TECHNICAL REPORT

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Outcome of the consultation with Member States and EFSA on the basic substance application for approval of sunflower oil for the extension of use in plant protection as a fungicide on vegetables (common bean, cucumber), *Rosaceae* (like *Prunus, Fragaria, Rosa, Rubus* etc.), apple, pear, grapevine, wheat, barley, potato and carrot

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 extension of use 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 an extension of use in plant protection as a fungicide on vegetables (common bean, cucumber), *Rosaceae* (like *Prunus*, *Fragaria, Rosa, Rubus* etc.), apple, pear, grapevine, wheat, barley, potato and carrot. The current report summarises the outcome of the consultation process organised by EFSA and presents EFSA's scientific views on the individual comments received.

Keywords: sunflower oil, basic substance, application, consultation, plant protection, pesticide, fungicide

Requestor: European Commission

Question number: EFSA-Q-2020-00646

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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 Medinbio for approval of an extension of use 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.

On 4 March 2016 EFSA received a first request from the European Commission to organize a consultation on the basic substance application submitted by the applicant Institut Technique de l'Agriculture Biologique (ITAB) 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. A Technical Report containing the finalised reporting table was issued by EFSA on 8 April 2016.

Sunflower oil was approved on 2 December 2016 by Commission Implementing Regulation (EU) 2016/1978, in accordance with Article 23 of Regulation (EC) No 1107/2009, for the use in plant protection as a fungicide on tomato crops in field.

By a further specific request, received from the European Commission in October 2020, following the application submitted by Medibio of sunflower oil as a basic substance for an extension of use in plant protection as a fungicide on vegetables (common bean, cucumber), *Rosaceae* (like *Prunus, Fragaria, Rosa, Rubus* etc.), apple, pear, grapevine, wheat, barley, potato and carrot, EFSA was asked to organise a consultation on the basic substance application, 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 acceptance of the specific request.

A consultation on the basic substance application for the extension of use of sunflower oil, organised by EFSA, was conducted with Member States via a written procedure in July – September 2020. 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 approval of sunflower oil for an extension of use in plant protection as a fungicide on vegetables (common bean, cucumber), *Rosaceae* (like *Prunus, Fragaria, Rosa, Rubus* etc.), apple, pear, grapevine, wheat, barley, potato and carrot, 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 a fungicide on vegetables (common bean, cucumber), *Rosaceae* (like *Prunus, Fragaria, Rosa, Rubus* etc.), apple, pear, grapevine, wheat, barley, potato and carrot against various fungal diseases.

With regard to the impact on human and animal health, it is agreed that fresh vegetable oils, such as sunflower oil, are of no concern to human and animal health as food stuff. Sunflower oil residues in crops can however result in degradation-, (photo)oxidation-, transformation products (e.g. by lipid peroxidation) that may be of concern to human health (including genotoxicity and carcinogenicity concerns). These potential degradation products were not quantified or compared with eventual natural

background levels. Exposure to these products may be relevant to consumers, workers and possibly residents.

Regarding environmental fate and behaviour, the information included in the application was insufficient to address the environmental exposure that would result from the intended uses that have been applied for. Information included in the application indicated that sunflower oil may not be considered readily biodegradable following its use in the way being requested.

In line with EFSA (2016), insufficient information was presented to perform a robust assessment for non-target organisms. Consequently, the risk assessment for birds, mammals, aquatic organisms, non-target arthropods, soil organisms and non-target terrestrial plants was considered unfinalised. A low risk to bees may be concluded only when mitigation measures are applied (i.e. treatment should be avoided during the flowering of the crop and weeds in the field).

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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 a first application from from Institut Technique de l'Agriculture Biologique (ITAB) for approval as a 'basic substance' to be used in plant protection as an insecticide on fruit trees, grapevine, potato, vegetables and post-harvest treatment on stored grains and as fungicide on vegetables and grapevine.

On 4 March 2016 the European Food Safety Authority (EFSA) was requested by European Commission to organise a consultation on the basic substance application submitted, 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. A Technical Report containing the finalised reporting table was issued by EFSA on 8 April 2016 (EFSA, 2016).

Sunflower oil was approved on 2 December 2016 by Commission Implementing Regulation (EU) 2016/1978[2], in accordance with Article 23 of Regulation (EC) No 1107/2009, for the use in plant protection as a fungicide on tomato crops in field.

In June 2018, the European Commission received a further application from Medinbio for approval of the basic substance sunflower oil for the extension of use in plant protection as a fungicide on vegetables (common bean, cucumber), *Rosaceae* (like *Prunus, Fragaria, Rosa, Rubus* etc.), apple, pear, grapevine, wheat, barley, potato and carrot.

Following a specific mandate received on 6 October 2020, EFSA organised a consultation with Member States on the basic substance application for the extension of use of sunflower oil, which was conducted via a written procedure in July – September 2020. 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 approval of sunflower oil for the extension of use in plant protection as a fungicide on vegetables (common bean, cucumber), *Rosaceae* (like *Prunus, Fragaria, Rosa, Rubus* etc.), apple, pear, grapevine, wheat, barley, potato and carrot, 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 the extension of use 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 (Medinbio, 2020).

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 Commission Implementing Regulation (EU) 2016/1978 of 11 November 2016 approving the basic substance sunflower oil in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 305, 12.11.2016, p. 23–25.

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 6 October 2020, EFSA was asked to organise a consultation on the basic substance application for approval of sunflower oil for the extension of use in plant protection as a fungicide on vegetables (common bean, cucumber), *Rosaceae* (like *Prunus*, *Fragaria, Rosa, Rubus* etc.), apple, pear, grapevine, wheat, barley, potato and carrot, 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 6 January 2021.

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.

2. Assessment

The comments received on the basic substance application for approval of sunflower oil for the extension of use in plant protection as a fungicide on vegetables (common bean, cucumber), *Rosaceae* (like *Prunus, Fragaria, Rosa, Rubus* etc.), apple, pear, grapevine, wheat, barley, potato and carrot, 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. Medinbio, 2020. Basic substance application extension on sunflower oil submitted in the context of Article 23 of Regulation (EC) No 1107/2009. February 2020, updated in October 2020. Documentation made available to EFSA by the European Commission (initial application) and by the applicant (updated application).

References

EFSA (European Food Safety Authority), 2016. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for sunflower oil for use in plant protection as insecticide on fruit trees, grapevine, potato, vegetables and post-harvest treatment on stored grains and as fungicide on vegetables and grapevine. EFSA supporting publication 2016:EN-1023. 51 pp.

Abbreviations

a.s.	active substance
BBCH	growth stages of mono- and dicotyledons species
DT_{50}	period required for 50% dissipation
GAP	good agricultural practice
GRAS	Generally recognised as safe, terminology of the United States environmental protection agency
IPM	integrated pest management
MS	Member State
OEPP	Organisation Européenne et Méditerranéenne pour la Protection des Plantes
OD	oil dispersion formulation
PAHs	polycyclic aromatic hydrocarbons
PEC	predicted environmental concentration
PHI	pre-harvest interval
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
PPP	plant protection product
RED	reregistration eligibility decision
USEPA	US Environmental Protection Agency

Appendix A – Collation of comments from Member States and EFSA on the basic substance application for the extension of use of 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)	1. Purpose	NL: Please replace the generic text "*Include here… organic agriculture*" by a short summary which explains (i) why the applicant proposes the substance for approval, (ii) what the intended use may be, (iii) whether it has a traditional use in farming, and (iv) whether it is of interest for organic agriculture.		Introduction modified	Addressed.
1(2)		DK: No comments			Noted.
1(3)		DE: No comments			Noted.

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 -> 2.1.5	NL: Please move all content presently under 2.1 to 2.1.5 where it actually belongs (i.e., specification data).		Modified: moved	Addressed.
2(2)	2.1.4	NL: Please provide a generic description summary of the production of sunflower oil.		Updated	Addressed.
2(3)	2.1.5 -> 2.1.7	NL: Please move most of the content presently under 2.1.5 to 2.1.7 where it actually belongs (i.e., methods of analysis).		Modified: moved	Addressed.
2(4)		DK: No comments			Noted.
2(5)		DE: No comments			Noted.

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(6)		NL: No comments			Noted.
2(7)		DK: No comments			Noted.
2(8)		DE: No comments			Noted.

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(9)		NL: No comments			Noted.
2(10)		DK: No comments			Noted.
2(11)		DE: No comments			Noted.

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(12)		NL: No comments			Noted.
2(13)		DK: No comments			Noted.
2(14)		DE: No comments			Noted.
2(15)	2.5 Description of the recipe, p.12	EFSA: probably a typo in the text as it states "0.01 to 0.03 g/l of sunflower oil in water (1 to 3%).	Instead of g probably kg is meant.	Corrected in g/L	Addressed: The typo was corrected.

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(16)	2.5 Recipe	NL: The current data are not sufficiently clear with regard to the dilutions. Moreover,		§ 2.5 modified Former recipe included	Addressed: The typo was corrected (see also 2(15)).

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
		they seem to conflict with the Review Report (SANTE/10875/2016), which states for the OD-preparation: 0.1 – 0.5 % v/v (sunflower oil in cold water). The recipe for the OD given under 2.5 suggests that the OD-preparation contains 1 – 3 % v/v. Subsequently, it is assumed that the OD-preparation is further diluted prior to use (to attain 0.1 – 1 % v/v). But, as said, this is not entirely clear. The applicant is requested to elucidate above points; what is the concentration in the OD-preparation. If this is the case: how is the OD-preparation further diluted.		OD-preparation: 0.1 – 0.5 % v/v Corrected OD-preparation contains 1 – 3 % v/v. Corrected OD-preparation contains 1 – 3 % v/v. Former recipe re-included	The mode of preparation of the dilutions was inserted in the updated submission. The updated use concentrations and the concentrations in the GAP table are still contradictory and different from the values from the Review Report. According to the GAP table the use concentrations are 0.5 - 1 % (v/v)
2(17)		DK: No comments			Noted.
2(18)		DE: No comments			Noted.

2.6. Function of plant protection					
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(19)		NL: No comments			Noted.
2(20)		DK: No comments			Noted.
2(21)		DE: No comments			Noted.

3. Uses of the substance and its product

3.1. Field of use

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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)		NL: No comments			Noted.
3(2)		DK: No comments			Noted.
3(3)	3.1.2.1.6	DE: The referred study "Medinbio 2018 Rapport Projet" is not attached to the dossier and not available on the internet. Thus, no evidence is provided for the usefulness of sunflower oil in the framework of plant protection with regard to the pathosystem *Daucus carota – Alternaria dauci*.		"Medinbio 2018 Rapport Projet" Provided	Addressed.

3.2. Effects on harmful organisms or on plants

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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)		NL: No comments			Noted.
3(5)		DK: No comments			Noted.
3(6)		DE: No comments			Noted.

3.3. Usefulness in the framework of plant protection

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)		NL: No comments			Noted.
3(8)		DK: No comments			Noted.
3(9)		DE: No comments			Noted.

3.4. 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(10)		NL: No comments			Noted.
3(11)		DK: Please exclude BBCH 60-69 from the intended uses. (See DK comment for section 8.3.1.)	DK: Revise the intended uses to exclude flowering growth stages (BBCH 60-69).	Corrected accordingly	Addressed: Growth stages were updated in the GAP table.
3(12)		DK: Please add a column for "Total rate" for a better overview.	DK: Please add a column for "Total rate".	Corrected	Addressed: Total rate was added to the GAP table.
3(13)	3.4, SUMMARY OF INTENDED USES	DE: Application from BBCH 00: Please explain the treatment of an obligate parasite before crop emergence.		Corrected for BBCH 09	Addressed: The BBCH was corrected in the GAP table.
3(14)	3.4, SUMMARY OF INTENDED USES	DE: In the GAP table for the new requested uses the column "Total rate" is missing. Without this information it is unclear how much sunflower oil will be applied in total.	DE: Please add this column for the new requested uses.	Corrected	Addressed. Total rate was added to the GAP table.

3.4. 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(15)	3.4 Summary of indended uses, p.31	EFSA: are the BBCH 00 stages relevant for these uses?		Corrected for BBCH 09	Addressed. The BBCH was corrected in the GAP table.

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			Noted.
4(2)		DK: No comments			Noted.
4(3)		DE: No comments			Noted.

5. Impact on Human and Animal Health

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
5(1)		NL: No comments			Noted.
5(2)		DK: No comments			Noted.
5(3)		DE: No comments			Noted.

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
5(4)		NL: No comments			Noted.
5(5)		DK: No comments			Noted.
5(6)		DE: No comments			Noted.

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
5(7)		NL: No comments			Noted.
5(8)		DK: No comments			Noted.
5(9)		DE: No comments			Noted.

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**
5(10)		NL: No comments			Noted.
5(11)		DK: No comments			Noted.
5(12)		DE: No comments			Noted.

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**
5(13)		NL: No comments			Noted.
5(14)		DK: No comments			Noted.
5(15)		DE: No comments			Noted.

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**
5(16)		NL: No comments			Noted.
5(17)		DK: No comments			Noted.
5(18)		DE: No comments			Noted.

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**
5(19)		NL: No comments			Noted.
5(20)		DK: No comments			Noted.
5(21)		DE: No comments			Noted.

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(22)	Metabolites	NL: Sunflower could form degradation, (photo)oxidation, transformation products (e.g. by lipid peroxidation) that may be of concern to human health. Please indicate whether there are metabolites formed and whether quantification of these metabolites is needed (e.g. looking at background levels).	EFSA: In line with comments by the NL (5(22)), DE (7(4)) and EFSA (7(5)) clarifications on ready biodegradability of sunflower oil are needed.	Bibliography: More ref added (Yap 2010) describing degradation Metabolites	The added bibliography does not address the concern raised as it describes solely the use of vegetable oils as extraction solvent for soil washing (such as polycyclic aromatic hydrocarbons (PAHs) removal). 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 potential degradation products were not quantified or compared

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**
					with eventual natural background levels. These residues are relevant to consumer, worker and possibly residential exposure to degradation products of sunflower oil.
5(23)		DK: No comments			Noted.
5(24)		DE: No comments			Noted.

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**
5(25)		NL: No comments			Noted.
5(26)		DK: No comments			Noted.
5(27)		DE: No comments			Noted.

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**
5(28)		NL: No comments			Noted.

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**
5(29)		DK: No comments			Noted.
5(30)		DE: No comments			Noted.

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**
5(31)		NL: No comments			Noted.
5(32)		DK: No comments			Noted.
5(33)		DE: No comments			Noted.

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**
5(34)		NL: No comments			Noted.
5(35)		DK: No comments			Noted.
5(36)		DE: No comments			Noted.

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(37)		NL: No comments			Noted.
5(38)		DK: No comments			Noted.
5(39)		DE: No comments			Noted.

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**
6(1)	6. Residues	NL: Why are 'residues' not applicable? Although sunflower oil is a food product itself, residues are still possible, particularly if metabolism/degradation of the sunflower oil takes place in/on the crops. Please, assess whether metabolites from sunflower oil can be expected, and if this is the case: -which metabolites are being formed, and at what level? -what are the toxicological characteristics of the metabolites?	EFSA: Applicant to provide information on the behaviour of the sunflower oil during the use as a PPP. Since it is applied on large surface and it is exposed to sunlight with the formation of the photo-oxidation compounds, the toxicity of these compounds and whether they raise any issue for the consumer should be assessed.	Bibliography: More ref added (Yap 2010) describing degradation Metabolites Decomposition in CO_2 demonstrated in.	The submission of the article (Yap 2010) does not address the concern on possible formation of photo-oxidation compounds that could be toxic and they could raise a consumer concern following the use of sunflower oil as a PPP. The respective article compiles only studies on vegetable oils used for the treatment of the contaminated soils with polycyclic aromatics hydrocarbons. See also comment on 5(22)
6(2)		DK: No comments			Noted.
6(3)		DE: No comments			Noted.

7. Fate and Behaviour in the environment

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)		NL: No comments			Noted.
7(2)		DK: No comments			Noted.
7(3)	7, Fate and behaviour in the environment	DE: As UK commented already in 2015, the cited references are brief abstracts mainly with regard to a single spilling event and provide only limited information in the way of considering the levels in the studies with potential exposure when sunflower oil is used as a pesticide. Quotation should be put into quotation marks or made distinguishable otherwise from the citations. More relevant and up to date citation than USEPA 1993 would be desirable.	DE: At least the magnitude of the oils spill should be mentioned (e.g. 250 t oil on 12.7 ha freshwater wetland).	Resume of the USEPA report conclusions added. i.e. Flower and vegetable oils met the criteria due to their use and availability for non-pesticide food uses; their regulatory status as a chemical classified as GRAS and their exemption from the requirement of food additive tolerances; their non-toxic mode of action as pesticides; that there is negligible human and environmental exposure to them as a result of their use patterns; and, the lack of reports of adverse effects	Updates to improve the quality of the application have not been made. The extra information from the US EPA (United States Environmental Protection Agency) RED (Reregistration Eligibility Decision) is not very helpful as the use patterns considered by the US EPA were not reported or compared to those being requested for the basic substance use in the EU. Note that the US EPA document states that 'The Agency will however assess the need for product specific risk reduction measures upon receipt of data that are being required under the product specific data.'
7(4)	7.1, Cecutti et al 2008	DE: In Figure 2, the biphasic behaviour is striking. For the test items 'Biolube', 'Hélianthe', and 'Biohydran'		Bibliography: More ref added (Aluyor 2009) describing degradation time of sunflower	The addition of this review (Aluyor 2009) does not change the results reported for Cecutti et al 2008 that

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**
		the first half-life amounts to roughly 9 days. However, after 10 days biodegradation stops completely. With respect to the environmental fate of sunflower oils, this finding is alarming! The authors write: 'This behaviour could be explained by the accommodation of the soil microbial communities to the pollutants'. However, it is an unexpected negative accommodation.		oil: 70-100% biodegradation in a period of 28 days.	after 10 days measured biodegradation stopped. Note that this is a very general review covering vegetable oils generally and not specifically sunflower oil. The review contains no primary research investigation confirming the ready biodegradability of sunflower oil. The citation of the applicant made in column 4 relates to a definition of what readily biodegradable means and was not attributed by the article authors to having been demonstrated for sunflower oil.
7(5)	7.1, Cecutti et al 2008	EFSA: The Commission basic substance approval was based on the premise that sunflower oil was readily biodegradable. As noted by DE in comment 7(4), this seems to be contradicted by the results in Cecutti et al 2008 that after 10 days biodegradation stopped.	More information regarding ready biodegradability seems to be needed to clarify the apparently contradictory information provided in the application.	Bibliography: More ref added (Aluyor 2009) describing degradation time of sunflower oil: 70-100% biodegradation in a period of 28 days.	The application contains information that indicates that sunflower oil may not be considered readily biodegradable. Aluyor, 2009 does not demonstrate / provide any clear evidence that sunflower oil would be readily biodegradable.

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(6)		NL: No comments			Noted.
7(7)		DK: No comments			Noted.
7(8)		DE: No comments			Noted.
7(9)		EFSA: Environmental exposure estimates / calculations have not been provided.	PEC in soil, surface water and sediment consequent to the uses applied for could have been calculated and should have been calculated for sediment as effects on sediment dwelling organisms have been reported.	PEC soil Calculations in the worst case (7 applications) provided	Information on PEC surface water and sediment were not provided. The application summary was not updated to include the PEC soil that had been provided (as an EXCEL spreadsheet). Note: no justification was provided for the 10 day soil DT_{50} that was used for the calculations in this spreadsheet. The soil depth used as the basis for these PEC soil calculations (10cm) is not an agreed assumption. The calculated PEC soil provided do not have the expected / usual reliability / meaning.

8. Effects on non-target species

8.1. Effects on terrestrial vertebrates

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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)		NL: No comments			In line with EFSA (2016), insufficient information was presented to perform a robust assessment for non-target organisms. Consequently, the risk assessment for birds and mammals is considered unfinalised.
8(2)		DK: No comments			
8(3)		DE: No comments			

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(4)		NL: No comments			In line with EFSA (2016), insufficient information was presented to perform a robust assessment for non-target organisms. Furthermore, the exposure assessment for surface water could not be completed with the available information. Consequently, the risk assessment for aquatic organisms is considered
8(5)		DK: No comments			
8(6)		DE: No comments			

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**
					unfinalised.

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(7)	8.3. Effects on bees and other arthropods species	NL: It is stated several times that sunflower oil can have an effect (physical mode of action) to bees and other non-target arthropods. Hence, some sort of warning sentence (linked to IPM) or restriction sentence (no application during flowering period to protect bees) should be necessary.			The applicant has updated the GAP table to exclude flowering growth stages. However, this does not completely exclude exposure to bees as flowering weeds and flowers in the field margin may also be contaminated. MS should consider whether risk mitigation is needed.
8(8)	8.3.1	DK: This section offers no risk assessment (qualitative or quantitative) for bees. In fact, the applicant writes that "oils as contact insecticides are toxic to bees", which is generally known to be true. Therefore, please exclude the flowering BBCH stages from the intended uses.	DK: Revise the intended uses to exclude flowering growth stages (BBCH 60-69).	GAP Revised	Refer to 8(7).

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(9)	8.3.1, Effects on bees	DE: We would like to point out that for the extension of the approval of the basic substance sunflower oil as a fungicide, also because no ecotoxicological data are available for bees, the already known insecticidal mode of action of vegetable oils must also be taken into account and that this should also be highlighted in the documents and the risk assessment. Consequently, the risk for bees, especially through contact exposure, must be excluded by appropriate risk mitigation measures or other requirements. Therefore, inconspicuous note below the GAP table (3.4, Summary of intended uses; p. 30-31) does not seem sufficient to us here. Please adjust accordingly.		GAP Changed OEPP codes added	Refer to 8(7).

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(10)		NL: No comments			In line with EFSA (2016), insufficient information was presented to perform a robust assessment for non-target organisms. Although an exposure assessment for soil was available, no risk assessment was provided. A paper was provided indicating that biodiesel and soy oil indicated toxicity towards earthworms, but data for sunflower oil was not provided. Consequently, the risk assessment for soil organisms is considered unfinalised.
8(11)		DK: No comments			
8(12)		DE: No comments			

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(13)		NL: No comments			In line with EFSA (2016), insufficient information was presented to perform a robust assessment for non-target organisms. Although an exposure assessment for
8(14)		DK: No comments			
8(15)		DE: No comments			

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**
					soil was available, the available information on the toxicity towards microorganisms was not suitable for risk assessment. Consequently, the risk assessment for soil microorganisms is considered unfinalised.

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(16)		NL: No comments			In line with EFSA (2016), insufficient information was presented to perform a robust assessment for non-target organisms. Consequently, the risk assessment for non-target terrestrial plants is considered unfinalised.
8(17)		DK: No comments			
8(18)		DE: No comments			

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(19)		NL: No comments			Noted.
8(20)		DK: No comments			Noted.
8(21)		DE: No comments			Noted.

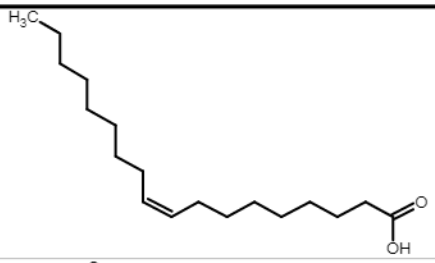
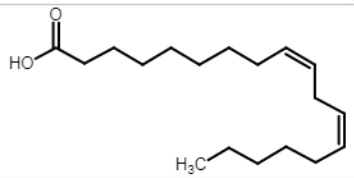
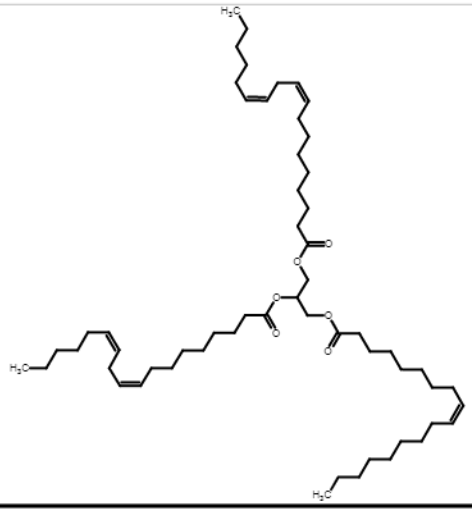
9. Overall conclusions with respect of eligibility of the substance to be approved as basic substance

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)	Chapter 9, Overall conclusions with respect of eligibility of the substance to be approved as basic substance	NL: The following is stated: *This extension of use does not induce an increase of exposure, do not increase quantities or volumes generated in field usages compare to the original application Usages.* But looking at the intended uses and comparing the new requested uses with the approved use (tomato), there are several new requested uses, which have a higher dose rate and application frequency than the approved use in tomato. Hence, the extension of use can induce an increase of exposure.		Sentence amended	The application has now been updated to acknowledge that total applied dose rates have been increased by a factor of 2. However, this statement does not cover the fact that off target spray drift exposure from the new uses requested on grapevines and apples will also be significantly higher than that which was approved on tomato (as a consequence of the use of air assisted broadcast spraying in these crops). Environmental exposure estimates off crop that will be higher than the approved tomato use, have not been adequately assessed in the application / submission made.
9(2)		DK: No comments			Noted.
9(3)		DE: No comments			Noted.

