TECHNICAL REPORT

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Outcome of the consultation with Member States and EFSA on the basic substance application for *Saponaria officinalis* L. roots for use in plant protection as acaricide and plant elicitor

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 *Saponaria officinalis* L. roots 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 *Saponaria officinalis* L. roots as a basic substance for use in plant protection as acaricide and plant elicitor. 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: *Saponaria officinalis* L. roots, basic substance, application, consultation, plant protection, pesticide

Requestor: European Commission

Question number: EFSA-Q-2017-00237

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Summary

Saponaria officinalis L. roots 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 Crop Research Institute 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 in March 2017, EFSA was asked to organise a consultation on the basic substance application for *Saponaria officinalis* L. roots, 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 *Saponaria officinalis* L. roots, organised by EFSA, was conducted with Member States via a written procedure in December 2016- February 2017. 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 *Saponaria officinalis* L. roots and presents EFSA's scientific views on the individual comments received in the format of a reporting table.

The basic substance *Saponaria officinalis* L. roots is prepared from ground, dried roots obtained from *Saponaria officinalis* L. meeting the requirements of the European Pharmacopoeia. The roots of *Saponaria officinalis* L. are used to prepare an extract by macerating the roots in water. Extracts from the roots of *Saponaria officinalis* L. are predominantly used in food and cosmetic industries.

Saponaria officinalis L. is listed in the EFSA compendium of botanicals that have been reported to contain toxic, addictive, psychotropic or other substances of concern (EFSA, 2009); specifically it has been reported to contain substances of concern including triterpenoid saponins. According to the Danish study 'List of Drugs' included in the EFSA compendium, the safe level of intake of *Saponaria officinalis* L. is 100 mg/person per day. However, it is not possible for EFSA to confirm this value, based on the available data. The animal safety of saponins in *Madhuca longifolia* L. as undesirable substances in animal feed has been evaluated by the Panel on Contaminants in the Food Chain (EFSA Contaminant Panel, 2009). The Panel could not set health-based guidance values (ADI, TDI) for saponins in *Madhuca longifolia* L. The toxicity of saponins as a component of fenugreek seed powder has been also assessed by EFSA (EFSA, 2010). EFSA considered that repeat dose toxicity of fenugreek seed powder was probably linked to the saponins content since no adverse effects were observed after the administration of debitterized seed powder (without saponins). Although the applicant provided further publications to address potential concerns, EFSA considered the available information still insufficient to rule out potential concerns. Human and animal health-based guidance values for saponins or a safe level of intake of *Saponaria officinalis* L. cannot be established based on the available information.

Information is missing to complete the estimation of consumer dietary exposure for all requested uses for human consumption. Given the amount of active substance applied and the very short post-harvest interval (PHI) (zero days and 1 day), the conclusion that significant residue levels of *Saponaria officinalis* L. will not occur on crops is not supported. It is noted that specifically tomato and cucumber are crops that to a large extent are consumed fresh and unprocessed; therefore a reduction of residues due to food processing cannot be assumed. Further to that, as a safe level of intake could not be established at toxicological level, the consumer risk assessment cannot be concluded for the uses of *Saponaria officinalis* L. roots in cucumber, tomato and hops.

Information on the rate of degradation of extract components in soil or natural sediment water systems were not available.

Although the applicant provided further information to address potential effects of *Saponaria officinalis* L. roots the information provided is still not sufficient in order to reach a conclusion regarding the risk to non-target organisms from the representative 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.

Saponaria officinalis L. roots is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from Crop Research Institute for approval as a 'basic substance' for use in plant protection as acaricide and plant elicitor.

The European Food Safety Authority (EFSA) organised a consultation with Member States on the basic substance application for *Saponaria officinalis* L. roots, which was conducted via a written procedure in December 2016- February 2017. 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 *Saponaria officinalis* L. roots 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 *Saponaria officinalis* L. roots 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 (Crop Research Institute; 2016, 2017).

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 23 March 2017, EFSA was asked to organise a consultation on the basic substance application for *Saponaria officinalis* L. roots 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 23 June 2017.

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 *Saponaria officinalis* L. roots 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 B and C, respectively.

