TECHNICAL REPORT

APPROVED: 8 April 2016 PUBLISHED: 15 April 2016

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

European Food Safety Authority (EFSA)

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 sunflower oil 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 sunflower oil as a basic substance 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. The current report summarises the outcome of the consultation process organised by EFSA and presents EFSA's scientific views on the individual comments received.

Key words: sunflower oil, basic substance, application, consultation, plant protection, pesticide, insecticide, fungicide

Requestor: European Commission

Question number: EFSA-Q-2016-00191

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Summary

Sunflower oil 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 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 in 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 4 March 2016, EFSA was asked to organise a consultation on the basic substance application for sunflower oil, 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 three months of receipt of the specific request.

A consultation on the basic substance application for sunflower oil, organised by EFSA, was conducted with Member States via a written procedure in September – November 2015. Subsequently, EFSA also provided comments and the applicant was invited to address all the comments received in the format of a reporting table and to provide an application update as appropriate, within a period of 30 days.

The current report summarises the outcome of the consultation process organised by EFSA on the basic substance application for sunflower oil and presents EFSA's scientific views on the individual comments received in the format of a reporting table.

Sunflower oil (sunflowerseed oil) is derived from sunflower seeds (seeds of *Helianthus annuus* L.). Its composition is depending on the geographical and/or climatic variations. High oleic acid sunflower oil is produced from high oleic acid oil-bearing seeds, mid-oleic acid sunflower oil is produced from mid-oleic acid oil-bearing sunflower seeds of varieties derived from sunflower seeds. Sunflower oil is mainly a triglyceride, but also contains lecithin, tocopherols, carotenoids and waxes. The potential phytotoxicity of sunflower oil could not be excluded.

The proposed uses of sunflower oil are spray applications as an insecticide on fruit trees, grapevine, potato, vegetables and post-harvest treatment on stored grains and spray applications as fungicide on vegetables and grapevine.

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.

Information on the degradation products of sunflower oil produced into the environment and its effects to human and animal health needs to be provided an assessed. 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. Risk managers should ensure that sunflower oil is not used in combination with other substances (even if basic) as e.g. surfactants. For the representative indoor use to stored grains, it may be assumed that the application can be managed in a way that prevents significant exposure to surface water.

In the ecotoxicology area the submitted information was considered not sufficient to perform a solid risk assessment. The risk to birds and mammals from the representative field uses of sunflower oil was not sufficiently addressed due to the potential occurrence of transformation products present in residues after environmental/sunlight exposure. A low risk to aquatic organisms could not be concluded for all the representative field uses. A low risk to bees was concluded only when mitigation

measures are applied (i.e. treatment should be avoided during the flowering of the crop and weeds in the field). The risk to earthworms, other macroorganisms and non-target terrestrial plants for the representative field uses should be further addressed. A low risk to soil microorganisms could not be concluded based on the available information for the representative field uses.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1107/2009[1] (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.

Sunflower oil is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from Institut Technique de l'Agriculture Biologique (ITAB) for approval as a 'basic substance' for use in plant protection as an insecticide on fruit trees, grapevine, potato, vegetables and post-harvest treatment on stored grains and as a fungicide on vegetables and grapevine (ITAB, 2015).

The European Food Safety Authority (EFSA) organised a consultation with Member States on the basic substance application for sunflower oil, which was conducted via a written procedure in September – November 2015. The comments received, including EFSA's comments, were consolidated by EFSA in the format of a reporting table. Subsequently, the applicant was invited to address the comments in column 4 of the reporting table and to provide an application update as appropriate. The comments received and the response of the applicant thereon, together with the application update submitted by the applicant, were considered by EFSA in column 5 of the reporting table.

The current report aims to summarise the outcome of the consultation process organised by EFSA on the basic substance application for sunflower oil 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 sunflower oil 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, 2016).

1.2. Interpretation of the Terms of Reference

On 6 March 2013 the European Commission requested 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 4 March 2016, EFSA was asked to organise a consultation on the basic substance application for sunflower oil, 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 being prepared by EFSA. The agreed deadline for providing the finalised report is 4 June 2016.

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.

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

2. Assessment

The comments received on the basic substance application for sunflower oil and the conclusions drawn by EFSA are presented in the format of a reporting table.

The comments received are summarised in columns 2 and 3 of the reporting table. The applicant's considerations of the comments, where available, are provided in column 4, while EFSA's scientific views and conclusions are outlined in column 5 of the table.

The finalised reporting table is provided in Appendix A of this report. In addition, an overview table on the identity and biological properties of the substance and the list of intended uses in plant protection (GAP table) are provided in Appendix C and D, respectively.

Documentation provided to EFSA

1. ITAB, 2015. Basic substance application on sunflower oil submitted in the context of Article 23 of Regulation (EC) No 1107/2009. August 2015. Documentation made available to EFSA by the European Commission.

2. ITAB, 2016. Basic substance application update on sunflower oil submitted in the context of Article 23 of Regulation (EC) No 1107/2009. January 2016. Documentation made available to EFSA by the applicant.

Abbreviations

a.s.	active substance
DAR	draft assessment report
GAP	good agricultural practice
EFSA	European Food Safety Authority
EU	European Union
FFA	free fatty acids
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
MRL	maximum residue level
MS	Member State
NESTI	national estimated short-term intake
OSR	oilseed rape
PBI	plant-back interval
PEC	predicted environmental concentration
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
PRIMo	Pesticide Residue Intake Model
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RMS	rapporteur Member State
TMDI	theoretical maximum daily intake

Appendix A – Collation of comments from Member States and EFSA on the basic substance application for sunflower oil 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 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1(1)		UK: We think that from a human health point of view Art 23 is met as the substance is a foodstuff. Therefore there is no concern for human health from its use as PPP. However, we would like to comment on the template and the way the data are presented. For most headings, references are given and described, with no overall conclusion about the relevance of such data or the conclusion to be drawn from such data. This is essential.	UK: The application should be updated to address this comment, but we do realise that this point might be something for future basic substance applications.	Conclusions at each chapters are expended	Addressed: An updated application was submitted.
1(2)	3.4 Summary of intended uses	DE: The intended uses are comparable to those for the active substance rapeseed oil. Why is sunflower oil considered as basic substance whereas rapeseed oil is treated as an active substance?	Such similar substances should be assessed in the same procedure under Regulation (EC) No 1107/2009.	DE MS request is pure discrimination against ITAB as applicant. No such question was asked to DK MS for sodium bicarbonate BSA regarding to approved potassium bicarbonate.	Addressed: This is a risk management decision.
1(3)		ES: No comments			Addressed.

