.9% 0.26                 |
| Apples                        | 0.8% 0.25                 |
| Bananas                       | 0.8% 0.24                 |
| Lettuces                      | 0.7% 0.21                 |
| Other lettuce and other salad plants | 0.6% 0.19 |
| Apples                        | 0.5% 0.16                 |
| Bananas                       | 0.5% 0.14                 |
| Lettuces                      | 0.2% 0.05                 |

#### Details – acute risk assessment/adults

| Commodity/group of commodities | Exposure (% of ADI) MS Diet |
|--------------------------------|---------------------------|
| Cucumbers                     | 3% 0.85                   |
| Tomatoes                      | 3% 0.83                   |
| Wheat                         | 2% 0.62                   |
| Tomatoes                      | 2% 0.47                   |
| Lettuces                      | 2% 0.45                   |
| Tomatoes                      | 2% 0.45                   |
| Onions                        | 1% 0.44                   |
| Wheat                         | 1% 0.43                   |
| Lettuces                      | 1% 0.42                   |
| Tomatoes                      | 1% 0.41                   |
| Spinaches                     | 1% 0.40                   |
| Spinaches                     | 1% 0.39                   |
| Bananas                       | 1% 0.38                   |
| Wheat                         | 1% 0.36                   |
| Lettuces                      | 1% 0.35                   |
| Apples                        | 0.9% 0.28                 |
| Wheat                         | 0.9% 0.27                 |
| Lettuces                      | 0.9% 0.26                 |
| Apples                        | 0.8% 0.25                 |
| Bananas                       | 0.8% 0.24                 |
| Lettuces                      | 0.7% 0.21                 |
| Other lettuce and other salad plants | 0.6% 0.19 |
| Apples                        | 0.5% 0.16                 |
| Bananas                       | 0.5% 0.14                 |
| Lettuces                      | 0.2% 0.05                 |

#### Details – chronic risk assessment

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

#### Conclusion

- LT adult
- DK adult
- UK infant
- Tomatoes
- Cucumbers
- Wheat
- Spinaches
- Apples
- Lettuces
- Bananas
- Other lettuce and other salad plants

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of acibenzolar-S-methyl is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.

## Show results for all crops

### Unprocessed commodities

| Commodity          | MRL/input (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodities | MRL/input (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|--------------------|-------------------|---------------------|-----------------------|-------------|-------------------|---------------------|-----------------------|
| Mangoes            | 0.6/0.6           | 47                  | 157%                  | Mangoes     | 0.6/0.6           | 12                  |
| Apples             | 0.3/0.3           | 32                  | 108%                  | Cucumbers   | 0.4/0.4           | 8.4                 |
| Pears              | 0.2/0.2           | 28                  | 92%                   | Pears       | 0.2/0.2           | 9.3                 |
| Cucumbers          | 0.4/0.4           | 26                  | 87%                   | Cucumbers   | 0.4/0.4           | 8.4                 |
| Kiwi fruits/green, red, yellow | 0.4/0.4 | 25                  | 83%                   | Kiwi fruits | 0.4/0.4           | 6.1                 |
| Melons             | 0.15/0.15         | 23                  | 76%                   | Melons      | 0.15/0.15         | 6.1                 |
| Peaches            | 0.2/0.2           | 19                  | 63%                   | Peaches     | 0.2/0.2           | 6.1                 |
| Courgettes         | 0.4/0.4           | 19                  | 62%                   | Courgettes  | 0.4/0.4           | 6.1                 |
| Watermelons        | 0.15/0.15         | 18                  | 61%                   | Watermelons | 0.15/0.15         | 6.1                 |
| Tomatoes           | 0.3/0.3           | 17                  | 58%                   | Tomatoes    | 0.3/0.3           | 6.1                 |
| Lettuces           | 0.4/0.4           | 15                  | 51%                   | Lettuces    | 0.4/0.4           | 4.9                 |
| Spinaches          | 0.6/0.6           | 14                  | 45%                   | Spinaches   | 0.6/0.6           | 4.9                 |
| Escaroles/broad-leaved | 0.3/0.3 | 12                  | 40%                   | Escaroles/broad-leaved | 0.3/0.3 | 3.3            |
| Bananas            | 0.08/0.08         | 7.8                 | 26%                   | Bananas     | 0.08/0.08         | 3.3                 |
| Apricots           | 0.2/0.2           | 7.0                 | 23%                   | Apricots    | 0.2/0.2           | 2.4                 |