10. Other 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)		NL: No comments			Noted.
10(2)		DK: No comments			Noted.
10(3)		DE: No comments			Noted.

Appendix B – Used compound codes

Code/trivial name[a]	Chemical name/SMILES notation[b]	Structural formula[c]
Oleic acid	(9*Z*)-octadec-9-enoic acid O=C(O)CCCCCCC/C=C\CCCCCCCC ZQPPMHVWECSIRJ-KTKRTIGZSA-N	
Linoleic acid	(9*Z*,12*Z*)-octadeca-9,12-dienoic acid O=C(O)CCCCCCC/C=C\C/C=C\CCCCC OYHQOLUKZRVURQ-HZJYTTRNSA-N	
example of a triglyceride	3-[(9*Z*)-octadec-9-enoyloxy]propane-1,2-diyl (9Z,12*Z*,9'*Z*,12'*Z*)di-octadeca-9,12-dienoate O=C(CCCCCCC/C=C\C/C=C\CCCCC)OC(COC(=O)CCCCCCC/C=C\C/C=C\CCCCC)COC(=O)CCCCCCC/C=C\CCCCCC VVEBTVMJPTZDHO-WECKWCTPSA-N	

(a): The metabolite name in bold is the name used in the report.
(b): ACD/Name 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 Jul 2019)
(c): ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 Jul 2019)

Appendix C – Identity and biological properties

Common name (ISO)	*Helianthus annuus* (Sunflower) seed oil (not ISO)
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
EINECS/ELINCS No	232-273-9
FAO specification	none
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 % of total fatty acids) high oleic acid sunflower oil: min. 75% oleic acid (as % of total fatty acids)
Relevant impurities	none
Molecular mass and structural formula	Not relevant, the substance is a complex mixture
Mode of Use	foliar application by spraying
Preparation to be used	Oil dispersion (OD) (0.5 - 1 % (v/v))
Function of plant protection	fungicide

Appendix D – List of extension of uses

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	kg a.i./hl min max	Water l/ha min max	kg a.i./ha min max (l)	kg a.i./ha min max (l)		
Vegetable Gardening Common bean *Phaseolus vulgaris* PHSVX	All Member States	Sunflower oil	F	Bean rust *Uromyces appendiculatus* UROMAP	Oil Dispersion (OD)	915 to 923	foliar application spraying	BBCH 09 to 60	1 to 3	7	0.92 (1 L)	200 to 500	1.84 (2 L) to 4.6 (5 L)	(6L) to (15 L)	2	* **
Vegetable Gardening like Cucumber *Cucumis sativus* CUMSA			F/ G	Powdery mildew *Podosphaera xanthi* PODOXA				BBCH 09 to 60 and 69 to 70	1 to 5					(6 L) to (15 L)		
Rosaceae Family Like *Prunus, Fragaria Rosa, Rubus* etc. 1ROSF				Powdery mildew *Podosphaera* spp. 1PODOG					1 to 7			200 to 700	1.84 (2L) to 6.44 (7L)	(14L) to (49L)		
Apple *Malus domestica Malus pumila* MABPM Pear *Pyrus communis* L PYUCO				Powdery mildew *Podosphaera leucotricha* PODOLE								200 to 600	1.84 (2 L) to 5.52 (6 L)	(14 L) to (42 L)		
Grapevine *Vitis vinifera* VITVI			F	Downy mildew *Plasmopara viticola* PLASVI												
Wheat *Triticum vulgare Triticum aestivum* TRZAX Barley *Hordeum vulgare* HORVX				*Puccinia* spp. like Wheat Black rust *Puccinia triticina* PUCCRT Barley brown rust *Puccinia hordei* PUCCHD				BBCH 31 to 51	1 to 3			200 to 300	1.84 (2 L) to 2.76 (3 L)	(6 L) to (9 L)		
Potato			F/ G	Late blight *Phytophthora infestans*				BBCH 19	1 to			100 to	0.92 (1 L)	(7 L) to		

Solanum tuberosum SOLTU				PHYTIN				to 60 and 69 to 70	7			300	to 2.76 (3 L)	(21 L)		
Carrot *Daucus carota* DAUCA				Alternariose *Alternaria dauci* ALTEDA				BBCH 09 to 60	1 to 3	15	0.46 (0.5 L)	200 to 500	0.92 (1 L) to 2.3 (2.5 L)	(3 L) to (7.5 L)		

* 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

(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