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Modification of the existing maximum residue levels for acibenzolar-S-methyl in grapes

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Syngenta Crop Protection AG submitted a request to the competent national authority in Italy to modify the existing maximum residue levels (MRLs) for the active substance acibenzolar-S-methyl in grapes. The data submitted in support of the request were found to be sufficient to derive MRL proposals for table and wine grapes. Adequate analytical methods for enforcement are available to control the residues of acibenzolar-S-methyl residues and of the metabolite acibenzolar acid (free and conjugated) in plant matrices 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 practices is unlikely to present a risk to consumer health.

Keywords: acibenzolar-S-methyl, table and wine grapes, plant activator, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta Crop Protection AG submitted an application to the competent national authority in Italy (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance acibenzolar-S-methyl in grapes.

The application, alongside the dossier containing the supporting data in IUCLID format, was submitted through the European Food Safety Authority (EFSA) Central Submission System on 22 September 2022. The appointed EMS Italy assessed the dossier and declared its admissibility on 4 November 2022. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential version of the dossier was published by EFSA, and a public consultation launched on the dossier. The consultation aimed to consult stakeholders and the public on the scientific data, studies and other information part of, or supporting, the submitted application, in order to identify whether other relevant scientific data or studies are available. The consultation run from 24 March 2023 to 14 April 2023. No additional data nor comments were submitted in the framework of the consultation.

At the end of the commenting period, the EMS proceeded drafting the evaluation report, in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 3 May 2023. To accommodate for the intended uses of acibenzolar-S-methyl, the EMS proposed to raise the existing MRLs in table and wine grapes from the limit of quantification (LOQ) to 0.4 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified points that needed further clarification, which were requested from the EMS. On 19 June 2023, the EMS submitted a revised evaluation report which replaced the previously submitted evaluation report.

Based on the conclusions derived by EFSA in the framework of Regulation (EC) No 1107/2009, the data evaluated under previous MRL assessments including the review of the existing EU MRLs under Article 12 of Regulation (EC) 396/2005 (MRL review) and the additional data provided by the EMS in the framework of this 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 (tomato), leafy crops (tobacco, lettuce) and cereals/grass (wheat). Acibenzolar acid (free and conjugated) was identified as the major metabolite in most plant commodities and was the main residue in fruit crops and cereals/grass crops. The metabolite 4-OH acibenzolar acid was observed at significant levels in lettuce.

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 relevance of metabolites and degradation products, the residue definitions for plant products were proposed as:

- residue definition for enforcement: Acibenzolar-*S*-methyl (sum of acibenzolar-*S*-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-*S*-methyl);
- residue definition for risk assessment:
  - for cereals/grass, fruit crops and tobacco: Sum of acibenzolar-*S*-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-*S*-methyl;
  - for other crops: open, depending on residue trials data and toxicological data, the metabolite 4–OH acibenzolar acid could be considered in the residue definition for risk assessment.

These residue definitions are applicable to primary crops, and processed products.

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

Sufficiently validated analytical method is available to quantify residues in grapes according to the enforcement residue definition. The method enables quantification of residues at or above 0.01 mg/kg in the crop assessed (LOQ). However, extraction efficiency of the method has not been demonstrated and new data were not reported to EFSA so far.

The available residue trials are sufficient to derive an MRL proposal of 0.4 mg/kg for table and wine grapes. Processing studies were provided, and the data were sufficient to derive the following median processing factors (PF) for wine, juice, raisins, grape seeds oil and jelly which are recommended to be included in Annex VI of Regulation (EC) No 396/2005:

- grapes/white wine: 1.46 PF
- grapes/red wine: 0.52 PF
- grapes/juice: 0.92 PF
- grapes/jelly: 0.77 PF
- grapes/grapeseed oil: 0.73 PF
- grapes/raisins: 2.80 PF

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 acceptable daily intake (ADI) of 0.03 mg/kg bw per day and an acute reference dose (ARfD) of 0.03 mg/kg bw. Acibenzolar acid is of a similar toxicity as the parent active substance.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The short-term exposure assessment was performed only with regard to table and wine grapes, in accordance with the internationally agreed methodology based on the highest residue (HR) value derived from supervised field trials. The estimated maximum acute exposure in percentage of the ARfD accounted for 55.9% (highest for table grapes).

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 table and wine grapes derived from the residue trials submitted in support of this MRL application, and the relevant STMR values derived in the framework of the EU pesticides peer review, 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 4% of the ADI (NL toddler). The contribution of residues in table and wine grapes to the overall long-term exposure was up to 0.52% and 0.83% of ADI, respectively.

EFSA concluded that the proposed use of acibenzolar-S-methyl on table and wine grapes 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 MRLs as reported in the summary table below.

Full details of all end points 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
Enforcement residue definition: Acibenzolar-*S*-methyl (sum of acibenzolar-*S*-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-*S*-methyl)				
0151010	Table grapes	0.01*	0.4	The submitted data are sufficient to support the intended NEU/SEU uses in grapes and to derive MRL proposals. Risk for the consumer unlikely.
0151020	Wine grapes	0.01*	0.4	

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue levels (MRLs) for acibenzolar-S-methyl in grapes. The detailed description of the intended uses of acibenzolar-S-methyl, which are the basis for the current MRL application, is reported in Appendix A.

Acibenzolar-S-methyl is the ISO common name for *S*-methyl 1,2,3-benzothiadiazole-7-carbothioate (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Acibenzolar-S-methyl was evaluated for the renewal of approval in the framework of Regulation (EC) No 1107/2009[1] according to Commission Regulation (EU) No 1141/2010[2], as amended by Commission Implementing Regulation (EU) No 380/2013[3], with France designated as rapporteur Member State (RMS); the representative uses assessed were foliar treatments on pome fruits, tomato, and tobacco. The renewal assessment report (RAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2014). The approval of acibenzolar-S-methyl for the use as plant activator was renewed[4] under Regulation (EC) 1107/2009 on 1 April 2016.

The EU MRLs for acibenzolar-S-methyl are established in Annex II of Regulation (EC) No 396/2005[5]. 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. After completion of the MRL review, EFSA has issued several reasoned opinions on the modification of MRLs for acibenzolar-S-methyl (EFSA, 2017, 2018b, 2019b, 2021b). The proposals from these reasoned opinions have been considered in recent MRL regulations.[6] Certain Codex maximum residue limits (CXLs) have been taken over in the EU MRL legislation by Commission Regulation (EU) 2018/687.

In accordance with Article 6 of Regulation (EC) No 396/2005 and following the provisions set by the 'Transparency Regulation' (EU) 2019/1381[7], the applicant Syngenta Crop Protection AG submitted on 22 September 2022 an application to the competent national authority in Italy, alongside the dossier containing the supporting data using the IUCLID format.

