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TECHNICAL REPORT

Outcome of the consultation with Member States and EFSA on the basic substance application for *Rheum officinale* and the conclusions drawn by EFSA on the specific points raised[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

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

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KEY WORDS

Rheum officinale, basic substance, application, consultation, plant protection, pesticide

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[2] Correspondence: pesticides.peerreview@efsa.europa.eu

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SUMMARY

Rheum officinale 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 the Institut Technique de l'Agriculture Biologique (ITAB) for approval as a "basic substance". Regulation (EC) No 1107/2009 introduced the new category of "basic substances", which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest of applying for approval may be limited. Article 23 of Regulation (EC) No 1107/2009 lays down specific provisions for consideration of applications for approval of basic substances.

In March 2013 the European Commission requested the European Food Safety Authority (EFSA) to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received from the European Commission on 3 March 2014, EFSA was asked to organise a commenting on the basic substance application for *Rheum officinale*, 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 3 months of acceptance of the specific request.

A consultation on the basic substance application for *Rheum officinale*, organised by the EFSA, was conducted with Member States and EFSA via a written procedure in November 2013 – January 2014. Subsequently the applicant was invited to address the comments received in the format of a Reporting Table, within a period of 30 days.

The current report summarises the outcome of the consultation process organised by the EFSA on the basic substance application for *Rheum officinale* and presents EFSA's scientific views on the individual comments received in the format of a Reporting Table.

A basic substance could only be used directly or in a product consisting of the substance and a simple diluent. It is not the case for this material as it is extracted by boiling for 45 minutes. Therefore, this should not be considered a basic substance.

The available data do not allow a sufficient characterisation of *Rheum officinale* to perform an adequate hazard and risk assessment in the mammalian toxicology section.

Since sufficient information on the characterisation and on the toxicological properties of constituent components of *Rheum officinale* was not provided, a qualitative and quantitative consumer risk assessment could not be performed.

Information was not provided that would enable an environmental exposure assessment to be carried out. Such an assessment would be needed to address the risk assessments for non-target organisms.

Since sufficient information was not provided in the ecotoxicology section, a qualitative and quantitative risk assessment to non target organisms could not be performed.

TABLE OF CONTENTS

Abstract 1
Summary 2
Table of contents 3
Background as provided by the European Commission 4
Terms of reference as provided by the European Commission 4
Evaluation 5
Documentation provided to EFSA 6
References 6
Appendix 7
Collation of comments from Member States and EFSA on the basic substance application for *Rheum officinale* and the conclusions drawn by EFSA on the specific points raised 7
Abbreviations 31

BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 1107/2009[3] (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.

Rheum officinale is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from the Institut Technique de l'Agriculture Biologique (ITAB) for approval as a "basic substance".

The European Food Safety Authority (EFSA) organised a consultation with Member States and EFSA on the basic substance application for *Rheum officinale*, which was conducted via a written procedure in November 2013 – January 2014. The comments received were collated by EFSA in the format of a Reporting Table. Subsequently, the applicant was invited to address the comments in column 3 of the Reporting Table. The comments received and the response of the applicant thereon, together with the application submitted by the applicant, were considered by EFSA in column 4 of the Reporting Table.

The current report aims to summarise the outcome of the consultation process organised by the EFSA on the basic substance application for *Rheum officinale* 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 *Rheum officinale* as a "basic substance" in the context of Article 23 of the Regulation, is key supporting documentation, therefore it is considered as background documentation to this report and will also be made publicly available, excluding its appendices (ITAB, 2013 and ITAB, 2014).

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

On 6 March 2013 the European Commission requested the 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 3 March 2014, EFSA was asked to organise a commenting on the basic substance application for *Rheum officinale*, to consult the applicant on the comments received, and to deliver their 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 prepared by EFSA. The agreed deadline for providing the finalised report is 12 June 2014.

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.

[3] 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 No L 309, 24.11.2009, p. 1-50.

EVALUATION

The comments received on the basic substance application for *Rheum officinale* and the conclusions drawn by the EFSA are presented in the format of a Reporting Table.

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

The finalised Reporting Table is provided in the Appendix of this report.

DOCUMENTATION PROVIDED TO EFSA

1. ITAB (Institut Technique de l'Agriculture Biologique), 2013. *Rheum officinale*. Basic substance application submitted in the context of Article 23 of Regulation (EC) No 1107/2009. October 2013. Submitted by ITAB (Institut Technique de l'Agriculture Biologique). Documentation made available to EFSA by the European Commission.