Documentation provided to EFSA

1. Crop Research Institute, 2016. Basic substance application on *Saponaria officinalis* L. roots submitted in the context of Article 23 of Regulation (EC) No 1107/2009. July 2016. Documentation made available to EFSA by the European Commission.

2. Crop Research Institute, 2017. Basic substance application update on *Saponaria officinalis* L. roots submitted in the context of Article 23 of Regulation (EC) No 1107/2009. April 2017. Documentation made available to EFSA by the applicant.

References

EFSA (European Food Safety Authority), 2009. Compendium of botanicals that have been reported to contain toxic, addictive, psychotropic or other substances of concern on request of EFSA. EFSA Journal 2009;7(9):281, 100 pp. doi:10.2903/j.efsa.2009.281.

EFSA Panel on Contaminants, 2009. Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the European Commission on Saponins in *Madhuca Longifolia* L. as undesirable substances in animal feed. EFSA Journal 2009;9(2):979, 36 pp. doi: 10.2903/j.efsa.2009.979

EFSA (European Food Safety Authority), 2010. Conclusion on the peer review of the pesticide risk assessment of the active substance fenugreek seed powder (FEN 560). EFSA Journal 2010;8(3):1448; 50 pp. doi:10.2903/j.efsa.2010.1448.

European Commission, 2012. Guidance document on botanical active substances used in plant protection products. SANCO/11470/2012– rev. 8. 20 March 2014. 28 pp.

Garcia, D., Ramos, A. J., Sanchis, V. and Marín, S., 2013). *Equisetum arvense* hydro-alcoholic extract: phenolic composition and antifungal and antimycotoxigenic effect against Aspergillus flavus and Fusarium verticillioides in stored maize. J. Sci. Food Agric., 93: 2248–2253. doi:10.1002/jsfa.6033

Abbreviations

a.s.	active substance
BAS	botanical active substances
BP	botanical pesticide
BS	basic substance
cGAP	critical good agricultural practice
DAR	draft assessment report
DC	dispersible concentrate
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
MIC	minimum inhibitory concentration
MRL	maximum residue level
MS	Member State
PHI	pre-harvest interval
PRIMo	Pesticide Residue Intake Model
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 *Saponaria officinalis* L. roots 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)		DE: Here *Equisetum arvense* L. is named as the subject of the application. This should be amended.		Corrected in the text.	Addressed: The name has been corrected.
1(2)		DE: Based on the available information and in consideration of the submitted information on effects of the human health unacceptable risks on human health can't be excluded.	It is proposed to regulate *Saponaria officinalis* L. according to Document SANCO/11470/2012 as a "Botanical active substance".	In our opinion, botanical active substances (BAS) are concerned in the document SANCO/11470/2012, which form part of commercial botanical pesticides (BP). These preparations, although utilising pesticidal effects of secondary metabolites of plants, are formulated in commercial products using various carriers and stabilizers. The difference between basic substances (BS) and BAS thus is that BSs are not primarily intended for plant protection; they are substances used in the food industry and the consumption	Noted For the considerations as regards human health, please kindly refer to Section 5. The issue whether *Saponaria officinalis* L. roots fulfils the criteria laid down in Article 23 (1a) is considered by EFSA a risk management issue

General					
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				of their residues does not give rise to any concerns about any negative effect on human health. In our opinion, this characteristic is fully satisfied by the extract from *S. officinalis* L. roots that is used in traditional medicine, cosmetics and food industry. Thus it has been used by man in the long term and no cases of any negative effects of extracts from the roots of this plant on man or other non-target organisms have been known, although effects of these extracts have not been scientifically explored in some directions. Long-term use of extracts from the roots of S. officinalis L., without any known described cases of poisoning or other negative effects on man, can confirm that the use of these extracts in plant protection is safe and fully compliant with the principle of BS authorisation. By the way, pesticidal effects	

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**
				are shown also by other, already approved BSs. For example, fungicidal effects have been found for the extract from *Equisetum arvense* (Garcia et al., 2013); or for Chitosan hydrochloride where our laboratory determined the MIC50 value lower than 1 mg/mL for some representatives of fungi classified in the genera Fusarium, Aspergillus and Penicillium.	
1(3)	Purpose of the application, p.4	EFSA: *Equisetum arvense L. should* be changed to *Saponaria officinalis L*		It has been changed.	Addressed: The change was made.

