TECHNICAL REPORT

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Outcome of the consultation with Member States and EFSA on the basic substance application for honey from rhododendron for use in plant protection as rodenticide

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 honey from rhododendron 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 honey from rhododendron as a basic substance for use in plant protection as rodenticide. 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: honey from rhododendron, basic substance, application, consultation, plant protection, pesticide

Requestor: European Commission

Question number: EFSA-Q-2016-00571

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Summary

Honey from rhododendron 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 Klaus Gasser + Partner 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 September 2016, EFSA was asked to organise a consultation on the basic substance application for honey from rhododendron, 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 honey from rhododendron, organised by EFSA, was conducted with Member States via a written procedure in June-August 2016. 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 honey from rhododendron and presents EFSA's scientific views on the individual comments received in the format of a reporting table.

It is acknowledged that the issue whether honey from rhododendron fulfils the criteria laid down in Article 23 (1a) of Regulation (EC) No 1107/2009 has been raised by some Member States during the commenting phase. EFSA considers this issue a risk management matter and does not provide an opinion in relation to that.

Proper batch analysis would be needed to determine the levels of grayanotoxins and other potential active or toxic substances, including relevant impurities in the honey from rhododendron intended to be used as pesticide. This would also allow demonstrating consistent composition and efficacy of the proposed product. Furthermore, specifications for content of grayanotoxins and other potential active or toxic substances including relevant impurities need to be proposed and agreed based on appropriate analysis of batches. Validated analytical methods for grayanotoxins and other potential active or toxic substances including relevant impurities in honey from rhododendron are not available and would need to be provided.

The substance honey from rhododendron is proposed to be used as rodenticide in baits. The applicant claims that field studies performed on their own, demonstrate that mice die as a result of the grayanotoxins in the honey. However, no proper scientific report has been provided to substantiate these claims.

For a basic substance no specific preparation should be needed since the raw technical product is supposed to be used. Therefore, EFSA did not assess the adequacy of the preparation proposed for the intended use (dosage gelatin capsules). However, the product would need to be conveniently labelled to prevent accidental human consumption.

Plant parts of rhododendron ssp. containing grayanotoxin are listed in the EFSA Compendium of botanicals that have been reported to contain toxic, addictive, psychotropic or other substances of concern. The applicant claimed that authorisation as a food supplement, labelled with maximum dosage levels, has been obtained in the EU, but that was not demonstrated by evidence or supported by submission of details regarding the composition of such food supplement and its safety assessment for human health. Non-dietary exposure was not properly addressed and cannot be excluded.

Regarding consumer exposure no data with respect to residue behaviour is needed as long as it can be guaranteed that honey from rhododendron containing grayanotoxins ('mad honey') is only used in bait boxes and that any contact with trees or crops is excluded.

No data with respect to the fate and behaviour into the environment and concerning the effect on other non-target organisms are needed, as long it is guaranteed that i) the proposed uses are exclusively in baits and ii) the bait design is as such that the basic substance cannot be released from the bait box. The bait to be used should close after the entering of the mouse and guarantee the death of the trapped animal inside the bait box, preventing it from becoming a prey of non-target predatory vertebrates. It is noted that further data are needed to ensure that non-target terrestrial organisms could not access the bait. Furthermore, the target species are yet to be defined. No information or evidence has been provided to demonstrate that mice are not subject of unnecessary suffering during the 2 to 4 days until they are supposed to die.

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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.

Honey from rhododendron is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from Klaus Gasser + Partner for approval as a 'basic substance' for use in plant protection as rodenticide.

The European Food Safety Authority (EFSA) organised a consultation with Member States on the basic substance application for honey from rhododendron, which was conducted via a written procedure in June-August 2016. 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 honey from rhododendron 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 honey from rhododendron 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 (Klaus Gasser + Partner; 2016 a,b).

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 20 September 2016, EFSA was asked to organise a consultation on the basic substance application for honey from rhododendron, 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 20 December 2016.

On the basis of the reporting table, the European Commission may decide to further consult EFSA to conduct a full or focussed peer review and to provide its conclusions on certain specific points.

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

2. Assessment

The comments received on the basic substance application for honey from rhododendron 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. Klaus Gasser + Partner, 2016a. Basic substance application on honey from rhododendron submitted in the context of Article 23 of Regulation (EC) No 1107/2009. January 2016. Documentation made available to EFSA by the European Commission.

2. Klaus Gasser + Partner, 2016b. Basic substance application update on honey from rhododendron submitted in the context of Article 23 of Regulation (EC) No 1107/2009. September 2016. 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

Abbreviations

a.s.	active substance
ADI	acceptable daily intake
CLP	Classification, Labelling and Packaging
DG SANTE	Directorates-General - Health and Food Safety
EU	European Union
GTX	grayanotoxin
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
MS	Member State

Appendix A – Collation of comments from Member States and EFSA on the basic substance application for honey from rhododendron and the conclusions drawn by EFSA on the specific points raised

1. Purpose of the application

General

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1(1)	1	DE: Please see 5.13: "acceptable daily intake for humans: less than 5 g of honey from Rhododendron with grayanotoxin". "The oral LD_{50} for mice is approx. 1 mg/kg...", please compare to parathion LD_{50} (mice) approx. 5-25 mg/kg. Therefore, the substance applied for is a substance of concern, this honey cannot be considered as food. DE: The introduction implicates as if the toxin Grayanotoxin would have been proven to be "an essential use" for fruit production.	Honey from rhododendron as described in the application is a substance of concern, it does not meet the criteria of a basic substance. The applicant should clarify that he speculates about the desired effects or cite public available data or own experimental reports about it	In Turkey this honey is sold as food with food certificate without labelling maximum dosage intake. ADI (Acceptable Daily Intake) for humans is estimated to be less than 5 g of honey with approx. 50 mg/ kg Grayanotoxins. The LD_{50} (mice) is approx. 3-5 mg/kg due to the different grayanotoxin versions I-VIII with individual potency levels. In literature the LD_{50} (mice/ grayanotoxin I) is described at approx. 5,1 mg/ kg body weight. This product is not in contact with agro production. A sophisticated rodenticide for organic and conventional fruit production is essential. Mice are expanding fast and less fruit is a loss of yield.	Honey from rhododendron as described in the application is a substance of concern as it may be considered as toxic or containing toxic components (see Section 5).
1(2)		DE: No (literature) studies have		Basic substance application	Some references from peer

