European Food Safety Authority

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TECHNICAL REPORT

Outcome of the consultation with Member States and EFSA on the basic substance application for sucrose/saccharose and the conclusions drawn by EFSA on the specific points raised[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The European Food Safety Authority (EFSA) was asked by the European Commission to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. In this context EFSA's scientific views on the specific points raised during the commenting phase conducted with Member States and EFSA on the basic substance application for sucrose/saccharose are presented. The context of the evaluation was that required by the European Commission in accordance with Article 23 of Regulation (EC) No 1107/2009 following the submission of an application for approval of sucrose/saccharose as a basic substance. The current report summarises the outcome of the consultation process organised by the EFSA and presents EFSA's scientific views on the individual comments received.

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KEY WORDS

sucrose, saccharose, basic substance, application, consultation, plant protection, pesticide

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SUMMARY

Sucrose/saccharose is an active substance for which in accordance with Article 23(3) of Regulation (EC) No 1107/2009 the European Commission received an application from the Institut Technique de l'Agriculture Biologique (ITAB) for approval as a "basic substance". Regulation (EC) No 1107/2009 introduced the new category of "basic substances", which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest of applying for approval may be limited. Article 23 of Regulation (EC) No 1107/2009 lays down specific provisions for consideration of applications for approval of basic substances.

In March 2013 the European Commission requested the European Food Safety Authority (EFSA) to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received from the European Commission on 3 April 2014, EFSA was asked to organise a commenting on the basic substance application for sucrose/saccharose, to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a Reporting Table within 3 months of acceptance of the specific request.

A consultation on the basic substance application for sucrose/saccharose, organised by the EFSA, was conducted with Member States and EFSA via a written procedure in November 2013 – January 2014. Subsequently the applicant was invited to address the comments received in the format of a Reporting Table, within a period of 30 days.

The current report summarises the outcome of the consultation process organised by the EFSA on the basic substance application for sucrose/saccharose and presents EFSA's scientific views on the individual comments received in the format of a Reporting Table.

Sucrose or saccharose are common names for α-D-glucopyranosyl-(1→2)-β-D-fructofuranoside or β-D-fructofuranosyl-(2→1)-α-D-glucopyranoside.

Sucrose is not predominantly used for plant protection purposes; it fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002. *Codex Alimentarius* Commission standard exists for sugars, including sucrose (CODEX STAN 212-1999 Codex standard for sugars, adopted in 1999, amendment in 2001)).

The intended uses as a basic substance are as an insecticide on apple against *Cydia pomonella* L and on sweet maize against *Ostrinia nubilalis* Hbn.

The substance is food grade and, despite the limited toxicological data available, it is not expected to give any health concern.

Having regard to the limited application rates (maximum 100 g/ha per treatment) and considering that sucrose fulfils the criteria of a 'foodstuff' under Regulation (EC) No 178/2002, no residues of concern are expected to be present in food and feed commodities at harvest.

Usable information on the amounts of extracellular sucrose that may be present in the different environmental compartments naturally and/or from the proposed use was not provided in the documentation provided in the application.

No specific data regarding the ecotoxicology section were provided. However, considering the nature of the active substance, no concerns were identified for non-target species for the intended uses.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 1107/2009[3] (hereinafter referred to as 'the Regulation') introduced the new category of "basic substances", which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest of applying for approval may be limited. Article 23 of the Regulation lays down specific provisions to identify a substance as a basic substance with a view to ensure that such active substances that do not have an immediate or delayed harmful effect on human and animal health nor an unacceptable effect on the environment can be approved as "basic" and used for plant protection purposes.

Sucrose/saccharose is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from the Institut Technique de l'Agriculture Biologique (ITAB) for approval as a "basic substance".

The European Food Safety Authority (EFSA) organised a consultation with Member States and EFSA on the basic substance application for sucrose/saccharose, which was conducted via a written procedure in November 2013 – January 2014. The comments received were collated by EFSA in the format of a Reporting Table. Subsequently, the applicant was invited to address the comments in column 3 of the Reporting Table. The comments received and the response of the applicant thereon, together with the application submitted by the applicant, were considered by EFSA in column 4 of the Reporting Table.

The current report aims to summarise the outcome of the consultation process organised by the EFSA on the basic substance application for sucrose/saccharose and to present EFSA's scientific views on the individual comments received in the format of a Reporting Table.

The application and, where relevant, any update thereof submitted by the applicant for approval of sucrose/saccharose as a "basic substance" in the context of Article 23 of the Regulation, is a key supporting documentation, therefore it is considered as a background documentation to this report and will also be made publicly available, excluding its appendices (ITAB, 2013 and ITAB, 2014).