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
No comments					

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(1)	2.2.1 Proposed name, p.6	EFSA: it seems that the a.s. is only the root as it is stated under 2.2.2	Clarification is needed on what exactly is considered the a.s and to give a name which is not misleading. The name *Saponaria officinalis* L. would mean the whole plant. *Saponaria officinalis* L. roots would be the name if this is the a.s. as it is probably correctly included in the GAP table	The text has been corrected and clarified. We hope that everything should be clear now. Considering that roots of *S. officinalis* will be used to prepare the extract, in our opinion the roots of *S. officinalis* can be considered as the BS being authorised. However, given that direct dependence has been found between the contents of the dissolved substances in the prepared extract and its acaricidal efficacy, the weight	Addressed: *Saponaria officinalis* L. roots is the basic substance.

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**
				percentage of the dissolved substances in the extract is considered as the active ingredients (a.i.). The main reason is to allow inspecting the quality of the application liquid. We hope that the reasons of this division are now explained and acceptable.	
2(2)	2.2.2 Chemical name, p. 6	EFSA: it seems that the CAS number refers to both root and leaf extracts	Clarification is needed on what is the a.s.: the whole plant, the root part only, the extract of the leaves or the extract of the roots? In these last two cases this is a plant extract.	It has been corrected and explained in the text of the appropriate section.	Addressed: *Saponaria officinalis* L. roots is the basic substance.
2(3)	2.2.4 Method of manufacture of the substance and of the product	EFSA: it is stated that the "extract is prepared…"	Clarification is needed on what is the extract: the substance or the product	It has been corrected and explained in the text of the appropriate section.	Addressed: The extract is the product used for application.

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
No comments					

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
No comments					

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(1)	Mode of preparation	DE: Please check the amounts used for the preparation. 300 g/10 L is only 3 % (w/w). The numeration of this chapter in the application is 2.6 instead of 2.5. The values given for the concentrations in the table	Please explain the protocols and correct the values.	Corrected and explained in the text of the appropriate section.	The percentage (30%) in the updated submission is still wrong. It should state 3% (300 g/10 l)

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**
		in Chapter 2.6 of the application seem to be wrong: 300 g root material extracted in 10 litres of water cannot result in 30.0 % but should be 3 %. Accordingly the extract of dry mass in the application liquid cannot be 4-5 %, as most of the dry substance should be eliminated by filtration, so that it should be much less than 3 %.			
2(2)	Mode of preparation	DE: Please correct typo: … in 10 L of natural **water …**		Corrected and explained in the text of the appropriate section.	Addressed.
2(3)	Description of the recipe	DE: The necessary filter step after the maceration should also be described.		Corrected and explained in the text of the appropriate section.	Addressed.

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)		DE: Data on the usefulness in plant protection of *Humulus lupulus* and ornamentals (listed in the GAP table) are not provided		The missing protocol has now been submitted.	Addressed: Protocol No CRI-SA1704 was submitted.
3(2)	GAP table	EFSA: it is not clear from where the a.s. content of 15 g/kg of the used DC formulation is originating from	To reach the maximum application rate per treatment there is a need for 400 kg of formulation, which would be correct, if the formulation itself is sprayed. Please clarify.	Corrected and explained in the text of the appropriate section.	The GAP table has been amended, however the application rate per treatment expressed in kg a.i./hl is still not understandable based on the way the preparation is obtained. (0.3 kg/10 l)
3(3)		EFSA: is the basic substance intended to be used only in one country or in whole EU?		Corrected and explained in the text of the appropriate section.	Addressed: The GAP table has been modified.

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

No comments

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(1)		DE: Is the product really a concentrate (DC)? In the experiments presented in the application the extract was used directly.	Please verify.	Corrected and explained in the text of the appropriate section.	Addressed: The filtered liquid was considered as a DC.
3(2)		DE: It is not clear what is meant by "a.i." (only the saponins, or the dry substance of the extract or the root granulate used for extraction).	Please specify.	Corrected and explained in the text of the appropriate section.	The a.s. is the *Saponaria officinalis* L. roots, and its extract is considered the product used for application.
3(3)		DE: In column "Application rate per treatment / kg a.i./ha"; line "cucumber..." wrong minimum value. It must be 3,6 instead of 4,5.	Please correct.	Corrected and explained in the text of the appropriate section.	Addressed: The value was corrected.