2. ITAB (Institut Technique de l'Agriculture Biologique), 2014. *Rheum officinale*. Basic substance application update submitted in the context of Article 23 of Regulation (EC) No 1107/2009. February 2014. Submitted by ITAB (Institut Technique de l'Agriculture Biologique). Documentation made available to EFSA by the applicant.

REFERENCES

None.

APPENDIX

COLLATION OF COMMENTS FROM MEMBER STATES AND EFSA ON THE BASIC SUBSTANCE APPLICATION FOR *RHEUM OFFICINALE* 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1(1)		DE: The fungicidal activity of the extract of *Rheum officinalis* or rather some of its components such oxalic acid and several anthranoid derivatives has been shown by several authors partly partly also mentioned in the application report of EFSA. Furthermore there exists already products such as "Kobe 1.2 SL" (http://www.sineria.org/files/KOBe.84187931.pdf) which contain *Rheum officinalis* extracts and are put on the market as "novel biofungicide". Although not predominantly used for plant protection purposes we would rather prefer regulation as plant protection product (considering reduced requirement for botanicals) considering the biological activity of the extract. This indicates also the problem of finding a comprehensible way for differentiating cases where such type of biologically active plant extracts should be regulated as basic substance and other cases where this should be done as active substance (biopesticide).	Anthranoid components are taken in account in the BSA Is, sale, placement on the market and advertisement of a biofungicide without any EU approval at regulation 1107/2009 appropriate and reasonable, as comment from M.S of a BS application written in order to provide source of evaluation for such extract? Attempt for regularization at EU level, in accordance with Regulation 1107/2009, covering all EU member states, of such type of plant extract, useful for agriculture, is the goal of our BSA(s).	It would seem that there was a product on the market. This would have to be an unapproved product. When the given link is now followed the website is not found. It can be concluded that Rheum officinale is not on the market as a PPP.

General				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1(2)		DE: We propose that with the application in general a basic risk assessment for non-target organisms should be required which should indicate the risk for the relevant groups of non-target organisms considering the expected exposure conditions. An appropriated **basic** risk assessment for *Rheum officinalis* is missing for most groups. However, considering the biological activity of the extract we would require more information especially for birds, aquatic and terrestrial invertebrates, and soil organisms.	BSA is for ***Rheum officinale*** More information is provided in BSA.	Sufficient information was not provided and a qualitative and quantitative risk assessment to non target organisms could not be performed.
1(3)		ES: No comments		

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

2.1. Predominant Use				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)		ES: No comments		

2.2. 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(2)	2.2.1, identity of the basic substance	EFSA: It is unclear what the specification of the basic substance is. If it is the European pharmacopeia then please provide the full details.	Added in section 2 European pharmacopoeia describe Rhubarb *rheum officinale* as *Rhei radix* European pharmacopoeia 2005 Rhubarb *Rhei radix*, Monograph Q-S, p.2363-2364 EC Commission Decision 96 335	The specification is that of the European pharmacopeia.
2(3)	2.2.1 Common name of the substance and product and their synonyms/plant nomenclature	ES: The synonym in Spanish should be included.	Corrected	This has been corrected.

2.3. Current Former and in case proposed trade names				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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.

2.4. Manufacturer of the substance/products				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(4)		ES: No comments		

2.5. Type of preparation				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(5)		ES: No comments		

2.6. 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(6)	2.6, recipe	EFSA: The regulation states the following. 'It is not predominantly used for plant protection purposes but nevertheless is useful in plant protection either directly or in a product consisting of the substance and a simple diluent.' This is not the case for this material as it is extracted by boiling it for 45 minutes. This is therefore not a basic substance.	No comment. No comment anymore.	This is not a basic substance because basic substance can only be the substance or a simple diluents. This is not the case for this material as it is extracted by boiling it for 45 minutes. This is therefore not a basic substance.
2(7)		ES: No comments		

2.7. Function on plant protection				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(8)		ES: No comments		

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 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.

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 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.

