REASONED OPINION

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Modification of the existing maximum residue levels for acibenzolar-S-methyl in aubergines and cucurbits with edible and inedible peel

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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 levels (MRL) for the active substance acibenzolar-S-methyl in aubergines and cucurbits with edible and inedible peel. The data submitted in support of the request were found to be sufficient to derive MRL proposals for all the commodities under consideration in this reasoned opinion. Adequate analytical methods for enforcement are available to control the residues of acibenzolar-S-methyl in plant matrices/on the commodities 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 intakes of residues resulting from the use of acibenzolar-S-methyl according to the reported agricultural practices are unlikely to present a risk to consumer health. The reliable end points, appropriate for use in regulatory risk assessment are presented.

Keywords: acibenzolar-S-methyl, aubergines, cucurbits, pesticide, MRL, consumer risk assessment

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Summary

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 levels (MRL) for the active substance acibenzolar-S-methyl in aubergines and cucurbits with edible and inedible peel. France 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 4 December 2017. To accommodate for the intended uses of acibenzolar-S-methyl, the EMS proposed to raise the existing MRLs from the limit of quantification (LOQ) 0.01 to 0.4 mg/kg for cucurbits with edible peel, and 0.15 mg/kg for cucurbits with inedible peel and aubergines.

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 Regulation (EC) No 1107/2009, the data evaluated under previous MRL assessment 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 applications was investigated in crops belonging to the fruit, leafy and cereals crop groups.

Hydrolysis studies investigating the effect of processing on the nature of acibenzolar-S-methyl demonstrated that the acibenzolar-S-methyl is stable under pasteurisation and baking-like processes and likely to degrade to acibenzolar acid under sterilisation conditions.

From the rotational crops metabolism studies, total radioactive residue (TRR) levels were found to be at or below 0.001 mg/kg and a specific residue definition for rotational crops is therefore not deemed necessary.

Based on the metabolic pattern identified in primary crops, rotational crops and processed commodities, and the toxicological profile of metabolites and degraded products, the residue definition for enforcement and risk assessment is proposed as sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-S-methyl. These residue definitions are applicable to primary crops, rotational crops and processed products.

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

The available residue trials are sufficient to derive an MRL proposal of 0.15 mg/kg for aubergines and cucurbits with inedible peel and an MRL proposal of 0.40 mg/kg for the cucurbits, edible peel group. For the intended use on aubergines following the soil treatment, Good Agricultural Practice (GAP)-compliant residue trials were not provided.

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

The occurrence of acibenzolar-S-methyl residues in rotational crops was investigated in the framework of the EU pesticides peer-review. Based on the available information on the nature and magnitude of residues, it was concluded that significant residue levels (> 0.01 mg/kg) are unlikely to occur in rotational crops, provided that the acibenzolar-S-methyl is used according to the proposed GAP.

Residues of acibenzolar-S-methyl in commodities of animal origin were not assessed since the crops under consideration in this MRL application are 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. Acibenzolar acid (free and conjugated) that is included in the residue definition applicable in the current assessment is of similar toxicity as the parent active substance.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The long-term dietary intake accounted for up to 3% of the ADI in the chronic consumers' intake scenario and the acute exposure does not exceed the acute reference dose for none of the considered crops (maximum 51% ARfD for cucumbers). Thus, EFSA concluded that the proposed use of acibenzolar-S-methyl on aubergines and cucurbits with edible and inedible peel 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 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
Enforcement residue definition: Sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-S-methyl				
0231030	Aubergines	0.01*	0.15	The submitted data are sufficient to derive an MRL proposal supported by residue data for the indoor use following spray application. Risk for consumers is unlikely
0232000	Cucurbits with edible peel	0.01*	0.40	The submitted data are sufficient to derive a MRL proposal for the indoor use. Risk for consumers is unlikely
0233000	Cucurbits with inedible peel	0.01*	0.15	The submitted data are sufficient to derive a MRL proposal for the indoor use. Risk for consumers is unlikely

MRL: maximum residue level.
*: 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 detailed description of the intended uses of acibenzolar-S-methyl in aubergines and cucurbits with edible and inedible peel, which are the basis for the current maximum residue level (MRL) application, is reported in Appendix A.