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**

No comments

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
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 commets					

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(1)		DE: No sufficient information on the genotoxicity of the active substance is available.		New information was sought and added to the appropriate sub-section in the application. We are convinced that the presented information will be	See comment 5(5)

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**
				sufficient to assess the safety of extracts from the roots of *Saponaria officinalis.* L.	

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(2)		DE: No sufficient information on the carcinogenicity of the active substance is available.		New information was sought and added to the appropriate sub-section in the application. We are convinced that the presented information will be sufficient to assess the safety of extracts from the roots of *Saponaria officinalis.* L.	See comment 5(5)

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(3)		DE: No sufficient information on the reproductive toxicity of the active substance is available.		New information was sought and added to the appropriate sub-section in the application. We are convinced that the	See comment 5(5)

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**
				presented information will be sufficient to assess the safety of extracts from the roots of *Saponaria officinalis* L.	

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**
No comments					

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**
5(4)		DE: The application is based on the argument that the active substance would be used as a traditional food in some regions of the world. However, in Germany this use is very limited and no sufficient experiences are available concerning impact on human health.		We cannot agree with this objection. The fact that foods with an addition of an extract from the roots of *S. officinalis* are not considered as common foods in Germany is not related to their safety. Considering that on the contrary, in other parts of the world this extract has been traditionally used, this indicates its safety, provided that the generally maximum safe level of consumption is observed, established at 1 mg/kg bw/day of plant (corresponding to 60 mg/die for a person weighing 60 kg). After all, traditional and long-term use of the extract in the food industry without any known negative impact on	See comment 5(5)

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**
				man is the best evidence of safety of the substance in foods.	

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(5)		EFSA: the assessment of *Saponaria officinalis* L as basic substance should include previous assessment at EU level of *Saponaria officinalis* L or components such as saponins: EFSA (European Food Safety Authority);2009. Compendium of botanicals that have been reported to contain toxic, addictive, psychotropic or other substances of concern on request of EFSA. EFSA	EFSA: the application should be amended to include relevant publications by EFSA on the toxicity of *Saponaria officinalis* L and saponins for human and animal health.	The suggested publications have been included in the evaluation text. They have been used in various sections.	*Saponaria officinalis* L. is a botanical that has been listed in the EFSA compendium of botanicals that have been reported to contain toxic, addictive, psychotropic or other substances of concern (EFSA, 2009), specifically it has been reported to contain substances of concern including triterpenoid saponins. According to the Danish study "List of Drugs "[2] included in the compendium, the safe level of intake of *Saponaria officinalis* L. is 100

[2] Danish list concerning toxicological evaluation of plants in food supplements; The list contains plants considered as unacceptable, plants with a restriction on daily use (max. level), and plants that are evaluated at a daily dose ("Drogelisten" (2000) and later update (September 2006)

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**
		Journal 2009; 7(9):281. [100 pp.]. doi:10.2903/j.efsa.2009.281. EFSA Panel on Contaminants, 2009. Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the European Commission on Saponins in *Madhuca Longifolia* L. as undesirable substances in animal feed. The EFSA Journal (2009) 979, 1-36. EFSA (European Food Safety Authority); 2010. Conclusion on the peer review of the pesticide risk assessment of the active substance fenugreek seed powder (FEN 560). EFSA Journal 2010; 8(3):1448. [50 pp.]. doi:10.2903/j.efsa.2010.1448 On the basis of available data a safety concern of saponins cannot be excluded concerning human and animal health.			mg/person per day. However, it is not possible to EFSA to confirm this value. The animal safety of saponins in *Madhuca longifolia* L. as undesirable substances in animal feed has been evaluated by the Panel on Contaminants in the Food Chain (EFSA Contaminant Panel, 2009). The Panel could not set health-based guidance values (ADI, TDI) for saponins in *Madhuca longifolia* L. The toxicity of saponins as a component of fenugreek seed powder has been also assessed by EFSA (EFSA, 2010). EFSA considered that repeat dose toxicity of fenugreek seed powder was probably linked to the saponins content since no adverse effects were observed after the administration of debitterized seed powder (without saponins). Although the applicant provided further publications to address potential concerns, EFSA

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**
					considered the available information still insufficient to rule out potential concerns. Human and animal health-based reference values for saponins or a safe level of intake of *Saponaria officinalis* L. cannot be established based on available information. See also comments 5(1), 5(2), 5(3), 5(4), 5(6).

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(6)		DE: In a submitted study (Szkudelska et al., 2015) the concentrations of T3 and of insulin were increased in cows. These effects are indications of possible endocrine disruption properties.		High doses of ground roots of *Saponaria officinalis* L. in the feed mixture (up to 660 g/day) were used in the tests; given the mean weight of a cow (650 kg), this amount corresponds to 1 g/kg, thus for an adult person 70-90 g/day (i.e. 1050 to 1350 mg/person/day). It is	See comment 5(5)

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**
				thus reasonable to believe that such high doses will not be consumed by people. Moreover, it is not certain whether saponins or rather other substances contained in insoluble root residues are responsible for the determined biological activity.	

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)	5.12. Additional information related to the use as food	EFSA: It is taken note that despite its toxic potential *Saponaria officinalis* L. finds use as a food additive in special products mainly in the middle east, however not in the EU. According to the application, when *Saponaria officinalis* L. is used as a food additive e.g. in halva production, it is subjected to strong processing conditions (60-70 min of heating at 105°C upon acidification). These conditions were reported to alter or even partially destroy saponins. Application as a pesticide however is intended very close to harvest (PHI 1 day) and to crops that are usually consumed raw (cucumber, tomato). Therefore, the actual residues of *Saponaria officinalis* L. roots on these vegetables should be addressed in order to assess consumer exposure and		Corrected and explained in the text of the appropriate section.	Food processing is reported to alter or even partially destroy saponins while application as a pesticide is intended to crops that are usually consumed raw such as cucumber and tomato, and very close to harvest (PHI 1 day). Therefore it is not appropriate to compare these two different scenarios. The applicant has submitted a theoretical calculation for cucumber, to demonstrate residues would be lower than the safe level of intake of *Saponaria officinalis* L. proposed as 100 mg/person per day in a Danish study (see comment 5(5)). However, it is not possible for EFSA to confirm this safe level, nor to reproduce the conclusion that 'any consumer may eat 4 not washed cucumbers to reach the assumed safe limit'.

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**
		safety.			If using for a theoretical estimation of possible residues the median harvest yield of cucumber production in all EU Member States (years 2011 to 2014; source: FAO Stat) which is approx. 60000 kg cucumbers/ha and the cGAP application rate of 6 kg a.i./ha in cucumber, the theoretical estimate for *Saponaria officinalis* L. residues is 100 mg/kg cucumber. The average unit weight for cucumber is 411.40 g (source: EFSA PRIMo rev.2). One cucumber may therefore theoretically contain a residue of 41 mg *Saponaria officinalis* L. No calculation of residues was submitted for tomato and hops nor was a dietary intake assessment performed considering all the requested uses. However, despite of this missing information on dietary exposure for all

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**
					requested uses, a safe level of intake could not be established at toxicological level, and therefore the consumer risk assessment cannot be concluded.
6(2)	5.13. Acceptable daily intake	EFSA: It is claimed that *Saponaria officinalis* L. is also consumed raw in several countries, however evidence supporting this information and consumption figures were not provided.		Corrected and explained in the text of the appropriate section.	EFSA takes note that the statement that *Saponaria officinalis* L. is also consumed raw in several countries has been removed from the application.
6(3)	6. Residues	EFSA: It is claimed that residues on crops resulting from application are negligible comparing to other uses of *Saponaria officinalis* L. This was not demonstrated and no evidence supporting this claim has been submitted.	Applicant should submit an quantitative estimate of consumer exposure to *Saponaria officinalis* L. roots resulting from the representative uses and qualitative and quantitative information regarding the exposure to Saponaria officinalis from other sources	Corrected and explained in the text of the appropriate section.	EFSA takes note that the statement that 'residues on crops resulting from application are negligible regarding other uses of *Saponaria officinalis* L.' has been removed from the application. A quantitative estimate of consumer exposure to *Saponaria officinalis* L. roots resulting from the use of cucumber was submitted, but not for the other uses. See also comment 6(1)

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)	7 Fate and behaviour in the environment	EFSA: The case made is reasonable regarding that the components in the extract will be natural plant components but there seems to be no evidence to support the statement that degradation would occur rapidly under aerobic conditions. All natural plant components do not degrade rapidly.	Experimental evidence of the degradation rate of extract components (provision of results from at least a ready biodegradability study but aerobic soil incubations investigations would be preferred) would help to support the statements made	Corrected and explained in the text of the appropriate section.	Though the updated application no longer has any statement that 'degradation would occur rapidly under aerobic conditions', information on the rate of degradation of extract components in soil or natural sediment water systems were not available. Some information on ready biodegradability of saponins derived from a different plant *Phytolacca dodecandra* L'Herit was available. A comparison of the nature of saponins from these different sources was not made by the applicant, but a comparison of the molecular structure of the two classes of saponins indicates that their structures are quite different, so the evidence of ready biodegradability for saponins from *Phytolacca dodecandra* cannot be simply read across to those of *Saponaria officinalis.*L.

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**

No comments

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)	8.1.1. Birds	DE: The natural origin of *Saponaria officinalis* L. does not necessarily mean that the substance cannot be toxic to birds. Saponins may have effects on wild birds. Contrary to the statement in the application the described intended uses are not predominantly in greenhouses.		Corrected and explained in the text of the appropriate section.	The information provided is not sufficient in order to reach a conclusion regarding the risk to terrestrial vertebrates from the representative uses (an assessment of the exposure levels is missing).
8(2)	8.1.1 Birds	EFSA: The information provided is not sufficient in order to reach a conclusion regarding the risk to birds from the representative uses of *Saponaria officinalis* L. roots It is also noted that the intended uses are not limited to greenhouses, see also comment from DE, 8(2)	Toxicity data and exposure estimates or scientific justifications should be provided in order to assess the risk to birds	Corrected and explained in the text of the appropriate section.	See comment 8(1)
8(3)	8.1.2 Mammals	EFSA: The information provided is not sufficient in order to reach a conclusion regarding the risk to wild mammals from the representative uses of *Saponaria officinalis* L. roots	Toxicity data and exposure estimates or scientific justifications should be provided in order to assess the risk to birds	Corrected and explained in the text of the appropriate section.	See comment 8(1)

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(4)	General comment	EFSA: The assessment of *Saponaria officinalis* L. roots as basic substance should include previous assessment at EU level of *Saponaria officinalis* L. or components such as saponins, see also comment 5(5).		Corrected and explained in the text of the appropriate section.	See comment 8(1)

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(5)	Ibid.	DE: The fact that the plant *Saponaria officinalis* L. is widely present in natural wetlands does not necessarily mean that the extract of the roots used as an acaricide is not toxic to aquatic organisms.		Corrected and explained in the text of the appropriate section.	The information provided is not sufficient in order to reach a conclusion regarding the risk to aquatic organisms from the representative uses of *Saponaria officinalis* L. roots It is additionally noted that information on the rate of degradation of extract components in natural sediment water systems was not available. See also comment 7(1)

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)	8.2. Effects on aquatic organisms	EFSA: The information provided is not sufficient in order to reach a conclusion regarding the risk to aquatic organisms from the representative uses of *Saponaria officinalis* L. roots, see also comment from DE, 8(5)	Toxicity data and exposure estimates or scientific justifications should be provided in order to assess the risk to aquatic organisms	Corrected and explained in the text of the appropriate section.	See comment 8(5)

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)		DE: The applicant presented a report on a preliminary experiment with some bees and other arthropods. From this no adverse effects could be deducted but neither excluded.	More data should be presented and the scientific literature publicly accessible on this topic should be discussed.	Considering that the extract showed only acaricidal efficacy and did not show any effects on other tested representatives of arthropods, it is likely that it may have a negative impact also on other mites in the tested concentration. Therefore it is reasonable to indicate this fact in the application table (in particular, due to a potential negative impact on predatory mites). This information has been added	The information provided is not sufficient in order to reach a conclusion regarding the risk to bees and other non-target arthropods from the representative uses of *Saponaria officinalis* L. roots In this respect it is noted, that in consideration of the acaricidal efficacy of the extract, in the application it is indicated that 'the extract should not be applied in vegetation where predatory mites are also present as

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
				to the text.	bioagents'.
8(8)	8.3.2. Effects on other arthopods	DE: Because of the supposed acaricidal effect of *Saponaria officinalis* L. a risk assessment for non-target arthropods is necessary.	Provide a sound risk assessment for non-target arthropods for the intended uses.	See comment 8(7)	See comment 8(7)
8(9)	8.2. Effects on bees and other arthropods species	EFSA: The information provided is not sufficient in order to reach a conclusion regarding the risk to bees and other arthropods from the representative uses of *Saponaria officinalis* L. roots, see also comment from DE, 8(7)	Toxicity data and exposure estimates or scientific justifications should be provided in order to assess the risk to bees and other arthropods.	Corrected and explained in the text of the appropriate section.	See comment 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)		DE: Data on effects on earthworms and soil macroorganisms are lacking.	They should be provided.	Corrected and explained in the text of the appropriate section.	The information provided is not sufficient in order to reach a conclusion regarding the risk to earthworms and other soil organisms from the representative uses of *Saponaria officinalis* L. roots

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**
					(an assessment of the exposure levels is missing) It is additionally noted that information on the rate of degradation of extract components in soil was not available. See also comment 7(1)
8(11)	Ibid.	DE: The natural origin of *Saponaria officinalis* L. does not necessarily mean that the substance cannot be toxic to earthworms or other soil macro-organisms.		Corrected and explained in the text of the appropriate section.	See comment 8(10)
8(12)		EFSA: The information provided is not sufficient in order to reach a conclusion regarding the risk to earthworms and other soil macroorganisms from the representative uses of *Saponaria officinalis* L. roots, see also comment from DE, 8(10)	Toxicity data and exposure estimates or scientific justifications should be provided in order to assess the risk to earthworms and other soil macroorganisms.	Corrected and explained in the text of the appropriate section.	See comment 8(10)

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)		DE: *Saponaria officinalis* L. extracts can have effects on soil microorganisms as shown in studies on their application in biodegradation of toxicants in soils. Such effects can be desirable but also adverse.	This should be addressed.	Corrected and explained in the text of the appropriate section.	The information provided is not sufficient in order to reach a conclusion regarding the risk to soil microorganisms from the representative uses of *Saponaria officinalis* L. roots (an assessment of the exposure levels is missing). It is additionally noted that information on the rate of degradation of extract components in soil was not available. See also comment 7(1)
8(14)	Ibid.	DE: The natural origin of *Saponaria officinalis* L. does not necessarily mean that the substance cannot be toxic to earthworms or other soil micro-organisms.		Corrected and explained in the text of the appropriate section.	See comment 8(13)
8(15)		EFSA: The information provided is not sufficient in order to reach a conclusion regarding the risk to soil microorganisms from the representative uses of *Saponaria officinalis* L. roots, see also comment from DE,	Toxicity data and exposure estimates or scientific justifications should be provided in order to assess the risk soil microorganisms.	Corrected and explained in the text of the appropriate section.	See comment 8(13)

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)			

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)		DE: In medicine saponins from *Saponaria officinalis* L. have good fungicidal effects for example against the yeast *Candida albicans*. Given that it is expectable that they may have inhibitory effects on the beneficial microflora in the phyllosphere.	A possible fungicidal effect should be addressed.	The screening of biological activity of the extract also included tests of its fungicidal efficacy. However, the tests showed no fungicidal activity and no growth-inhibiting effects on the tested organisms. The protocol has been attached for a review. It is thus unlikely that application in the recommended dose will have any negative impact on microscopic fungi. However, the efficacy may differ in higher doses or if pure substances are used. Nevertheless, this effect is unlikely in the concentration applied by us.	See comment 8(13)

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(17)		EFSA: The information provided may not be sufficient in order to reach a conclusion regarding the effects on biological methods of sewage treatment, see also comment 7(1)	A scientific justification should be provided in order to assess the effects on biological methods of sewage treatment.	Corrected and explained in the text of the appropriate section.	The information provided is not sufficient in order to reach a conclusion regarding the effects on biological methods of sewage treatment from the representative uses of *Saponaria officinalis* L. roots

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**

No comments

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)	General comment	EFSA: The assessment of *Saponaria officinalis* L. roots as basic substance should include previous assessment at EU level of *Saponaria officinalis* L. or components such as saponins, see also comment 5(5) and 8(4)		Corrected and explained in the text of the appropriate section.	Addressed. See comments 5(5) and 8(1)

Appendix B – Identity and biological properties

Common name (ISO)	*Saponaria officinalis* L. root
Chemical name (IUPAC)	Not relevant
Chemical name (CA)	Not relevant
Common names	Saponariae rubrae radix
CAS No	84775-97-3 (root/leaf extract)
CIPAC No and EEC No	283-921-2 (EINECS)
FAO specification	none
Minimum purity	950 g/kg
Relevant impurities	none
Molecular mass and structural formula	Not relevant
Mode of Use	spray
Preparation to be used	DC
Function of plant protection	Acaricide, plant elicitor

Appendix C – List of uses

Crop and/or situation (a)	Member State	Example product name as available on the market	F, G, I(b)	Target (c)	Product*		Application**				Application rate per treatment***			PHI (days) (m)	Remarks
					Type (d-f)	Conc of B.S. 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)	Water l/ha min max	kg a.i./ha min max (kg/ha) (l)		
Cucumber, *Cucumis sativus*	EU Member States	Saponaria e rubrae radix, *Saponaria officinalis* roots	F, G	*Tetranychus urticae*	minced plant material (MPM)***	>950	at first infestation of plants, high volume spraying	From - BBCH 12 - 2nd true leaf on main stem unfolded - to BBCH 79 - 9 or more fruits on main stem has reached typical size and form.	2-10	7-10 days	1.2-1.5	300-400	3.6-6.0	1 day	
Humulus lupulus	EU Member States	Saponaria e rubrae radix, *Saponaria officinalis* roots	F	*Tetranychus urticae*	minced plant material (MPM)***	>950	at first infestation of plants, high volume spraying	From - BBCH 21 - First pair of side shoots visible- to BBCH 61 - Beginning of flowering: about 10% of flowers open	2-5	10-12 days	1.2-1.5	500-800	6.0-12.0	none	

Crop and/or situation (a)	Member State	Example product name as available on the market	F, G, I(b)	Target (c)	Product*		Application**				Application rate per treatment***			PHI (days) (m)	Remarks
					Type (d-f)	Conc of B.S. 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)	Water l/ha min max	kg a.i./ha min max (kg/ha) (l)		
Tomato, Lycopersicum esculentum	EU Member States	Saponaria e rubrae radix, *Saponaria officinalis* roots	*F, G*	*Tetranychus urticae*	minced plant material (MPM)***	>950	*at first infestation of plants, high volume spraying*	*From - BBCH 21 - First primary apical side shoot visible - to BBCH 89 - 80% of fruits show typical fully ripe colour*	2-10	10-12 days	1.2-1.5	300	3.6-4.5	1 day	
ornamental plants	EU Member States	Saponaria e rubrae radix, *Saponaria officinalis* roots	F, G, I	*Tetranychus urticae*	minced plant material (MPM)***	>950	at first infestation of plants, high volume spraying	From - BBCH 21 - Principal growth stage 2: Formation of side shoots	2-10	5-7 days	1.2-1.5	300	3.6-4.5	none	

*The product is homogenate of plant roots, extracted with water and filtered (extract)

** The application cannot be applied in case of hot temperature (>35 °C).

*** The active ingredient (a.i.) is understood as weight percentage of the dissolved substances in the application liquid prepared by extraction of *Saponaria officinalis* roots. The reason is to gain better control of quality of the application liquid. It is not recommended to perform application in combination with bioagents based on predatory mites.

(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. biting and suckling insects, soil born insects, foliar fungi, weeds

(d): e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR), minced plant material (MPM)
(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): g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to
(i): compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
(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 15