### Processed commodities

| Commodity                      | MRL/input (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodities | MRL/input (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|--------------------------------|-------------------|---------------------|-----------------------|-------------|-------------------|---------------------|-----------------------|
| Escaroles/broad-leaved endives | 0.3/0.3           | 20                  | 66%                   | Courgettes/balled | 0.4/0.4          | 9.1                 |
| Spinaches/frozen               | 0.6/0.6           | 20                  | 66%                   | Courgettes/balled | 0.4/0.4          | 6.1                 |
| Pumpkins/balled                | 0.15/0.15         | 13                  | 47%                   | Pumpkins/balled | 0.15/0.15        | 5.0                 |
| Ghirkins/pickled               | 0.4/0.4           | 9.2                 | 31%                   | Ghirkins/pickled | 0.4/0.4          | 2.7                 |
| Peaches/canned                 | 0.2/0.2           | 4.1                 | 14%                   | Peaches/canned | 0.2/0.2          | 2.7                 |
| Shallots/balled                | 0.15/0.15         | 2.4                 | 8%                    | Shallots/balled | 0.15/0.15        | 1.4                 |
| Tomatoes/juice                 | 0.3/0.1           | 2.1                 | 7%                    | Tomatoes/juice | 0.3/0.1          | 0.93                |
| Kiwi fruits/juice              | 0.4/0.05          | 0.90                | 3%                    | Kiwi fruits/juice | 0.3/0.1          | 0.33                |
| Apple/juice                    | 0.3/0.01          | 0.54                | 2%                    | Apple/juice   | 0.3/0.01         | 0.14                |
| Peaches/juice                  | 0.2/0.03          | 0.50                | 2%                    | Peaches/juice | 0.2/0.03         | 0.33                |
| Pear/juice                     | 0.2/0.01          | 0.33                | 1%                    | Pear/juice    | 0.2/0.01         | 0.14                |
| Cranberries/juice              | 0.15/0.05         | 0.26                | 0.9%                  | Cranberries/juice | 0.15/0.05        | 0.14                |
| Wheat밀king (Flour)            | 0.05/0.02         | 0.24                | 0.8%                  | Wheat밀king (Flour) | 0.05/0.02       | 0.03                |
| Wheat밀king (Wholemeal)-bi     | 0.05/0.02         | 0.11                | 0.4%                  | Wheat밀king (Wholemeal)-bi | 0.05/0.02 | 0.11       |
| Quinces/am                     | 0.2/0.01          | 0.01                | 0%                    | Quinces/am    | 0.2/0.01         | 0.01                |

### Results for children

- No. of commodities for which ARfD/ADI is exceeded (IESTI): 2

### Results for adults

- No. of processed commodities for which ARfD/ADI is exceeded (IESTI): 0

### Conclusion:

The estimated short term intake (IESTI) exceeded the toxicological reference value for 2 commodities. For processed commodities, no exceedance of the ARfD/ADI was identified.
Appendix D – Input values for the exposure calculations

**D.1. Livestock dietary burden calculations**

Not relevant to the present MRL application.

**D.2. Consumer risk assessment**

| Commodity                                      | Chronic risk assessment | Acute risk assessment |
|------------------------------------------------|-------------------------|-----------------------|
| | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Hazelnuts | 0.06 | STMR | 0.07 | HR |
| Bananas | 0.02 | STMR (EFSA, 2013) | | |
| Mangos | 0.21 | STMR tentative (EFSA, 2013) | | |
| The group of lettuce and other salad plants including Brassicaceae, except lettuce | 0.11 | STMR (EFSA, 2013) | 0.07 | HR |
| Herbs | 0.14 | STMR (EFSA, 2013) | | |
| Barley grain | 0.02 | STMR (EFSA, 2013) | | |
| Wheat grain | 0.02 | STMR (EFSA, 2013) | | |
| Pome fruits (except apples) | 0.01 | STMR (EFSA, 2014) | | |
| Tomatoes | 0.11 | STMR (EFSA, 2014) | | |
| Kiwi fruits | 0.05 | STMR (EFSA, 2017) | | |
| Apples | 0.01 | STMR Codex (FAO, 2016) | | |
| Apricots | 0.05 | STMR Codex (FAO, 2016) | | |
| Peaches | 0.05 | STMR Codex (FAO, 2016) | | |
| Strawberries | 0.045 | STMR Codex (FAO, 2016) | | |
| Cranberries | 0.045 | STMR Codex (FAO, 2016) | | |
| Garlic | 0.05 | STMR Codex (FAO, 2016) | | |
| Onions | 0.18 | STMR Codex leaf lettuce (FAO, 2016) | | |
| Shallots | 0.285 | STMR Codex (FAO, 2016) | | |
| Abergines | 0.04 | STMR (EFSA, 2018b) | | |
| Cucurbits edible peel | 0.12 | STMR (EFSA, 2018b) | | |
| Cucurbits with inedible peel | 0.04 | STMR (EFSA, 2018b) | | |
### Appendix E – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChIKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|---------------------------------|-------------------------------------------------|---------------------------------|
| **acibenzolar-S-methyl**        | S-methyl benzo[1,2,3]thiadiazole-7-carbothioate | ![Structural formula](image) |
| CGA 245704                      | O=C(SC)c1cccc2nnsc12 UELITFHSLAHKR-UHFFFAOYSA-N | |
| **acibenzolar acid**            | 1,2,3-benzothiadiazole-7-carboxylic acid        | ![Structural formula](image) |
| CGA 210007                      | O=C(O)c1cccc2nnsc12 COAIOOWBEPAOFY-UHFFFAOYSA-N | |
| **4-OH acibenzolar acid**       | 4-hydroxy-1,2,3-benzothiadiazole-7-carboxylic acid | ![Structural formula](image) |
| CGA 323060                      | O=C(O)c1cccc(O)c2nnsc12 RZSJWCHAQOKSRQ-UHFFFAOYSA-N | |

<sup>(a)</sup>: The metabolite name in bold is the name used in the reasoned opinion.

<sup>(b)</sup>: ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 Dec 2014).

<sup>(c)</sup>: ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 Dec 2014).