Acibenzolar-S-methyl is the modified 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 was evaluated in the framework of Directive 91/414/EEC with France acting as the designated rapporteur member state (RMS). Acibenzolar-S-methyl was included in Annex I of Directive 91/414/EEC by Directive 2001/87/EC[1] which entered into force on 1 November 2001. 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[2], as amended by Commission Implementing Regulation (EU) No 380/2013[3], with France as designated RMS for the representative uses as foliar spraying on pome fruit, tomato and tobacco. The renewal assessment report (RAR) prepared by the RMS has been peer reviewed by EFSA (2014).

The renewal of acibenzolar-S-methyl was approved[4] for the use as plant activator 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[6]. After completion of the MRL review, EFSA has issued one reasoned opinion on the modification of MRLs for acibenzolar-S-methyl. The proposals from this reasoned opinion have not been considered yet for EU MRL legislation.

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 aubergines and cucurbits with edible and inedible peel. France 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 4 December 2017. To accommodate for the intended uses of acibenzolar-S-methyl, the EMS proposed to raise the existing MRLs from the limit of quantification (LOQ) 0.01 to 0.4 mg/kg for cucurbits with edible peel, and 0.15 mg/kg for cucurbits with inedible peel and aubergines.

EFSA based its assessment on the evaluation report submitted by the EMS (France, 2017), 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, 2009, 2012, 2017b) including the review of the existing MRLs for acibenzolar-S-methyl according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2013) and the Codex Committee on Pesticide Residues (CCPR) Report (EFSA, 2017a).

[1] Commission Directive 2001/87/EC of 12 October 2001 amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market to include acibenzolar-s-methyl, cyclanilide, ferric phosphate, pymetrozine and pyraflufen-ethyl as active substances. OJ L 276, 19.10.2001, p. 17–20.

[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, p. 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, p. 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. OJ L 73, 18.3.2016, p. 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, p. 1–16.

[6] 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.

For this application, the data requirements established in Regulation (EU) No 544/2011[7] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013). 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[8].

A selected list of end points of the studies assessed by EFSA in the framework of the this MRL application, review, including the end points of relevant studies assessed previously, submitted in support of the current MRL application, are presented in Appendix B.

The evaluation report submitted by the EMS (France, 2017) 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 (CGA 245704) 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 (CGA 210007) followed by ester conjugation with sugars in tomato, wheat, tobacco and lettuce (EFSA, 2013). It was agreed during the peer review process, that 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, 2014).

1.1.2. Nature of residues in rotational crops

Since the crops assessed under the current application might be grown in rotation and the soil DT_{90} varies from less than 100 days (DT_{90}: 0.7–3.3 days) for acibenzolar-S-methyl to more than 100 days (DT_{90} 43.9–354 days) for the major soil metabolite (acibenzolar acid), residues in rotational crops need to be considered in the current assessment (European Commission, 1997a–g).

Metabolism in rotational crops has been previously investigated in lettuce, radish, wheat, maize and mustard (EFSA, 2013, 2014). All total radioactive residue (TRR) levels were found to be at or below 0.001 mg/kg and thus it can be concluded that residue levels in rotational crops commodities are not expected to exceed 0.01 mg/kg, provided that acibenzolar-S-methyl is applied in compliance with the intended uses on the crops under consideration. A specific residue definition for rotational crops is therefore not deemed necessary.

1.1.3. Nature of residues in processed commodities

Standard hydrolysis studies were available to investigate the nature of residues in processed commodities (EFSA, 2013, 2014). Residues were considered to be stable under conditions that simulate pasteurisation and baking, brewing and boiling process. Significant degradation into acibenzolar acid under sterilisation conditions; based on this characterisation, residue pattern in processed commodities is similar to the residue pattern in raw commodities.

1.1.4. Methods of analysis in plants

Validated enforcement analytical methods for the determination of residues of acibenzolar-S-methyl and acibenzolar acid (free and conjugates) at a LOQ of 0.01 mg/kg in high water commodities, high acid content commodities and tobacco are available (EFSA, 2013, 2014, EFSA, 2017a,b) by using high-performance liquid chromatography with tandem mass spectrometry detector (HPLC–MS/MS). Since

[7] 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.

[8] 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.

aubergines and cucurbits are crop items belonging to the high water content matrices, sufficiently validated analytical methods are available to enforce the MRLs to be derived at a LOQ of 0.01 mg/kg.