3.3. Summary of intended uses				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(1)	3.3 Summary of intended uses	EFSA: Are the dose rates correct? 0.004 - 0.048 g/ha would be homeopathic doses. Should this be rather 0.004 - 0.048 kg/ha (4 - 48 g/ha)?	Doses and rate are in kg/ha accounting that all 200 g of rheum in 100 L are the product. This was done to encompass the entire weight, subject to the decoction, independent components.	The GAP table has been corrected.
3(2)		DE: the descriptions of intended uses are not every time consistent with the efficacy results of experiment reports listed. Complete control of diseases is not probable.	Complete control of disease is not a goal for a BS application. Usefulness is indeed pursue, not the eradication of disease. It is not an application for PPP with claimed and required efficacy.	It is not expected that complete control can be achieved.
3(3)	GAP-Table: Application rate per treatment	DE: The application rate for grapevine is given as 100 to 300 L water / ha min	Taken in account, no change.	The proposed water volume remains.

3.3. Summary of intended uses				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		max. Since the culture is three dimensional, 100 to 300 L/ha seem to be too low.		
3(4)	3.3 Summary of intended uses	ES: In the "Remarks" of the tables, it is said "… to be used 24 h after preparation" and it should say "…to be used up to a maximum of 24 hours after preparation".	Corrected	This has been corrected.
3(5)	3.3 Summary of intended uses	ES: In the "Remarks" of the table of the intended uses, the use as fungicide on "wheat seeds" is included. This seems to be a mistake as it is foliar application spraying. So the use should be corrected by "wheat".	Corrected	This has been 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 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. Impact on Human and Animal Health

5.1. Effects having relevance to human and animal health arising from exposure to the substance/its products or to impurities				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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(1)	General comment	EFSA: the available data indicate that the a.s. consists of a complex of "natural" compounds. The clear characterisation of the toxicological properties of each component is not given in sufficient details, either alone or in the representative combination, to perform an adequate hazard and risk assessment.	The concept of active substances is not relevant. In Garlic DAR, for example it is stipulated that active ingredient was not really identified; also chemicals are clearly known as DMDS (dimethyl di sulphide) for example.	The available data indicate that *Rheum officinale* is not sufficiently characterised (the complex of compounds and the single substances need to be detailed) to perform an adequate hazard and risk assessment

5.2. Toxicokinetics and metabolism in humans				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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.

5.3. Acute toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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(2)	5.3, p. 21	DE: The extract contains a mixture of several anthracene-derivatives. It should be noted that some of these are known as sensitizers or as irritants. Thus the irritating and sensitizing potential of the mixture should be addressed under section 5.3.	In *Rheum off.* Decoction for humans, Acceptable amount mg/kg/day Lowest Human Recommended Dose (LHRD) = 20 mg of hydroxyanthracene derivates (Ref: HMA 2013) See also EFSA Journal 2013;11(10):3412 Included in BSA	See 5(1)

5.4. Short–term toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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.

5.5. Genotoxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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(3)	2.2, p. 5&6, 5.5 p. 23	DE: The extract that is subject to the application has been found to be mutagenic in several studies. These concerns have not been addressed in further studies. Hence the extracts cannot be considered as substance of no concern based on the data presented. Thus, § 23 (a) is not met and the substance cannot be approved	It is not clear at all, is *Rheum off.* Extract or decoction of concern or sold as PPP in some member states safely without problem and without approval or evaluation?	The extract showed some mutagenic and carcinogenic concerns in the available studies, therefore *Rheum officinale* cannot be regarded as a basic substance.

5.5. Genotoxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		for being used as a basic substance.		

5.6. Long-term toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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(4)	5.6, p. 23&24	DE: The term equivocal evidence for carcinogenicity needs clarification. In some of the cited studies there is evidence for an increase in tumour formation. Considering the positive findings on mutagenicity these data have to be taken into account for the decision making process.		The extract showed some mutagenic and carcinogenic concerns in the available studies, therefore *Rheum officinale* cannot be regarded as a basic substance.

5.7. Reproductive toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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. Neurotoxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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.

5.9. Toxicity studies on metabolites				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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.

5.10. Medical Data adverse effects reported in humans				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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.

5.11. 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 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.

5.12. Additional information related to use as food				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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.

5.13. 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 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.

5.14. 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 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(5)	5.14 (exposure assessment)	DE: The risk assessment for oxalic acid and hydroxyanthracene derivates can not be followed completely due to a lack of information. Which amounts of oxalic acid and hydroxyanthracene derivates have been assumed to be present in *Rheum officinale*?		See 5(1)

6. Residues

Residues				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
6(1)		ES: No comments		

7. Fate and Behaviour in the environment

Fate and Behaviour in the environment				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7(1)	Section 7 Fate and behaviour in the environment	EFSA: An EU evaluation relevant for fate and behaviour in the environment is not referred to and therefore is probably not available. Therefore derogation from Article 4 of the Regulation is not possible and an exposure assessment, as needed to address the risk assessments for non-target organisms, are necessary and is not available.		Information was not provided that would enable an environmental exposure assessment to be carried out. Such an assessment would be needed to address the risk assessments for non-target organisms.
7(2)	Section 7 Fate and behaviour in the environment	EFSA: An ACS health and safety data sheet for one of the constituents of the extract (oxalic acid) is not sufficient information to assess environmental exposure of this component, let alone other biologically active components reported to be present in the extract.		See above.
7(3)		ES: 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)	Section 8, Effects on non-target organisms	EFSA: An EU evaluation relevant for ecotoxicology is not referred to and therefore is probably not available. Therefore derogation from Article 4 of the Regulation is not possible and risk assessments for non-target organisms are necessary.		Information was not provided that would enable to address the risk assessments for non-target organisms.
8(2)	Section 8.1, Effects on terrestrial vertebrates	EFSA: Please refer to Section 5 regarding the available information for mammals. In addition, an acute and long-term risk assessment, taking account the likely exposure to wild mammals following the proposed uses, is required.		See 8(1) An acute and long-term risk assessment, taking account the likely exposure to wild mammals following the proposed uses, is required.
8(3)	Section 8.1, Effects on terrestrial vertebrates	EFSA: No information has been provided to address the risk to birds. Data and risk assessment are required.		See 8(1) No information has been provided to address the risk to birds. Data and risk assessment are required.
8(4)		DE: In the report it is mentioned that Rheum leaves are known to be toxic for birds but no further reasoning is given why application of Rheum in the intended application rates might be still acceptable. Therefore a risk assessment is completely missing.		See 8(1) and 8(3)

8.2. Effects on aquatic organisms				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(5)	Section 8.2, Effects on aquatic organisms	EFSA: The underlying study used to derive the referenced acute fish LD50 for oxalic acid should be submitted. It is not considered appropriate to refer to a MSDS which only summarises the toxicity.		The underlying study used to derive the referenced acute fish LD50 for oxalic acid was not provided. It is not considered appropriate to refer to a MSDS which only summarises the toxicity.
8(6)	Section 8.2, Effects on aquatic organisms	EFSA: Information to address the risk to fish from rhein and emodin are required. Moreover, a risk assessment, taking account the likely exposure to surface water following the proposed uses, is required. The assessment should consider both acute and chronic effects.		8(1) No information has been provided to address the risk to fish. Both acute and chronic data and risk assessments are required.
8(7)	Section 8.2, Effects on aquatic organisms	EFSA: No information has been provided to address the risk to aquatic invertebrates and algae. Data and risk assessment are required.		See 8(1) No information has been provided to address the risk to aquatic invertebrates and algae. Data and risk assessment are required.
8(8)		DE: Information is not sufficient to allow for an appropriate risk assessment to aquatic non-target organisms other than fish (see also DE comment 1(2)). More information is at least needed with respect to the effects on invertebrates after an application at the intended uses.		See 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(9)	Section 8.3.1, Effects on bees	EFSA: i) The acute contact LD_{50} study by Mamet (2012) is mostly given in French. An English translation is needed. ii) The study appears not to have been performed in accordance with GLP. iii) The study only considers the acute contact toxicity to honey bees. No information has been provided regarding the acute oral toxicity. iv) The available data should be used in a risk assessment.		The available information is not sufficient to address the risk to bees.
8(10)	Section 8.3.1, Effects on bees	EFSA:The study Brødsgaard (1998) appears not to have been published in a scientific journal. In addition, the study only considers the effects of exposure to oxalic acid, and not rhein and emodin.		The study Brødsgaard (1998) appears not to have been published in a scientific journal. In addition, the study only considers the effects of exposure to oxalic acid, and not rhein and emodin.
8(11)	Section 8.3.2, Effects on other arthropods	EFSA: The referenced information does not provide any useful information which can be used to address the risk to **non-target** arthropods. Further information is required and should be used in a risk assessment, taking account the likely exposure following the proposed uses.		No further information was provided. The referenced information does not provide any useful information which can be used to address the risk to **non-target** arthropods.
8(12)		DE: Information is not sufficient to allow for an appropriate risk assessment to terrestrial invertebrates (see also DE comment 1(2)). More information is needed with respect to the effects on		See 8(11)