The appointed EMS Italy assessed the dossier and declared its admissibility on 4 November 2022. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential version of the dossier was published by EFSA, and a public consultation launched on the dossier. The consultation aimed to consult stakeholders and the public on the scientific data, studies and other information part of, or supporting, the submitted application, in order to identify whether other relevant scientific data or studies are available. The consultation run from 24 March 2023 to 14 April 2023. No additional data nor comments were submitted in the framework of the consultation.

At the end of the commenting period, the EMS proceeded drafting the evaluation report, in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 3 May 2023. To accommodate for the intended uses of

[1] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, pp. 1–50.

[2] 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, pp. 10–19.

[3] 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, pp. 4–4.

[4] 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 C/2016/1556 OJ L 73, 18.3.2016, pp. 77–80.

[5] 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, 16.3.2005, pp. 1–16.

[6] For an overview of all MRL Regulations on this active substance, please consult: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/mrls

[7] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, PE/41/2019/REV/1. OJ L 231, 6.9.2019, pp. 1–28.

acibenzolar-S-methyl, the EMS proposed to raise the existing MRLs in table and wine grapes from the limit of quantification (LOQ) to 0.4 mg/kg.

EFSA based its assessment on the evaluation report submitted by the EMS (Italy, 2023), the renewal assessment report (RAR) (and its addendum) (France, 2013, 2014), the European Commission review report on acibenzolar-S-methyl (European Commission, 2020a), 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, 2019b, 2021b), including the review of the existing MRLs for acibenzolar-S-methyl according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2013).

For this application, the data requirements established in Regulation (EU) No 544/2011[8] and the guidance documents applicable at the date of submission of the IUCLID application are applicable (European Commission, 1997a,b,c,d,e,f,g, 2010, 2017, 2021; 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[9].

The assessment of the confirmatory data following the peer review of the active substance is not yet finalised, and therefore, the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of that assessment (EFSA, 2021a).

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 (Italy, 2023) 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.[10]

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 fruit crops (tomato), leafy crops (tobacco, lettuce), cereals/grass (wheat) has been investigated in the pesticides peer review in the framework of the renewal of approval of the active substance under Regulation (EC) No 1107/2009 (EFSA, 2014).

The metabolic pathway of acibenzolar-S-methyl proceeds via hydrolysis of the parent compound to acibenzolar acid followed by ester conjugation with sugars. Subsequent hydroxylation of the phenyl ring leads to 4–OH acibenzolar acid and to 5–OH acibenzolar acid (tomato, tobacco, lettuce) followed by conjugation as *O*-glycoside. Acibenzolar acid (free and conjugated) was identified as the major metabolite in most plant commodities. The metabolite 4-OH acibenzolar acid was observed at significant levels in leafy crops (lettuce, up to 20% total radioactive residue (TRR)), and in the peer review process, it was recommended that this metabolite could be considered for inclusion in the residue definition for risk assessment for crop groups other than fruit crops, cereals and tobacco, depending on residue trials and toxicological data (EFSA, 2014).

For the intended uses, the metabolic behaviour in primary crops is sufficiently addressed.

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.

[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, pp. 1–66.

[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.

[10] Background documents to this reasoned opinion are published on OpenEFSA portal and are available at the following link: https://open.efsa.europa.eu/study-inventory/EFSA-Q-2022-00783

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of acibenzolar-S-methyl was investigated in the framework of the EU pesticides peer review (EFSA, 2014). These studies showed that acibenzolar-S-methyl is hydrolytically stable under conditions that simulate pasteurisation and baking, brewing and boiling process; however, these studies showed that the acibenzolar-S-methyl significantly degrades (50.5% of applied radioactivity (AR)) into acibenzolar acid under sterilisation conditions. Based on this characterisation, it was concluded that the residue pattern in processed commodities is similar to the residue pattern in raw commodities (EFSA, 2013, 2014).

1.1.4. Analytical methods for enforcement purposes in plant commodities

Analytical methods for the determination of acibenzolar-S-methyl residues and of the metabolite acibenzolar acid (free and conjugated) were assessed during the EU pesticides peer review and in previous MRL applications (EFSA, 2014, 2017, 2019b). The methods allow quantifying residues at or above the LOQ of 0.01 mg/kg for the total residue (Acibenzolar-*S*-methyl (sum of acibenzolar-*S*-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-*S*-methyl)) in crops belonging to the group of high water content, high acid content, high oil content commodities and dry tobacco leaves. EFSA concludes that the method for the determination of residues of acibenzolar-S-methyl and acibenzolar acid (free and conjugated) is sufficiently validated in the crops under consideration.

EFSA notes that the extraction efficiency of the analytical methods applied for enforcement is not proven as indicated according to the requirements of the extraction efficiency Guidance, SANTE 2017/ 10632 GD (European Commission, 2017), and the lack of these data introduces additional uncertainty of the present assessment.

To satisfy the current criteria of the guidance further investigation on this matter would be required. EFSA would therefore recommend re-assessing the extraction efficiency in the framework of the peer review for the renewal of approval of the active substance.

1.1.5. Storage stability of residues in plants

The storage stability of acibenzolar-S-methyl and acibenzolar acid in plants stored under frozen conditions was investigated in the frameworks of the EU pesticides peer review and previous MRL applications (EFSA, 2014, 2017, 2019b). It was demonstrated that in high acid content matrices (relevant for the crops assessed in the framework of this application), residues were stable for at least 10 months when stored at −21°C (EFSA, 2017).

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 EU pesticides peer review (EFSA, 2014) in the framework of the renewal of approval of the active substance under Regulation (EC) No 1107/2009:

- Residue definition for enforcement: Acibenzolar-*S*-methyl (sum of acibenzolar-*S*-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-*S*-methyl);
- Residue definition for risk assessment:
  - for cereals/grass, fruit crops and tobacco: Sum of acibenzolar-*S*-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-*S*-methyl;
  - for other crops than cereal/grass and fruit crops: open, depending on residue trials data and toxicological data, the metabolite 4–OH acibenzolar acid could be considered in the residue definition for risk assessment.

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).

In the previous MRL application, the relevance of 4-OH metabolite in the risk assessment was investigated for leafy crops and pulses/oilseeds (EFSA, 2021b). Lacking the data to characterise the general toxicity of metabolite 4-OH acibenzolar acid, a definitive conclusion could not be derived whether the plant metabolite 4-OH acibenzolar acid (free and conjugated) should be included or excluded from the residue definition for risk assessment for leafy crops and pulses/oilseeds. For beans

with pods and peas with pods, the risk assessment residue definition as defined for cereals/grass, fruit crops and tobacco was concluded as appropriate considering low levels of this metabolite present in treated crops. For the leafy crop group, the uncertainty to the metabolite exposure remained since residue trials did not provide a coherent picture on the magnitude of this metabolite in leafy crops. Thus, for the leafy crop group, the risk assessment residue definition remains open.

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition for enforcement. The same residue definitions are applicable to processed products.

Taking into account the proposed uses on grapes assessed in this application, EFSA concluded that the residue definitions as derived for fruit crops are appropriate and further data are not required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted results from 16 GAP-compliant (good agricultural practice) independent field trials on grapes, performed in Northern Europe (NEU) and Southern Europe (SEU) over the growing season of 2021 (Italy, 2023). Considering the geographical distribution and the diversity of the residue trial locations as well as different agricultural practices applied, conduction in only one season instead of at least two is acceptable. Acibenzolar-S-methyl was applied six times as foliar spray and samples of grapes were taken at the intended preharvest interval (PHI) of 28 days. Half of the trials were designed as decline trials, with samples being taken at the PHI of 0, 7, 14, 21 and 28 days. The samples were analysed for acibenzolar-S-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-S-methyl in accordance with the residue definition for enforcement and risk assessment. Residue levels found in grapes ranged from 0.02 to 0.23 mg/kg.

According to the assessment of the EMS, the liquid chromatography with tandem mass spectrometry (LC–MS/MS) method, used to generate residue data of acibenzolar-S-methyl, acibenzolar acid and its conjugates, was sufficiently validated and fit for purpose, and included hydrolysis steps to release conjugated forms. Upon EFSA's request, the justification was provided that the extraction efficiency has been sufficiently demonstrated according to the EU guidance document (European Commission, 2017) in high acid content matrices. In the metabolism study conducted in a high water content matrix (tomato), using the same extraction solvent as in the risk assessment method (alkaline extraction followed by the addition of methanol), a large fraction of the TRR (> 70%) was extractable. Since the pH is controlled in the conditions of alkaline extraction, the results are also applicable to the high acid matrix (Italy, 2023).

The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated (Italy, 2023). The results of residues studies are summarised in Appendix B.1.2.1.

The intended SEU and NEU GAPs on table and wine grapes are identical and the two data sets belong to similar statistical populations (Mann–Whitney *U*-test). Therefore, for the purpose of estimating more robust input values for the dietary exposure, the NEU and SEU data sets were combined (European Commission, 2020b).

1.2.2. Magnitude of residues in rotational crops

Investigation of the magnitude of acibenzolar-S-methyl residues in rotational crops is not required in the context of the present MRL application. The intended uses are on grape which, as a permanent crop, is not used in rotation with other crops.

1.2.3. Magnitude of residues in processed commodities

The applicant submitted a study where the magnitude of acibenzolar-S-methyl was investigated in wine, juice, raisins, jelly, grape seeds oil and other by-products obtained from processing of grapes (Italy, 2023). Three residue trials reflecting the intended application rate but shorter PHI (3 days) were conducted.

Samples were analysed for parent compound acibenzolar-S-methyl and acibenzolar acid including conjugates. Residue levels in grapes were found between 0.08 and 0.22 mg/kg and in processed commodities always above the LOQ. Processing studies demonstrated that production of white wine and raisins leads to a concentration of the residues in the processed products and by-products (wet

and dry pomace) (Italy, 2023). A reduction of residues is observed in red wine, grape juice, grapeseed oil ad grape jelly. The number and quality of the processing studies is sufficient to derive robust processing factors which are recommended to be included in Annex VI of Regulation (EC) No 396/2005.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for the commodities under evaluation (see Appendix B.4). In Section 3, EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as grape is not used for feed purposes.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018a, 2019a). 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, 2016a).

The toxicological reference values for acibenzolar-S-methyl used in the risk assessment (i.e. ADI of 0.03 mg/kg bw per day and ARfD value of 0.03 mg/kg bw) were derived in the framework of the EU pesticides peer review (European Commission, 2020a).

The metabolite acibenzolar acid, included in the residue definition for risk assessment in free and conjugated form, is also a major rat metabolite and was shown to share the toxicity potential of the parent acibenzolar-S-methyl; therefore, the reference values of the parent are applicable to this metabolite (EFSA, 2014). The toxicity of 4-OH acibenzolar acid, which was considered as a candidate for inclusion in the risk assessment residue definition for crops other than fruits crops, cereals/grass crops and tobacco, was assessed in the previous EFSA output, where it was concluded that the genotoxicity potential of this metabolite could be ruled out, but the general toxicity remains not addressed (EFSA, 2021b). An indicative consumer exposure calculation from the intake of 4-OH acibenzolar acid was estimated in the previous EFSA assessment and was not further updated in the framework of the present assessment.

Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed for the commodities assessed in this application. The calculations were based on the HR value derived from supervised field trials and the complete list of input values can be found in Appendix D.2.

The short-term exposure for acibenzolar-S-methyl and acibenzolar acid (free and conjugated) did not exceed the ARfD for the crop assessed in this application (the highest exposure was calculated for table grapes: 56% of the ARfD, for more details, see Appendix B.3).

Long-term (chronic) dietary risk assessment

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level (EFSA, 2013). EFSA updated the calculation with the relevant STMR values derived from the residue trials submitted in support of this MRL application for grapes, and the STMRs derived in the EFSA conclusion published after the MRL review (EFSA, 2014) and in subsequent EFSA opinions (EFSA, 2017, 2018b, 2019b, 2021b), as well as the STMRs derived by the JMPR for the acceptable CXLs included in Regulation (EC) No 396/2005 (FAO, 2016b). The input values used in the exposure calculations are summarised in Appendix D.2. The crops on which no uses have been reported in the MRL review or in the subsequent EFSA outputs were not included in the exposure calculation.

The estimated long-term dietary intake for acibenzolar-S-methyl and acibenzolar acid (free and conjugated) accounted for up to 4% of the ADI (NL toddler diet). The contribution of residues expected in the table and wine grapes to the overall long-term exposure is low and is presented in more detail in Appendix B.3.

Based on these calculations, EFSA concluded that the long-term intake of residues resulting from the existing uses and the proposed uses of acibenzolar-S-methyl on grapes is unlikely to present a risk

to consumer health with regard to residues of acibenzolar-S-methyl and acibenzolar acid (free and conjugated).

Risk assessment for crop groups other than cereals and fruits is affected by additional non-standard uncertainty due to the lack of data to conclude on the relevance of metabolite 4–OH acibenzolar acid for the consumer exposure.

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 available data are considered sufficient to derive an MRL proposal as well as risk assessment values for the commodity under evaluation. The submitted data are considered sufficient to derive an MRL proposal of 0.4 mg/kg for grapes.

EFSA concluded that the proposed uses of acibenzolar-S-methyl on grapes 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
AR	applied radioactivity
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex maximum residue limit
DAT	days after treatment
dw	dry weight
EC	emulsifiable concentrate

EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
HPLC	high-performance liquid chromatography
HPLC-MS	high-performance liquid chromatography with mass spectrometry
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
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS	mass spectrometry detector
MS/MS	tandem mass spectrometry detector
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PF	processing factor
PHI	preharvest interval
P_{ow}	partition coefficient between n-octanol and water
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SCPAFF	Standing Committee on Plants, Animals, Food and Feed (formerly: Standing Committee on the Food Chain and Animal Health; SCFCAH)
SEU	southern Europe
STMR	supervised trials median residue
TRR	total radioactive residue
UV	ultraviolet (detector)
WG	water-dispersible granule
WHO	World Health Organization

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				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s. (g/kg)	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (days) min–max	g a.s./hL min–max	Water (L/ha) min–max	Rate min–max	Unit		
Grapes	NEU	F	*Phytoplasm Flavescence Doree Candidatus Phytoplasma solani*	WG	500	Foliar spray	53–81	1–6	7		100–1,000	75–100	g a.s./ha	28	
Grapes	SEU	F	*Phytoplasm Flavescence Doree Candidatus Phytoplasma solani*	WG	500	Foliar spray	53–81	1–6	7		100–1,000	75–100	g a.s./ha	28	

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; WG: Water dispersible granules.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. 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 analytical methods for enforcement purposes in plant commodities

B.1.1.1. Metabolism studies, analytical methods 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 × 0.0152 kg a.s./ha, interval 14 days; total application rate: 0.0456 kg a.s./ha	0, 30	[^{14}C-U-phenyl]-acibenzolar-S-methyl (France, 1998, 2014; EFSA, 2013, 2014)
	Leafy crops	Tobacco	Foliar, G 3 applications; total application rate: 0.170 kg a.s./ha	0, 17, 27, 35, 45, 52	
		Lettuce	Foliar, G 4 × 0.105 kg a.s./ha; total application rate: 0.42 kg a.s./ha	0, 7	
			Foliar, G 4 × 0.035 kg a.s./ha; total application rate: 0.14 kg a.s./ha (1st application 7–9 leaf stage)	0, 7	
	Cereals/ grass	Wheat	Foliar, F 1 × 0.05 kg a.s./ha (Application at the end of tillering)	0, 14, 28, 75	
			Foliar, G 1 × 0.05 kg a.s./ha (Application at 4 leaf stage)	0, 1, 3, 7, 14	
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, 2014)
	Leafy crops	Lettuce	Bare soil application, F, 0.05 kg a.s./ha	30, 113, 141, 337	
	Cereal (small 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		Degradation into acibenzolar acid accounting for 50.5% of applied radioactivity (EFSA, 2013, 2014)
	Other processing conditions		–		–

Can a general residue definition be proposed for primary crops?	No	EFSA (2014)
Rotational crop and primary crop metabolism similar?	Yes	EFSA (2014)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA (2014)
Plant residue definition for monitoring (RD-Mo)	Acibenzolar-*S*-methyl (sum of acibenzolar-*S*-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-*S*-methyl)	
Plant residue definition for risk assessment (RD-RA)	EFSA, 2014: Cereals/grass, fruit crops groups/tobacco: Sum of acibenzolar-*S*-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-*S*-methyl. For other crops: depending on residue trials data and toxicological data, the metabolite 4-OH acibenzolar acid (CGA 323060) could be considered in the residue definition. EFSA, 2021b: Beans with pods and peas with pods: Sum of acibenzolar-*S*-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-*S*-methyl	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Matrices with high water content, high acid content and tobacco: HPLC-MS/MS with an LOQ of 0.01 mg/kg (EFSA, 2014, 2017) Matrices with high water content, high oil content and dry tobacco leaves: HPLC-MS/MS, LOQ 0.01 mg/kg. Confirmatory method not required. ILV available (EFSA, 2019b)	

DAT: days after treatment; PBI: plant-back interval; F: field; G: greenhouse; a.s.: active substance; MRL: maximum residue level; HPLC-MS/MS: high performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

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	EFSA (2019b)
	High oil content	Hazelnuts	−20	197	days	Acibenzolar-S-methyl, acibenzolar acid	Study to continue up to 12 months (EFSA, 2019b)
		Rape seed	−20	12	months	4-OH acibenzolar acid	EFSA (2019b)
	High protein content	Dried beans	−20	12	months	4-OH acibenzolar acid	EFSA (2019b)
	Dry/High starch	Wheat grain	−18	24	months	acibenzolar-S-methyl	EFSA (2013)

		Wheat grain, straw	−20	20	months	Acibenzolar acid	
		Wheat grain, potato tuber	−20	12	months	4-OH acibenzolar acid	EFSA (2019b)
	High acid content	Strawberries	−21	10	months	acibenzolar-S-methyl, acibenzolar acid	EFSA (2017)
		Kiwi fruit	−20	12	months	4-OH acibenzolar acid	EFSA (2019b)
	Processed products	–	–	–	–	–	–
	Others	Wheat straw	−20	12	months	4-OH acibenzolar acid	EFSA (2019b)
		Forage	–	–	–	–	–

B.1.2. Magnitude of residues in plants

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

Commodity	Region/[a]	Residue levels observed in the supervised residue trials (mg/kg)[e]	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CF[d]
Table and wine grapes	NEU	**Mo = RA:** 0.05, 0.07, 0.09, 0.10, 0.11, 0.12, 2x 0.16	Residue trials on grapes compliant with GAP. NEU and SEU data sets similar, MRL derived from merged data. MRL_{OECD}: 0.36/0.40	**0.4**	0.23	0.10	–
	SEU	**Mo = RA:** 0.02, 0.03, 0.05, 0.07, 0.08, 2x 0.19, 0.23					

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe.
(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): Measured residues of CGA210007 converted to equivalent acibenzolar-S-methyl residues using a multiplication factor of 210.3 (MW acibenzolar-S-methyl)/178.9 (MW CGA210007 (=1.167).

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	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)
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	EFSA (2018b)

B.1.2.3. Processing factors

Processed commodity	Number of valid studies	Processing Factor (PF)		CF_P [(a)]	Comment/ Source
		Individual values	Median PF		
Grape/White wine	3	0.45, 1.46, 1.95	1.46	n.a.	Italy, 2023
Grape/Juice	3	0.92, 0.97, 0.01	0.92	n.a.	
Grape/Red wine	3	0.96, 0.52, 0.40	0.52	n.a.	
Grape/Refined grapeseed oil	3	0.62, 1.60*, 0.73	0.73	n.a.	
Grape/Raisins	3	2.80, 1.94, 3.49	2.80	n.a.	
Grape/Grape jelly	3	1.00, 0.77, 0.15	0.77	n.a.	

PF: processing factor; n.a: not applicable.
*: Crude grapeseed oil due to insufficient amount of oil for refining.
(a): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing residues trial.

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

ARfD	0.03 mg/kg bw (European Commission, 2020)
Highest IESTI, according to EFSA PRIMo	Table grapes: 55.9% of ARfD Wine grapes: 10.6% of ARfD
Assumptions made for the calculations	The calculation is based on the highest residue levels (HR values) expected in raw agricultural commodities under consideration. Calculations performed with PRIMo revision 3.1

ADI	0.03 mg/kg bw per day (European Commission, 2020)
Highest IEDI, according to EFSA PRIMo	4% ADI (NL toddler) Highest contribution of crops assessed: Wine grapes: 0.83% of ADI (PT general) Table grapes: 0.52% of ADI (NL toddler)
Assumptions made for the calculations	The calculation is based on the median residue levels derived for raw agricultural commodities (STMR values). The risk assessment was performed using the STMR value derived from the residue trials on grapes submitted in support of the intended uses in the present MRL application. For remaining commodities the risk assessment values derived in previous EFSA reasoned opinions or JMPR assessments (see appendix D.2) were used to refine the exposure calculation. The crops on which no uses have been reported in the MRL review or in the subsequent EFSA outputs were not included in the exposure calculation. For the commodities included in the calculation that belong to crop groups other than cereals and fruits: Risk assessment is affected by additional non-standard uncertainty due to the lack of data to fully characterise metabolite 4–OH acibenzolar acid which was identified in the peer review as candidate to be included in the residue definition for risk assessment for leafy crops. Calculations performed with PRIMo revision 3.1

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; MRL: maximum residue level; STMR: supervised trials median residue; CXL: codex maximum residue limit.

B.4. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Acibenzolar-*S*-methyl (sum of acibenzolar-*S*-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-*S*-methyl)				
0151010	Table grapes	0.01*	0.4	The submitted data are sufficient to support the intended NEU/SEU uses in grapes and to derive MRL proposals. Risk for the consumer unlikely.
0151020	Wine grapes	0.01*	0.4	

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

Appendix C – Pesticide Residue Intake Model (PRIMo)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Acibenzolar-S-methyl

LOQs (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw/day):	0.03	ARfD (mg/kg bw):	0.03
Source of ADI:	European Commission	Source of ARfD:	European Commission
Year of evaluation:	2020	Year of evaluation:	2020

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment | Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	4%	NL toddler	1.19	0.8%	Beans (with pods)	0.5%	Table grapes	0.5%	Spinaches		4%
	3%	GEMS/Food G06	0.98	1%	Tomatoes	0.5%	Wheat	0.4%	Table grapes		3%
	3%	DE child	0.76	0.5%	Table grapes	0.4%	Apples	0.4%	Tomatoes		3%
	2%	RO general	0.66	0.7%	Tomatoes	0.6%	Wine grapes	0.3%	Wheat		2%
	2%	NL child	0.63	0.3%	Table grapes	0.3%	Beans (with pods)	0.3%	Wheat		2%
	2%	GEMS/Food G07	0.60	0.5%	Wine grapes	0.4%	Tomatoes	0.3%	Wheat		2%
	2%	IE adult	0.57	0.4%	Wine grapes	0.2%	Mangoes	0.2%	Beans (with pods)		2%
	2%	FR child 3 15 yr	0.54	0.4%	Beans (with pods)	0.3%	Tomatoes	0.3%	Wheat		2%
	2%	GEMS/Food G08	0.54	0.4%	Tomatoes	0.3%	Wine grapes	0.3%	Wheat		2%
	2%	GEMS/Food G15	0.54	0.4%	Tomatoes	0.3%	Wine grapes	0.3%	Wheat		2%
	2%	GEMS/Food G10	0.54	0.5%	Tomatoes	0.3%	Wheat	0.1%	Wine grapes		2%
	2%	PT general	0.53	0.8%	Wine grapes	0.3%	Tomatoes	0.3%	Wheat		2%
	2%	FR toddler 2 3 yr	0.51	0.7%	Beans (with pods)	0.2%	Wheat	0.2%	Tomatoes		2%
	2%	FR adult	0.49	0.8%	Wine grapes	0.2%	Beans (with pods)	0.2%	Tomatoes		2%
	2%	DK child	0.48	0.7%	Cucumbers	0.3%	Wheat	0.2%	Tomatoes		2%
	2%	IT toddler	0.48	0.5%	Tomatoes	0.4%	Wheat	0.1%	Lettuces		2%
	2%	GEMS/Food G11	0.48	0.3%	Wine grapes	0.3%	Tomatoes	0.2%	Wheat		2%
	1%	SE general	0.45	0.3%	Tomatoes	0.2%	Wheat	0.2%	Lettuces		1%
	1%	IT adult	0.43	0.4%	Tomatoes	0.3%	Wheat	0.2%	Lettuces		1%
	1%	ES child	0.42	0.4%	Tomatoes	0.3%	Wheat	0.2%	Beans (with pods)		1%
	1%	ES adult	0.40	0.3%	Tomatoes	0.2%	Beans (with pods)	0.2%	Lettuces		1%
	1%	DE women 14-50 yr	0.38	0.3%	Wine grapes	0.3%	Tomatoes	0.1%	Wheat		1%
	1%	NL general	0.37	0.2%	Beans (with pods)	0.2%	Wine grapes	0.2%	Tomatoes		1%
	1%	DE general	0.36	0.3%	Wine grapes	0.2%	Tomatoes	0.1%	Wheat		1%
	1%	FI 3 yr	0.35	0.4%	Cucumbers	0.2%	Tomatoes	0.1%	Bananas		1%
	1%	FR infant	0.32	0.4%	Beans (with pods)	0.2%	Courgettes	0.2%	Spinaches		1%
	1.0%	UK vegetarian	0.29	0.3%	Wine grapes	0.2%	Tomatoes	0.1%	Wheat		1.0%
	1.0%	DK adult	0.29	0.3%	Wine grapes	0.2%	Tomatoes	0.1%	Cucumbers		1.0%
	0.9%	UK toddler	0.27	0.3%	Wheat	0.2%	Tomatoes	0.1%	Table grapes		0.9%
	0.9%	FI 6 yr	0.27	0.3%	Cucumbers	0.2%	Tomatoes	0.1%	Wheat		0.9%
	0.9%	UK adult	0.26	0.4%	Wine grapes	0.2%	Tomatoes	0.1%	Wheat		0.9%
	0.7%	FI adult	0.20	0.2%	Tomatoes	0.1%	Cucumbers	0.1%	Wine grapes		0.7%
	0.7%	PL general	0.20	0.3%	Tomatoes	0.1%	Table grapes	0.1%	Apples		0.7%
	0.6%	UK infant	0.19	0.2%	Wheat	0.1%	Tomatoes	0.1%	Bananas		0.6%
	0.6%	LT adult	0.18	0.2%	Tomatoes	0.2%	Cucumbers	0.1%	Wheat		0.6%
	0.2%	IE child	0.05	0.1%	Wheat	0.0%	Tomatoes	0.0%	Table grapes		0.2%