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

On 6 March 2013 the European Commission requested the EFSA to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received by EFSA on 3 April 2014, EFSA was asked to organise a commenting on the basic substance application for sucrose/saccharose, to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a Reporting Table.

To this end, a Technical Report containing the finalised Reporting Table is prepared by EFSA. The agreed deadline for providing the finalised report is 12 June 2014.

On the basis of the Reporting Table, the European Commission may decide to further consult EFSA to conduct a full or focussed peer review and to provide its conclusions on certain specific points.

[3] 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 No L 309, 24.11.2009, p. 1-50.

EVALUATION

The comments received on the basic substance application for sucrose/saccharose and the conclusions drawn by the EFSA are presented in the format of a Reporting Table.

The comments received are summarised in column 2 of the Reporting Table. The applicant's considerations of the comments, where available, are provided in column 3, while EFSA's scientific views and conclusions are outlined in column 4 of the table.

The finalised Reporting Table is provided in the Appendix of this report.

DOCUMENTATION PROVIDED TO EFSA

1. ITAB (Institut Technique de l'Agriculture Biologique), 2013. Sucrose/saccharose. Basic substance application submitted in the context of Article 23 of Regulation (EC) No 1107/2009. September 2013. Submitted by ITAB (Institut Technique de l'Agriculture Biologique) and CETU Innophyt. Documentation made available to EFSA by the European Commission.

2. ITAB (Institut Technique de l'Agriculture Biologique), 2014. Sucrose/saccharose. Basic substance application update submitted in the context of Article 23 of Regulation (EC) No 1107/2009. February 2014. Submitted by ITAB (Institut Technique de l'Agriculture Biologique) and CETU Innophyt. Documentation made available to EFSA by the applicant.

REFERENCES

None.

APPENDIX

COLLATION OF COMMENTS FROM MEMBER STATES AND EFSA ON THE BASIC SUBSTANCE APPLICATION FOR SUCROSE/SACCHAROSE AND THE CONCLUSIONS DRAWN BY EFSA ON THE SPECIFIC POINTS RAISED

1. Purpose of the application

General				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1(1)		ES: No comments		Addressed

2. Identity of the substance/product as available on the market and predominant use

2.1. Predominant Use				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)	2.1. Predominant uses of the substance outside plant protection, p.5	EFSA: food grade sucrose is used mainly as a food, as defined in Art.2 of Regulation 178/2002	Included in BSA.	Sucrose meets the criteria for definition of 'food' as defined in Art.2 of Regulation 178/2002.
2(2)		ES: No comments		Addressed.

2.2. Identity and Physical and chemical properties of the substance and product to be used				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(3)	2.2.5. Description and specification of purity of the active substance and product, p.8	EFSA: as the Codex standard for sugars "Codex Stan 212-1999" applies to several types of sugars, but not all of them contain sucrose, it seems that the description and the specification of purity of the substance should be more precise.	REGULATION (EEC) No 1265/69 of the COMMISSION of 1 July 1969 establishing methods for determining the quality of sugar bought-in by intervention agencies. COUNCIL REGULATION (EC) No 1260/2001 of 19 June 2001 on the common organisation of the markets in the sugar sector.	"Codex Stan 212-1999" contains purified and crystallised sucrose, powdered sugar, soft white sugar, soft brown sugar, raw cane sugar According to Council Regulation (EC) No 1260/2001 of 19 June 2001: a)'white sugars' means sugars, not flavoured or coloured or containing any other added substances, containing, in the dry state, 99,5 % or more by weight of sucrose, determined by the polarimetric method b)'raw sugars' means sugars, not flavoured or coloured or containing any other added substances, containing, in the dry state, 99,5 % by weight of sucrose, determined by the polarimetric method.
2(4)	2.2.1 Common name of the substance and product and their synonyms/plant	ES: The synonym in Spanish should be included.	Included in BSA.	Addressed.

2.2. Identity and Physical and chemical properties of the substance and product to be used				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
	nomenclature			

2.3. Current Former and in case proposed trade names				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(5)		ES: No comments		Addressed.

2.4. Manufacturer of the substance/products				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

2.5. Type of preparation				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(6)		ES: No comments		Addressed.

2.6. Description of the recipe for the product to be used				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

2.7. Function on plant protection				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

3. Uses of the substance and its product

3.1. Field of use				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(1)		DE: The second sentence needs to be corrected: neither plant strengthening nor fungicidal effects are intended but insecticidal effects.	Corrected.	The sentence was changed to: "*SUCROSE / SACCHAROSE* water solution is intended to be used as plant strengtheners with insecticidal effects"
3(2)		ES: No comments		Addressed.

3.2. Effects on harmful organisms or on plants				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

3.3. Summary of intended uses				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(3)	3.3. Summary of intended uses, column "Example product name as available on the market", p.13	EFSA: the product as available on the market is the sucrose - solid table sugar, therefore the box should not state "solution of sucrose"	Corrected.	Addressed.
3(4)	3.3. Summary of intended uses, p.13	EFSA: the asterisks put in the table do not correspond to the explanations below the table (e.g.*"** e.g. The product is a plant homogenate extracted with hot*	Corrected.	Addressed: comments deleted, however the corresponding *s were not removed from the heading of the table

3.3. Summary of intended uses				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		water and filtered (decoction)" does not make sense).		

4. Classification and labelling of the substance

Classification and labelling of the substance				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5. Impact on Human and Animal Health

5.1. Effects having relevance to human and animal health arising from exposure to the substance/its products or to impurities				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(1)	General comment	EFSA: the substance is food grade and, although the reported data are extremely limited, it is not expected to give any health concern.	Included in BSA.	Sucrose meets the criteria for definition of 'food' as defined in Art.2 of Regulation 178/2002.

5.2. Toxicokinetics and metabolism in humans				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.3. Acute toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.4. Short–term toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.5. Genotoxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.6. Long-term toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.7. Reproductive toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.8. Neurotoxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.9. Toxicity studies on metabolites				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.10. Medical Data adverse effects reported in humans				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.11. Additional Information related to therapeutic properties or health claims				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.12. Additional information related to use as food				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.13. Acceptable daily intake, acute reference dose, acceptable operator exposure level				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.14. Impact on human and animal health arising from exposure to the substance or impurities contained in it				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

6. Residues

Residues				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
6(1)		ES: No comments		

7. Fate and Behaviour in the environment

Fate and Behaviour in the environment				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7(1)	Section 7. Fate and behaviour into the environment.	EFSA: An EU evaluation relevant for the natural environment is not referred to and therefore is probably not available. Therefore derogation from Article 4 of the Regulation is not possible and risk assessments for non-target organisms are necessary.	Rank Chemicals by Reported Environmental Releases in the United States : No data on environmental releases in Scorecard. • Occurs in low percentages in honey and maple sap • Sugar cane contains from 15-20% and sugar beet from 10-17% sucrose • The quantity of sucrose synthesized by all plants on earth is estimated to be 150 x 10E+9 t/year.	Addressed Derogation from Article 4 of the Regulation is not possible as an EU evaluation relevant for assessing risk to the natural environment has not been referred to. An assessment based on hazard identification for non-target organisms is presented in section 8.
7(2)	Section 7. Fate and behaviour into the environment.	EFSA: Natural origin of a substance does not preclude environmental risk and is not usually acceptable as a waiver, if not supported by data on natural background levels and its relation with the amounts applied for the proposed use. Nevertheless, taking into account the substance, the uses and application rates proposed, it seems that such a case could be easily elaborated by the applicant in this case.	1- The quantity of sucrose synthesized by all plants on earth is estimated to be 150 x 10E+9t/year. 2- 10 g of saccharose / ha, as one application consist in, means 1 mg/m² at the maximum on soil of a non-biocide, non-toxic, naturally biosynthesized sugar (sucrose / saccharose). 3- Numerous metabolites, including sucrose produced by the plant through the leaf cuticle and the same tree bark, and are naturally present in the leaf surface. The amounts of sucrose vary with photosynthesis and also for the apple with variety. They remain low and are of the order of what is sprayed. However, quantities may be greater with the phenomenon of leaching. Rain, dew	Information that can be traced back to observations and measurements have not been provided. The reference cited (Tukey 1958) has not been provided. Whilst it is accepted that plant leaves may exude sugars, especially when insects such as aphids are present, no observations or measurements relating to this have been provided or cited. Whilst it is accepted that plants synthesise huge quantities of sucrose, this sucrose is retained within plant cells / tissues. Information regarding amounts that might be present on leaf surfaces and or reach other environmental compartments, not retained within cells, have not been provided. In Europe the quantities of sugars that might be leached in forests from vegetation to soils is not expected to bear

Fate and Behaviour in the environment				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
			accelerate the release of these metabolites are leached. In the tropics the leached amounts of sugars can be several tons per hectare and go into the ground (see Tukey 1958). 4 - The amounts of sucrose in the leaf surface are not altered by the application of sucrose compared to control 24h, 6 days and 20 days after spraying. So NOTHING is changed in the space 24 with regard to the composition of sucrose on the surface of leaves.	any resemblance to that which occurs in tropical rain forests.
7(3)		ES: No comments		Addressed.

8. Effects on non-target species

8.1. Effects on terrestrial vertebrates				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)	Section 8, Effects on non-target organisms	EFSA: An EU evaluation relevant for ecotoxicology is not referred to and therefore is probably not available. Therefore derogation from Article 4 of the Regulation is not possible and risk assessments for non-target organisms are necessary.	• The quantity of sucrose synthesized by all plants on earth is estimated to be 150 x 10E+9 t/year. • Additionally plants smashed, spilled and falling in rivers are usual.	Addressed An EU evaluation relevant for ecotoxicology is not referred to and therefore is probably not available. However, considering the nature of the active substance, no specific information concerning the ecotoxicology is necessary.
8(2)	Section 8.1, Risk assessment for birds	EFSA: A risk assessment is considered relevant as the proposed use can lead to exposure to birds. Therefore, it would be more transparent to explain the reasons why an avian risk assessment is not considered necessary.	Many fresh fruits contain high levels of sucrose, including nectarines, mangoes, jackfruit, peaches, cantaloupe, apricots and bananas. Sucrose makes up about 73 percent of the 8.5 g of total sugar in 100 g of fresh apricots and about 67 percent of the 14.8 g of total sugar in 100 g of mangoes. Bananas contain 15.6 g of total sugar, but sucrose makes up only 42 percent of that total. All these fruits are eaten by birds.	It is noted that also the bird species other then frugivorous can be likely exposed to sucrose/saccharose following the representative uses in sweet maize fields and apple orchards. Nevertheless, Considering the lack of toxicity to mammals, this substance it is not expected to be toxic to birds. Therefore, overall, the risk to birds can be considered as low.

8.2. Effects on aquatic organisms				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(3)	Section 8.2, Risk assessment for aquatic organisms	EFSA: A risk assessment is considered relevant as the proposed use can lead to exposure to surface water. Therefore, it would be more	No data, no toxic cases reported. Example of sucrose use with fish: Doudoroff P. et al. 1964 Trout production in an experimental stream enriched with	Addressed See 8(1)

8.2. Effects on aquatic organisms				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		transparent to explain the reasons why a risk assessment for aquatic organisms is not considered necessary.	sucrose. *J Wildlife Manage*: 617-660	

8.3. Effects on bees and other arthropods species				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(4)	Section 8.3, Risk assessment for non-target arthropods	EFSA: No assessment has been provided to address the risk to non-target arthropods other than honey bees. Some form of explanation as to why the proposed use of sucrose poses as low risk to non-target arthropods should be provided.	• No data found, although sucrose solutions are used commonly for control solution in biocide evaluation. This should be a proof of non biocidal properties of sucrose, if necessary.	Addressed See 8(1)

8.4. Effects on earthworms and other soil macroorganisms				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(5)	Section 8.4, Risk assessment for earthworms	EFSA: A risk assessment is considered relevant as the proposed use can lead to exposure to soil. Therefore, it would be more transparent to explain the reasons why a risk assessment for earthworms is not considered necessary.	Tentative of explanation could be found in Zirbes L. Mescher M. Vrancken V. Wathelet JP. Verheggen F. Thonart P. Haubruge E. 2011 Earthworms Use Odor Cues to Locate and Feed on Microorganisms in Soil, PLoS ONE 6(7): e21927 Chemoreceptors have been identified on	Addressed See 8(1)

8.4. Effects on earthworms and other soil macroorganisms				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
			the prostonium and the buccal epithelium of earthworms and have been shown to detect sucrose, glucose and quinine.	

8.5. Effects on soil microorganisms				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

8.6. Effects on other non-target organisms (flora and fauna)				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(6)	Section 8.1, Risk assessment for non-target terrestrial plants	EFSA: A risk assessment is considered relevant as the proposed use can lead to exposure to of non-target terrestrial plants. Therefore, it would be more transparent to explain the reasons why a risk assessment for non-target terrestrial plants is not considered necessary.	Automated negative comment or real question? The quantity of sucrose synthesized by all plants on earth is estimated to be 150 x 10E+9 t/year.	Addressed See 8(1)

8.7. Effects on biological methods of sewage treatment				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

9. Overall conclusions with respect of eligibility of the substance to be approved as basic substance

Overall conclusions with respect of eligibility of the substance to be approved as basic substance				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

10. Other comments

Other comments				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

ABBREVIATIONS

BSA	basic substance application
EFSA	European Food Safety Authority
EU	European Union
ITAB	Institut Technique de l'Agriculture Biologique
m	metre
mg	milligram