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		NTA after an application at the intended uses.		
8(13)	Effects on bees	DE: The recommended use pattern for rhubarb (*Rheum officinale*) prepared as a plant homogenate extract includes application in cucumber, eggplant, potato, grapevine and wheat. Rhubarb contains among other things oxalic acid and its neutral salts in high concentration. Vaporized oxalic acid is used by some beekeepers as a miticide against the parasitic *Varroa* mite and EU regulations permit its use in biological beekeeping (EU Council Regulation, No. 1804/1999). The best effects against the mite are achieved using oxalic acid with 3.5 %. However bees tolerate a single concentration up to 4.5 % oxalic acid without causing any damages. An assessment based on the submitted study of Plan d'étude Testapi no 178 2012 is not possible because the study is only released as a summary and available only in French. It is concluded that rhubarb (*Rheum officinale*) prepared as a plant homogenate extract will not adversely		See 8(9)

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		affect bees or bee colonies when used as recommended.		

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(14)	Section 8.4, Effects on earthworms and soil macro-organisms	EFSA:The referenced information does not provide any useful information which can be used to address the risk to earthworms. Further information is required and should be used in a risk assessment, taking account the likely exposure following the proposed uses. The assessment should consider both acute and chronic effects.		See 8(1) No further information was provided. The referenced information does not provide any useful information which can be used to address the risk to earthworms.
8(15)		DE: Information is not sufficient to allow for an appropriate risk assessment to soil organisms (see also DE comment 1(2)). Considering that the *Rheum* extract shows anthelmintic activity, its impact at intended use rates on the soil mesofauna, e.g. soil nematodes, remains unclear. As the extract seems already to be used as bio-fungicide there should exist at least some more information on this aspect.	Kobe 1.2 SL cited here is a mixture of *Rheum off* extract and *Rumex cripus* extract plus an unknown formulating adjuvant (as mentioned technical active ingredient).	See 8(14)

8.5. Effects on soil microorganisms				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(16)	Section 8.5, Effects on soil micro-organisms	EFSA:The referenced information does not provide any useful information which can be used to address the risk to soil microbial processes (nitrogen transformation and carbon mineralisation). Further information is required and should be used in a risk assessment, taking account the likely exposure following the proposed uses.		No further information was provided. The referenced information does not provide any useful information which can be used to address the risk to soil microbial processes (nitrogen transformation and carbon mineralisation).
8(17)		DE: Information is not sufficient to allow for an appropriate risk assessment to soil organisms (see also DE comment 1(2)). Considering that the *Rheum* extract shows fungicidal activity, its impact at intended use rates on the soil microorganisms remains unclear.		See 8(16)

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(18)	Section 8.6, Effects on other non-target organisms	EFSA: No information has been provided to address the risk to non-target terrestrial plants. Further information is required and should be used in a risk assessment, taking account the likely exposure following the proposed uses.		No information has been provided to address the risk to non-target terrestrial plants. Further information is required and should be used in a risk assessment, taking account the likely exposure following the proposed uses.
8(19)		DE: No information on possible effects on		See 8(18)

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		NTTP is provided. Therefore the risk for NTTP cannot be evaluated. As the extract seems already to be used as bio-fungicide there should exist at least some more information on this aspect.		

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 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.

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
9(1)		DE: see DE comment 1(1) regarding the criteria for regulation as basic substance and the necessity to provide an appropriate basic risk assessment for non-target organisms.		See 1(1)
9(2)		ES: No comments		

10. Other comments

Other comments				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
10(1)		ES: In the name of the basic substance, it should be specified that it is a" root extract" (Title page of the application).		Noted.

GR has considered the dossier of *RHEUM OFFICINALE* and confirmed that they have no comments to submit.

ABBREVIATIONS

µg	microgram
µm	micrometer (micron)
a.s.	active substance
BSA	basic substance application
DG SANCO	European Commission Directorate General Health and Consumers
EU	European Union
g	gram
kg	kilogram
L	litre
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
mg	milligram
mL	millilitre
mm	millimetre
PEC	predicted environmental concentration
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
PPP	plant protection product