EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Safety of the food chain
Pesticides and Biocides

Basic Substance
fructose
SANCO/12680/2014– rev. 3
17 July 2020[1]

Final Review report for the basic substance fructose
Finalised in the Standing Committee on Plants, Animals, Food and Feed
at its meeting on 14 July 2015 and amended on 17 July 2020
in view of the approval of fructose as basic substance
in accordance with Regulation (EC) No 1107/2009

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of fructose made in the context of the assessment of the substance provided for in Article 23 of Regulation (EC) No 1107/2009[2][3] concerning the placing of plant protection products on the market, with a view to the possible approval of this substance as basic substance.

In accordance with the provisions of Article 23(3) of Regulation (EC) No 1107/2009, the Commission received on 12 March 2014 an application from ITAB, hereafter referred to as the applicant, for the approval of the substance fructose as basic substance.

The application and attached information were distributed to the Member States and European Food Safety Authority (EFSA) for comments. The applicant was also allowed to address collated comments and provide further information to complete the application, which was finalised in the new version of July 2014.

In accordance with the provisions of Article 23(4) of Regulation (EC) No 1107/2009 the Commission requested scientific assistance on the evaluation of the application to EFSA, who delivered its views on the specific points raised in the commenting phase.

EFSA submitted to the Commission the results of its work in the form of a technical report for fructose on 24 October 2014[4].

The Commission examined the application, the comments by Member States and EFSA and the EFSA Technical report on the substance together with the additional information and

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1 The Standing Committee on Plants, Animals, Food and Feed took note of revision 3 of the review report on 17 July 2020. The review report was amended to include the extension of uses on apple, sweet corn, grain corn and grape vine as an insecticide and fungicide (see chapter 5 and Appendix II).

2 Does not necessarily represent the views of the Commission.

3 OJ L 309, 24.11.2009, p. 1-50.

4 European Food Safety Authority, 2014; Outcome of the consultation with Member States and EFSA on the basic substance application for fructose for use in plant protection on apple trees with indirect action in the control of insects. EFSA supporting publication 2014:EN-684. 27 pp.

comments provided on it by the applicant, before finalising the review report, which was referred to the Standing Committee on Plants, Animals, Food and Feed for examination. The draft review report was finalised in the meeting of the Standing Committee of 14 July 2015.

In August 2018, the Commission received from l'Institut Technique de l'Agriculture Biologique (ITAB) and from CETU Innophyt, UFR Faculté des sciences et techniques an application for the extension of the use of fructose as an insecticide and fungicide. For this application for extension of use, the Commission did not seek the assistance of EFSA due to the nature of the substance and the extent of the request. The current amended review report was finalised in the meeting of the Standing Committee of 17 July 2020.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the EFSA technical report on the first application, and the comments and clarifications submitted (background document C), all these documents are also considered to be part of this review report.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, has been developed in support of the **Commission Implementing Regulation (EU) No 2015/1392**[5] concerning the approval of fructose as basic substance under Regulation (EC) No 1107/2009.

The review report will be made available for public consultation by any interested parties.

Without prejudice to the provisions of Regulation (EC) No 178/2002[6], in particular with respect to the responsibility of operators, following the approval of fructose as basic substance, operators are responsible for using it for plant protection purposes in conformity with the legal provisions of Regulation (EC) No 1107/2009 and with the conditions established in the sections 4, 5 and Appendixes I and II of this review report.

EFSA has made available to the public all background documents and the final Technical Report of EFSA, as well as the application without the Appendixes and excluding any information for which confidential treatment is justified in accordance with the provisions of Article 63 of Regulation (EC) No 1107/2009.

Products containing exclusively one or more basic substances do not require authorisation in line with the derogation set under Article 28 of Regulation (EC) No 1107/2009. As a consequence, no further assessment will be carried out on such products. However, the Commission may review the approval of a basic substance at any time in conformity with the provisions of Article 23(6) of Regulation (EC) No 1107/2009.

5 OJ L 215, 15.8.2015, p. 34.

6 OJ L 31, 1.2.2002 p. 1-24 - Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

3. Overall conclusion in the context of Regulation (EC) No 1107/2009

The overall conclusion based on the application, including the results of the evaluation carried out with the scientific assistance of EFSA, is that there are clear indications that it may be expected that fructose fulfils the criteria of Article 23.

Fructose is the common name for β-D-fructofuranose.

Fructose fulfils the criterion of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002. A Codex Alimentarius Commission standard exists for sugars, including fructose (CODEX STAN 212-1999 Codex standard for sugars, adopted in 1999, amendment in 2001).

Considering the EFSA technical report on the basic substance application for fructose, the rate of application and the conditions of use which are described in detail in Appendix I and II, it is concluded that the use of fructose would not lead to concerns for human health. Furthermore, no residues are expected as the conditions of use would not significantly increase the background level due to the natural occurrence of the substance.

Fructose is not a substance of concern and does not have an inherent capacity to cause endocrine disrupting (according to the interim criteria in Regulation 1107/2009), neurotoxic or immuno-toxic effects and is not predominantly used for plant protection purposes but nevertheless is useful in plant protection in a product consisting of the substance and water. Finally, it is not placed on the market as a plant protection product.

It can be concluded that the substance has neither an immediate or delayed harmful effect on human or animal health nor an unacceptable effect on the environment when used in accordance with the supported uses as described in Appendix II.

In fact, these indications were reached within the framework of the uses which were supported by the applicant and mentioned in the list of uses supported by available data (attached as Appendix II to this review report) and therefore, they are also subject to compliance with the particular conditions and restrictions in sections 4 and 5 of this report.