Conclusion:
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.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
94%	Mangoes	0.6 / 0.36	28
61%	Apples	0.3 / 0.17	18
57%	Cucumbers	0.4 / 0.26	17
56%	Table grapes	0.4 / 0.23	17
42%	Pears	0.2 / 0.09	12
40%	Melons	0.15 / 0.08	12
40%	Courgettes	0.4 / 0.26	12
35%	Kiwi fruits (green, red,	0.4 / 0.17	11
33%	Watermelons	0.15 / 0.08	9.8
29%	Tomatoes	0.3 / 0.15	8.7
29%	Peaches	0.2 / 0.09	8.6
27%	Spinaches	0.6 / 0.36	8.1
26%	Bananas	0.08 / 0.08	7.8
23%	Lettuces	0.4 / 0.18	6.9
23%	Escaroles/broad-leaved	0.3 / 0.17	6.8
18%	Beans (with pods)	1 / 0.48	5.5
13%	Peas (with pods)	1 / 0.48	3.9
10%	Apricots	0.2 / 0.09	3.1
7%	Quinces	0.2 / 0.09	2.2
7%	Pumpkins	0.15 / 0.08	2.1
7%	Wine grapes	0.4 / 0.23	2.1
7%	Aubergines/egg plants	0.15 / 0.08	2.0
5%	Onions	0.15 / 0.06	1.4
4%	Strawberries	0.15 / 0.08	1.3
4%	Medlar	0.2 / 0.09	1.2
2%	Gherkins	0.4 / 0.26	0.73
2%	Lamb's lettuce/corn salads	0.3 / 0.17	0.48
2%	Roman rocket/rucola	0.3 / 0.17	0.46
1%	Cranberries	0.15 / 0.08	0.36
1.0%	Wheat	0.05 / 0.02	0.29
0.8%	Chervil	0.3 / 0.18	0.23
0.8%	Hazelnuts/cobnuts	0.2 / 0.07	0.23
0.7%	Garlic	0.15 / 0.06	0.21
0.7%	Parsley	0.3 / 0.18	0.20
0.5%	Chives	0.3 / 0.18	0.15
0.5%	Sage	0.3 / 0.18	0.14
0.4%	Basil and edible flowers	0.3 / 0.18	0.13
0.4%	Barley	0.05 / 0.02	0.11
0.3%	Celery leaves	0.3 / 0.18	0.09
0.2%	Cress and other sprouts	0.3 / 0.17	0.05
0.06%	Shallots	0.15 / 0.06	0.02
0.04%	Thyme	0.3 / 0.18	0.01
0.02%	Rosemary	0.3 / 0.18	0.01
0.01%	Laurel/bay leaves	0.3 / 0.18	0.00

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
31%	Mangoes	0.6 / 0.36	9.3
26%	Table grapes	0.4 / 0.23	7.8
24%	Cucumbers	0.4 / 0.26	7.2
20%	Courgettes	0.4 / 0.26	6.1
18%	Wine grapes	0.4 / 0.23	5.5
16%	Apples	0.3 / 0.17	4.8
12%	Beans (with pods)	1 / 0.48	3.7
11%	Escaroles/broad-leaved	0.3 / 0.17	3.4
11%	Watermelons	0.15 / 0.08	3.2
10%	Melons	0.15 / 0.08	3.1
9%	Pears	0.2 / 0.09	2.7
8%	Tomatoes	0.3 / 0.15	2.4
8%	Kiwi fruits (green, red,	0.4 / 0.17	2.4
7%	Lettuces	0.4 / 0.18	2.2
7%	Aubergines/egg plants	0.15 / 0.08	2.2
6%	Bananas	0.08 / 0.08	1.7
6%	Peaches	0.2 / 0.09	1.7
5%	Peas (with pods)	1 / 0.48	1.6
5%	Gherkins	0.4 / 0.26	1.6
5%	Spinaches	0.6 / 0.36	1.4
5%	Quinces	0.2 / 0.09	1.4
4%	Pumpkins	0.15 / 0.08	1.2
3%	Apricots	0.2 / 0.09	0.98
3%	Red mustards	0.3 / 0.17	0.90
3%	Onions	0.15 / 0.06	0.89
2%	Strawberries	0.15 / 0.08	0.75
2%	Medlar	0.2 / 0.09	0.62
1%	Lamb's lettuce/corn salads	0.3 / 0.17	0.32
0.7%	Parsley	0.3 / 0.18	0.22
0.7%	Roman rocket/rucola	0.3 / 0.17	0.20
0.6%	Wheat	0.05 / 0.02	0.17
0.5%	Shallots	0.15 / 0.06	0.16
0.3%	Barley	0.05 / 0.02	0.10
0.3%	Cranberries	0.15 / 0.08	0.09
0.3%	Hazelnuts/cobnuts	0.2 / 0.07	0.08
0.2%	Cress and other sprouts and	0.3 / 0.17	0.06
0.2%	Celery leaves	0.3 / 0.18	0.06
0.1%	Garlic	0.15 / 0.06	0.04
0.1%	Sage	0.3 / 0.18	0.04
0.1%	Chives	0.3 / 0.18	0.03
0.07%	Basil and edible flowers	0.3 / 0.18	0.02
0.06%	Rosemary	0.3 / 0.18	0.02
0.06%	Rosemary	0.3 / 0.18	0.02
0.06%	Rosemary	0.3 / 0.18	0.02
0.06%	Rosemary	0.3 / 0.18	0.02
0.05%	Chervil	0.3 / 0.18	0.01