General					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
1(4)		NL: No comments			Addressed.

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

2.1. 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** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
2(1)	2.1.5. Description and specification of purity of the active substance and product	ES: It is reasonable to think that sunflower oil contains free oleic acid, as result of the important content in this unsaturated fatty acid in the triglyceride. Therefore, the content of free oleic acid should be established, taking into account that oleic acid is currently approved as active substance.		Ke, 1978 Free acid determination Method and Sherazi, 2014, and new CODEX reference are added	Addressed: Reference to CODEX STAN 210-1999 was introduced, where the oleic acid content and the fatty acid composition of sunflower oils, as determined by gas liquid chromatography from authentic samples 1 (expressed as percentage of total fatty acids) are presented.
2(2)	2.1.5. Description and specification of purity of the active substance and product	ES: It might also be suitable to establish a maximum acid value in sunflower oil, since this is an important indicator of the content of free fatty acids.		New CODEX reference are added	Addressed: The introduction of the reference to the CODEX STAN 210-1999 implies that the sunflower oil should meet the requirements of this standard. The max. acidity was introduced in the updated

2.1. 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** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
					application in point 2.1.6
2(3)	2.1.7.1	NL: The data presented here does not correspond to the data in the reference given. Please clarify. Furthermore, in our opinion this data might be better placed at 2.1.6		Data migrated to 2.1.6	Addressed: Point 2.1.6 was updated in the updated application.
2(4)		EFSA: The sunflower oil has to be food grade.		Title corrected	Addressed: The proposed substance should be food grade.

2.2. Current Former and in case proposed trade names					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
2(5)		ES: No comments			Addressed.
2(6)		NL: No comments			Addressed.

2.3. Manufacturer of the substance/products					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
2(7)		ES: No comments			Addressed.
2(8)		NL: No comments			Addressed.

2.4. Type of preparation					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
2(9)		ES: No comments			Addressed.
2(10)		NL: No comments			Addressed.

2.5. 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** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
2(11)		ES: No comments			Addressed.
2(12)	2.5 and 2.6	NL: In section 2.5 a dilution of 1 to 3% is stated while in section 2.6 2 to 3% is given. Please clarify.		Corrected to be consistent with GAP Table	Addressed: The proposed concentration range was updated in the revised application.

3. Uses of the substance and its product

NL: no comments.

3.1. Field of use					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
3(1)		DE: No specific data were provided which allow a detailed description of the cited GAPs.		More references are provided	Addressed: The references were updated in the revised application.

3.1. Field of use

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(2)		ES: No comments			Addressed.
3(3)	3.4 Summary of intended uses	EFSA: Please amend the units in the column for 'Application rate per treatment' and 'total rate'. It should be clearly indicated whether the application rate is in terms of kilograms or grams. Currently both units are indicated.		Units corrected in GAP Table	Addressed: The units in the GAP table were corrected.

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 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(4)		DE: The literature cited and submitted does not provide the prediction of sufficient efficacy in the intended uses.		Question is not in coherence with initial request of equivalence with rapeseed oil. More references were collected anyway.	Addressed: The literature search was compiled on the consideration that sunflower oil has similar mode of action as other oil-based products.
3(5)		ES: No comments			Addressed.
3(6)		EFSA: Efficacy data for the proposed uses have not been provided and should be provided.		More references are provided on repellence	Addressed: The literature search was compiled based on the consideration that sunflower oil has similar mode of action as other oil-based products.

3.3. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(7)		DE: No specific data were provided which allow the exclusion of potential phytotoxic effects.	Please provide reasons for your opinion that no phytotoxicity must be expected.	More references are provided, see §8 Sclar D. 1999	The provided references did not address the phytotoxicity of sunflower oil.
3(8)		ES: The units of "Aplication rate per treatment" and "Total rate" should be revised in GAP table.		Units corrected in GAP Table	Addressed: The GAP table was corrected.
3(9)		ES: Remarks; In the use as fungi static activity for grapevine Vitis vinifera it is specified that "PHI is due to avoid eventual effects on vinification". A similar phrase and the same days (14) should be included for this crop in the use as insecticide acaricide activity.		Corrected in GAP Table	Addressed: The GAP table was corrected.
3(10)		EFSA: Crop safety data have not been provided and should be provided.		More references are provided, see §8 Sclar D. 1999	See 3(7)

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 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
4(1)		NL: no comments.			Addressed

5. Impact on Human and Animal Health

NL: no comments.

5.1. Toxicokinetics and metabolism in humans

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
No comments.					

5.2. Acute toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
No comments.					

5.3. Short-term toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA		Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
No comments.					

5.4. Genotoxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
No comments.					

5.5. Long-term toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
No comments.					

5.6. Reproductive toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
No comments.					

5.7. Neurotoxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 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. Toxicity studies on metabolites

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(1)	5.8 toxicity studies on metabolites	EFSA: it is agreed that sunflower oil does not present health concern or may even present some health benefits. It is however noted that degradation/(photo)oxidation/	EFSA: Information of the effects of degradation/transformation products of sunflower oil produced into the environment on human and animal health needs to be provided and	FFA lit to 2% is included in specifications. New CODEX reference added REACH evaluation added.	The information given relates to the active substance but not to its degradation / (photo) oxidation/ transformation products potentially present in residues after environmental/

5.8. Toxicity studies on metabolites

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		transformation products of vegetable oils formed on treated plants in the environment may be of concern to human health (including genotoxic or carcinogenic effects) that are relevant as plant residues (EDER, 2002, see also comment 7.6 below).	assessed.		sunlight exposure. It is agreed that fresh vegetable oils are of no concern to human and animal health as food stuff, but human health concerns (including genotoxicity and carcinogenicity) may arise from its residues in crops (such as by lipid peroxidation). These residues are relevant to consumer, worker and possibly residential exposure to degradation products of sunflower oil.

5.9. Medical Data: adverse effects reported in humans

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.10. 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 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 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 use as food

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
No comments.					

5.12. 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 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
No comments.					