Extension of the use pattern beyond those described above will require an evaluation at Community level in order to establish whether the proposed extensions of use can still satisfy the requirements of Article 23 of Regulation (EC) No 1107/2009.

The following point was considered as open by EFSA (2014) for fructose in the original dossier, however the risk is considered small or negligible for the following reason:

- Natural back ground levels of fructose in different environmental compartments. It is considered that the conditions of use would not significantly increase the background level due to the natural occurrence of the substance and the low application dose per hectare.

The application for extension of use concerns some alignments with the approved basic substance sucrose as an elicitor of plant defence mechanism, and an extension to the use on grapevine and the use on maize (grain corn). Based on the elements mentioned above, it can be assumed that the additional uses of fructose referred to in Annex II also fulfil the criteria of Article 23.

4. Identity and biological properties

The main properties of fructose are given in Appendix I.

The active substance shall have a purity as food grade.

It has been established that for fructose as notified by the applicant, no relevant impurities are considered, on the basis of information currently available, of toxicological, ecotoxicological or environmental concern.

5. Particular conditions to be taken into account in relation to the uses as basic substance of fructose

Fructose must be identified by the specifications given in Appendix I and must be used in compliance with conditions of supported uses as reported in Appendixes I and II.

The following conditions for use deriving from assessment of the application have to be respected by users:

- Only uses as basic substance being an elicitor of the crop's self-defence mechanisms are approved.

Use of fructose must be in compliance with conditions specified in the Appendixes I and II of this review report and the maximum application rate of fructose for a single treatment is: 100 g/ha.

On the basis of the proposed and supported uses (as listed in Appendix II), no particular issues have been identified.

The identification of fructose as food ingredient implies that the Regulation (EC) No 178/2002 on food safety applies.

6. List of studies to be generated

No further studies were identified which were at this stage considered necessary.

7. Updating of this review report

The information in this report may require to be updated from time to time to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 23 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on Plants, Animals, Food and Feed, as appropriate, in connection with any amendment of the approval conditions for fructose in Part C of Annex of the Regulation (EC) No 540/2011.

8. Recommended disclosure of this review report

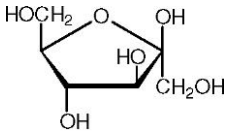
Considering the importance of the respect of the approved conditions of use and the fact that a basic substance will be not placed on the market as plant protection product, hence, no further assessment will have to be carried out on it, it is very important to inform not only applicants but also potential users on the existence of this review report.

It is therefore recommended that the competent authorities of Member States will make available such report to the general public and operators by means of their national relevant websites and by any other appropriate form of communication to ensure that the information reaches potential users.

APPENDIX I

Identity and biological properties

FRUCTOSE

Common name (ISO)	fructose
Chemical name (IUPAC)	β-D-fructofuranose
Chemical Name (CA)	NA
CAS No	57-48-7
EC No	200-333-3
Codex alimentarius	CODEX STAN 212-1999
Minimum purity	Food grade
Molecular formula	$C_6H_{12}O_6$
Relevant impurities	Not applicable
Molecular mass and structural formula	180.156 g/mol  β-D-fructofuranose
Mode of Use	Fructose as specified above to be used in cold water solution for application on crops as listed in Appendix II.
Preparation to be used	Fructose to be diluted in compliance with rate of application reported in Appendix II.
Function of plant protection	Elicitor, having an insecticidal and fungicidal effect via the stimulation of natural defence mechanisms.

APPENDIX II
FRUCTOSE

Crop and/or situation (a)	Member State	Example product name as available on the market	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	g a.i./hl min max (g/hl)	Water l/ha min max	g a.i./ha min max (g/ha) (l)	g a.i./ha min max (g/ha) (l)		
Apple trees/ orchards *Malus pumila Malus domestica* MABPM	All MS	*Fructose*	F	fruits borer like Codling moth: *Cydia pomonella* * CARPPO	Water Soluble Powder (SP)	**998 to 1000**	Foliar application spraying early in the morning before 9 AM (solar time)	From spring BBCH stage 65	5 to 7	21 days	**10**	600 to 1000	60 to 100	300 to 700	None	Cold Water Solution prepared just before application
Maize (Corn grain) *Zea mays* subsp. mays L. (ZEAMS) Sweet Maize (Sweet corn) *Zea mays L.* convar. saccharata Koern (ZEAMX)				Symphylans *Scutigerella immaculata* * SCUTIM			Treatment in seedling line before 9 AM (solar time)	–	1	–	**10**	40	4	4		
							Foliar application Spraying early in the morning before 9 AM (solar time)	1 application at 2-3 leaves (BBCH 12-13) + 1 application at 4 leaves (BBCH 14)	2	1 to 2 BBCH stages	**10**	82	8,2	16,4		
Zea mays subsp. mays L.																

Grapevine *Vitis vinifera* VITVI				Vine leafhopper *Scaphoïdeus titanus* * SCAPLI			Foliar application spraying early in the morning before 9 AM (solar time)	From the BBCH stage 17 to 57	3	7 days	**10**	150	15	45		
Grapevine *Vitis vinifera*				Downy mildew *Plasmopara viticola* * PLASVI			Foliar application spraying early in the morning before 9 AM (solar time)	From 1st shoots to cluster tightening Spring (BBCH 10- 57)	up to 12	15 days	**10**	100 to 200	10 to 20	10 to 240		

* Indirect action, no direct insecticide and fungicide properties

(a) For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* pests as biting and sucking insects, soil born insects, foliar fungi, weeds or plant elicitor
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR) etc..
(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO)
(j) Growth stage at 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
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval