



EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Food and Feed Safety Innovation
Pesticides and Biocides

COMMISSION STAFF WORKING DOCUMENT¹

Basic Substance
Sunflower Oil

SANTE/10875/2016
7 October 2016

Final

Review report for the basic substance sunflower oil

Finalised in the Standing Committee on Plants, Animals, Food and Feed
at its meeting on 7 October 2016

in view of the approval of sunflower oil as basic substance in accordance with
Regulation (EC) No 1107/2009

Sunflowerseed oil (sunflower oil) is derived from sunflower seeds (seeds of *Helianthus annuus* L.).

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of sunflower oil, made in the context of the assessment of the substance provided for in Article 23 of Regulation (EC) No 1107/2009² 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 4 September 2015 an application from ITAB (Institut Technique de l'Agriculture Biologique), hereafter referred to as the applicant, for the approval of the substance sunflower oil 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 January 2016.

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

¹ Does not necessarily represent the views of the Commission.

² OJ L 309, 24.11.2009, p. 1-50.

EFSA submitted to the Commission the results of its work in the form of a technical report for sunflower oil on April 2016³.

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 comments provided on it by the applicant, before finalising the current draft 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 on 7 October 2016.

Given the importance of the EFSA technical report, the comments, additional information 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 **Commission Implementing Regulation (EU) 2016/1978⁴** concerning the approval of sunflower oil 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 178/2002⁵, in particular with respect to the responsibility of operators, following the approval of sunflower oil 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 the conditions established in the sections 4, 5 and Appendices I and II of this review report.

EFSA will make available to the public all background documents and the final Technical Report of EFSA as well as the application without the Appendices 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.

³ Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for sunflower oil for use in plant protection as insecticide on fruit trees, grapevine, potato, vegetables and post-harvest treatment on stored grains and as fungicide on vegetables and grapevine. 2016:EN-1023.51 pp.

⁴ OJ L 305, 12.11.2016, p. 23–25.

⁵ 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 sunflower oil fulfil the criteria of Article 23.

Sunflower oil fulfils the criteria of a ‘foodstuff’ as defined in Article 2 of Regulation (EC) No 178/2002.

Considering the EFSA technical report on the basic substance application for sunflower oil, 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 sunflower oil would not lead to concerns for human health and environment. Furthermore, no residues are expected as the conditions of use would not significantly increase the background level due to the natural occurrence of the fatty acids of which it is composed.

Sunflower oil 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 immune-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 points were considered as open by EFSA (2016) for sunflower oil, reasons follow to explain why the risk is considered negligible:

Chapter 3 – Field of use

- *The potential phyto-toxicity of sunflower oil could not be excluded.*

On the basis of condition of use and bibliography provided on efficacy, one supported use could be retained: on tomatoes.

Chapter 5 – Impact on human and animal health

- *As food stuff, sunflower oil does not present concerns regarding human and animal health. However once applied on crops, it forms degradation, (photo)oxidation, transformation products (e.g. by lipid peroxidation) that may be of concern to human health (including genotoxic and/or carcinogenic compounds) that are relevant to consumers, workers and possibly residents exposed to these degradation products. No*

quantification is available on the amount of potentially toxic compounds formed after sunflower oil applications.

Considering previous EFSA conclusions on similar active substances such as rape seed oil and fatty acids, it is expected the substance to be ready biodegradable, confirmed also by the evaluation under REACH. Moreover, given the properties of the substance, the rate of application and the conditions of use in tomato it is expected that the application will not result in a significant increase of the natural level occurrence of the substance components and their possible degradation compounds.

Chapter 7 – Fate and behaviour in the environment

- *Environmental exposure and effects of sunflower oil and its degradation products as result of the proposed application rates over a number of seasons need to be assessed. Particular attention should be given to contamination of groundwater by degradation/transformation products of sunflower oil.*

Ready biodegradability of the substance is reported in the REACH evaluation of existing entries in Annex IV⁶. As above-mentioned, given the rate of application and the conditions of use it is expected that the application will not result in a significant increase of the natural level occurrence of the substance components and their possible degradation compounds.

Chapter 8 – Effects on non-target species

- *In the ecotoxicology area the submitted information was considered not sufficient to perform a solid risk assessment.*

Considering the composition of sunflower oil and its biodegradability, the rate of application and the conditions of use it is expected a low risk for non-target organisms.

4. Identity and chemical properties

The main properties of sunflower oil are given in Appendix I.

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

Food grade specifications must be complied with.

⁶ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (O.J. L 396, 30.12.2006, p.1).

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

Sunflower oil must be identified by given specifications in Appendix I and must be used in compliance with method of preparation and condition of use as reported in Appendices I and II.

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

- Only use as basic substance being a fungicide for tomato crops are is approved;
 - Period of treatment should be avoided during flowering time.

Use of sunflower oil must be in compliance with conditions specified in the Appendices I and II of this review report.

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

The identification of sunflower oil 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 Article 23 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on Plants, Animals, Food and Feed, in connection, as appropriate, with any amendment of the approval conditions for sunflower oil in Part C of Annex of the Regulation (EC) No 540/2011⁷.

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 not be placed on the market as a plant protection product and 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 of the substance 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.

⁷ OJ L 153, 11.6.2011, p. 1–186.

APPENDIX I

Identity and biological properties

SUNFLOWER OIL

Common name (ISO)	Not available.
Chemical name (IUPAC)	Not relevant, the substance is a complex mixture.
Chemical name (CA)	Not relevant, the substance is a complex mixture.
Common names	Sunflower oil
CAS No	8001-21-6
CIPAC No and EEC No	Not available.
FAO SPECIFICATION	Not available.
Purity	Purity is depending on the origin. Oleic acid: 14-40% linoleic acid: 48-74% mid-oleic acid sunflower oil: min. 70% oleic acid (as % of total fatty acids) high oleic acid sunflower oil: min. 75% oleic acid (as % of total fatty acids)
Molecular formula	Not relevant, the substance is a complex mixture.
Molecular mass and structural formula	Not relevant, the substance is a complex mixture.
Mode of Use	Spray applications
Preparation to be used	Oil dispersion (OD) 0,1- 0,5 % (v/v) Sunflower oil as specified above to be used in cold water solution for application on crops as listed in Appendix II.
Function of plant protection	Fungicide.

APPENDIX II

List of uses supported by available data SUNFLOWER OIL

Crop and/or situation (a)	Member State or Country	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)	kg a.i./hl min max	Water l/ha min max	kg a.i./ha min max	kg a.i./ha min max (l)		
Tomato <i>Lycopersicum Esculentum</i>	All Member States	Sunflower oil	F	Tomato powdery mildew <i>Oidium neolycopersici</i>	Oil Dispersion (OD)	915 to 923	foliar application spraying	BBCH 32-37 then BBCH 61-71	2 to 4	8	0.092 (0.1L) to 0.46 (0.5L)	500 to 1000	0.46 (0.5L) to 4.6 (5L)	0.92 (1L) to 18.4 (20L)	2	* ****

*** Precautions must be taken to avoid overwatering and spilling of the dispersion**

****** Period of treatment should be avoided during flowering time**

- * For uses where the column „Remarks. As above or other conditions to take into account
- (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,
- (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 between the plant – type of equipment used must be indicated