5.13. 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 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(2)	5.13, non-dietary exposure assessment	EFSA: the comment made on degradation products on plants in the environment may be relevant to worker and residential exposure assessments.	See 5(1)	Choe 2006 Reference provided, but 1-3% maybe less relevant than pure oil exposure uses as food for consumers and kitchen workers.	See 5(1)

6. Residues

Residues					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
3(1)		ES: No comments			Addressed.
3(2)		NL: No comments			Addressed.
3(3)		EFSA: No comments			The submitted assessment assumed that the sunflower oil will remain of food grade quality when applied in the field and therefore no information is made available or required on the actual composition /quality of the oil residues upon use as a PPP. EFSA notes that the conditions that go along with the use of sunflower oil in the field (oil being spread over a large surface and exposed to sunlight) will significantly promote photo-oxidation, hydrolysis and other degradation processes. Hence it is expected that the quality of the applied sunflower oil is significantly changing since conditions described above lead to a larger and more accelerated generation of oxidation products (e.g. aldehydes and ketones)

Residues					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
					compared to any potential rancidification that may set in cooking oils, margarines etc. used in the human diet. It is well-know that oxidative rancidity presents potential health hazards (see 5(1)) and therefore strict quality criteria apply to food grade vegetable oils for marketing. The information submitted with regard to the PPP use of sunflower oil is insufficient to conclude on a consumer risk assessment. It would have been desirable that information on the qualitative composition/ alteration of the oil under use conditions, expected exposure levels of consumers to oxidation products etc. had been made available to facilitate an assessment.

7. Fate and Behaviour in the environment

NL: no comments.

7.1 Fate and Behaviour in the environment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7(1)	Page 21	UK: The reference to inclusion of sunflower oil in the US EPA list of 'partially exempt chemicals' is not useful as the meaning and significance of this listing is not explained. According to the EPA website, "Chemical substances are included on this list only if EPA has determined that there is low current interest in the processing and use information for that substance." However, that has no obvious relevance for environmental fate and behaviour.	UK: Further explanation/discussion of how inclusion on the US EPA list of 'partially exempt chemicals' contributes to our understanding of fate and behaviour of sunflower oil when used as a pesticide.	Reference added Ştefănescu 2005 REACH evaluation added.	Addressed US EPA list of partially exempt substances is not relevant with respect to the assessment of potential adverse effects of the use of sunflower oil as a pesticide in EU.
7(2)	7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, ground water, surface water).	DE: We agree with the notifier: Vegetable oils, petroleum oils, and animal fats share common physical properties and produce similar adverse environmental effects. The notifier suggests to take precautions to avoid overwatering and spilling. If such precautions are necessary, can sunflower oil be assessed as a basic		Sunflower oil is a foodstuff, so an intrinsic basic substance (Reg. 178/2002). We work to regularize field uses of such substances. Why don't you take some times to do such work on the hundreds of illegal sale (regarding Reg. 1107/2009) of "pflanzenstärkungsmitteln" sold	The issue if sunflower oil can or not be formally considered a basic substance is a management / legal issue out of the scope of EFSA scientific assessment. EFSA agrees with Germany and the Notifier that vegetable oils,

7.1 Fate and Behaviour in the environment					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		substance?		as plant strengtheners (see Doc Sanco 1003/2000 rev.3) in DE.	petroleum oils, and animal fats share common physical properties and produce similar adverse environmental effects and that appropriate management is needed to prevent such adverse effects. Based on the available data it is not possible to perform a risk assessment to identify the needed management measures and / or its actual effectiveness. For the representative indoor use to stored grains, it may be assumed that the application can be managed in a way that prevents significant exposure to surface water.
7(3)		ES: It should be noted (included in remarks) that "Precautions must be taken to avoid overwatering and spilling of the dispersion".		Integrated in GAP	See 7(2)

7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, groundwater, surface water)					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
7(4)	Page 22 - 23	UK: The cited references are brief abstracts and provide little in the way of considering the levels in the studies with potential exposure when sunflower oil is used as a pesticide. It is unfortunate that the references appear to be related either to spillage of large volumes of vegetable oils with potential negative ecological impacts or possible use of large volumes of vegetable oils for remediation of contaminated land, with their own potential impacts. They appear to contribute little to our understanding on estimation of exposure of different environmental compartments of soil surface water or groundwater following use of sunflower oil as a pesticide or the resultant environmental risk.	UK: Further discussion of how the references may be used to consider environmental exposure following use of sunflower oil as a pesticide. It may be worth considering whether any lesson from the 'List 4' plant oils and plant extracts can be applied to this basic substance, although this could potentially apply to all areas of the assessment.	More references added REACH evaluation added.	EFSA agrees with the UK view that available information does not facilitate the understanding on estimation of exposure of different environmental compartments of soil, surface water or groundwater following use of sunflower oil as a pesticide or the resultant environmental risk. See also 7(2).
7(5)		UK: A reference in section 8.2		Reference included in 7.2.	Addressed

7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, groundwater, surface water)					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		(Pereira et al 2003) may be potentially relevant for behaviour in aquatic environments, although it is recognised that this is in a saltmarsh environment.			
7(6)		EFSA: A number of mild to severe adverse effects to the environment are listed in the application report (shared by sunflower oil and other vegetable and mineral oils). In the intended uses table a maximum use rate of 40 L / ha is proposed. However, no assessment is available to demonstrate that the use at these rates over a number of subsequent seasons has no adverse effect to the environment. Vegetal oils (as sunflower oil) can undergo autoxidation and photosensitized oxidation processes into the environment. Oxidation products and other	EFSA: Information on the degradation products of sunflower oil produced into the environment and its effects to human and animal health needs to be provided an assessed. (for potential oxidation products that can be formed into the environment see for eg. Choe, E.; Min, D.B. **Mechanisms and Factors For Edible Oil Oxidation**. *Comprehensible Reviews in Food Science and Food Safety. Vol 5, 2006, 106-186. http://onlinelibrary.wiley.com/doi/10.1111/j.1541-4337.2006.00009.x/pdf*) 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 the sunflower oil. If the oil is intended to be applied with	REACH evaluation added. No surfactant is allowed with basic substances	Information on the degradation products of sunflower oil produced into the environment and its effects to human and animal health needs to be provided and assessed. 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. Risk managers should ensure that sunflower oil is not used in combination with

7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, groundwater, surface water)					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		transformation products of vegetal oils are known to have health adverse effects. However, no assessment has been performed on potential degradation products of sunflower oil in the environment, its effects to human and animal health and its potential to contaminate soil and surface and ground water. In our opinion, this information is essential to assess the risks associated to the agricultural use of sunflower oil.	surfactants the effect of such surfactants on the environmental fat of the oil and its mobility would need to be assessed. For the representative indoor use to stored grains, it may be assumed that the application can be managed in a way that prevents significant exposure to surface water.	No surfactant is allowed with basic substances	other substances (even if basic) as eg. surfactants. For the representative indoor use to stored grains, it may be assumed that the application can be managed in a way that prevents significant exposure to surface water.
7(7)		ES: No comments			Addressed

8. Effects on non-target species

NL: no comments.

8.1. Effects on terrestrial vertebrates

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)	Page 23	UK: The statement 'no effect expected' is not considered sufficient to address the risks to birds and mammals. While a full toxicity dataset would not be required, Article 23 of Directive 1107 states: *'The application shall be accompanied by the following information:* *(a) any evaluations of its possible effects on human or animal health or the environment carried out in accordance with other Community legislation regulating the use of the substance; and* *(b) other relevant information on its possible effects on human or animal health or the environment.'*	Further consideration of this point is needed drawing on available data and any risk/hazard assessment carried out in accordance with other Community legislation regulating the use of sunflower oil for purposes other than for a plant protection product.	REACH evaluation added.	See 8(4)
8(2)	5.6. Reproductive toxicity + 8.1.2 Mammals	DE: The study of Santillán (2010) showed that the offspring of mice fed with a sunflower oil enriched diet were shorter than the control	Give a sound assessment of the risks for wildlife mammals and especially their reproduction in the field/orchard/storeroom when in		Addressed. The applicant did not submit any

8.1. Effects on terrestrial vertebrates

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		group and that puberty onset was delayed. This can seriously affect the populations of mammals in the areas treated with sunflower oil.	contact with sunflower oil.		response or comment with regard to the study of Santillán (2010). EFSA agrees that results should have been summarised in more detail. However it is noted that only one test item concentration was assessed and oils were added with butyl hydroxytoluene which was not added to the control diet. Moreover, the study did not show any significant difference in pup weights during lactation or at weaning. The difference with respect to the control in body length was 6.64%, 11% and 7.9% at 7, 14 and 21 post natal days. Regarding the onset of puberty in the offspring, the vaginal opening was delayed by 2 days (post-natal day 21 in the control and post natal day 23 in the sunflower treatment group). In the treatment group, the vaginal opening occurred in 100% of the offspring with one day of delay respect to the control. Overall it is considered that the mentioned results are

8.1. Effects on terrestrial vertebrates

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
					of debatable biological relevance. See also 8(4)
8(3)		ES: No comments			Addressed
8(4)	8.1.1 and 8.1.2, Effects on birds and mammals	EFSA: The statement "no effect expected" should be supported by a clear justification.	Some form of risk assessment and/or scientific justification should be submitted in order to explain why a low risk to birds and mammals (acute and reproductive) can be concluded for the representative uses of sunflower oil. Information on the toxicity could be taken from the literature (if available) and the mammalian toxicology assessment.	REACH evaluation added.	The assessment of the effects on birds and mammals was not provided by the applicant in the updated application. It was only reported that no effect is expected, but a scientific justification or any form of risk assessment was not submitted to support the statement. The REACH evaluation table was provided by the applicant and it included toxicological endpoints. However, they were mainly read across from corn oil and no study was provided. However, no significant risk is expected from the dietary exposure to sunflower oil of birds and mammals for the representative field uses. Nonetheless, degradation / (photo) oxidation/ transformation products present in residues after environmental/

8.1. Effects on terrestrial vertebrates

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
					sunlight exposure cannot be excluded (see also 5(1) and 7(6)). Such an assessment was not provided. Overall a data gap is identified.
8(5)	8.1.1 and 8.1.2, Effects on birds and mammals	EFSA: For the representative indoor use to stored grains, a low risk to birds and mammals can be concluded due to low exposure.		REACH evaluation added.	Noted. For the representative indoor use to stored grains, a low risk to birds and mammals can be concluded due to low exposure.

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(6)	Page 24	UK: Brief abstracts have been provided from 2 studies. There is no detailed summary or critical evaluation of these data. Additionally the information has not be drawn together in order to consider the potential effect on aquatic organisms from the use of sunflower oil.	Some consideration of the available information and what this indicates regarding potential effects on aquatic organisms from the use of sunflower oil should be provided.	REACH evaluation added.	See 8(12) The applicant did not provide more detailed study summaries and/or any consideration of the available information regarding potential effects on aquatic organisms from the use of sunflower oil. The REACH evaluation submitted by the applicant is not considered directly relevant to this comment.

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(7)	Page 22	UK: Other potentially relevant information is included in the environmental fate and behaviour section that is not discussed in the ecotoxicology section, i.e. the studies by Oberholster et al. (2010) and Mapurunyane et al. (2013).	All relevant information should be considered in the context of the risk to aquatic organisms from the use of sunflower oil.	REACH evaluation added.	See 8(12) The applicant did not provide any consideration of the information included in the environmental fate and behaviour section (Oberholster et al., 2010 and Mapurunyane et al., 2013) in the updated BSA document. The REACH evaluation submitted by the applicant is not considered directly relevant to this comment.
8(8)	7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, ground water, surface water) + 8.2 Effects on aquatic organisms.	DE: The notifier recommends to generate additional studies for other test organisms than Hyalella azteca at various trophic levels for acute and chronic risk assessment. We agree with this recommendation.		REACH evaluation added.	See 8(12) No additional study was submitted by the applicant in the updated application. The REACH evaluation submitted by the applicant is not considered directly relevant to this comment.
8(9)	7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, ground water, surface	DE: The study of Oberholster et al. (2010) shows that sunflower oil inhibited the growth of sensitive phytoplankton species and promoted that of tolerant species. Phytobenthos diversity and abundance were	Give a sound risk assessment for aquatic organisms for the use of sunflower oil as described in chapter 3.4 of the application. The application includes a recommendation of the notifier to generate additional studies	REACH evaluation added.	See 8(12) The applicant did not provide any consideration of the mentioned information included in the environmental fate and behaviour section (Oberholster et al., 2010) in the updated

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
	water) + 8.2 Effects on aquatic organisms.	significantly suppressed. It cannot be reasoned that the use of sunflower oil is harmless for aquatic organisms.	with aquatic test organisms. These could support a realistic assessment of the risk for aquatic organisms.		application. The REACH evaluation was submitted by the applicant but it cannot be considered directly relevant to this comment.
8(10)	7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, ground water, surface water) + 8.2 Effects on aquatic organisms	DE: The study of Pereira et al. (2003) shows that sunflower oil degrades only slowly in sediments. The effects on sediment-dwelling organisms are not described in the application.	Give a sound risk assessment for sediment-dwelling organisms for the use of sunflower oil as described in chapter 3.4 of the application.	REACH evaluation added.	See 8(12) and 7(6) No further data on sediment-dwelling organisms was provided by the applicant. The REACH evaluation submitted by the applicant is not considered directly relevant to this comment.
8(11)		ES: No comments			Addressed.
8(12)	8.2 Effects on aquatic organisms	EFSA: Only two abstracts have been summarised. The summarised papers do not provide sufficient information to be able to reach a conclusion regarding the acute and chronic risk to aquatic organisms from the representative uses of sunflower oil. The study of Li, Zhengkai et al. (2007) suggests that other test organisms need to be assessed in both acute and	Toxicity data and exposure estimates should be provided in order to perform a risk assessment for aquatic organisms. Alternatively, a clear and scientific justification could be provided to explain why the representative uses pose a low risk to aquatic organisms.	REACH evaluation added.	No further scientific justification or data on toxicity and exposure estimates was provided in order to perform a risk assessment for aquatic organisms. The applicant submitted the results of the REACH assessment which concluded "no aquatic toxicity based on information submitted by stakeholder SH2". No further data was provided to support this information. Overall, given the following:

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		chronic toxicity studies.			- The study by Zhengkai et al. (2007) submitted in the application reported that "additional studies over a wide range of incubation conditions (e.g., temperature, nutrient concentration) and other test organisms at various trophic levels are recommended for both acute and chronic toxicity assessment. - The study by Pereira et al. (2003) submitted in the application reported that "sunflower oil (…) has the potential for longer lasting effects in marine environments". - The studies by Oberholster et al. (2010) and Mapurunyane et al. (2013) were not considered. - According to the comment 7(6)

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
					(Information on the degradation products of sunflower oil produced into the environment and its effects to human and animal health needs to be provided and assessed (…)Particular attention should be given to contamination of groundwater by degradation/transformation products of sunflower oil.) A low risk to aquatic organisms cannot be concluded for the representative field uses.
8(13)	8.2 Effects on aquatic organisms	EFSA: For the representative indoor use to stored grains, a low risk to aquatic organisms can be concluded due to low exposure.		REACH evaluation provided.	Addressed For the representative indoor use to stored grains, a low risk to aquatic organisms can be concluded due to low exposure.

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 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(14)	Page 24-25	UK: Brief abstracts have been provided from 3 studies. There is no detailed summary or critical evaluation of these data. Additionally the information has not be drawn together in order to consider the potential effect on bees and other arthropods from the use of sunflower oil.	Some consideration of the available information and what this indicates regarding potential effects on bees from the use of sunflower oil should be provided.	Horticultural oils, cons1stmg of lightweight petroleum or vegetable oils, are used to smother pest insects and are only harmful on contact (Applied Bionomics, Ltd 2006). These products should be applied only during late evening, night, carly moming, or as a dormant treatment (Riedl et al. 2006).	No consideration of the available information (submitted studies) and what this indicates regarding potential effects on bees from the use of sunflower oil was provided. See 8(20) and 8(21).
8(15)		DE: No data were submitted for the assessment of the product with regard to risk for bees.	Please indicate in dossier.	Included in GAP Table § 8 modified	Addressed No sunflower oil toxicity study to bees was submitted. The following footnote was added to the GAP table: - As a contact insecticide, period of treatment should be avoided during flowering time in GAP. See 8(20) and 8(21).
8(16)		DE: No experimental reports were submitted from which information about effects on beneficial organisms can be derived.	Please indicate in dossier.	**** As a contact insecticide, period of treatment should be avoided during flowering time in GAP	See 8(17), 8(20) and 8(21).
8(17)	7.2 Estimation of the short and long-term exposure of	DE: The presented studies are not suitable to assess the risk for non-target arthropods. Because	Present suitable studies and/or data for a sound risk assessment for non-target arthropods.	§ 8 modified	No sunflower oil toxicity study to bees and other non-target arthropods was submitted. No

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 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
	relevant environmental media (soil, ground water, surface water) + 8.3 Effects on bees and other arthropod species	sunflower oil is used due to its insecticidal effect a risk assessment for bees and other non-target arthropods is very important.			risk assessment or scientific justification was provided. A footnote was added to the GAP table (recommendation to avoid applications during flowering) that is not considered to entirely cover the risk to bees and other non-target arthropods. See 8(20) and 8(21).
8(18)		ES: No comments			Addressed
8(19)	8.3.1 Effects on bees Calderone Nicholas W., Shimanuki Hachiro 1995	EFSA: The study is only briefly summarised and as such does not provide any useful information for the risk assessment for bees. In addition to assessment on the effectiveness of sunflower oil to control mites in the honey bees, were there any assessments made on the health status of the bees?		**** As a contact insecticide, period of treatment should be avoided during flowering time in GAP	No further information was provided in the application regarding the effects assessment on the health status of the bees in Calderone & Shimanuki, 1995. The response from the applicant is not considered relevant for this comment.
8(20)	8.3.1 Effects on bees	EFSA: Only two studies have been summarised and are considered insufficient to be able to perform a risk assessment for bees for the representative uses of sunflower oil. The use of sunflower oil to control insects	Toxicity data and exposure estimates should be provided in order to perform a risk assessment for honey bees. Alternatively, a clear and scientific justification could be provided to explain why the representative uses pose a low	**** As a contact insecticide, period of treatment should be avoided during flowering time in GAP	It is agreed that bees will mostly be exposed by contact to sunflower oil. However it is considered that the mitigation measure proposed (treatments outside the crops flowering) is not sufficient to conclude a low risk as bees may forage on the

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 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		will lead to different exposure to bees than foraging on sunflowers.	risk to honey bees.		weeds in the field at the time of the application. The risk to bees can be considered addressed only if, as an additional mitigation measure, the weeds in the field are managed in order to minimise the exposure of bees (e.g. mowing the flowering weeds before the application)
8(21)	8.3.2 Effects on other arthropods	EFSA: Only a single study has been summarised and is considered insufficient to be able to perform a risk assessment for non-target arthropods for the representative uses of sunflower oil.	Toxicity data and exposure estimates should be provided in order to perform a risk assessment for non-target arthropods. Alternatively, a clear and scientific justification could be provided to explain why the representative uses pose a low risk to non-target arthropods.	**** As a contact insecticide, period of treatment should be avoided during flowering time in GAP	No relevant information was provided by the applicant to conclude a low risk to non-target arthropods (i.e. Toxicity data and exposure estimates or a clear and scientific justification explaining why the representative uses pose a low risk to non-target arthropods). The mitigation measure proposed (i.e. treatments outside the crops flowering) cannot be considered to cover the risk to non-target arthropods other than bees for the field uses.
8(22)	8.3 Effects on bees and other arthropods	EFSA: For the representative indoor use to stored grains, a low risk to bees and non-target arthropods can be		REACH evaluation added. Global conclusion revised.	Noted For the representative indoor use to stored grains, a low risk to bees and other non-target

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 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		concluded due to low exposure.			arthropods can be concluded due to low exposure.

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 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(23)	Page 25	UK: A brief abstract has been provided of a study. There is no detailed summary or critical evaluation of this data. Additionally the information has not been used to consider the potential effect on earthworms from the use of sunflower oil.	Some consideration of the available information and what this indicates regarding potential effects on earthworms from the use of sunflower oil should be provided.	REACH evaluation added. Global conclusion revised.	No additional information was provided in the application to take into consideration and to justify the relevance of the study by Zhengkai et al (2007). It is therefore still unclear what it is meant regarding potential effects on earthworms from the use of sunflower oil. The REACH evaluation is not considered to provide relevant information to conclude a low risk to earthworms. See 8(27)
8(24)		DE: Robust experimental studies carried out with relevant soil macroorganisms (e.g. the standard test earthworm *Eisenia fetida*) were not submitted.	Please indicate in the dossier		No additional information was included in the updated application. See 8(27)
8(25)	7.2 Estimation of	DE: Sunflower oil degradation	Give a sound risk assessment for		No additional information was

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 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
	the short and long-term exposure of relevant environmental media (soil, ground water, surface water) + 8.4 Effects on earthworms and other soil macro-organisms	resulted in the decrease of soil pH. What are the effects of this pH value change on earthworms and soil macro-organisms?	earthworms and soil macro-organisms for the use of sunflower oil as described in chapter 3.4 of the application.		included in the updated application regarding the estimation of the short and long-term exposure of relevant environmental media (soil, ground water, surface water). See 8(27)
8(26)		ES: It is remarked in the dossier that "although degradation occurs in soil, process can be take months when large quantities of oil are spilled." Considering this, it is important to pay attention to soil fauna.			No additional information was included in the updated application. See 8(27)
8(27)	8.4 Effects on earthworms and other macroorganisms	EFSA: Only a single study has been summarised and is considered insufficient to be able to perform a risk assessment for earthworms and other macroorganisms for the representative uses of sunflower oil. In fact the study of Li, Zhengkai et al. (2007) discusses the persistence in sediment and not soil and the	Toxicity data and exposure estimates should be provided in order to perform a risk assessment for earthworms and other macroorganisms. Alternatively, a clear and scientific justification could be provided to explain why the representative uses pose a low risk to earthworms and other macroorganisms.		No relevant information was provided by the applicant in the updated application (i.e. Toxicity data and exposure estimates or a clear and scientific justification explaining why the representative uses pose a low risk to earthworms and other macroorganisms). A low risk to earthworms and other macroorganisms cannot

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** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		summary suggests that other test organisms need to be assessed in both acute and chronic toxicity studies.			be concluded based on the available information for the representative field uses.
8(28)	8.4 Effects on earthworms and other macroorganisms	EFSA: For the representative indoor use to stored grains, a low risk to earthworms and other macroorganisms can be concluded due to low exposure			For the representative indoor use to stored grains, a low risk to earthworms and other macroorganisms can be concluded due to low exposure.

8.5. Effects on soil microorganisms					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
8(29)	Page 26	UK: A brief abstract has been provided of a study. There is no detailed summary or critical evaluation of this data. Additionally the information has not been used to consider the potential effect on soil micro-organisms from the use of sunflower oil.	Some consideration of the available information and what this indicates regarding potential effects on soil micro-organisms from the use of sunflower oil should be provided.		Addressed. No additional information was provided in the updated application to take into consideration and to justify the relevance of the study by Thaweboon et al (2011). It is therefore still unclear what is the potential effect on soil microorganisms from the use of sunflower oil. See 8(32)
8(30)		DE: No robust experimental reports were submitted from which	Please indicate in the dossier		No additional information was included in the updated

8.5. Effects on soil microorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		information about effects on soil micro-organisms can be derived			application. See 8(32)
8(31)	7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, ground water, surface water) + 8.5 Effects on soil micro-organisms	DE: Sunflower oil degradation resulted in the decrease of soil pH. What are the effects of this pH value change on soil micro-organisms?	Give a sound risk assessment for soil micro-organisms for the use of sunflower oil as described in chapter 3.4 of the application.		No additional information was included in the updated application regarding the estimation of the short and long-term exposure of relevant environmental media (soil, ground water, surface water). See 8(32)
8(32)	8.5 Effects on soil microorganisms	EFSA: Only a single study has been summarised and this study does not provide information on the effects of sunflower oil on soil microroganisms.	Toxicity data and exposure estimates should be provided in order to perform a risk assessment for soil microorganisms. Alternatively, a clear and scientific justification could be provided to explain why the representative uses pose a low risk to soil microorganisms.		No relevant information was provided by the applicant in the updated application (i.e. Toxicity data and exposure estimates or a clear and scientific justification explaining why the representative uses pose a low risk to soil microorganisms). A low risk to soil microorganisms cannot be concluded based on the available information for the representative field uses.
8(33)	8.5 Effects on soil microorganisms	EFSA: For the representative indoor use to stored grains, a low risk to soil microorganisms can be concluded due to low exposure			For the representative indoor use to stored grains, a low risk to soil microorganisms can be concluded due to low exposure