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		been provided with this application. A detailed evaluation of rhododendron honey only from the provided report is not possible.		(BSA) updated with online references and literature.	reviewed scientific literature on toxicological effects of honey from rhododendron have been submitted. However, explanations on how these references have been searched and selected, is not provided. A more systematic review would be necessary to guarantee that the search is exhaustive and unbiased.
1(3)	5.2	DK: We question if honey from Rhododendron fulfils the criteria laid down in Article 23 (1a). The severity off the acute effects presents an inherent capacity to cause an adverse effect on humans and this might not be completely neglected by applying a risk management perspective (bait boxes).		In Turkey this honey is sold as food with food certificate. It has been declared admissible by DG SANTE on this basis. The substance placed in a bait box secures zero contact with other animals + humans, even small insects like ants can't enter the bait box, although this substance is still a legal food product.	The issue whether honey from rhododendron fulfils the criteria laid down in Article 23 (1a) is considered by EFSA a risk management issue and EFSA does not provide an opinion in relation to that.
1(4)	9	DK: Please clarify/elaborate what is meant/implied by the sentence "*Also for other diseses, honey from rhododendron with grayanotoxins may be a plant protection product*		Baits are included in plant protection product (PPP) regulation. BSA corrected: "*diseases*" removed, modified.	Only uses in bait boxes which close after the entering of the mice and guarantee that the mice die inside the bait boxes, without release of basic substance into the environment, are considered

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		with perspectives." Rodents are not a disease, and any other application than bait boxes will likely not fulfil the criteria laid down in Article 23 (1a).			by EFSA for this application.
1(5)		NL: it is said that the honey from rhododendron should be used with a special bait box. If the bait box in combination with the honey is placed on the market as a PPP, it cannot be regarded a basic substance anymore as according to regulation 1107/2009 it is not allowed to market a basic substance as a plant protection product.		This application is for honey from rhododendron with GTX (grayanotoxins), to be placed in bait box.	Only uses in bait boxes that close after the entering of the mice and guarantee that the mice die inside the boxes, without release of basic substance into the environment, are considered by EFSA for this application. See also 1(3)
1(6)		PL: The LD_{50} value for mice specified by the applicant concerns the intraperitoneal route of administration not oral. Oral LD_{50} for mice is about 5-fold higher. Moreover, it is not specified for which grayanotoxin this value applies	EFSA: please clarify the source of information for the different endpoints mentioned in the report.	The oral LD_{50} for mice is approx. 5,1 mg/kg (Grayanotoxin I) and 4,9 mg/kg (Grayanotoxin III) according to literature.	The origin of the information on the oral toxicity (LD_{50}) for mice has not been clarified by the applicant in column 4. See Section 5 for further information.

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

2.1. Identity and Physical and chemical properties of the substance and product to be used

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)		DE: The numeration in the application sheet and in this commenting table are in different orders.	The applicant should modify his order to avoid misunderstandings	The numeration of chapters in the BSA has not been updated to avoid misunderstandings in the BSA.	Noted The numeration of chapters in the BSA has not been updated by the applicant.
2(2)	2.2.5 Description...	DE: Rhododendron honey is known in Turkey as "Mad Honey" because of its toxic effect. It is stated that the concentration of grayanotoxins in honey as food product ranges from 10-60 mg/kg. However the applicant intends to produce a special honey with higher toxin content. Therefore it is not clear which substance resp. specification is applied for; honey with food grade or honey which must not recommended for human consumption due to its content of toxins. The intended concentration of Grayanotoxins in the self-produced honey cover a	The applicant should state here why a more than doubled concentration of toxin could be still marked. For efficacy reasons a concentration would probably not be necessary. Please give proof that the achieved content of toxins (up to 150 mg/kg) is acceptable for a substance of no concern.	The concentration of grayanotoxin in the honey can have a range from 10-60 and 10-300mg/kg depending on final production and purpose of usage. This substance is still a legal food product. It does not make a challenging difference if you place honey with 10mg or 300mg/kg inside of a bait box. The mg/kg grayanotoxin level must be clearly labelled on the product.	Honey from rhododendron as described in the application is a substance of concern as it may be considered as toxic or containing toxic components (see Section 5).

2.1. Identity and Physical and chemical properties of the substance and product to be used					
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		very wide range (10 – 150 mg/kg). Is a safe use ensured with such a high uncertainty in the concentration in the capsules? Is ensured that the mice eat enough of the capsules when the concentration of the toxins in the honey is low?		We developed a quality assurance system to deliver this honey in different grayanotoxin levels or mg/kg thus it is possible to measure the amount of honey one mouse must eat. (Updated BSA with reference to analytical method. (annex I; references in § 2)	
2(3)	2.2.5	DE: No information is provided regarding the composition of rhododendron honey especially with respect to the content of the different grayanotoxins and possible other substances which have effects regarding the proposed use.		The mice die from grayanotoxin. Grayanotoxin versions range from 1-8 and the most potent are GTX I + III. This substance is a legal food product. Composition of GTX is variable as all natural substances.	Proper batch analysis would be needed to determine the levels of grayanotoxins and other potential active or toxic substances, including relevant impurities in the honey from rhododendron intended to be used as pesticide. This would also allow demonstrating consistent composition and efficacy of the proposed product. Furthermore, specifications for content of grayanotoxins and other potential active or toxic substances including relevant impurities need to be proposed and agreed based on appropriate analysis of batches.

2.1. Identity and Physical and chemical properties of the substance and product to be used					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
2(4)	2.2.5	DE: No specification in terms of minimum and maximum contents for the different grayanotoxins has been provided.		We measure GTX I + III only. If other versions occur in the honey it's a surplus. This substance is a legal food product. Composition of GTX is variable as all natural substances.	Specifications for content of grayanotoxins and other potential active or toxic substances including relevant impurities need to be proposed and agreed based on appropriate analysis of batches.
2(5)	2.2.7	DE. No methods for the determination of grayanotoxins in rhododendron honey have been provided.		(Updated BSA with reference to analytical method. (annex I; (references in § 2)	It is not clear to which reference in Annex I the applicant is referring to. However, no proper validated analytical method report seems to be available as part of the application. A validated method for grayanotoxins in rhododendron honey is not available. See 2(10)
2(6)	2.2. IDENTITY AND PHYSICAL CHEMICAL PROPERTIES OF THE SUBSTANCE AND PRODUCT TO BE USED	NL: The product to be used is honey from rhododendron. The identity should reflect this. Information regarding all grayanotoxins and other compounds that are expected to contribute to the efficay should be given. Also the source for the		Grayanotoxin I+ III are the versions contributing to the executive effect. (Updated BSA with reference to analytical method. (annex I and references in § 2)	See 2(4)

2.1. Identity and Physical and chemical properties of the substance and product to be used					
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	(2.2.1, 2.2.2, 2.2.3)	information grayanotoxins should be stated. (references)			
2(7)	2.2.5 Description and specification	NL (July 2016): It is claimed that honey from rhododendron sold from food contain 10-60 mg/kg grayanotoxin. What is the source of this information?		We used honey from rhododendron with approx. 50mg/kg (grayantoxin I + III/ honey) but we used many different concentrations and of course if the grayanotoxin level is higher then mice must eat less in order to die.	See 2(4) and 2(5)
2(8)	2.2.5 Description and specification	NL: A specification should include a range for all compounds that contribute to the efficacy. Also other mayor components and any relevant impurities should be included. References should be given were the information was obtained.		Mice die from grayanotoxin only (reference in annex 1, BSA).	See 2(4) and 2(5)
2(9)	2.2.6 Identity of inactive isomers, impurities and additives	NL: Honey contains many compounds that do not contribute to the efficacy. The mayor components and any relevant impurities should be included. References should be given were the information was obtained.			See 2(4) and 2(5)
2(10)	2.2.7.1 Methods of	NL: the method of analysis		(Updated BSA with reference	See 2(3) and 2(5)

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**
	analysis	should be clearly described for all compounds that contribute to the efficacy. References should be given were the information was obtained.		to analytical method. (annex I and references in § 2)	Validated analytical methods for grayanotoxins and other potential active or toxic substances including relevant impurities in honey from rhododendron are not available and would need to be provided.
2(11)	2.2.7.2 Analytical methods for determination of relevant impurities	NL the applicability of these methods depends on the presence of relevant impurities (to be clarified at point 2.2.5 and 2.2.6). References should be given were the information was obtained.		Updated BSA, we measure grayanotoxin I + III only. Composition of GTX is variable as all natural substances.	See 2(10)
2(12)	Identity and physico-chemical properties	PL: Physico-chemical properties are given only for grayanotoxin I. Not given characteristics of grayanotoxin III, which can be even more toxic than grayanotoxin I, moreover, occurs in rhododendron honey in significant quantities		Grayanotoxin III is a bit more toxic than grayantoxin I, BSA application updated with the mg/ kg value of GTX I+ III.	No physico-chemical properties are available for grayanotoxins contained in honey from rhododendron.
2(13)	Molecular and structural formula	PL: As above; data was given only for grayanotoxin I		BSA application updated and added value for GTX 3.	Noted

2.2. Current Former and in case proposed trade names

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(14)	2.3. CURRENT, FORMER AND IN CASE PROPOSED TRADE NAMES OF SUBSTANCES/ PRODUCTS AS PUT ON THE MARKET	NL: The basic substance should be already on the market for other purposes that plant protection. In this case, honey from rhododendrons should be sold and be recognisable as honey from rhododendrons. The toxicity of the grayanotoxin makes honey from rhododendrons unsuitable for human consumption and therefore cannot be classified as foodstuff. This makes it unlikely for this honey to be sold for any other purpose than as a rodenticide. We therefore assume the honey cannot be accepted as basic substance. The name of the product(s) on the current market should be clear. According to regulation 1107/2009, it is not allowed to market a basic substance as a plant protection product. Therefore, produce honey from rhododendron cannot be produced solely as a plant protection product.		The honey is already on the market in Turkey and sold with food certificate. In the EU it is possible to sell it as food supplement and clearly label maximum dosage levels for human intake. Typical food stuff, no brand name except "Rhododendron Honey" or "Honey from Rhododendron" (made by Klaus Gasser + Partner for example) Its usage consists of the honey from rhododendron inside a bait box. The bait	The toxicity of the grayanotoxin makes honey from rhododendron unsuitable for human consumption and therefore cannot be classified as foodstuff. See Section 5

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
				box closes doors and keeps death mice inside.	
2(15)	2 General	EFSA: As presented it seems the product is not yet in the market and that it is intended to be produced as hoc for its use as rodenticide. At any case this honey could not be considered food and would need to be properly labelled to avoid accidental human consumption of it.		In the EU it is possible to sell this honey as food supplement and clearly label maximum dosage levels for human intake.	See 1(1) and Section 5
2(16)	2 General	EFSA: As already indicated by MS the content of grayanotoxins and other potential toxins in this honey would need to be clearly specified.		The concentration of grayanotoxin will be measured for each batch and clearly labelled. (Updated BSA with reference to analytical method. (annex I and references in § 2)	See 2(4) and 2(5)
2(17)	2 General	EFSA: validated methods of analysis of grayanotoxins and other active components in the honey would need to be provided.		(Updated BSA with reference to analytical method. (annex I and references in § 2)	See 2(5) and 2(10)

2.3. Manufacturer of the substance/products					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
2(18)	2.4	DE: There is a clear wish to develop a product visible in the application.	The applicant should be cited here as manufacturer.	Klaus Gasser + Partner produce and/ or sell this honey.	Noted
2(19)	2.4. MANUFACTURER	NL: a manufacturer has to be included		Klaus Gasser + Partner	Applicant clarifies that the manufactures is: Klaus Gasser + Partner

2.4. Type of preparation					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
2(20)	2.5. TYPE OF PREPARATION	NL: In our opinion, pure honey can be best classified as an Any other Liquid (AL) type formulation. Only a product (or a simple diluent) which is already on the market but not predominantly used for plant protection purposes a can be regarded as a basic substance. In this case the honey is to be packaged in capsules which could imply that a product will be placed on the market especially for PPP purposes. The packaging in capsules solely		The honey is packaged in dosages and dosages can be labelled as maximum levels for human intake as well. It is sold as honey from rhododendron.	For a basic substance no specific preparation is needed since the raw technical product is supposed to be used. Therefore, EFSA does not assess the adequacy of the preparation proposed for the intended use (dosage gelatin capsules). Anyhow, the product would need to be conveniently labelled to prevent accidental human consumption since it is poisonous to humans.

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**
		for the use as plant protection product cannot be accepted.			
2(21)	Type of preparation	PL : It is not clear whether the gelatin capsule of honey will be an attractive bait for mice			See 2(20)

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(22)	2.5 Type of preparation of the substance/product	DE: The honey shall be used pure and/or will be packaged in capsules made of gelatin. When the honey is used pure, are the bait boxes still impervious?		BSA application updated. The honey will be packaged in dosages only and the packaging consists of capsules (gelatine etc.), nylon, bio plastics, plastics, paper, bio degradable plastics etc.	See 2(20)
2(23)	2.6	DE: A product will be sold for use in baits.	The applicant should describe the use in baits in more details and point out how selective the baits probably are.	Open bait box, place honey packaged in dosages, close bait box. Bait boxes which close doors and keeps mice inside are fine. Air holes in Bait box must have a micro grid in order that small animals and even ants can't enter the bait box.	Addressed. It should be clarified that the use of bait boxes which close doors and keeps mice inside should be considered mandatory, not an option.

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(24)	2.6	DE: A capsulation of rhododendron honey with gelatin is planned. However, gelatin is not an approved basic substance. It seems that this would be an application as plant protection product.		Gelatine, nylon, plastics or bio plastics, bio degradable plastics, paper are just the ordinary packaging materials used for bait independently – honey is the basic substance.	See 2(20)
2(25)	2.6. DESCRIPTION OF THE RECIPE FOR THE PRODUCT TO BE USED	NL: It is stated that the product will not be sold as plant protection product since it proceeds with no contact with agricultural productions. However, this cannot be accepted. If the product is sold for the elimination of mice a regular product authorisation as a plant protection product or biocide is required (depending on the place of use)		The product is sold as honey from rhododendron and accepted as food stuff.	See 2(20)
2(26)	2.6. DESCRIPTION OF THE RECIPE FOR THE PRODUCT TO BE USED	EFSA: It does not seem that the product as presented (capsules) may be prepared by the farmers directly from a honey available in the EU market. Ad hoc honey conveniently formulated needs to be used. Also the		We want to produce the honey as well and label maximum dosage levels for human intake. In the EU we can market this honey as food supplement and clearly label max dosage levels for human intake.	See 2(20)

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**
		product would need to be conveniently labelled to prevent accidental human consumption since it would be poisonous to humans.			

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: No correct field of use has been provided here; no reasoning of the intended use has been provided.	Please indicate Harmful organism, cultivated plant and so on. Provide publications which reason the layout of the intended use.	We have done real on field tests/ studies with positive results of its intended use. BSA Updated.	Applicant claim that field studies performed in-house demonstrate that mice die as a result of honey with grayanotoxins. However, no proper scientific report has been provided to substantiate these claims.
3(2)	3.2	DE: Mice are said to die within 2-4 days after ingestion. Due to confusion they would be more prone to predators. However, it is stated in other chapters, that mice should be trapped in bait boxes after having entered	The applicant should give evidence for his statement that mice will not suffer unnecessarily.	Mice stay in bait box and die in bait box.	Since the effect on other non-target predatory animals that could eat the dying mice has not been assessed, the type of bait box should be such the mice stay in bait box and die in bait box. No information or evidence

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
		the bait box.			has been provide to demonstrate that the mice are not subject of unnecessary suffering during the 2 to 4 days until they are supposed to die.
3(3)	3.3	DE: The description of intended uses is inconsistent with GAP table e.g. number of capsules per bait box, use with or without bait boxes. Please see also 2.6: "natural honey from Rhododendron ... used pure and/ or ... in capsules".		BSA application updated. The honey is packaged in dosages.	See 2(20)
3(4)		NL: No comments.			Noted

3.2. Effects on harmful organisms or on plants

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(5)	Ibid. and 3.1	DE: In the application it says that mice die within 2-4 days after eating the honey and that the bait boxes keep dead mice in the box. Does this mean that the mice are		Please indicate the corresponding law in Germany. The application is for the EU, in case we would need to find another solution for Germany.	See 3(2)

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**
		held in the boxes dying for 2-4 days? In DE such traps are not allowed. Either the mice have to die instantly in the traps or they have to be able to leave the traps and die after 2-4 days somewhere outside.			
3(6)	Ibid.	DE: Here it is stated that the mice are more accessible to predators after eating honey from rhododendron because they show signs of confusion. When the mice are accessible to predators they cannot be in the traps anymore. That's a contradiction to the statement that dead mice are kept in the boxes.		BSA application updated. Mice stay in bait box and die in bait box. Air holes in the bait box must have a micro grid to avoid that small insects or even ants can enter the bait box.	See 3(2)
3(7)		DE: The applicant did not provide any public available publications. Only some temporary Internet-links were cited showing indirectly aspects cited in the application.	The applicant should include publications to verify his assumptions. Especially data about the pain of mice should be provided.		See 3(2)
3(8)		NL: No comments.			Noted
3(9)		PL: It is not clear how poisoned mice can get out of the bait		Mice stay in bait box and die in bait box.	See 3(2)

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
		box and be available to predators			

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(10)		DE: Member state is unclear.	Please clarify whether Italy or EU is meant.		No further clarification provided by the applicant.
3(11)		DE: Column "Application" seems not to be correct concerning b).	Please clarify.		No further clarification provided by the applicant.
3(12)		DE: Column "Application rate" seems not to be correct concerning a).	Please clarify Min/Max.		No further clarification provided by the applicant.
3(13)		NL: No comments.			Noted
3(14)		EFSA: If poisoned mice can leave the bait and be available to predators, the potential indirect poisoning of non-target wild predators (eg. eagles, foxes etc…) needs to be carefully considered in the eco-toxicological assessment.		Mice stay in bait box and die in bait box.	See 3(2)

4. Classification and labelling of the substance

Classification and labelling of the substance					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
4(1)		DE: The reported acute oral LD_{50} for grayanotoxin is in the range of a very toxic compound (Acute Tox. 1).		Still food stuff allowed	See 1(1) and Section 5
4(2)		NL: No comments.			Noted
4(3)		PL : Grayanotoxin I and III are not classified according to Regulation (EC) No 1272/2008[2] as amended		Still food stuff allowed	Noted. See also 2(14), 2(20) and Section 5

5. Impact on Human and Animal Health

5.1. Toxicokinetics and metabolism in humans					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
5(1)		EFSA: a more robust literature review should be conducted on the impact on human and animal health of the components of honey from rhododendron. The outcome of the published literature		Still food stuff allowed	A robust literature review was not conducted on human and animal health.

[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–1355.

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
		should be well reported with clear reference to the studies.			
5(2)		EFSA: Rhododendron spp is included in the Compendium of botanicals that have been reported to contain toxic, addictive, psychotropic or other substances of concern (EFSA, 2009).		Still food stuff allowed BSA updated.	Rhododendron spp is included in the Compendium of botanicals that have been reported to contain toxic, addictive, psychotropic or other substances of concern (EFSA, 2009).
5(3)	5.12 5.13	DE: No evidence is given that honey with grayanotoxins is used as food. DE: It is stated that the acceptable daily intake for humans is less than 5 g/day. This clearly indicates that the substance must not be considered as food.	It must be doubted that the substance applied for can be considered as food. It rather seems a substance of concern.	In Turkey this honey is sold with food certificate. Therefore it is not a substance of concern.	Evidence has not been submitted to underpin the claim that honey from rhododendron containing alkaloids (grayanotoxin) is a food product in the EU. As food poisoning is associated with grayanotoxin-contaminated honey (also called 'mad honey') honey with such properties cannot be considered compliant with provisions in EU food law. Plant parts of rhododendron ssp. that containing grayanotoxin are listed in the EFSA Compendium of botanicals that have been

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**
					reported to contain toxic, addictive, psychotropic or other substances of concern, which is part of the Guidance on Safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements. The applicant claimed that despite of this, listing authorisation as a food supplement (labelled with maximum dosage levels) has been obtained but that was not demonstrated by evidence; nor supported by submission of details regarding the composition of such food supplement and its safety assessment for consumers.

5.2. Acute toxicity					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
5(4)	5.3	DE: The reported acute oral LD_{50}		In Turkey this honey is sold	See 5(1), 5(2) and 5(3).

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
		for grayanotoxin is in the range of a very toxic compound (Acute Tox. 1).		with food certificate. Therefore it is not a substance of concern.	
5(5)		PL: The LD_{50} value for mice specified by the applicant concerns the intraperitoneal route of administration not oral. Moreover, it is not specified for which grayanotoxin this value applies. Oral LD_{50} for mice is reported as 5.1 mg/kg for grayanotoxin I and 4.9 mg/kg for grayanotoxin III.	EFSA: the applicant should clearly indicate the values for each grayanatoxin and the route of exposure.	In Turkey this honey is sold with food certificate. Therefore it is not a substance of concern.	See 5(1), 5(2) and 5(3).

5.3. Short-term toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA		Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(6)		PL: Not specified whether these symptoms relate to human or animals poisoning. Moreover, there are acute toxicity studies of grayanotoxins in rats especially regarding hepatotoxicity and		In Turkey this honey is sold with food certificate. Therefore it is not a substance of concern. Substance not intended for environmental uses (spray) but confined in bait box.	See 5(1), 5(2) and 5(3).

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
		nephrotoxicity			

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(7)		DE: Not sufficient data reported to allow a firm conclusion.	References could be added.		See 5(1), 5(2) and 5(3).
5(8)		PL: Only preliminary studies were conducted in vitro. Grayanotoxins II and III did not cause chromosomal damage in cultured human lymphocytes. However, grayanotoxins structure provide these compounds a possible mutagenic activity, thus further studies should be performed.		In Turkey this honey is sold with food certificate. Therefore it is not a substance of concern. Substance not intended for environmental uses (spray) but confined in bait box.	See 5(1), 5(2) and 5(3).

5.5. Long-term toxicity

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

No comments.

5.6. Reproductive toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(9)		PL: The applicant has not entered data about the effects on reproduction. Existing data from a study in mice and chicken embryos indicate that grayanotoxin I did not show embryotoxicity or teratogenic effects even at maternally toxic doses		In Turkey this honey is sold with food certificate. Therefore it is not a substance of concern. Substance not intended for environmental uses (spray) but confined in bait box.	See 5(1), 5(2) and 5(3).

5.7. Neurotoxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(10)	5.4/5.8	DE: The symptoms described in Sections 5.2 and 5.4 are neurotoxic symptoms. This would be in line with effects reported in the Internet (https://en.wikipedia.org/wiki/Grayanotoxin).		In Turkey this honey is sold with food certificate. Therefore it is not a substance of concern. Substance not intended for environmental uses (spray) but confined in bait box.	See 5(1), 5(2) and 5(3).
5(11)	5.7 neurotoxicity	NL: grayanotoxins are known neurotoxins which prevent inactivation of sodium channels and hereby cause persistent activation. Regulation 1107/2009 states that basic substances should not have		In Turkey this honey is sold with food certificate. Therefore it is not a substance of concern. Substance not intended for	See 5(1), 5(2) and 5(3).

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
		an inherent capacity to cause neurotoxic effects. Although, we do agree that considering the intended use in bait boxes there is no actual concern related to the potential neurotoxic effects.		environmental uses (spray) but confined in bait box.	
5(12)		PL: Rhododendron honey poisoning caused by grayanotoxin is associated with autonomic nervous system symptoms, such as excessive perspiration, hypersalivation, vomiting and bradycardia. Animal study confirmed autonomic symptoms of grayanotoxin intoxication.		In Turkey this honey is sold with food certificate. Therefore it is not a substance of concern. Substance not intended for environmental uses (spray) but confined in bait box.	See 5(1), 5(2) and 5(3).

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
5(13)		DE: In the Internet there are anecdotal reports of uses and effects in humans (https://en.wikipedia.org/wiki/Grayanotoxin) also from grayanotoxin containing honeys from other plants.	A systematic review of open literature should be done.	References in annex I.	See 5(1), 5(2) and 5(3).
5(14)		PL: Rhododendron honey intoxication's symptoms are dose-related. In mild form dizziness, weakness, excessive perspiration, hypersalivation, nausea, vomiting and paresthesias are present. Severe intoxication may lead to life threating cardiac complication such as complete atrioventricular block. Reported amount of honey causing poisoning is between 5 to 150 g		Quantities described here are largely above uses in bait, no contact with people is possible. In Turkey this honey is sold with food certificate. Therefore it is not a substance of concern. Substance not intended for environmental uses (spray) but confined in bait box.	See 5(1), 5(2) and 5(3).

5.10. Additional Information related to therapeutic properties or health claims

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(15)		DE: The applicant reported that honey from rhododendron is used as treatment in traditional medicine and as a health product.	References should be submitted.	BSA updated.	See 5(1), 5(2) and 5(3).

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(16)		DE: It is unclear whether honey from rhododendron is available as food on the EU market.	References should be added clarifying whether it is available as food on the EU market.	In Turkey it is sold with food certificate. In EU it is possible to sell it as food supplement and label maximum dosage levels for human intake.	See 5(1), 5(2) and 5(3).
5(17)		EFSA: It is doubted that honey from rhododendron that contains alkaloids (grayanotoxins) can be considered a food product. Not all rhododendrons produce grayanotoxins and therefore rhododendron honey may indeed be marketed, but this type of honey is not the same product that is subject to this application. In fact, honey that contains grayanotoxins (mad honey) is considered contaminated and it is associated with food poisoning.	It is suggested be more distinctive and the application concerning the food use of honey from rhododendron, or submit evidence for authorised marketing as a food product of honey that contains grayanotoxins.	In Turkey it is sold with food certificate. In EU it is possible to sell it as food supplement and label maximum dosage levels for human intake.	See 5(1), 5(2) and 5(3).

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(18)		DE: From the description of the intended use, it is unclear how the baits come into the box. In case there is an exposure of the user, a reference dose might be necessary.	Please clarify the handling of the baits and the box. Where relevant, please derive a reference dose.	Open box, place packaged honey dosage, close box. The operator must not eat packaged dosages.	The applicant clarified the product handling; however non-dietary exposure was not properly addressed and therefore cannot be excluded.
5(19)		DE: Not sufficient data reported to allow a firm conclusion whether the basic substance has an inherent capacity to cause endocrine disrupting or immunotoxic effects.	References could be added.	In Turkey it is sold with food certificate and consumed since centuries.	See 5(1), 5(2) and 5(3).
5(20)		DE: Based on the few summarised data, it is difficult to draw a firm conclusion whether the basic substance is not a substance of concern.	References could be added.	In Turkey it is sold with food certificate and consumed since centuries.	See 5(1), 5(2) and 5(3).

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(21)		DE: With respect to the high oral toxicity of grayanotoxin it should be ruled out that any	Description of the bait boxes, the bait (honey only in capsules or pure as well) and the	Packaged honey dosages will be placed in the bait box.	See 5(1), 5(2), 5(3) and 5(18).

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**
		exposure to operators, workers, bystanders or residents (especially children) occurs. Otherwise, a risk assessment is necessary.	handling of the bait boxes.		

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)		EFSA: The applicant states that rhododendron honey is used inside of bait boxes that would close in the trapped mice. Therefore, exposure of trees /crops is not relevant. However, it is also stated that the substance may have a positive influence on soil, roots and trees. This statement casts doubt over the non-relevance of exposure of the soil and the fruit trees, respectively, to grayanotoxins.	Clarification should be given on the possibility that soil and trees (via uptake from soil) could be exposed to the grayanotoxins of rhododendron honey under the use conditions intended. If this scenario cannot be excluded, evidence should be submitted that soil up-take and translocation of grayanotoxins in plants is not relevant.	BSA application updated. Honey is packaged in dosages and thus it is not relevant for soil, roots and trees. Honey can't leave the bait box even if it is raining the honey can't leave the bait box.	Addressed The applicant has clarified that the product design is as such that the honey cannot get out of the bait box and therefore soil and tree exposure is not considered a relevant scenario.

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)		EFSA: see comment 8(3) in relation to possible release from the baits when exposed to rain and comment 3(14) in relation to indirect poisoning of predators of the poisoned mice (when they leave the bait).		Bait box keeps mice inside and mice die in bait box.	Addressed Applicant has clarified that for the intended uses in bait, the bait to be used has to close after the entering of the mice and not to allow the trapped mice to leave the bait, guaranteeing the mice will die inside the bait box.

7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, groundwater, surface water)

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7(2)		No comments			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)	Ibid.	DE: It has to be ensured that the bait boxes do not attract other terrestrial vertebrates than mice.		Small animals, insects and even ants can't enter the bait box due to a micro grid covering air holes in the bait box.	See 8(2)
8(2)	3.2 Effects on harmful organisms or on plants	NL: According to the information provided by the applicant, the use of the substance is as a rodenticide to control the mice which can cause damage to orchards. the substance will be provided in a bait box. Upon oral exposure, the mice will die within 2-4 days. According to Article 23(2), a basic substance shall be approved where "any relevant evaluations show that the substance has neither an immediate effect on human or animal health nor an unacceptable effect on the environment". NL acknowledges that by the use of the substance in a bait box there is no further	A better solution for controlling the vole presence in orchards will be by mechanically removing or reducing the vegetative cover between the trees. This will create an unfavourable habitat for voles.	The solution of packaged honey in dosages placed in bait box is for any type of mice. It is recommended to place bait boxes around mice holes, especially if two or more holes are closed together.	The target species were not defined. More information on this point is needed. From the available information it cannot be excluded that non-target organisms could access the bait. Indeed the micro grid covering the air holes would not prevent non-target terrestrial vertebrates to access the bait from the same entrance as the one for the target organisms.

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
		exposure of the environment, birds, aquatic environment, non-target arthropods, bees, soil organisms and plants. The "mice" are not really defined by the applicant in terms of species. The meadow and pine vole are known to eat the bark and roots of fruit trees and thus NL assumes that the substance is meant to control these organisms. Furthermore by using the substance as a rodenticide exposure of other small mammals which inhabit the orchards cannot be excluded. Furthermore how many of these bait boxes will be placed in orchards and for how long the exposure of small mammals will be? What will the tree growers do with the carcasses, will there be a chance of secondary poisoning of bigger predators? The voles in general to not have the definition as "pest		If mice would die outside box (which is not the case, because mice can't leave the bait box) GTX is consumed and metabolized therefore secondary poisoning is not expected. Furthermore quantities for mice are largely lower than these for higher animals.	

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
		organisms" under 1107/2009. In the Netherlands they are protected under a national law "Flora and Fauna Wet". Only in certain cases exemptions can be given to control to vole population.			
8(3)	8. Effects on non-target species	EFSA: From the information provided in the application, it is assumed that the exposure to non-target organisms is low, due to the use in bait boxes. It is, however, noted that under point 3.3 Summary of the intended uses it is reported that 'it is recommended to use capsules in baits when it's not raining and when the ground and soil are dry', does this mean that in case of rain/wet soil exposure in the environmental compartment can be expected and that the above mentioned conditions of use should be considered as risk mitigation measures? See also comment from DE 8(13) (under Section 8.5).	Further information on the potential exposure for non-target organisms needs to be provided. Applicant to clarify the reason why it is recommended to use capsules in baits when it's not raining and when the ground and soil are dry.	BSA application updated. Even if it is raining honey can't leave the bait box and water can't touch honey in the bait box. Honey is packaged in nylon, plastic, bio degradable plastic or bio plastic, paper, capsules of gelatin.	Addressed. Applicant has clarified that the basic substance cannot leave the bait box even during rainfall events. See also 6(1) and 7(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)	8.1 Effects on non-target vertebrates	EFSA: The target/pests organisms should be better identified e.g. in term of species. Also, it is not demonstrated that the bait boxes are specific to the target organisms. See also comments from DE and NL.	Further details on the target species are needed. In addition, it should be demonstrated that the exposure potential for non-target small mammals or other non-target organism is expected to be low.		See 8(1) and 8(2)
8(5)		EFSA: More data are needed in order to assess the potential risk for terrestrial organisms, see also 8(4). It should be ensured that the risk assessment covers the representative uses of honey from rhododendron.	A risk assessment and/or a scientific justification should be given in order to address the risk to terrestrial vertebrates from the representative uses of honey from rhododendron.	Small insects, animals and even ants don't have a chance to access and enter the bait box due to a micro grid covering air holes in the bait box.	See 8(2)

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)		NL: No comments			Noted
8(7)		EFSA: From the information provided in the application, it is assumed that the exposure to non-target organisms is low due to the	Applicant to clarify the reason why it is recommended to use capsules in baits when it's not raining and when the ground and soil are dry.	BSA application updated. Even if its raining honey can't leave the bait box and water can't touch honey in the bait box. Honey is packaged in	Further data are not needed as long as it is guaranteed that the basic substance is used in baits, that the affected target organism die

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
		use in bait boxes. It is, however, noted that under point 3.3 Summary of the intended uses it is reported that 'it is recommended to use capsules in baits when it's not raining and when the ground and soil are dry', does this mean that in case of rain/wet soil exposure in the environmental compartment can be expected and that the above mentioned conditions of use should be considered as risk mitigation measures? See also comment 8(13) from DE (under Section 8.5) and 3(14) form EFSA in relation to potential indirect poisoning of predators. .	A risk assessment and/or a scientific justification (e.g. exposure based) should be given in order to address the risk to aquatic organisms from the representative uses of honey from rhododendron.	nylon, plastic, bio degradable plastic or bio plastic, paper, capsules of gelatin.	in the bait and not in the open environment and that the bait design is as such that the basic substance cannot be released from the bait box. See also 8(3)

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(8)		DE: The applicant wrote: "The substance is not expected to	The applicant should correct the sentence: "The substance is	BSA application updated. It is not relevant since trap baits	Addressed

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**
		be toxic for bees". This is not correct.	toxic for bees. For the intended use this is not relevant because the honey is applied in capsules and baits."	are not a target for bees and due to the micro grid covering air holes in the bait box bees can't enter the bait box.	
8(9)		NL: No comments			Noted
8(10)		EFSA: Considering also the comment from DE, a risk assessment and/or a scientific justification should be given in order to address the risk to bees from the representative uses of honey from rhododendron.	A risk assessment and/or a scientific justification should be given in order to address the risk to bees from the representative uses of honey from rhododendron, see also comment 8(8).	Bees are looking for flowers, honey is not a target for bees in environment, although they may do some pillage. Furthermore, this honey (under nectar) is already collected, concentrated stored and eaten by bees in corresponding beehives! if this honey (or nectar) was toxic the beehive would have die from this operation in ordinary beehives and logically, this honey would not exist! Bees can't enter the bait box.	Addressed, see 8(8)

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(11)		NL: No comments			Noted
8(12)		EFSA: From the information provided in the application, it is assumed that the exposure to non-target organisms is low due to the use in bait boxes. It is, however, noted that under point 3.3 Summary of the intended uses it is reported that 'it is recommended to use capsules in baits when it's not raining and when the ground and soil are dry', does this mean that in case of rain/wet soil exposure in the environmental compartment can be expected and that the above mentioned conditions of use should be considered as risk mitigation measures? See also comment from DE 8(13) (under Section 8.5) and 3(14) form EFSA in relation to potential indirect poisoning of predators.	Applicant to clarify the reason why it is recommended to use capsules in baits when it's not raining and when the ground and soil are dry. A risk assessment and/or a scientific justification (e.g. exposure based) should be given in order to address the risk to earthworms and other soil macroorganisms from the representative uses of honey from rhododendron.	Baits are a very good security to avoid environment drift or spilling, accessibility to higher animals or smaller animals and insects. This confined application is driven in order to reduce risk to minimum (or zero) environmental possible contamination.	See 8(3)

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)	Ibid.	DE: Because of the bactericidal effect of honey from rhododendron it has to be ensured that the bait boxes are impervious (especially when the honey is applied pure and not in capsules) thus to prevent the honey entering the soil.		Honey is packaged in capsules (gelatin), nylon, plastics, biodegradable plastics, bio plastics and paper.	See 8(3)
8(14)		NL: No comments			Noted
8(15)		EFSA: From the information provided in the application, it is assumed that the exposure to non-target organisms is low due to the use in bait boxes. It is, however, noted that under point 3.3 Summary of the intended uses it is reported that 'it is recommended to use capsules in baits when it's not raining and when the ground and soil are dry', does this mean that in case of rain/wet soil exposure in the environmental compartment can be expected and that the above mentioned conditions of use should be considered as risk	Applicant to clarify the reason why it is recommended to use capsules in baits when it's not raining and when the ground and soil are dry. A risk assessment and/or a scientific justification (e.g. exposure based) should be given in order to address the risk to soil microorganisms from the representative uses of honey from rhododendron.	Honey is packaged in capsules (gelatine), nylon, plastics, paper, bio degradable plastics and bio plastics. BSA application updated.	See 8(3)

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
		mitigation measures? See also comment from DE 8(1) (under Section 8.5)			

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)		No comments			No comments

8.7. Effects on biological methods of sewage treatment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(17)		No comments			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** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
9(1)		DE: It is proposed to checked from a legal point of view, whether the applied use is covered by the definition of plant protection product in Article 23(1)(a). In line with Article 23(1)(c) and (d) such uses would be out of scope for a basic substance. Additionally it should be checked whether the applied use is covered by the definition of a biocidal product according to regulation 528/2012[3].		It is marketed as honey from rhododendron (food product) and labelled with maximum dosage level for human intake.	See 1(1) and 1(3)
9(2)		NL: Based on the comments above, honey from rhododendron cannot be regarded a basic substance.		Honey from Rhododendron is indeed sold as basic "food product"	See 9(1)

[3] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products. OJ L 167. 27.6.2012. p. 1–123.

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)		DE: Due to the lack of citations in the evaluation report, it is difficult to perform a proper evaluation. It is noted that some references were listed in appendix I but they were not made available.		Uses are confined to bait box, no spray.	See 10(2)
10(2)		PL : Although the concept of the use of rhododendron honey as a natural rodenticide is interesting, however, the documentation presented for evaluation should to be clarified and supplemented		BSA application updated.	Noted. However see also 1(2) and 5(1)
10(3)		PL: In our opinion, we used the following references: 1. Koca I., Koca A.F. (2007): Poisoning by mad honey: a brief review. Food Chem. Toxicol. 45, 1315-1318 2. Gunduz A. et al. (2006): Mad honey poisoning. Am. J. Emerg. Med. 24, 595-598 3. Akinci S. et al. (2008): An unusual presentation of mad honey poisoning: acute myocardial infarction. Int. J.		BSA application updated References taken in consideration	See 10(2)