1.1.5. Stability of residues in plants

Residues of acibenzolar-S-methyl were demonstrated to be stable in frozen conditions in high starch/dry commodities (wheat grain) for a period of 24 months and in high water commodities (cabbage, squash, lettuce, tomatoes, and turnip roots) and in tobacco for 21 months (EFSA, 2013). Acibenzolar acid was demonstrated to be stable in high water commodities (cabbage, squash, lettuce, tomatoes and turnip roots) and tobacco for 21 months (EFSA, 2013). An additional storage stability study has been evaluated in a previous MRL application and demonstrated that acibenzolar-S-methyl and acibenzolar acid are stable in high acid content commodities (strawberries) for 317 days.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies and the toxicological significance of metabolites and of degradation products, the residue definition as sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-S-methyl are applicable in the current assessment for enforcement and risk assessment to primary crops, rotational crops and processed products.

The residue definition for the enforcement of the MRLs is identical to that one in the EU MRL regulation.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To support of the MRL applications of acibenzolar-S-methyl, two different good agricultural practices (GAPs) were submitted; for the indoor use on aubergines, cucurbits, edible peel and cucurbits, inedible peel, a GAP with a foliar spray application (indoor, 2 × 16 g/ha preharvest interval (PHI) 3 days) was provided. A second GAP where the active substance is applied by soil drip (Indoor, 1 × 12.5 g/ha PHI 14 days) is also reported for the use in aubergines but not supported by supervised residue trials.

The applicant submitted eight GAP-compliant decline residue trials for foliar spray application on aubergines, eight GAP-compliant residue trials on courgettes with a possible extrapolation to the whole group of cucurbits, edible peel and eight GAP-compliant residue trials on melon with a possible extrapolation to cucurbits, inedible peel. The soil drip treatment GAP on aubergines is not supported by residue data to derive an MRL. Details of the residue trials are available in Table B.1.2.1. In all available trials, samples were analysed in accordance with the residue definitions for enforcement and risk assessment. Overall, the residue decline occurs in most of the residue trials except in four residue trials where higher residues were detected at longer PHI. Those residue values, underlined in Table B.1.2.1, were considered for MRL setting and risk assessment.

The methods used were sufficiently validated and fit for purpose for the analysis of acibenzolar-S-methyl residues according to the assessment of the EMS (France, 2017). The samples of these residue trials were stored for a maximum of 8 months under conditions for which integrity of the samples has been demonstrated. For all the above considerations, the residue trials were considered valid.

1.2.2. Magnitude of residues in rotational crops

Since all residue levels in the crops investigated were found to be equal or below 0.001 mg/kg following a use pattern into the bare soil with an application rate of 50 g/ha, it is concluded that residue levels of acibenzolar-S-methyl in rotational crops commodities are not expected to exceed 0.01 mg/kg provided that the active substance is applied in compliance with the GAP under assessment.

1.2.3. Magnitude of residues in processed commodities

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 were considered sufficient to derive MRL proposals of 0.15 mg/kg for aubergines and cucurbits, inedible peel and of 0.40 mg/kg for cucurbits, edible peel. Risk assessment values were also derived from the residue data package (see Appendix B.1.2.1).

In Section 3, EFSA assessed whether residues resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

The crops under assessment are not used to feed livestock; therefore the impact of residues of acibenzolar-S-methyl in livestock from the intended use does not need to be assessed.

3. Consumer risk assessment

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

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. The long term dietary intake accounted for up to 3% of the ADI in the chronic consumers' intake scenario and the acute exposure does not exceed the acute reference dose (ARfD) for any of the crops considered (maximum 51% ARfD for cucumbers).

EFSA concluded that the proposed use of acibenzolar-S-methyl on aubergines and cucurbits, edible and inedible peel, will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

4. Conclusion and Recommendations

The MRL proposals for aubergines and cucurbits with edible and inedible peel are fully supported by data and a consumer concern has not been identified for any of the intended uses assessed.

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
CCPR	Codex Committee on Pesticide Residues
CEN	European Committee for Standardisation (Comité Européen de Normalisation)
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{90}	period required for 90% dissipation (define method of estimation)
EMS	evaluating Member State
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
ISO	International Organisation for Standardisation

IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
MRL	maximum residue level
MS/MS	tandem mass spectrometry detector
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
RAR	renewal assessment report
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern Europe
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
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			Unit	PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages and season[c]	Number min–max	Interval between application (min)	kg a.s./hL min–max	Water L/ha min–max	Rate a) max rate per appl b) max total rate per crop/ season			
Cucurbits edible peel	HU IT ES PT EL CY MT TK	G	Thrips, whiteflies, Lepidoptera	SC	12.5 g/L	Foliar spray	BBCH 12–89	1–2	8 days	n/a	250/1,000	a) 16 b) 32	g a.s./ha	3	–
Cucurbits, inedible peel	HU BG IT ES PT EL CY MT RO	G	Thrips, whiteflies, Lepidoptera	SC	12.5 g/L	Foliar spray	BBCH 12–89	1–2	8 days	n/a	250/1,000	a) 16 b) 32	g a.s./ha	3	–
Aubergines	BG, CY, ES, GR, HR, IT, PT, MT	G	Various	SC	12.5 g/L	Foliar spray	BBCH 12–89	1–2	7 days	0.0016–0.0064	250/1,000	0.016	kg a.s./ha	3	–
Aubergines[e]	BG, CY, ES, GR, HR, IT, PT, MT	G	Various	SC	12.5 g/L	Soil drip	BBCH 12–89	1	–	0.000625–0.00125	10,000–20,000	0.0125	kg a.s./ha	14	–

NEU: northern European Union; SEU: southern European Union; MS; Member State; a.s.: active substance; SC: suspension concentrate.
(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.
(e): The GAP is not supported by residue data.

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 Reference: France (1998, 2009), 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 Reference: France (1998), EFSA (2013)
	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	Reference: EFSA (2014)
	Baking, brewing and boiling (60 min, 100°C, pH 5)	Yes	Reference: EFSA (2014)
	Sterilisation (20 min, 120°C, pH 6)	No	Significant degradation into acibenzolar acid under sterilisation conditions Reference: EFSA (2014)
	Other processing conditions		

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

Can a general residue definition be proposed for primary crops?	No	Reference: EFSA (2014)
Rotational crop and primary crop metabolism similar?	Yes	Reference: EFSA (2014)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	Reference: EFSA (2014)
(RD-Mo)	Sum of acibenzolar-S-methyl and acibenzolar-acid (free and conjugated), expressed as acibenzolar-S-methyl	
Plant residue definition for risk assessment (RD-RA)	Sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-S-methyl (limited to fruit crops, cereals and tobacco) For other crops (lettuce) depending on residue trials data and toxicological data, the metabolite 4-OH acibenzolar acid (CGA 323060) could be considered in the residue definition (EFSA, 2014)	
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; France, 2016)	

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)
	Dry/High starch	Wheat grain	−18	24	Months	Acibenzolar-S-methyl acibenzolar acid	EFSA (2013)
	High acid content	Strawberries	−21	10	Months	Acibenzolar-S-methyl Acibenzolar acid	EFSA (2017a,b)
	Others	Straw	–	–	–	–	–
		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)[b]	Comments/source	Calculated MRL (mg/kg)	HR[c] (mg/kg)	STMR[d] (mg/kg)	CF[e]
Aubergines	Indoor	2 × 0.02, 0.03, 2 × 0.04,0.06, 0.06, 0.08	Residue trials on tomatoes compliant with foliar treatment GAP. Extrapolation to aubergines possible	**0.15**	0.08	0.04	1
Cucurbits, edible peel	Indoor	0.03, 2 × 0.09, 0.11, 0.13, 0.14, 0.15, 0.26	Residue trials on courgettes compliant with GAP. Extrapolation to the whole group of cucurbits, edible peel possible	**0.40**	0.26	0.12	1
Cucurbits, inedible peel	Indoor	0.01, 0.02, 2 × 0.03, 0.04, 0.05, 0.05, 0.08	Residue trials on melons compliant with GAP. Extrapolation to the whole group of cucurbits, inedible peel possible	**0.15**	0.08	0.04	1

MRL: maximum residue level; GAP: Good Agricultural Practice.
(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): Underlined values represent higher residues at longer PHI than the PHI of the intended GAP.
(c): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(e): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

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 metabolites' identification could not be therefore conducted to depict a metabolic pathway in rotational crops.
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	No residue above 0.01 mg/kg is expected in rotational crops.

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 for the commodities under assessment.

B.3. Consumer risk assessment

ARfD	0.03 mg/kg bw (EFSA, 2014)
Highest IESTI, according to EFSA PRIMo	Cucumbers: 51% of ARfD Melons: 40% of ARfD Courgettes: 40% of ARfD Watermelons: 33% of ARfD Gherkins: 14% of ARfD
Assumptions made for the calculations	Only the residues at the highest residue (HR) level as observed in supervised field trials in the crops under assessment has been considered in the acute exposure scenario

ADI	0.03 mg/kg bw per day (EFSA, 2014)
Highest IEDI, according to EFSA PRIMo	3% ADI (DE child) The maximum daily intake expresses in % of ADI for the commodities under assessment was 1.4% of ADI for cucumbers (Danish children diet)
Assumptions made for the calculations	The calculation is based on the median residue levels derived for raw agricultural commodities under
	consideration in the current MRL applications and in previous MRL assessments implemented in the EU Regulation The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation After the peer-review process and due to changes in the toxicological reference values, an exceedance of the ARfD was identified tomatoes and consequently the MRL for tomatoes was lowered to a safe level. Likewise during the peer-review, residue data has been submitted to fulfil the data gaps identified during the MRL review in support of the uses in pome fruits (EFSA, 2014; Reg. (EU) 2016/1866). Exposure calculations were updated in the PRIMo by considering the STMR values reflecting the situation above Likewise, MRLs at the LOQ were not considered in the exposure calculation given that the uses are not expected to produce a residue situation that might affect consumers

B.4. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-S-methyl				
0231030	Aubergines	0.01*	0.15	The submitted data are sufficient to derive a MRL proposal based on the indoor use following spray application. Risk for consumers is unlikely
0232000	Cucurbits with edible peel	0.01*	0.40	The submitted data are sufficient to derive a MRL proposal for the indoor use. Risk for consumers is unlikely
0233000	Cucurbits with inedible peel	0.01*	0.15	The submitted data are sufficient to derive a MRL proposal for the indoor use. Risk for consumers is unlikely

MRL: maximum residue level.
*: 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)

Acibenzolar-S-methyl			
Status of the active substance:	**Approved**	Code no.	
LOQ (mg/kg bw):	0.01	Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.03**	ARfD (mg/kg bw):	**0.03**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:		Year of evaluation:	

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum
	1 3
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
2.9	WHO Cluster diet B	1.1	Tomatoes	0.6	Wheat	0.2	Cucumbers	0.1
2.3	DK child	1.4	Cucumbers	0.4	Wheat	0.2	Tomatoes	0.1
2.1	DE child	0.5	Cucumbers	0.4	Apples	0.4	Tomatoes	0.4
1.7	NL child	0.3	Wheat	0.2	Tomatoes	0.2	Cucumbers	0.2
1.7	IT kids/toddler	0.5	Tomatoes	0.4	Wheat	0.2	Courgettes	0.0
1.5	IT adult	0.4	Tomatoes	0.3	Wheat	0.2	Lettuce and other salad plants	0.0
1.5	SE general population 90th percentile	0.3	Tomatoes	0.3	Cucumbers	0.2	Wheat	0.0
1.5	WHO cluster diet D	0.4	Wheat	0.4	Tomatoes	0.2	Cucumbers	0.0
1.5	FR toddler	0.4	Courgettes	0.3	Spinach	0.3	Tomatoes	0.1
1.3	WHO regional European diet	0.4	Tomatoes	0.2	Wheat	0.2	Lettuce and other salad plants	0.0
1.3	IE adult	0.2	Wheat	0.1	Tomatoes	0.1	Courgettes	0.1
1.3	ES child	0.4	Tomatoes	0.3	Wheat	0.2	Lettuce and other salad plants	0.1
1.1	ES adult	0.3	Tomatoes	0.2	Lettuce and other salad plants	0.2	Lettuce and other salad plants	0.0
1.1	FR infant	0.6	Courgettes	0.2	Spinach	0.1	Apples	0.1
1.1	WHO Cluster diet F	0.2	Tomatoes	0.2	Wheat	0.1	Lettuce and other salad plants	0.0
1.0	WHO cluster diet E	0.3	Wheat	0.2	Tomatoes	0.1	Gherkins	0.0
0.9	FR all population	0.2	Wheat	0.2	Tomatoes	0.1	Lettuce and other salad plants	0.0
0.8	NL general	0.2	Tomatoes	0.1	Wheat	0.1	Cucumbers	0.0
0.8	UK Toddler	0.3	Wheat	0.2	Tomatoes	0.1	Cucumbers	0.1
0.8	LT adult	0.3	Cucumbers	0.2	Tomatoes	0.1	Wheat	0.1
0.8	PT General population	0.3	Tomatoes	0.3	Wheat	0.0	Lettuce and other salad plants	0.0
0.7	UK vegetarian	0.2	Tomatoes	0.1	Wheat	0.1	Cucumbers	0.0
0.7	DK adult	0.2	Cucumbers	0.2	Tomatoes	0.1	Wheat	0.0
0.6	FI adult	0.2	Cucumbers	0.2	Tomatoes	0.1	Wheat	0.0
0.5	PL general population	0.3	Tomatoes	0.1	Apples	0.1	Cucumbers	0.1
0.5	UK Infant	0.2	Wheat	0.1	Tomatoes	0.1	Bananas	0.1
0.5	UK Adult	0.2	Tomatoes	0.1	Wheat	0.1	Cucumbers	0.0