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 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(34)	Page 26	UK: Brief abstracts have been provided from 2 studies. There is no detailed summary or critical evaluation of these data. Additionally the information has not be drawn together in order to consider the potential effect on other non-target organisms from the use of sunflower oil.	Some consideration of the available information and what this indicates regarding potential effects on other non-target organisms from the use of sunflower oil should be provided.		See 8(37)
8(35)	7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, ground water, surface water) + 8.6 Effects on other non-target organisms (flora and fauna)	DE: The study of Gong et al. (2008) shows that the growth of A. sativa and B. rapa was affected by sunflower oil. Which effects has the use of sunflower oil as a basic substance on non-target terrestrial plants?	Present a sound risk assessment for non-target terrestrial plants.		See 8(37)
8(36)		ES: No comments			Addressed.
8(37)	8.6 Effects on other non-target organisms	EFSA: A study by Gong et al. (2008) was briefly summarised. The study indicates adverse effects on the growth of *A. sativa* and *B. rapa.* Further details of the	Further details of the observed effects in the study of Gong et al. (2008) should be included in the study summary. The effects should be considered in relation to the predicted exposure to		No additional detail on the adverse effects on *A. sativa* reported in the study by Gong et al. (2008) with reference to the predicted exposure for the representative field uses was

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** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		observed effects should be included in the study summary.	non-target plants for the representative uses of sunflower oil i.e. a risk assessment should be provided. It is also suggested that any additional data (perhaps in efficacy studies) is submitted and considered in the context of the risk to non-target plants.		provided in the updated application. No further data (i.e. phytotoxicity assessment from efficacy studies) were submitted. An additional study was cited but no summary was provided. The sunflower oil was reported to have an impact on the Soil pH profile and thus it may have a potential negative impact on non-target terrestrial plants. A low risk to other non-target organisms (flora and fauna) cannot be concluded for the representative field uses.
8(38)	8.6 Effects on other non-target organisms	EFSA: For the representative indoor use to stored grains, a low risk to soil microorganisms can be concluded due to low exposure			For the representative indoor use to stored grains, a low risk to non-target organisms can be concluded due to low exposure

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 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(39)	Page 27	UK: Reference is made to use as a foodstuff but further information regarding effects on biological methods of sewage treatment from this use are not provided.	Article 23 indicates that any evaluations of sunflower oil's possible effects on human or animal health or the environment carried out in accordance with other Community legislation regulating the use of the substance can be used but should be provided.	Sunflower oil is usually thrown directly to sewage. Sewage treatments have separation facilities for vegetable oil in general.	See 8(42)
8(40)	Page 27	UK: While extrapolation from other Community legislation regulating the use of sunflower oil for purposes other than for a plant protection product is appropriate, extrapolating from a US EPA assessment may not be. Without further details of the underlying evaluation it is difficult to conclude.	If the US EPA registration of sunflower oil in pesticide products is to be used as part of this evaluation then the underlying US EPA assessment should be provided.		Addressed No additional information was provided.
8(41)		ES: No comments			Addressed.
8(42)	8.7 Effects on biological methods of sewage treatment	EFSA: For the representative uses of sunflower oil, a low risk to sewage treatment organisms can be concluded due to low exposure.		Global evaluation done during REACH inscription concluded to GREEN qualification in each compartments.	For the representative uses of sunflower oil, a low risk to sewage treatment organisms can be concluded due to low exposure.

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 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
9(1)		UK: It can be considered a basic substance from the human health point of view, but there are many uncertainties on the environmental side.		Global evaluation done during REACH inscription concluded to GREEN qualification in each compartments.	See comments under 8 and 9 above.
9(2)	Pag 27 Point 8	ES: In conclusions of point 8, it is indicated that "in the case of maximum number of applications, total rate is not equal to maximum concentration x maximum number of application but minimum concentration x maximum number of application". In some cases, the value (total rate max) included in the GAP table for some crops, should be revised.		GAP table corrected	Addressed: The GAP table was corrected.
9(3)	Pag 27 Point 8	ES: In the label; It should be specified that "As a contact insecticide, period of treatment should be avoided during flowering time"		Included in GAP	Addressed: The note was included in the GAP table
9(4)	General comment	ES: The fulfilment of the criterion "(d) is not placed on the market as a plant protection		FFA lit to 2% is included in specifications. New CODEX reference added	Addressed: See 2(1) See also 5(1)

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** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		product" is questionable, since the content of free oleic acid could be high (please, see comments above for issue 2.1.5). This criterion should be guaranteed by establishing requirements that assurance the absence of free oleic acid in the sunflower oil composition (e.g. a maximum acid value in sunflower oil).			
9(5)	concluding text	NL: It seems FR relies completely on the USEPA conclusion which might be less relevant for the EU registration process. However, enough underlying data are submitted to underpin the registration in the EU as well. We would have liked the conclusion relied upon that information more than on the USEPA conclusion.		Global evaluation done during REACH inscription concluded to GREEN qualification in each compartments.	Noted.

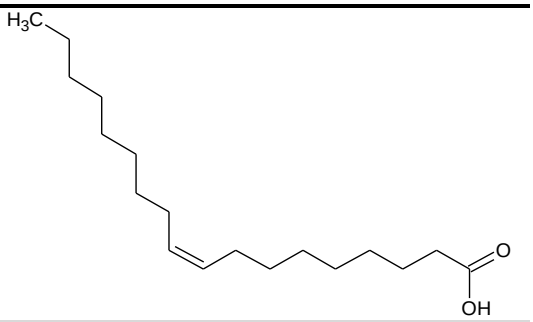
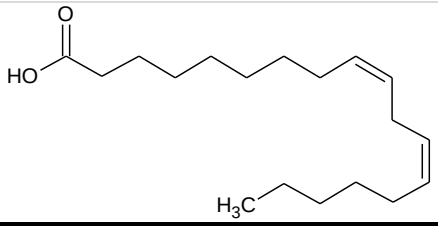
10. Other comments

NL: no comments

Other comments

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
10(1)		ES: No comments			Addressed.
10(2)		DE: General comment on the efficacy evaluation in the dossier: the idea of the authorisation of basic substances is that no product authorisation takes place after the final decision on the a.s.	Therefore, it should be made clear that neither sufficient efficacy nor side effects are well approved and may occur.	Global evaluation done during REACH inscription concluded to GREEN qualification in each compartments.	See 3(6) and 3(7)
10(3)	Conclusions §8	DE: Regarding the points mentioned in this passage: Can sunflower oil be assessed as a basic substance?	Assess sunflower oil as an active substance like rapeseed oil.	Sunflower oil is a foodstuff, so an intrinsic basic substance (Reg. 178/2002). We work to regularize field uses of such substances. Why EU don't urge the evaluation of the hundreds of "pflanzenstärkungsmitteln" sold illegally regarding Reg. 1107/2009 as plant strengtheners (see Doc Sanco 1003/2000 rev.3) in DE. Proof is made that DE evaluation is always dedicated to Basic Substances Dossier destruction. Is this targeted to stop any further BSA application?	The issue if sunflower oil can or not be formally considered a basic substance is a management / legal issue out of the scope of EFSA scientific assessment.