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
38%	Escaroles/broad-leaved endi	0.3 / 0.17	11
31%	Courgettes / boiled	0.4 / 0.26	9.2
24%	Pumpkins / boiled	0.15 / 0.08	7.1
20%	Beans (with pods) / boiled	1 / 0.48	6.0
20%	Gherkins / pickled	0.4 / 0.26	6.0
17%	Spinaches / frozen; boiled	0.6 / 0.36	5.0
13%	Wine grapes / juice	0.4 / 0.09	4.0
8%	Peaches / canned	0.2 / 0.09	2.3
7%	Tomatoes / juice	0.3 / 0.11	2.1
3%	Tomatoes / sauce/puree	0.3 / 0.11	1.0
3%	Shallots / boiled	0.15 / 0.06	0.97
3%	Kiwi fruits / juice	0.4 / 0.05	0.90
2%	Pears / juice	0.2 / 0.02	0.65
2%	Apples / juice	0.3 / 0.01	0.54
2%	Peaches / juice	0.2 / 0.03	0.50

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
20%	Courgettes / boiled	0.4 / 0.26	5.9
15%	Pumpkins / boiled	0.15 / 0.08	4.4
12%	Escaroles/broad-leaved	0.3 / 0.17	3.5
11%	Wine grapes / wine	0.4 / 0.34	3.2
10%	Spinaches / frozen; boiled	0.6 / 0.36	3.0
6%	Wine grapes / juice	0.4 / 0.09	1.9
5%	Peas (with pods) / boiled	1 / 0.48	1.6
3%	Tomatoes / sauce/puree	0.3 / 0.11	0.90
3%	Table grapes / raisins	0.4 / 0.64	0.79
2%	Peaches / canned	0.2 / 0.09	0.74
2%	Onions / boiled	0.15 / 0.06	0.56
1%	Shallots / boiled	0.15 / 0.06	0.37
1%	Apples / juice	0.3 / 0.01	0.33
0.5%	Barley / beer	0.05 / 0	0.14
0.3%	Wheat / bread/pizza	0.05 / 0.02	0.09

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Acibenzolar-S-methyl is unlikely to present a public health risk.

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	Existing/ proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment[a]
Risk assessment residue definition: Sum of acibenzolar-*S*-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-*S*-methyl						
Hazelnuts/cobnuts	0.2	EFSA, 2019b	0.06	STMR-RAC (EFSA, 2019b)	0.07	HR-RAC (EFSA, 2019b)
Apples	0.3	CXL (FAO, 2016b)	0.01	CXL STMR-RAC (FAO, 2016b)	0.17	HR-RAC (FAO, 2016b)
Pears	0.2	EFSA, 2014	0.02	Tentative STMR-RAC (EFSA, 2013)	0.09	Tentative HR-RAC (EFSA, 2013)
Quinces	0.2	EFSA, 2014	0.01	STMR-RAC (EFSA, 2014)	0.09	HR-RAC (EFSA, 2014)
Medlar	0.2	EFSA, 2014	0.01	STMR-RAC (EFSA, 2014)	0.09	HR-RAC (EFSA, 2014)
Loquats/Japanese medlars	0.2	EFSA, 2014	0.01	STMR-RAC (EFSA, 2014)	0.09	HR-RAC (EFSA, 2014)
Other pome fruit	0.2	EFSA, 2014	0.01	STMR-RAC (EFSA, 2014)	0.09	HR-RAC (EFSA, 2014)
Apricots	0.2	EFSA, 2013	0.03	EU STMR-RAC (EFSA, 2013)	0.09	EU HR-RAC (EFSA, 2013)
Peaches	0.2	EFSA, 2013	0.03	EU STMR-RAC (EFSA, 2013)	0.09	EU HR-RAC (EFSA, 2013)
Table grapes	0.4	Italy, 2023	0.1	STMR-RAC (Italy, 2023)	0.23	HR-RAC (Italy, 2023)
Wine grapes	0.4	Italy, 2023	0.1	STMR-RAC (Italy, 2023)	0.23	HR-RAC (Italy, 2023)
Strawberries	0.15	CXL (FAO, 2016b)	0.045	CXL STMR-RAC (FAO, 2016b)	0.08	CXL HR-RAC (FAO, 2016b)
Cranberries	0.15	CXL (FAO, 2016b)	0.045	CXL STMR-RAC (FAO, 2016b)	0.08	CXL HR-RAC (FAO, 2016b)
Kiwi fruits (green, red, yellow)	0.4	EFSA, 2017	0.05	STMR-RAC (EFSA, 2017)	0.17	HR-RAC (EFSA, 2017)
Bananas	0.08	EFSA, 2013	0.02	STMR-RAC (EFSA, 2013)	0.08	HR-RAC (EFSA, 2013)
Mangoes	0.6	EFSA, 2013	0.21	Tentative STMR-RAC (EFSA, 2013)	0.36	Tentative HR-RAC (EFSA, 2013)
Garlic	0.15	CXL (FAO, 2016b)	0.05	CXL STMR-RAC (FAO, 2016b)	0.06	CXL HR-RAC (FAO, 2016b)
Onions	0.15	CXL (FAO, 2016b)	0.05	CXL STMR-RAC (FAO, 2016b)	0.06	CXL HR-RAC (FAO, 2016b)
Shallots	0.15	CXL (FAO, 2016b)	0.05	CXL STMR-RAC (FAO, 2016b)	0.06	CXL HR-RAC (FAO, 2016b)

Commodity	Existing/ proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment[a]
Tomatoes	0.3	EFSA, 2014	0.11	EU STMR-RAC (SEU)[b] (EFSA, 2014)	0.15	EU HR-RAC (SEU)[b] (EFSA, 2014)
Aubergines/egg plants	0.15	EFSA, 2018b	0.04	STMR-RAC (EFSA, 2018b)	0.08	HR-RAC (EFSA, 2018b)
Cucumbers	0.4	EFSA, 2018b	0.12	STMR-RAC (EFSA, 2018b)	0.26	HR-RAC (EFSA, 2018b)
Gherkins	0.4	EFSA, 2018b	0.12	STMR-RAC (EFSA, 2018b)	0.26	HR-RAC (EFSA, 2018b)
Courgettes	0.4	EFSA, 2018b	0.12	STMR-RAC (EFSA, 2018b)	0.26	HR-RAC (EFSA, 2018b)
Other cucurbits – edible peel	0.4	EFSA, 2018b	0.12	STMR-RAC (EFSA, 2018b)	0.26	HR-RAC (EFSA, 2018b)
Melons	0.15	EFSA, 2018b	0.04	STMR-RAC (EFSA, 2018b)	0.08	STMR-RAC (EFSA, 2018b)
Pumpkins	0.15	EFSA, 2018b	0.04	STMR-RAC (EFSA, 2018b)	0.08	STMR-RAC (EFSA, 2018b)
Watermelons	0.15	EFSA, 2018b	0.04	STMR-RAC (EFSA, 2018b)	0.08	STMR-RAC (EFSA, 2018b)
Other cucurbits – inedible peel	0.15	EFSA, 2018b	0.04	STMR-RAC (EFSA, 2018b)	0.08	STMR-RAC (EFSA, 2018b)
Lamb's lettuce/ corn salads	0.3	EFSA, 2013	0.11	STMR-RAC (EFSA, 2013)	0.17	HR-RAC (EFSA, 2021b)
Lettuces	0.4	CXL (FAO, 2016b)	0.12	CXL STMR-RAC (leaf lettuce) (FAO, 2016b)	0.18	CXL HR-RAC (leaf lettuce) (FAO, 2016b)
Escaroles/broad-leaved endives	0.3	EFSA, 2013	0.11	STMR-RAC (EFSA, 2013)	0.17	HR-RAC (EFSA, 2021b)
Cress and other sprouts and shoots	0.3	EFSA, 2013	0.11	STMR-RAC (EFSA, 2013)	0.17	HR-RAC (EFSA, 2021b)
Land cress	0.3	EFSA, 2013	0.11	STMR-RAC (EFSA, 2013)	0.17	HR-RAC (EFSA, 2021b)
Roman rocket/ rucola	0.3	EFSA, 2013	0.11	STMR-RAC (EFSA, 2013)	0.17	HR-RAC (EFSA, 2021b)
Red mustards	0.3	EFSA, 2013	0.11	STMR-RAC (EFSA, 2013)	0.17	HR-RAC (EFSA, 2021b)
Baby leaf crops (including brassica species)	0.3	EFSA, 2013	0.11	STMR-RAC (EFSA, 2013)	0.17	HR-RAC (EFSA, 2021b)
Other lettuce and other salad plants	0.3	EFSA, 2013	0.11	STMR-RAC (EFSA, 2013)	0.17	HR-RAC (EFSA, 2021b)
Spinaches	0.6	CXL (FAO, 2016b)	0.19	CXL STMR-RAC (FAO, 2016b)	0.36	CXL HR-RAC (FAO, 2016b)
Chervil	0.3	EFSA, 2013	0.14	STMR-RAC (EFSA, 2013)	0.18	HR-RAC (EFSA, 2013)
Chives	0.3	EFSA, 2013	0.14	STMR-RAC (EFSA, 2013)	0.18	HR-RAC (EFSA, 2013)
Celery leaves	0.3	EFSA, 2013	0.14	STMR-RAC (EFSA, 2013)	0.18	HR-RAC (EFSA, 2013)
Parsley	0.3	EFSA, 2013	0.14	STMR-RAC (EFSA, 2013)	0.18	HR-RAC (EFSA, 2013)

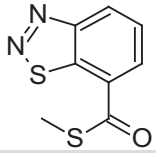
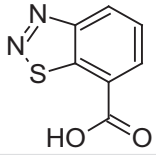
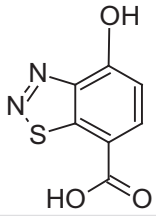
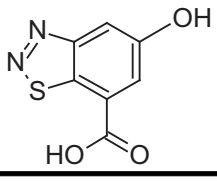
Commodity	Existing/ proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment[(a)]
Sage	0.3	EFSA, 2013	0.14	STMR-RAC (EFSA, 2013)	0.18	HR-RAC (EFSA, 2013)
Rosemary	0.3	EFSA, 2013	0.14	STMR-RAC (EFSA, 2013)	0.18	HR-RAC (EFSA, 2013)
Thyme	0.3	EFSA, 2013	0.14	STMR-RAC (EFSA, 2013)	0.18	HR-RAC (EFSA, 2013)
Basil and edible flowers	0.3	EFSA, 2013	0.14	STMR-RAC (EFSA, 2013)	0.18	HR-RAC (EFSA, 2013)
Laurel/bay leaves	0.3	EFSA, 2013	0.14	STMR-RAC (EFSA, 2013)	0.18	HR-RAC (EFSA, 2013)
Tarragon	0.3	EFSA, 2013	0.14	STMR-RAC (EFSA, 2013)	0.18	HR-RAC (EFSA, 2013)
Other herbs	0.3	EFSA, 2013	0.14	STMR-RAC (EFSA, 2013)	0.18	HR-RAC (EFSA, 2013)
Beans (with pods)	1	EFSA, 2021b	0.275	STMR-RAC (EFSA, 2021b)	0.48	HR-RAC (EFSA, 2021b)
Peas (with pods)	1	EFSA, 2021b	0.275	STMR-RAC (EFSA, 2021b)	0.48	HR-RAC (EFSA, 2021b)
Barley	0.05	EFSA, 2013	0.02	STMR-RAC (EFSA, 2013)	0.02	STMR-RAC (EFSA, 2013)
Wheat	0.05	EFSA, 2013	0.02	STMR-RAC (EFSA, 2013)	0.02	STMR-RAC (EFSA, 2013)
Other crops/ commodities				The contributions of commodities where no GAP was reported in the framework of the MRL review or subsequent MRL applications were not included in the calculation.		The contributions of commodities where no GAP was reported in the framework of the MRL review or subsequent MRL applications were not included in the calculation.

STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity; PeF: Peeling factor.

(a): Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey

(b): EFSA assumed the EU GAP for indoor use on tomatoes assessed in the MRL review has been revoked following identification of possible exceedance of the ARfD (EFSA, 2014), and consequently, risk assessment values are derived from outdoor use (SEU).

Appendix E – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChIKey[b]	Structural formula[c]
acibenzolar-*S*-methyl CGA 245704 benzothiadiazole	*S*-methyl 1,2,3-benzothiadiazole-7-carbothioate O=C(SC)c1cccc2nnsc12 UELITFHSCLAHKR-UHFFFAOYSA-N	
acibenzolar acid CGA 210007	1,2,3-benzothiadiazole-7-carboxylic acid O=C(O)c1cccc2nnsc12 COAIOOWBEPAOFY-UHFFFAOYSA-N	
4-OH acibenzolar acid CGA 323060	4-hydroxy-1,2,3-benzothiadiazole-7-carboxylic acid O=C(O)c1ccc(O)c2nnsc12 RZSJWCHAQOKSRQ-UHFFFAOYSA-N	
5-OH acibenzolar acid CGA 324041	5-hydroxy-1,2,3-benzothiadiazole-7-carboxylic acid O=C(O)c1c(O)ccc2nnsc12 KFCBKGUXJXJRLM-UHFFFAOYSA-N	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2021.1.3 ACD/Labs 2021.1.3 (File Version N15E41, Build 123232, 07 July 2021).
(c): ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123835, 28 August 2021).