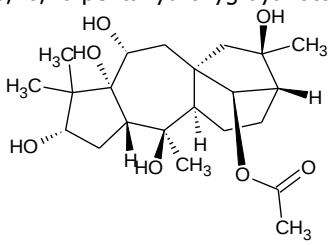
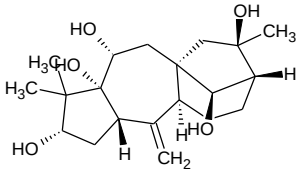
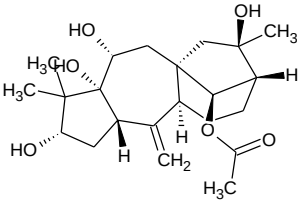
Other comments

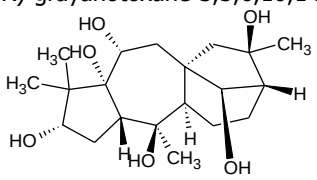
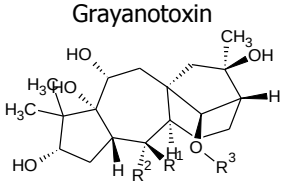
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		Cardiol. 129, e56-e58 4. Gunduz A. et al. (2008): Clinical review of grayanotoxin/mad honey poisoning past and present. Clin. Toxicol. 46, 437-442 5. Jansen S.A. et al. (2012): Grayanotoxin poisoning: "mad honey disease" and beyond. Cardiovasc. Toxicol. 12, 208-215 6. Ascioglu M. et al. (2000): Effects of acute grayanotoxin-I administration on hepatic and renal functions in rats. Turk. J. Med. Sci. 30, 23-27 7. Silici S. et al. (2016): Acuye effects of grayanotoxin in rhododendron honey on kidney functions in rats. Environ. Sci. Pollut. Res. 23, 3300-3309 8. Onat F. et al. (1991): Site of action of grayanotoxin in mad honey in rats. J. Appl. Toxicol. 11, 199-201 9. Kim S.E. et al. (2010): Presynaptic effects of grayanotoxin III on			

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**
		excitatory and inhibitory nerve terminals in rat ventromedial hypothalamic neurons. Neurotoxicology 31, 230-238 10. Hikino H. et al. (1979): Subchronic toxicity of ericaceous toxins and rhododendron leaves. Chem. Pharm. Bull. 27, 874-879 11. Cucer N., Eroz R. (2010): Investigation of mutagenic effects of grayanotoxin II and III on cultured human lymphocytes. Al Ameen J. Med. Sci. 3, 293-299 12. Kobayashi T. et al. (1990): Developmental toxicity potential of grayanotoxin I in mice and chicks. J. Toxicol. Sci. 15, 227-234			
10(4)		EFSA: As highlighted in the comments from DE and PL, some references were listed but were not made available. A need to further supplement the provided documentation is identified. It is not clear whether a literature search in line with	Applicant to update the application by integrating the information at the basis of the application with information on any EU assessment (if available) and with a literature search in line with the EFSA Guidance on the submission of scientific peer-reviewed open literature	BSA application updated	See 10(2)

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**
		the EFSA Guidance on the submission of scientific peer-reviewed open literature under Regulation (EC) No 1107/2009 was performed. Also, if available, EU assessments of honey from rhododendron should be reported. It is noted that additional references were provided by PL.	under Regulation (EC) No 1107/2009. The additional references indicated by PL should be considered further.		

Appendix B – Identity and biological properties

Common name (ISO)	Not applicable
Chemical name (IUPAC)	Not applicable
Chemical name (CA)	Not applicable
Common names	Honey from rhododendron, Mad Honey
CAS No	Not applicable
CIPAC No and EEC No	Not applicable
FAO specification	Not applicable
Minimum purity	Specifications for content of grayanotoxins and other potential active or toxic substances including relevant impurities are not available and need to be proposed
Relevant impurities	Active compounds grayanotoxins and other potential active or toxic substances and / or relevant impurities need to be determined.
Molecular mass and structural formula	For the active toxins found in the honey from rhododendron (secondary plant metabolites of rhododendron- *Rhododendron ponticum*-) Grayanotoxin I (3β,6β,14*R*)-3,5,6,10,16-pentahydroxygrayanotoxan-14-yl acetate  CC(=O)O[C@H]2[C@@]34C[C@@H](O)[C@@]1(O)[C@@H](C[C@H](O)C1(C)C)[C@](C)(O)[C@@H]4CC[C@H]2[C@](C)(O)C3 Grayanotoxin II (3β,6β,14*R*)-grayanotox-10-ene-3,5,6,14,16-pentol  C[C@@]3(O)C[C@]24C[C@@H](O)[C@@]1(O)[C@@H](C[C@H](O)C1(C)C)C(=C)[C@@H]4CC[C@@H]3[C@H]2O Grayanotoxin III (3β,6β,14*R*)-3,5,6,16-tetrahydroxygrayanotox-10-en-14-yl acetate  CC(=O)O[C@H]2[C@@]34C[C@@H](O)[C@@]1(O)[C@@H](C[C@H](

	O)C1(C)C)C(=C)[C@@H]4CC[C@H]2[C@](C)(O)C3 Grayanotoxin IV (3β,6β,14*R*)-grayanotoxane-3,5,6,10,14,16-hexol  C[C@@]3(O)C[C@]24C[C@@H](O)[C@@]1(O)[C@@H](C[C@H](O)C1(C)C)[C@](C)(O)[C@@H]4CC[C@@H]3[C@H]2O Grayanotoxin  **Grayanotoxin** / **R^1** / **R^2** / **R^3** Grayanotoxin I / OH / CH_3 / Ac Grayanotoxin II / CH_2 / H Grayanotoxin III / OH / CH_3 / H Grayanotoxin IV / CH_2 / Ac Ac =acetyl
Mode of Use	Mice baits boxes
Preparation to be used	According to the applicant, honey from rhododendron will be packaged in dosages consisting of capsules (gelatine etc.), nylon, bio plastics, plastics, paper, bio degradable plastics etc.
Function of plant protection	Rodenticide

Appendix C – List of uses

Use No	Member States	F G I	Pests or group of pests controlled (additionally: development stages of the pest)	Application Method/ Kind	Application Timing/ Growth stage of crop & season	Application Max Number (min interval between applications) a)Per use b)Per crop/ season	Application Rate kg, g product/ ha a)Max rate per appl. b)Max total rate per crop/ season	PHI (days)	Remarks (Safener, Synergist per ha)
1	Italy, EU	F	Mice	Basic substance is used inside of a bait box. Bait boxes close the door and keep death mice in bait box. Should water be inside bait box > operator must remove it from bait box	Autumn, Winter, Spring and when mice growth is visible.	a) 4-7 days	a) Min. 10 dosages per bait box b) Position 1 bait box each 5-15 m next to fruit trees.	Not relevant	