Appendix B – Used compound codes

Code/trivial name	Chemical name/SMILES notation	Structural formula
oleic acid	(9*Z*)-octadec-9-enoic acid O=C(O)CCCCCCC/C=C\CCCCCCCC	
linoleic acid	(9*Z*,12*Z*)-octadeca-9,12-dienoic acid O=C(O)CCCCCCC/C=C\C/C=C\CCCCC	

Appendix C – Identity and biological properties

Common name (ISO)	There is no ISO common name for this substance
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
Minimum 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 a % of total fatty acids) high oleic acid sunflower oil: min. 75% oleic acid (as % of total fatty acids)
Relevant impurities	CODEX STAN 210-1999
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) 1 -3 % (v/v)
Function of plant protection	Insecticide, fungicide

Appendix D – List of uses

Insecticide acaricide activity

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	F GI (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 (kg/hl) (L/hl)	Water l/ha min max	kg a.i./ha min max (kg/ha) (L/ha) (l)	kg a.i./ha min max (kg/ha) (L/ha) (l)		
Pome Fruit *Malus domestica*	DE et al. FR France All Member	Sunflower	F	Woolly apple aphid *Eriosoma lanigerum*	Oil Dispersion	915 to 923	Brush application on single infested parts of the trees	BBCH 00-75	1-2	10 days	pure	none	0.92 (1L)	0.92 (1L) to 1.84 (2L)	14	***
Fruit trees Apple fruit *Malus domestica* Peachtree *Prunus persica* Cherry tree *Prunus avium* *Prunus padus* Pear tree *Pyrus sp* Quince *Cydonia oblonga* Nashi *Pyrus pyrifolia*				Aphids & mites *Aphis pomi* European red mite *Panonychus ulmi* Peach Silver mite *Aculus cornutus* Cherry blackfly *Mysus cerasi* Yellow mite *Lorryia formosa* Apple mealybug *Lepidosaphes ulmi* Leafcurl Plum Aphid *Brachycaudus helichrysi* Green peach aphid *Myzus persicae*			foliar application	adult	2 to 4	8 days	1.84 (2L)	500 to 1000	9.2 (10L) to 18.4 (20L)	18.4 (20L) to 36.8 (40L)		* ** ***
Grapevine *Vitis vinifera*				Yellow mite *Eotetranychus carpini* twospotted spider mite *Tetranichus urticae*							2.76 (3L)	100 to 300	2.76 (3L) to 8.28	5.52 (6L) to 11.04		****

Potato *Solanum tuberosum*	States	oil		Potato aphid *Macrosiphum euphorbiae*	(OD)		spraying	stages			1.84 (2L)	300 to 500	5.52 (6L) to 9.2	11.04 (12L) to 18.4		
Vegetable Crops Bush bean Peppers Squash				Spider mites *Tetranychus* spp							0.92 (1L) to 1.84 (2L)	500 to 1000	4.6 (5L) to 9.2 (10L)	9.2 (10L) to 18.4 (20L)		

* Notes: Thorough coverage of the insect is important. The temperature should be below 32° C, and plants should not be water stressed.
** As a matter of fact, in this case of maximum number of application, total rate is not equal to maximum concentration x maximum number of application but minimum concentration x maximum number of application.
*** Precautions must be taken to avoid overwatering and spilling of the dispersion
**** As a contact insecticide, period of treatment should be avoided during flowering time

Insecticide post-harvest protection

Crop and/or situation (a)	**Member State or Country**	**Example product name as available on the market**	**F GI** (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** (kg/hl) (L/hl)	**Water l/ha min max**	**kg a.i./ha min max** (g/ha) (L/ha) (l)	**kg a.i./ha min max** (kg/ha) (L/ha) (l)		
Stored grains pigeonpea *Cajanus cajan* (L.) Millsp. cowpea *Vigna*	FR France All Member States	Sunflower oil	I	pulse beetle bean weevil *Callosobruchus chinensis L. C. maculatus*	Oil Dispersion (OD)	915 to 923	Grain application spraying	adult stages	1	-	0.92 (1L) per quintal of grains			0.92 (1L) per quintal of grains	-	*

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

Fungifuge activity

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 (g/hl)	Water l/ha min max	kg a.i./ha min max (g/ha) (l)	kg a.i./ha min max (g/ha) (l)		
Vegetable Gardening Tomato *Lycopersicum esculentum*	FR France All Member States	Sunflower oil	F	Tomato powdery mildew *Oidium neolycopersici*	Oil Dispersion (OD)	915 to 923	foliar application spraying	BCH 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
**** As a contact insecticide, period of treatment should be avoided during flowering time

Fungi static activity

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 (g/hl)	Water l/ha min max	kg a.i./ha min max (g/ha) (l)	kg a.i./ha min max (g/ha) (l)		

Grapevine *Vitis vinifera*	DE et al. FR France All Member States	Sunflower oil	F	Fungal diseases reductions Yellow mite reductions *Eotetranychus carpini* twospotted spider mite *Tetranichus urticae*	Oil Dispersion (OD)	915 to 923	foliar application spraying	adult stages BBCH 00-85	1 to 8	5 days	0.92 (1L)	400 to 1600	0.92 (1L) to 7.36 (8L)	0.92 (1L) to 7.36 (8L)	14	* ** ****

* PHI is due to avoid eventual effects on vinification
** Precautions must be taken to avoid overwatering and spilling of the dispersion
**** As a contact insecticide, 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 suckling 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