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Acibenzolar-S-methyl is unlikely to present a public health concern.

Acute risk assessment/children – refined calculations	Acute risk assessment/adults/general population – refined calculations

The acute risk assessment is based on the ARfD.
For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.
In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.
Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
50.7	Cucumbers	0.26/ -	50.7	Cucumbers	0.26/ -	23.4	Courgettes	0.26/ -	17.6	Courgettes	0.26/ -
40.4	Melons	0.08/ -	40.4	Melons	0.08/ -	17.1	Cucumbers	0.26/ -	17.1	Cucumbers	0.26/ -
40.3	Courgettes	0.26/ -	32.6	Watermelons	0.08/ -	14.1	Pumpkins	0.08/ -	14.1	Pumpkins	0.08/ -
32.6	Watermelons	0.08/ -	28.8	Courgettes	0.26/ -	10.8	Watermelons	0.08/ -	10.8	Watermelons	0.08/ -
14.1	Gherkins	0.26/ -	10.2	Gherkins	0.26/ -	10.5	Melons	0.08/ -	10.5	Melons	0.08/ -
No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---				**No of commodities for which ARfD/ADI is exceeded:** ---			
		***)				***)	
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	
				4.4	Apple juice	0.2/ -	
				1.9	Tomato (preserved-fresh)	0.3/ -	
				1.3	Peach preserved with	0.2/ -	
				0.8	Quince jelly	0.2/ -	
				0.7	Bread/pizza	0.05/ -	

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
**) pTMRL: provisional temporary MRL.
***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:
For Acibenzolar-S-methyl, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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

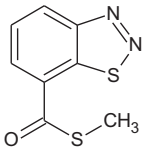
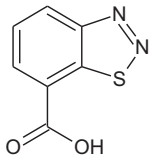
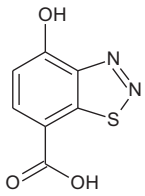
Not relevant for the commodities under assessment.

D.2. Consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Aubergines	0.04	STMR (Table B.1.2.1)	0.08	HR (Table B.1.2.1)
Cucurbits edible peel	0.12	STMR (Table B.1.2.1)	0.26	HR (Table B.1.2.1)
Cucurbits with inedible peel	0.04	STMR (Table B.1.2.1)	0.08	HR (Table B.1.2.1)
Kiwi fruits	0.05	STMR (EFSA, 2017b)	Acute risk assessment undertaken only with regard to the crops under assessment	
Pome fruits	0.01	STMR (EFSA, 2014)		
Tomatoes	0.11	STMR (EFSA, 2014)		
Other commodities of plant origin	See table 4-1 in reasoned opinion on Art 12. MRLs review (EFSA, 2013)			

STMR: supervised trials median residue; HR: highest residue; MRL: maximum residue level.

Appendix E – Used compound codes

Code/trivial name	IUPAC name/SMILES notation/InChIKey[a]	Structural formula[b]
acibenzolar-S-methyl CGA 245704	*S*-methyl benzo[1,2,3]thiadiazole-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	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system.
(a): ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).
(b): ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).